

NATIONAL QUALITY FORUM

**Moderator: Reva Winkler
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2:00 pm CT**

Operator: Welcome to the conference, everyone. Please note today's program is being recorded. Please stand by.

Reva Winkler: Good afternoon everybody. This is Reva Winkler at the National Quality Forum. I'm here with (Katie Streeter) and Jessica Weber in Washington.

Thank you all for joining us for the work group call of the Pneumonia Thoracic CT Work Group of our Pulmonary and Critical Care Endorsement Maintenance Project. Just a reminder that this is a public call. We do have audience members listening.

At the end of the call, we will provide an opportunity for any public comment, should anyone like to ask a question or make a comment. Also a transcript of this call and a recording will be posted in a couple of days on NQF's Web site for others to view. With that, our goal today is for this work group, which is a subset of the entire steering committee for this pulmonary critical care project, is to look at a subset of the measures, particularly those addressing pneumonia.

And we do have the one measure for thoracic CT use. Our goal today is to take a look at the preliminary evaluations done by the work group, for you all to have an opportunity to compare your thoughts. We really want to be able to identify the areas where there may be concerns or disagreements to give you an opportunity to discuss those measures, and those issues. Our measure developers are with us on this call, so they can respond to any questions.

Also if there may be some follow-up issues you'd like to have them address before our in-person meeting - fundamentally our goal is to prepare ourselves to be able to have a discussion at the in-person meeting. Each of you has been assigned one or two measures to be the lead discussant, both on the work group call as well as at the meeting.

And so we want you to have the benefit of having a chance to discuss the various measures among other work group members and become more familiar with the evaluation process as we go forward. So we do have nine measures to discuss today. In two hours, that will be a bit challenging. The other work groups are doing it, so we do have to be a little bit careful about time.

Now one issue I just want to make committee members aware of, here at staff we have an apology to grant, to give you. There apparently is one other measure for maintenance, measure 232, which is vital signs in patients with pneumonia that somehow it fell off our desk and didn't get into your share point folder, didn't get onto our agenda. So we will be circulating the information on that measure to you after this and we do apologize for that oversight.

So we will get to it. We won't skip it, but we won't be able to talk about it today. So are there any questions from the work group members in terms of what we're going to try to do today? Okay, has David Rhew joined us? I know - I think David's a West Coast person. I'm hoping he's got his time zones together. Okay, so maybe we'll skip the first two measures and move down.

Operator: David has joined.

Reva Winkler: I'm sorry?

Operator: David Rhew has joined.

Reva Winkler: Oh, great. Okay. Dr. Rhew, welcome.

Dr. David Rhew: Hi, everyone.

Reva Winkler: Hi, there. We were just about ready to get started talking about the measures, and you do have the first two measures on the agenda. Do you need a little bit of time to get organized, or are you ready to kind of talk about the measures?

Dr. David Rhew: Oh, no. I'm ready. And in fact I had ordered a set of slides which I believe (Kathryn) or (Katie) had sent to the rest of the team. Is that right?

Reva Winkler: Yes.

Dr. David Rhew: ...essentially summarized some of the evidence, actually a large part of the evidence around selective quality indicators. Two of them, the first two measures, 0096 and 0147, are very similar. They're about the ((inaudible)) antibiotic therapy for CAP, and initial antibiotic selection for community acquired pneumonia.

So I've got to talk about them collectively or together, but I think the key issues are the same for both of them. So while there might be some slight variations, I believe that the key issues that we really need to talk about, is there a strong process outcome link, or you know, specific empiric

antibiotic recommendations which are essentially based on current IDSA ATS, CTS guidelines, with specific outcomes.

And then, is there a significant opportunity for improvement. And so I think really I'd like to just focus my discussion on those and then open it up to the group. Does that sound good?

Reva Winkler: Okay, that sounds good, because those are both subcriteria for the first area of importance.

Dr. David Rhew: Okay. So you know, I think with regards to the process outcome link, and I've reviewed several of the materials and actually read several of the studies and ((inaudible)) again. And I feel like the crux of the matter is you know, we looked at the data analysis that was published, and this was actually one that was - has been updated several times by the Cochran review, around the antibiotic selections.

As most of you are well aware, the IDSA ATS, CTS guidelines strongly promote the coverage of atypicals, and the question is whether the coverage for atypicals results in better outcomes, no different outcomes, or worse outcomes. And much of our understanding in the earlier years was based on large retrospective analyses. (Patrick Gleason), (Peter Hobbs), you know, and then Brown, Medicare analyses finding a very strong association between coverage rates and ((inaudible)) 30 day mortality.

And I think that's been a large part of the justification of why this is a quality indicator. The question is now that we have some more data around randomized controlled trials, and a med analysis around this, and the med analysis has been updated several times, most recently looked at in 2010, does that change our opinion about this, and if you'll reflect on slide four in the deck I sent, it was just a summary of the Cochran review, 25 randomized controlled trials, finding no

differenc in mortality between atypicals and non-atypicals, and the subgroup, which was actually presented in - on both the next two slides, of ((inaudible)) typically North American studies.

Only three of them, not a huge number of patients, but nonetheless randomized controlled trials, not retrospective, finding no difference as well. So I'm going to pause there, because I think that in itself is a conundrum. You know, do we feel that we should just say that well, these were done in European, or you know, we don't really acknowledge that the Cochran is a sufficiently valid study, or do we feel that you know, something else. So I'll pause and see if there's questions, thoughts, in terms of what I just shared.

Reva Winkler: All right. Any comments from the work - other work group members?

Dr. John Pellicone: Yes, this is John Pellicone. You know, I'm still a practicing pulmonologist. You know, I can tell you that the concerns about atypicals and most recently, at least in the patient group that I see, and that is, you know, adults who could potentially have pertussis as a coinfection, you know the use of the coverage for the atypicals on an empiric basis certainly seems to be a successful approach, especially when cultures are negative as they so often are in the hospitalized patients with pneumonia. So from the clinical and practical perspective, you know, covering those atypicals certainly makes sense.

Dr. David Rhew: I guess I'm only troubled about mandating the atypical coverage up front, when in fact the vast majority either don't have it or respond well to the coverage even absent that. And what we showed in the data collection is that it really is hard to prove a patient-centered outcome benefit. I have no doubt that there are individuals that it seems like a pretty good idea, but we're creating or endorsing kind of a systematic approach to this. It's just not clear to me the evidence is behind the dual therapy.

Reva Winkler: Any other thoughts from the work group members? Okay, would any of our measure developers, either from Oklahoma, like Dale, I know you're on the line, or from PCPI. Any comments from you all?

Dale Bratzler: Yes, well, this is Dale. I don't have the information that Dave sent out, so I - Dave, I wasn't able to see it, so I think...

Reva Winkler: Yes, on the Webinar we're projecting it, but...

Dale Bratzler: Oh, okay. I am on the Webinar, I think. Let me just - so the performance measure, at least the CMS performance measure for in-patients, does have some patient categories for which dual coverage is not required. And the performance measure also is - I think we have to be a little bit cautious talking about atypical coverage, remembering that the performance measure includes two populations of patients, and that includes those in the non-ICU and the ICU settings.

In the ICU setting, whether atypical coverage is important or not is arguable, although particularly in patients that are very sick or something, the - at least the members of our technical expert panel, which is most of the authors of the IDSA ATS performance guidelines, still strongly recommend considering atypical coverage in that population that are particularly ill. The other thing that we had demonstrated in the past, again a retrospective review was that atypical coverage seemed to vary certain years, certain times of the year, and certain parts of the country.

We didn't find the effect of reduced mortality in all sections of the country at the same time, and not all times of the year, but certainly in the fall, in the early - the winter months, we found that atypical coverage seemed to have more of an impact on mortality based on a retrospective review. The performance measure from the CMS standpoint is reviewed by the technical expert panel every three months.

They've recently made some changes to the performance measure on antibiotic selection that broadened choices, particularly in the ICU setting, to account for substance protocols that hospitals have in place around the country, and also address one of the newer antibiotics that's on the market that has been trialed in non-ICU patients, so tigecycline as an example was added as an acceptable alternative because of clinical trials showing its effectiveness.

But the performance measure is routinely recommended by the - our technical expert panel every three months meet and again, the panel includes most of the members of the writing panel for IDSA and ACM.

Reva Winkler: Thanks, Dale. Anything further from the work group? David?

Dr. David Rhew: I think one thing that you know, is probably important for us to kind of establish up front is whether or not, you know - guidelines are certainly - this is absolutely an important guideline.

The difference between a guideline and a quality indicator, and if we feel that you know, to become a quality indicator there has to be a proven or a definitive process outcome link, or there has to be one in which it's suggestive or - and then you can fill in the rest with expert opinions, because I think it will, as it goes through some of the others, we'll find that maybe there isn't as strong a process outcome link as we'd like.

But expert opinion would suggest that it is the right thing to do and that - I'd like some guidance to know how much of this should be based on proven process outcome versus expert opinions. That will help me determine whether or not...

Reva Winkler: Sure.

Dr. David Rhew: ...I will need the process quality indicators, as opposed to guidelines.

Reva Winkler: Yes, and if you look at the details of the measure evaluation criteria, you'll find that we really are trying to focus in on evidence. However, there are exceptions, because as you mentioned there are these sorts of circumstances so that with you know - we don't expect this to happen a lot because we really do want measures that are well-grounded in good studies and the evidence.

But if it - if there is a compelling argument such as perhaps might be the case in this circumstance, that the consensus around it - certainly that's something the steering committee can acknowledge and form the basis of your recommendation.

Donald Yealy: Yes, and this is Don. That's actually my concern, is that there's a difference between a recommendation and a quality indicator, and I understand the recommendation, but as presented, we heard was the benefit varies by year, per location, and even then the evidence - the systematic evidence doesn't really support - it's just hard to - it's hard to move that into being a base line measurement of the quality of care, particularly the length of an outcome.

I struggle with that. I don't struggle with the - about, you know, providing antibiotics. I struggle with this particular dual coverage for all comers up front, because it's - we're hearing all the variation in it. It's hard to imagine that individual practitioners' judgments, which may be not congruous with our quality metric, would really put people at harm.

Dale Bratzler: So this is Dale again. I want to make one thing pretty clear, and that's the performance measure actually doesn't necessarily require dual coverage for all patients. So in fact there are four different options for the non-ICU populations. They include tigecycline monotherapy,

fluoroquinolone monotherapy, beta lactam plus the macrolide doxycycline, and then in that one group of patients, those patients that are relatively young, that haven't - don't have risk factors for drug resistance, macrolide monotherapy actually is acceptable for that population of patients.

And all that's built into the performance measure. The only group for which we currently have a performance metric that requires dual coverage is the ICU population. It turns out nationally, at least in the in-patient quality reporting system, that about 12% of the in patients end up in the intensive care unit, and for that group of patients, and remember that the performance measure specifies that the reason for admission to ICU has to be because of pneumonia, and for that population, the performance metric does require dual therapy as recommended in the guidelines.

Dr. David Rhew: Yes, I apologize for the term dual therapy, but with the exception of the macrolide monotherapy in the less sick, for in many locations we're talking about a dual therapy, because the monotherapy option is less attractive in certain sites because of downstream consequences.

So we have a - we're forcing people to make a choice that in fact has unintended consequences, and we can't prove that there's - that it has a true quality patient-linked outcome benefit, except in tiny groups, subsets, that seem to vary in locations and over time. I'm just uncomfortable requiring the atypical coverage at all.

Male: Dale, is it fair to say that the IDSA, ATS, and CMS quality indicators around it do not support beta-lactam or cephalosporin monotherapy?

Dale Bratzler: That is correct.

Male: Because that would be the analysis that they - specifically that Cochran looked at, looking at quinolone pretty much versus the beta-lactam mono and not finding the difference. And that's why

you know, I think the question is, if someone were to do, just, you know, ceftriaxone or whatever without the macrolide or even the quinolone added, then that's considered poor care and the question is, is - you know, does the evidence support that as being poor care?

Dale Bratzler: Well of course, as you know, I mean, most of those performance measures and the guidelines were built upon those very large retrospective reviews. I don't - I'm not sure which three North American trials you have in the Cochran analysis. I don't remember which three individual studies were there or how big those ((inaudible)) were. So I'm - I can't comment on those three.

Male: Yes, they were really small. I mean, ((inaudible)) 1991, had about 50 patients; Kahn, 1989, about 120; Peters in 1988, about 60 patients.

Dale Bratzler: So I think that makes a good point, because when you look at the large retrospective studies that were done showing benefit of the combined therapy, most of which had tens of thousands of patients, the absolute differences in mortality were relatively small, so a randomized control trial perspective would have to be very large to demonstrate the differences in mortality. And yet we - the position has always been that it's relevant because just in the Medicare program alone there are about 700,000 pneumonia hospitalizations annually.

Male: Right. Certainly the amount of volume in the retrospective is overwhelming, and I think that's certainly why it is a quality indicator today. I guess the question, you know, with the ((inaudible)) and herein, in a retrospective analysis versus a randomized control trial, what we're left with here for the RSAT is just very small studies, and - that does that even throw into question the - or does this - and again, here's where I don't know where to draw the line.

We feel that that's, you know, the information that's been put forward is something that we should just say, yes, we know, but we don't believe it or we don't acknowledge it because of A, B, C, D

reasons. Or do we say that, hey, this kind of throws into question whether or not, since we don't have that large multi-center randomized control trial, but look at this, whether or not this actually does have that strong process outcome link.

Dr. David Rhew: Yes and I guess my concern is the retrospective trials are really - they were powerful, but they are awfully dated. And in addition to the inherent limits of it - and again I fall back to, I understand how they could help drive a guideline or recommendation, but is it the best evidence to use for determining quality?

Dale Bratzler: I guess the only other thing that I will add and I'm sure you'll all understand, is that we do routinely meet with the technical expert panel and review these issues. I do know - I don't know where it's at. I believe IDSA ATS are reformulating their guideline committees, re-look at their - update their guidelines.

I think they're working on maybe health care associated first, but I do believe they are working on getting their guidelines, and we do try to keep on top of any changes in guideline recommendations, and incorporate those into performance measures. So if you look at this performance measure today, it's very, very different than it was just two years ago.

Reva Winkler: Okay. This is Reva. I think we're going to need to move on to some of the other criteria.

David, you had mentioned that you had some issues around the opportunity for improvement as well. Why don't you comment on measure 96 for - on that criterion? Did I lose you?

Dr. David Rhew: Oh, I'm sorry. I was on mute. Yes, so specifically as we think about what is publicly available right now in the hospital compare database, and you looked at the nationwide adherence rate to these quality indicators, we're at 94%, and that's nationwide.

And so the question is, is 90 - at what threshold do we believe we kind of got to the point of diminished returns, where you know - is it 90%? Is it 95%? Is it 97%? I know at one point beta blockers were taken off because they, you know, we had achieved such a high rate of adherence that - I don't know what that threshold is. Maybe you could give me some insight into at what point do we say that we've got a pretty high level of adherence?

Dr. Charles Stemple: This is Chuck Stemple and I think I'm the only managed care person on this and certainly when we look at measures for our physician and hospital practices, anything that gets to 94%, we assume there's going to be minimal to no improvement just obviously from some specific variation in care that's going to occur. So I would think removing this would be appropriate with that level of retainment of the measure and relooking, you know, the period of time down the road to see if it's maintained that level of performance.

Reva Winkler: Okay. Okay. Other thoughts from other folks? Let me just throw in sort of another wrinkle to this whole thing, is we certainly have seen measures that have been perhaps victims of their own success, a great many of them that have reported on hospital compare for quite a while.

Concern that the measures are still very good measures, they meet all of the other criteria, particularly for scientific acceptability, usability, feasibility, but the opportunity for improvement is probably limited going forward. We have created a new status for those measures which is called a reserve status.

It's sort of like we put them on the shelf, acknowledging they're still good measures, but their utility and driving additional improvement may be limited, but they do - still are considered endorsed measures. So if indeed you all feel that the measure meets all of the other criteria solidly, then that is an additional option for a measure you feel has very limited opportunity for improvement going forward.

Dr. Charles Stemple: Hey, Reva, can I just make one point again?

Reva Winkler: Yes.

Dr. Charles Stemple: Remember, there is actually two measures embedded here. Joint commission breaks them out into the non-ICU and the ICU population. It's actually, and I don't have that break out in front of me. The ICU population is where we see lower rates of performance of the guideline recommended antibiotics. So there is a little bit of difference between the two populations.

Reva Winkler: Dale, I know that you keep trend data as well, and perhaps that might be useful to see what change has occurred over the past, I don't know, couple of years in those two populations. And perhaps that would be helpful to the committee in understanding where they think this measure has additional opportunities.

Dale Bratzler: Looking to see if I can pull up current data.

Reva Winkler: Yes. Well, I think since it's - I think that's something that perhaps we might be able to provide to the committee before our in-person meeting and before they make their final recommendations.

Dale Bratzler: Yes, I think that's a critical point to see - it's a good point that if it's been at this level for a couple years or just achieved so, the trend would be nice to see before that final decision, so it'd be nice to have.

Reva Winkler: Okay. Now, so this was measure 147, the hospital measure. Were there any concerns among any of the committee members on the other criteria for scientific acceptability, usability, or

feasibility? In general what I see on the four people that submitted your preliminary ratings is generally moderate to highs with a sense that it does meet the criteria.

So David's concern I think was the one that he has raised, and you've had an opportunity to discuss. So was there anything else about the hospital measure per se? And I think it'd be very helpful to get that additional data from the developers prior to our in-person meeting. Okay, then, let's look at 96, which is the clinician level measure from PCPI. Again, you're - David mentioned it's very similar. David, did you have any, or have concerns about the opportunity for improvement here?

Dr. David Rhew: You know what? And there - here's one where I'd actually like to get some of the more raw data and utilization or adherence rates. I didn't have that because I got hospital compared, and I think it's mostly inpatient, right? So if there are sources out there that can better identify it, I think that would really be, you know, the same approach that we should take for the inpatient as well as the outpatient.

Reva Winkler: Okay. Elvia. Who's on from PCPI?

(Ann Pearney): Hi, Dr. (England). This is (Ann Pearney) with the PCPI. Hi. I - the data that we have from this measure regarding the most current national usage comes from the PTRS program, and so we could certainly - I noticed that ((inaudible)) mentioned as far as lack of information on the 2009 performance rate, which is the most current information that's been made publicly available.

So we could certainly share that, but we probably don't have the level of detail that you would have access to from hospital compare, just because of the nature of the program - of the PTRS program as compared to the hospital compare program. But I can tell you the 2009 performance rate, the mean performance rate was 92.18%.

Unfortunately the data does not indicate the variations across, and I know that for the 2008 data that we did receive from CMS, that there was quite a bit of variability from the 10 percentile to for example the 90th percentile, so that's the current data we have. We could certainly add that additional information about 2009 if that would be helpful.

Dr. David Rhew: Yes, mean, median, and mode, and also variation would all be, you know, interesting things to know.

Reva Winkler: All right. And David, in terms of the - for measure 96, was there any other concerns on scientific acceptability, usability or feasibility? In general what I see in the initial ratings were moderate to high ratings without any significant issues identified. Would - is that a fair summary?

Dr. David Rhew: Yes, I'll...

Reva Winkler: Okay. Just in the interest of time, we need to move on to some of the other measures. Were there any other issues about the empiric antibiotic therapy for either hospitals or clinicians anybody wanted to raise before we move on? Okay. So I think it's - let's move on to the next measure, which is measure 148, and this is blood cultures performed in the emergency department prior to an initial antibiotic received in the hospital. This is the measure from CMS at the hospital level. And Dr. Yealy, I think it's your turn.

Dr. Donald Yealy: Okay. So this is one where we saw quite a big spread in the analysis of the evidence, and where essentially every grade was given across the three of us who scored it. This measure requires that if blood cultures are to be obtained that they be obtained before antibiotics are given in the emergency department.

And the concern is, is that it's not linked really to a health income, and yet it is that this particular process of care improves either a broad patient-based outcome. Or a surrogate for that is actually fairly weak, and primarily that is a basis - is based on the fact that blood cultures themselves in pneumonia defined in this measure are infrequently a tool that will alter care.

Therefore the drawing before or after empiric antibiotic therapy - it can't - could not possibly be used as a quality indicator because there isn't really. We all understand that you know, drawing a blood culture after administering antibiotics doesn't make a lot of intellectual sense, but it's hard to link that to some change in a patient-centered outcome or interfering with the ability to change an outcome.

So if you look at the supportive evidence, it's actually fairly small, observable-based, lots of confounding potential. And the second concern is that the actual timing of the blood culture sampling and the antibiotic administration, while each can be captured in an electronic record, it's not clear that the accuracy of the specific event, in other words, the timing of the culture versus the initiation of the antibiotic therapy, is reliable.

It may be actually accurate, but it may not be reliable at the same moment in time. In other words, little bits of differences in time depending on how HR logs these could present a dramatically different picture, even if you believe the measure was scientifically valid. So my concern is that I don't think there's a lot of science behind this, and it can't possibly improve outcomes in most people. Therefore it's very difficult to use as a quality measure.

Reva Winkler: Thoughts from any of the other committee members on the importance criteria, particularly the evidence that Dr. Yealy's raising.

Dr. David Rhew: Yes, this is Dave Rhew. I would agree with Dr. Yealy. In fact if you look at the slides that I forwarded, I provided some very specific examples of all the different studies that look at blood cultures and you can see that starting with a systematic review, it doesn't impact in a good number of cases the care, especially for ((inaudible)).

And then additionally I've done my own analysis, and you can see on some of the slides that there do appear to be some certainly variations between ICU, the yield, and non-ICU, so maybe there is perhaps a subcategory that we might want to consider. But if you look specifically at clinical outcomes, localities, and specifically, there doesn't seem to be differences when your trial looks specifically at the clinical outcomes.

The one study in which there was a trend towards improvement in outcomes was the one by (Thomas Mien), which is sort of the classic gamma 1997 one, but subsequent ones which were smaller in nature have not been able to demonstrate that definitively, so again, here I'm sort of thinking, you know, does it make sense? Certainly give it before antibiotics.

You can see that the data represents that - it dramatically improves the yield, but the question is, is there a strong process outcome link? And I'm not entirely convinced of that.

Reva Winkler: Yes. Just to - this is Reva. Just to let you know, one of the other measures that is on the list that was evaluated by the critical care work group is indeed blood cultures for patients admitted to the ICU. So there is another measure.

Dr. David Rhew: Right, and my concern - we talked about this before the pre-call, or during the pre-call - was that the two measures are overlapping but not necessarily congruent. In other words, the other measure which we're not here to discuss actually sanctions obtaining a blood culture almost at any moment in time, irrespective the timing of empiric antibiotic therapy.

And it just strikes me as odd to have ones that are that overlapping but in theory could be dyssynergy, or dissynchronous, and it's just hard for this one. You mentioned the (Tom Mien) trial. We actually designed one of our trials based on that, and (Tom) was a co-investigator.

If I could take it back, I would have - I used it as a quality metric in a trial, and once you standardize the other process of care, it actually falls completely away. His data said it was likely a surrogate for doing a better job paying attention to people with pneumonia rather than the specific act.

Male: So would you recommend the other work group potentially keeping their ICU and us removing this one, if I'm hearing you?

Dr. David Rhew: Well if I had to choose - if I had to make a choice between keeping one and getting rid of one, that's the direction I would go. I did not spend a lot of time because I wasn't assigned to that group on examining the ICU only data on that, so I guess I feel a little uncomfortable making any comments there. But I don't think having these two together makes a lot of sense, and this strikes me as being - as a weak measure.

Reva Winkler: Yes.

Male: Yes.

Dale Bratzler: I would support removing it, and then letting the ICU group decide the validity in the ICU, but I think that would make more sense.

Reva Winkler: Just remember that ultimately at our meeting in March, the entire committee, including you all, will make decisions about all of the measures including that one. But they have discussed that measure as well.

Dale Bratzler: Okay. So Reva, can I just make just one quick point?

Reva Winkler: Sure, Dale, go ahead.

Dale Bratzler: I'm sorry. And so I want to make it clear that blood cultures are not required. There was a lot of confusion in the provider community, but there is no requirement to do a blood culture for the pneumonia population for this particular measure. The decision to do the blood culture is left entirely to the clinician at the bedside. It only applies to patients when they're in the emergency department.

Once they leave the emergency department or actually have orders for admission, they're excluded from the measure denominator, so we're only looking at those patients when they first come in. If somebody decides to do a blood culture, do they draw it before the antibiotics are given? And I will not disagree with Dave or anybody else about the process outcome link, if you're looking at the outcome being mortality or patient length of stay or anything else.

The reason the technical panel has continued to support blood cultures, and there's been controversy around blood cultures, but they've supported it for reasons other than patient outcomes, in part to identify the epidemiology of pneumonia within an organization, to actually get culture data and to know what your resistance patterns are.

So that's why in the IDSA guidelines they have a very limited category of patients, but they do have specific populations for whom they do recommend blood cultures. Most of the trials that

Dave talked about showing no mortality benefit are the ones where blood cultures would often routinely be done on all patients and that is not required in this measure.

Dr. David Rhew: Can I speak on behalf of the emergency medicine community? I don't think there's confusion about you don't have to draw them. It's just of the value, and secondly, the occasional trap that the electronic capture of the timing of the two interventions can give the illusion of antibiotic before blood culture, when in fact it didn't even exist. And so you have almost a double whammy.

You're measuring something that only rarely provides microbiologic evidence and almost never alters the clinical actions, and then occasionally creates a false sense of lack of compliance. Invariably these are captured at two different levels, although stored in electronic records. I think it creates an even bigger problem.

The best way to be compliant with the measure, at least that I hear from the ED community, is to have a wide spacing between these two so that there can't be any confusion about when each particular event is logged. If you think about it what we're doing is we're telling people to withhold the clearly helpful therapy which is antibiotics, so that the clearly unhelpful event doesn't create a - any confusion.

I really we don't have to do - the alternative would be to just not draw the blood cultures at all, but sometimes there are other reasons or people have done it for what they believe is the right reason and then get essentially whacked over the head.

Reva Winkler: Okay. Just because you know, it sounds like this is going to be an important decision point issue, but are there any other concerns about this measure for either the opportunity for improvement or the scientific acceptability, usability, feasibility of this measure?

Dr. David Rhew: Well, I think the feasibility is what I've talked about as far as tracking, kind of like it goes into that also, the ability to accurately track the timing of the intervention, particularly since it's measured in the emergency department, where the interventions are in minutes to hour as opposed to hours to days. And so it actually is not particularly hard to misidentify the timing of events, even with an electronic health record.

Male: So I assume you're saying the validity of the data would be very low and would not be supported in terms of - is validity the correct word, or is it the timing to really create - this is a critical outcome measure?

Dr. David Rhew: Yes, I'm saying I don't think the length and outcome measures and the feasibility of collecting information accurately in these two independent events I think is under question.

Male: Yes. Being an ER doc, though I haven't practiced in a while, I would say the time to order entry would be highly suspect, and yes, I would totally agree with you.

Reva Winkler: All right. Does anybody else have anything they want to - more they want to say on measure 148 before we move on? Okay, the next measure we want to talk about is measure 231. This is inpatient pneumonia mortality. This is an IQI from Fark. I think is a measure of - an outcome measure that's been around for quite a while, and again, Dr. Yealy, I think this is yours to discuss.

Dr. Donald Yealy: Just want - I suspected a lot less concern. It looks like the scoring is grouped together very well. It essentially looks at the ultimate - you know, the kingpin of items, which is dead or alive at some interval, with a patient group that is easily identified. There is some question about the

homogeneity of the group. I actually don't have any concerns about the underlying evidence about this.

The only threat to the criteria that I see is the ability to contemporaneously and accurately assess the risk of the illness or the acute illness burden isn't incorporated into this for obvious reasons, and then it's meant to be a simple metric. And it potentially could profoundly impact on the mortality rate, and be fairly independent of the quality of care delivered.

In other words, if Site A had mostly class four and five using the pneumonia severity index patients, and Site B had mostly class one and two, Site B might have a death rate that's double what's predicted but look a whole lot better than Site A, for reasons unrelated to quality care. I'm not as bothered by that because we have some of the other core elements of either pneumonia severity index, the curve tool, or the SCAP score in some of the other measures.

So while that type of data anomaly in theory could throw off one metric, you would likely pay the price in a different metric. And so I'm not as bothered by that, and my read on this and looking at the rest of the scores is that we don't have a lot of problem on it.

Reva Winkler: Yes. Just a comment, (John), are you on the line, or anybody from Arc?

(John Carpenter): Yes, (John Carpenter) here.

Reva Winkler: Did you want to respond?

(John Carpenter): No, I'm largely gathering notes for the forthcoming call. The risk adjustment is spelled out in the application, and perhaps there's aspects of what you could potentially adjust for risk on that are not present in the current risk adjustment. Oftentimes we have to go into some detail to

explain how all patient refined DRGs are truly integrated into the risk adjustment, and we can do that more at that time.

Reva Winkler: Okay.

Dr. Donald Yealy: Right.

Dale Bratzler: And you know, measure 1895 and 233, those are two of the big ticket risk adjusters right there, at least the acute illness.

Reva Winkler: So it sounds like - does anybody else on the work group have any other issues or concerns they want to raise about measure 231? Okay. The outcome measure was the easy one. All right, so okay. Then let's move on to 233, which is assessment of oxygen saturation for community acquired pneumonia. Dr. Pellicone, I think this is your measure.

Dr. John Pellicone: Correct. So on the surface this seems rather straightforward. I mean, it's a non-invasive test, and it's a piece of data that you really cannot assess accurately just by looking at the patient. It's - and I certainly think it's certainly more appropriate to have this kind of information than just throwing patients on oxygen, which is what we see frequently.

The - you know, the reduction in oxygen saturation does however have to be taken in the context of the patient's pre-morbid or pre-pneumonia state, which you know, and the measure here doesn't necessarily discuss, but I think is inherent in the interpretation of the numbers.

And there's no doubt that given the information about hypoxemia being associated with more severe cases and worse outcomes, it's certainly indicated if there are other factors about the patient that point toward an ICU-type pneumonia admission. So and it looks pretty straightforward.

Reva Winkler: Okay.

Donald Yealy: This is Don. You know, obviously this is a big part of the - I guess it's not clear to everybody else, and I - the pneumonia severity indexes are at work here. And I'm not even as bothered by the acute versus preexisting hypoxemia, because in large data sets, the timing and the organ dysfunction doesn't seem to be as important as do you have it together with a pneumonia.

So whether - even if you had preexisting, I don't - that just is a different type of negative effect on predicting the outcome, not - but it doesn't - it actually doesn't mitigate it that much, so this is another one that's simple. The only concern I would have about this is what's the frequency of the current use and is it - is there still opportunity for improvement.

My gut feeling is from looking at the data and realizing that while we think this should be done in 100% of the cases, it actually still - there is still room for improvement, and this is the kind of action that I would still think we would put our foot on the gas, even if compliance was above 90%.

It's so incredibly basic, and a helpful tool that from other things we talked about once you got much over 90, particularly on the action kind of things, that maybe there wouldn't be quite the bang for the buck. I'm not as convinced in oxygen assessment that that is true. And so we get - we consistently hit 98 and above, I think. I suspect that there's not much public health benefit, but I don't think we're there yet.

Reva Winkler: You know, this is Reva. I was going to - I'll ask (Sam Kearney) again. (Sam), is this another measure where perhaps you've got the 2009 CQRF data?

(Sam Kearney): Yes, we do have that, and again, sorry it wasn't included in the submission. But we use performance rates for 2009, was 92.72%. But again, we don't have the variability for 2009, but we do have the variability for 2008, which indicates quite a difference from the 10 percentile to the 90th.

Donald Yealy: That's really helpful, and I guess my point would be different from some of the other ones. This is one that I would strongly recommend that we keep our foot on the gas.

Dr. David Rhew: Hi, this is Dave Rhew. I - you know, it's interesting, because as you look at the literature on this, clearly there's not an outcome association in terms of mortality, but a lot of the outcomes are associated with sort of delays in terms of the impact of a delay of oxygenation assessment, and yet the measure that we're looking at is simply a yes or no. Was it performed or not? I'm wondering whether or not it would actually make more sense to add an element of timing, like perhaps within one hour or something of that sort, because isn't that really more important than just simply having it done, perhaps you know, sometime during whatever time period? It's the timing element, the real important piece, that we're not capturing here.

Donald Yealy: This is Don. I actually would have no gripe about that anytime in the first few hours as an assessment tool. It is linked to the outcome, but you can't prognose the outcome. Ergo, tailor therapy if you don't actually know their risk assessment, and no matter which tool you use, this is going to be part of it. There's no way around it.

Dr. David Rhew: Right, and clearly if you do it early, it seems to be associated with better outcomes, but you know, someone could satisfy the measure and simply do it at the very tail end, and that's - you know, what's the point of that?

Donald Yealy: The only rub is I don't know when the exact right time is, so we'd be - speaking very bluntly, we'd be making it up. The PSI data which is probably the largest on this just referred to first oxygen assessment, but that could have been anytime during the ED stay.

Dr. David Rhew: The study by (Bulotte) in critical care medicine in 2007 is that they found that a delay of greater than one hour in this oxygen assessment was associated with increased time to antibiotic therapy. And they also find that a greater than three hour delay of oxygen assessment was associated with increased mortality.

So you know, it's clearly one hour - three hours is too late. One hour is probably - you know, less than an hour is probably optimal. But you know, it's something we could probably discuss in further detail, but I do think that there are some parameters laid out in the literature that we could use as a basis.

Donald Yealy: And we're talking about this in the emergency room? I just...

Dr. David Rhew: I don't think this one is ED specific. Well, and so if you're admitted to the emergency department, which across the US on average, 75% of people with pneumonia are. But on my - I don't guess - I switched to a different file, but I didn't think this one was ED-specific.

Donald Yealy: It doesn't say ED, so we would - if we put a time frame it would be upon patient arrival either to ED or inpatient. I would assume it would not be type specific. Then we would expect that in the ED as well as an inpatient bed.

Dr. David Rhew: Exactly. Irrespective of the entry portal, and given the mortality data we talked about, I'd probably lean toward the three-hour, because we have a hard stop there. I recognize - I'm not

arguing that doing it at two hours and 59 minutes is a good thing, but it's what the data supports with little debate.

Reva Winkler: This is Reva again. The suggestions back to the measure developer on ways to improving the measure is definitely in bounds for everybody, but realize that at this point we're really asking you to make an assessment of the measure as is, and so keep that in mind when you're doing your evaluations. All right.

Where there any concerns or issues about the reliability and validity of this measure? They did present the evidence or the results of their testing, particularly of the EDHR measure. We've got you know, one rating of moderate and one rating of high. Any comments or thoughts from the committee on the - how well it meets that criterion?

Dr. David Rhew: So I'm the one who forgot to put in a different score. I would have given it high.

Reva Winkler: Okay.

Dr. John Pellicone: I just - this is John Pellicone. I just have a question about, is there an assumption here that the person recording the saturation is familiar enough with the equipment to know when a cool and vascularly constricted finger is not giving an adequate assessment of the - you know, the absorption of the two wave lengths of light through that pulse. I mean, is that just - is that assumed in the measure?

Donald Yealy: This is Don. I actually didn't read that into the measurement, because the point is seeking it in itself is the potentially helpful event.

Dr. John Pellicone: Okay.

Donald Yealy: And if you do - with that - the patient you described, you get a different type of useful information. And I realize that's not really what we're trying to benchmark here, but I just didn't read that into the measure.

Dr. John Pellicone: Okay.

Reva Winkler: All right. O Desk, the members of the work group that have not entered your ratings for these measures, if you could do so since you have reviewed them, it would help give a more comprehensive summary when we go to the meeting in March. Does anybody else have any comments about measure 233 before we move on to the next one? Getting along, here.

All right. If not, then we've got two outcome measures. The first one is measure 506. This is the hospital 30 day all cause risk standardized readmission rates, aligned pneumonia hospitalization. This comes to us from CMS, and I believe we've got our developers from CMS (Ann Hale) on the line with us, and so Dr. Stemple, I think 506 was your measure to lead?

Dr. Charles Stemple: Okay. I apologize. I didn't realize this was my measure to lead, so I absolute apology about that.

Reva Winkler: Okay. How about any other members of the work group? Several of you have submitted ratings and generally have rated it fairly well. In terms of importance, this is an outcome measure. Readmission rates are considered outcome measures, so that sort of takes care of the evidence there.

The opportunity for improvement that has been submitted shows that the mean readmission rate was 18.4% with a range of 13 to 26. Inter-cortel range of 17 to 19. Any other thoughts on the importance criteria from other - from the work group?

Dr. Charles Stemple: Well, in the - and I'm sorry not having the data at my hands - so critically within - you know, with all clinical arenas and certainly managed care, I think this is one of the critical issues looking at effectiveness of initial therapy, and certainly the readmission rates of this population, and I would certainly support it as a clinical outcome measure, and even as we look further now, you know, within our populations more in the Medicare world, and I don't know if there's reason to look at readmissions from for all packs of rehab, because we're having - more focused on those readmissions and our people getting appropriate level of care and alternative level of cares and those that ((inaudible)) infections in those environment.

So I didn't data separating out readmissions from other, you know, downstream facilities, not acute inpatient. But I don't know if there's an opportunity to look at separating readmission, discharged to home, and readmission if discharged to a ((inaudible)) rehab or other post acute care type of facility.

Reva Winkler: You folks from Yale, maybe want to comment?

(Ann Hale): You want us to comment specifically on the focus on readmissions from those settings?

Reva Winkler: Yes, I mean, did those get captured in this measure at all?

Susannah Bernheim: Yes, so we don't - the measure doesn't look - sorry, this is Susannah Bernheim from Yale. I should have introduced myself. We don't look at the discharge dispositions, so it's an all-cause readmission measure, so patients - once they are discharged to a non-acute setting,

they are included within the measure, but we don't differentiate either within this measure about where they are coming back from, but those patients are certainly included.

Male: Was there consideration in looking at population as a separate measure, or was there thoughts that that separation would not be a clinically valid distinction, or would you mind - thoughts on separating that population out?

Susannah Bernheim: Sure. So there was some thought given to that in general our feeling has been that it's important to look at all cause readmission regardless of the discharge disposition, as a more holistic way to evaluate what's happening at a hospital.

But more specifically to this question, one concern when thinking about this is that some amount of where you go has to do with sort of regional supply, so there may be areas of the country where patients because of availability are more likely to go into those settings, and other areas where they aren't, so that might not be a particularly fair comparison.

And when we've looked for heart failure for pneumonia, we do see an incredible range in terms of the percentage of patients that go into different settings, and we have not seen a real relationship between what percentage of patients are going into say a skilled nursing facility setting and the readmission rate.

So we have not felt that that was particularly useful for this measure. I do think that there are efforts in other parts of CMS to look more specifically at readmission from long term care settings, but this measure does not do that.

Male: Okay.

Dr. John Pellicone: This is John Pellicone. I just wanted to clarify one point there. So if the patient goes home and on the first day home - or on the 31st day, or the 29th day, fractures a leg and comes back, that's counted in as a readmission.

Susannah Bernheim: Right. So for this measure it's an all cause readmission measure, and the important thing is we're not expecting readmissions to be zero. There will be both useful readmissions, important readmissions, and there will be accidental completely non-preventable readmissions.

Dr. John Pellicone: Right.

Susannah Bernheim: But our expectation is because it's a comparison to what's expected that those are going to be randomly distributed and that won't make a hospital look particularly worse.

Dr. John Pellicone: Okay, thanks.

Reva Winkler: Okay. In terms of the work group, as far as on the reliability and validity of this measure, I will point to the - to a very detailed document that describes the evaluation of the measure in an all tier data set. Previously this measure had been restricted to patients over the age of 65 because of the Medicare data.

However, just in the past year, with encouragement by lots and lots of stakeholders, the developers have tested this in an all-tier data set so that - and found that the risk model that they use is appropriate, reliable, and valid for use for all patients admitted with pneumonia.

And so I would point you to that data in terms of the reliability and validity of this measure, and the very - fairly comprehensive risk model. Any thoughts or concerns from members of the work group on the reliability and validity and risk adjustment for this measure?

Donald Yealy: This is Don. The only question I have is how do we handle the second health care contact if the patient is not formally admitted but placed in an observation status? That's the work around that I would expect, and how is that handled? That's a growing opportunity right now.

Male: And you know, certainly in our database from a managed care payor perspective, if they go into observations that's not tracked as a readmit, would be excluded from our metrics as we track this on a routine basis.

Reva Winkler: Susannah, did you want to comment?

Susannah Bernheim: Yes, I do. It's a great question, and it's something our group has been thinking a lot about. So currently, as the person who asked the question, sorry I missed your name - pointed out, if you come back to a hospital in observation status and are not formally admitted, it would not show up in this measure. We have begun to look at this issue.

Right now the rates of that happening are very low, but not surprisingly, are increasing a little bit. And I think that this is something that CMS plans to track and would consider, you know, based on what they're seeing there. It doesn't seem to be having much of an impact on the measures right now, but I think it is something that's worth keeping an eye on.

Donald Yealy: Yes. And this is Don. I would expect next time we do this review that it'll be a much more interesting question.

Dr. Charles Stemple: So will you be - this is Chuck. Will you be prospectively just monitoring that going forward? Or at what point in time, because obviously with the whole CMS readmission payment methodology, I assume facilities and accountable care and all these other organizations would

look to measure these to an observation kind of status if they can at all, so your monitoring of this data - at what point would you have further data relative to that, if that's the right question?

Susannah Bernheim: So that's a great question. So we have done some preliminary analyses, and I can talk to CMS about whether - they are not public at this point, but I can talk to CMS about whether we could bring them to share with the steering committee at the time of the review of this measure.

Reva Winkler: Okay, yes. That would be helpful, Susannah. Thank you.

Susannah Bernheim: Sure.

Reva Winkler: Any other concerns or questions, issues for the work group members on reliability and validity and risk adjustment? How about the other criteria of usability and feasibility for the raters who've already submitted their generally high to moderate ratings? No real issues identified. Thoughts from any of the other members of the work group?

Male: I have the same view.

Reva Winkler: Okay. All right. Amazing, how it doesn't take long to talk about the outcome measures. Okay, so we're just scampering through these quite quickly. So the next measure is another outcome measure, sort of the pair to the previous one, 468. This is a 30-day all cause risk-adjusted mortality rate for pneumonia hospitalization, and Dr. Pellicone, I think this is yours.

Dr. John Pellicone: Yes. Well, I'm the first to admit that this stretches my knowledge of the statistical analysis; however, it's certainly what - I think what the measure emphasizes is the potential effect of comorbidities and their effect on the treatment of the pneumonia, you know, including things like

the type of unit in which the patient is placed and the intensity of control of those other comorbidities like the intensity of control of diabetes ((inaudible)).

It is a measure to assess how the hospital is doing compared to the expected deaths based on the case mix. But you know, I could use a little help here on some of the other statistical analysis.

Reva Winkler: Sure. Well let me start with importance, just to review the opportunity for improvement.

This measure has been used for several years, and the mean for the 2007 to 2009 is 11.7%, but the range is 6.9% to 20.4%, so it's a fairly significant range, with the inner cortile range at 10.4%.

So one of the things that we are doing in house in terms of the scientific acceptability for some of these more complicated measures, but this is something we're gearing up to do a pilot for, that I think might be helpful, is we do have some of our folks in house with some external consultants gearing up to look at some of the more complex measures, particularly with some of these risk adjustment methodologies, and they are in a position to do kind of a first hatch review to highlight some of the issues that the steering committee probably want to consider or be aware of in looking at some of these more complex measures.

And in talking with my colleagues, it looks like they would be able to provide that for you a couple weeks before the steering committee meeting if you would find it to be helpful as kind of a trial, and you can tell us how helpful it is or isn't for you. So that's something I can provide for you before the meeting, if that would be helpful.

Male: Yes, okay. Sure.

Reva Winkler: Okay. Any other thoughts? I believe this measure has been around a while. Does anyone have any thoughts on the usability feasibility of this measure? I think one of the issues that

commonly comes up in terms of feasibility is capturing the 30 day - the deaths that occur outside the hospital within the 30-day window in terms of how that's done and the time frames. Any concerns or questions about that?

Male: So it includes those deaths outside the hospital, not just - certainly not just in the hospital.

Reva Winkler: Correct.

Male: Yes.

Donald Yealy: This is Don. I actually don't have any concerns about it at all, I mean, not that there aren't opportunities for haphazard error, but I don't see any systematic problems.

Reva Winkler: Okay. All right. Don - I mean Susannah, just because we see this in comment whenever one of these type of measures come up, and we've seen these before in cardiovascular, would you like to just maybe explain really quickly the source of that data that you used, particularly in the all payor data set?

Susannah Bernheim: Yes, I am not the expert on my team on this matter, so I can bring you more information. But the California payor data set actually links to I think the death master file. I think it's related to the social security data, but I can confirm that for you. And so that's a source there. Now yes, so the mortality measures - I was thinking about readmission measure there for a moment - yes. And of course the CMS data is updated quite regularly, their enrollment file, with vital status data.

Reva Winkler: Okay. Yes, and this is a question that comes up perhaps you know, many of the stakeholders have heard the response with some of the other measures. But it's often a topic that

gets raised. So are there any other issues? Another question that gets raised a lot is we've seen a measure for inpatient mortality, and we now have the measure for 30 day mortality. Your thoughts on the usefulness of one or the other or both measures?

Dr. David Rhew: I think - this is Dave Rhew. I think you have to have both, because you know, there's always the caveat of sort of squeezing the balloon. What happens inside of the hospital? Patients may get sent out. They eventually do better or they're in hospital but then they die outside of the hospital so you have to cover their entire episode of care. And for us to just focus on one area would really send the message that hey, it's okay to really ignore the other area.

Donald Yealy: Yes, I - this is Don. I agree completely with Dave. If you were only asking about readmissions, I would - and I was cynical and moneygrubbing, I would hope that they all died real quickly after I discharged them, because they can't get readmitted then.

Reva Winkler: Right. Okay. Again, that's another question that pops up, so I'm glad to see that you guys feel comfortable with that. Now our next measure, measure 513, is one that didn't fit into the pneumonia group. It got added in here, and it's more of an imaging measure.

Is Dr. (Kasarini) with us today? Right. She's our radiologist member of the committee, and she's the lead for this particular measure. And I would - I'd just ask the other committee members, do you feel that you would want to wait for her kind of lead on the discussion of this measure rather than try and stumble through it ourselves today?

Donald Yealy: Well, this is Don. This one to me looked like a no-brainer, and I have no concerns with it, and I would score it as much as I could score it right now.

Reva Winkler: Okay.

Dr. John Pellicone: Yes, this is John Pellicone. I mean, I agree with this as well, that this question comes up every day in clinical practice, and you know, you just have to know - you've got to know your parameters and you've got to know what you're looking for. And you certainly have the opportunity to discuss it with the radiologist, and there really is almost no reason to have both of them.

Donald Yealy: The only weakness of the measure, and I don't think it's enough to get rid of the measure, is the clear link - I'm not as convinced of the clear link to global patient outcome, but it still is - there still is enough information that I'm not bothered by it at all.

Reva Winkler: I think in many ways, this is looked at as a potential sort of two-element overuse measure as well as a patient safety measure. And it's really - those are the...

Christy Whetsell: This is Christy. So my only concern was - and the reason I said that I thought it had an outcome measure is the concentration that we're doing here on our facility of contrast related to renal function and effect on renal function. And did this group think that that's where they were trying to go with this?

Reva Winkler: Well we do have - do we have anybody from our - from the measure developer who'd like to just maybe respond to that? Anybody from CMS or the contractor? Perhaps not. I mean, traditionally, Christy, the discussion around this measure is usually - I think you're right, the patient safety aspect of the contrast...

Christy Whetsell: Okay.

Reva Winkler: ...and the appropriate use thereof.

Donald Yealy: Taken in a risk benefit context, especially in the setting of renal insufficiency.

Male: Right.

Christy Whetsell: Okay.

Reva Winkler: Okay. Well, hopefully we're expecting at the meeting Dr. (Kasarini) will be able to bring the radiology perspective in as well so we sort of have the balance of thinking around this measure. But if you all feel that there aren't any major issues with it, then we can move on.

You guys are the most efficient group around. Okay, we've got our last measure on our list for today, and that's measure 1895, and this is assessment of mental status for community acquired bacterial pneumonia and Christy, I guess this one's yours.

Christy Whetsell: Yes, I can just say I'm in awe of all the discussion that has gone on these other measures. I kind of look at it a different way, and I kind of thought this was a no brainer that we should be doing this.

Donald Yealy: Christy, this is Don. I agree with you completely. I mean, this is one of the other big tickets by any scoring system you use to prognose outcome. So if you don't do it, you can't possibly really know. This is invariably the single biggest modifier of someone's assessment with acute community acquired pneumonia. So this parallels oximetry with even more oomph behind it.

Christy Whetsell: I kind of thought with the oximetry discussion because I did kind of correlate those two together when I was reading through these, and the discussion earlier where it needed to be done within so many hours of admission, I kind of think might be applicable to this one also.

Donald Yealy: Yes, you're probably right. I just don't know what that time would be. Clearly assessing level of consciousness or mental status in five minutes before discharge after a ten-day hospitalization wouldn't be helpful.

Christy Whetsell: Right.

Reva Winkler: Any other comments from the other members in terms of the testing of the measure, the reliability and the validity of the measure? We do have the results of the testing of the EHR measure, I believe, and in terms of usability, feasibility, I guess one of the questions I would ask the committee is, you know, we've seen two measures.

You've identified them as important elements. Is this the kind of thing we want to see perhaps combined, you know, into a measure that has all of these important elements together rather than separate individual measures that could get parsed out or picked apart?

Donald Yealy: That would make sense if we could show that the timing of the measurements were similar. I don't know that that's true for them yet. I just don't think we know yet.

Reva Winkler: Okay. All right. So again, usability, feasibility for these measures, work group members don't seem to have any particular issues or concerns.

Donald Yealy: Was there a specific way that mental status was supposed to be assessed using like a mini-mental test exam or do we specify the exact methodology? Is this just up to anyone's discretion, or - I don't remember if it was laid out.

Reva Winkler: (Sam), did you want to respond to that?

(Sam Kearney): Yes, it doesn't specify - there's no specific tool that's required. It just has to be an assessment of mental status.

Donald Yealy: I mean, I think that's a little bit of a challenge because somebody's interpretation of ISS data - they're awake, versus I did a full mini-mental status exam and - that could lead to some variability in terms of how it's applied.

(Sam Kearney): I'm sorry. If I could just add, thank you for that comment, and I think that that's certainly very valid. I just looked at the documentation we had just a little bit closer, and we do provide a definition of ((inaudible)) assess may include, although it still doesn't get to the level of specificity that was suggested. It just says that documentation - that it may include documentation by a clinician that the patient's mental status was noted, for example patient is oriented or disoriented.

Donald Yealy: So that's all you need to know to satisfy, if they're oriented or disoriented?

(Sam Kearney): Yes, so the measure doesn't - I mean, someone could do a mini-mental status or a very thorough assessment. It's just as a minimum essentially says you have to include some type of notation related to their orientation. But certainly you could do something more extensive.

Donald Yealy: Yes. I mean, I think you know, there's such a - it's hard to know what the level - I mean, there's oriented to person, place, time, and situation, and you know, I mean, it's so hard to know where do you stop or draw the line and say that - leave it to them to determine. But there's got to be some level of specification I would presume to make it wholly reproducible and consistent.

Male: You know the rub on this is, is if you look at most of the prospectively assembled ((inaudible)) trials, they either don't define it or use a fairly loose role. And the retrospective ones take anything

that's available. So while I agree with you from a design standpoint, where it emanates from, that type of consistency just doesn't exist yet, to my knowledge, having done a couple of these trials.

Reva Winkler: All right. Any other thoughts on that particular measure? All right, as I mentioned, you guys buzzed through these quite quickly. Just to let you know what's going on, to follow up, for those of you on the work group that haven't submitted your thoughts and ratings for all of the measures, we'd ask that you do that, because we want to prepare a summary of your kind of group ratings and your thoughts and comments that will assist the presentation discussion the meeting - of the measure at the meeting.

At the meeting we're going to ask you to lead discussions, to walk the committee through the measure criteria. So we want you to report out you know, the - your thoughts on how well the measure meets, you know, the opportunity for improvement, meets the evidence, because the entire group will make a final decision on the rating for those; similarly for reliability and validity, and usability, feasibility.

And then there will be an overall recommendation. So that'll give you something to kind of think and prepare yourself for your role as a lead discussant for the various measures at the meeting. So any questions or thoughts from the work group members?

Donald Yealy: No, this is great. My only - I sent you an email, if you could just send me the Survey Monkey link. I don't know that I saved it, so I can finish out the scoring.

Reva Winkler: Great. Will do. We can do that. We'll send one out to everybody, just a reminder, and okay. And I think everybody got dated slides that we sent out before the meeting, so we will be creating sort of a summary, and as I mentioned, both the transcript and recording of this call will be posted.

We'll use the transcript to create this summary of your discussion and for your discussion points. And we will be getting that to you ahead of the meeting so that will help your role as lead discussants and committee members in evaluating all of the measures that will be here. Also the one measure that fell off our desk, we will be sending to you.

And if you could take a look at that as well, and we'll have that on the agenda for the meeting. (Katie), Jessica, and I are here and available if you have any questions or there's any concerns or issues you want to raise in preparing for the meeting, and we're happy to help you through it.

Otherwise if we've got no further comments from the steering committee, I'll ask our operator, Kelliann, would you see if there are any questions or concerns from public comments, please?

Operator: Certainly. At this time if you do have a question or comment, you may press star one on your touch-tone telephone. And we have no questions or comments at this time.

Reva Winkler: Thanks, Kelliann. All right. If there's nothing else from the steering committee, then hearing none, thank you all very much for being with us. To our measure developers also as well, thank you very much for being with us. And we're all pulling everything together to meet in March, and I look forward to seeing you all then. Thanks all very much for your time today.

Male: Great, thanks, everyone.

Donald Yealy: Thank you.

Female: Thank you.

Operator: That concludes today's conference. Thank you for joining us.

END