NATIONAL QUALITY FORUM

Moderator: Infectious Disease
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Operator: This is conference #: 92648946.

Operator: Welcome, everyone. The webcast is about to begin. Please note today's call is being recorded. Please stand by.

Christy Skipper: Good afternoon, everyone; and welcome to the post-comment call – post-meeting call for the infectious disease standing committee. My name is Christy Skipper, project manager.

And just to give you all a purpose of the call today, we are going to vote on the three HRSA measures that we were not able to vote on last week at our in-person meeting. And we're also going to have a discussion on the measure portfolio and any gaps that have been filled or identified. And then, we'll also talk about related and competing measures.

As I said, my name is Christy Skipper, project manager. And I'll turn it over to my colleagues to introduce themselves.

Mauricio Menéndez: Hi, everyone. Mauricio Menéndez, project analyst.

Melissa Mariñelarena: Good afternoon. Melissa Mariñelarena, senior director and welcome, everybody; all committee members; measure developers and anyone else who's on the phone today.

Christy Skipper: And, right now, we will go ahead and start out with a roll call.

Mauricio Menéndez: Please say here when I call your name. Woody Eisenberg?

Woody Eisenberg: Here.

Mauricio Menéndez: Adam Thompson?

Adam Thompson: Here.

Mauricio Menéndez: Emily Aaronson? Amesh Adalja? Esther Babady?

Esther Babady: Here.

Mauricio Menéndez: Nanette Benbow? Kathleen Brady?

Kathleen Brady: Present.

Mauricio Menéndez: Laura Evans? Piero Garzaro?

Piero Garzaro: Here.

Mauricio Menéndez: Donald Goldmann?

Donald Goldmann: Here.

Mauricio Menéndez: Jeffrey Hart?

Jeffrey Hart: Here.

Mauricio Menéndez: Michael Lane?

Michael Lane: Here.

Mauricio Menéndez: Jeff Lewis?

Jeffrey Lewis: Here.

Mauricio Menéndez: Rocco Orlando?

Rocco Orlando: Here.

Mauricio Menéndez: Jamie Roney? Pranavi Sreeramoju?

Pranavi Sreeramoju: Here.

Mauricio Menéndez: If you're here and I didn't call your name, can you speak up now please?

Amesh Adalja: Amesh Adalja.

Mauricio Menéndez: Thank you.

Christy Skipper: All right. Thanks, everyone. Before we get started, I just want to make a couple of announcements to remind you all to – if you're listening and via your computer to please mute your – mute your computer to eliminate any feedback.

And then, also, that you should have logged in to this meeting – if you are a committee member, you should have logged in to this meeting via the web link sent out by Shawnn at CommPartners that will enable you to vote and view the slides and material we have for you today.

As with the in-person meeting, we're going to start off with the developers introducing the measures and then we would turn it over to the lead discussants to begin the discussion of the measure. So, without further ado, our measure rep is number 2080 Gaps in HIV Medical Visits.

Woody Eisenberg: Melissa, this is …

(Crosstalk)

Woody Eisenberg: Could we just check to make sure that there aren't any committee members that had difficulty logging in to their personalized URL?

Melissa Mariñelarena: Sure. Thanks, Woody.

(Crosstalk)

Donald Goldmann: Yes. This is Don. I had no trouble logging in, but I'm not sure I know how to vote.

Woody Eisenberg: Right. That's true too.

Christy Skipper: When we come to the portion of the call where it's time to vote, we will have our operator give you voting instructions, but, in short, a slide will pop up and you'll be able to see what you're voting on and record your vote from your computer. But we will definitely give you instructions when we come to that.

Donald Goldmann: Great.

Woody Eisenberg: OK. I think we're ready to go.

Christy Skipper: Thank you. All right. Well, our lead discussant for 2080 are Kathleen Brady and Jeffrey Lewis. But, first of all, I'm sorry, the developer, if you could introduce the measure?

Marlene Matosky: Good afternoon, Christy. Can you hear us?

Christy Skipper: Hi. Yes, we can.

Marlene Matosky: Great. Good afternoon, everyone. This is the Health Resources and Services Administration here. In the room, we have a combination of folks who are on the development team of the paper measure, as well as folks who participate in the development of our eCQM. So I think primarily it's going to be Dr. Laura Cheever and myself talking.

You may remember I introduced last time Dr. Laura Cheever is a board-certified infectious disease physician. She practices at Johns Hopkins, but, in addition to that role, she is the associate administrator for the HIV/AIDS Bureau at HRSA. And I'm Marly Matosky. I am a nurse consultant here at HRSA and I've been involved with the measure development for a number of years.

So before – so, right now, we have a paper measure for gap in HIV medical visits. This measure is a little different than other measures you may have seen. Although the measurement period is a 12-month period, it's looking for folks who had a visit in the first six months of that 12-month period. Those

folks would be classified as being in the denominator. And the numerator includes people who did not have a visit in the second six-month period.

So, for instance, a client, to meet the denominator would have a visit in the first six months of January through June, if we're looking at a calendar year, but they did not have a subsequent visit from July through December. And with this measure, it's a little different than (other) measures in that lower performance is what we're looking for. We're looking for people who did not have gaps in visits.

Very similarly to our medical visit frequency measure, this measure is focused on retention and care. And I hope that all the committee members were able to download and review the additional evidence that we provided around retention and care that, number one, identified in the IAPAC Guidelines, the International Association of Physicians in AIDS Care Guidelines and their recommendation of an A1 for monitoring retention and care.

And then, additionally, because those are – that's the only set of guidelines that are rated for retention and care, I also supplied additional information around the importance of retention and care, more specifically, some recent articles and evidence that's emerged in the last three years since we last saw endorsement of this measure.

Most notably, I think this came up with the other measure, folks were wondering about cost of care. And there has been a group that's been doing a number of models and specifically around cost and they have this – building a body of evidence. And you will notice in the evidence that I provided that there is a significant cost reduction in terms of adverting new exceptions by retaining people in care. And there's also a significant gain in quality years of life as well with retention and care.

Dr. Cheever, is there anything else you would add?

Laura Cheever: No, I think that's a great (story).

Marlene Matosky: Thank you. We'll turn it back (to you).

Woody Eisenberg: Christy, this is Woody. I have a question for Marlene first. Marlene, could you explain to us also why this measure that is looking at a specific six-month period, something that is valuable in addition to the previous measures that we recommended a couple of weeks for endorsement that looked overall at a longer period of time.

Marlene Matosky: That's a very interesting question. Thank you for posing that. So, for folks who are participating last Tuesday, I believe it was, this group recommended endorsement of a medical visit frequency measure and it looked over – for retention, over a two-year span. And in that measure you had to have at least one visit in each six-month quadrant over a 24-month long measurement period.

As you correctly identified, this measure does look at a shorter period time. There is congruency between the two measures in that we are looking at measure – or, sorry, visits within six-month blocks. However, we're looking at a significantly reduced timeframe.

That's twofold; one, is that even though longer retention is supported in HIV care and treatment because people living with HIV are going to need lifelong care, number one, so that's why we've looked at the long-term measure. But being that it is a longer-term measure, it takes longer – more time to see or experience increases in performance, whereas this measure is much more – much shorter in duration.

We've heard from the field that they paired this measure with the long-term measure and that this measure is doing – giving them a – not a numerator population, shall we say, that is much more actionable that can help support that longer-term retention.

Woody Eisenberg: Very good. Thank you.

Marlene Matosky: Welcome. Thank you.

Christy Skipper: OK. So if there – I'll turn it over now to our lead discussants, Kathleen and Jeffrey Lewis – Kathleen Brady and Jeffrey Lewis.

Jeffrey Lewis: OK. Kathleen, did you want to start with that or …

Kathleen Brady: I can – I can certainly do that.

Jeffrey Lewis: OK.

Kathleen Brady: One second. I have multiple open documents here. OK. So I guess we may have to sort of walk through the evidence then based on what was just presented.

But I think for the most part it probably still holds that, based upon the review, it is not a systematic review of the evidence that's specific to the measure and the quality, quantity and consistency of the evidence was not provided although evidence is graded within the recommendation both in the human guidelines, as well as what was just presented in the IAPAC data. And so, I think based upon this, the preliminary rating for the evidence would indeed be insufficient.

Jeffrey Lewis: I would concur with that as well based on the evidence or lack of. Can we go to the next slide?

Christy Skipper: So, yes. So we're following along on the measure worksheet, so if there are no comments or questions about anything that Kathleen and Jeff just presented, then we can vote on evidence.

Melissa Mariñelarena: If the committee wants to vote.

Christy Skipper: If the committee would like to vote on evidence keeping in mind that this is a maintenance measure. So if there anyone – is there anyone on the call that would like to vote on the evidence criterion?

Adam Thompson: Before we move on – this is Adam, I just have one follow-up question. And I think this question kind of lingers from the last measure which is I don't think any of us were arguing against retention. I think retention was pretty much supported across the table.

I think the concern was where is the evidence aligning with two medical visits and I think that's still a question here and just wondering if the measure

developers have any further comment or just kind of still the pick in the number in the middle.

Marlene Matosky: So, again, just to re-orient folks back to the Department of Health and Human Services guidelines, it says depending on where you are in your HIV disease, you would at most be having laboratories drawn on a very frequent basis perhaps within a few weeks of changing a regimen, starting a regimen or if you had any clinical indications otherwise.

And then, if you were stable – had a stable viral load for two years or more, then you would be having a set of labs every – at least every six months. And I believe this committee had a very robust discussion and I think we sort of agreed – or we came to (no's) consensus in terms of the relationship between visits and laboratory – laboratories that are drawn in terms of is it the visit or is it labs. You know, we kind of hold true to the consensus that visits don't necessarily happen in the absence of labs and labs don't happen in the absence of visits.

Jeffrey Lewis: And the – excuse me, this is Jeff again. And my understanding and the question was whether labs constituted a visit or not and did you have to have a face-to-face visit with a provider for that to constitute an encounter or visit, right?

Marlene Matosky: So that was another part of the discussion as I recall. When we wrote this measure, we talk about a visit between a patient and a provider with prescribing privileges. We do not define that it has to be face to face. We do acknowledge and accept that there is a significant – or a growth, shall we say, in Telehealth and we have not ruled out the inclusion of Telehealth.

Jeffrey Lewis: OK.

Adam Thompson: So if a patient were to have labs ordered by that prescriber and they have the labs completed, would that count in your own book as a visit or would it have to be some kind of verbal interaction between the two, the patient and the provider?

Marlene Matosky: The latter. It would – we would require an interaction between the provider and the patient.

Adam Thompson: OK. Thanks.

Woody Eisenberg: This is Woody. Are there any other questions from the committee for the developers? If not, is there anyone on the committee that would like to have a vote on the evidence or do we agree that things are not changed and that they are still standing?

Female: (I'm changed).

Melissa Mariñelarena: OK.

(Off-Mic)

Melissa Mariñelarena: No, she said changed. So this is Melissa. So, then, I recommend that the committee vote and you can also have the discussion that if this measure also qualifies for insufficient evidence or passes on insufficient with exception, I don't know that's a discussion that we can have now if we have or – and then, we would vote like we did last time. You vote it insufficient and then you vote if there is insufficient, what was it, with exception.

Woody Eisenberg: And, Melissa, could you just explain to us again what that means?

Melissa Mariñelarena: Sure. So we haven't …

Male: Melissa, I just wanted to clarify, I was suggesting that we not vote and move on I said – when I said that. So …

Melissa Mariñelarena: OK.

Male: … I want to make sure you didn't misunderstand that, so I'm not calling for a vote.

Melissa Mariñelarena: OK. So, just to be clear, the preliminary analysis says that the evidence was insufficient. The two primary reviewers agreed that it was insufficient.

In the past, the past committee passed it. So if you just pass it, you're saying that it is sufficient, so you disagree with the preliminary …

(Crosstalk)

Amesh Adalja: This is Amesh Adalja. In the past, when it was passed, it was a pass without qualification or as an exception?

Melissa Mariñelarena: It passed without qualification and our criteria was a little less stringent than it is now. So you can still do what you did with the other one if you believe that the – that the evidence is insufficient, however, you can pass it on exception, which is what we did with the other ones. You may never have the evidence to support a measure like this. But if you – if you go on and vote – or say we don't need another vote, you're saying the evidence is sufficient.

Amesh Adalja: I think we should vote.

Male: Yes. I think we should vote.

Melissa Mariñelarena: OK.

Male: Yes. I agree then with voting.

Woody Eisenberg: OK. Good.

Christy Skipper: So now we'll turn it over to our operator to give instructions to the committee how to vote.

Operator: Thank you so much, Christy. So, right now, you'll see a plain slide on the screen that shows you the options you'll have in a moment to vote on. When we advance to the next slide, you'll see boxes next to each of the options.

You'll simply click in the box next to the option of your choice and your votes will be populated in real time. This would be for voting committee members only. And if for some reason you did not use your personalized link to access the platform earlier, we've made allowances with the link you have connected with now so it should register your vote.

Christy Skipper: OK. So we're now voting on evidence for measure 28 and your options are, one, moderate; two, low; three, insufficient.

Jeffrey Lewis: I'm not getting a box on my screen here.

Female: Yes. Neither am I.

Operator: Christy, do you want to go to the next slide? There we go. There we go.

Male: There it is.

Jeffrey Lewis: OK. I'm sorry.

Operator: And we are looking for 13.

Amesh Adalja: I don't – I don't have one (on some). I'm just going to put it in the chat.

Male: And if we check a box it's going to automatically be recorded. We don't have to hit anything else?

Christy Skipper: Correct.

Operator: That is correct.

Christy Skipper: OK. I thought I heard someone say they were going to chat in their vote.

Male: Yes.

Operator: It looks like it was Amesh.

Christy Skipper: OK.

Amesh Adalja: Yes. Amesh, yes. I did that.

Christy Skipper: OK. One moment.

OK. So voting results are 17 percent, moderate; 0 percent, low; and 83 percent, insufficient. This measure does not pass on evidence.

Kathleen Brady: I thought we could vote on an exception though.

Christy Skipper: Yes.

Kathleen Brady: OK.

Melissa Mariñelarena: So the next step is for us to go and you want to vote on the exception like we did for the other one. We do not have a slide for exception, but it is a pass it on exception yes, pass it on exception no. Correct?

Christy Skipper: Yes.

Melissa Mariñelarena: OK. So if you could just type in the chat box – everybody has access to the chat box, either yes or no for passing this on exception for evidence.

Jeffrey Lewis: Oh the chat box, OK.

Melissa Mariñelarena: And what you're saying yes or no to is the committee agree that it is OK or beneficial to hold providers accountable for performance in the absence of empirical evidence of benefits to patients.

Jeffrey Lewis: I'm not able to put anything in that chat box they sent.

Melissa Mariñelarena: Are you getting chats?

Christy Skipper: I am getting chat.

Melissa Mariñelarena: And who was that who was not able to insert …

Jeffrey Lewis: That was Jeff. I'm sorry. That was Jeff Lewis.

Melissa Mariñelarena: Would you like to give your vote verbally?

Jeffrey Lewis: Yes, that's fine. Yes, with exception.

Melissa Mariñelarena: OK. So I have 12 yes for the exception, one no for the exception. So the measure does pass on the exception to the evidence criterion. We should now move on to performance gap.

Kathleen Brady: OK. So in terms of performance gap, developer presented data from the RSR and we've heard all about that at the in-person meeting. The mean performance for gaps in medical visits has fluctuated over time, but currently stands at 21.7 percent as of calendar 2014. And you can see that this is data ranging in 2010 on 324,455 individuals to 316,087 in 2014 with over 800 providers and the mean was 21.7 percent for gap, the median was 15.6 in 2014 and the 10th percentile was 6.5 with the 90th percentile at 45.1 percent.

And they also provided some disparities information specifically a table – that table shows there's gaps – higher gaps in medical visits among patients aged 20 to 34 by race, ethnicity. It's higher among native Hawaiian-specific islanders and American-Indian Alaskan native; and by gender, higher for transgender patients with 19.8 percent gap versus – in transgender patients versus 15.5 percent in female and 18 percent in males.

Woody Eisenberg: This is Woody. Do we know how a gap is defined?

Marlene Matosky: Hi. This is the measure developer. A gap in medical visit is if a patient had one visit in the first six months of the measurement year and did not have a visit in the second six months.

Woody Eisenberg: I see. So the gap is defined to correlate with this measure?

Marlene Matosky: Yes.

Woody Eisenberg: OK. So if I understand the data correctly then, could you scroll back up? The – so the gap is 21.7 percent in 2014 or the gap is 78.3 percent?

Marlene Matosky: No. There are 21 percent of patients who had a gap in medical visits, meaning that had a – had a visit in that first six months and no visit in the second six months.

Woody Eisenberg: OK, 21.7 percent of patients meet your definition of a gap in 2014.

Marlene Matosky: Yes. And just to remind folks, the lower the number, the better.

Woody Eisenberg: Right.

Marlene Matosky: So a gap of 5 percent is better than a gap of 25 percent.

Jeffrey Hart: This is – this is Jeff Hart. So we are actually – we're actually seeing that the gap is increasing, not decreasing. Is that – is that how I understand this?

Marlene Matosky: You are correct. When you look at this data, in 2014, it was 21, nearly 22 percent of patients had a gap versus, in 2010, nearly 19 percent had a gap. So we've seen roughly a 3 percent rise in gaps.

Woody Eisenberg: And was this endorsed measure in effect and being used at the Ryan White clinics during this period of 2010 to 2014 or does this precede even the existing measure?

Marlene Matosky: So this measure was endorsed in 2012 and in the Ryan White HIV/AIDS program we don't mandate which performance measures site to use. They can select the ones that are most appropriate to their patient population, so there are some who are using and some who are not.

Woody Eisenberg: Thank you.

Christy Skipper: Is there any other discussion or presentation on gap? OK.

Woody Eisenberg: This is Woody. I would just make a comment that it's possible that gaps are getting larger because of changes in practice. It might be reflecting – still reflecting good care. The gaps are getting larger and I don't know what the implications of that are for the need for this measure, but it's something to think about.

Kathleen Brady: Yes. That's something …

(Off-Mic)

Kathleen Brady: look …

(Off-Mic)

Kathleen Brady: … as we use this measure locally. We've actually had our providers do quality improvement projects related to it and we actually use this measure for data to care efforts.

And I can tell you that it's – typically, the people who – the vast majority of the people who have a gap are not the virally-suppressed individuals. It's about 80 percent are not and about 20 percent are. So, I mean, it might – it may be a reason why there's been a slight increase because the guidelines have changed over this time period. But it doesn't make it a – it doesn't change it to be a non-useful measure by increasing it by only 3 percent.

Woody Eisenberg: Thank you.

Jeffrey Lewis: And when you – this is Jeff again. When you say the guidelines have changed, in terms of the length of time, from the year or the two-year time period? What has exactly changed?

Kathleen Brady: It's basically – talking about visit frequency within the guidelines.

Jeffrey Lewis: OK.

(Off-Mic)

Kathleen Brady: ... executed in 2012. And so, that may be in part why, you know, there's been …

Jeffrey Lewis: The number grew. OK.

Kathleen Brady: Yes. But I – it's not – it's not had a major I think impact on this measure, the vast majority of the people who have a gap to really have a gap.

Jeffrey Lewis: OK.

Jeffrey Hart: I'm sorry. This is Jeff Hart. Could you explain that – the guideline change again? I didn't quite catch that.

Kathleen Brady: So, basically, the guidelines for the most part have basically – to say that viral load should be checked every six months, but requirements for actual visits is

really kind of – for people who have durable viral suppression is really up to the discretion of the provider and could be increased to be on an annual basis.

Jeffrey Hart: OK. Thank you. That helps.

Christy Skipper: Any other questions? OK. Now, we will move to vote on performance gaps.

Mauricio Menéndez: So performance gap for 2018 vote one for high, two for moderate, three for low, four for insufficient.

Christy Skipper: OK. We're waiting on two more votes. If you haven't voted, I'll give you a couple more seconds. OK. Just one moment.

OK. All right. So there were three votes for high, 10 votes for moderate, zero votes for low and four votes for insufficient and the measure does pass on performance gap. I'm going to note that two people have chatted in their vote. So what you see on the screen I just added in the votes that were chatted in so the measure does pass on gap. And we can now move to discussion of reliability.

Kathleen Brady: OK. So, for this measure, it's specified at the facility level or clinician office clinic. And so, I think we've already sort of discussed with the other specification. Should we go into reliability then?

So in the previous review of this measure, the developer conducted signal-to-noise testing to assess reliability and reliability testing was completed for the 2010 – the 2014 time period. And the results of the reliability testing are right there now. And so, they used the 2014 RSR.

And so, reliability scores fall from zero to one with a reliability score of one implying that all variations caused by real difference and performance across entities. And a score of zero indicates that all variation is attributed to measurement error.

So what they found is that very high reliability testing from 0.969 in 2010 to 0.973 in 2014. And they also gave distributions to provider-level reliability scores by year with – and I'm going to look at 2014 information with 94

percent of the providers having a score of greater than 0.7 percent. And the mean reliability in 2014 was 0.973 as I said previously. So based on the algorithm, the preliminary rating for reliability based on this information would be high.

Melissa Mariñelarena: Hi. And this is Melissa. And again, because this is a maintenance measure, you can choose to pass or use the ratings or the vote from reliability from the previous – from the previous project. If there's no issues with the reliability, if anybody has any questions, if you want to have a discussion, if you want to vote, if you do not, you can say that you do not want to vote and we can move on to reliability – I mean, to validity, I'm sorry.

Does anybody have any issues with the reliability testing that has been provided? Hearing no issues, is anybody opposed to not voting on reliability and accepting the reliability results from the previous review? Hearing nothing, we will move on. We'll accept reliability from before and we will move on to validity.

Kathleen Brady: OK. So for validity testing, at the previous review of this measure, the sub-committee agreed that the measurement met the scientific acceptability criteria, face validity was used to established measure validity. Validity testing has not been updated. The testing level was the measure score.

And, as I said before, it was face validity only. And face validity was established using a technical advisory panel. The panel presented – was presented with current research in HIV care and treatment and members then voted on the domains for the proposed measure based on importance, ability to assess quality of care, feasibility and use in quality improvement activities. And the developers stated that the technical workgroup agreed that the measure could assess and improve the quality of HIV care.

In terms to threats to validity, patients are included if – from the measure if they die during the measurement period. And to examine the effect of exclusion on the performance where the developer calculated the proportion of patients excluded due to death out of the total number of patients. And the percentage points difference between performance versus with and without

the exclusion for death was calculated and the developer reported less than 1 percent of patients were excluded due to death each year and so would have a minimal impact.

And so, in terms of meaningful difference from 2010 to '14, the data shows variability across providers allowing for the identification of meaningful differences across sites. Of the top performers in this measure in 2014, 6.5 percent of the patients had a gap in care compared to 45 percent of patients with a gap in care among lower performers. And so, based on the preliminary rating, this would actually – since it's based on face validity, it would be rated as insufficient.

Melissa Mariñelarena: Sure. Let me explain again. This is Melissa. So we rated it insufficient only because our exact words were not used. I think we have this discussion last week. HRSA also explained that they did not update their face validity because they're focusing on the e-measures.

There is not an accompanied e-measure that was – that was submitted to this project because – and it was – it's all nuances depending on what they could submit and, Marlene, correct me if I'm wrong, but you are developing a measure – an accompanying e-measure for this – for gap, correct?

Marlene Matosky: Yes, that's correct. We are actually in – right in the process as we speak of field testing an electronically-specified measure for gap in visits. And just to underscore, we did not submit the e-measure because NQF will not review an e-measure for which it's not currently used in a CMS program.

Melissa Mariñelarena: Right, without full testing. But once it's fully tested and it comes back to us in this committee, we'd review that measure. So you have a couple of options. You can choose not to vote and accept the validity from – results from before and it passed on validity in the past. If anybody wants to vote on validity, you may do so. Those are the two options.

Woody Eisenberg: And Melissa, this is Woody. If we don't – if we decide not to vote, then it would move forward as approved or approved with exception – what's the result of that?

Melissa Mariñelarena: This would move forward as approved. We just accept the validity of results from the past and that was approved and then we move on.

Woody Eisenberg: OK.

Melissa Mariñelarena: So I will ask, is anybody opposed to accepting the validity results from before?

Female: No.

Melissa Mariñelarena: OK. Hearing no other opposition, we will accept validity results from the past committee. We will not vote for this measure and validity passes. And then, we will move on to feasibility.

Jeffrey Lewis: Feasibility. OK.

Melissa Mariñelarena: Thank you.

Kathleen Brady: Well, this one's an easy one. So the developer reports that all data are generated or collected by and used by health care personnel during the provision of care and that all data elements are in defined fields in electronic health records and there are no fees, licensing or other requirements to use this measure and it's actually fairly easy to implement.

Christy Skipper: Any questions of the developer or discussion by the committee on feasibility?

Jeffrey Lewis: And if you don't mind, I can talk about – I'm sorry, go ahead.

Adam Thompson: No. I was just going to say to add in just a comment around, you know, people can actually – can collect the data and maybe this falls more under usability. But it had to do with the fact that it is calculated in the inverse so that people have to look for the lower number to equate at the higher performance. It's very confusing for folks out in the field – the only comment.

Jeffrey Lewis: OK.

Melissa Mariñelarena: Jeffrey, was that you? Did you have something else to add?

Jeffrey Lewis: I was just going to – I can talk about usability, that's all. I was going to offer to talk about usability and use as part of just my contribution I guess. I'm having problems with my slides itself. I had it open, but now I can't operate it myself.

But as a person – I just want to comment that – on the usability and look at that. And I had a question as it relates to – you had mentioned earlier that not all Ryan White receivers of those funds use this measuring tool. Is there a selection process or is it just voluntary?

Melissa Mariñelarena: Jeffrey, let me stop you. We have to vote on feasibility.

Jeffrey Lewis: OK. I'm sorry.

Melissa Mariñelarena: So if we could vote on feasibility and then we'll move on to usability and have that discussion if that's OK.

Jeffrey Lewis: That's fine. I'm sorry.

Melissa Mariñelarena: OK. Are there any other questions or discussion around feasibility? If not, you don't get off that easy because you do have to vote on feasibility. And for those of you that are having trouble with your voting slides, just send your vote in the chat and Christy will count it.

Mauricio Menéndez: OK. Voting is now open for feasibility 2080. One for high, two for moderate, three for low, four for insufficient.

Operator: And if for some reason you've lost view of the voting slide, you can always refresh your session by pressing F5.

Jeffrey Lewis: F5. Let's see.

Christy Skipper: And we have 12 votes. I see that only one person chatted in their vote at this time. So overall, we have – we now have 13 votes – 10 votes for high, 3 votes for moderate. The measure does pass on feasibility.

Melissa Mariñelarena: Great. OK. Now, we can move on to usability and use.

Jeffrey Lewis: And that's where I had the questions about – anyway, they came up earlier whether is this 20 federal programs are using – are not currently using it? And I was just kind of wondering if there's a selection process for those who chose to use it or didn't use it or why weren't they kind of all having to use it?

Marlene Matosky: So just a slight amount of background, the Ryan White HIV/AIDS program is a legislatively-bound program meaning that congress passes legislation for this program and we need to implement the program that's written in the legislation. And the legislation does not specify which performance measures our grant recipients would use. It's just that they have to have a clinical management program that includes performance measurement and quality improvement.

So with that being said, we've developed a number of performance measures because all of you already know that developing performance measures is an awfully complicated, tricky process. So we've developed these measures. We make them available to our, you know, 600 plus grant recipients; 1,200 providers across the country and they select which measures to use in their programs that are applicable for their patient population.

I will say that we do have a significant portion of our providers that are using this measure and when we implement any sort of improvement initiatives, we include this performance measure. And we see once people understand what this measure is and what the intended purpose of this measure is and that they understand that low performance is good performance, they find it to be a very useful measure in terms of quality improvement.

Jeffrey Lewis: Quality improvement. Great.

Marlene Matosky: Thank you.

Adam Thompson: And this is Adam. I would second what Marlene just said. I'm seeing that all the clinics that I'm working with whether they're scheduling traditionally six months out or using the new more open access models of sort of on-demand scheduling, the gap measure is probably one of the most useful measures that

they use to predict how to begin scheduling patients. So this is highly usable in all the sites that I'm seeing.

Jeffrey Lewis: And as a person who works in – who uses it in his daily work, I would definitely support and kind of echo that in regards to the concern and the question that I have in terms of the support that goes along with the measurement tool in terms of – if there is a gap or how do you do the outreach in terms of – to reach those people that fall into that gap, the support, the outreach worker, the case manager and things of that nature that go along with that retention and the use of the tool once you identified those people in the gap? Does that make any sense?

Kathleen Brady: You are asking about …

Melissa Mariñelarena: Thank you.

Kathleen Brady: … how you do it?

Jeffrey Lewis: Yes. In terms of implementation, if you don't have the electronic medical records, would you have still be able to track it as effectively as those who have EHR?

Adam Thompson: I can tell you – this is Adam. I have two clinics that I work in that are paper-based clinics, they do have small patient population, so it's a little bit easier. But they do hand count this measure and they are able to do it.

If you are on a – the larger population, I think looking at, you know, 500 to 1,000 or higher I think it would be very difficult. There are very few sites that I've seen across the country, and if others have more information you can put it in, that don't have some kind of technological method to track it, whether an EHR or an Excel spreadsheet or some other method.

Jeffrey Lewis: Or manual. OK.

Kathleen Brady: Or Careware because a lot of Ryan White-funded facilities that may have EHRs, but the way they track this is actually through the information that gets put into Careware which is often manual data entry.

Jeffrey Lewis: On a state level? Because I don't know a state-wide level on most cases, the Careware?

Kathleen Brady: No. That would be on a facility level.

Jeffrey Lewis: OK. And so, I – in looking at the outcome, the preliminary rating results of usability, given those questions I just had answered, I agree with the – with the high rating.

Christy Skipper: All right. If there are – is there any other discussion on usability and use? OK. Then, we will go ahead and vote.

Mauricio Menéndez: OK. Usability and use voting is now open for measure 2080. Vote one for high, two for moderate, three for low, four for insufficient.

Christy Skipper: All right. All votes are in. 77 percent of votes were high and 23 percent of votes were moderate. The measure passes on usability. And we'll now pass – move on to an overall recommendation for endorsement.

And I just want to note that I read out the vote that was chatted in. I read out the votes including the vote that was chatted in. So there were 10 votes for high, three votes for moderate and that comes out 77 percent high, 23 percent moderate.

So we'll now move on to voting for overall recommendation for endorsement. All right. So voting for overall suitability for endorsement vote one, yes; two, no.

Mauricio Menéndez: OK. 100 percent of the vote was yes for overall (suitability), 2080.

Melissa Mariñelarena: OK. Great.

Christy Skipper: So now we'll move on to measure 2383, Prescription of HIV Antiretroviral Therapy. And this – there is a paper-based measure and an e-measure associated with this. So your discussion on evidence and gap for the paper measure, as well as your vote, will carry over to the e-measure.

So we'll start out with the paper measure and our lead discussants are Jeffrey Hart and I believe Woody and Adam will also be discussing this measure.

Jeffrey Hart: Is the measure steward going to speak first or should we just move in?

Christy Skipper: You are correct. Thank you for catching me. So we would ask the developer to introduce this measure.

Marlene Matosky: All right. So this is the final measure concept that we're going to review today. It's the prescription of antiretroviral therapy. So the definition is the percentage of patients, regardless of age with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year.

So the denominator is patients you had at least one medical visit with the prescribing provider and the numerator is the patient was prescribed antiretroviral therapy during the measurement year. And the measurement year is a 12-months period. One note I want to make about this measure is that when we're defining antiretroviral therapy, we're looking for evidence of at least one medication. We did that in order to simplify the performance measure.

As many of you know, as very skilled clinicians, you can look at a client's medication list and very quickly be able to determine whether that prescription of antiretroviral therapy is appropriate or not. However, when we're looking in electronic systems and trying to calculate this in an electronic format, it becomes very difficult to code the 26 odd different medications and appropriate combinations. So i.e. we're looking for at least one medication.

The other thing I would say about this measure is guidelines changed about 2010-2011 or so and those guidelines used to say that you would prescribe antiretroviral therapy based on somebody's CD4 count. That's no longer the case.

Everyone, as per the guidelines, should be prescribed HIV antiretroviral therapy regardless of their CD4 count. So there is no need to wait anymore and anybody with HIV could be prescribed with medications regardless of any

other clinical presenting conditions. Dr. Cheever, would you like to say anything?

Laura Cheever: Just that this – the other guidelines, I think we had the discussion the other day, we don't ever expect this to be 100 percent because there are patients that are going to be refusing treatment for any variety of reasons and so the expectation is not to get to a 100. We don't want to sort of imply any coercion on the part of the clinician.

Marlene Matosky: And I think now we'll turn it back over to you, Christy. Thank you.

Christy Skipper: All right. So we'll turn it over to our lead discussant, Jeffrey, Woody and Adam to start out with evidence.

Jeffrey Hart: Great. Thank you. This is Jeff Hart. The evidence – I think we've discussed much of the evidence in the past regarding the HIV measures and the use of HIV antiretrovirals. Current treatment guidelines show that universal prescriptions for HIV antiretroviral therapy for sustained viral load suppression which in turn is directly related to the reduction of disease progress and reduction in potential for transmission of HIV infection.

Among persons in care, sustained viral load suppression represents accumulative effect of prescribed therapy, ongoing monitoring and patient adherence. The proposed measure will direct provider's attention to the quality improvement efforts toward this important outcome.

We've reviewed the description and the numerator and denominator. In this measure, there are no exclusions. It's a processed measure.

I don't know if there are any questions at this point about the evidence. Like I said, I think it's very consistent with the other measures that we've reviewed thus far. So let me just ask if there's any questions and we can move forward from that.

Woody Eisenberg: Yes. This is Woody. I do have a question or really it's a comment that, as far as I could tell, the evidence that's provided as pointed out by NQF staff doesn't directly address the prescription of antiretroviral therapy, but rather,

it's directed at other aspects of care according to the continuum like viral suppression, most importantly. So one of the things that I think we should consider is whether the mere prescription of antiretroviral therapy rather than the receipt by the patient of that therapy is adequate evidence.

Marlene Matosky: So this is Marlene the developer. And I believe we may have touched on this very briefly previously. So I think that's a very interesting proposition that you're proposing and that we would measure that the client is actually receiving those medications. But there is no connection within electronic health records for us to track that patients have actually picked up their medications either at the pharmacy or that they have a delivery service of their medications to their homes.

Laura Cheever: Yes. This is Laura Cheever. So, yes, that's one issue. I think this is also why we do pair this with viral suppression because the first step, if we look at the 1999 WHO goals for elimination of – for the elimination of the epidemic is that you need to get 90 percent of people prescribed medication that's kind of the first step. And then, of this 90 percent, should be virally suppressed. So we look at that whether or not the patient is actually taking their medication in terms of reducing all those barriers to accessing medication through that viral suppression measure, so we use these two in tandem.

Melissa Mariñelarena: And this is Melissa from NQF. I just want to remind the committee that when you're looking at this measure, you look at this measure on its own merit. And, you know, does the evidence – like Woody said, does the evidence support the measure focus and the focus is on the prescription of antiretrovirals.

So you have the option, again, if you disagree with the preliminary analysis that the evidence is sufficient you can accept the previous committee's vote and pass it. If you want to have more of a discussion, we can continue having the discussion if you want to vote. If you think that this is a type of measure that you'll never have, you know, some RCTs on it and that it should be passed on evidence with exception, that's another option that you have as well which is similar to the past three other measures.

Marlene Matosky: And this is Marlene on the development team. I did want to note that in our submission form and I don't – I'm not sure perhaps it might have been an overlook or what have you – we did submit information from the Department of Health and Human Services Guidelines. Those are, "the guidelines" for HIV care and treatment in this country.

And in those guidelines, it's an A1 recommendation. You don't get any stronger than an A1 recommendation around the prescription of antiretroviral therapy. To quote – let me pull it up here – where is my evidence?

It says, "Antiretroviral therapy is recommended for all HIV-infected individuals regardless of CD4 T lymphocyte cell count to reduce the morbidity and mortality associated with HIV infection." And that's an A1. So, in fact, I don't believe it should have been initially rated insufficient.

Kathleen Brady: I agree. This should be rated high.

Woody Eisenberg: I'm sorry. Who is – who is agreeing?

Kathleen Brady: I'm sorry. It's Kathleen Brady from Philadelphia. I'm not sure that I'm understanding the question.

Woody Eisenberg: This is Woody. Let me – let me explain the way I'm looking at it. I think there's a difference between writing a prescription than a patient actually receiving a drug.

And I'm very sensitive to Marlene's explanation and Dr. Cheever's explanation that their clinics actually don't have any access to the records of what's dispensed by the pharmacy and that's a problem nationwide for lots of measures. So I'm very aware of that.

And I'm sort of hoping that as we go forward with better information systems that that information will become available to all of the prescribers. But, right now, what we're left with is simply that prescription is written. We don't know if the patient gets that prescription, so the actual link between the prescribing and eventually suppression of viral load I think doesn't really exist.

I think the preliminary rating for evidence should be insufficient. Now, that's not to say that I don't think this is a valuable measure. That's another question for later on in our voting period. I'm just looking at it early from an evidence perspective.

Kathleen Brady: But I think there's two – there are two different issues. One looks at – is really about did the provider write the prescription and follow the guidelines. And so, that's what this is looking at and the other part is looking at viral suppression which, in many cases, is looking at appearance of the patient and they are very distinct issues. You know, you can't – you can't become virally suppressed if your provider didn't write you a prescription.

Jeffrey Hart: This is – this is Jeff Hart. The guidelines say, as you stated, the antiretroviral therapy is recommended. It doesn't say antiretroviral therapy prescription by a provider is recommended. And I think that's perhaps the distinction that Woody is referring to. My assumption is that when they state antiretroviral therapy that the patient is taking the medication. So, any comment there?

Kathleen Brady: I think the guidelines are about that – there used to be about – information about CD4 criteria. That wasn't about whether the patient was taking the medicine. That was about the providers prescribing the medication. So it's really looking at two different issues.

Jeffrey Hart: OK.

Jeffrey Lewis: I'm sorry. This is Jeff. So you're looking at treatment guidelines. Is that – Jeff Lewis.

Jeffrey Hart: That appears to be the case. That is the evidence for us for the creation – and using this measure is to see if providers are following the guidelines.

Jeffrey Lewis: OK.

Kathleen Brady: Correct.

Jeffrey Hart: The evidence is graded. We don't have quality, quantity and consistency of evidence provided. And in other situations, we have rated these measures as insufficient.

Marlene Matosky: Hi. This is Marlene. NQF, can you – can you please perhaps outline the process for this section? It is my understanding as the developer that graded guidelines are what you're looking for in this section. Is that accurate?

Melissa Mariñelarena: Hi, Marlene. This is Melissa from NQF. We are looking for graded guidelines if the committee agrees that the guideline – the recommendation in the guideline that you mentioned supports the measure focus and it is graded A1. The highest it would still be that this – we would give on evidence would be moderate because we asked for a systematic review and a QQC which was not provided. But we have a guideline that is graded.

If the committee agrees – again, if the committee agrees that that one part of the guideline supports the measure focus. On the preliminary analysis that the staff did, we did not think that that – that that guideline supported the measure focus because it was – as previously stated, the measure focuses on the prescription – writing the prescription for patients where the guideline, you know, just talks about the recommendation for antiretroviral therapy. That was the difference that we thought, but we're not the experts. We leave that to the committee to decide if that evidence is sufficient.

Marlene Matosky: So, to clarify, just – I think I'm just going to provide a little background I think perhaps for the committee. So the Department of Health – the Department of Health and Human Services is – has this long rich respected history of putting out guidelines for providers for providing treatment and care of people living with HIV. These guidelines didn't turn up last week or last year. They've been around for a number of years.

And I think I would look to our positions on the committee who are providers of HIV care to perhaps speak to that. So I would – I would highly encourage the committee to look to the experts on this panel about the stature of these guidelines and not question these guidelines because I think if we start

questioning these guidelines we're going to be going down a very – a very bad place.

Secondly, it is our understanding, as provided in the NQF documentation, if you provided graded – or sorry, if you provided graded recommendations and they – I provided the most recent ones, I did not have to provide a re-summarization of additional evidence because I had done that previously.

Melissa Mariñelarena: Marlene, this is Melissa. So, first of all, we're not questioning the guidelines. That's not what we deal with. If the grading is there, that's what we go by. We don't go and try to find additional grading or everything. There is grading with that statement.

What I ask of the committee is to determine whether that recommendation in the guideline supports the measure focus, number one. Number two, for our evidence, we didn't – we don't ask you to re-summarize everything, but that's not the same thing as providing a systematic review and a quality, quantity and consistency of the evidence which can come from a guideline. Providing just guidelines is fine, but it doesn't give you higher than a moderate.

If you go to our algorithm, we need a systematic review, then we ask for quality, quantity and consistencies. Like I said, that could come from the guideline that you're using to support the measure focus. But we want to know the number of studies that went into that guideline. So we want to know the number which would be the quantity, the quality, were they observational, are they expert opinion, are they RCTs and then the consistency which way they're going.

That's how we get into – can you pull up the – Mauricio is just going to pull up the algorithm. So scroll up, so that's how you go end up in the rated as high, moderate or low based off of the systematic review.

We don't have a systematic review for your measure. So with no, if you look into box six, we went with no QQC from a systematic review. Moderate is the highest potential rating. That doesn't mean that we're – that's not a judgment on the guidelines themselves. That's just based on what was submitted to us.

Marlene Matosky: Because we had submitted the systematic review with the prior endorsement, it was my understanding we did not have to resubmit it again.

Melissa Mariñelarena: If the – if the evidence changed, then you do – only when the evidence changes. If the evidence doesn't change …

Marlene Matosky: No. There's been no change in this evidence.

Melissa Mariñelarena: Then, I have to go back and look what you provided before. But, right now, the highest that the committee can you give you is moderate. But again, that's not – that's not saying that that is – that's not a judgment on the guidelines themselves. This is based on what is in the submission form.

Marlene Matosky: With that being said, the panel does not need to vote on evidence if they find it's acceptable. It's acceptable evidence that's been submitted last time.

Melissa Mariñelarena: Correct. If the committee agrees that the evidence is sufficient, we do not have to vote again. lf there is somebody who does not believe it it's sufficient, then they need to vote. So I'm going to turn this back over to Adam and Woody to facilitate this discussion.

Woody Eisenberg: OK. This is – this is Woody. So we've heard a lot of explanation about how the – about how NQF sees this and how the developers intended it to be. So is there any more discussion at this point? Melissa, there seems to be no more discussion. Would you like to then pose the question about whether the committee would like to bring this to a vote or simply accept the decisions from the past committee?

Melissa Mariñelarena: Sure. We could do that. So is there anybody who feels that this evidence is insufficient? Hearing no objections, the question now is, is the – is the committee willing to accept the past committee's vote and accept the evidence as sufficient?

Kathleen Brady: Are you hear – what are you asking for, objections or people to say yes?

Melissa Mariñelarena: People to say yes on the last question.

Kathleen Brady: Then …

Woody Eisenberg: Ask us again, please, Melissa.

Melissa Mariñelarena: OK. I'll start with the first question, f I could remember it now. Does anybody – does anybody object to the evidence being sufficient? Did I say it – I think I said it even more confusing this time.

Christy Skipper: Are there any objections to the evidence that was presented on this measure?

Woody Eisenberg: No objection.

Jeffrey Lewis: No.

Melissa Mariñelarena: No.

Male: No.

Melissa Mariñelarena: OK. Hearing no from everybody, then what the next move is we will accept the past committee's vote and we will take the evidence as sufficient and not vote on this and we will move on. Is that OK?

Male: Yes.

Male: Yes.

Jeffrey Lewis: Yes.

Male: Yes.

Female: Yes.

Male: Yes.

Melissa Mariñelarena: OK. Thank you. So now – yes, go ahead.

Jeffrey Hart: Yes, go ahead. OK. We'll move on to the gap in care and the opportunity for improvement, as well as disparities. From the table provided, we can see from 2010 to 2014 that there has been improvement over time from 68.4 to 77.6.

There were 316,087 patients that had one medical visit and the denominator, there was 255,342 that had – with viral suppression. Is that accurate? I guess I'm questioning again we're getting a number of patients who had viral suppression as opposed to patients who had a prescription and I'm confused about that. I don't know if it's mislabeled or if this is – and perhaps I should let the measures steward speak to that.

Marlene Matosky: So what I'm seeing up here is it's looking at the number of patients who had greater than one medical visit that was the denominator. Those are the folks who made it at the denominator criteria and the numerator is – sorry?

Woody Eisenberg: Or equal to one visit, right?

Marlene Matosky: It's – yes, greater than or equal to one visit and then the numerator are the patients who were prescribed the antiretroviral therapy. So it's just really just breaking out the numerator and the denominator population for you.

Jeffrey Hart: OK. I'm sorry about that. I was looking at a completely different table. So perhaps that was updated. The mean was 78, the median was 90, the standard deviation 28, 10th percentile was 29.6, 90th was 98.3 and there were 813 facilities included in the 24 measurement.

I think it's clear from this analysis that there is a gap and that the analysis itself is very consistent with the other measures that we've seen although the data, of course, is different. At this point, does anyone have any questions about the – any of that information? OK. Hearing nothing.

OK. Again, this is a different table. I must – I must have printed this before it was updated. The race ethnicity data shows that there are disparities – no, this looks to me to be a display of the number of patients in each of these groups and I'm not sure if that's correct.

But some of those rates – well, the rates don't really pan out in my view. I don't know how a group could have 0.4 percent adherence to this measure such as the American Indian, Alaska native. So is my understanding correct that this is the actual percent of patients in this – in the population?

Marlene Matosky: I'd have to look back at the actual submission that we sent, but I believe this is a distribution of the patients who were included in the measure, not their actual performance I believe because if you look at, for instance, gender, if you add up – I'm looking at 2014, 70 percent plus 28.4 percent plus 1 percent, that would add up to 100.

Jeffrey Hart: OK. That was my understanding as well. So I do believe the information may have been provided with relation to the actual rates, but I'm not sure if that's true or not. Again, we can see that there is a large group of individuals that could definitely be in the disparity group. But again, I'm not sure that we have the data to support that there are disparities. Does …

Woody Eisenberg: You know, Jeff, this is – this is Woody. I agree with you. I – this table I think as Marlene explained just breaks out the different race and ethnicity of the population and the denominator, but it doesn't tell you if there are disparities in the performance on the measure.

Jeffrey Hart: All right. OK. I just looked through my document which may be an old document, but I don't see that – any information on that. So that's a – that's a – the full table can be found here. That looks like there's a link.

Christy Skipper: Yes. We are trying to pull that up for you all now to display on the screen.

Melissa Mariñelarena: It's on SharePoint.

Christy Skipper: And if you all have access to the SharePoint site which you all have – should have, you can pull up the measure worksheet. But I believe we're getting it up in front of you right now. So just if you could bear with us for a moment.

Mauricio Menéndez: Should it be on the whole …

Melissa Mariñelarena: So while you're pulling that up, I'll take a moment to say, we have a – I believe in the submission form it was two-page table and it was landscape in orientation that really describes I think the data that perhaps you were looking for, Jeffrey, where we look at by a variety of different patient characteristics their prescription of antiretroviral therapy.

So, for instance, I'm just going to look at 2014 – so in 2014, 62.8 percent of patients ages 20 years old to 24 years old were prescribed antiretroviral therapy versus 82.3 percent of patients 65 years or older. So you can see that there is a wide distribution between those two patient populations.

One area that we feel like we've done a great amount of work is really around race and ethnicity. So if you look at African American patients, 74.3 percent of those folks have been prescribed antiretroviral therapy compared with 76.5 percent of the white patients. So there is a very small difference between those two groups.

And then, additionally, we looked at it by health care coverage as well because that's something that we're always interested in. And then, we looked at national priority population, so we broke the data out and looked at black women, black men, Hispanic men and women use which we categorized from 13 to 24 and also transgender women. So you can see where they were, what their performance was for those subgroups across multiple years in that table.

Jeffrey Hart: Great. I can't see that table, but I have no doubt that the evidence – there we go – the evidence shows that there are disparities. I don't know if other committee members have access to that table just because I don't – I don't want to hold up the entire group.

Kathleen Brady: Yes. I have it. I downloaded it from – it's Kathleen Brady – from the NQF web site.

Jeffrey Hart: OK.

Kathleen Brady: And the numbers that were reported by Marlene were – are indeed correct.

Jeffrey Hart: OK. Great.

Kathleen Brady: Although, a question actually related to – this actually – it does indicate that only 30.4 percent of individuals less than 13 are – were on antiretroviral therapy in 2014. Is that correct, Marlene?

Marlene Matosky: Say that one more time, Kathleen? You broke up there.

Kathleen Brady: Sorry. According to the table, it says 30.4 percent of individuals with HIV less than 13 in 2014 were on antiretroviral therapy or prescribed antiretroviral therapy. Is that correct?

Marlene Matosky: Hold on. I'm pulling up my table.

Kathleen Brady: OK.

Marlene Matosky: Yes. That is accurate.

Kathleen Brady: OK. I mean, it looks as though the numbers were as low as 28.9 percent in 2010.

Marlene Matosky: That is absolutely accurate.

Kathleen Brady: OK.

Christy Skipper: And just a moment while we are pulling that up and apologies for the delay.

Jeffrey Hart: Perhaps we could just – well, I don't – I was going to suggest that we move on and begin discussion of reliability in the meantime so as not to waste time, but I'm not sure how the moderators feel about that.

Woody Eisenberg: Jeff, this is Woody. I think you're right because really what we're supposed to be deciding now is whether there's opportunity for improvement and I think that the data that you've reviewed that's available to us, as well as what Marlene has added, gives us enough information for that. So I think …

Jeffrey Hart: Go ahead. I would agree. Yes. I actually think we could probably vote on that, but again, I leave that up to you.

Woody Eisenberg: Do we need to vote on that or is this too something that we could accept the previous committee's decision on?

Christy Skipper: Woody, you have the – right now, up on the screen.

Woody Eisenberg: Great.

Melissa Mariñelarena: Yes. We are sharing the table and we'll make sure that you all have it too. First, I have amazing data on disparities. This is probably the robust – the most robust information I've seen on disparities.

By age, HIV status, race, ethnicity, gender, transmission risk, injection drug use, heterosexual contact, perinatal infection, there's a whole lot of information here. We'll send it out to you via e-mail to make sure you do have it. And they've provided this information for all the measures. If you didn't get a chance to look at it, we'll send it to you for all of the measures.

But for this – so for gap, you do have to vote. This is a criteria that you have to vote. So if there's no further questions or discussion on gap, we could go ahead and vote.

Jeffrey Hart: No questions.

Melissa Mariñelarena: All right.

Jeffrey Hart: Now, is – are we able to vote at high or are we not? I have …

Melissa Mariñelarena: Yes. For gap, there is – there's high, moderate, low or insufficient.

Jeffrey Hart: OK.

Melissa Mariñelarena: Go ahead, Mauricio.

Mauricio Menéndez: Right. So the voting for performance gap for 2083 is now open, vote one for high, two for moderate, three for low and four for insufficient.

Melissa Mariñelarena: And we're just waiting for one more vote. OK. There it is.

Mauricio Menéndez: OK. So the final count is 100 percent for high for 2083 for performance gap.

Melissa Mariñelarena: Did you get a vote on (tracks)?

Christy Skipper: Yes. I did.

Melissa Mariñelarena: So it's a total of 12 votes for – of high?

Christy Skipper: Yes.

Melissa Mariñelarena: OK. Thank you. We did need that for the record.

Jeffrey Hart: Right.

Melissa Mariñelarena: OK. You passed this on gap. OK, we can move on to reliability.

Jeffrey Hart: I've asked Woody and – Woody to take the reliability and validity section, so Woody?

Woody Eisenberg: I would – OK. So reliability, this is a measure that's extracted from paper records and it also says electronic health records which I didn't understand. Marlene, is even the paper version of this rely into some extent on electronic health records?

Marlene Matosky: No. We recognize that – as you probably know, more and more providers are going to electronic health records, so we still scope this measure out as a paper measure. We do recognize that there are some folks that are doing some manual extraction out of their electronic records for this. But after we finish this measure as a paper measure, we're going to review it as an eCQM hopefully.

Woody Eisenberg: OK. Good. Thank you. The measure is specified at the facility level and it has a numerator and denominator that are very clearly specified. There are no patient exclusions to this measure and that surprised me because, like some of the other measures, I thought that if patients die between – at some point during this period that that might exclude them. So, Marlene, could you comment on that?

Laura Cheever: Yes. This is Laura Cheever. Yes, so the two reasons we don't exclude people is that, one, the mortality rate in HIV is so low today that it's not a – it's not a significant number and it's a huge – it's a burden to try to calculate those people in. And, two, given the relatively short time, once again, there'll be very few people dying. So we thought the burden on the recipients was

relatively high compared to what we would get from actually trying to include that information.

Woody Eisenberg: Right. Thank you. And as you told us before you're not expecting 100 percent necessarily on any of these measures, so that fits in also.

Moving on to the reliability testing, the testing was done at the measure score level and the reliability testing method was the beta binomial model which we've seen before and which was explained to us earlier by Kathleen for the previous measure. So unless anybody wants another explanation of that method, I'll move on.

OK, hearing none, the results of the reliability testing was consistently very high. They quote a 0.99 which is an extremely high result. There was no updated testing information presented which I think is appropriate because of the high reliability of that data that we've seen in the past. And from the NQF staff's preliminary rating for reliability, they gave it a very high rating which I would agree with. Are there any comments or questions from committee members about that? If not, I'll move on. Melissa, I don't – I can move on now, right?

Melissa Mariñelarena: Well, before we move off of reliability, if there are no other questions or discussions, the committee can decide not to vote on reliability. We can just accept the reliability results from the previous review if that is OK and then we can move on validity.

So I will ask, are there any objections to accepting the past committee's vote for reliability? OK, hearing no objections, we will accept the past reliability vote from the past committee. We will not vote on reliability and move on to validity.

Woody Eisenberg: For the validity of the specifications, the specifications were consistent with the evidence that we've discussed previously and I didn't – I don't have anything else to say about that.

Melissa Mariñelarena: OK. So last time – let's see what did we do on the last one – did not vote. So again, I'll ask the committee, it's the same issue with the face validity.

HRSA did not update their face validity and testing because they're focusing on the eCQM.

The reason they did not meet our criteria is because they did not use these specific wording. If the committee as the experts in the field decide – if you feel that – if they are valid and you want to accept the vote from last time, we can accept the vote and pass validity. Or if anybody objects, we will have the committee vote on validity.

So I will start off by asking are there any objections to accepting the last committee's vote and move on with validity? Hearing no objections, the committee accepts the validity vote from the last committee. The measure passes on validity and then we will move on to feasibility.

Jeffrey Hart: OK. Let me – let me take feasibility. This is Jeff. So feasibility for this measure I think is quite strong. The developer reports that the required data elements are available in electronic or – am I reading the wrong one? No – or in other electronic sources although patient health records that are on paper I think would be adequate as well. The operational use of the measure is readily available in the health records and provided annually in the Ryan White program.

I believe the data elements are routinely gathered and used in the care delivery. I believe that the data elements are available in electronic format, but that's not important for this measure because it's not an eMeasure. And the data collection strategy is ready and is actually already in operational use. So, I suggest we move on to a vote for that.

Christy Skipper: If there are no questions or discussion from the committee, we'll now vote on feasibility.

Jeffrey Hart: No.

Mauricio Menéndez: OK, feasibility voting is now open for Measure 2083, vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient. So, the final count is 11 high; and one moderate; zero, low; zero, insufficient.

Melissa Mariñelarena: And for the record, that is how many votes from the chat box? Two votes came in for – from the chat for high, so we added those to the nine that you see on the screen, so yes, 11 high, one moderate. Thank you.

Jeffrey Hart: OK, we'll move on then to usability and use. This measure is already reported publicly and it's used in accountability programs. The Ryan White HIV/AIDS Program uses it for accountability as does the PQRS and the merit-based incentive program. It's included in the National HIV Strategy. And we see that there has been improvement over time since 2010 to 2014. There's been an increase from 68.4 percent to 77.6 percent.

The Ryan White Program has experienced a 10-plus-point increase in viral suppression. Am I reading the right thing because – anyway, the – there's a positive unexpected finding and that is CMS measurement programs.

The Department of Health and Human Services has chosen this as a core HIV indicator and countless ambulatory and outpatient healthcare settings and health departments are using this measure.

There are no identified potential harms. There has been vetting for this measure, and again, I believe this is consistent with some of the other measures that we've reviewed. The data is available to the public.

Ryan White Program uses this data and indicates that it is timely, feasible and usable as to the national partners, the grant recipients, and they continue to use this data in all of these formats.

And initial development of the measure in the chart abstracted form, there was formal feedback gathered, and as a result of that, there were no changes to the measure itself.

So, I believe that we probably can move on to a vote. The performance results show that it's of high quality and improved high quality and efficiency of care, and that it has been vetted in the real-world setting. So, I think we can move on to a vote.

Woody Eisenberg: Jeff, let's just see if there are any comments or questions from the committee members first.

Jeffrey Hart: OK, are there any questions or comments?

Woody Eisenberg: Now, we can move on to a vote.

Jeffrey Hart: There we go.

Mauricio Menéndez: OK, voting for usability and use for 2083 is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

(Off-Mic)

Mauricio Menéndez: So, the final count is nine votes high and three for moderate, with one vote coming into the chat.

Jeffrey Hart: Very well. I guess that means it passed that.

Christy Skipper: Yes, and that was like …

Jeffrey Hart: Go ahead.

Christy Skipper: We would just move on to vote for overall recommendation for endorsement. So, on your screen, vote 1 yes and 2 no.

(Off-Mic)

Mauricio Menéndez: So, we have a 100 percent for yes with 12 votes, one coming from the chat for overall suitability for endorsement for Measure 2083.

Christy Skipper: Great. All right. Now, we can move on into the discussion of 3211, the eMeasure, and I want to note that what you, all, discussed and decided for evidence and gaps will be applied to this measure so we can start out with the reliability section.

Woody Eisenberg: All right. That's me again.

Christy Skipper: OK.

Woody Eisenberg: Let me get myself there. So, for this measure, really, the only difference is that now, we're talking about electronic health records only because this is an eMeasure. The measure specification is unchanged, the calculation is unchanged, and those have all been looked into and found to be reliable.

There is a table that's included that is of some importance because what it demonstrates is that the measure developers have been using the standard – all of the standard formats that are available in terms of HQMF specifications and the use of value sets, all of which are standardized. So, they didn't have to invent anything new for this measure, which is a good thing because these are all tried and true parts of the methodology.

In terms of reliability testing, now, we're going to see something that's new because for electronic measures, what's becoming the standard for reliability testing is the use of a new tool which is called the BONNIE testing system.

And the BONNIE testing system relies on the synthesis of mock patients that contain the characteristics that those patients who would actually be subject to the measure need to contain. And you can see them listed here.

And based upon the needed characteristics, 34 synthetic patients were created, all of which went through the BONNIE testing system successfully, including specific ways to look for those patients that might sort of test the system in terms of being right on the edge for one of these characteristics.

So, the results of this were that the bundled demographics did very well mimic the HIV/AIDS population and that the results of the BONNIE testing really conformed quite well to expectations for a very reliable measure.

In terms of some questions that we were asked, is the test sample adequate to generalize for widespread implementation, I think that's a little hard to say based upon the experience so far with BONNIE testing, but I think at this point, the answer is yes.

Do the results from the BONNIE tool demonstrates sufficient reliability so that differences in performance can be identified? Again, I would say the

answer is yes. And do you agree that the reliability test results of the eMeasure will be comparable to the paper-based measure? It's a leap of faith to some extent, but we're getting more and more confidence in the sort of testing, so I would say, yes.

And in terms of the guidance that we get from NQF staff, I agree with their preliminary rating for reliability which is moderate. And again, based mostly just on the experience that we have to-date with this way of testing reliability.

Are there any comments or questions either from the – let's start with the committee members? If not, do the developers had anything that they would like to say about this?

Christy Skipper: OK, hearing none, it looks like we will go ahead and vote on reliability for this measure.

Melissa Mariñelarena: And this is Melissa. As you're voting, just I want to remind you that BONNIE testing is sufficient for legacy measure which is what this is, so that's when we accept the synthetic – the synthetic patient deck which is BONNIE. And HRSA and MITRE did a really good job and I know they gave a really good description of how they did the testing during the meeting last week, but I just wanted to remind everybody of that.

Mauricio Menéndez: So, voting for reliability for Measure 3211 is now open. Vote 1 for moderate, 2 for low, 3 for insufficient. The final count is 100 percent moderate with 12 votes, one coming in through the chat.

Christy Skipper: All right. We can now move on to discuss validity.

Woody Eisenberg: OK, the validity for the specifications, the specifications are consistent with the evidence. And in terms of going onto testing, here, there is a little bit of difference from the paper-based measure because for that, the validity testing level was up at the measure – at the measure score whereas here, the testing is different and that it focuses on the data element, testing against the gold standard.

Now, Melissa, I was a little confused by that. Is the BONNIE testing considered the gold standard or is there some other gold standard?

Melissa Mariñelarena: This is – it's not really against the gold standard. This is really testing the measure logic.

Woody Eisenberg: Yes.

Melissa Mariñelarena: And this shows that it does – if the measure does work, and this pretty much the best that we can do. I'm looking at what we wrote here. Sometimes they will provide as the developers will provide us with testing against the gold standard which could be, you know, testing against the paper chart.

Woody Eisenberg: Right. That wasn't provided here so …

Melissa Mariñelarena: Yes. So, this is officially what they did and it actually tested really well, but it is looking at the logic, making sure that it – it's able to calculate the measure correctly.

Woody Eisenberg: Right. And one of the ways that they check that was that they had a small panel of experts that looked at each of the synthetic patients and gave – and assign them an expected outcome which then correlated perfectly with the results of the BONNIE testing. So, whether we want to consider that a gold standard or just a very good sort of baseline test, I don't know, but it seemed to hold up quite well.

So, that the BONNIE testing results reached 100 percent for this kind of accuracy for all of the cases. So, in my opinion, the test sample was adequate to generalize, the results demonstrated sufficient validity so that the conclusions about quality can be made, and the score from this measure specified is an indicator of quality.

In terms of threats to validity, there were no exclusions. This is a process measure. There was – there was no risk adjustment.

They also provide a table that looks at the percentage of patients with viral suppression across providers and providers with greater than 80 percent

patients with antiretroviral therapy, which I guess is good indirect evidence of prescribing.

And there was a nice correlation here in terms of – oh, I'm sorry, there was prescribed in patients greater than 80 percent patients prescribed ART. So, this table, in fact, supports their supposition that there is a direct relationship between a prescribing and suppression of viral load.

And then the last question here, does the committee agree with eMeasures will demonstrates similar results to the chart abstracted measures, from my opinion, the answer to that is yes. And then based upon all of this, I agree with the preliminary rating of moderate for validity.

Are there any comments or questions from any of the committee members? Now, if not, Melissa, I think we can move on to a vote.

Melissa Mariñelarena: OK.

Mauricio Menéndez: OK, voting for validity for 3211 is now open, 1 for moderate, 2 for low, 3 for insufficient. We have 100 percent moderate with 12 votes with one coming in through the chat.

Melissa Mariñelarena: All right. This passes on validity. So, we can move on to feasibility.

Jeffrey Hart: OK, this is Jeff, I'll take that again. Feasibility, the developer did not identify ERs – EHRs that were used in feasibility but instead, as we've discussed, used – they can talk to the consensus of panel of MITRE clinical informatics measurement development and eCQM standards experts.

They looked at various summary of EHR capabilities which are listed there. On a scale of 1 to 3, where 3 is the highest, all, but three of the data elements received the score of 3. And those data elements were, one, encounter performed, face-to-face interaction, and two, patient characteristic payers or payer, which scored 2 on the data standards, and the 2 means that the terminology standards for this data element are currently unavailable, but this is not consistently coded to standard – I said, no – they are currently available

but they are not consistently coded to the standard terminology in the EHR or the EHR does not easily allow such coding.

And the other element was patient care characteristic expired, and I had a question about what that means, but this data element scored number 2 as well and the data accuracy looked at the correctness of the information contained in the data element, and whether the data source recorded the specific information that was specified.

The definition for the 2 in this situation for data accuracy is that the information may not be from the most authoritative source or has a light – moderate likelihood of being correct such as self-reporting of a vaccination is an example of that kind of thing.

So, the feasibility at the current time appears to be 98.33 percent, which, of course, is very high, and they expect that in the next year or two, the feasibility will increase to 98.89 percent.

So, the data elements are routinely generated and used in the course of care delivery. The data collection strategy is ready and is being put into use and – certainly, and medication already is. And the eMeasure feasibility scorecard demonstrates that acceptable feasibility is shown in multiple EHR systems and sites.

I guess for that one, we're not quite sure because we didn't actually tested in the EHR but the assumption is that it would be.

So, are there any questions at this pointy before we move on to a vote, or comments from the measure stewards or developers?

Woody Eisenberg: This is Woody, I have a question. Could somebody explain to me maybe, Marlene, it's you, how you calculate the feasibility? What is 98.33 percent mean, how was that calculated?

Marlene Matosky: So, I'm actually going to turn it over to one of our clinical (informaticist) who worked on this. Her name is (Rose) and she's on the MITRE team. (Rose)?

(Rose): Hi, there. So, the 98.33 percent was calculated from the feasibility scorecard, so all of those numbers that were input per data element for those four categories were added up. And there is a calculated field within that worksheet that comes up with the 98.33 percent.

Marlene Matosky: And that feasibility score – sorry, I was going to say – sorry. Go ahead.

(Crosstalk)

Woody Eisenberg: … 100 percent?

Marlene Matosky: Correct. And the feasibility scorecard had been provided by NQF, and as the measure steward, we're required to fill that out.

Woody Eisenberg: Very good. Thank you.

Melissa Mariñelarena: Yes, this is Melissa. The feasibility scorecard is in the – on your SharePoint site with the documents for the measure. Mauricio is trying to pull it out, but it does. It calculates – it's a long spreadsheet with multiple tabs that calculates it and it has all the definitions for all the data elements, everything. We just tried to summarize what we thought would stood out the most within the feasibility scorecard.

(Off-Mic)

Melissa Mariñelarena: If anybody has any questions and – after this call, if you want us to go through the feasibility scorecard with you, we're more than happy to do that because hopefully when Marlene – when the – when these eMeasures come back fully tested, you'll be looking at that again.

Woody Eisenberg: OK.

Melissa Mariñelarena: So, it's right there. Now, it's the spreadsheet.

Woody Eisenberg: That's OK. I don't think I need to see it. I just wanted that explanation, thank you.

Melissa Mariñelarena: Yes. And we can send it out to you, but like I said, if anybody has any questions, just send me, Melissa, and email and I can go through it with you. And you know, and it might change before the end but at least you could be familiar with it.

Jeffrey Hart: And this scorecard is used for all eMeasures then?

Melissa Mariñelarena: Correct. All eMeasures, whether they are legacy measures, a fully tested eCQM, our trial used measures that are also eCQM. And so for all eCQMs, we would fire the feasibility scorecard.

Jeffrey Hart: OK, great.

Melissa Mariñelarena: Yes.

Woody Eisenberg: And Melissa, is there some cutoff that you look for, you know …

Melissa Mariñelarena: No.

Woody Eisenberg: No, OK.

Melissa Mariñelarena: No, this is – this is a new – this is updated feasibility scorecard within the past probably two months or so. So, it's a little more – it has a little more information than it used to be …

(Off-Mic)

Melissa Mariñelarena: So, like I said, if anybody has any questions, just send me an email and I'm happy to go through it with you. We can jump on a call real quick and I'll go through it with you. It's actually really interesting to do a deep dive into it.

Woody Eisenberg: OK.

Jeffrey Hart: I would suggest then we go ahead and vote.

Mauricio Menéndez: OK, voting for feasibility for 3211 is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

Christy Skipper: Yes, go ahead.

Mauricio Menéndez: OK, the final count is 75 percent high with nine votes, 25 percent, moderate with three votes. So, this will pass on feasibility.

Christy Skipper: OK. And just in the interest of time, we're coming close to the top of the hour. If we can just briefly hear on overview of usability and then we'll move to vote on that committee discussion and then overall recommendations for endorsement. So, for usability.

Jeffrey Hart: Great. The usability here is consistent with the paper-based Measure 2083 and I would just then open it for any questions that anyone has and then if there are none, I would recommend we move toward a vote.

Christy Skipper: OK, hearing no questions, it sounds like we can move on to a vote.

Mauricio Menéndez: OK. Voting for usability and use for Measure 3211 is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient. OK, the final count is 58 percent high with seven votes, 42 percent moderate with five votes. So, this will pass on usability and use.

Melissa Mariñelarena: OK. So, now, we will move on to an overall vote for consideration – for recommendation for endorsement.

Mauricio Menéndez: And voting is now open. Vote 1 for yes, 2 for no. We're still waiting on one more vote. OK, the final count is 100 percent yes with 12 votes. This Measure 3211 will move on.

Christy Skipper: All right. Thank you, Mauricio. And I just want to note, we are at the top of the hour. We do have a couple of more things on our agenda. We will follow up with you, all, following this call via email for feedback on gaps within the measure portfolio.

And before we close the call, I'd like the operator to open the line to hear if there are any member in public comments.

Operator: Thank you. At this time, if you'd like to make a comment, please press star then the number 1 on your telephone keypad. We'll pause for just a moment.

And there are no public comments at this time.

Christy Skipper: OK, thank you, operator, and thank you, committee, for your time this evening or this afternoon. And again, we'll follow up with you via email on next steps as far as gaps. So, have a good afternoon.

Melissa, did you want to say anything?

Melissa Mariñelarena: Yes. One last thing on related and competing, we really don't have any competing measures that we did have a handout that showed some related measures. And I think we'll have that discussion during our post-comment call.

I just want to get the committee's thoughts on just two of viral suppression measures that are similar but there is a rationale from the team that they provided around harmonization and alignment.

So, I just wanted to share that with you and get that in the report. But we can discuss that further on the post-comment call. So, we will be following up on email because we want to get your thoughts on gaps so we can put that on gaps within the portfolio so we can put something into the draft report that we're currently working on.

But besides that, thank you, all, for calling in today and for getting us through these measures. And thank you to Marlene and her team for sticking it out with us again. Adam or Woody, do you have anything? Would you like to say anything?

Woody Eisenberg: Nothing from me.

Adam Thompson: I'll just say thank you, everyone, for all the work they put in. It's been great.

Melissa Mariñelarena: Yes.

Jeffrey Lewis: Thank you as well.

Melissa Mariñelarena: All right. Thank you. Have a good day.

Jeffrey Lewis: You, too. Thank you.

Woody Eisenberg: Bye-bye.

Jeffrey Lewis: Bye.

Male: Thank you.

Operator: This concludes our call, and you may now disconnect.

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