NATIONAL QUALITY FORUM

Moderator: Alexis Morgan
November 9, 2012
12:00 p.m. ET

Alexis Morgan: (Nathalie), I think we're hearing some background noise. If everyone could mute their computers, that might cut down on the background noise.

Good afternoon and welcome to the Infectious Disease Post Comment Conference Call to review and discuss the submitted comments on the committee's recommendation. The comment period was extended due to Hurricane Sandy, and it closed on Monday, November 5th.

Please note that the sepsis measure is currently out for comment, and the comment period will close on November 20th as the committee will meet via conference call to discuss those comments on December 5th. For this comment period, we received a total of 54 comments from eight organizations and Steph has summarized those comments in the briefing memo that we sent you earlier this week.

However, you can review all the comments that were submitted in the comment table, which is the Excel document. We also asked the measurable (versus) to provide responses to certain comments pertaining to the measure itself, and how it's specified and/or tested.

But the majority of the comments that we did receive were in support of the recommended measures. However, we did receive several comments in disagreement with the committee's recommendation. And so, today on the call, the committee will need to decide after reviewing and discussing the comment, whether or not you wish to change your evaluation of any of the criteria or the overall recommendation of any of the measures.

And as we go through your comments, Reva and I will definitely point that out if you need to decide whether or not you'd like to change your evaluation or recommendation. If you do decide to revote on any of the criteria or the overall recommendation of any of the measures, you'll do so following the call via SurveyMonkey.

On today's call, the lead discussant will lead the discussion for the measures, in which comments were submitted, and on Wednesday, I e-mailed the committee the lead discussant's assignment. These were your original assignments when you did the preliminary evaluations in the workgroup calls, and I'm leading and facilitating the discussion at the in-person meeting.

So, as the lead discussant, we asked you to summarize the comments and provide your thoughts and opinions on the comments received for that particular measure. And so, that's just the logistics for today's call, and before we get started, does anyone have any questions or would Dr. Septimus or Brotman have any comments before we continue.

Edward Septimus: Yes. This is Ed. I thank all of you for getting back on the call. I think, Reva, you might want what the next steps are and when the actual NQF board actually will vote on this.

Reva Winkler: Adeela, don't you want to just summarize that for him?

Adeela Khan: OK, yes. Sure. I can do that. Sorry. Here we go. I have the slide so…

Reva Winkler: What happens after these comments is your final decisions are then incorporated into what we call the voting draft of the report, and that's a red lined version of a report that went out for comment that represents any changes made as a result of reviewing the comments.

And then the NQF membership is given an opportunity to vote on the recommendations. The results of that voting will then go to the Consensus Standards Approval Committee which is the subcommittee and the board of directors whose job it is just kind of oversee the whole consensus process.

We are on schedule to take these measures, this group of measures to the CSAC on their December call, I think it's December…

Alexis Morgan: December 10.

Reva Winkler: … ten, that's what it is. And after that, it will go to the board of directors for ratification of those recommendations and endorsement. So, we're looking at an endorsement date around the first of the year. And so, that will be the next steps for these measures.

After the endorsement is announced, there is the opportunity for 30-day appeal period as the final step in the consensus process. So, that's kind of the next steps. Does that – and may be questions about that?

OK? Anything out there?

Alexis Morgan: Are there any other – oh. Are there any other questions before we dive into the comments?

Reva Winkler: I think what we like to do is let Dr. Septimus and Dr. Brotman kind of lead the discussion, but we're happy to introduce each section to kind of help the committee through this, if that will work for you.

Male: Oh, sure. Go ahead and let them get started.

Reva Winkler: OK.

Male: Right.

Reva Winkler: I'm so sure we're going to get theme one, right?

Alexis Morgan: Yes. So, you're going to definitely follow along on the webinar. We'll list all of the comments on the webinar, but feel free to also use the briefing memo or the comment table. So, Steph identified six major themes in the comment. And the first theme was a general theme and then applied to all or the majority of the measures.

The first one, they use as measure in current programs. We received some comments, indicating that the committee should consider measures when reviewing that has been accepted by federal agencies, such as CMS, is meaningful use incentive program, and they commented that measure 0403, which is the HIV/AIDS medical visit from NCQA and measure 0407 which is the HIV RNA control after six months of potent ART also from NCQA were both not recommended by the committee for continued endorsement.

However, they are a part of the final stage two EHR meaningful use role. And just to briefly state why these two measures were not recommended by the committee to help facilitate the discussion. Measure 0403 was not recommended because the committee felt that there was no evidence presented to suggest that medical visits unrelated to HIV-related issues will benefit the patient.

And some committee members indicated that if there is no requirement that the medical visit be for HIV care, then the intent of the measure, which is how providers are attempting to retain patient and care for HIV may not be meaningful and useful.

For measure 0407, the committee did not recommend the measure because it didn't pass scientific acceptability, and there was some uncertainty regarding which viral load was used, whether it was any viral load less than 200 in the measurement year or if it was the last viral load in the measurement year. And the committee also question how potent ART will be identified using an electronic health record.

So, I guess we can start the discussion on that comment under theme one.

Do any other committee members have any thoughts about the comment that was submitted?

Reva Winkler: Well, this is Reva. Just to sort of think about the type of comment they're talking about or using current programs. This is – would look – address the criteria of usability. Going forward from now and further projects, NQF's usability criteria will be looking at use and usefulness, though it is not a must pass criteria, and we know that this is a very rapidly-evolving world around

quality measures and often use of measures that have been endorsed often take a while to get into implementation phase. And so, there is often a – sort of a lead on the endorsement, and the implementation often likes behind. So, there are often these – you will see measures that have been endorsed or no longer endorsed continue in certain programs for a while.

Marlene Matosky: Hi Reva. This is Marlene from HRSA. Can I just make just one comment about the comment of the use of 403 and 407 in meaningful use stage two?

Male: Of course.

Reva Winkler: All right.

Marlene Matosky: So, I just wanted to point out, as you know, the final (rule) for stage two was released, I believe in August, maybe either while you're at the steering committee meeting down in D.C., and it's important to note that 403 and 407, in fact, are not in the final (rule). Those measures that are in the final role were changed in the specification process. So, they're not even going to be called 403 and 407 in the final (rule). So, I just wanted to be clear about that.

Reva Winkler: Thank you. Essentially, we just want the committee to be aware and look at he comments to see if this changes your thoughts about any of the measures. So, if there's – if committee members are not, you know, feel there's anything further to discuss. We do have quite of long agendas, we might as well move on. But we don't want to shortchange anybody's opportunity to say something if you want to.

Kathleen Brady: Hi. It's Kathleen Brady and I just – I don't think we should put the meaningful use, you know, thing before, you know, our evaluation of these measures. So, what's most important is what the evaluation results that, you know, adapted. And so, I disagree with the statement.

Alexis Morgan: OK. Any other comments?

Reva Winkler: OK.

Alexis Morgan: OK.

Female: Yes. I just wanted to comment. Sorry, I was trying to get off mute.

Female: It's OK.

Female: Yes. This is (inaudible). I agree with what she just said. But I wanted to underscore that as I understand it, and you can correct me if I'm wrong, but as I understand it, there are lot of things that we have gone over that makes sense to do just on a – on a (inaudible) level and maybe there's some lower level evidence.

But we were differentiating between what might be good for guideline is different than what might be good for pay-for performance and for public reporting. We were – am I right on this? We're supposed to be looking at this based on is there sufficient evidence, sufficient quality of evidence, sufficient reliability and validity that this has gone beyond a guideline measure to – we should implement this to the level that if a hospital or a clinic or a doctor does not implement it, then they should be reported to the public as not meeting standard of care and that the hospital and the physician should not be paid for that service. Am I correct in the way we're looking at it?

Reva Winkler: Basically – this is Reva – yes, I mean NQF's evaluation criteria are set to focus in on measure that are strongly evidence based and reliable and valid because the intended use of NQF measures are for fairly high stakes purposes, for accountability, for public reporting and are frequently used in payment incentive programs and the like.

So yes, we really want decisions to be based around the criteria and be solidly meeting those criteria. They were established because NQF-endorsed measured are used for accountability and other high stake purposes.

Female: Well then, just so we're all like – just you know, to reinforce what you said, so that we're all clear, just because it's been endorsed before and just because it's been in guideline doesn't mean that it may be at the level that we're going to implement this because the standards of implementation, there's a much higher threshold to meet.

So, I just wanted to, you know, make sure that we were all sort of looking at it from the same sheet of music. So, thank you very much.

Reva Winkler: OK. We need to kind of keep moving along. Ed, Steve, if you're OK – Alexis, can you just describe the second sort of general comment?

Alexis Morgan: Yes. So, also under theme one, we received comment recommending that all HIV/AIDS measures allows stratification for disparities data, and we spent some time throughout the in-person meeting, discussing disparity and how the measure submission forms then include measure results to assess disparity. So, that has been included in a report that went out for comment, but we just wanted to see if anyone had any additional thoughts about this comment.

Female: (Nathalie), can you check (Dawn Elam's) line from NCQA. I think it's on mute.

Operator: The line is open, but she just rejoined back. Her line is open. She can speak.

Alexis Morgan: OK. Thank you. Any other comment on stratification for disparity?

OK.

Female: All right.

Alexis Morgan: Before we jump in to the measure specific comment, I just wanted to touch on theme five, the additional areas for measure development. We had two that were submitted. One area was the lack of outcome measures or follow-up for screening test, noting that there were a lot of process measure submitted in this project, and only one outcome measure.

And the comments indicated that outcome measures are more meaningful to consumers and process measures. So, the commenters wanted the additional gap to be added to the report. And the second area is that there is a measure gap in screening for (SCIs) and HPV.

So, I just wanted to quickly get any comment in regarding to adding these two areas to the report for future measure development.

Edward Septimus: This is Ed. In terms of the outcome measures, and correct me if I'm wrong, because this is – that there has to be studies done on risk adjustment. And I think that's been one of the barriers for a lot of outcome measures being endorsed by NQF. So, I don't know if the person who raised this understood what the standard is.

Reva Winkler: Ed, I think what you're – what you're saying is the comment reflects sort of a fairly widespread sense of a lot of stakeholders that outcome measures are more meaningful. And while they may be, you know, methodologically more challenging, the work needs to be done to foster development of more outcome measures.

There was only one outcome measure in this particular project, and a lot of stakeholders would like to see more outcome measures. Sometimes, there are only intermediate outcome measures; they're not necessarily long-term outcome measures. But you're right, methodologic challenges are definitely one of the issues around outcome measures.

Edward Septimus: And the other challenge, independent in my other comment, is that some of the process measures are not that we link in improve outcomes.

Reva Winkler: Right.

Edward Septimus: Even though the actual process measures have been shown in individual studies, they potentially have benefit but not always linked to outcome.

Reva Winkler: Right. It's hoped that you know, with use of these measures and further data collection, we can further demonstrate or refuse those relationships when you look to see how groups performed on the process measures and then look at their outcomes and see if how closely the measures predict the outcome and validate that relationship. So, that I think is what we hope to see going forward as we get better and better information and more data around these measures.

OK. Let's move on to the next – the measure-specific comments. And there were several measures around the medical visit, and we did receive comments on them. If you recall, there were three measures from first, at 2079, the

medical visit frequency measure, and then there is 2080, which is gap in medical visits. And then, we apologize, the cut and paste didn't happen nicely as we'd like – measure 2081, newly enrolled in medical care.

So, there are comments on all of them, as well as the measure 403, which was not a previously-endorsed measure on medical visits which was not recommended. So, well just kind of want to touch on all of these. And remember that essentially, the point of this discussion is to read the comments to see if there are things that might change your thoughts or your opinion on the evaluation and recommendation of the measure. So, that's really the bottom line for today. After looking at the comments, do you want to change your recommendations?

And so, the first one, around measure 2079, the medical visit frequency measure from HRSA is the comment or the HIV Medicine Association is asked to – the committee to revisit those 403 and 2079.

They suggest that the 403 measure from a practical standpoint makes more sense than in 2079. They don't believe the fact that 403 is based on CPT II coding should have been ruled out. And also, they discussed the 12 months medical visit frequency in 403, which is distinct from the 24 months frequency in 2079, and they questioned the practicality of that.

And so, also they mentioned the fact that the 2079 measure was tested only in HIV-specific clinical setting and whether that's applicable across the board. So, you know, in general, I think, a lot of these comments or work issues that the committee did discuss, but are any thoughts from the committee members on that comment?

Male: Really? You want them to comment on 2079 and 2080?

Reva Winkler: Well, I think – if you want to look at the whole group together, that's fine. The comment on measure 2080 is the gap in medical visit and there were two comments that were pretty much opposite each other. One, again from HIV Medicine Society, questioning whether the information yielded from the measure would justify the additional burden of collecting the data.

But another attack from a consumer group is that this measure captures an event that high correlation with outcome and they do feel that retention in care is an important thing to measure and further suggest that both 2079 and 2080 be paired, such that going forward, both of these measures will be performed and reported on as a complementary measures.

Male: Right. And I guess, a couple of ways to go here, in one week, we could (inaudible). Is Adam on the phone?

Adam Thompson: Yes, I'm here.

Male: Adam, you look at 2079, and (Michael) looked at 2080. Is the developer on the line for this?

Reva Winkler: Yes, Marlene, sir.

Male: OK.

Marlene Matosky: Yes, I'm here.

Male: So, perhaps we can ask the developer to comment on this. You have, I think, the comments in your Excel, but may be the developer can comment on this and then we can have Adam and (Michael) comment from their perspective. Is that OK with everybody?

Male: Sure.

Male: OK. Go for it.

Marlene Matosky: Sure. So, my name is Marlene Matosky, I am from HRSA HIV/AIDS Bureau, and I have along with me Tracy Matthews from HRSA and also Pascale Wortley and Abigail Viall, and they're from CDC. And as you may recall, CDC and HRSA jointly developed these measures together.

So, I just want to state that up front. So, first and foremost, I guess you wanted to point out that we feel as though the science behind 2079, the medical visit frequency is stronger, and it's more supportive looking at retention over a 24-month period.

We note that – we note (inaudible) said that retention in care over a 12-month period has modest gains in patient outcomes. However, it's substantially sufficed rather quickly, whereas looking at retention over a 24-month period has a more sustained obviously because you're looking over a longer period of time, impact on morbidity and mortality.

So, we want to point that out first. And we do note that there probably was a time and a place where looking at retention over a 12-month period was sufficient. But because our knowledge of HIV and HIV care and treatment is expanding that rather rapidly, we feel some measurement needs to keep up with this – with the pace of this item.

Next, I'd like to note the piece with respect to the commenter had made looking at the 12-month measure and measuring it sequentially across two years. So, just measuring, you know, twice in a row, would yield the same results as implementing a 24-month measure, and we respectfully disagree with that because we feel as though when you look at one measure twice over to 12-month period, you're not using the same denominator.

And so, we know that there are patients who will fall-out during that first year, and they won't be captured in that same year. So, you won't have that consistency across the measurement period. I also just want to note that it was, I think, more emphasized in the letter as opposed to in the comment that was submitted to NQF. The comment came from the HIV Medical Association that came from specifically Dr. Horberg, and he had noted that you know, Kaiser and V.A. have been using this measure. So, you know, thinking about this, and I think, you know, Kaiser on an annual basis (is) about 19,000 patients, you know, people living with HIV, and the V.A. (is) about 25,000 nationwide.

You know, together those aren't small number. However, you know, (based) from the Ryan White Program, and we serve over a half million number of patients a year and we touch about 80 percent of the provider that are caring for people living with HIV.

So, if you were so, you know, with respect to the comments of where this measure was tested, we feel that one, you know, the Ryan White Program is providing care to the – in a majority of the people living with HIV out there. Number two, the Ryan White Program is funding the majority of the providers who are caring for people living with HIV.

And we don't feel as though the comments with respect to where the measure was tested, you know, really it, you know, has a validity. And then, if we also just think about the concept between – behind science to take acceptability, it's not really about where the measure was tested.

It's really about the validity and the reliability of the measure itself. And NQF really hasn't placed any emphasis on where it's been tested, and if you saw the data that we provided comparing the demographics but there were two where in our testing clinic versus the data that CDC publishes on the epidemic.

It was, you know, virtually the same. We might have been off like hundreds of a percent or you know, tens of a percent it wasn't, you know, anything substantial. I'm just looking here at my notes. I apologize. And then, just with the comment with respect to the gap measure, we feel as though, you know, the gap measure has a – is a great utility and quality improvement and folks have (probably) did this before.

Performance measurement is just 1/2 of quality management. The other half is that quality improvement patch. I know where you're focusing on the measurement piece, but we don't want to forget the improvement side. And so, when we think about the gap measure, it does tell you to stay with quality improvement because the folks who are in your numerator are in fact, those that who have the gap and those folks that need immediate action to find them and get them back into care.

So, we would argue respectfully that the gap measure has great utility. We would, you know, we appreciate some comment in the gap measure and the frequently measure should be cared. We don't have the authority to say they should be cared, but when we do promote it among star programs we would probably promote it in that manner moving forward.

And then, you know, last but not least, I just wanted to point out one thing, back in July, the end of July, Dr. – sorry, Secretary Sebelius, the head of Department of Health and Human Services approved seven measures across all HHS programs that all HIV-funded programs will be reporting on.

So, of those seven measures, we have – we on the measure of the four that you all have suitable for endorsement were included in that set. So, you know, we're moving towards (far) some (money). We're moving towards the line, and this process along with the HHS process that Secretary Sebelius has underscored, is really moving up in that direction and has really brought us together on the pieces.

My colleagues from HRSA and CDC, would you like to add anything else?

Female: May be speaking to that the V.A. point (inaudible) letter the V.A. will also be moving to 2079 in all likelihood because that's now the endorsed measure for HHS agency. So, what was used in the past by V.A. and various other agencies may have been 403 because that's the measure that was in existence. As the science changes, the measures changed and likely, many providers and programs and agencies will change too, probably towards 2079.

Marlene Matosky: And one last point, you know, I know that the 24-month measure might be something a little different for folks to wrap their hands around because they're still used to seeing a 24-month measure period. But we're not studying facts in this area. In fact, there is a cervical cancer screening measure and a breast cancer measure, a breast cancer screening measure that then endorsed and is used in this CMS meaningful use program that looks – will be on – sorry, 12-month period.

So, it's not in the where, I mean, I would love –to end your cutting edge in that respectful. We're not the first one to go down the road of having a greater measurement period. And I'll be happy to take any questions that any one on the panel has.

Thank you.

Male: Thank you very much. (Anne) and (Michael), would you like to comment? Sorry, it was Adam.

Adam Thompson: Yes. I mean, I would just say, you know. I think Marlene did a great job explaining it. The only thing I would add would be that I was present for the conversation around the comment from the – and the belief there was that the 24-month period was something they really liked about it.

Because in that sense, it gave them a picture of sort of where an individual was in their care versus what they thought the 12-month measure was almost something what they thought is the old way we measure things, may really like the fact of looking at it over a 24-month period. They felt that it was a more rich image of how an individual was doing in their care.

Male: Thank you. (Michael)?

Reva Winkler: Is (Michael) with us? May not be. I didn't hear him check in.

Male: Oh, I'm sorry. I thought I saw his name.

Reva Winkler: Yes.

Male: No, I'm sorry. He's not – you're right, he's not.

Reva Winkler: Alexis, did you – have you heard – we heard some (Michael) in?

Male: No, I…

Alexis Morgan: No.

Male: No, no, no.

Alexis Morgan: No. He should be on the call. May be he's just running a little bit late.

Male: But anybody else, any other committee members like to further comment?

OK. Why don't we go on to the next.

Reva Winkler: Yes. And I think the bottom line, to be sure we're very clear is, after having looked at these comments, does anybody on the committee think that the committee should revote on their evaluation and recommendation?

Steve Brotman: This is Steve Brotman. I just think the comments by Adam and the HRSA actually just confirm our conversations that we've had during the steering committee, though I don't believe so.

Reva Winkler: OK. In terms of the pairing question, pairing is something that NQF steering committee often will choose to do if they feel that two measures are closely related and that they complement each other. And so, that would be an – that would be an opportunity if the committee thinks that that's worthwhile to recommend that the endorsement include that these measures be paired, such that going forward, they're used together and reported together.

And so, are any thoughts from the committee you'd like to add that to your recommendation?

There must be a brave soul out there with an opinion.

Adam Thompson: This is Adam. I would actually ask the developers what they're thought on that is as far as pairing them whether that's something they would recommend or they see a reason to keep it separate.

Reva Winkler: Well it's not – the measures are still separate. It's more a matter of the pairing is really a recommendation from NQF on how we would like to see the measures used going forward.

Marlene Matosky: Reva, this is Marlene. Perhaps the point of clarification about pairing…

Reva Winkler: Uh-hmm.

Marlene Matosky: … if the committee were to put in their final report that they would recommend that the measures were paired, would that be an absolute that moving forward wherever these measures would be used in (covered) programs that would need to be paired?

Reva Winkler: That would be the implication.

Marlene Matosky: I think it would be more of a – it's more of a strong suggestion.

Reva Winkler: Well, it would be of effect. It would be part of the endorsement recommendation. So, it would be endorsed at paired measures. So, with the expectation they would be used together going forward.

Kathleen Brady: Hi, I'm Kathleen Brady. So, based on that comment, I would say, no, that we should not pair these measures, because, you know, the – I guess that 0403 did not meet the standards, when we reviewed it. So, I don't think that's changed, and so, I don't think we should pair it for any other reason.

Reva Winkler: Kathleen, the pairing would be for 2079 and 2080.

Kathleen Brady: Oh, 2079 – I'm sorry, that's what I meant. We rejected 2079 on – excuse me – on, you know, I don't have the results right in front of me, but it didn't meet some of the standards. So, I don't think we should endorse a measure that isn't up to the quality standards.

Reva Winkler: OK. Let's just really clear it. The committee did recommend 2079 – both 2079 and 2080.

Steve Brotman: Reva, this is Steve Bowman. I just wanted to clarify – when you – when you do a pairing and it's out there as an endorsed group pairing, if anyone of those groups drops out of favorability and criteria for endorsement, then the whole pair drops off. Is that correct?

Reva Winkler: Not necessarily, because it will happen during a maintenance review or something like that. And so, the – like if one of them goes away, then the new endorsement of the remaining measure can stand.

Steve Brotman: That's very helpful.

Reva Winkler: I'm not really getting a strong support for pairing these measures from the committee, and if it's that the case, if I'm hearing you – hearing your silence accurately, perhaps we should move on.

Thomas Giordano: Reva, this is Tom Giordano. I guess, I'm just not clear what it means to pair it. What are the – what are the benefits of having measures paired? What's the downside?

Reva Winkler: OK. The benefit part …

Thomas Giordano: I would …

Reva Winkler: … is the pairing really is kind of a forcing of using both measures as opposed to picking and choosing. That's the perceived benefit of it.

You know, the downside is if someone only wants to do one or the other, they're a little bit more coerced into not being able to pick one versus the other.

Thomas Giordano: And the measures are the two-year retention and the gap measure, right?

Reva Winkler: Correct.

Thomas Giordano: OK. I would say, don't pair.

Female: I would agree. This is – this is the same.

Thomas Giordano: People have flexibility.

Female: I would agree with both of them.

Reva Winkler: OK.

Female: If that makes sense, now that I understand which measures we're looking at.

Reva Winkler: OK.

Female: And it would be really help, if just – never mind. It's fine.

Reva Winkler: OK. All right. If nothing else on those, we have one more comment. This is the one that we left out in the memo and Alexis got a follow-up e-mail, and that's measure 2081, which is The Patients Newly Enrolled in Medical Care. And this was the measure that the committee did not recommend and the

comment is that they disagree with that recommendation. They believe this is an important measure for newly diagnosed patients and thoughts from the committee.

Female: I don't see anything that they provided within their comments that would make me want to reevaluate that decision. I don't know how many other people on (inaudible) deal.

Reva Winkler: Any other thoughts?

Male: I'm sorry. Could you repeat the question?

Reva Winkler: Well, we're talking about the comment that was submitted on measure 2081. The committee did not recommend this measure be endorsed. The commenter disagrees with that recommendation and would ask for the committee to rethink that original recommendation. The arguments being that patients who are newly diagnosed are or special population that this measure focuses on and that there is important information to be gleaned from this particular measure as well.

Steve Brotman: This is the …

Female: What is amazing is I have a problem with that the fact that they can (put) information to be gleaned from, because we're not supposed to be – we're not supposed to be evaluating. This is how to evaluate information. It isn't to collect new information, it's because that information has already been collected, and we're a making a decision based on data that is already there. Not to collect data that's not there. Is that a wrong assessment?

Reva Winkler: I'm not, I - this is Reva. I was a little unclear as to what you mean. When I say new information, I just mean the results of a measure.

Female: Right.

Reva Winkler: And measure will…

Female: And what I got – what I got out of what the – what the commenters said when they talked about measuring how a new diagnosis and adhering to medical

visit – it sounded to me and perhaps I read it incorrectly was that it would be important to collect new data on this topic, but passing this measure is not to collect new data. We're supposed to pass a measure based on data that has already been collected, evaluated and felt to me as specific threshold.

Male: I think that's what we said in the meeting, right? If there's insufficient evidence that supported this particular measure was going to impact outcome.

Female: Exactly. And if this – if the point that becomes represented was, well, we can get that information if we implement this measure. There are other – there are other more appropriate venues to which someone would request the potential studies to collect that information, this is not that venue, if I'm understanding the commenter correctly.

So, I guess, I'm still saying that I didn't see anything that the commenter presented that would make me feel differently than the way we assess this to begin with.

Female: And the other thing that I would say is I don't know if we need another measure to do that. I think you could do the same thing with the measures that have been approved. There could be, you know, a recommendation, the subgroup analysis be done on people who are newly diagnosed. Correct?

Adam Thompson: Yes. This is Adam. I think we had that discussion when we said we could do the same thing with the gap measure as long as they pull the data on just on individuals who are newly enrolled to care.

Female: I think – I don't think we need a separate measure for that. I just think that a group that should be, you know, looked at within as a subgroup within the measures that we've already approved.

Reva Winkler: That's good. Any other thoughts before we move on?

OK. So, essentially the next group of measures is comments that disagreed with this committee's recommendation for a measure, so, and there are three of those.

So, the first one is 2082, and this is again, a measure where there was a similar previously endorsed measure - measure 407, and so the measure that we're talking about is 2082 HIV Viral Load Suppression, which captures a percentage of all HIV-diagnosed patients that have achieved RNA control in a given 12-month period compared to the measure 407, which captures viral control within a six-month window from the start of treatment for patients on antiviral therapy.

So, these comments suggested measure 2082 will penalize providers that have higher numbers of long-term nonprogressors in their patient populations and if the measure does not account for clinical judgment and patient choice is not to begin antiretroviral therapy for various reasons. Then - and also sort of as a next note that if all patients with HIV are presumed to be on ART, then there's no need for measure 2083, which is prescription of ART, so.

There is another comment about this measure that does support it, noting that this is the sole outcome measure in this group of measures and strong correlation between the reduction of viral loads and that of morbidity, mortality in HIV transmission. So, we do have two comments that oppose one another.

So, thoughts on the committee would ultimately, "Are you comfortable with the recommendations you've made or do you want to make any changes?"

Female: No changes.

(Aaron Wilson): I agree. This (Aaron Wilson). I agree with these comments. I do think we discussed this. So, if someone can just remind me as to why - you know, I think for this and for 2083, there were discussions about some of these obvious issues about penalizing people that are – whose patients fall into the exceptions that aren't being captured at exceptions. And I wonder if someone wants to just re-articulate why we are willing to penalize people that are – that had patients who have fallen to the exceptions that we're not capturing.

Reva Winkler: I think the expectation is that it will never be 100 percent and so – and the baseline data would need to be achieved, and so– I think that was the major issue.

Thomas Giordano: Reva, this is Tom. I think we also felt that there was a benefit to knowing the proportion of patients in the population who were suppressed. For whatever reason, some people are not going to be suppressed, but I don't think there's any argument that you want to drive that number of suppressed people up as high as you can in your clinic population.

And so, this, I'm thinking that - if I recall quickly, the impression was that this is going to give us the best snapshot and opportunity to really make changes at a broader clinical level. I don't think we would say that – if I recall the discussion correctly – the idea of the sixth month, after starting ART, has some implementation and feasibility issues around it.

And we also want to look at everyone, who should be on ART in the sixth month after starting ART, doesn't get as bad. It's only people who started ART.

And finally I would comment that the portion of people who are long-term nonprogressors, who are undetectable without therapy, is incredibly small. And if you happen to have a clinic that accumulates large numbers of those, you know, yes, this could make your clinic look goofy, but there are too many of those out there. So, I'm not concerned about that.

Reva Winkler: And the recommendations are for those individuals that are not lead controllers that they'd be on antiretroviral therapy. So, I don't – I think the number of lead controllers is extraordinarily small and would not affect anyone's numbers with any great significance.

And I would agree about the six-month window. I think that was the major issue. We care about long-term, not just, you know, if people get suppressed within six months, what about long-term suppression, and that's really what we need to look at. And this measure, you know, is able to better assess that than the other measure.

Thomas Giordano: I think it was a great comment. Thank you. I would just – I would say one thing, a note that is – again, the measures, I don't think at least my understanding what these are for. They shouldn't be the capture or snapshot

of data. I mean, the goal should be that we're assessing people's performance against what's accepted evidence, not capturing snapshots of what the kind of actual practice is.

Female: I would agree and this is exactly the comment that I was trying to bring up on the last – on the last discussion that we had, that this is not to create data for us to study. The whole point of implementing these measures is because we're saying that there is sufficient data to support. There's a sufficient threshold of data to support whatever it is that we're agreeing to beyond any reasonable doubt. This is not to try to collect data or glean data or this is to make decisions based on data that's already there, not to capture data that's not there.

Reva Winkler: OK. Any other comments on measure - on the comments for 2082? What I'm concluding from these comments is that you want – the committee wants to stay where they are with their recommendations, no changes. OK.

Male: I want to believe…

Female: The fault was here that we originally had agreed to this and the question is, are we willing to reevaluate that decision, correct?

Reva Winkler: We remember that these comments are feedback on your decisions.

Female: Mm-hmm.

Reva Winkler: And so, it's important that you – we look at this feedback and really think about whether there's any new information, any persuasive arguments that would make you want to change your initial evaluation and recommendation. That's the purpose of this.

Female: I understand that. It would be – the thing is that when we're looking at all of these, it's really hard to think back on the discussions that we had. You know, there were something that had some sort of summary of the major points that we had discussed on that, it would be really helpful, because we could remember what that was.

Right now as we're going through, I'm going OK with the one that we expected. OK, that was the one that we rejected. I'm, you know, so…

Reva Winkler: When I asked you that question is because I want to make sure like a previous speaker a few minutes ago, we're trying to make sure which one are we talking about - was this the one that we've expected? Was this one that we rejected? And I'm just trying to make sure that we're cleared.

Female: Sure.

Alexis Morgan: This is Alexis. We're going to upload the draft report to the webinar and you'll be able to click on it and open up the PDF file. So, we're doing the process, we're doing it now.

Reva Winkler: So, if this – if this question is - yes, we rejected this, which is what we did - are we willing to reevaluate it? I mean, wait, we – which one was the one that we expected and we were being asked whether or not we will reevaluate that decision first. OK.

And based on the information that has been provided here, I mean, I would be willing to re-look at that measure.

Any other thoughts from any other committee members?

Female: I think our recommendation should stand.

Male: I agree. I don't – we went through the process, this is what we came back at. We knew that there's a clinical utility knowing if someone is suppressed at six months, but I don't – we went through process and this is what we've decided. So, I don't think that – unless we think the process was flawed, I don't think that the commentator has brought up anything new.

Female: This is (inaudible). I agree also, it would be helpful. I think, when we look at these comments in the context of the process that we followed at the committee meeting because it's not clear to me that – as was already said, but to build on that, whether all the elements that we - the process eventually in terms of assessing the data, the reliability, validity – I'm sure these comments

are really reflecting which of that process is being perhaps questioned or challenged for reconsideration.

Reva Winkler: OK. That's a fair comment.

Female: That's a very fair comment.

Female: That's an excellent comment.

Reva Winkler: OK. Any other thoughts? I really generally hearing more people saying they're comfortable with the original recommendations and not really looking to reevaluate them. Is that accurate?

Female: Yes.

Female: Yes.

Male: Yes.

Male: Yes.

Male: Yes.

Female: Frankly, yes.

Reva Winkler: Hearing lots of yeses. OK.

So, similar (vein) just so the committee is aware of the comments submitted on measure 2083, which is Prescription of HIV Antiretroviral Therapy.

Again, we've got very similar kind of comments where 2083 and the similar measure 406, which was not recommended. They talked about difficulty in operationalizing both of the measures such that it agrees with current clinical practised guidelines and specifically around the definitions of potent ART and exclusion of ART combinations that are contraindicated. But I think the comment from the consumers adds another interesting element and that is they feel the measure – or they don't really think the measure goes far enough, because it doesn't.

It only focuses in on the prescription and not whether the patient received the medication and took the medication and had an impact or had an effect on the patient, and so this is sort of a corollary to their earlier comment about the outcome measure being particularly important and meaningful to consumers.

(Sue Ewieman): I think, this is (Sue Ewieman). I had the 2083 at the meeting in Washington. I think that we had great discussion around both of those issues. And the groups still agreed to support 2083 as submitted.

Steve Brotman: Yes. This is Steve Brotman. I agree with that and thank you, (Sue), for chiming up. I think we have discussed some of those issues. I mean, it's very hard to determine if the patient actually takes the meds and you know at anything beyond that. So, we did have a discussion regarding that.

Reva Winkler: All right. Any other comments on that particular measure?

Male: (Sue), with that – could someone, again, just give us a one-liner on – because I remember bringing out this issue of defining potent antiretroviral therapy. And when I looked at the voting, we all voted again and support. There were no – it was pretty consistent, the voting. There was no split vote really.

But if – this is the one that had exceptions listed and the developer showed ways they can actually identify or was this the one where we had discussed that we were going to allow them to add exceptions to the measure and it was kind of approved with the understanding that – can someone just remind us of why?

So, I think we should be still consistent that we didn't vote this one down, the other one down for not being able to find potent antiretroviral therapy and this one was approved with some more language.

Female: Well, this measure 2083 was written with, you know, no exceptions to it. It was just basically that all patients diagnosed. We did have quite a conversation on antiretroviral therapy.

I'm just kind of looking through my notes here and I'm not sure that I have the information to answer that second part of your question. I don't know if

anybody else does. But what we decided as far as definition of – I don't think that we – I don't think we defined potent. I think it was just antiretroviral therapy.

Marlene Matosky: Actually, this Marlene, the developer. May I comment on the potencies?

Female: Please.

Marlene Matosky: Hi. 2083 is version measure. We do not have the "potent antiretroviral therapy" in our measure. It was in the measure that was voted down because of the past experience with the measure that was voted down, they could never define what potent was. So, we really screwed it away from talking about what potent was. We talked about...

Male: That's fine.

Marlene Matosky: So...

Male: That's all I need to hear. Thank you for clarifying. I just like...

Marlene Matosky: OK. Thank you.

Male: No. Thank you.

Female: It actually – and Marlene just clarified. So, it's prescription of any antiretroviral therapy.

Female: We're calling it any antiretroviral therapy except those that appear in Table 8 of guidelines, the number recommended.

Female: Right. Fine. OK. Thank you.

Female: You're welcome.

Reva Winkler: OK. Any other further thoughts on measures for prescription of antiretroviral therapy?

OK. And – so the next one on this group is measure 404 for HIV/AIDS –CD4 Cell Count or percentage performed. This comment is, basically, it says that

there's a proxy for the patient retention measures. Something they feel is better captured by the medical visit and gap measure. And that the measure provides your patient contact to a greater extent, then it provides meaningful information on the effectiveness of therapy. So, that is one comment.

Another comment also says the measure doesn't include closing the loop with the patient such that the results were discussed with the patient and that knowledge by the patient is an important aspect of clinical care. There were two comments on this measure.

Steve Brotman: I believe (Katherine Breese) is on with us. Maybe she could tell us her thoughts of – from her discussion when – from our discussion when we had it in Washington.

Reva Winkler: You know, I think this is a different question because it's asking whether it duplicates the retention measures and we didn't really discuss that. But from my own experience doing quality management in our Part A Ryan White Program, I can tell you that we actually, on a regular basis, do a comparison of the CD4 count measurements in the visit measure. And it, actually, provides complementary information. There are times that – where folks meet a medical visit measure and specifically at some facilities where they may not meet the CD4 count measures.

So, sometimes that's because people are coming in only when they're sick. So, they meet a visit measure but they're not really meeting a quality. The quality indicator was getting that HIV care. And it's often, you know, just a signal that, you know, HIV is sometimes a secondary issue.

So, I think they actually complement each other rather than, you know, show the same information. And some examples of where we've seen, you know, differences is where lab – you know, the collection of labs is offsite so people don't end up getting there. And you can identify specific issues that can be addressed to improve the quality of people with HIV care. So, I think that they definitely are not the same and we should probably keep both.

Edward Septimus: This is Ed. I agree. I think they're complementary measures.

Thomas Giordano: This is Tom. I would also point out that some places may not have electronic data for appointment keeping very readily accessible where they might have electronic laboratory datum or readily accessible to use. So, I agree we should keep both.

Steve Brotman: This is Steve. I believe we should keep both. I think they're complementary as well.

Reva Winkler: OK. So, well, that concludes the group of measures where you recommended them but commenters weren't really agreeing with you, and we're going to move on to the next group of measures in which we're looking at the measures that you did not recommend and commenters are disagreeing with that and are advocating that the measures be recommended.

So, the first one of these, I think is pretty straightforward. This is the 298, the central line bundle compliance. This is the measure that is used and has been endorsed previously. And I'll just remind everyone that this measure – the measure developer said that the measure has not been tested for reliability and validity. And therefore, you know, it can't meet NQF criteria for scientific acceptability. And that's pretty much all you can say about it. But we drafted the proposed response for you. I want to be sure that you were aware and agreeable to the response that we're going to provide.

Male: Hey, (inaudible). Do, you want to comment on that?

Male: Yes. It's, you know, I fully agree with the statement and nothing changed them. In the – I've read the commenters', you know, notes. And this just describes what they have in their hospital, their success with using the checklist, but it doesn't provide any additional, you know, data or information. So – I mean, I'm supportive of the statement that was drafted.

Male: Any other comments from the committee members? I mean, there are—there are some who believe that the maintenance line compliance actually made – they have a higher level of evidence in the insertion bundle which is what this primarily relates to.

Thomas Giordano: This is Tom. Ed and others on the committee, have far more expertise on this than I do. But wasn't it just that a (JAMA) article showing how line bundles have dramatically cut line infection rates?

Female: Yes. They did. But you know that – Ed also brought up an article during our last discussion which a new article that had recent been – recently been published that showed that (femoral) lines may not be as bad as we once thought they were. It might have been the method placement rather than the location of placement. And one of the parts of this bundle was to specifically stay at the (femoral) lines would not be used. That's beyond that...

Male: It's just – maybe the comment to go back to would be something, yes that the evidence is still shifting in this one?

Male: You know, can I clarify that again. I think – I think we also had a nice discussion on this as far to the other bundles that we talked about in the few weeks, about bundle versus individual element. Like is there days, day that actually filling out the checklist as opposed to doing the measures? Like you're saying, this is about was the bundle actually complete? Was there a checklist completed? Not, where the elements completed? If that's what's making the difference. It wasn't there a discussion about that?

Male: That's, you know, that's fully my point of view, too. Yes. It's so – I mean, that's a great point that you're raising. And I think we just discussed it in August. The same discussion happened, you know, whether it's just filling the sheets or filling the components are being done.

Male: Well, the other – the other thing is be on the checklist and that is there was a cultural adaptive component. All of those studies. And so, it's not just about the checklist.

Male: Right. Absolutely. (Cost) was a major part of what (inaudible) I mean. Well, (cost) is one of the major ones that has been used in reduction perhaps all over the country. There was cultural component.

Female: It isn't a major component here that in order for it to be passed from our perspective, it had to be tested for reliability and validity. And if it hasn't

been, then, it's in fact – isn't that sort of answer the question from our standpoint?

And if from a guideline standpoint, "OK. Great. This will be a great thing to include in guidelines." But from our standpoint, we have to assess based on the tested reliability and validity. And so if that hasn't been tested, then it's sort of answered the question. Doesn't it?

Male: I want to reiterate that because I think that's the difference between a guideline and a quality measure is that you write the guidelines, can say these are things you should do. But we were – I think what were being asked to say is, "Should filling out of forms or whatever a checklist in EMR is saying you've done this. Is that actually going to improve the patient's care or it lead to outcome difference?"

Male: And I believe this true that in terms of public reporting, may have given up on reporting on compliance.

So, I think we can go on to the next measure.

Female: And as we're talking about things that we discussed in the previous face-to-face meetings, I was looking – I know – I know that Alexis didn't you say second ago that you uploaded that document. I was looking for that on the Web site. And can you – can you show where that is? So that we can access it.

Alexis Morgan: It's actually, we – I've loaded to the webinar. So, if you look on the left-hand side where it says, "Link" and it will say, "Draft Report" and you just click on those words "Draft Report."

Female: Great. Thank you so much.

Alexis Morgan: Sure.

Male: They're pretty techy at NQF.

Reva Winkler: OK. Are we ready to move on?

Male: Yes. I think we got to move on, Reva.

Reva Winkler: The next – we received two comments – one from the developer, one form CDC about the measure 400 which is Hepatitis B vaccination in patients with hepatitis C. And I think, if you recall, there was a fairly lengthy conversation around this. And both of these comments are encouraging the – or recommending this measure for continued endorsement. If you recall, the big issue that committee focused in on was the fact that the measure only requires one injection and not completion of the entire series. And I think that the commenters would basically have provided, you know, argument that they feel that that is efficient. So ...

Male: (That's) me, again. You know, I think we passed the hepatitis A vaccine, hepatitis C patients.

Reva Winkler: Correct.

Male: And I think that one of the things that – if I'm not mistaken, the developer is making a point out is that hepatitis B is, you know, is quite important in this population. If they get infected with hepatitis B, their outcomes are not going to be good. And I think they reported about 35,000 people getting quickly infected with hepatitis B every year in the country.

We got stuck with the issue of, you know, is one dose enough because of the serologic positivity after one dose is between 30 and 50 percent. Then, and whether we should have the three doses augmented versus one. I think that was issue we had in the committee.

I mean, that also makes sense that even one is better than nothing. And documenting one is better than not, you know, pushing for at least a one dose is better than not having any. And I think this is the point that they're trying to make. You know, so I'm – I mean they have – yes, I think we we're really split in the committee. I don't remember the numbers, how many were supportive how many were not.

Reva Winkler: And well, yes. In terms of the voting, this argument revolves around the evidence criteria and in terms of meeting the evidence. The group said it was

zero yes, nine no and 11 insufficient information. And then, the group was split whether to make an exception on the evidence.

Male: Mm-hmm.

Female: Listen what I remember – I remember the discussion also being around that – there was data presented for the protection for after one dose of a hepatitis A vaccine.

Male: Mm-hmm.

Female: And which is adequate for many individual and the second shot is really just a booster so that, that's why we approved that measure. But I thought the reason in terms of the evidence, the issue we have is that there's no evidence provided by the developer regarding what projection was after just a single dose of hepatitis B vaccine.

Male: So, the issue was the – you know, with the comments they have is it's about third to half of the patients would be protected with one shot.

Female: Yes. So that...

Male: And, you know, with hep C if I'm not mistaken is more than 80 percent. So, I think that was one of the discussions now, the issue are we – I mean, is it – I mean, you can see some and I'm not, you know, pushing to change our opinion, but you can see benefit in a patient population where it's may be disaster if they get infected with hepatitis B on top hepa C. So, even if it's a third of population getting, you know, the serologic – I mean, the antibody then this would worth it.

(Sophia): So, I remember – this is (Sophia). As I remember, and again I'm going back on this a little bit. But it – didn't it also have to do with fact that there wasn't much epidemiology data that were presented that even showed us how many people in the United States having hepatitis B and are co-infected with hepatitis C. And additionally, there was also a no – if I'm remembering correctly, there was no risk adjustment for this which was part of – one of the

requirements that we had to – we had to look at because there no epidemiology, there couldn't any risk stratification.

Male: Well, I think the other part of the discussion was that – well, there were a couple of things. Personally, a single dose, you get are response of about 50 percent in a healthy population. But I'm not sure about the duration or protection with a single dose.

And the second was should we accept something we know is below the optimal schedule, and I think – I think this consensus of the meeting was that we really should have – we really should (want) and have a whole three doses and not just one as an acceptable. We should try to get the clinician to try to get those people and have all three doses.

Female: But that's what – wasn't this with the surrogate, that the one dose was a surrogate for the entire dosing regimen. And there was no additional dosing data that demonstrated it because they got the one, they would get the rest.

Male: If you know the – I'm story.

Female: Yes.

Male: The developer states in his – in his or her comment, moreover, who is unaware of any data that demonstrated physicians who give one hepatitis E shot, do not go on to complete the three-shot series. I got – they have to get with the evidence that...

Female: Can you repeat that one more time? I'm sorry can you repeat that one more.

Male: So, what they're trying to say is that, you know, if we look at the documentation of one shot given, you know, it doesn't mean that the other two are not given later on.

Female: But it doesn't mean that they were either. Correct?

Male: I agree – I agree with you.

Female: Yes. To me, its...

Male: I mean...

Female: I'm sorry, go ahead.

Male: No. I mean, the issue again is how much margin of benefit do we accept. I mean, I understand the three shots is the optimal but the protection of – let's say, so someone who has a high risk behavior has hep C, and you give the one shot of hepatitis B. And you push for that and then they inject drugs and you know from someone who is hepatitis E positive and, you know, and they have a chance of 1/3 protection. Wouldn't we have something like this better than having nothing?

Female: It would. But wouldn't that be something for a guideline rather than pay-for performance and for public reporting. Is there – I mean…

Male: Yes.

Female: ... that's the different step. And then we think it's a good idea nobody is saying that it's not a good idea. I mean, I agree that it's a great idea. The question isn't that – and the question isn't that we want to confer some protection to someone versus no protection. I mean, that's not what we're arguing. I mean, I really do believe that that I want everybody to get whatever medical care we can give them at all.

The question that's – that is in point here is that, there are the difference between recommending something because there are sufficient evidence for recommending it. We think it's a good idea. That's a guideline. Right now, we're talking again about, is it sufficient, does it need the threshold for public reporting and pay-for performance?

Male: And you know, another thing I want to raise and, you know, I'm not related to any drug companies. So, I don't even remember the name of the drug company but, you know, they come together, that's A and B vaccines. So, the ease of vaccinating at least the first dose using both together is present. So, to comply with the measure like this but that's another, you know, it's like – it's

like the ease of giving both vaccines at the same time at doctors' office, and hopefully providing some protection to the patient.

Female: It's a great idea.

Male: That's that…

Female: I certainly agree.

Male: It's a great idea but is that the point of the measure?

Female: Right. I mean, it's a great idea but again…

Male: Yes. Well, the measure is the protector…

Female: (Inaudible).

Male: … right? I mean, the measure is to, you know, with pushing the measure is to protect our patients. I mean, that's why we're doing it. It's not that as much – I mean, you know, it's not the guideline. It's the – I mean, the measure – the reason for the measure is to push for a better quality.

Male: Right. And in that spirit…

Female: That's right.

Male: … you know, at least one injection where we have the issue is as opposed to complete service.

Male: I think if it was a complete series, I think we probably would have passed it.

Male: Yes, I agree with that.

Male: But that's not what we're being asked to evaluate here. So, maybe we – I guess comments back to them could be that we think that hepatitis B vaccination is important, but we believe that it should – for a quality, we should (use) for the full three doses.

Female: OK.

Male: Would that be OK with the committee?

Male: But would the feasibility be present in that case? You know, especially the patients may not stay – and there's another comment they made. The patients may not stay with the same physician all through, you know, six months this day.

Male: Well, let's say they don't like go to another physician, shouldn't he take that history?

Male: I mean, yes. But the – I mean do we have – if EHR able to account for the other, you know, for the other physician's destination. I mean, I don't know but…

Female: I'm just remembering was this the thing that the CDC had provided a comment about or was that a different one? That there was something (that looked) at CDC data regarding number of injections…

Reva Winkler: Yes, there's a comment…

Female: … any comment?

Reva Winkler: … that's a CDC data show that 30 to 55 percent of patients who are protected after one vaccination, 75 percent after two shots and the third shot is essentially the booster and can be administered at any time. And so they – well…

Female: So, I'm just wondering since we're having so much discussions about this – is this something that maybe the whole group should take another look at the measures?

Female: I don't think so. I would say no.

Male: You know – yes, I would say no because I think – again, I think discipline it should be done clinically but the question is, is there evidence to say that one vaccine of hepatitis B protects against or protective in this patient population

that – I thought – I thought we were objective when we reviewed this at the – at the meeting.

Male: You know, that comment about this CDC. I mean, is, you know, is anyone from CDC available to comment about this or developer about, you know, where that got that information from?

Female: I don't think that data was included in the – in the information that we received.

Male: Reva, this is – that – which data here on the slide is correct? So, I don't know whether that data is actually people who have chronic hepatitis C who get hepatitis B vaccine. I think that's for the general population.

Reva Winkler: OK, yes. That makes the difference.

Male: Yes. But I…

Female: So, again, it comes back to – there's really not a lot of epidemiology data on this and there's also not a lot of data regarding whether or not somebody who has hepatitis C who gets the hepatitis – one hepatitis B vaccination. How much immunity can person – how long is (conferred)?

I don't think anybody argues the fact that it's a great idea. I think that what we're talking about here is – is it the venue that we're – if we were in different venue – if we were in the guideline venue, it would be a different conversation. There is a different purpose and – associated with this venue. And I think that we came up with regarding our first assessment with this is correct.

Even though I think it's a great idea.

Male: OK, and I think we'll comment back to…

Female: Yes.

Male: … the – I guess this was from (Dr. Ward).

Reva Winkler: No, we also had comments from two organizations both from the PCPI developers and CDC. (Inaudible) folks from PCPI and (Dr. Hwang) are on the line to discuss. If you wanted to ask them any questions?

Male: I think we sort of reach the consensus on this. So, I think we just have to go on.

Reva Winkler: OK. So, the next measure that the comments or, again, it comes from PCPI is measure 393, this is the testing for chronic hepatitis C confirmation of hepatitis C viremia, and this is one where the committees said that the evidence criteria was not met. The comment notes that some committee members did discuss some indirect evidence linking the process of the outcome.

There was additional information provided by the developer at the in-person meeting and that (source) to the comment is around that the absence of a confirmatory viral testing made leaves 15 to 20 percent of patient who – yes, resolve their viremia, their status may be unknown without confirmatory testing, and so to confirm what their viral status is, is the purpose of this measures.

David Spach: This is David Spach. I'm on the (con). So, I can summarize the comments that came as well, too. And just to put this in perspective again in terms of the importance, unlike really any other disease that we have out there, we have a tidal wave that is expected to hit in the next 15 to 20 years, very hard with people chronically infected with hepatitis C, an estimated three million to four million people, and they are slowly progressing on and developing cirrhosis and the whole idea behind viral load testing is to sort out and identify those individuals who indeed need to be linked to medical care to a provider who's able to provide counseling for their hepatitis C and potential treatment and to differentiate from the individuals who have resolved the infection and that's what that 15 to 20 percent of people or resolved infection.

So, the comments that came in from CDC were very focused related to performance gap which was a big issue in the discussion that came up in the summer. This was a maintenance measure and a lot of the discussion was

around is there really a problem with what's going on now and is this really at the level of pay (and) performance and for public reporting or is this the guideline measures.

The CDC comments came from three different individuals from (Dr. Pearson), (Dr. Ward) and (Dr. Hwang) and the day that was presented – that they submitted, there was some significant new information, and they submitted some information that included a large percentage of people, 47 percent of people who in a large database from the CDC, more than 20,000 where antibiotic-positive individuals did not have hepatitis C RNA testing. There was a second study that was cited which involved about 9,000 people and four groups of health care systems and electronic records their integrated health care systems and among – is a little bit more than 9,000 people. There were approximately 37 percent of people who did not have follow-up HCV RNA testing.

And then the third study that they cited which was very recent and was presented only in abstract form because it was just presented several weeks ago where they found actually a drop off in this performance measure from 73 percent in 2005 to 2007 to 63 percent in 2008 to 2011. The CDC essentially the Birth Cohort Testing recommendations came out in late August where much more explicit in that document that viral load testing should be done than all sort of previous documents that had come out.

And so I think they also, in their comments, illustrated the potential negative impact of not actually discriminating individuals that are chronically infected or resolved infection and they go on to cite that there were some bad or not some bad but there were consequences of people who ended up not having these issues sorted out where they were identified as having, "hepatitis C" this is propagated in their record and there were issues of people going on and getting subsequent cost of testing that was not necessary since they did not have chronic active hepatitis C infection.

So, I think there was significant information that was presented in the three documents that came out where the three comments from the CDC, and there

were new references that came in and some of this information was very new and just very recently presented.

Male: So, with your recommendation, do we consider this?

David Spach: My recommendation would be to reconsider it. In my opinion, I think it's actually at the level past just the guideline measure that this is really – it is essential and that the only way that people can be linked to care and basically given an opportunity to receive treatment for hepatitis C is if this actual test is performed, and this is the gold standard and I think it's beyond just a guideline measure. I think it's very reasonable to say from a public performance standard that people should be – should be doing this because there's no other way that individuals be sorted out. There's no other way that people be linked to care if they do not have this, and there's no one out there without performing now practice that should be ever treating anyone with hepatitis C without a viral load testing.

And the question that came up in the discussion in the summer was we'll want to just wait and do the viral load test when you're going to treat them. The argument against that and is that people really need active counseling about their hepatitis C in terms of alcohol use and they need to be linked in the care for overall management of their hepatitis and evaluate it for screening for hepatocellular carcinoma in these issues and evaluation for fibrosis to even have a discussion about treatment, and you can't even get to that point unless you've had this test is performed.

Male: And you said, I agree with that. I (put) down reviewing for today's call, and this is one that I think the committee could consider especially the comments I think they're right on point and there is a substantial performance gap.

David Spach: And let me just also emphasize that we have an extremely unique opportunity in this country where there's a very tight window here with the basic ramp-up of diagnosis and testing with hepatitis C unlike sort of any other disease that we've seen in the past where we know this wave is coming, we know all the really great drugs are coming right around the corner and we really need to, as a society, I think the responsible for getting all these people plugged in to care

where they can be teed up and ready and this is the measure that actually really identify those people who need to be linked to care and plugged in to medical care for this.

Male: OK. Reva, just again, point of process that if other committee members feel the same way, would this be one that we put out in the SurveyMonkey to be reconsidered?

Reva Winkler: Yes. What we can do is because the committee did not vote that it met the evidence of criteria and you want to reevaluate that, we will ask you to evaluate all four of the criteria plus the recommendation and to assist you in doing that, we will – with the notification, we will attach the measures submission information that we have for you to be able to review.

Steve Brotman: Reva, this is Steve Brotman. Are the evidence that was presented will be updated with the additional evidence that David may have mentioned?

Reva Winkler: You know, I will look and see whatever documents were submitted. The other thing we can do is we can also pull the excerpt to the transcript for that discussion on the meeting day and give that to you as well.

Steve Brotman: That would be very helpful.

Male: Can I just say a question, I know we didn't discuss the second part of this because it didn't pass the evidence, but can you – just came up with some other measures, can you comment on if remember from the testing that was done for this one, one thing that I would foresee or a lot of people there are tested by their primary care doctors, they have a positive serology and they're auto-referred to either an I..D. doctor or hepatologist, so I guess one of the fundamental questions I'd want to know about is how that's going to be captured through EMR something else so that primary care providers aren't (ding) for not doing a PCR when – in fact they've done as a referral to another provider.

Reva Winkler: Perhaps, we can ask the measure developers on the line if they'd like to respond to that.

Female: Reva, we would be happy to get back you on that. We cannot answer that at this moment, but we also wanted to mention that we're happy to put the additional evidence provided in our letter in the form if you would reopen them for us if that's what the committee would like.

Male: And I guess – I guess, I just wonder when that date is available because if that date is available, it's going to be really hard to assess the reliability of this.

Female: We submitted a letter. It's included in your materials for today's call and the references are in there, but we can also put them in the form. It's up to you how you'd like us to present it.

Reva Winkler: Probably in the long-term, but right now they do have it at hand. I think though that (Erin) is asking about the data around the reliability and validity, and what was submitted will be in those submission forms (Erin).

Male: And is (Dr. Hwang) on the call? Or if he wanted to make a comment as well?

(Hwang): No, I think you summarized it very well, and I'm glad to hear that you all are reconsidering.

Female: It does say here and, you know, we'll have that I supposed. You know, we'll be able to look at this a little bit more completely later but it does say that the CDC recent (review) that electronic health record is greater than six million adults but – and it says, "Of those 9,000 patients with positive HBV antibody test; 3,000 had no documented follow-up." It's talking about the electronic database and the testing from the electronic database.

But I – perhaps, if we're going to reevaluate this, it would be a benefit for the – for (Dr. Hwang or whomever else has a presidential senate to make sure that we do have the information on the reliability and validity if you don't want to have to come back to have the discussion again because it has the scientific evidence but it didn't pass reliability and validity.

Male: OK. That sounds – we'll get that on the Monkey Survey and the information then.

Male: Because you remember, this is the same thing that came up with some of the HIV testing about included providers. You know, I know we had concerns about OB/GYNs being listed as primary providers of HIV and then not seeing patients back within six months, and I think we were – we were very conscious of how people were going to be captured under a certain provider.

I think this is especially – I think because treating hep C and managing the diagnosis of hep C is still not the norm. I think there may be providers that see hep C serology and refer without doing a the PCR, and yes, I agree that getting a hep C PCR is integral for management but it doesn't necessarily mean that it was (spurring) you're not practicing good care.

Male: OK. We can move on.

Male: Yes. I guess we'll go to the next one.

Reva Winkler: OK. The next one is 397, this is the hepatitis C antiviral treatment prescribed, and I think if you recall this with the conversation at the committee had at length around the current status of treatment for hep C and the fact that it's expected that there will be new drugs available in what – a year or 18 months and that their providers and patients may very well be deciding to wait until those new regimens are available and but the commenter believes that this measure would have the largest impact on the outcome because hepatitis C is overall an undertreated disease.

Female: I think wasn't it (Adam) who commented quite persuasively on this, and they say – was that – was that – is that right?

(Adam): I mean the only question I raised about it was looking at – I believe that what I've spoke mostly to was there was comment raised about how patients couldn't necessarily afford the medication and my concern was around that comment being related back to how we prescribe HIV medication that if the person needed it, it shouldn't be a question of whether or not they can afford it as to whether they've prescribed it.

Female: Why don't you – did you also discussed regarding new medication for treatment of the hepatitis that that – are you recommending or that your voluntary group was recommending that they wait?

Male: Oh, yes, yes. Absolutely that people we know with hep C especially and I think that's kind of speak a little bit to that in the sense that there are obviously individuals who are in need of that treatment currently that probably need to be captured. However, I think, you know, I would refine my previous comments to state that most people that we were dealing with are nearly diagnosed or don't have any indicators that they would need to start treatment.

So, I think you get into a situation where we have to decide, you know, how much of the populations needs it currently and how many are able to put it off. And I am not sure about the data on where people are in that – to this trajectory related to hep C.

Steve Brotman: And this Steve. So that measure failed on the scientific acceptability criteria but I don't think any validity was in – testing was included and did not do well on reliability criteria?

Male: So, I – unless has anyone has the other sounds like what we think as they were.

Female: Mm-hmm. I agree.

Male: I agree with that.

Male: OK. Let's go to the next one.

Reva Winkler: OK. And the last one I believe is measure 401. This is for hepatitis C patient counseling regarding risk of alcohol consumption. That comment is from CDC to they disagreed saying that that recommendation is included in CDC recommendations for a screening patients with hepatitis C, and they give the reference.

Mary Blank: And Reva, this is Mary Blank. That was my measure and that is the – it was MMWR that was put out by the CDC on August 17th of this year. It does state that this talks about – as we did as a committee about the importance of making sure that they are doing alcohol screening and consulting with the patient but what did not see in the original information was the evidence to support there would be a behavioral change that's by virtue of providing counseling.

And I'm not sure if anybody else looked at that MMWR but I – and is anyone from the CDC on the call to provide comment, Reva?

Reva Winkler: I'm not aware if they are. I think we have the measure developer but I'm not sure anybody…

Mary Blank: (Inaudible). So, just looking at the information, I wasn't sure that I was seeing anything other than we knew if the time will be met back in August except for the fact that they had incorporated the measure into their MMWR report and not to measure the recommendations of counseling.

Female: I would agree. I don't see anything here that would make me change what we have already decided.

Steve Brotman: This is Steve. I agree with that.

Male: Any…

Male: (Because we're) in violent agreement.

Male: Yes. I think we're in full agreement on this.

Reva Winkler: Let's drink to that.

Male: OK.

Male: I think we have another one?

Reva Winkler: All right. No, I think that's all the specific measures. Now…

Male: (Inaudible).

Reva Winkler: … just to point out…

Male: Was it there one on…

Reva Winkler: … in the…

Male: … testing for STD – (STD3)?

Reva Winkler: I'm sorry. What are you referring to?

Male: I thought for sexually-transmitted disease 0409…

Reva Winkler: Mm-hmm.

Male: …. that question about whether or not we should modify the (stage) should be yearly and not just one time or that I miss this?

Reva Winkler: Well, I think that was a comment that was part of the conversation in the original discussion. If you'd like to revisit that we'll certainly can.

Male: I'd like to hear for the rest of the committee, but I think the comments I thought – I sort of agree with that that perhaps this should be done in a yearly basis but I'm open to hear other committee members today.

Adam Thompson: This is Adam. I seemed to remember the conversation going. I was one of the advocates for it being annual but I think when we had the discussion what came out with that or wasn't evidence to support that it was needed for more than once after diagnosis of HIV that there wasn't enough data to show that people we're getting reinfected after that period to make the test sort of cost effective to be delivering to the whole population on an annual basis.

Male: I'm fine if that's – if that's what the discussion was (around), and I'm not aware clear evidence of reinfection but if they do remain sexually active maybe it's a logic. I would seem they would certainly be at risk but there isn't the evidence of – I would draw any comments.

Male: Yes, I mean, I completely agree with you. I mean, I was the one that raised the concern around that – around there being an assumption, that persons with HIV's (sexual) activity and I think it goes from the behavior change. Being I don't think that the population of people with HIV just stopped having sex after diagnosis. I mean, (inaudible). That was – but I didn't have any evidence to back it up. There's a just a belief around what I know about myself and my community.

Male: When there are question about did the (reason) what a capture inpatient's sexual activity but how would we identify patients that we're not sexually active? And screening should be targeted with patients with sexual activity and how would that be captured? Could they further define the population?

Male: Yes, we did talk about sexual screening and one of the concerns I had raised was that that's something that is, from our community standpoint, that's poorly done on a large scale basis. So, I mean, I think that's what the evidence (stuff) like this.

Reva Winkler: Are there any other comments on that particular comment from the committee or if you look at the comments submitted in the comment table, we didn't pull out absolutely everything. There were some comments that were referred to the developer about, you know, clarifying titles or, you know, questions around the specifications and the developers have responded to those comments, and we provided them for your review and there are – anybody from the committee want to, you know, raise any other issues to discuss around the comment?

Adam Thompson: There was – this is Adam. There was just one comment around changing the medical visit frequency to saying HIV medical visit frequency and that recommendation was HIV/AIDS and the developer responded by saying, "They would have HIV and I agree with that." I don't see any reason to put the word AIDS and then I think HIV disease is more what the community sort of finds acceptable these days from outpatient viewpoint.

Male: Yes and in (the data), I would agree with that.

Reva Winkler: Thank you. Anything else from the comments that anybody wants to raise?

OK. Then I think – well, things are fresh. What we're going to do is for the one measures 393 that we want to reevaluate is we're going to package up at the information that we have about the measure along with the link to the SurveyMonkey that will then ask you all to evaluate the measure on all four the criteria (won't) make the recommendation.

And I know this is a, you know, long weekend coming up but is it reasonable to hope that the committee might be able to do that to review this up and do the evaluation by the middle of next week.

Female: Well, I think it would also depend on whether or not there is information in the data that's been submitted to us regarding the reliability and the validity of testing that measure.

Reva Winkler: Right. It's in the…

Female: Right. I'm getting it from the electronic medical record that was the one thing that we were still wondering about. So, with all the information, we need to evaluate is already there in the…

Reva Winkler: The information around the testing is in the submission form.

Male: Are you asking if we can vote next week? Are we not going to – are we going to – all the others, we haven't even discussed reliability where we should – we actually discussed that before we vote. I think that was at least some of my and others questions about the census (bundle). The e-mail went out. We voted by e-mail with the expectation that there's going to be discussions that wasn't – discussion. I just wanted to be clear about if we vote next week, are we voting as a final vote or will there be discussion maybe on the call in December.

Reva Winkler: All right. Well, I think that's a recommendation. We can pull this one measure out because you really heloma durum nothing – no other changes to rest of them and we can pull it out, and yes, we do have a conference call scheduled for the 5th, and we could have that conversation then if that would (suit) everybody.

Female: I think that was…

Male: And I'd recommend it from the developers, we try and get some more specific informations for the…

Male: That would…

Female: I – that would be best, too. I think we're going to need a little bit more time because of the holidays.

Reva Winkler: OK. All right. That's sounds fine. We can do that. We'll pull that aside, and we're able to continue on with the others, but we'll pull this from aside just as we've done with the sepsis measure and we do have an opportunity to meet again and have that conversation then.

Does that suit everybody? Ed? Steve?

Male: Yes, I think that's the best choice really.

Reva Winkler: OK. All right. We can do that.

So, as we're coming up to the end of our time, any other thoughts or comments from anybody on the committee? Operator, did you say, we don't have anybody in the audience lines?

Operator: (We) do have no participants.

Reva Winkler: Did you say no participant?

Operator: Yes, ma'am, no.

Reva Winkler: OK. Then is anybody from, no – any of the developers or anybody else who might be on the line, did you have any comments, questions?

Marlene Matosky: This is Marlene from HRSA. I just wanted to thank you – thank everyone for their diligence and their challenging questions. We really appreciate it. I think it just made us produce a very strong (product). So, thank you very much.

Reva Winkler: Anything from anybody else?

Yes, Steve, comments from you before we close?

Steve Brotman: I just want to thank everyone for joining and participating. Thank you so much.

Male: (Did all) for me and I also (did all) again to the NQF staff making this manageable.

Male: Yes, thank you very much.

Reva Winkler: All right. Well, thanks everybody. We're available and we'll be giving information out to you in preparation for that December 5th poll and our two agenda items will be to comment on the sepsis measure and the reevaluation of measure 393. OK?

Male: Perfect, and you'll send that – I assume you'll send out some information to the folks…

Reva Winkler: Yes.

Male: … who could not make this call…

Reva Winkler: Right.

Male: … because obviously they need to know exactly what happened today, and what we're going to discuss on the next call.

Reva Winkler: Correct.

Male: OK?

Reva Winkler: Okidok.

Male: Thank you. Have a great weekend.

Male: Thank you all.

Reva Winkler: Bye.

Female: Thank you.

Male: Thank you. Bye.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.

END