NATIONAL QUALITY FORUM

Moderator: Reva Winkler
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2:00 p.m. ET

Reva Winkler: Good afternoon, everybody. This is Reva Winkler at NQF. I'm here with Alexis Morgan and Adeela Khan of project team. And also with us here in the office are several folks from Revolution Health who are representing one of the measures that we'll be discussing. So far we don't have anybody from PCPI and we are fervently trying to contact them and see where they might be. But …

Female: Good afternoon.

Reva Winkler: Yes …

Female: … PCPI has joined.

Reva Winkler: Oh, great. Welcome. Glad to have you aboard.

Female: Apologize for the delay.

Reva Winkler: No problem. Thanks.

OK. So in terms of the workgroup, we have (Dr. Steven Rothman) and (Dr. David Spach) and (Dr. Doug Campos-Outcalt). So guys, thanks very much for being with us. (Dr. Ray Chang) is not able to be with us today. He is on an airplane. So he did submit some comments and ratings and so I'll try and represent those when we get to his measure.

The purpose of today's call is to give the members of this workgroup an opportunity to review the preliminary ratings that you each have done in your first pass review of the seven measures in this particular group. They are all focused around management of hepatitis C.

You should have received a summary of the ratings and comments submitted by members of the workgroup. This document kind of summarizes the basic information about the measure and then the ratings and comments. Does everybody have that document?

Male: Yes.

Male: Yes.

Reva Winkler: Great. OK, good. Because that for the other workgroup does the primary document that everybody has been working off of. If you're following the webinar that's the document we are also projecting.

So what we've gone quite successfully with the other workgroups is to go through the each measure through the evaluation criteria in order starting with the sub-criteria (round) importance and then on to scientific acceptability and then usability and feasibility.

So are there any questions from anybody before we get started?

OK. So our first measure is Measure 393; testing for chronic hepatitis C, confirmation of hepatitis C viremia. And that measure is to present patients 18 years and older with the diagnosis of hepatitis of hepatitis C seen through an initial evaluation who had hepatitis C RNA testing ordered or previously performed.

So (Dr. Spach), I believe this is your measure?

(David Spach): Correct. So let me just ask you several protocol things. Do you want me to make some comments and then we have discussion as we're moving along or do you want me to make about five minutes of comments and then let discussion occur after that? What would you prefer?

Reva Winkler: The first is what work well. As we go through each of the criteria, focus the comments on that criteria and let everybody chime in. If there are any questions you'd like to post to the developers, feel free to do so.

(David Spouge): That sounds great. That's what I prefer as well, too. That sounds great.

Reva Winkler: Yes. It's informal.

(David Spach): Well, first of all, I think the major first thing we're looking at is the impact of this measure. And the impact of this measure is obviously very important, because of the overall disease burden of hepatitis C in this country with, you know, somewhere in the range of 2.5 to 3 million people chronically infected.

This measure took a notch up in terms of its impact based on CDC recommendations that were issued last week, which essentially to do age-based testing which will affect millions of Americans and will make this test particularly relevant. The particular measure is also extremely important, because it is the (fentanyl) test that sort out whether or not an individual has resolved hepatitis C infection or chronic hepatitis C infection.

And, so I think the overall impact of this, of the measure is extremely important and I think it's very clear. So that's part A of measure 1. What I do want to get some and clearly I think we can open up discussion on that. But I think based on everything in the field of hepatitis C it's pretty hard to argue that this measure isn't important in terms of the clinical utility and ultimate ability to diagnose people with hepatitis C and then engage them in care based on this result.

Now, the area that I'd like to try and get some more feedback is the issue of B, which is looking at the overall, how frequently this is done. So there were several comments that came one of them not for me that were. There was a question about is this test already being done at a significant frequency that yes it's an important measure but it is already being done in such a high measure that the impact of the measure will not be substantial because it's already being done.

So the CMS data from 2008 to 2009 had presented, but may be I can get some feedback and comments at this point just about the data in terms of the presentation where the – it's actually under one B2 where the 10 percentile data of 87.5, the 20 percentile 100 percent and maybe the CMS PQRIS folks that on the call could comment on that. I'm new to this and this type of reporting so it will be helpful for me and maybe others to hear more about this.

Reva Winkler: Any comments from any other of the workgroup members?

(Doug Campos-Outcalt): With that comment he reported – this is (Doug Campos-Outcalt) – it was my comment. I thought it was more or less – I just didn't see where you're going to improve on that very much. Some possibly, but it's a pretty high performance rate now.

Reva Winkler: All right.

(Doug Campos-Outcalt): And so I just don't – and I'm also new to this so I don't know. But it seemed to me like the impact of having this is going to be minimal based on the fact that it was so highly performed now.

Reva Winkler: Yes. Any comments from PCPI? Would you want to respond to (Dr. Spach) question?

(John Wong): Hi. This is (John Wong). I'm one of the co-chairs for the workgroup. And I guess my comment would be simply that the essence of confirmation of the viremia could potentially mistakenly lead to treatment with medications that are both expensive and have side effects. In addition, the absence of confirmation can lead to worry – in the absence of treatment could lead to worry and concern on the patient's part. And as such, even though the performance seems to be very high, I would probably encourage effort to try to get it even higher.

Reva Winkler: Yes …

(Doug Campos-Outcalt): But that to me that doesn't answer the question, which is what's going to be the impact of going of 2 percentage points higher. I mean, all you

said is true and it will be said – that same thing will be said about a number of things and we're trying to figure out what should be included in a limited set of performance measures.

So are we really going to get much impact? That's I think the question. I don't know, nobody is arguing how important it might be.

(John Wong): OK.

(Ed Septimus): This is (Ed Septimus), also one of the co-chairs.

Reva Winkler: Oh, great.

(Ed Septimus): Let me ask some question. This is a maintenance measure, correct?

Reva Winkler: Correct.

(David Spach): Yes. It's a maintenance measure. It was initiated in July 2008 – oh, no, no, maybe yes, I think 2008.

(Ed Septimus): So one of the questions I would have to the developers has this measure driven performance upwards? And what will be the impact if it was retired?

(Catherine): This is Catherine from the AMA-PCPI. We just wanted to discuss a little more the PQRS data that's cited in the submission form, because PQRS is not representative of all eligible professionals that could report on the measure. So that's an important piece about this data.

And CMS has published a 2010 experience report as well on their website, which we weren't able to get into the sufficient form. But they have average performance rates for eligible professional as different than some of the confidential data that we cited from other years.

So in 2010, it says that the performance rate was 34.8 percent. But it seems to be it is going up and down with the performance of this measure.

(David Spach): This is (David Spach) again, if I can just add in one comment. I also had sort of the same initial take like (Doug) that this rate does look very high. The one

thing that I will say, as I just mentioned, with the CDC rolling out these recommendations for this age-cohort testing, there are going to be a lot of people that this test may be thrust upon that may not have done it or that ay not understand as well as people have in the past.

So I don't know that the performance in the past is going to be indicative of the performance in the future since the number of people and the (breath) of people that they're going to be doing hepatitis C testing in the next four or five years is going to change substantially. So that's one thing to think about I think as well, too.

(Doug Campos-Outcalt): So how is the committee? Are we supposed to (do as best) something like that?

(David Spach): That was what I was struggling as I was reviewing it.

Reva Winkler: Well, again, all of these criteria and the sub-criteria meant to help dissect out sort of important characteristics about the measure. But there is not a totally objective sort of thing that's why we ask you all who are out there in the world doing this and have the expertise to tell us what, how to look at that from a real world perspective.

So remember that the overall assessment of importance is around. Do we have something a process of care that is solidly evident spaced that we know that there will be a beneficial impact on patient? Do we know that there is a performance gap or quality problem that if the measure is continued to be used is going to further improvement and then will it affect sufficient number of people so that impact is meaningful?

And so with that constellation of things and you brought up several issues that could very much affect that, so as a group, you know, you have to consider and weigh those various issues.

(David Spach): And I guess, can I just ask you again about the weight we should placed on if a measure was retired what that impact would be? So in other words if the measure is at, you know, 95 percent or 96 percent of people doing it and you

take the measure away and that goes down there would be a big impact, how much should we weigh that in our overall decision process?

Reva Winkler: That is sort of small caveat to looking at opportunities for improvement, because really the focus is on measures that still have some room to further improvement. There is the theoretical concern that is always raised when measures are retired or endorsement is removed that perhaps performance will fall off, but that's an unknown.

And so I guess the other thing, you know, I would add simply because we see a lot of (precarious) measures. I just want to point out to the committee that the data that PCPI has presented is on 1,148 cases in 2009 and the number of professionals reporting was 91. So perhaps this is also a small sample.

Male: So again, how do we deal with that? I mean …

Reva Winkler: Again, you know, please try and just weigh it in terms of whether you think it is, whether you can extrapolate it to the, you know, what's going on in the nation or not. Or do you have some sense in your area or region about this being ongoing problem or not.

(Joe Brill): So Reva, this is (Joe Brill) from (inaudible). Can I just offer a comment?

Male/Female: (inaudible)

(Joe Brill): Is that OK?

Reva Winkler: Yes, sure.

(Joe Brill): OK. I think the thing that certainly the committee reviewers need to consider is that up until this point this and some of the measures that are we're going to follow really focused primarily on patient in whom you're considering treatment for patients with hepatitis C. But I think that (Dr. Spach) has really addressed the (core stimulus) change. CDC recommendation really opens up this, you know, now screening of populations of new baby born for generation.

So you're absolutely correct at one hand that the numbers reported by PCPI and the numbers reported in PQRS have been relatively low simply because the number of overall patients with hepatitis C in the population is overall low compared to some other conditions, which we would be evaluating. This will change now that the CDC recommendation has been issued.

So I think it would be a mistake too soon based on the small number that there isn't opportunity for improvement where in fact there's significant opportunity for improvement.

(David Spach): This is (David Spach). One more point as well too of clarity. The CDC former recommendation in their algorithm and their testing algorithm was they and had this antibody test screening with a lot of emphasis on doing the (inaudible) follow-up and not doing the hepatitis C RNA test, like it's recommended in this measure. And that was very confusing to a lot of providers.

In the new MMWR with the CDC recommendation, they also outlined now their approach will be antibody test followed by the hepatitis C RNA just like is in this measure. So one good piece of news is that at least in terms of national recommendation there'll be consistency coming from the CDC with this measure in which there was not in the past.

Maybe I should move on then in terms of …

Reva Winkler: Yes.

(David Spach): The other issue to look at was in 1B as well as with the disparities issue. And it's very clear in the overall field of hepatitis C that there is disparity in terms of the epidemiology and poor response rates in African-American individuals and so on.

The question that I struggled with again, being new to this, is that there wasn't any data that was presented regarding disparities and how this test is actually ordered and performed. So in other words if you have, you know, thousands of African-American patients, are they not getting this test where as Caucasians are getting that.

So I just bring that up as I'm not sure how we're supposed to evaluate that as well. But clearly in the overall disparities, there is a large amount of data that clearly suggests the disparities in the field of hepatitis C. There isn't any data that I've seen regarding disparities in this particular testing ordered and, you know, minority populations of African-American population.

Reva Winkler: Great. If that's the state of the science, that's the state of the science. I mean, clearly, a lot more data and a lot of these questions would be very useful for helping us understand. But if that was good as we can be at this point in time that's where we're at.

(David Spach): OK. And then I know there was a question about the longer term overall evident and this is not the health outcome, but in terms of looking at the overall evident I think one of the reviewers very appropriately said there's not really a lot of randomized control data that would suggest that we're in a position of documenting overall benefit with treating people of hepatitis C.

Although there is a very review that came out last year by (Purman) and clinical infectious disease, which really outlined the cumulative data regarding individuals who are treated with hepatitis C who then get a sustained virologic response. And I think putting the strings together here or pinning everything together you would say the idea is that you're going to screen based on the CDC recommendations.

This measure comes in to sort out who has chronic infection, who has resolved infection, those with chronic infection. We now know that we have about 70 to 75 percent range or 60 to 75 percent range of getting a sustained virologic response, which correlates with the long-term cure which does have health benefits granted there aren't great randomized control, there's more just retrospective data in that regard.

So anybody jump in or I'll keep moving on, and I know we diverted a little bit so I'll try and wrap up pretty quickly.

In terms of the next issue to look at the scientific acceptability of the measure, I think the four reviewers we had three that felt that that was valid, one voted

no. And if anybody is on the call that voted no and wants to make a comment on that or want to jump in, please fell free to do that.

When I reviewed this, I felt like the actual test itself is very reliable test. The performances of this hepatitis C RNA test are very good. The only question I had was there was one mentioned and one of the measures where they talked about this test being a predictor of virologic response. But that really isn't the purpose of this measure and that was kind of extraneous information that was in the measure that I didn't think should have been there.

The feasibility to do this I think there wasn't a lot of dissent on that and the usability there was one individual that felt with high and three that felt with medium usability. So I think in terms of the scientific acceptability of the measure, the biggest question again that came up was the test was not underused and there may not be room for improvement. But I'll leave at that if anybody else wants to make any comments on that.

Reva Winkler: Other comments from workgroup members?

This is Reva and I had a couple of questions or comments. You mentioned in the comment that the test, the laboratory test itself is highly reliable and that's great. I'm glad to hear that. But the reliability we're asking for in this evaluation is about the measurement …

(David Spach): Yes.

Reva Winkler: … collecting that data and looking at that data. So try and separate those two things.

(David Spach): Right. And I should have – I should have said that. So the test because it's a laboratory test and is an electronic medical records and at least what they presented here it looks like there would be essentially no major issues and being able to reliably collect that information and collect that data.

Reva Winkler: The other thing I would note is the testing in this case was done at the level of the measure score, right, for reliability and validity. And so, as we talked about the criteria to rate it as a high needs to have empiric testing of the

reliability and validity at both the level of the data element and at the level of the measure score.

So in this particular case really with only testing done at the level of the measure score, you really should only be rating it as high as moderate, which is still sufficient to pass, but just to – just to focus on the data element.

And I guess the one thing on the testing I wanted to ask PCPI is in your analytic method you talked about the analysis including the percent agreement as the denominator and the numerator as well as the (CAPA) statistic. But I didn't see the result of the percent agreement for the denominator and the numerator.

Female: Could you please repeat the question?

Reva Winkler: Yes. On your testing methodology, you said your analysis included the percent agreement as the denominator and the numerator, but I see no results for that.

Female: We're going to have to look at that at the submission form and then we'll get right back to you.

Reva Winkler: Yes. It's the same in all of them, so that's fine, as long as you can look that up.

Anybody else have any questions or comments on this measure?

(Steven Rothman): Hi. This is (Steve Rothman). I guess I took more of a (curious) look at this since I don't necessarily treat patients on a day to day basis regarding this. So I was looking at from the basis of the measure and looking at the evidence, looking if the measure steward PCPI and others were presenting the evidence in some sort of a detailed fashion and it almost looks to me that is they presented a clinical practice guideline and just referred to it, but never sort of examine the quality, quantity, and consistency that comes from that are guideline or refers to it in extreme detail to some extent it is referred to.

But, you know, going forward there will be a lot of different practice guidelines from different sources. And I think it's important when we get measures or NQF gets measures for evaluation that there is sort of this extensive delineation or analysis of that evidence. And, you know, a lot of us will probably have, the ones that do clinical work may have that in their background. But even for transparency, it's just nice to have that out there for the ratings in the future. And that tackles also in terms of the reliability and validity rather testing for dissections.

Any comments related to that?

(David Spach): One, Steve. This is (David Spach). I had the same feeling as well, too. And actually, if you look at most of the measures that we're looking at today, they similarly sort of defaulted to the AASLD guidelines. But your, you know, good guidelines are based on evidence.

But the original data is not presented and essentially the same guidelines and the same statements are presented in each of the measures, which made it a little difficult for me to try and sort out. Should I be using all the information and knowledge I have or should I be rating this specifically just on what is in the pages in front of us?

So I would agree with you there. I think some more specific information is opposed to just referring to the guidelines would be helpful in the future.

(Steven Rothman) Right. And given that this is maintenance, I understand that. But some of the guidelines are probably four or five years old in terms of thought and analysis. Obviously, things have progressed over and will progress again over the next couple of years in tremendous efforts. So that's why I think updating these are really important to make the maintenance process a lot easier the (best way).

Reva Winkler: Right. This is Reva. And just to tie the workgroup members and we'll talk about this a little bit more at the meeting. Essentially, though we're really asking you to do your rating based on what is submitted, all right?

And at the time we ask you to assess the evidence, we really are asking you to apply the criteria of how many studies, what type of studies and do they perform consistent results. If you don't – aren't presented with the information so that you're doing – so you're able to make that assessment then really you have no option but to rate at this insufficient information. And …

(Steven Rothman): So each and every one of the measures that we represented on hepatitis C would have been so rated.

Reva Winkler: OK. And we understand that and we do have a next step if that happens. But we are asking you to kind of go with us and look at what's presented first.

Then what we're going to do is ask a follow-up question. If indeed you indicate that no, we can't say that it passes the criteria based on what's submitted, we'll ask you the follow-up question which is, "OK. Does the steering committee itself, members of the committee have personal knowledge that they would like to share that would help the committee understand whether indeed there is sufficient evidence to meet the criteria?"

So that it isn't an automatic but it does. We are asking that the first vote be around what's submitted.

(David Spach): And Reva, how does it work when somebody is submitting something? They're saying, "We have all the data. It's based on evidence, but it's in the guideline."

Reva Wrinkler: Right.

(David Spach): I mean that's what was confusing to me.

Reva Winkler: Sure. And we've actually gone through this. After the taskforce created these sub-criteria in such detail and we've watched some of the struggles with these measures that they've come through. And last month we took this to our subcommittee at the board who oversees this whole process and, you know, explain to them some of the struggles we were observing and the difficulties people were having.

And nonetheless, they felt that the need to have the evidence based very clearly delineated for the measures was essential. And really what was feedback that we received from members and other stakeholders as being really to something we have to maintain. And so that's why I understand that you feel quite in quandary, because being experts in this field you have knowledge that perhaps didn't find this way on to the piece of paper. So we are going to make an allowance for that.

And if you feel that you can, you know, comfortably state that even though it's not presented, there is solid evidence that meets the quantity, quality, and consistency criteria, you can invoke that if you will. You can say, "OK. They didn't write it down but I know it – we know it's there." And if the entire committee is comfortable with that, you can allow that to pass. OK?

(David Spach): Yes.

Reva Winkler: And I understand the position that puts you guys in and it's a difficult one. But we're trying to, you know, be sure that the measures that are recommended and endorsed are very strongly evidence based. And we need to have some, some way of establishing that fact.

For the people who, primarily for our audiences, who are going to come back and say, you know, "Are these measures solidly evidence based?"

Are there questions?

OK. On this one measure I just – and maybe my ignorance but I'm just wondering about the testing the hep C-RNA testing, how do patients get into the denominator to have a diagnosis of hep C without having have that done?

(David Spach): So the initial screening – this (David Spach) – the initial screening test is an anti-body base test...

Reva Winkler: Right.

(David Spach): … and that's your, essentially you're casting out a very wide net to try and find anyone who's ever been infected.

Reva Winkler: Right.

(David Spach): So if you got infected with this virus, you have about a four out of five chance that you'll go on and continue to be infected and can pass it on to other people and have disease. One out of five people basically spontaneously resolved it on their own. So you screen to try and find anybody who's ever been infected and then this test sorts out those four out of five people who currently or still infected and have a threat of the virus to go on and cause liver disease.

Reva Winkler: So just having a positive antibody is enough for you to have a diagnosis of hep C?

(David Spach): Correct. It's enough to have – enough to say that someone has been infected with hepatitis C.

Reva Winkler: OK. That's why I'm just trying to figure it how the denominator was determined.

OK. So anything else on measure 393? OK.

(Catherine): Reva?

Reva Winkler: Yes?

(Catherine): This is (Catherine). I was wondering if I could make a comment about the evident section.

Reva Winkler: Sure.

(Catherine): Just that as it – we've talked about this. But as measure developers, we've always relied on the guidelines as the folks that have done the systematic evidence review, as you know, so we have not been in the practice of looking for separate systematic evidence reviews. So at the time that these measures were submitted, only what was in the guideline was placed in the submission form.

We just wanted to let you know that subsequent to that one of our workgroup members that's (inaudible) has put together a list of systematic evidence reviews that may help if the committee needs some more just citations and data. Right now, it's in the form of an abstract and there's quite a few of them and they pertain to most if not all of the measures. So I just wanted to let you know that we have that and we can send that if the committee would like to see it.

(Mark Canton): And Reva this is (Mark Canton), if I can add to what (Catherine) has said. Having reviewed the list of systematic reviews the she referred to, we would be delighted to try to tease out information on the quality, quantity, and consistency of evidence from that list of reviews. But it's unfortunately not – it's not within our ability to look at the description of the systematic reviews and be able to tease that out across a large number of studies covered in a significant number of systematic reviews.

So I think our best option at this point is to send the list to you as they are. And we're happy to have the steering committee review that information.

Reva Winkler: All right.

Male: Is there any way to group the list that would be relevant so that have, you know, eight studies that are related to measure 093 and then there's 12 that are related to three to five or is that beyond the scope of what you would be doing?

Female: Yes, that should be possible. Right now it is – it's not grouped like that at the moment with the abstracts. It is grouped like that with just the titles of the evidence reviewed.

Male: Yes.

Female: But with the abstract, they'll take just a little bit of work to get the abstract right after each measure.

Reva Winkler: Whatever you send us we'll be more happy to share with the committee.

Female: Great. Thank you.

Female: And then I had just to follow up on the question earlier about the (confidence) versus the reliability. I apologize we did not remove the word, the agreement percentage. We didn't provide agreement percentages, because we did a little bit more sophisticated analysis on these measures, looking at more of the agreement for patients who were found to be in measure met by the automated report, how likely was that to the agreement with the abstracter.

And then we put our patients to the report who did not meet the measure and patients to the report found to the exception. And we thought that was maybe just a little confusing. But if there are any measures where the (CAPA) is you don't find to be acceptable on their own, we'd be happy to provide that analysis. I think it just will take through discussion to explain the statistics that we did to this committee.

Reva Winkler: OK. All right.

(Ned): This is Ned. Can I suggest we go on to the next measures …

Reva Winkler: Probably right.

(Ned): … enough time for everything?

Reva Winkler: Yes. The next measure is – which one is it – 395. Yes, 395, RNA testing before initiation of treatment. (Doug), I think this one is yours?

(Doug Campos-Outcalt): It is. But, you know, you could go through this and just say (ghetto).

Reva Winkler: OK.

(Doug Campos-Outcalt): It's more or less exactly the same issues. So if you, you know, the impact again, you're not going to argue that hepatitis C is not a significant problem. Once again, there's pretty high performance on this already. If I remember correctly it was 90 percent or close to. And again, not knowing what I'm doing that does seem like not too much room for improvement.

The evidence based was again a clinical practice guideline with no specimen to ask for the quality of the evidence of the quantity. And therefore you couldn't judge things like consistency across studies and so forth. Again, if you could go down to the reliability and practicality and everything, it's more or less the same as the one we just went through.

Reva Winkler: OK. So comments from anyone else? The other workgroup members?

I guess I would ask you then (Doug), I mean, do these two measures overlap? And if so, to what degree?

(David Spach): This is (David Spach). Yes, go ahead, sorry.

(Doug Campos-Outcalt): No. You obviously say they – oh, not really. I mean the first one is to confirm if somebody has chronic infection. The second is not everybody who has chronic infection going to chose to be treated.

(David Spach): Yes.

(Doug Campos-Outcalt): And if they chose to be treated then you should do this prior to treatment.

(David Spach): Exactly. Theoretically, it could overlap if a person got diagnosed, got the test on and then a month later started on treatment. But otherwise I think they're separate measures.

The one thing that isn't brought up into the discussion it's a reason to do this test as well, too. There are rarely people who on their own just clear the virus over time. So it would actually be very poor form to treat someone based on the original test you may have gotten two or three years ago.

This has actually happened to me in my own practice several times where we went to treat somebody, we did this test right before the treatment and they had actually cleared the virus they would have gotten unnecessary treatment. So I think it separate than the previous measure.

Reva Winkler: OK. Then are there any other points about either the scientific acceptability or usability or feasibility that might be different that you'd want to raise? Or do you feel that really the conversation applies to both?

(Doug Campos-Outcalt): From my perspective, the latter.

Reva Winkler: OK. Anybody else disagree?

All right. Then we'll move on to the next measure. All right. And essentially, a similar topic, this is Measure 584. This is the viral load test for patients with hep C and this one is from Resolution Health.

And I just wanted to point out that this measure is the level of analysis is at the health plan level and this measure uses administrative (planes) as its data source.

The measure prior that's similar is the level of analysis is different and that's at the clinician level or group practice level. So these measures are very similar. However, they are used by different stakeholders and different end users. And so the thing we would be most concerned about here would be harmonization. Are the measures constructive the same way in measuring things similarly so that there's a consistency of measurement for those different levels of analysis?

So (Dr. Rothman)?

(Steven Rothman): Yes. OK. So again …

Female: (inaudible)

(Steven Rothman): Yes. This is a maintenance endorsement from 2009. And I'll try to go quickly, because I know we're behind time.

When you look at the importance the measures impact is rated as high by 3 and moderate by 1 performance gap, all concur with moderate rating of 4 from four people with comments about again hepatitis C being important disease burden in the U.S. unfortunately. And performance gap is reported from 1.8

million administration claims. I don't know if there is any discussion that flows from that.

But when we go look at evidence again, there's somewhat of a high consistency, three reporting high, one moderate for quantity, for quality. Again, one reporting high, three reporting moderate inconsistency the same reporting three moderate and one high. This was based on (modern) analysis that had been used that it used 12 studies with expensive data from solid trials that some people have noted.

There was one comment that someone does not agree with the statement as listed. But, however, patients with rapid virologic response no matter the genotype respond to short treatment within 12 to 16 weeks. And even with direct acting antiviral therapy and response-guided therapy treatment for genotype 1, it's not 12 to 16 weeks.

The statements in the measure are not entirely accurate with the RGT and GT1, genotype 1 therapy. Shortened duration therapy is not just based on rapid virologic response but will require extended virologic response.

Any comments related to that?

So then I guess we'll go on to scientific susceptibility and reliability. Two people are rated that this is high, one medium and one low; validity, one high and one moderate rather; and I have one low here.

And the comments are the validity testing did not include review of medical records. It's uncertain how you'd identify the patient with recent hepatitis C RNA obtained by another medical provider, for example referring physician that obtains it and sends it to an expert who then initiate therapy without repeating the HCV RNA level.

As far as usability, one rated high, three moderate and reporting comments reporting 92 percent in 2011 for all the measure viral load maybe at anytime fired starting therapy with new measures of the viral load within six months of starting therapy is only 68 to 84 percent.

Going to feasibility, one rated high, three moderate and some comments that test is easy to obtain, normally obtainable as part of routine care. It's easy to locate in the EMRs. The only issue, not having EMR documentation for recent HCV RNA obtained by another provider. And if the test was inaccurate, there would be major consequences and there's collection with electronic claim.

So the preliminary assessment criteria met for suitability, three for yes and one no. So the comments relate to direct overlapping with the measure 0395. So I want to note that (inaudible) potential for collaboration with patient records and with favor. This one is about the 395.

Reva Winkler: Comments from the other workgroup members or anyone else from the committee?

Hi, (Dale). Any thought?

Essentially, these two measures I think are very much analogous, very similar and I think the one question would be if there's any further ability to harmonize them. Certainly, the main thrust of the measure of doing the RNA test within six months beginning therapy is the same.

Any comments from the measure developer? (Jeff Simon) …

(Jeff Simon): Yes.

Reva Winkler: … here in the office.

(Jeff Simon): Thanks. I have two comments. As Reva pointed out, originally the – this measure is designed to (operate) the health plan level and by doing so we – the health plan would expect to have all of the (inaudible). So if the test was performed by another doctor, presumably it'll still be paid for by the health plan. And so evidence in the form of claims would be available.

So that addresses the concern expressed under item 2B. Any thoughts about that?

Reva Winkler: Does somebody who have that question, one of the workgroup members who have that comment?

(David Spach): I had that comment – this is (David Spach) – based on clinical practice for somebody who will see a provider, they'll do an initial evaluation, they will send a person on with paper records to another clinic for treatment and I didn't realize that from the payor standpoint that you'd be able to easily track it down. So that makes sense to me it addresses my concern.

(Steven Rothman): If I may I'd like to address the second concern about the compete – the competition with the PCPI measure. I agree that the intent is nearly identical. But I think that there are significant differences based on the perspective. And our perspective is that the data concerning various data elements, critical in (neurologic) rule, comes from claims data and it does not come from EMR data.

So it's important – and another thing we have that's very important to us is to preserve the modeling after traditional HEDIS process measures. Hence, we have a number of criteria or requirements that are different than the requirements of the corresponding PCPI measure.

In particular, our measure required continuous medical benefits or medical eligibility during the period of time, the six-month period of time during which we are looking for evidence of the viral load test. Our measure also required continuous prescriptions drug (inaudible) for the period during which we are seeking to establish the new start of the antiviral therapy. And these are constraints that are include in PCPI measure perhaps because the focus of that measure or if that measure not optimized for use with administrative data.

There are number – there are four other differences that I can go ahead and list. One is the inclusion of J codes. So these are six-fixed codes, a (prefix) with the letter J used for billing of medications that are administered by a provider and do not have Rx norm terms associated with those. They usually do not have (MDC) codes and certainly do not come to health plans in the form of prescription drug claims. So it's important for us to have a measure that takes that into account.

Reva Winkler: Anything else?

(Steven Rothman): I had two other things, but if you heard enough then.

Reva Winkler: Comments from the committee? Or thoughts? Anything more? Anybody wants to say on this measure before we move on to the next one?

OK. I'm assuming silence is agreement. So the next measure we have is Measure 396, which is HCV genotype testing prior to treatment. (Doug), I think this one is yours?

(Doug Campos-Outcalt): Yes, it is.

You know, once again, a lot of the same issues that have come up on some of the prior ones on the importance, I think everybody on impact rated it higher moderate; three high, one moderate. Performance gap, however, because once again it seems to be a pretty high performance. And based on current treatment algorithms, it is kind of hard to imagine somebody starting treatment without having done this. So that's again there's in prior ones were performance of the test is already pretty high. What exactly is the room for improvement is the question.

On the evidence, exactly the same issue as before which is we have a guideline presented and so you're not able – we're not able to do things like quantity, quality, and consistency of evidence. So if we were to apply a (purest) approach to this which I'm perfectly willing to do we would say it doesn't meet the criteria. However, you know, there were three votes in favor of it based on evidence and one against. I think the one against was mine, but it is going to be continual issue for us I think.

So going on down to scientific acceptability, three yeses and one no. I don't see the negative comment. I don't know if somebody wanted to state why they might have said no on that one.

Male: My figure shows about, you know, the reliability scores and general validity scores and the (CAPA). It was – I'm just looking. I don't know if anything

goes here. I'm not sure how many the (CAPA) was based upon, but it's not exceedingly high.

(Doug Campos-Outcalt): Yes. I will say that in that particular topic, some guidance says what's the threshold for considered to be a high versus lower (CAPA) would be helpful. I'm not that familiar with that (inaudible) I could use some help if that.

Reva Winkler: If you – if you take a look at the memo that I sent it's called Staff Notes, I actually put (inaudible) at the bottom of it, at the end of it. It talks about (CAPA) and how the various designations for the different numerical results gap. But I can – I can get that to you separately (Doug).

(Doug Campos-Outcalt): Is there like cutoff of some kind it's considered, you know, like a P 0.05. Is there a (CAPA) of something rather?

Reva Winkler: It's not quite like that. I mean, it's sort of applying moderate and low …

(Doug Campos-Outcalt): Yes.

Reva Winkler: … different values.

(Doug Campos-Outcalt): OK.

Reva Winkler: You know, I'll make sure you've got a copy of that.

(Doug Campos-Outcalt): Yes. OK, thanks.

For usability, feasibility, pretty good agreement. By that I mean everybody was higher moderate on those two. And then under the, you know, the last one is suitable for endorsement. We split down the middle and I think, you know, the issue is the evidence provided. Without the evidence, it really doesn't meet the criteria.

Reva Winkler: OK. All right. Thoughts from anybody else on the committee? Anything else to contribute?

All right. Suddenly, we're galloping along. The next measure is 397, hepatitis C antiviral treatment prescribed. And again, as I mentioned, (Dr. Chang) was not able to be with us today. And so I'll just go through this, but I need the help from the rest of you guys as we go through this.

This is the measure where the presented patients age 18 and older with the diagnosis of chronic hep C were prescribed at a minimum peginterferon and ribavirin therapies within the 12 months' reporting period. So this is really the rate of prescription of therapy in patients with the diagnosis of hep C.

And (Dr. Chang's) comments were general. He rated the impact as high due to large population numbers with the finite progression to end-stage liver disease and death from liver failure. He related or rated the performance gap as moderate. The important caveat being that a very large number of patients are untreated because of perceived intolerability or prior treatment experience.

This is the treatment area in (flocks) as genotype 1. Standard care is now the addition of – I forget what it is – (CVR) or (BOC) will soon give way in transferring and all oral regimens in the next two to three years. So I think that's a caveat he wanted to be sure everybody was aware of.

And then the evidence he is invoking I think his own thoughts and that there are large number of studies to support high rates of sustained response.

So thoughts or comments from the other members of the workgroup?

(David Spach): This is (David Spach). The only thought I had is that the whole field of hepatitis C treatment for the genotype 1 patient is evolving very, very rapidly. And the measures are sort of implying that if you see someone you should get them treated in this very short period of time. The reality is that the next wave of drugs coming down the road one to two or three years down the road is something that many people are waiting for because they are much better tolerated and they're going to be all oral regimens.

So this measure doesn't really – I couldn't see sort of how it allowed for an (out) that someone would essentially have a lower performance based on not treating somebody where they may have a very good rationale for doing this.

As a matter of fact it maybe even the most expert providers knowing what's on the road, down the road and one to two years maybe deferring their patients that don't need immediate treatment.

So I don't know how to get around that. But assuming if you're telling me that there'll be a way that that would be captured and the initial evaluation then that would, you know, that's fine. But that's one thing wasn't taken into account.

Reva Winkler: Thoughts from other folks? Comments from the developers?

(Ed Septimus): I have a question. This is (Ed). Maybe I'm missing something here. Is there any numerator and denominator mentioned in this? I don't have the full thing in front of me.

Reva Winkler: Yes. The numerator is patients who are prescribed at a minimum peginterferon and ribavirin therapy within the 12 months' reporting period and the denominator is all patients age 18 years and older with the diagnosis of chronic hep C.

(Ed Septimus): And what are the exclusions?

Reva Winkler: The exclusions are documentation of medical reasons why a patient was not prescribed and then – or documentation of patient reasons why patient was not prescribed or three documentations of system reasons why a patient was not prescribed.

(Ed Septimus): So a patient could refuse treatment and that will be an exclusion.

Reva Winkler: This is the claim?

Male: Yes.

(Ed Septimus): OK. So and also this – tell me if I'm wrong – this measure can be modified within the three years when it's up for re-review, correct?

Reva Winkler: Yes. NQF asks for annual updates from the developers to determine if there have been any updates or revisions to the measures. So if the developer

should decide to make revisions to the measures, we would want them to tell us about it on an annual basis.

(Ed Septimus): So I guess what I'm getting at is that, you know, because of the toxicity of the drugs and the opportunity for a non interferon, these regimen could be available in the near future. Some patients may decide to wait and that would be I guess considering a refusal and would be an exclusion. And then as these new drugs come online, the developer can notify this measure.

Reva Winkler: Comments from the measure developer?

Female: I think that's exactly what we had in mind. Instead of trying to rework this measure now, waiting until more research and more treatments have come down the pipeline, but having the exceptions of the measure allows for treatment decisions to be made based on medical or patient reasons and so we were hoping for system reasons. So thinking that keeping the measure is the most flexible for the time being and updating it when the new treatment guidelines come down will be the best approach.

(David Spach): This is (David Spach). I'm just adding that many providers with experience with hepatitis C who have patients with lower levels of fibrosis are going to defer their patients in treatment for the newer drugs coming down the road in a couple of years. And that's not – that's not going to be a patient refusal but it's going to be a provider based decision. And there's no inclusion of them and exclusion that would account for that.

Reva Winkler: All right. I think that would be a medical reason?

(Doug Campos-Outcalt): No. Medical reason is more like you can't tolerate the medication.

(David Spach): Yes. They're anemic or they're depressed. That would be the – it's almost like a line needs to be in there that documentation of deferral of treatment for non-interferon based regimen or for future regimen or something like that.

But I mean, I would just imagine the impact of it if you have this measure going out and there's a bunch of expert hepatitis C treaters who are getting (ding-donged) that they are not treating their patients they'll come back and

say, "Look, I am very expert in this. I am not treating them because I got something better that I know is going to be FDA approved in 6 to 12 months and my patient doesn't need immediate treatment."

(Doug Campos-Outcalt): Very good point.

Female: Around the table, the AMA-PCPI, we feel that deferring treatment for a medical reason, such as the new treatment is better for the patient, seems still to be a medical reason to us.

(David Spach): OK.

Female: We can certainly discuss this with our workgroup as well.

Reva Winkler: Any other comments in the workgroup?

This is Reva. I just had a question. Do you have any data on the exception rate for this measure as is being used in PQRS?

Female: Reva, did you ask if the measures are being use in PQRS?

Reva Winkler: No. I ask, do you have any data on the exception rate?

(David Spach): The number of people being excluded basically?

Female: Yes.

Reva Winkler: Yes.

Female: We can provide that. We don't have that at our fingertips at the moment.

Reva Winkler: Yes. It just seems like it would be good to know because there do seems to be a lot of potential patients that are going to fall into this exclusion categories and it would be nice to see what that number is.

(David Spach): And Reva, this is (David Spach). And I would say the number of people that are excluded in clinical practice now is greater than the number of people treated. So it's going to be a number that's greater than 50 percent. Whereas these other measures we're talking about in extremely no number of people

where you wouldn't do a genotype for some reason only cost or something. We're talking about there's going to be a large percentage of people here who are not going to be treated for very good reasons.

Reva Winkler: OK. I think that will be an interesting data to see if they can provide it.

Any other thoughts from this measure in terms of scientific acceptability, the reliability or usability for this measure?

OK. So I think the measures were all pretty much constructed similarly. So I think it's reasonable that we'll have a similar thought.

(Doug Campos-Outcalt): I had a distinct feeling that once I'd seen one I'd seen them all.

Reva Winkler: Yes, well. OK. So the next one is 398, HCV RNA testing at week 12 of treatment. So (Dr. Spach), I think that's you again?

(David Spach): Yes. So just briefly, I think again, many of these issues I won't rehash all of them. In terms of the impact, I think the impact of this is very high and that there are really numerous studies that have shown that the early responses to hepatitis C treatment are extremely important and not only determining a person's link of therapy but nowadays also determining reasons to stop therapy and avoiding giving somebody toxic drugs for very long period of time. So I think the impact of this measure is very important.

The committee was split on this on a, you know, yes-no two and I think again this may have been based on a gap issue and that it's commonly done in clinical practice.

In terms of – there were a couple of comments that again, in terms of the evidence that was taken from the guidelines and there really wasn't additional supporting evidence. When I actually rated it, I based a lot of my comments based on information outside of the guidelines that were presented.

The one comment that I would add that makes this measure a little bit complicated is this measure was introduced in 2008 or '09. And the monitoring of people in the first 12 weeks of treatment on hepatitis C

treatment is completely different now than it was when this measure was initiated.

So I think, you know, (Ray Chang) said about this but any of the other treaters who are on calls well may want to comment on that just having a measure that says you're going to obtain a viral load some time in the first 12 weeks is really extremely vague considering what is actually done in clinical practice now.

The other problem that I think was generating some of the comments was that it wasn't a precise measure in that. It says some time in the first 12 weeks, but that could be at week 1, it could be at week 4, it could be 8 and information obtained at any of those points would provide very different information.

So the overall impact was split two and two. In terms of the usability, there was one high vote and one-three that were in the moderate. And the feasibility was split, two and two. And again I think these are the same issues that we've had in the past. I think the real question that came up in terms of whether or not to endorse was split two and two, was I think, number one, there may have been votes "no" based on the amount of data that was presented.

But secondly, I think there may have been issues related to the precision of the measurement based on current treatment of care which is really not simply just attain a viral load, sometime in the first 12 weeks but a much more precise measurement strategy that is done in clinical practice now.

I'll open that up for comment.

(Ed Septimus): Well this is (Ed). Could I develop a comment on that because I think that's a very good comment. I mean, I think it's meant to say you should get a viral load probably in the first two to three – after two to three month's therapy, not after two weeks.

Male: In the clinical practice now with all genotype 1 infection is that they all should get a viral load at four weeks after the hepatitis C protease inhibitor started. And I don't know if this is implying that if you just do it in 12 weeks that that

is implying that's now an acceptable standard but I had problems personally with this guideline not being specific enough.

Reva Winkler: Somebody from PCPI want to comment?

(John Laren): This is (John Laren). I'm one of the co-chairs of the PCPI workgroup on hepatitis C and I'll say we spent a vast majority of our time talking about this particular measure. One of the – and in particular, with regard to the specificity that (Dr. Spach) mentioned, we well recognize the timing for the assessment of viral load response could be much more specific than prior to 12 weeks.

One of the primary reasons we opted to create what I would call a low-bar measure – meaning that it would be easier for a physician to satisfy the measure as opposed to a more specific measure is that the response and the timing of the measurement differs between the telapravir and the boceprevir.

And also we thought that it would be a bit problematic to be very, I guess, narrow, you know, in terms of specifying the exact time range that patients would get those tests done whether they're half a week late or a week late or early. In addition, we thought that – I didn't know whether or not the patient had genotype 1, 2 or 3 would make the measure more problematic in terms of implementation at various providers and health plans where results of special tests like genotype testing may not be available.

We share your concern. We did not think of an easy way to characterize the measure to ensure the highest quality and as such, we backed off to one that we thought will get at the general concept with the hope that individuals who are using these new drugs are using them at the testing frequencies that are recommended.

(David Spach): (John), this is (David Spach). Thanks for the explanation. The only other thing that I would add is that at the top bar of the measurement, it is saying hepatitis C RNA testing at week 12. And then when it's actually, you know, spelled out, it says that no greater than 12 weeks from initiation of antiretroviral treatment. So I'm assuming that what's officially in the

numerator is what the measure is and not the title. Is that correct? Because at week 12 and no greater than week 12 are two different statement.

(John Laren): Yes, you're absolutely right. You're absolutely right. And I don't – speaking personally, I don't know quite – the measure is less than 12 weeks – (inaudible) 12 weeks. I don't know how that initially translates into the title but we'll have to fix that.

(David Spach): OK. Thank you.

Reva Winkler: Any other thoughts from other committee members? Any other discussion on this measure specifically? (Dr. Spach), do you have anything else you wanted to make?

(David Spach): I think that explanation for me is very helpful to understand how the measure would be used. And so that I think is – there's a lot of logic behind what had been said and that's, you know, that satisfies sort of my objection to the measure.

Reva Winkler: Given that they've said that they've created a very non-specific kind of measure, what do you think the ability of this measure to drive quality improvement is likely to be?

(David Spach): Personally I think that your ability to drive quality improvement would be much greater if that was a more specific measure. But with that said, if you're trying to have a lower bar to make sure there's a minimum standard that's done, this is a very important measure. But if you were to have, you know, two separate measures, one was based on genotype 1 and one was based on genotype 2s and 3s, or, you know, it just was somehow brought into point of week 4 after protease inhibitor therapy has started. That is the single measurement point that is probably going to have the biggest impact on clinical practice.

So that's just my opinion but I understand the rational for making sure that this as a minimum is a reasonable goal to try and do. And maybe we're thinking about – this is a really good measure but maybe the next measure that will follow this, as therapy evolves will really have to take in account that week 4

rapid biologic response measure, which really is going to drive much of the cost of clinical practice and length of treatment.

Reva Winkler: Any other thoughts from anybody else from the committee? All right, ready to move on to the last one – Measure 394, Counseling Regarding Use of Contraception Prior to Antiviral Treatment. And just for the information of the committee, unfortunately, (Sharon Baskerville) had to withdraw from participation on the committee because of some family health issues and so (Dr. Rothman) has kindly stepped in to take the lead on this measure.

(Dr. Rothman): Hi. The description on this is the percentage of female patients aged 18 to 44 and/or men aged 18 years and older with a diagnosis of chronic hepatitis receiving antiviral treatment who were counseled regarding contraception prior to the initiation of antiviral treatment.

In terms of importance to measure – one vote for "yes" and two for "no". Going to impact, one rated it as high, three for moderate. And the performance gap – three were rating it for moderate. The comments related to – it's not clear how well the contraceptive counseling actually reduces pregnancy while under ribavirin and it's not clear why men would purposely need to be counseled.

The high impact on the summary on the measure just defaults to a high impact of hepatitis C disease. It is not specifically addressing the high impact that this measure addresses. And as far as the performance gap – exists in African-Americans have a poor response. It's not clear if minority groups receive lower rate of counseling for use of contraception prior to starting ribavirin.

Looking at the evidence, there is one reporting "yes" and three "no". The quantity, when you break it down, there's one reporting moderate, two, low and one for insufficient. And that's the way it goes for quantity – quality, rather, and consistency as well. And maybe based on that same clinical practice guideline lack of explanation of the evidence in general.

Looking at the scientific acceptability of the measure properties – three "yes" one "no". Reliability, in the breakdown – one high, two moderate and one

low. And validity – none reporting high but three moderate and one low. Of the comments related to that, the wordings is ambiguous and could be misinterpreted as counseling the patient to take contraceptives prior to the treatment versus counseling the patient prior to starting treatment that they need to use contraception during the treatment for six months after taking ribavirin.

The main issue is that counseling is not a standard item in the EMR. Let's see – looking at usability, two reported high, two reported moderate. And noting that's it's been in use since 2008, it's easy to understand the (inaudible) that the person receive the counseling. The other question is, is this just sort of a check-the-box type of issue. And the measures are available in the PCPE website.

Looking at feasibility – one reported high, two moderate and one low. And comments related to that – that data should routinely be generated in all patients prior to starting therapy as a part of good clinical care. And data regarding counseling is likely to be more difficult to find in the archived medical record as compared to lab data. Only unintended consequence would be possibly the misinterpretation of the measure based on ambiguous wording. Another comment related to that – there's no difficulty and measure is easy to implement.

So as a summary of the (clearing) assessments, two was split two and two and the comments related – it's critical that treatment does not cause permanent severe side effect with the (girl with) ribavirin during pregnancy or within six months of becoming pregnant. So you have the wording of the measure not ideal to ambiguous and from the measures not entirely clear.

What wording should be used in counseling which is extremely important. So there's an example given that "Females need to use contraception so that you don’t get pregnant while taking ribavirin and for the following six months after finishing ribavirin treatment." And for males, "Use effective contraception so you do not get your female partner pregnant while you are taking ribavirin and for the six months after finishing ribavirin treatments."

That's somewhat similar to what you see, I believe, in clinical trials and consent forms regarding that.

Male: So the issue with ribavirin is on spermatogenesis? I mean, why does the man who's getting ribavirin for hepatitis C need to not get his girlfriend pregnant?

(John Wong): This is (Dr. Wong) – or (John Wong) from the – co-chair for the PCPI. I actually went to do some literature searching about this particular issue today when I saw it on the agenda. And there are two potential reasons for ribavirin has a very long half-life outside of the plasma – as long as 40 days. And it is given on a daily basis for those receiving treatment for hepatitis C. So it is possible that it could accumulate and it's only you know, (fully lost) because of the (half) of 40 days.

So it is possible that it could have an effect on the sperm. The second concern is again, because of its long half-life ,whether over that duration of time, sufficient amounts of it could concentrate in the seminal fluid and as such eventually affect fetal development in the womb. I went so far as to see what experience – so the primary teratogenicity from ribavirin has been demonstrated in animal models.

I went to look and see if I could find any cases where the father had taken ribavirin and consequences of the pregnancies were determined. And what I identified were 25 pregnancies in the literature of which 11 pregnancies resulted in normal babies. There were five miscarriages out of the 25, two elective abortions, presumable because of the concern about teratogenicity, and then seven pregnancies were lost to follow up. That's the extent of the literature.

Male: So this is a theoretical concern that has some potential harm if people are getting inappropriate terminations of pregnancy based on a theoretical risk that may or may not exist.

(John Wong): Yes. In fact, that was one of the main premises within one of the papers that I identified. And. You know, I think there is this tension – again, I can't speak for the product manufacturer but because of these animal data, I suspect they're very concerned about potential risk to the babies and like it to err on

the side and have this very strict recommendation. And as you know, we can't easily extrapolate animal data to humans. And I assume this has been carried through.

Now for many drugs, we have very little primary data and obviously we're going to get much less primary data when this kind of warning on the label for the drug. And, you know, that's an FDA/drug manufacturer decision. That's out of my hands.

Male: Sure. But whether or not that's enough to make it a quality measure is a whole another issue.

(John Wong): Yes. I see the issue you say.

Reva Winkler: Any other comments from any of the committee members? This is Reva and just – this comes from the fact that I practiced gynecology for 20 years before coming to NQF and so contraception was my life. I guess what's your experience in terms of counseling because frankly, just telling someone to, you know, do some things to prevent a pregnancy is not exactly the most effective thing I've ever done.

And so I guess the question is what's your experience in terms of really, you know, assisting these patients in preventing pregnancy while they're on this drug? And just take counseling – is that really sufficient?

Male: Yes. To me, an outcome measure of the number of women ribavirin who become pregnant. And that should be – you can do an outcome measure, not just a process thing.

Male: As an outcome measure, you have to have risk adjustment. It's much more complicated.

Male: And it doesn’t seem like it's very robust. You're asking a very individual question. I mean, with – I mean, you could have a thousand measures being submitted just to answer one small partition of information.

Reva Winkler: How about – somebody mentioned something about it being a checkbox measure. That's kind of a red flag sort of thing for folks at NQF. We're not real – we've been trying to get away from pure checkbox measures. Who was it that made that comment?

(Dr. Rothman): I just mentioned it at the start just because, you know, when you do something like this, there's no attention to the quality or the type or just quantity of information that you're providing. It's just saying that you talked to someone. And there's – it doesn't have to be any more information that's gleaned from that. So I'm not quite sure, you know, it just could be something that, "Yes, I did that." You know, no big deal. And you're going to get different responses from different providers about how they actually provided that information counseling that they provide. So that doesn't get captured in this measure.

Reva Winkler: Thoughts from anyone else?

Male: I think this – we've come up with a lot of reasons why this wasn't a particularly desirable (measure).

Reva Winkler: Just one other question that sort of starts with this measure but extends to all of them – what about children and adolescent with Hep C – for any of these measures. You know, would some of them be applicable to management of children and adolescent, specifically.

(David Spach): This is (David Spach). It's unusual – I mean, I could see some situations but it's very, very unusual sort of based on the natural history of hepatitis C and the acquisition and risk factors. There's some pre-natal transmission of hepatitis C but it's unusual and since most of the acquisition is through injections, drug use or sex, you know, late adolescents, most of those individuals – because the natural history of hepatitis C taking usually 10 to 20 years before significant fibrosis would take place, I think it'd be unlikely to see very many people under age 18 being treated in this country. I don't know the statistics but I bet the numbers are very low.

Reva Winkler: OK. Thanks. I appreciate that. So there are a couple more hepatitis C measures that workgroup D is going to do tomorrow. And so there is – there were a large number but they all are constructed very similarly and to form

this group. So we'll – you're certainly welcome to join the call tomorrow to see what that workgroup has to say about the remainder of the hepatitis measures.

So what we're going to do next week at the meeting is something very – is very similar to what we've done here but a little bit more structured. What we're going to be asking the committee to do – each of you is the lead for one or two measures – is present the measures through the criteria like we've done today. But at each point, we will be asking the committee as a whole to vote on whether they believe the measure meets the criteria.

So we'll have you vote on impact, we'll have you vote on opportunity for improvement, we'll have you vote on evidence. Similarly, for reliability, validity, usability, feasibility and then whether you feel the measure meets the criteria for endorsement. And so it will be a little bit more structured.

So it is important that everybody keep an eye on what the criteria are as we go through them and to really raise, when you're leading the discussion, the issues that you talked about or thought about that are particularly strong or particularly weak for a measure as it applies to the criteria. Because that will help the entire committee be able to come to an assessment of whether the measure is sufficiently meeting all of the NQF criteria to go forward.

So that's what we're going to be doing next Tuesday and Wednesday. Anybody have any questions about the upcoming in-person meeting and what you're expected to do.

(David Spach): So, Reva, did is (David Spach). So obviously, the thing that came up over and over again was the question about the extent of the data. So I don't know if we're going to have access to those additional abstracts – if that's going to be part of the measure or that is just considered for our own information or is that enveloped into the measure that we now include this as part of the rationale when people are voting?

Reva Winkler: Yes. You're right. That's a good question. We'll provide – we'll get you whatever information they send us because the actual request is to summarize the information. And so we'll see if what information you have and we'll be

able to apply it. I need to think about that a little bit but it's an excellent question. But we will guide you through that.

Any other question? All right. Well we are concluding a little bit on the early side. Does anyone have any questions in general about the projects, the measures, the process …

(Ed Septimus): This is (Ed). Is there a time for – is there anyone on the line who wants to have a comment?

Reva Winkler: Yes. That's what I wanted to check with the operator.

Operator, do we have anybody on the audience line who wanted to ask a question or make a comment?

Operator: At his time, if you would like to ask a question, please press star then the number one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Reva Winkler: (Ed's) being an excellent co-chair in reminding me of those things.

(Ed Septimus): It's a shared responsibility.

Reva Winkler: Thank you. I appreciate it.

Operator: At this time, you have no questions from the phone line.

Reva Winkler: OK. Thank you. So again, anything from anybody currently on the line – folks from RHI who are here or folks from PCPI. Any other questions or comments before we close?

(David Spach): This is (David Spach). I'm so glad to …

(John Wong): This is (John Wong). I was just – if PCPI were to provide you with the summary, what would be the best form for that summary?

Reva Winkler: For this point, just because there probably just isn't time to embed them in the submission forms, you can send it in a separate document I can forward on to

the committee. But ultimately we would want that information embedded into that submission.

(John Wong): Thank you.

Male: I do have a question.

Reva Winkler: OK. Here's – Jeff Clyman is here from Resolution Health. Jeff, what's your question?

Jeffrey Clyman: It's not about y particular measure but more in general. I was impressed by the discussions surrounding the guidelines. And I'm wondering whether you are considering or has considered recognizing a limited number of (deeming) authorities – for a lack of a better term – so, organizations that you recognize as being legitimate endorsers of recommendations.

Reva Winkler: At his point, no. Though certainly that question gets raised and has certainly been discussed. But at this point in time, it's not included in the NQF criteria.

Male: Is that part of our job presenting the information to the larger committee as to say we think this organization is highly reputable. We think these are state-of-the-art, top-of-the-line guidelines. Is that part of our job?

Reva Winkler: No, it's not.

Male: OK.

Reva Winkler: No, it's not.

Male: Except, for example, the American College of Cardiology will publish a 100-page – a guideline of congestive heart failure or suggesting that the measure developer should summarize the evidence leading to that.

Reva Winkler: Until we see – that's currently what the criteria requires.

Male: OK.

Reva Winkler: OK. So questions from any other committee before we close out? Again, all right. Well thank you all very much for joining us today. I look forward to seeing all of you next week at our meeting. In the meantime, if you have any questions, please don't hesitate to get in touch with us.

We will be summarizing your discussion and including it in this table. There will be a table with these ratings, comments and summary of your discussion for every measure for use with the meeting next week. And we're hoping to get that out to you by late on Friday so you'll have the weekend to take a look at it is you wish, or on your plane ride.

But I think that's all we really need to do today. So unless there any last questions, thanks very much and we'll see you next week.

Male: Thank you.

Male: Bye-bye.

Reva Winkler: Bye.

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

END