NATIONAL QUALITY FORUM

Moderator: Laura Ibragimova
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2:00 p.m. ET

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

Suzanne Theberge: Good afternoon everyone. The NQF project team is on the line. This is Suzanne and I'm here with Jesse, Andrew and Laura. I don't think we're quite ready to get started but I just want to see if there are committee members on the line, if you could just let us know.

Chris Cook: Hi. This is Chris Cook.

Suzanne Theberge: OK.

Josh Rising: Josh Rising.

Iona Thraen: Iona.

Suzanne Theberge: OK. Anyone else? You know we're excepting a few other workgroup members. So we can wait a moment to get started and see – wait for them to join. I know it takes a minute or so to get into the call. Community measure developers on the line?

Lynn Pezzullo: Hi. This is Lynn Pezzullo from PQA and to the Woody Eisenberg will be joining shortly and Julie Kuhle will join the call at approximately 3 p.m.

Suzanne Theberge: OK, great.

Erin Giovannetti: And this is Erin Giovannetti and Rita Lewis from National Committee for Quality Assurance.

Suzanne Theberge: Great.

Kyle Campbell: This is Kyle Campbell from FMQAI.

Suzanne Theberge: OK. I think we've got all our developers. Have any committee members joined the line?

Leslie Schultz: Leslie Schultz is here.

Suzanne Theberge: Great.

I can see we've got one or two more committee members on the webinar portion. Tracy, are you on the phone?

Tracy Wang: Yes I am.

Suzanne Theberge: OK, great. And Lynda, are you on the phone?

Lynda Smirz: Yes, I am.

Suzanne Theberge: Great. And Richard?

OK. I guess we're just waiting for one more. Operator, is anybody still getting connected to the call?

Operator: I do not see anyone else dialing in at the moment.

Suzanne Theberge: All right, should we – and since we have almost everybody, should we go ahead and get started?

Jesse Pines: Sure, sounds great.

Male: Yes.

Jesse Pines: OK. Why don't we go ahead and get started here. Welcome everyone to the work group 2 call for this patient safety and complications committee. What

we're going to be doing today is doing a quick round of introductions and then going through each of the measures in detail, that the way that we wanted to do this is we have two folks who are going to be presenting each of the measures. And then we're going to be having a discussion of the measures and there are, just to let you know, measure developer representatives are on the call for all five measures. So, they will be able to answer any specific questions. And then towards the tail end, what we're going to do is make sure that any of the public comments are directly addressed by the committee here and to see what sort of comments we have or how should we respond to those.

So, why don't we go ahead and do a quick round of introductions. I'll start myself. So, I'm Jesse Pines. I am a consultant in NQF and a faculty member in emergency medicine and health policy at George Washington University.

Male: OK.

Andrew Lyzenga: Hi. This is Andrew Lyzenga. I'm a senior project manager here at NQF. And I'm working on this project along with few others.

Male: All right.

Laura Ibragimova: Hi everyone. My name Laura Ibragimova and I'm a project analyst here at NQF.

Suzanne Theberge: Hi, everyone. It's Suzanne Theberge. I'm the project manager for this project.

Jesse Pines: OK. And why don't we go around and do introductions for our work group members next. We're going to go over folks who can see the slides online. We're going to go from − in alphabetical order here. So, is Richard on?

Richard Brilli: Yes. I just joined.

Jesse Pines: Just give like a one-liner intro about your background.

Richard Brilli: Hi. I'm Rich Brilli, a pediatric intensivist and chief medical officer at Nationwide Children's Hospital in Columbus, Ohio.

Jesse Pines: Great. Thanks. Thanks Richard. Chris Cook?

Chris Cook: Yes. I am here. I am the director of Quality and Performance Measurement Strategy at GlaxoSmithKline. My background is as a clinical pharmacist and an outcomes researcher.

Jesse Pines: Great. Josh?

Josh Rising: Hi. This is Josh Rising. I'm a pediatrician and currently, I work at the Pew Charitable Trusts running a project on medical device safety.

Jesse Pines: Great. Lynda?

Lynda Smirz: My name is Lynda Smirz, and I am the chief medical officer and vice president of quality at Universal Health Services and I'm an OB/GYN by training.

Jesse Pines: Great. Iona?

Iona Thraen: Iona Thraen. I'm the patient safety director for the Utah Department of Health.

Jesse Pines: Great. And Tracy?

Tracy Wang: Hi. I'm Tracy Wang. I'm the public health program director at WellPoint and I lead Patient Safety initiative working with external stakeholders.

Jesse Pines: Excellent. Welcome to our work group members. We look forward to seeing everyone in person. So we also have developers on the line. There are three separate developers today, one from the PQA, from NCQA, and then FMQAI which is our CMS subcontractor. So, PQA, can you give us a quick intro?

Lynn Pezzullo: Hi. This is Lynn Pezzullo. I'm a pharmacist and I am director of performance measurement in research at Pharmacy Quality Alliance. And I think − I'm not sure if Woody Eisenberg has joined.

Jesse Pines: Woody, are you on?

OK. Any other representatives from PQA? And you said there was going to be a third person that was joining at 3 p.m.?

Lynn Pezzullo: Yes, Julie Kuhle. Julie also is a pharmacist (inaudible) senior director of performance measurement in PQA. She had a conflict with the first hour of the call but I see that are measures are towards the end of the list. So, she'll be joining us at that time.

Jesse Pines: Great. So, we have someone from NCQA on the line?

Erin Giovannetti: Hi. This is Erin Giovannetti. I'm a research scientist here at NCQA and I'm joined by my colleague.

Rita Lewis: Yes. This is Rita Lewis, and I'm project manager for our measures here at NCQA.

Jesse Pines: Great. And the CMS subcontractor or you said FMQAI, is that right, Kyle?

Kyle Campbell: Yes, that's correct. This is Kyle Campbell and I'm a pharmacist and executive director for the CMS Medication Measures Special Innovation Project. I'm joined by my colleagues here Sherry Yang and Patti McKay, and then I believe we also have on the line from RAND, Elizabeth Sloss. Liz, are you there?

Elizabeth Sloss: Yes, I am. Yes. This is Liz Sloss. I'm an epidemiologist at the RAND Corporation and we're working with FMQAI to develop quality measures for CMS.

Jesse Pines: Thanks everyone. Is there anyone else who has dialed into the call who has not yet introduced themselves?

Female: Yes. This is (Inaudible). I'm at the University of Florida and also in Kyle's team.

Jesse Pines: OK, great. OK. Well, so, we're going to quickly move into our measure discussion. We're going to be doing the five measures today. We've got about probably about an hour and five minutes or so of active discussion, you

know, sort of realizing that we don't want to cut-off any discussion but we're going to (inaudible).

Female: OK. Just quickly interrupt − sorry. If you have your computer speakers on, please turn (inaudible) we just started the streaming audio for this and the computer speakers that will interfere with your phone. And other related note, if you're not speaking, if you could put us on mute but please don't put us hold during the call. That will appear with the rest of the call. Thank you (inaudible).

Sorry, that echo is because the speaker is on so.

Jesse Pines: Great. OK. I think all speakers are off and we're not on hold. So, I will move forward. So, for – again, we've got five measures to discuss here. We've got an hour and 45 minutes or so because we will at the end be going through NQF member and public comment. So there may be other folks who are called in, listening in and we want to make sure that we have enough time for them to give any comments.

So again, about an hour and 35 – actually an hour and 35 minutes of actual active discussion time here. So, what we will be doing is just giving people a reminder at 20 minutes in from the discussion that if the – that we are 20 minutes in. But, you know, again, if there's – we don't want to cut off any discussion but we will be giving you a reminder that we should be sort of nearing – near in the end potentially.

So with that, why don't we go ahead and get started.

The first measure were going to be discussing is 2371 which is Annual Monitoring for Patients on Persistent Medications which the measure developer is the NCQA. So I'll turn it over to Chris Cook.

Chris Cook: All right, and let me just ask from a − conform within this. Do I n need to go ahead and, I guess, we got about 20 minutes, but if we're leaving it for discussion, please let me know as I'm going along if I'm going on too much detail or if we need to stop and go into a little more detail in to the sections. As you have up on the screen, a brief description of this measure is that it

assesses the percentage of patient who are 18 years and older who received at least a half a year or 180 days treatment of ambulatory medication therapy for one of the selected therapeutic agents. And they had at least one monitoring event for that therapeutic agent within the measuring year.

So the three primary therapeutic agent classes that they were really looking for are − if someone is on the ACE or in ARB and if they are in one of those, then they need to make sure that there's a therapeutic monitoring for serum potassium and serum creatinine within the measurement year. If they were on digoxin, that a serum potassium, serum creatinine, and a serum dig level was pulled during the measurement year, or if they are on a diuretic, that at least a one serum potassium and serum creatinine was pulled during that measurement year.

So the way that this is completely pulled together for the measure is a total rate, meaning that it is the sum of the three numerators divided by the sum of the three denominators. And so as I went through the criteria, what I looked for, one A which was the evidence to support the measure focus. In reviewing the literature review that was provided, it did seem extensive to me of obviously a need for measurement and monitoring for each of these therapeutic agents. I think that was provided within the levels − within the literature review, so I considered it pretty high for the ACE inhibitors and ARBS as well as the dig as well as diuretics.

When I went into the performance gap, and the reason for it, they definitely have done a large look at this with it being claims-based that within the HEDIS, there were over 120 million covered lives who have, you know, been reviewed within this. The means across the product lines range anywhere from 79 percent on the commercial PPO up to 92 percent within a Medicare HMO. So from one standpoint, you could look that there's actually good clinical performance but there's definitely room for improvement in this area. And for me, I thought, adequate for us to be able to move forward from a priority (sets) which was measure 1C. I considered it a high impact to book individual patient care as well as when you look at it from a population health standpoint of ways to avoid emergent care as well as avoid cost to our system.

It was not a composite measure. And so that was not applicable. When I look into the second criteria, they did provide specifications for all the panels and it seemed very adequate within the descriptions themselves. One thing that I did notice in here and I was wondering if it was just an error, was that I could not find the actual specifications for pulling the dig levels. And will say that as a pharmacist, I'm not the one who typically pulls from the lab processes but maybe this is a question to NCQA. What I found was that there was phenobarbital, carbamazepine, and phenytoin and valproic acid, so I believe it may had just been a wrong set that was attached with the data that I had. Is that a, I guess, a spot to stop and just clarify that at this point?

Jesse Pines: Sure. NCQA, did you want to (inaudible).

Female: Yes, I apologize for that, that was an error on our part. It's probably because this measure is simultaneously going through an update right now for our own process and we are updating all those codes, but I can make sure that those − that values I just added.

Jesse Pines: OK, thank you.

Chris Cook: Yes, and, I guess, I at least demonstrated − I did read all of those stuff and tried to make sure with all that material that I was being thorough, so I caught the curve ball on that one.

From a reliability testing, definitely had good reliability scores across the different, you know, 0.7 threshold for all three medication classes, in commercial, Medicaid and Medicare. The only exceptions was found within the Medicaid population for digoxin, to where there was a reliability score of 0.36 and it was attributed to being a small patient population within the cohort which definitely seems reasonable and logical. The measure developers said that they will continue to monitor as expansion within the Medicaid population continues.

And so from an overall sense from a reliability piece, I rated this as being high in its methodology and how they did that. From the validity testing, the element validity had good to excellent sensitivity, being 89 to 99 percent and a positive projective value of 89 to 98 percent. The measure, it also had good

specificity at between 62 and 91 percent and again, the only exception within this is the digoxin and that is recently been added and will be examined in future years moving forward.

The empirical validity, the indicators were highly correlated at between 0.8 and 1.0 and were highly significant at 0.001 and as well as the overall piece had sufficient face validity. And so I consider the validity of this measure as being quite high. The threat to validity, the only exclusions were actually built-in and if that is – if a patient was identified as being admitted into an inpatient facility during the measurement year. Good justification for that and that once someone is admitted to the hospital, they should have these panels run automatically and may not be able to capture that within the full data set. And so those patients were the only patients excluded. No risk adjustment testing was needed or reported for this measure. And within the measure did have highly significant differences reported in the (inter core trial) range for each of the indicators and across three different patient populations. So the threats to validity seemed to be reasonably examined and justifiable in what the results appeared. So it appeared to be complete there.

2D also referred to a composite measure which this was not, so we can exclude that. So then that leads us to the construct, the third construct, the feasibility. And from that way, I really looked at this as (sensitive) through electronic administrative claims data sets, readily available data for the plans and the integrated delivery systems which the measure is intended, and should be quite feasible to be able to perform. And then for usability and use, there is current adoption within this measure both in public reportings including annual state of healthcare quality, CMS Medicaid Adult Core Set as well as regulatory and accreditation programs of the HEDIS ACO, Quality Compass, NCQA, Health Plan Rankings, and Quality Improvement with Benchmarking.

And so from that standpoint, it does appear that others believe in its clinical application and use. And again I rated that is quite high.

So that is my assessment and I will, I guess, open up to comments.

Jesse Pines: Great. I'd also just − thanks, Chris, that was a very nice summary there. Just as another way to focus our discussion, so I think everyone should have the document, the review and update guidance for evaluating evidence and measure testings which is on SharePoint, that we're going to be more, you know, having a very – a deeper discussion of this in the in-person meeting, but as we're talking about clinical evidence, there are several algorithms that had been developed by NQF just recently that we really would like to adhere to. So, if you go − if you can go to that document on page nine, the Algorithm 1, where it says Guidance for Evaluating Clinical Evidence. It's (pertinent). And also in that same – in that same document page 15 and 17 will refer to − I'm sorry, 15 and 16 refer to reliability and validity. So …

Chris Cook: Sorry, Jesse, I just want to note I've also saved those on the SharePoint site, this is separate document (inaudible) the evidence algorithm testing algorithm are out there, so you could pull those as well separate?

Jesse Pines: Great. Let's continue on with the discussion on this measure.

Yes, thanks again, Chris, for that summary. It's just − so, let's see if are there any other comments or thoughts or questions from the other members of the work group?

I guess you covered it all, Chris, that was very thorough.

Chris Cook: Well, I was going to say, I did – I did use those algorithms in my determination out of it. So I hope that that's consistent and again, I'm a rookie on this, first time through these calls, so.

Jesse Pines: That is an excellent review, very good, very nice.

Josh Rising: Hi, this is Josh Rising. I just have one question about − in how the measure is summed at the end? (Inaudible) as you know, potentially, you could have a patient certainly in − who has more than one of this medications, right? And so, you know, let's say you've gotten all you'd, you know, you had done the test because, you know, doing one test will basically get you credit for a kind of all of them. So in essence, our, you know, by then kind of summoning the number of patients and kind of the number of tests that were done is that, you

know, I'm just trying to think through the methodology of doing that versus kind of counting that person once.

Does that make sense?

Jesse Pines: Sure, maybe, Erin, can you comment on that?

Erin Giovannetti: Sure, so really, it's done for (ease) of reporting for the health plans rather than trying to figure out (inaudible) and calculated by health plans, it can get quite complicated to see this person on digoxin and ACE and ARBs (inaudible) diuretic, digoxin, I think you could go multiple base with calculating the total but we hope that with the transparency that this total is based of of prescribing and testing that it – at least transparent system that someone could be in there twice. And that the other thing is that, you know, because digoxin does have the additional dig level, you do have to do that extra step for that particular one.

Josh Rising: Yes, yes, I understand that. And I think (inaudible) let's say I have two patients, all right, kind of, you know, both of whom qualify and one is just on a diuretic and one is on, you know, both on ACE and a diuretic. And I test that person, you know, then it looks like I'm measuring 66 percent of the time and it seems like a more accurate measure would be that I'm testing 50 percent of the time. But …

Erin Giovannetti: Well that's …

Josh Rising: … I understand. I certainly understand because the much more complex is, you know, if you're dealing with many more than two patients for …

Erin Giovannetti: Right.

Josh Rising: … across the range of, you know, large payers et cetera.

Erin Giovannetti: Right, I mean, I think that that's why we've always report publicly the individual rates with the total rate?

Josh Rising: Yes.

Erin Giovannetti: So you'd have to look at both really to see the (inaudible) picture of …

Josh Rising: OK.

Jesse Pines: Thank you. Any other questions or comments on this measure?

All right. Sounds like there was a (inaudible).

Male: (Inaudible).

Jesse Pines: OK, I guess we might as well just − we got a little bit of time here to − is there any …

(Crosstalk)

Female: The time is running.

Male: Yes

Jesse Pines: We did get some comments in our online forum and one did comment on this measure. This is from (Kelly Rogerson) at Providence Health & Services. She's says, "We support this measure and believe it is very important, however, our concern that it will require a much more specific – sophisticated (crafting) and reporting capability that's currently available. There's also the issue of patient adherence that may not be considered effectively through this measurement." So I just wanted to see if any of our work group members had any comments on that or thoughts or reaction to that comment.

Iona Thraen: This is Iona. Andrew, could you make the – make it larger so we can see a little better.

Jesse Pines: Yes, Laura, can you zoom in a little bit.

Suzanne Theberge: You know can also (inaudible) figure by clicking the enlarge button on the top of your (inaudible). That's an individual screen control.

Iona Thraen: OK, thank you.

Jesse Pines: Is that better, can you see that?

Iona Thraen: Yes, I'm still working online, but go ahead.

Jesse Pines: All right, great. Again, any thoughts or reactions to that comment from the work group? Agreements, disagreements?

Chris Cook: Well, this is Chris. When I look at this and knowing how much health plans are already doing this especially the advanced nature of most of our IDNs. I didn't (inaudible) necessarily heard of nature pushback from administrative claims data sets from either of those two groups. And I want just sort of − it caught me off-guard. I was hoping to hear potentially more if others had experienced that, but I've not necessarily seen that in my workings with our customers who are payer and IDNs.

Jesse Pines: Maybe we could have the developer − if you have any response as well or thoughts on the comment.

Erin Giovannetti: You know, we were a little confused by the comment as well. We think that because this measure is reported by 100 percent of all Medicare advantage plans as well as a very large portion of commercial health plans that we don't think that this is difficult in terms of feasibility , it seems very feasible. And even the high performance we see, we think that these systems are coming up with sophisticated tracking capabilities to understand who's on these medications and who needs to have what test.

With regard to adherence, we agreed that patient adherence is not at all addressed through this measure. It's not an adherence measure but, you know, obviously, any encounter or (touch) to the patient even if that is a test, even though if that is just a monitoring test, this is a medication to address adherence to a medication. But this measure doesn't specifically intend to address that.

Jesse Pines: Right, thanks Erin.

Tracy Wang: And this is Tracy. (Inaudible) of pushback from our health (line) regarding to – in regards to this measure, but I'm happy to double check.

Jesse Pines: Thanks Tracy.

All right, if there are no other comments or questions on that measure or the comments that came in (inaudible), we can go ahead and move to the next one. Hearing none, next, we're going to be talking about measure 0555 CMS − I'm sorry, FMQAI measure. It is related to INR Monitoring for Individuals on Warfarin. We have both Josh Rising and Tracy Wang (find us) lead discussions for this. I don't know if you guys want to (inaudible) give a brief intro or (inaudible).

Tracy Wang: I can start, and then Josh, please chime in.

Josh Rising: I will. Thanks, Tracy.

Tracy Wang: So, with the measure 0555. It's the International − the INR testing Monitoring for Individuals on Warfarin. And the measure (started) CMS. The description of the measure, we're looking at those population of people, 18 years and above who have had at least 56 days of warfarin therapy and they have received international normalized ratio test during each of those intervals, 56-day interval with warfarin.

And in terms of 1A evidence, they provided an algorithm in terms of the link of this process measure to (inaudible). So the thought is that the regular monitoring in patients who are on warfarin with INR testing provide a more time within the therapeutic range of Warfarin and (inaudible) bleeding and thromboembolic events and then should at least to lower hospitalization rates and lower mortality rate.

Now, in terms of the recommendation from the body of evidence, it's − they received the 2B which is recommendation with moderate quality evidence. And so the question for the committee would be, you know, given that there are two main studies for (inaudible) a demonstrated relationship between and on monitoring (inaudible) outcomes is that sufficient to demonstrate that the monitoring is appropriate. And do we pause for questions or want to wait until the end?

Jesse Pines: Yes. Why don't you just go through your comments first and then we can open it up for discussion.

Tracy Wang: And then in terms of gap, the mean performance across the plan is about 75 percent with a minimum of about 59 percent to a maximum of 88 percent. And so the question, again, for the committee is, is there a gap within the care? And I had made a yes. And in terms of disparity, the data that's − since you demonstrate that across the group, there is differences. So there is disparity. In terms of priority, it is a high priority – higher INR is associated with high risk (inaudible) and lower INR is associated with a high risk of thromboembolic events and they're also related to the national priorities area strategy.

And in terms of reliability (QA), the − (inaudible) OK. So in terms of reliability the, sorry (inaudible), there seem to be a high risk − there is reliability and − and then the question for the committee is, you know, whether that the (data on this) is clearly defined. And then validity, they provided a face validity where there is somewhat a high agreement. And then the question for committee is whether the agreement is sufficient enough, 26 percent and 53 percent − only agree and then 53 percent owes the committee, the technical district panel agreed.

And that in terms of − sorry looking through.

And in terms of feasibility, this is a measure that is pulled from claims data with pharmacy data, so it is feasible, you know, high feasibility, and then in terms of usability, this is a measure that is currently calculated or a part of the – this is a measure that has been submitted for CMS Shared Savings (gains). And so it is (inaudible). And I think that concludes the different sections. Josh, do you have anything else to add?

Josh Rising: I think that was a great summary. Yes, I think, you know, the things that brought (attention) (inaudible) I think for discussion and it is whether, you know, it's really the evidence, and you started that kind of at the beginning, Tracy, about with, you know, kind of two studies, you know, showing some of the not overwhelming association between INR monitoring and the patient

outcomes. You know, how comfortable do we feel with that, you know, low quality of evidence we have towards ultimate benefit going forward.

Jesse Pines: Great. Other comments from the work group on this measure?

Iona Thraen: This is Iona and I want to ask you a question follow up to that last statement. So you raised the question of whether or not INR (inaudible) monitoring has any real impact from patient outcomes. Can I ask a reverse question which is, does the lack of INR monitoring have any increase in patient safety events? Bleed out − any other kind of patient safety events that might occur. Is there no any date on that?

Jesse Pines: Maybe we can get our measure developers to comment, whether − and go through these evidence summary here. I didn't specifically see that.

Kyle Campbell: Yes, absolutely. This is Kyle Campbell from FMQAI. So one of the main studies that we cited is a study by (inaudible) and all that was recently published in 2013. And this is a retrospective match cohort study. And in this particular study, patients that weren't adherent to INR monitoring had a statistically significant increase in thromboembolic events. They did not demonstrate a statistically significant increase in bleeding, but they did demonstrate a statistically significant increase in thromboembolism events. In addition, we know that from the study published by (Adam Rose) from the VA which is also cited in our forum in 2013 that INR testing intervals are tightly associated with time in the therapeutic range.

And there are a number of studies that demonstrate time in the therapeutic range that's associated with outcome. And for this particular study which have retrospective cohort studies about 56,000 patients in the VA system, the risk adjusted TTRs were above or below the expected value based on their model given the number of gaps they had in INR monitoring. And that was statistically significant at the (P) less than 0.001. So while there are limited data concerning, you know, study designs that actually looked at INR monitoring intervals, there are still data concerning increased bleeding or thromboembolic events on patients who are outside of the therapeutic range.

Iona Thraen: And then in follow up to that, the 56-day point − time point …

Kyle Campbell: Right.

Iona Thraen: Where did that come from?

Kyle Campbell: So that came from a review, from our technical expert panel. This measure when it was originally endorsed, looked at a 40-day interval, I'm sorry − which was based on the original recommendation from the CHEST guidelines of a 30-day interval with a grace period. And so when we went back to review evidence with regards to what the appropriate interval should be, the most recent CHEST guidelines for patients that are, you know, stable with regard to their INR, meaning they had six INRs in a row that were stable, they recommended the potential to extend the interval to 12 weeks.

Our technical expert panel and work group that focus on anticoagulation felt like that this was a recommendation for minority of patients within our denominator, which is basically all patients in warfarin. And that they felt from a patient safety perspective while there was no, you know, exact right answer in terms of what the interval should be, they felt strongly that we should air on the side of safety. And the VA, based on the study by (Adam Rose), put into place the performance measure using the 56-day interval. And I believe it's the strongest study with regard to the relationship of INR monitoring gaps and time of therapeutic range.

So for the reason that harmonization with the VA measure, having the strongest evidence with this interval would be the most appropriate interval, and then because such a small proportion of the denominator population would qualify for an interval longer than 56-days, the committee or our technical expert panels felt this the most conservative approach to revision the measure. It all (just splits) the difference between the recommendation of CHEST and the recommendation from ACC regarding INR monitoring for patients with A-fib which remains a month interval.

Iona Thraen: Thank you.

Jesse Pines: OK, thanks. Other comments from the work group on this measure, or question?

Male: (Inaudible) we have a number, sort of comments on this one as well (inaudible).

Jesse Pines: This comment is from the same person actually, it's that the same person commented (inaudible) each of those (inaudible). It said, "We support this measure, however, would appreciate more details rationale and how does this 56-day timeframe to work (inaudible). So I think (inaudible) good about that.

Is there any other additional clarifications or questions from the committee for the work group on that?

Josh Rising: I do think that it would be beneficial to have a little more explanation on the 56-days. We don't need it now but, you know – but, you know, that could be added and that would be helpful, you know, outside of this because the VA does it, right? And, you know, likely it's going to be due to some of the, you know, I imagine the therapeutic of half life of the medication et cetera. But I do think that and I would just kind of help address to any questions about this going forward because 56 days is an odd number and I'm sure there will be more questions about it.

Jesse Pines: OK, thank you. To check with the developers, do you – are you clear on that request to get a little bit more of a clear rationale for the 56-days timeframe?

Kyle Campbell: Sure. We can put together an amount for the steering committee just providing in detail additional rationale for that.

Jesse Pines: Perfect, thank you so much.

All right, if there are no other comments on that measure, we can move to the next which is a similar measure, INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications. We'll have both Josh and Tracy on this one as well. Josh, do you want to go first this time?

Josh Rising: Sure. I'm happy to do that. So this measure is similar to the last one in the (inaudible) INR measurements. And what this measure does is the quality measure looks at how many times or the percentage times in which the INR is

measured three or seven days after starting one of the many anti-infective medications that's known to have interactions with warfarin. And there's a lengthy table kind of in the back that looks at those relationships between the anti-infective medications and warfarin.

In terms of then kind of going through − so the numerator and the denominator, you know, some (early) (inaudible), you know, number of episodes in which the test had been done over the number of times in which it could have been done. There are some exclusion criteria. For this one, unlike the other one, it's – those individuals have a diagnosis of cancer and there's a lengthy list of the ICV codes that are associated with cancer diagnosis. And then also individuals who are monitoring INR at home are also excluded from this particular measure.

So, going through it kind of the, you know, just a process measure and similar to the last one we went through, there is (inaudible) 2C evidence. It's kind of weak evidence with a low grade and in part, they (inaudible) the difficulty of doing the real study to really backup evidence kind of along these lines.

You know, I think certainly you can do randomized trials but, you know, I think doing certainly some cohorts or, you know, retrospective studies could be sufficient in that, but there's not great data showing that outcomes are affected by measuring the INR after prescribing one of these many anti-infectives. So, they kind of then lay out the data in terms of how much the gap in care is there. For the last one we saw, you know, pretty high measures in terms of how frequently. This was being done and I think for this measure, it − the rates are much lower for when the INR is being measured. So certainly, a pretty significant gap. So again, questions around how much of this gap ultimately drives outcomes.

For disparities, they did not find significant disparities. They did find that individuals who are younger are less likely to have the test than those who are older. Going to the priority section, again, you know, we know that one of the primary national patient safety goals is to reduce the likelihood of harm associated with anti-coagulant therapy. So we are kind of aware of this as a national priority. And I think one of the questions, again, as well with the

impact of the anti-inspective medications on INR levels, or on how much is that contributing to this particular problem. In terms of, you know, going through some of the scientific measures, you know, (inaudible) claims-based data. You know, I think like the other measures that have been discussed before, I think, you know, the same, you know, pros and cons apply but generally I'm feeling like there's a good reliability and validity kind of with this particular measure. And similarly, feasibility was high.

So I think that's kind of the quick overview that I would like to give on that and then, you know, let's hear kind of other questions or thoughts that the other committee have on this (patient) measure.

(Inaudible) too quickly through part of it but, you know, I felt like we've discussed on a bit before with the last measure on INR measurement.

Jesse Pines: Sure. Thanks so much Josh. So other comments from the work group?

Iona Thraen: Yes. This is Iona. I just tried to – I need some (open of) knowledge in this area related to the impact of the anti-infectives on warfarin-taking patients. What are the risks associated with that?

Jesse Pines: Maybe if we could …

Iona Thraen: (Inaudible).

Jesse Pines: … yes, ask the developers?

Kyle Campbell: Sure. So, this is Kyle Campbell from FMQAI. So actually, each individual drug that's been included in the measure has an officiated systematic review like drug facts and comparisons which is the compendia that we used to select the drugs that are included in there. And the anticoagulant effects the drug, the interacting drug can either increase the anticoagulant effect putting the patients at greater risk for a bleed or it could potentially decrease the anticoagulant of that putting patients at risk for a thromboembolic event.

We selected drug interaction facts severity ratings for those that were major or moderate and included those drugs within the measure. And as I mentioned in

our submission form for each individual drug by drug class, we list out, break out the studies either epidemiological studies or pharmacokinetic studies or (page) reports that have been done for each drug.

Iona Thraen: So, OK. So I'm going to say something that's probably not politically correct in this realm, but it seems to me that what you're describing is more of a measure (route), the electronic medical records systems, the decision support (inaudible) rather than measuring physicians' behavior associated with − I mean, so if there's differing risks at differing levels of severity associated with differing medications that are interacting with patients on warfarin, to me the pharmacological decision support question at the point of care as opposed to measuring someone from a performance perspective by the national level. That makes sense?

Kyle Campbell: Yes. So, this would be assessing, you know, the physicians order to have an INR test for these patients in the acute phase right after the interacting drug that's prescribed and only the specifications only do this for newly started anti-infective. So, let's say a physician prescribed the drug, adjust the warfarin dose appropriately. And the INR becomes stable and this is a chronically administered drug, then the case or episode wouldn't show up again.

The concern is that oftentimes, these anti-infective medications are prescribed by physicians other then the primary care physician who may or may not be aware of it. And if the patients aren't monitored appropriately, that leads oftentimes to the potential for the ED visits and hospitalization. And warfarin is the highest drug for patients 65 years of age and older associated with hospitalization.

And so this is a very important acute phase to be monitoring these patients and you can see that from the performance rate, patients are not monitored very frequently at all. So there's a really large gap and performance and we think that is an important place to start for patient safety to try and get these patients more appropriately monitored.

Male: OK. But the challenge − so this would apply to their patient's primary care provider.

Josh Rising: Correct. Who have you said may not be the one who has prescribed the new anti-infective medication.

Kyle Campbell: Well, what – we have specified the measure for state level plan level accountable care organization and large physician groups, so we think that, you know, in operational use of this measure, a plan or a solution group or an account of care organization would be, you know, would be appropriate to (inaudible) for a measure like this.

Iona Thraen: I am just going to say this seems like more of a decision support problem than a performance problem, and that's just how I (should get).

Male: Iona and Chris, can you talk a little bit more about how you see that – why you see this one differently compared to the last one?

Iona Thraen: Well, because I think that − and I could be wrong but a physician prescribing warfarin has taken that responsibility to prescribe warfarin as a responsibility with monitoring the care. I think that is a fairly common standard of care. A physician who has a patient on warfarin who then is somewhere along (inaudible) has been either themselves or somebody else prescribe with anti-infective and there's multiple options with varying impacts.

The idea of their monitoring (because) of patients on warfarin but then building in another monitoring request or requirement because of the use of a particular medication can be more easily solved upfront in the decision making process, the decision support process when they go to prescribe that medication with the warning that says this is going to either under or over coagulate or impact in that area and should you be prescribing that medication, and if so, then you need to monitor. So rather than a performance measure, it seems like it would be better handled at the decision support level.

Chris Cook: Iona, this is Chris. And I hear what you're saying off of that but what I can say as a pharmacist and a lot of times that review comes in, you absolutely look at that but you don't have a lot of options for a patient. And so it

becomes the triggering event and the reason I think this is – it's still a crucial measure to be done. It's no matter where in the system that this is taking place that you add that additional risk for the patient care. But you need to make sure that you're having that follow-up because you just introduced something new within these narrow therapeutic agents of being warfarin that has severe adverse effects, if it's under-dosed or overdosed that you need to make sure that you'll have that antibiotic being put on and you know that it could potentially do that but you don't know when that individual patient is there going to be a small reaction or a very large reaction. And so as a clinician, what you have to do is make sure you are monitoring to assess that risk.

And I think that actually comes in to the fact of whether or not you see it as being just getting the monitoring relates over to the outcome because it may be a small percentage of the population that actually when you get that outcome on that INR, if it's out of range then you make the dosage adjustment. So I guess I'm more concerned about the fact of did not having the evidence of the direct correlation but I don't know how as a clinician. I would not be in favor of when you introduce and you have potential reaction on drugs that you would not have the follow-up in the monitoring visit.

Iona Thraen: So if you're going to – if you're going to urgent care for some sort of infection-related issue and you're on warfarin from your primary doctor whom ever your specialty doc as well, and you get prescribed an antibiotic for that infection. The performance measure in the way that this is constructed seems to me goes back to the whoever is the primary doc. Or if it's, if the urgent care is going to give anabiotic for my infection, is the urgent care going to take the responsibility to follow-up in three to five days on my warfarin levels. It just doesn't seem like it's right target, the right focus. I get the earlier one in terms of monitoring for warfarin. I think that's appropriate but this one − this doesn't seem to be as – the target doesn't − it seems to be offline.

Josh Rising: I think the developers have said that the measure would apply to, you know, to plans, very large providers groups rather than kind of an individual primary care provider who I agree would have difficulty in, you know, sometimes even knowing that, you know, a new medication had been written. But certainly, you know, a health plan should know that it has been dispensed and

it should have some responsibility for, you know, contacting in the primary care provider to make sure that they are on the loop.

Iona Thraen: That's a lot of should.

(Crosstalk)

Chris Cook: It gets in to the continuity of care and the transition of care which is really …

Female: Yes.

Chris Cook: … you know, where a system fails a lot.

Josh Rising: Yes. (Inaudible) (get a lot of) compliance is 20 percent with this one at this point in time.

Iona Thraen: One more quick question, what's the scope of the problem again? How big – how many folks are we talking or percentage wise are we talking that are on warfarin and do encounter an antibiotic questions? And what percentage of that over to 65 populations or whatever it is? Does anybody know?

Jesse Pines: Are the developers still on the line? Do you have a quick answer?

Male: Yes. So, I was just looking at the denominators across our ACOs and we have 31 ACO's and the denominator population range from approximately 36 patients to 874 patients. As far as the state level of across all 10 states, we had approximately 111 – I'm sorry, 103,025 eligible patients across 10 states. And their compliance again for the states, was 20.7 percent. So it's extremely low numerator compliance.

Again, just to restate, we don't envision this occurring at the individual clinician level in terms of accountability. We feel that this is a shared accountability as was brought up by the steering committee members. We feel that it is a very important transition of care and at this point, you know, in terms of patient safety, we have a really large quality gap. But I mean, we're nowhere even close to the measure rates that we see with NQF 555.

Iona Thraen: Thank you.

Male: Sure.

Jesse Pines: And just so (inaudible) note a quick time check, we're running a little faster scheduled. So maybe we should just ask if there are any additional comments on this measure at this point. (At one) comment (inaudible) support of this measure, not really (inaudible) discuss there.

All right, well hearing no more comments, let's move on to the next. This is our first PQA measure. And hopefully, we got the right people on the call at this point. We're just hitting 3:00. This measure is number 0541, Proportion of Days Covered 3 Rates by Therapeutic Category, adherence measure. Chris Cook and Iona Thraen, we have both of you on this. When does − one of you guys want to lead off, you know, into this measure?

Iona Thraen: I'm good with Chris going if you want.

Chris Cook: Yes, I don't mind. I just …

Iona Thraen: We didn't really − we didn't talk about (inaudible).

Chris Cook: OK. So on this measure, Proportion of Days Covered 3 Rates by Therapeutic Category, and one thing to mention right off the bat here is within this being a (re-review) on this, but it has been moved from − there were five rates previously. Two of those rates have been removed, so it is left with the 3 rates. And that is around the renin-angiotensin system antagonist, the diabetes medications and the statins. And basically, what we're looking at is for the percentage of patients who are 18 years and older who have met the Proportion of Days Covered which is PDC, a standard way of measuring our compliance, having a threshold of 80 percent or more during the measurement in a year. And, the goal of this measure overall is to evaluate the supply of chronic medication that is available to a patient over time.

And going through our criteria within the 1A of the evidence piece of it, I found that the quantity of evidence is substantial. The primary literature reviews retrospective administrative claims analysis and the national patient organizations being American Heart and the ADA. I consider this fairly

strong evidence despite the fact that there are few randomized control clinical trials truly assessing within this area. There is a performance gap of part 1B that exist with considerable room for improvement. I think it's fairly well common knowledge of medication adherences not always the best within chronic medications. The priority is high. It is areas identified by the national priorities partnership by NQF and it does have a high impact aspect towards healthcare. It is not a composite measure. We've passed that part.

I felt that the specifications were fairly clear to perform the analysis and to identify the medications that were needed to include. There was fairly strong reliability testing with this measure, all of these are illustrative claims databases. And then I thought PQA did a nice job in its correlations of the PDC rates, and (in as far) I move it on to validity testing across the three different patient populations and found fairly consistent results there.

The process for specific multi-stakeholder review in separate organizational testing of the measure was also provided. I was not able to see more into that, it was basically just stated. And through the algorithm from a valid − a validity testing that was rated as moderate. The threats to validity were assessed and they appeared to be sufficient with evidence from Medicare Part D range and variability within response by different health plans. So I thought that that was well done.

And then feasibility. Again with this being electronic administrative claims databases, the data would be readily available and utilizes an accepted calculation method for the compliance, and then finally usability in use. I rated as high as this has been adopted in the public reporting CMS star ratings in IHI − IHA, excuse me, as well as a quality improvement with benchmarking.

Iona Thraen: This is Iona. I'm going to support everything the he has just said except for one (call back). Would you − could you go back to the performance gap section on this one. I had in my notes indicated that the overall performance was on average somewhere between 80 and 90 percent. And I just wanted to verify that I actually got that − that is appropriate to this one or I've mixed it

up because I think you said you saw a performance gap and I just wanted to verify.

Jesse Pines: Is PQA on the line? Lynda?

Lynda Smirz: OK, hold on. I think you're (inaudible).

Male: You wanted the performance scores?

Lynda Smirz: OK, so it looks like − I'm off. So OK. I see different rates unless they're looking at something else.

Female: (Inaudible).

Julie Kuhle: Yes, this PQA, this is Julie Kuhle of PQA. Just to so − having those to the variation and testing submissions. If so, the difference doesn't enter the (salary) range of PDC rates which has quite a variation. And then there's a standard deviation measure that also shows tons of variations.

Iona Thraen: Yes, I see it now. OK. I'm off, never mind, thank you.

Julie Kuhle: Sure.

Male: Well, and Iona, I think you up − it's interesting. Anytime you talk about medication adherence, it always seems that it is, again, one of those shared responsibilities that everybody has responsibility for nobody really takes. It's going to be the whole system to really to be able to move and change that.

Male: And just a comment from (staff) because there was not a formal staff review on this. So, Chris didn't directly mentioned but the evidence is not medication specific. This is sort of a, you know, general evidence on adherence.

Female: The other thing I wanted to point out was that the − they make comment about improvement that seems, I think, on average around three percent improvement between 2010 and 2012 (inaudible) the document – later on in the document. So I think that, provides evidence to support the idea of having this as a national performance measure in terms of actually impacting improvement. So, we're looking at maybe 1 percent of year improvement

over the course of time. So they only have to have another 10 to 20 years of this performance measure to get closer to their goal.

Jesse Pines: Any more comments or questions on that measure? We do have another comment on this (inaudible) be there of quickly and if you could pull it up for us. The comment is that this measure would be difficult to meet without an integrated outpatient pharmacy system capable of providing data back to the provider. Additional question to be answered are whether this measure is calculated based on pharmacy claims, and how is this managed in cases where patients do not (tell us) prescription that is provided? If the work group members have any reactions to that or if the developer (has a) response.

Julie Kuhle: This is Julie Kuhle again with PQA. And I did respond to these questions, the − and the measure is really − I'm sorry can you hear me?

Jesse Pines: Yes, go ahead. Sorry, Julie.

Julie Kuhle: So the measures really meant to be measured with description claims data at a health plan level although it could be − we put it out as it is done with IHA for members within a certain physician-based organization. But again it's help (inaudible). So I think that − I hope that clarification was made back to the commenter.

As far whether if a prescription is not filled, you know, they're absolutely right. That's a different problem than adherence called primary medications non-adherence. And we would not capture that person. So if they don't get the prescription filled, we're not able to capture the information to measure adherence.

Male: Well, and even with the PDC, you actually have to have two prescription claims for that target medication, so, they − the proportion that don't feel it, you know, after the doctor writes but then there's also a (whole another) that will all fill it once and never take it again take it again. And like, I think, what Julie said there is correct in that − that's a whole another issue that we'd (try) to figure out how to correct.

Julie Kuhle: Yes, exactly.

Jesse Pines: OK, thanks. Any other comments or questions about that comment or an − about the measure in general, any aspects the measure?

Hearing none, we can move on to the next business. (Inaudible) another PQA measure, anti psychotic use in children under five years old. Richard Brilli and Lynda Smirz, (inaudible) be discussing on this one when you want to start this off.

Lynda Smirz: So, this is Lynda and I'll be happy to get us started. I want to preference it by saying − as Chris did, that this is the first time I've done this, (inaudible) being a pharmacist did a phenomenal job on his (stuff). But this is a process measure that assesses the use of antipsychotics in children under the age of five based on a Medicaid multi-stake prescription data from claims from January 1st to 2007 to December 31st of 2007. And prescription claims from Mississippi's Medicaid program in the year 2012.

And it looks at variation by state via Medicaid data with respect to the process measure. The gap, I believe, was the children under the age of five treated with antipsychotics have an increased risk of diabetes, metabolic and cardiovascular disease, theoretically.

And addition adverse effects such as increased triglycerides, cholesterol, weight, heart rate and liver function abnormality are also noted in these individuals. But it's difficult to asses because you don't see it in the children in such a short period time as a theoretical risk. I consider that however a high priority I that over a 10-year period of prevalence of antipsychotic medications and the Medicaid PDF or population increased from 1.2 percent to 3.2 percent. And it was cited that between 1999, antipsychotic use has resin in children under the age of five from 7,759 to 19,045. I think that the (inaudible) specifications, the critical data elements used in this measure are age, prescription medication, (inaudible) plan enrollment. Literature has shown that prescription claims data are reliable and valid measures of medication use. And the reliability of age information was assessed and was found to be less than 1.8 percent of beneficiaries, the date of birth was not available.

Monthly enrollment data was available on reliable since this data is what's use for the Medicaid coverage in the state. Face validity was tested through the review by the PQA quality metric expert panel and the four PQA membership was advised − was also look at this. The health plans had piloted the measure. QMEP, the metrics panel voted unanimously that the measure be considered for endorsement. The only missing data analysis that could be tested for was age and as I mentioned previously, 1.8 percent of the individuals did not have a date of birth listed. And it was felt that this was not significant with respect to the validity of the study. All data elements were available in electronic health records or other electronic sources that (inaudible) the claims from the pharmacy. There were no negative consequences incurred by individuals or populations during testing. Performance results were publicly reported and it provides a quality improvement via benchmarking.

So, my evaluation of the measure was that there is significant worry that the percentage of children under the age of five are being dispensed antipsychotic medications with increasing frequency, that there's a discrepancy between those children who are in foster care versus those that are not in foster care, receiving antipsychotic medications more frequently.

In addition, non-Caucasians, also received the antipsychotic medications more frequently. I did not appreciate the DRG analysis as to why, I don't – I'm unsure if they're being use as a chemical restraint. I noticed that Iona had also reviewed this and had some information. So, you know, I would ask her as well to give her impression and (inaudible) also.

Richard Brilli: Yes, this is Rich. I'm glad Lynda went first, very thorough review and I support everything you just said. I would just add a couple of clinical perspectives on this. This is a gigantically important measure that is really harming a lot of kids. There really is no indication for the use of these medications under age five, and there are only a couple of approved medicines which are rarely used, Chlorpromazine and Haloperidol. The rest of them really aren't indicated in having – and haven't been approved for the use in children. I think that you mentioned chemical restrain or something − who knows exactly why they're being used but almost all the time that they're being used, one could say it's inappropriate.

So, I think shinning a light on this, I'm looking at how often it's being used has significant potential to reduce harm and children. In fact one of the data points that I saw that if we could just to improve or reduce the rate of this to the 75th percentile in one of the studies, there may be as many as 7,500 kids who don't have harm.

The only other slight thing I would take just clarify it. I don't know that − I think that there is real harm associated with these. We see these kids admitted to the intensive care unit, actually on the regular basis with overdoses and those kinds of things. So just having it around when it shouldn't be there in the first place (inaudible) significant harm or potential harm. So I'm very supportive of this and I hope we are able the keep this instituted and reduced (inaudible) across the country. It's alarming that it's going up instead of going done.

Iona Thraen: So this is Iona. I'll just make a couple of comments. So, I actually had been involved in a Utah-specific effort with our foster care program. The Department of Health has a healthy you kind of approach with − in contract to this foster care program here in the state. So, there's a couple pieces of information that may or not be helpful. One is that as soon as these children are taken under these traumatic abusive situations and put into foster care, Medicaid becomes the payer.

And then secondly, and in Utah, there's a much more thorough medical analysis that's done on these kids in the foster care system and follow up and monitoring that takes place as a result of being in foster care. (Some of) that was motivated by a lawsuit gazillion years ago. So, I will admit to the fact that it's come about as a result of external pressure.

But as we were looking at this issue for ourselves to look at the kids that were on antipsychotics and age groups et cetera, we did do sort of a database (inaudible) to this, a performance measure kind of approach. And as we started to look at the kids that fell into the bucket, we quickly realized that that was out additional clinical review that the data have really limited meaning. So that even though the numbers are showing that they're going, first of all,

kids who are in dramatic situations do have a higher percentage of difficulties. So that's given, given their experience but without pharmaceutical and child psychiatry specifically those two clinical pieces of critical input to look the use of the drugs, we found that it wasn't really that helpful. Now, used a flagging process to begin to identify the cases in your particular state for example, and I don't – I just don't know in terms of health plans whether that's useful at health plan level because it's − because of the fact that as soon as you're taken out of the home, in our state, Medicaid picks up because up.

I don't know if that true across other states or not. So I just raised those kinds of questions for practical perspective, whether or not you're really going to get kind of the information you're trying to get. I don't disagree that it's an important issue but I'm just not sure if a national measure aimed at health plans when health plans don't have − are not covering by virtue of the fact that they're in this foster care system. (Inaudible) the kinds of thoughts that I was

Jesse Pines: Thanks Iona. Thank you.

Richard Brilli: And certainly, this is Rich. I'd certainly haven't studied it like Iona. So I really I really appreciate that perspective. We certainly are looking (about in our) accountable care organization here in Columbus. We have 300,000 covered. And we do use it as a marker. I don't that you can drive this to zero but I think that it's significant over use and I think to not have it as a measure, would be mistake. Maybe we need to use it as a marker instead of as just the only number that's tracked.

Female: Does the data – the sponsor have any thoughts about the fact the, you know, the kids are − when they get into a foster care environment, they're being picked up by Medicaid and no longer covered by the private insurers or any ideas about that kind to the issue.

Woody Eisenberg: This is Woody Eisenberg with PQA. I know that this is a focus of intention for many state Medicaid plans and I know also that the office of the inspector general has identified this as a focus of their investigations. One of the – the American Psychiatric Association has identified this as a problem and have recently come out with a statement. Basically saying that this drug should

pretty much never be used in kids under the age of five. So, that it also the topic of an ongoing mark, study which the results of which have not been publish yet. So, I can't answer your questions specifically other than to say that it is a great focus of retention for state federal and other organizations?

Female: Well, I absolutely agree with that. The foster care program brought this QR attention to with Department of Health for all those reasons that you just cited, as well those Medicaid reasons because as I just said, there kids are covered by Medicaid. So it is definitely a timely area. Again, I'm just wondering if this is the right approach, I mean, I don't know, I'm just raising it as a question.

Chris Cook: This is Chris. Just kind of a quick question around − just the operation is very much what Iona is talking about. And I know that some states manage their own Medicaid themselves at which point, I know that it's just a request from CMS at this point, you know, you have the adult quality measure set. Would this be appropriate for childhood measure set going state by state so that for those states who operate their own Medicaid versus many others all have it as a, you know, third party administration which would be our traditional and commercial health plans operating Medicaid within those states where that's an option.

I guess I'm looking at the viability of this measure being applicable sort of in either type of, you know, measure set and would it capture where we have overuse of these medications or inappropriate use of these medications.

Woody Eisenberg: Chris, this is Woody again from PQA. Given that it's dependent only on claims, we think it would be suitable for both carve in and carve out pharmacy programs in any state.

Richard Brilli: I guess the other piece just to reiterate − this is Rich again − is that there are virtually no indications for this in this age group. And so while, you know, we may not capture all of the kids, it just really any use of it is not indicated. So I think that we're missing the point here.

Iona Thraen: Well, this again – OK, so I'm using a very specific experience here which is with in consultation with our child psychiatrist and a child pharmacist reviewing these individual cases, they did find a reason for use – for appropriate use. So, you know, I just – again, it came down to clinical judgment call and variation of the treatment amongst clinicians. And so, you know, if you're saying that there's a standard out there that says actually no, you know, that the standard has been promoted or community which is − medical standard has been promoted that these particular drugs are not appropriate. I mean I found that there was variation in opinion.

And so that was – that's part of the piece that I'm struggling with that when it comes down to clinical judgment and you've got your specialist of the table saying, "Yes, that makes sense for this particular reason," or, "You've got these kids coming out of state hospitals that have been there for several months and they're using these multiple antipsychotic medications to address their issues," it just seems like it's too clinically sensitive to − on an individual basis to be able to make sort of a blanket statement that it is or is not appropriate.

Woody Eisenberg: This is Woody again from the PQA. Might I comment on that?

Iona Thraen: Sure.

Woody Eisenberg: It's not our goal to drive the use to zero. We recognize for this measure – as for all of our measures that there are appropriate uses of these drugs. But in the phase of an increase in volume that's been between three and five times over the last − about 10 years, and given the fact that there are very limited appropriate uses of these drugs for kids at this age, we think that this is an appropriate measure to stimulate everyone to think twice at least before prescribing these drugs.

Iona Thraen: And that's kind of the point that we came to is in our own internal efforts is to use it as flag.

Woody Eisenberg: Yes, you know.

Iona Thraen: (Inaudible) attention to ask for a full review with the trial specific, pediatric specific clinical expertise.

Jesse Pines: Thanks everyone. Any more comments or questions or thoughts on that measure?

Male: I will – just more digging about the medical indications for this stuff, I talked to our child psychiatrist here at Nationwide in Columbus and get a little bit more clinical perspective. If not, zero is pretty limited. So let me get some more understanding with all due respect to Iona. There may be other approaches.

Iona Thraen: I think that's great. I'd support that. And then you're not sending me in anyway. I'm just − this is one state specific experience, it's very anecdotal.

Male: Developing measures is an iterative process, that's what we are with …

Iona Thraen: OK.

Jesse Pines: All right. So that concludes our set of measures we are looking at today. We didn't get any public comments on that measure specifically but at this point we − unless there are any other comments from the committee members they wanted to make. We could open the line up for other comments.

Operator? All right go ahead.

Operator: At this time, if you have a question or a comment, please press star then the number one on your telephone keypad.

And there are no questions or comments at this time.

Jesse Pines: OK. Thank you.

Do we have any – are there any sort of, I know, Suzanne is going to go through the next steps and just tell you about a few things that are upcoming that you want to keep in mind. I don't know if Suzanne if you had any other sort of logistical things to discuss or sort of issues to bring up?

Suzanne Theberge: No, just the next steps. I can go into that and then if anybody have any questions, we definitely have time for that.

So the next steps for the committee members is to review the remaining measures in the project, the other 10 measures that you haven't look at yet for this work group, and just review those and be prepared to talk about them at the in-person meeting in April.

There's another work group call on next Tuesday afternoon, also at 2 p.m. Eastern. If you're interested in listening in to that, you're welcome to join us. And we will be discussing the remaining kind of general types of patient safety measures. We've got a couple of composite measures and radiation case measures and things, a couple other things in there.

But the committee's next meeting will be the in-person meeting in April. You should have received an e-mail this week from our meeting's team with your travel and lodging information. So if you did not get that e-mail, please let me know to make sure that it comes out to you and that just contains information on how to book your flight and your hotel room.

So we will be in touch with you by the end of March with an agenda for the meeting in April, and much more information to come. We'll be posting the transcript and recording for this call and the other work group calls next week when they're available. And that, you know, feel free to touch base with us if you have questions.

Does anyone have any questions right now?

Male: Who was that that was just talking?

Suzanne Theberge: This is Suzanne from NQF.

Male: OK. Thank you.

Suzanne Theberge: Well, if there's no question and, of course, you can e-mail us at anytime if something comes up later. Jesse and Andrew, do you have anything to add or should we give folks half an hour back.

Male: Yes. Let's give them time to back. I did want to – I just − it occurred to me that we could maybe introduce Katie on this call. Katie is on. I don't know if you're on the line Katie or you're just on the webinar but for our work group members and I guess for the developers as well, Suzanne is actually expecting any and is going to be going out on maternity leave shortly and we're going to have Katie Streeter step in as the project manager to hold this over while Suzanne is out.

Katie, are you on the line?

Operator: Katie is not on.

Suzanne Theberge: I think, yes, she e-mailed me that she was just listening to the audio stream.

(Crosstalk)

Suzanne Theberge: (Inaudible) to today's call but she's not on the phone with us. But yes, Katie will be taking over in early April. We'll send her out an e-mail about that but that is upcoming.

Male: Great.

Male: Great. All right, well then, yes. That's about it from our end so I think we can give everybody their time back.

Thanks to everybody for joining us. We appreciate you taking the time (inaudible) let us know if you have any questions or follow-up comments or anything like that and we will talk to you again soon.

Male: Great. Thank you.

Female: Thank you.

Female: Have a good one.

Female: Thanks, everyone.

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

END