

## **NATIONAL QUALITY FORUM**

**Moderator: Andrew Lyzenga  
December 2, 2011  
1:00 pm CT**

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

Speakers all lines are now open. Please go ahead.

Andrew Lyzenga: Hi everybody. Welcome to the Patient Safety Complications Workgroup A conference call. This is Andrew Lyzenga. I'm the Project Manager for this project. We've also got a few other people from NQF on the line with us; Heidi Bossley, Jessica Weber and (Akim Dumahine).

I'd like to thank you all for taking the time to call in for this. We know you're all extremely busy and we gave you pretty short notice on this. So we really appreciate that you could make it on.

The call today is scheduled for two hours but we've only got four measures to review. So I don't expect this will take up that full amount of time. And hopefully we can let you off a little early.

We got some good comments through the online evaluations and I think we've got a good discussion ahead of us. So to just give us - give you an idea of what we'd like to accomplish through this call. What we'd like to do is to just do some preliminary evaluation of the measures in front of us in a smaller group in advance of the in person meeting.

We're hoping this will help you think through the measures a little bit and hash out any questions you have so that you've got a little bit more of a comfort level with both the measures and the evaluation process itself. We think that'll help us work through the measure of use at the end person meeting a little more efficiently.

For the workgroup members, we've assigned each of you as a primary reviewer for one of the measures. And what we can do if you don't mind is to have the primary reviewer give a quick overview of the measure. Maybe just the basic gist of it and any issues or questions that occurred to you as you read it over.

We can take a look at your preliminary online evaluations. If you're on the Webinar we'll display them on the screen. I understand that there's been a bit of a problem with the Webinar but we'll try to get that sorted out. And if we do get them up we can use those as sort of a jumping off point for discussion. Otherwise we can just have the primary reviewers sort of give their thoughts and then have everybody chime in as needed.

It might be useful as we do that to work through each of the evaluation criteria one by one. And at the end of each of those we can maybe get a sort of informal sense from all of you whether you think the criterion in question has been met and why or why not.

Before we get into that though maybe we could just go around and have each of the workgroup members introduce themselves. Start with (Christina).

(Christina Mahalik): Hi everybody. I'm (Chris Mahalik) and I'm a Medication Safety Specialist and Pharmacist by background at the Institute for Safe Medication Practices.

Andrew Lyzenga: Thanks. ((inaudible)) Gina.

Gina Pugliese: Yes. Gina Pugliese. I am a nurse by training. I am Vice President of the Safety Institute at the Premier Healthcare Alliance and Associative Faculty at Rush University College of Nursing and University of Illinois School of Public Health.

Andrew Lyzenga: Great. Thanks. Patricia, you want to go ahead.

Patricia Quigley: Sure. Thank you. I'm Pat Quigley and I'm a Nurse Practitioner and Clinical Nurse Specialist, Associate Director of Patient Safety Programs at the Tampa VA in Florida. And I'm also Associate Chief for Nursing Research. And my work is fall prevention and reducing fall related injuries in frail, elderly and people with disability. Thank you.

Andrew Lyzenga: Thank you. And Tracy, give a...

Tracy Wang: Hi. I'm Tracy Wang. I'm Clinical Research Manager for WellPoint in the Public Health Policy area. I'm also serving as the Enterprise Patient Safety Lead to build partnerships and strategies that accelerate improvements in both quality and safety. Intimately involved in a couple of safety projects in different states and so very looking forward to working with you all.

Andrew Lyzenga: All right. Thank you very much. So let's maybe just we can take these measures in order. We can start with Measure 0021, therapeutic monitoring and annual monitoring for patients on persistent medications. And I think we have Gina Pugliese as the primary reviewer for that. Do you want to just give a quick overview of the measure and your thoughts on it?

Gina Pugliese: Yes. And is the measure developer on the call as well?

Andrew Lyzenga: Yes. We should have the measure developers on the line. We - I'm not sure if they're on our open line. But if you have any - if they're not, if you have any questions just let us know and we can ask the operator to open their lines up.

Gina Pugliese: Okay. So I can give a quick overview but the questions that I have are each of the sections that we're asked to evaluation. Do you want me to just save those all to the end?

Andrew Lyzenga: If, you know, you can sort of summarize a little bit, we can - I think...

Heidi Bossley: Andrew, maybe it makes sense to have her give an overall conversation of the measure and then why don't we just get into importance in it.

Andrew Lyzenga: Right.

Heidi Bossley: I think (Dawn) is on. That's...

Gina Pugliese: Okay.

Heidi Bossley: ...faster. I don't - we'll see.

Andrew Lyzenga: Yes.

Gina Pugliese: Okay. Well just looks like everybody reviewed the measure and scored it so I think everybody should know what the measure is. It's the percent of members over age 18 who've received at least 180 days of a medication therapy in the ambulatory care setting for four agents and have one therapeutic monitoring event for each of the agents in the measurement year.

And the measure describes those drugs as an aid on ARB, the Jackson Diuretics or and anti-anticonvulsant. And so the measure is - the sum of the four numerators divided by the sum of our four denominators. So that's the measure.

I did have a question on the measure and, you know, in various sections of the discussion and the supporting materials there was information on monitoring for statins and monitoring for tricyclic antidepressants and just wondered if that was something that was supposed to be included in the measure.

And I believe that it was a little bit different than what was on the NQF Web site in terms of what the measure specified. So just wondered about that. So that...

Andrew Lyzenga: Okay. ((inaudible)).

Gina Pugliese: ...was one of the questions I had about the measure.

Andrew Lyzenga: Well maybe - I think we have (Dawn Alyon) on the line. (Dawn), are you on the open line? Sounds like she's not. Operator, could we open (Dawn Alyon)'s line?

Operator: Actually I don't see (Dawn) on the line. (Dawn) if you're sitting on the line with someone, please press star then 1 on your Touch-tone phone.

Andrew Lyzenga: Think they're on the Webinar but.

Operator: And Jeremy Gottlich line is open.

Female: Yes.

(Dawn Alyon): Hello.

Andrew Lyzenga: Hello.

(Dawn Alyon): Hi. This is (Dawn Alyon) and Jeremy Gottlich from NCQA. We're the measure developers.

Andrew Lyzenga: Great. Thanks for joining us.

(Dawn Alyon): And...

Andrew Lyzenga: Did you hear the question that was just raised a moment ago?

Jeremy Gottlich: Yes we did. It was about statins and tricyclic antidepressants.

Andrew Lyzenga: Yes.

Gina Pugliese: Yes.

Andrew Lyzenga: (Probably) those were lifted in a sort of later on part of the measure but they're not included in a numerator statement. So we're just wondering if those measures are - or those medications are included in the measure.

Jeremy Gottlich: I'm not too sure. I think we need to go back to the measure work up and we can have that information after the meeting.

Andrew Lyzenga: Okay.

Gina Pugliese: Okay.

Andrew Lyzenga: Gina, do you want to just repeat which ones you're concerned so they can have a - know specifically what they need to go back and look for?

Gina Pugliese: Yes. Well in the worksheet the measure description includes its ACE inhibitors, ARB, the Jackson Diuretics and anti-convulse and - but in some of the supporting materials it talks about monitoring for statins and ((inaudible)) antidepressants. I just wondered if that was intended to be in the measure or not.

I think statins if I can recall was in the measure originally. And there was a suggestion the measure liver enzymes on the NQF Web site. So if this is a maintenance measure, just wondered what it was supposed to include or whether those are being dropped and if so, why. So that's my question. So that would have made it five drugs.

Andrew Lyzenga: So the NCQA folks if you're not sure about it right now, maybe you could take a look at come back with a answer for us at the in person meeting on that.

Gina Pugliese: So because the statins were not listed in the statement of the measure, I have to assume then that all the rest of the information applies to the - only to the four drugs that were listed in the measure - the description of the measure. So then ((inaudible)) on the denominator. Is that right that I proceed on that assumption?

Andrew Lyzenga: I think that's fair for now.

Gina Pugliese: Okay. So...

Patricia Quigley: Excuse me Gina and Andrew. This is Pat Quigley's voice.

Andrew Lyzenga: Yes.

Patricia Quigley: Hi. I apologize for interrupting but I just wanted to mention that I see on the worksheet that was sent out to us - the Excel sheet that my answers aren't in there.

Andrew Lyzenga: Oh, are they not in there?

Patricia Quigley: No. I don't see them for - and I was looking for the 0021. And, you know, when I first started working on our SurveyMonkey Web site, I did contact (Jessica) because once I entered it in there and then continued to try and work, it wouldn't let me back in. So I don't know if my comments and my scoring of this one was not saved. I see them for the other three ones.

Gina Pugliese: They're on there. I see them.

(Crosstalk)

Gina Pugliese: Yes. You said impact insufficient as a brief description of the measure has too large a population.

Patricia Quigley: Okay. Maybe I just can't see them.

Gina Pugliese: Fifteen years or older. Yes. I'm having trouble with the Excel file. I don't know why it's freezing but I can't see my scores on the Excel file.

Patricia Quigley: Okay. Well thank you. I was afraid that my comments weren't saved because I knew I had trouble with that monkey and so (Jessica) did a change so I could keep adding.



Gina Pugliese: You know what. If you put your cursor over the square where the comments are supposed to be, which would be the rational Column E, sometimes they come up in that bar across the top. That's the only way I could see them.

Patricia Quigley: Okay.

Gina Pugliese: I don't know why. I don't know what the setting in the Excel is that it keeps me from seeing certain squares.

Patricia Quigley: Yes. Okay. I apologize for interrupting you.

Gina Pugliese: No, no. That's all right.

Andrew Lyzenga: Yes. We'll try to get that fixed for the next call.

Gina Pugliese: And, you know, ((inaudible)), you know are consistent with yours Pat. I just - they don't always appear in the same section. But in terms of the measure, a couple of comments. There's a new - most of the references in here refer to a (Van) Budnitz article from 2006. But there's a really nice update of that of similar research that was published in November 24, 2011 in the New England Journal of Medicine.

And, you know, just in terms of importance, I gave it a moderate in terms of impact because in this recent study that we've done, it showed that although these drugs are included in the top 13 of those most implicated in emergency hospitalizations, the rates for these are extremely low in compared to some of the other drugs that are being monitored.

The top three is more for insulin than oral antiplatelet agents at 33%, 13%, 13% of those hospitalizations. But the ones that we're looking at in this particular measure are fairly low at 3%

for (ditch), 2.9% for ACE inhibitors and then those bottom two are ((inaudible)) diuretics at about 1%.

So just in terms of the big picture of importance and I think that because these are drugs that do have complications and admissions associated with them, you know, they are important.

I just wonder compared to other - monitoring of other things and, you know, and when we look at the harmonization across other measures whether these are ones we want to continue to look at just because they're kind of low whether we want to focus more on the other therapy. That's why I gave it a moderate for impact.

Patricia Quigley: Well Gina, this is Pat's voice again. And, you know, I had a question just in the beginning because I didn't know who members were. You know, the denominator had defined as members and I didn't know what the definitions of members was Andrew. You know, that was like ensuring agencies or healthcare facilities. I didn't know what that population base was.

Do you - does anyone know what members means? It says members on persistent medications. It that insured people?

Andrew Lyzenga: Again, if we got the NCQA folks on the line, maybe they could give us an answer to that.

Gina Pugliese: You know, in the Web site - the NQF Web site they don't call them members. They call them patients. So...

Patricia Quigley: Yes. That's why I had - I had not idea what members was if it...

Gina Pugliese: Yes. I'm thinking - yes, there were some differences in the way that described the measure and whether or not that was significant and what was going to appear in the final measure. I know there was a comment later on about that they edited it to be consistent with NQF ((inaudible)) measure - actually looking for it.

Patricia Quigley: Yes.

Gina Pugliese: I wondered if maybe there was some editing done to it.

Patricia Quigley: So I needed some clarification on that. But in addition, my biggest concern with this submission is that the age group was so large, I mean this was a percent of members 18 years of age and older. But all the evidence essentially that supported for this was very similar to that for 022 for the elderly.

So, you know, I just thought so much of this was insufficient to be able to support what they were asking for because the evidence wasn't there just like the - explain the benefits of using this was not answered. So that was my biggest issue in marking sufficient is I thought that the evidence that was here was really so similar to 0022, it didn't really support everyone 18 years and older. That's such a huge population.

Gina Pugliese: Yes. I mean I had similar comments under ((inaudible)) evidence of quantity, quality and consistency of the evidence. I thought, you know, that the impact was still moderate. That these drugs do have an impact. Maybe not specifically on this population but kind of in general. So I kind of gave my moderate score for impact based on that.

But I agree and I pointed that out in a couple of the places Pat just what you mentioned that, you know, have they ever really look at the risks in this very young population? But, you know, and all

the data that's published really supports these issues in the elderly including this recent Budnitz article.

So that's - so those questions I guess have to be answered. Just the description of the denominator by the measure developer, member versus patient and what exactly is it going to include in terms of the four drugs or five.

And so under performance gap I think that if we assume that we're going to be looking at the measure in this 18 to 65, I think that in looking at the data that's been supplied on the performance gap, there is a performance gap for these four drugs in the population they describe. I mean this is an existing measure. It is being monitored and there is data to show that there is a gap. And we haven't closed that gap yet.

So I gave the performance gap a high because if you assume that these four measures and they've been monitoring for them, there still is a gap.

Andrew Lyzenga: All right. Great. Thanks.

Heidi Bossley: This is Heidi.

Andrew Lyzenga: Yes Heidi.

Heidi Bossley: ...give NCQA a change to answer some of the questions that they're able to now?

Andrew Lyzenga: Sure. Sure.

Heidi Bossley: Hey (Dawn) or (Jerry) are you able to answer the question about the denominator and then also the evidence piece?

Operator: Jeremy, your line is open.

Andrew Lyzenga: ((inaudible)).

Jeremy Gottlich: All right. Can you hear me?

Andrew Lyzenga: Yes.

Female: Yes.

Female: Yes.

Jeremy Gottlich: As far as the members go, these are members of health plans that report data -  
((inaudible)) NCQA. For this measure that includes members in commercial, Medicaid and  
Medicare health plans. And they asked us that the eligible population criteria identified in the  
measure.

Patricia Quigley: So those are patients?

Jeremy Gottlich: Yes. Those are patients. But they have to be a member of the health plan.

Patricia Quigley: Thank you. This is Pat Quigley. Thank you.

Jeremy Gottlich: Yes.

Gina Pugliese: Any comment on the past comment about 18 to 65 being included in this since all the data  
really supports the older population?

Jeremy Gottlich: In our most recent reevaluation of the measure we did take, you know, the measure as it is, 18 and older. Our geriatric expert panel, we didn't have any comments from the group about the age group but I can definitely go back and bring this up with some of our experts offline and see what they have to say.

Patricia Quigley: And sir, this is Pat Quigley's voice again. You know, my question is is all the evidence that is supported for the most part is for the population 65 and older. So that's why, you know, and it's so similar to that other one but the, you know, the population that you want included in this indicator is 18 and higher. So it, you know, where's the evidence to support those people who are 18 to 65?

And I know we have a pharmacist on our workgroup too so I know we'll get to hear from here. But that wasn't really the limitation being unable to have the supporting evidence that would support this for the entire adult population.

Jeremy Gottlich: Okay. I'll go back and look at our measure history, some of the minutes from the past meetings and see what I can have for you ready for the - when we meet in a couple weeks.

Gina Pugliese: You know, and just to add to that I mean what would be important to know is if you did include the 18, you know, is it because it's just easier to capture the whole population in your data collections?

I mean it doesn't add an additional burden to collect the data from that population because certainly even though the literature's focused on the over 65 and older, you know, if you're younger and you're on these medications, you're - and you don't get monitored, you're still at risk. It's just there's just not a lot of data about those risks and specifically what they are. So just an added comment.

Okay. The next section is the performance gap. I think I mentioned that. That, you know, there are some studies ((inaudible)). Now the next ((inaudible)) quantity, quality, consistency of the body of evidence. For the quantity I gave it a moderate. I think there's seven studies cited but I think as was pointed out also by another workgroup member that they're not all relevant to the drugs that are listed in the measure.

For example, one of them was actually focused on drug monitoring for a patient on a thyroid replacement ((inaudible)) 2006. And most of them are over 65 focused. Some of - and (Sloan) 2006 just looks at the patterns of use but really not adverse drug reactions or monitoring, so.

In terms of quality I have it a moderate as well. Most of the studies again look at the frequency of the prescriptions in the elderly and their contributions to ER visits but not to the ones specific in the measure at hand.

The other questions I had in terms of the quality ((inaudible)) I wondered if there were any studies that looked at the frequency or the ((inaudible)). The measure right now talks about a monitoring event at some time during the 180 days of therapy. Someone was on it for 180 days.

But there's nothing about baseline testing or how frequently that testing should be or what ((inaudible)) 180 days. Should it be in the first couple of weeks that they're placed on it or is there - is anytime okay? Like, you know, close to the end of the six-month period that they're on it.

Wondered if there was any data about that from the - because if there's a measure that's been out there if you've ever looked at that.

I mean that would really be kind of helpful because maybe some of these people need to have the measure looked at at a specific timing during the first six months that they're on it.

Andrew Lyzenga: Jeremy or (Dawn), do you have any comment about that on the timing of testing whether that be slide test or frequency of testing?

(Dawn Aylon): Can you hear us?

Andrew Lyzenga: Can you hear us operator?

(Dawn Aylon): Hello.

Heidi Bossley: Yes, we can hear you.

(Dawn Aylon): Okay. We can't answer that at this time but we can definitely get back to you before the Steering Committee meeting.

Andrew Lyzenga: Okay. Great. Thank you.

Gina Pugliese: And the same comments for the consistency. I also gave it a moderate because there really aren't any guidelines for monitoring frequency but the FDA - did point out that the FDA has labeling but it doesn't really recommend labeling for all - doesn't recommend monitoring for all these drugs. And if it does, it's not always specific.

For example, Ramipril, which is an ACE inhibitor, suggests monitoring renal function in the first few weeks and monitoring potassium often - frequently I think is the word they sued. So, you know, maybe there is some rationale for the timing of the monitoring maybe and not just generic statement of once in 180 days.



But I think that because there's - the study suggests that medications are used frequently and there are related hospitalizations and ER visits. There has been a sort of monitoring over the course of therapy, you know, as a conservative standard of care.

Reliability I gave it - I gave it a high. Again, I mentioned earlier that we need clarification of whether a statin or tricyclic antidepressants need to be included. But the reliability scores are pretty high. There are specific CPG codes to identify the numerator and the denominator and I think the (shield) testing was adequate.

There was a ((inaudible)) worksheet that said that the revisions were made to the measure specifications so that it meets desirable attributes of the heated measure.

And I wondered if that could be explained to us because I wonder if that is why there's differences in the measure as it's posted on the NQF Web site and discussed in this document versus what was listed as the actual measure description - the brief description at the very beginning of the worksheet. There just seems to be differences in that. So maybe that would explain it. I don't know.

Also just they mentioned that an expert panel was involved in this measure development and they just listed names. And it would really be helpful to have the credentials of the people that were listed. It just gave their name and their organization. Just to see if there were - there was a mix of, you know, of different clinical backgrounds, you know, including pharmacists on there.

I Googled a couple of the names and found, you know, some of them were MDs and PharmDs. But it would just be helpful to have that in a worksheet so we could tell when some of these decisions were made by an expert panel. So just a suggestion there.

Under validity, I gave validity a high. On the face validity again was done with a panel of experts and I Googled them and found out that they were fairly representative of practices that would be important to review face validity. I think the exclusions are appropriate. Anybody that's been admitted of course they could have had their testing done in the hospital.

And the other question I had is that, you know, maybe if the measures have - measures who are submitting them as ((inaudible)) measure the developers have looked at resource utilization or stratification by age, which I mentioned earlier, to see if maybe the target population could be smaller, that would really be helpful.

Usability and usability - I mean this measure's being used right now to ((inaudible)) and it's included in a variety of public reports, NCQA's Quality Compass, the NCQA State of Healthcare audio report. So out there it's being used. And it's feasible. It's readily available and generated during care although it's quoted by somebody else and it's abstract for review as a quality measure.

So just in summary based on the ratings and how those ratings apply to whether it's suitable for endorsement I think that some of these questions are answered. I think in general that it's suitable for endorsement but it would be before - did have some of those questions answered. So those are my comments.

Andrew Lyzenga: Thanks. Any of the other workgroup members have any comments? I know Pat I see you rated reliability and validity as having insufficient evidence it looks like because of the issue with the age groups.

Patricia Quigley: Yes. That's correct. You know, it was really because - and also I didn't know what the definition of members was. But I thought, you know, to be able to look at this in relationship to having any kind of impact and having something that would be meaningful for patient safety and

health outcomes that the population was just entirely too large with the literature review that they were submitting.

So I didn't feel I had enough information to be able to make a decision. And that's why I really said I feel like an insufficient in some of these areas and then indicated a no at this time.

Andrew Lyzenga: (Dawn) and Jeremy again, that's something to maybe keep in mind as we approach the in person meeting.

Gina Pugliese: And, you know, this is Gina. Just one last comment. Since this measure is currently a heated measure, I just wondered if there were any data about whether the ((inaudible)) done or not in comparing those groups had anything to do with patient outcomes or complications in this population.

That would be really interesting to see if the patients that were not monitored if there were any adverse outcomes to really sort of support this monitoring at some point during the 180 days. I don't know if that's - that data's available but I wonder if there were any future plans to collect any link on that compliance with the measure and help outcomes. That would be really nice.

Patricia Quigley: This is Pat Quigley again. And I was able to say I didn't know if (Chris) or Tracy were going to comment. But I could see (Chris)', of course I didn't see any comments and I didn't see anything from Tracy. So I didn't know - is Tracy on the call did I hear?

Tracy Wang: Yes.

Patricia Quigley: So I didn't know if we were going to get to hear any of your comments or (Chris).

Tracy Wang: So I think it's on the Webinar. You're not able to see it.

Patricia Quigley: I see - for (Chris) I see scores but I don't see comments. And I don't see any - I don't see Tracy's scores. Can you all see Tracy's scores?

Andrew Lyzenga: We can see your scores. I think not everybody filled in the comments for each of the - each of the fields. But if Tracy or (Chris) if you have any input...

Patricia Quigley: Oh so sorry. I wanted to say I see comments from an (Ed Septema).

Andrew Lyzenga: Yes. I think we put him in there because he had offered his voting on there but we can...

Patricia Quigley: Yes.

Andrew Lyzenga: ...disregard that for now.

Patricia Quigley: And again, I apologize. I just don't see Tracy's then. But thank you.

Andrew Lyzenga: You're welcome.

(Christina Mahalik): This is (Chris). And I don't think that this is unreasonable, this measure. I do agree with all the comments that Gina made. You know, looking at one drug level for somebody on anticonvulsants and this period of time, I don't find that unreasonable. I think a lot of this stuff really goes back to, you know, the - how these drugs should be monitored in patients.

You know, there's a lot of variability between monitoring a potassium and renal function for somebody on ACE and ARB and monitoring a (didge) level. I mean certainly patients - once a patient is toxic on (digoxin) or shows symptoms of that, they're likely going to be hospitalized.

I just didn't think that it was an unreasonable expectation. It's from a quality standpoint that we'd be looking at these things once. And I actually - I look at this as once a year as long as the patient received 180 days of treatment. If I'm incorrect in that assumption, if somebody could correct me, I'd appreciate that.

Andrew Lyzenga: (Dawn) or Jeremy, are you still on the line?

Jeremy Gottlich: Yes we're here. Can you hear us?

Andrew Lyzenga: Yes.

Female: Yes.

Jeremy Gottlich: Yes. So yes, that is - as far as I understand, that's correct. That is - can just be one event and as long as you have 180 days it would count towards the numerator compliance.

Andrew Lyzenga: Thanks. All right. So if nobody has any additional comments or thoughts on the reliability or...

Gina Pugliese: You know, I have one last thought just in answer to that question. So the measure's looking at 180 days and whether you've been monitored once in the 180 days. So to be in compliance with the measure, you're looking - I assuming - asking the measure developers here. If you look at that one block of time, the 180 days, and you get one monitoring done, you've complied with the measure.

So I'm assuming that if you were on the measure for 365 days roughly that you would have a second monitoring event because you really don't know which of the 180 days you're going to be

grabbing in terms of their being on it for a consistent period of time. I don't know. Maybe I didn't ask that right but.

So if you were on it for the entire year, you'd only be looking at 180 days period. But would you assume that they would do it twice if they were on it for a full year or just once?

Jeremy Gottlich: It will just be counted once for the measurement year. And this is just per each rate. So it'll be reported for each rate with a total.

Gina Pugliese: So you're only going to grab 180 day time period even if they were on it for a year.

Jeremy Gottlich: That's right.

Gina Pugliese: And would you be looking at whether they got the test any time in the full 12 months or only any time during that selected 180 days?

Jeremy Gottlich: We're looking in the measurement year and I think - looks like we can count medications dispensed in the year prior to a measurement year. Like they can be kind of towards 180 days.

Gina Pugliese: So all they have to do is be on it for 180 days at a minimum but you'll look through the whole measurement year for one monitoring event?

Jeremy Gottlich: That's correct.

Patricia Quigley: But that doesn't make sense though. Like what if you're off it on day 181? You're still going to look for potassium? That makes no sense.

Jeremy Gottlich: I can clarify the measurement period for the next meeting.

Gina Pugliese: Okay. Thank you.

Andrew Lyzenga: Thanks Jeremy.

Jeremy Gottlich: ((inaudible)).

Andrew Lyzenga: Any other thoughts or questions in that area? If not I think we can move on to usability and feasibility and Gina you can go ahead and give your thoughts on that.

Gina Pugliese: Are you talking - I'm sorry, you're asking me?

Andrew Lyzenga: Oh yes, sorry. I was just thinking we could move on to usability and feasibility and your...

Gina Pugliese: Oh I did. I gave them both high.

Andrew Lyzenga: Okay. Great.

Gina Pugliese: Yes. I finished them and because of heated measure already and it's already in public reporting, it's definitely usable and it's feasible because all the information is coded and generated. But again, this is all based on, you know, the clarity of that measure and what are the drugs that it includes.

I supposed that it's now that includes statins and tricyclic antidepressants then I'd have to go back and look at it again because it would be different than the data they submitted to support it. You know what I mean?

Andrew Lyzenga: Any other thoughts from the workgroup members or questions about usability or feasibility? All right. Well hearing none, we can - again, I don't know if I mentioned this but we're not doing any voting on this call.

This is again really just to do a sort of preliminary review and just talk through the measure a little bit, get any questions answered. So we won't do sort of full vote on whether we want to recommend this for endorsement. We'll do that at the in person meeting.

I think we got some good questions for the developers for them to go back and take a look at before the in person meeting. And I think we can probably move on to the next measure if nobody objections.

Female: No objection.

Female: Sure.

Andrew Lyzenga: All right. Well the next measure is 20 Measure 0022, drugs to be avoided in the elderly. Pat I think we had you as the primary reviewer on that. So if you want to just sort of give your initial thoughts about it. ((inaudible)).

Patricia Quigley: Sure Andrew. Thank you so much. Appreciate that. Sure. This measure was really indeed very focused on specific population, the use of high-risk medications in the elderly. I thought it was very clear in terms of the indicator that they were addressing, which was the percent of Medicaid - Medicare patients 65 and older who had received at least one of these really high risk medications that we know can result in harm and should be avoided.



So the rate was very clear. This was a process measure that they want to look at this population. Anyone who had had at least one prescription of these high risk meds in a year's period of time divided by the number of patients 65 and older that were receiving care in a year's period of time.

So they had the one measure for at least one of these high-risk medications and then the second measure for those people who would receive two of these very high-risk meds.

And these medications were based on the 2003 Beers criteria for medications that really should not be given to the elderly. So when you look at the Excel spreadsheet our reporting system, it looks like we had very good agreement. And Andrew I did figure out how to find my name on that first one. I...

Andrew Lyzenga: Okay.

Patricia Quigley: ...just had to adjust the size of the rows is what it was.

Andrew Lyzenga: Great. Great.

Patricia Quigley: So yes, they like overlap. I'm working on this Excel spreadsheet. But I was able to see the feedback from (Chris) and Gina. But I don't see Tracy. So Tracy if you want to share as we go along.

Tracy Wang: Sure.

Patricia Quigley: But there's - for high impact and the gap performance, we all rated high. I had made a suggestion on what to - you know, so I think the overall there's very good agreement on this one across all the three raters that I'm able to see because this is indeed medications that should not be prescribed for any of the elderly patients over the age of 65.

So again, for high impact and the performance gap we all rated high. And then for the held outcome there was one person, Gina, that had a no but I had a yes. And this wasn't marked by (Chris). So those are the first categories in relationship to - and there was high opportunity for unmarked high opportunity for improvement as well high impact high opportunity for improvement.

In terms of the evidence, the evidence was supportive. There was - it was very clear with the literature review. I thought it was very relevant and comprehensive. Mostly realizing that these were descriptive studies based on expert opinion and consensus panels, the bodies of evidence that were presented.

In the section of reliability and validity, let's see here. Oh, the quality of the evidence. For the most part we all had high and moderate for those in terms - the quality of the evidence - the quantity and the consistency.

We were looking to see if possibly the Beers criteria had been updated since 2003 but I don't think it has. I did try to look at that. That was the only comment that I had had.

(Crosstalk)

Patricia Quigley: Yes.

(Christina Mahalik): I don't know if everybody on the call is aware but the American Geriatrics Society is - has - is actively working with the Beers criteria to update it. They actually had a draft criteria out for commenting that was done this month. It just closed November 28.

So it is actually actively being worked on. And they're looking to break them down based on drugs that are independent of diagnosis and then drugs that are due to drug disease interactions. And they have an expert panel working on it. So it is in the works.

Patricia Quigley: Great. And who's voice is that?

(Christina Mahalik): It would be the American Geriatrics Society.

Patricia Quigley: Oh no, no. I'm so sorry. I mean who are you. I just didn't - I don't know your voice.

(Christina Mahalik): Sorry, it's (Chris). Sorry. ((inaudible)).

Patricia Quigley: Okay (Chris). Thank you. I'll get to know your voice but I just didn't know at this moment.

Oh that's very helpful. Very good. So when are they expecting to have that ready?

(Christina Mahalik): I don't know. They just pulled it. You can't get it anymore from the Web site. They just pulled it obviously because we're just a few days beyond the comment date. And they do have - the whole plan of how they're going to revise it. They have an expert committee. It'll be good. And I agree with everything you're saying so far on this measure.

Patricia Quigley: Oh very good. Thank you (Chris). And so Andrew we all have as well - for the whole group we all have high rating for usability and feasibility. So I think there's all...

Andrew Lyzenga: Yes.

Patricia Quigley: ...we have very much consensus on there. The only comment - the only question I had was for Tracy if you had any questions or comments or ratings because I just didn't see yours.

Tracy Wang: Yes. I submitted them a little bit late. The - it's pretty consistent with the group.

Andrew Lyzenga: Yes.

Patricia Quigley: Okay. Very good. But I think this one could go pretty quickly Andrew unless anyone - if anyone has any questions or other additional comments that you want to provide.

(Crosstalk)

Patricia Quigley: Okay. Go ahead.

(Christina Mahalik): I was just curious. Some of these medications are over the counter. And I just didn't know how we were going to be able to measure that.

Andrew Lyzenga: Jeremy or (Dawn), are you even still on the line?

Jeremy Gottlich: Jeremy. Our geriatric panel is aware that many of these drugs are OTC. And it is more difficult for plan - system ((inaudible)) OTC is. So we are aware of it. For now they wanted to maintain all drugs that are according to evidence are harmful in this population and keep them in the measure even if it's difficult to get data on it.

Andrew Lyzenga: Thanks.

Patricia Quigley: Yes. And this is Pat. Thank you for that question. I think that was (Chris)' voice. So I had reviewed this whole as well with a couple geriatricians that I work with. And they said, you know, even when you look at trying to get a hold of all the medications - to capture all the medications that patients come to us on is that these would be medications that we would tell them to stop or, you know, try and discontinue.

So that's why they were - when you're trying to capture that whole medication profile that patients are taking that there might be some way to be able to get access to this especially in our electronic medical record to answer (Chris)' question.

Female: Great.

Patricia Quigley: So is that okay Andrew? Is that enough?

Andrew Lyzenga: I think so. Yes. Looks like we've...

Patricia Quigley: All right.

Andrew Lyzenga: ...gotten a, you know, a high degree of consensus on this one.

Patricia Quigley: Yes sir.

Andrew Lyzenga: If anybody has any other thoughts or comments they'd like to add, you can feel free.

Otherwise we can move onto the next measure. All right.

The next measure is 0419. That is documentation of current medications in the medical record. This is a - this is a CMS measure. And I believe we've got a couple of the developers on the line as well. Operator, could you open the lines for - I'm taking a look to see who's on the line. I believe we have Kyle Campbell from FMQAI and Noni Bodkin from CMS.

Operator: And yes, their lines are open now.

Andrew Lyzenga: They're open. Okay. And if you're listening, if there's anybody else from CMS who'd like to add any input, operator is it star 1 that you press to...

Operator: For questions?

Andrew Lyzenga: Yes or for - if anybody wants their line open at this point from CMS, anybody on the developer side.

Operator: Yes. With the star 1, their lines are actually opened individually. But I do have Kyle and Noni's line open at this point...

Andrew Lyzenga: Okay.

Operator: ...for the duration. So if any additional callers need to comment, it is star 1.

Andrew Lyzenga: Okay. Great. Hi Kyle and Noni.

Noni Bodkin: Andrew.

Andrew Lyzenga: Yes.

Noni Bodkin: Hi. Hi, this is Noni. Andrew actually this measure is a CMS measure. But it is - it has another measure steward in FMQAI.

Andrew Lyzenga: I see. I see.

Noni Bodkin: So if you need that contact person, I can work through ((inaudible)) and get that information for you.

Heidi Bossley: This is Heidi.

Andrew Lyzenga: Okay.

Heidi Bossley: I think they may be on. It's Quality Insights. Correct?

Noni Bodkin: Yes. I think so Heidi.

Heidi Bossley: Is Sharon or Don on? Sharon and I have been swapping emails so I think she might be.

Operator, can you...

Andrew Lyzenga: Let's see.

Heidi Bossley: ...give anyone - Don Wilson or Sharon Hibay on?

Operator: Sharon's line is now open. Don is not on the line.

Heidi Bossley: Okay. Sharon, are you there?

Sharon Hibay: Yes. Hi Heidi. It's Sharon Hibay.

Heidi Bossley: Okay.

Sharon Hibay: Actually I'm with a nice contingent with Quality Insights including Dr. Don Wilson.

Heidi Bossley: Great. Okay. So we'll - as we go through this, all on you if we have any questions.

Sharon Hibay: Thank you.

Andrew Lyzenga: All right. So I think we - for 419 we had Tracy Wang as the primary reviewer. So Tracy if you want to just give any initial thoughts or...

Tracy Wang: Sure.

Andrew Lyzenga: ...you know, your - just the thoughts about the measure to get us started.

Tracy Wang: Absolutely. So this is a CMS metric. It's on the documentation and current medications and medical record. And that he's basically looking at the percentage of patients who are 18 years and older and who would have had a list of their current medications on file documented by their (position).

And the documentation would include the drug name, dosage, frequency and route. So the denominator again it's (release them both). Every - all of the patients who are 18 years or older on the date of the patient encounter and the numerator would be the medication list documented by the provider.

And then there is a opportunity to exclude certain patients ((inaudible)) as those who refuse to participate or those patients who are in urgent - in urgent situations and where, you know, the time is of essence and the delayed treatment would jeopardize their health or they're cognitively impaired and no authorized representative is available.

So and I don't - I hope all of you can see on the Webinar page. So for in terms of the impact I had given it high and performance gap a moderate. And I think it's somewhat consistent from the group except for Patricia noting that the - that was low because the, you know, included - the medications included all OTCs, vitamins, et cetera, and it might be difficult.



So one of the questions I have for the developer on - are in terms of the denominator and also the documentation, specific the documentation are the drugs - I mean what specifically need to be documented? If it's missing one of the items noted in - is that - does that get included in the numerator? And can a documentation include this other physicians with self-reported data?

Sharon Hibay: Yes. This is Sharon Hibay again. The documentation of positive performance for this measure would be including all of the pieces, the drug, the name, the dosage, the frequency, the root, et cetera. So you need to have all of those pieces to be considered a performance past.

Tracy Wang: Got it. And it just - is it documentation for the patient's physician or if it can be also - I mean I don't know, can patient (bring) based on what a prescription by another provider to be included in the documentation?

Dr. Don Wilson: Hi. This is Don Wilson. It can be any medicines that the patient's one but the provider, whoever's seeing the patient reporting the measure should, you know, should be...

Female: Document.

Dr. Don Wilson: ...document - should be the one that actually documents whether it's present or not or whether they're on it or not.

Tracy Wang: Got it. Okay. Okay. Great. So I, you know, so I think overall in terms of impact and performance gap it's high. So there's definitely opportunities for improvement. Any questions or additional comments from the group? Pat.

Patricia Quigley: Well this is Pat Quigley. I'm the one that marked low on this one. And, you know, part of my comments in relating it to low and I haven't seen everyone's comments. I really did not know

how feasible this really was because it includes everything. It includes over the counter medications, herbs, vitamins, mineral, dietary supplements.

You know, these are just not prescribing medications that we order on the patients that we see. So I honestly - I had a lot of trouble with this in terms of the brief description in trying to see if this is something that was really feasible and linked to quality.

I certainly understand in relationship to medications that we prescribe. But part of the issue was in the verification piece is that there is discussion - let me just see if I can find it. I wrote that in my notes. There's - there was trouble being able to actually verify this information; that it was going to be even more difficult once we moved into electronic medical records.

It has poor agreement about the documentation and verification processes, poor reliability in determining medications that were documented and verified. And even there was an expert panel that concluded verification of this is very difficult. So I had difficulty with this indicator.

(Jane): Okay. This is (Jane). We had some conversations about that in our technical expert panel about including over the counters and vitamin, mineral supplements, et cetera.

And the technical expert panel actually recommended that that needs to be a part of the documentation of medication partially because of the, you know, the interference of some of these over the counters and nutritional supplements with medications that the patient may be currently taking. And they felt that by not including that you put the patient at more risk.

As far as the reference to verification, the original measure in 2009 included a verification, not just the documentation piece. And after our technical expert panel, an environmental scan was completed; the technical expert panel recommended that the word verification be removed

because it was the providers were having some difficulty interpreting that after our testing was completed. That the measure also went to public comment back in 2010 when that occurred.

Patricia Quigley: Thank you for that feedback.

(Christina Mahalik): This is (Chris). This is (Chris) from ISMP. I definitely think from a quality standpoint to do that reconciliation of all the meds is important. I'd be amazed it's actually getting done that often. I hear the challenge. I believe there's probably challenges in trying to validate that.

From an ISMP standpoint, a safety - medication safety standpoint, we even go a step further. We ask people not only about to get those - prompt patients with questions about those vitamins and OTC meds. We even ask them to prompt questions about implantable drug delivery devices.

It's - if we're talking about quality, this - you know, these things have been linked to errors. This lack of coordination of all the medications the patient's taking in those transitions of care. So from that standpoint, I think it definitely fits.

I do - when I was reading this I had to think boy, it would be great if people could really do this. You know, to the degree it's happening, you know, I'm skeptical.

Gina Pugliese: This is Gina. And I just have a question. In terms of documenting the medications, so it's documented by a provider. And even though there isn't verification that was taken out, can a provider affirm somebody else's review of the medication? So if they're doing medication reconciliation by some other person and the provider ((inaudible)) documentation count if he or she actually didn't do it?

Dr. Don Wilson: I'm trying to consider your question. I mean I think again it's the matter that whoever's - this was mean to be - is designed to be done in the ambulatory setting. So it's really whoever's

billing that particular encounter would be the one to have to make sure that it's documented I would think in that note.

And actually in our most recent - as we were looking at revising the measure for 2012 I think we actually added the words as part of the encounter in there that I don't think that's probably on the documentation that you have.

Gina Pugliese: That's helpful. Thank you.

(Christina Mahalik): This is (Chris). I have another question. As far as that - do we - and I don't remember this from reading this measure. Is there ever - are we just collecting that they documented they did it or is there - I'm just paging through trying to see. Or did we - does this actually say that we're going to - we're going to go and actually look at charts to see if it's occurred?

Specific, you know, is it just...

Female: ((inaudible)) question.

(Christina Mahalik): ...looking at them saying they did it or actually ((inaudible)).

Female: My understanding is that it's a - they look at the claims data with a G code.

(Christina Mahalik): Okay.

Dr. Don Wilson: Right. This is Don Wilson again. If I can - yes, I mean exactly. When you - basically the provider has to self attest that they've done it. But then there, you know, they always have to understand that they'll be chances especially if they're reporting in a ((inaudible)) that there's a

change that they would be audited and they would then have to show there was, you know, the documentation to validate the codes that they submitted.

And that's what our testing was done, you know, was all about was we'll review requested records based on records that were submitted to CMS. Then we got to - a cadre of those records and then basically did do an audit to see, you know, how - what the agreement was between whether if the provider said that they reported the meds, you know, could we actually find them in the chart. So that's what our testing data's all about.

(Christina Mahalik): And then you said that data you looked for all those pieces to be there, right.

Dr. Don Wilson: Correct.

(Christina Mahalik): Yes. That's good.

Tracy Wang: Great. Then we'll move onto the body of evidence. I gave it moderate all throughout my - looking at - it's pretty consistent with the rest of the review team. But there is - Pat you had insufficient. Do you want to talk a bit more about why you think it's insufficient? I think it's...

Patricia Quigley: Well I had marked yes if it was focused on the health outcome. My issue was the evidence to support all that was being - all the - not just the prescribed medications but the vitamins, all of those kinds of things. That's more of what I was looking for in terms of the evidence to support that. So that was part of what my issue was.

And I did support the comment that (Chris) said too that it was realistic. That's part of what made me wonder if it was even feasible to do all of this for all of the classes that you had - that was included in the brief description.

Sharon Hibay: This is Sharon Hibay again. Actually, you know, what - as part of a provider's outpatient problem list which should also include a list of the medications, it's pretty standard there that they have a list of, you know, medications including herbals, over the counters, et cetera, as standard, you know, safe practice to medication documentation. So it's just another classification in the assessment as being as a type of a medication.

Tracy Wang: And I guess, you know, one comment would be that - so it's looking back on the numerator what is included. And so there needs to be - the (charter) audits on the ((inaudible)) even for the herbal medication it would need to have a dosage if we ((inaudible)).

So I, you know, I know that I know sometimes when I go to the doctors, I - if they ask if I'm - any vitamins, I probably would just give the name of the vitamin, not necessary how often I take it.

And so I don't know, I guess with the documentation, would that suffice?

Sharon Hibay: Well, you know, if they said that you were on a vitamin, if they didn't put one tab or if they didn't put the amount or the frequency, then it would be their obligation then to write the information was not available. Just to write that you're on a MultiVit without saying how, you know, the dose or the frequency would be insufficient information.

Whether it is a over the counter medication, a prescription, whatever, they have to have all of those pieces on there to say that they had credit for appropriate and sufficient medication documentation.

Tracy Wang: Thank you.

Female: That makes sense.

Heidi Bossley: This is Heidi. If I could just ask a question because as I - as staff is when we reviewed - Sharon, I'm not sure I understand your responses in 1C6, 7 and 8. And it's possible that it's a typo. But you only discussed that it's met the criteria for time limited, which is not the question that was asked here for quality, consistency and net benefit.

Which I think is - I'm assuming Pat, I don't want to put words in your mouth but I think that might have been part of the reason why you struggled rating...

Patricia Quigley: Yes. And actually I have that highlighted. It's the 1C8 where the measure has met all the criteria for time limited prior to the time limited endorsement. I have that highlighted.

Heidi Bossley: Yes. I think Sharon it would be useful if you could go back and work with Andrew and (Jessica) to refine the responses in here because I think when we get to the in person meeting, there's going to be questions as to that.

It doesn't really speak to what you referenced up in 1C5, which is the position paper - the prospective study, et cetera, which is what I would have assumed would have been then further discussed under quality, consistency and then eventually the net benefit.

Sharon Hibay: You know what Heidi, as you know, over the last few days you and I have been sharing a few emails about this process and I - it was certainly our belief that this was a time limited review instead of a maintenance review. We do have that information. And so we will be happy to provide that and have that prepared for this next meeting.

Heidi Bossley: Perfect. Yes. I - that's one reason why it helps to have these workgroups so we can iron out these kinks. So...

Sharon Hibay: Okay. Thank you very much Heidi. I appreciate that.

Patricia Quigley: Heidi, you must have been reading my notes. I actually have that whole section highlighted in my report. Thank you.

Heidi Bossley: I know. Yes, Andrew can tell you I did the same thing. Yes.

Patricia Quigley: Yes.

Heidi Bossley: I think it's just missing data so we just need to get it for you and then it'll help.

Tracy Wang: Great. Okay. So moving on. For the - let's see, reliability and validity, I have given it high and moderate. Most of the review team also gave it high and moderate. Let me see. The - get back to my comments. There was a pretty extensive analyses done by Quality Insights as a separate attachment. And so I didn't know if there's any other additional questions from the team.

Andrew Lyzenga: Pat, I think you had looked at those as...

Tracy Wang: Pat, right.

Andrew Lyzenga: ...((inaudible)). Did you have any thoughts on that?

Patricia Quigley: I did. Yes. Well, you know, again, mine - my issues were related to the feasibility to even be able to - be able to obtain this information. And I know the patients that were - that are cognitively impaired are going to be excluded and, you know, I deal with - well, if the information is coming from electronic medical record, you know, I think that is a gold standard to be able to get this information.



But I'm just hoping that it's really realistic. I know it is the expectation to have this but the reliability and the validity of actually being able to grade someone on this I think is going to, you know, it'll be a - has to be done.

So that's part of what I had ((inaudible)) so that was including all of these medications and I was just a little worried how they were going to be able to do this with the documentation system with that - or in place. It's just - it's a huge initiative. I can tell that.

Tracy Wang: All right. Okay. So in terms of usability and feasibility, most of us also rated either high or moderate. The - you know, I think if we could address the feasibility of, you know, capturing all of the information necessary for herbals and OTCs, I think that'd be very helpful.

Let's see. And the verification component was eliminated as a result of the field testing. And documentation on those would be adequate for this metric. And Pat, do you have any other additional comments? I know you had given it sufficient. Again, you know, going back to the large category.

Patricia Quigley: Well, I guess some of it - besides the strength of the evidence for all of these different classes is, you know, how do you deal with issues surrounding patient preferences and willingness to be able to say the medications that they're on and ever remembering it because it's not even just people who are cognitively impaired. It's a lot of the elderly - don't know.

But if it's going to be linked to actually the performance of providers, I certainly think that this is relevant for the medications that we prescribe. But some of these patients have rights to take and, you know, they have preferences.

And so I think that there might be some things that are really uncontrollable factors that it would be really difficult to be able to document knowing that people go to lots and lots of providers.

There isn't just one person. Even in primary care, you know, when you've got some - you've got 20 minutes to see a patient to be able to make sure all this is done and cover all of this.

But I think it is an expectation from gold standard. So I guess the issue would be is can we move from one higher - one level of performance to a higher level of performance?

Tracy Wang: One other question I had regards - are there benchmarking information for this metric? And since it's internal use I didn't know if there are any publicly aggregated datasets that allows for some sort of benchmarking threshold.

Dr. Don Wilson: I'm sure we did a gap analysis ((inaudible)).

Sharon Hibay: We're looking for that information right now.

Tracy Wang: Oh you - okay.

Dr. Don Wilson: Yes. I'm sure we did a gap analysis when we did the measure to determine. It's just I can't remember what the, you know, what the number said. And I guess the other question I would have is looking at our testing data, what did we find on the - I don't even have that in front of me at the moment. But as far as what was our pass rate on the cases that we pulled for testing.

Sharon Hibay: Yes. We look at the trending of the performance rates the provider tested performance rates over the reporting period whether they're by six months that aggregate information. And we also have the gap analysis information, which we can provide you for next time.

Patricia Quigley: Well this is Pat. There's some of your performance rating in this narrative. Is this what you - this is - isn't this what you reported in terms of age groups with the performance by region too, lower reporters?

Sharon Hibay: But we have performance in here by all sorts of different aggregations. We have it by rate, have it by gender, we have it by underserved and non-underserved. We have it by provider population.

Patricia Quigley: Exactly.

Sharon Hibay: ((inaudible)) by gender. There's all sorts of information that is in there. But I think I was looking - when you were saying for benchmarking. That's where my...

(Crosstalk)

Sharon Hibay: ...answer to my question was trying to come through. So we do have that aggregate data analysis across different reporting periods. But as far as the gap analysis information, that's what I want to get back to you on.

Tracy Wang: Right. Because, you know, I'm interested in - and with the results that are quoted, you know, is it 80% - is that pretty good or is that, you know, is that the (standard) and there's still room for improvement?

Sharon Hibay: Right.

Tracy Wang: That's sort of what I'm trying to get at ((inaudible)).

Sharon Hibay: Exactly. Without the measuring sticks, where are we in the land of performance?

Tracy Wang: Correct.

Sharon Hibay: Exactly.

Female: Anything else?

Tracy Wang: So in terms of suitability for endorsement, there's four yeses and one no. And again that goes back into just being - the overall - the indicators a little bit too general and documentation would be perhaps somewhat cumbersome and difficult to document. But any other comments?

Andrew Lyzenga: Great. Thanks Tracy.

Tracy Wang: Okay.

Andrew Lyzenga: And I think we can go ahead and move onto the next measure then.

(Christina Mahalik): This is (Chris) and I have Measure 1729. It's poly therapy with oral antipsychotics.

Andrew Lyzenga: Yes.

(Christina Mahalik): This is actually a new measure. And just a little bit of background. Monotherapy with antipsychotics has demonstrated efficacy. But there are a percentage of patients and depending on, you know, which article or study or research you read, it could be between 20 and 30% of patients will fail monotherapy or have an incomplete response.

Using more than one antipsychotic has not been consistently proven to be either safe or effective - or more effective in those patients that failed one. But despite all that, you know, and it surprised me even to see some of these statistics, polytherapy is quite common.

In these patients that failed one drug, Clozapine or Clozaril is the only proven effective alternative based on studies. And those studies really were just in treatment resistant schizophrenia. The problem with Clozapine is it does have side effects and, as you probably all are aware, you have to monitor WBCs and AMCs at least every two weeks for most patients. If you're on it a longer period of time, you can push that out.

So as a result, some clinicians will try polytherapy. There are actually two joint commission sponsored NQF measures, Number 560 and 552 related to patients on multiple antipsychotic medications upon discharge and then those that are on multiple antipsychotic medications upon discharge that have appropriate justification.

And a justification would be either a history of three or more failed trials with one drug if they were cross titrating with the goal of getting to one drug or if they were on two drugs but one of the drugs was Clozapine.

So the numerator for this measure is the percentage of individuals 18 years of age and older with persistent use of two or more oral antipsychotic meds. The denominator are those who are prescribed at least one.

From an impact standpoint, I really tried to use all the scoring guidelines that were sent to us from NQF. I scored it high because it affects a large number of patients and it utilizes a large amount of resources and by that I mean dollars.

Overuse of medications is a priority under safety. And I mentioned there are other measures related on the inpatient side. There was a staff note on this measure, which I appreciated all those notes, that the measure's more a resource one and I do agree with that. It is very resource driven but also overuse is a priority.

And, you know, just from an overarching principle, we really shouldn't be thinking of giving patients medications that they really don't need or not proven - have been proven effective.

From a performance gap, it does appear that overuse is evident by the statistics in the measure. Although I did have some curiosity if those percentages that were in the measure, the 8.9% of the 5.1% of Medicare beneficiaries, which is I think that's on Page 2 - Page 3 if you're following. I was just wondering if that included patients on Clozapine if we were talking about the same thing.

So my other questions in 1B1, it's really only addressing resources, not quality. There are a wide range of articles that are cited on - as far as the evidence. There's - in the quality of the studies in the body of evidence they cite 34 studies but they didn't give us all those in this measure to even be able to cite.

The staff note for this section was that the citations were somewhat dated and I do agree with that. It's probably because there really isn't anything more recent out there.

I did do - I don't know if I was supposed to do this but I did do a quick search to see what was out there. And there is some more information out there. I think it's more on the other measures that have been approved on the discharge piece trying to correlate them with quality and outcomes and effect those changes.

Moving on to the quantity. I scored that a moderate based on the list in 1C15. There's a lot of non-guideline evidence although there are guidelines out there. It's not necessarily official and most of them were really related to schizophrenia.

There was from my count and looking at that list of articles, I guessed, you know, that there was only really five that were randomized clinical trials but I could be wrong. I don't have this evidence here. I'm hoping that the expert panel that reviewed this looked at that criteria making sure that there are more. But that's why I scored it moderate.

And I did not - I apologize. I didn't type all this in. The only randomized clinical trial that has examined effectiveness and safety was one that looked at switching from two drugs to one drug. And it found that being on more than one drug was associated with weight gain and being on one drug was associated with weight loss.

So and they actually cited that the methodology limited the quality of the safety evidence. So there is some evidence issues. It does appear limited and the staff - NQF staff that reviewed this noted that and I do agree with that as well.

From the quality standpoint of evidence, I scored that moderate as well. Again, based on that limited number of randomized clinical trials. Although having said that, the citations do seem to all show or say the same thing; that combining antipsychotics really lacks in peer support and has not shown to be more effective than one unless you're talking about Clozapine.

And then consistency I also scored moderate. And again, despite all the above, everything does seem to move in the same direction and everything is saying the same thing even though there's a lack of trials. Everything seems to support monotherapy.

You know, the guidelines do show max out the dose of one agent before you change to another and everything - all the articles, everything that's in print really supports combination with Clozapine only.

The goal in general in psychiatry is to avoid polytherapy. Unfortunately there's just not a lot of evidence out there. The staff note that it seems like it's a narrow and cautious guideline to base a measure on. I agree with that too but it may just be hard to find any published guidelines that are supporting polytherapy. And again, a lot of the guidelines that are available really specifically look at schizophrenia and not some of the other diagnoses.

Moving onto reliability. I scored that moderate. I thought the specifications were a little ambiguous. The numerator and denominator seemed appropriate in scope to me and the reliability scores were really good and they were all within what would be the acceptable range but not for when you got down into all of the physician groups.

And I'm not really sure how that's going to affect the measure reporting. It seemed like a very complex method to pull the data and NQF staff noted that as well. I do agree it looks very complicated. I tried to really get my head into how that was going to work. So I don't know if that's going to be a feasibility issue or not. It may be, you know, if the authors are here, they can comment at some point on that.

I also scored the validity moderate. I thought the focus of the measure was consistent with the evidence that was available. I saw that there was the expert panel was listed. Their credentials were listed. You know, I couldn't be 100% certain that they had psychiatric specialty background but at least I saw that there were specialists in there.



They did note that the assessed face validity, which reading the scoring that made me score it moderate as opposed to anything higher than moderate. And I thought the authors really did a nice job describing the process and identifying potential threats.

And then usability I thought it had high usability. I thought that the results should be understandable. I felt they were meaningful to the care of patients and 83% of the expert panel that they used on this measure strongly agreed or agreed that the scores were interpretable.

And then from a feasibility standpoint, I scored that high because based on what I was reading, it looks like all the data was going to be coming from electronic claims, which I think they noted in there as well. I thought that that data should be available and it should be acceptable.

And there - really they didn't identify really any threats to the validity of that data. So I thought that feasibility was high for that. So I'd be curious to hear what other people thought about this new measure.

Patricia Quigley: Well this is Pat Quigley. I'm happy to share but I've done a lot of sharing if other people want to go first.

Andrew Lyzenga: You're welcome to Pat.

Patricia Quigley: Okay. Well (Chris), I certainly value your expertise. I can just tell the amount that you know. But I had a little difficulty with this measure. And I, you know, I realize too I'm learning the process as I'm a new member to this.

My issue was that if the goal is to get to monotherapy instead of polytherapy, you know, the indicator is the percent of all adults over the age of 18 are on more than one. So I imagine the goal is to get - to reduce that number.

But that being said, you know, I knew that this was a high important issue related to this, but I really had trouble with the evidence in terms of quality, consistency and quantity.

And (Chris), my issues were that the description of those measures, and you'll see my notes there. It is for all age groups. However, the literature review really focuses on the antipsychotic drug use in the elderly. It's not for 18 years and older - and younger or older, you know, to the elderly. But then on Page 9 where it says looking at stratifying by age group that omits the age group at 65 and older.

So, you know, I don't know about that. And then there's so many patients where we do need to have multiple medications to be able to manage them. So, you know, my issue was in terms of a quality indicator is really the number of medications so much the quality indicator of trying to get to profiling safe medication prescribing to be able to manage these very difficult patients. You know, the lowest possible deals with the lowest number of medications.

So, you know, those are some of my comments. And the reason why I rated the reliability and the validity a little bit lower is because it seemed to me that in the - even though the literature review was related to the elderly, they were excluded from the analysis and reliability and validity as a stratified age group.

And then for usability and feasibility I did put insufficient there because I wasn't clear how these rates for patients receiving more than one antipsychotic medication is really linked to quality of care when really maybe the quality of care is better defined as the type and the lowest dose of medications to be able to manage these patients with behaviors and, you know, behavioral problems and psychosis.

So those are - that was - those are my general themes in trying to read this. You know, is it just the number of medications as really a quality indicator. And I did two think that the focus was more on cost and really quality of care. You know, safe quality care to be able to manage these very difficult patients.

(Christina Mahalik): Yes. To your questions, the - as far as the references go, I do think that they could have done a better job of presenting the evidence. I am unclear myself. I actually know that from things that I've read that the younger age group are the ones more likely to have polytherapy. But that's what I read.

But I agree with what you said about the references. And I do - it would be - again, is that age - the age range just like in the other measure makes me question if we're able to get all the information. And if we can, that's - I'm okay with that. I just - I do think if they presented the references a little bit better, we might think differently about it.

As far as what you said about the lowest does and I think that's a quality indicator as well. I don't think they're mutually exclusive, polytherapy and, you know, step wise approach to therapy and maxing out, you know, one drug before you get to the - before you switch to another - add another and only giving the dose that needs, you know, the lowest dose possible to the affect that you need.

And again, I guess with the - as far as the high impact, it's really a lot - it is a lot based on cost. I agree. And unless, you know, again if the authors are on the call, if they have other thoughts or want us to think differently about that, you know, taking that - you know, just looking at a broader sense like I started with. We certainly don't want to put patients on meds that they don't need. You know.

This has probably raised to a higher level this group of medications because of the cost. That's my thought on it.

Female: Thank you (Chris).

Andrew Lyzenga: Do we have any comments...

Heidi Bossley: And I do think we have the developer on.

Andrew Lyzenga: Yes.

Heidi Bossley: It may be helpful to have them perhaps clarify. Kyle, did you want to say anything?

Kyle Campbell: Sure. The first comment that I heard was the question about whether Clozapine was excluded. It is excluded from the measure. So the measure rate excludes beneficiaries with Clozapine. So that impact analysis that's in there.

The other issue that I heard was concern about stratification. And, you know, beneficiaries to 18 years and older are included. And in the attachment there is a complete stratification breakdown for beneficiaries 65 to 74, 75 to 84 and 85 plus.

(Christina Mahalik): Just a clarification. On that - when you say - I know that Clozapine is excluded from the measure as it should be. But one - those percentages there, just curious. It's still powerful either way. But was Clozapine in there or out of there?

Kyle Campbell: The - you mean the 8.9%, the overall rate?

(Christina Mahalik): Yes.

Kyle Campbell: Yes. That's without Clozapine.

(Christina Mahalik): Oh, okay. Good.

Kyle Campbell: Yes. So and in fact under the exclusions section, we presented data with the measure rate with and without Clozapine.

(Christina Mahalik): Right. That's right.

Male: Page 7.

Operator: We do have a question or a comment from the phone line. Would you like to take that at this point?

Andrew Lyzenga: Sure.

Operator: Marcela Horvitz, your line is open. Please go ahead.

Marcela Horvitz: Yes. Hi. So I just wanted to address - I seem to have heard concern about the - how data is to be evidence was or not dated. And we did present evidence from a number of studies that have been conducted on this over the years.

But one of them is a meta analysis that included - that itself was published in '08 and included - was a very systematic and in depth search for all studies that have looked at polypharmacy with a randomized control trial design over the years.

So that - and actually I did some, you know, searches on my own to see if there were any important ((inaudible)) that have been missed. And the answers no. So that is a very - it's, you know, reluctantly we sent a study that summarizes the evidence - the randomized control trial evidence on this matter not just for the U.S. but also abroad.

And that's by (Correl) site. And there's been a few other studies that have come out since which we also included namely or the most important one is an (Essic) study that came out this year.

I also wanted to address the issue of whether this is a quality of care matter or not. And at least in terms of mental health services researchers who've been very concerned about the growth of polypharmacy use - antipsychotic pharmacy use in - among chronically mentally ill. There is a concern based on the fact that this is overuse of a practice that has no evidence base for non-Clozapine combinations.

There's very little done in schizophrenia, which we presented. There's almost nothing done in other disorders. So there's just no evidence that it offers a benefit - clinical benefit to patients. But there is benefit. I mean - sorry, there's evidence that it doesn't help patients in many other respects including physical health indicators; adherence, mortality and yes (cough).

(Christina Mahalik): All excellent comments. Thank you for sharing.

Marcela Horvitz: Sure.

Andrew Lyzenga: We have any other comments or thoughts from the workgroup on this measure?

Patricia Quigley: Well this is Pat. I was wondering if Gina was still on the call if she had some comments.

Gina Pugliese: I'm still on the call. Yes. No, I pretty much agree with (Chris)' commentary about the measure. And most of my comments are very similar.

Andrew Lyzenga: All right. Well, if there are not more comments, then I think we can start to wrap up. Does anybody have any more thoughts or anything they'd like to add?

Patricia Quigley: Well the - again, this is Pat. The only other comment that I - ((inaudible)) could still continue to be concerned is if a number of medications is if there is a balance with those patients who may need to have medications and looking at, you know, safe prescribing and lowest possible dose and some other kinds of things.

You know, I don't know if it's just exclusive to mono pharmacy because there are some very difficult patients that are out there. And if there's some way to not focus so much just on cost but actually the health benefits or the adverse events that are associated with the multiple prescribing because that really did stand out to me is that I thought it was more focused on the cost issue rather than the quality and the safety.

But I think the comments were every well received. Thank you. So.

Gina Pugliese: And this is Gina. Just one last comment. The ((inaudible)) a new measure rather than a maintenance. Is there any instructions provided or any required follow up while this measure is being used to sort of look at, as Pat pointed out and (Chris) as well, in terms of, you know, the quality aspect of it?

And if there's another way to look at, you know, complications to people that are on more than one or a particular age group where this is problematic so that efforts could be focused on a certain group. I don't know if any of that is done when that measure is being used, you know, so

that when it gets ready for the next maintenance, some of that data would be available since it going to be collected on this measure. Just a thought.

Heidi Bossley: This is Heidi. If I could just add; I think those are really good comments. Part of what we can do and what we will do at the meeting is start collecting the gap areas. And I think this would be one.

And I think the other message that we can send back to the developer, they're on the phone now, and can continue to is that we want them to start looking at the actual impact of the measure and if there's other ways that, like you said, to perhaps measure it or specific groups to look at. So I think it's just part of what we will incorporate in as the comments on the measure. So very good points.

Gina Pugliese: And the age - focusing on the age groups for all of the...

Heidi Bossley: Yes.

Gina Pugliese: ...you know.

Heidi Bossley: Exactly.

Andrew Lyzenga: Now this is Andrew again. And we'll see - and we'll try to collate some of your comments and questions and feed them back to a developer so they can have sort of a list of items they can look into and come back to us at the in person meeting.

Female: Thank you.

Heidi Bossley: Andrew we need public comment. Correct?



Andrew Lyzenga: Public comment yes. So if nobody has any other comments or thoughts or questions, we can move to the public comment period. Hearing none, operator, could you ask for public comment?

Operator: To the audience...

Andrew Lyzenga: Yes.

Operator: ...if you have a comment or a question today, please press star then 1 on your touch-tone phone. Please make sure your mute button is turned off to allow your signal to reach our equipment. We'll pause for just a moment.

And it appears we have no questions at this time.

Andrew Lyzenga: All right. Thank you. So I thought that was a great discussion. I thought you all - all of the workgroup members did a really good job of summarizing their thoughts and questions. We'd love you - free to do something very similar to that at the in person meeting.

We'll probably assign, you know, each of you the same measure that you reviewed here at the in person meeting. So we'd like you to give a - maybe a quick overview of your thoughts, maybe some - a summary of what we talked about at the meeting or at this workgroup meeting and the other workgroup members on the call can help support that primary reviewer.

And we can just try to get the full group started on a discussion with that, you know, as - with the workgroup discussion as kind of a jumping off point. We will probably send out another of these online surveys in advance of the in person meeting so you can go through and rate these

measures again and as well as the rest of the measures that are going to be considered at that meeting. And we'll just run through a pretty similar process at that meeting.

Anybody have any questions about that or comments or concerns? Well hearing none, thanks to everybody for participating. Again, we really appreciate you taking the time out of your schedule to get on this call and have the discussion. Thanks to the developers as well and any members of the public on the line.

And we will speak to you soon.

Female: Thank you.

Andrew Lyzenga: Thanks everybody.

Female: Thank you.

Operator: And again, that does conclude today's conference. We thank you all for joining us.

END