National Quality Forum

Moderator: Katie Streeter
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Katie Streeter: Hi. Good afternoon everyone. This is Katie Streeter here at National Quality Forum. I am here along with Angela Franklin our Senior Director and Ann Phillips, our Project Analyst.

Thank you for participating in today's number three (call) for submitting your preliminary evaluations on line. Also just a quick reminder this is a public call and we'd also like to thank our developers for joining us today. So welcome to you as well. Angela.

Angela Franklin: So with that we'll call roll, Roger Chou?

Female: He may not have dialed in, I guess.

Angela Franklin: Steven Brotman?

Steven Brotman: Here.

Angela Franklin: Christian Dodge?

Christian Dodge: Here.

Angela Franklin: And (James Daniels)? OK. I think (James) will probably be a little bit late. And I think we were expecting Dr. Chou.

Roger Chou: Yes, I'm here now.

Angela Franklin: Oh, great. Thank you.

Female: Thank you.

Angela Franklin: All right. Thanks again to you all for joining. And this is Angela Franklin, the Senior Director for the project. I want to briefly go over the purpose of today's call. Just want to remind everyone we won't be voting on today's call, we do want to have an in-depth discussion about the measures as this small group ahead of our full steering committee meeting in May. And our goal today is to really think light issues that you've identified any questions you may have for the developer that they may be able to answer between and the in-person meeting. And we do expect each committee member on a workgroup to have a very good grasp of all the measures within this workgroup. But also familiarize yourselves with all the measures in the project ahead of the in-person meeting during which all the measures will be reviewed and voted on.

For today's call, as Katie was saying we do have measure developers so they can respond to your questions as committee members and please use this opportunity to ask any questions you may have about the evaluation process in the criteria and of course if we can answer right away, we'll get back to you via e-mail with the call, I mean after the call.

So, we also want to let you know that we're piloting certain (aids) for Steering Committees during this project including new committee guide book and new measure evaluation algorithms. And if you could give us any feedback about how those items are helping you that would be most appreciated.

I'd also like to set the stage a bit for the – for new E-measures that we're going to be reviewing on the call today. For this project NQF is piloting a new trial implementation pathways for many of the E-measures in this project and as you reviewed this four measures you might have noticed that the testing portion has not been provided at this time, these E-measures could still be eligible for endorsement by this committee on a trial basis until testing is able to be completed by the developer. And that's provided that the other criterion for the measures are met and then testings then becomes the only question.

So the committee should review and evaluate the evidence criterion and the feasibility in this criterion with the understanding that testing to support the measures will be submitted by the developer at a later time. Also for these E-measures, staffs are conducting an internal review of the electronic specifications that were submitted and we'll provide a report to the Steering Committee in May about our results of those review. We'll also be able to explain the piloting of the trial implementation pathway in greater detail at the in-person meeting in May.

So I'd just like to pause and ask are there any questions so far from the committee members? OK. And also just generally for today's discussion, I'll just remind everyone that we have to review the measures as they are in the current form, please feel free to express your observations about the measures you're reviewing based in the criteria and the guidance. This is the key part of the process and we rely our members to identify issues and thoughtfully reach consensus on these measures. So we certainly appreciate your free (part) and respect for differences of opinion among these committee members and developers.

So, quickly I'll go through the process for today. We have approximately 20 minutes for discussion for each measure today. So I'd asked discussants to keep that in mind if they work through the measures and if there's questions that will require detailed follow up by the staff or by the developers, we can record those and present answers back to you via e-mail following the call. We're also asking that the lead discussants as they do their reviews, step through each criterion, importance, scientific acceptability, feasibility, and usability using this process, first introduce the measure overall giving a quick description of the measure and then quickly summarize the initial comments from the group about the criterion that's in focus, and then as the second, third discussants if they have anything to add without repeating information and then open the floor for Steering Committee members to discuss generally.

And we'd also ask if it's possible that questions of the developer be held until the floor has been opened so that we can share we have – they surely have crisp and crystalized questions to ask of the developer.

Are there any questions about the process? OK. So, I hope we'll just take a pause and make sure that we have our developer for these measures that the American College of Rheumatology, I just want to identify if we have representative on the call?

John FitzGerald: This is John FitzGerald, I'm a physician who was participating with the project and I'm from UCLA but working with the ACR.

Angela Franklin: Perfect. Thank you. All right. And a little programming note, we – besides that we want to start with as our first measure, measure number 2521 regarding Gout: Serum Urate Monitoring and our lead discussants are Drs. Brotman today and Dr. (Daniels) we hope he will join us shortly. So doctor …

Steven Brotman: So – Can I start?

Angela Franklin: Yes, go ahead, please.

Steven Brotman: OK, so the measure 2521, the title is Gout: Serum Urate Monitoring by the American College of Rheumatology as the developer (Stewart) and just as a brief description of the measure, this presents the patients with a gout diagnosis who have been treated with or actually who have been started on or changed urate lowering therapy who's serum urate was measured within six months after dose change. And the numerator statement management consist of patients with serum urate measured within six months after date of new or changed urate-lowering therapy ULT prescription and the denominator statement is adult more than 18 years of age with established gout initiating or changing dose of urate-lowering therapy.

There is no exclusions, this is one of the newly proposed E-measures submitted for a time-limited endorsement meaning as discussed before, there is no measurement testing submitted with this and if we could just go to the importance criteria we'll look at evidence and performance gap and an impact. The evidence for this, the developer tried to explain the rationale for this on that patients with lower serum urate levels have less gouty attacks and less gout problems. And it's based on the ACR, American College of Rheumatology guidelines on gout that recommends that the patients with

frequent attacks with gout to a more attacks per year, the clinical presence of tophi or tophi in an exam or erosion should be initiated on urate-lowering therapy.

But there is very little evidence, they point to the guidelines, the evidence mentioned in the guideline or mentioned here on the measure on information sheet is not exactly on point and from the other comments that we've received, there is no direct evidence to support the proposed measure a lot of the evidence that is proposed in the guidelines is level grade C evidence and there are no side of trials of uric acid monitoring versus no monitoring or treatment for uric acid therapies or other strategies. As you know not everybody with gout is treated with long-term uric-lowering – uric acid-lowering therapy.

So it's not clear what exactly is this measure is as the percentage of patients with uric acid levels measured or just symptomatic patients, what about cancer patients, diabetic patients, and so there's a lot of questions involved regarding the evidence which is not addressed and it looks like the evidence is not presented in the fashion that should be presented in a case like this where you look at the – you present the quality here that happens, the consistency and the quantity of evidence to make your case and, you know, I'd like to get some inputs from the American College of Radiology if possible on some of the questions that are posed. But at this point it looks briefly from the looking at their guidelines and from looking at other evidence that is out there that there is not – is either insubstantial evidence at this point supporting such a claim.

The other thing to just be aware of is that, you know, when you're talking about people that had gout if their diet and other lifestyle management property is as well as education of the patient probably makes the – one of the biggest amounts of difference, I'm not a rheumatologist but I do know that a number of people, of patients, previous patients that have had gout and the education and that understanding of the gout process does affect them in positive ways so that they don't run into the troubles that they can run in to.

So, given that the other point of this is I guess priority and impact, the ACR mentions, the developer mentions that gout affects 8 million Americans and that they may be so but I'm not quite sure of those 8 million how many are on

ULT, urate-lowering therapy and it's not really discussed and a good portion of those may actually just be treated as one of with other types of anti-inflammatories and other agents.

So I would put it back to the developer at this point and stop there. There is no testing that goes on further because it is an E-measure. The developer states that it's going to be submitted for full NQF endorsement after testing later this year and I would support that maybe there are something that should happen before they should actually go back and re-examine the evidence before presenting all that.

So if there's any comments?

(James Daniels): Also, (Jim Daniels) I'm sorry I'm late, I'm on now.

Angela Franklin: Great. Dr. (Daniels), I'm not sure how much you were able to hear but did you have anything to add to your observations about the importance of the measure?

(James Daniels): And please help me because there's a couple, which measure are we talking about right now?

Angela Franklin: Sorry about that, so we're working actually we started with measure number 2521 Serum Urate Monitoring and we're right now reviewing the importance criterion and a walk-in through those subsets of the importance criterion and soliciting information from the Steering Committee or thoughts from the Steering Committee as they evaluate at the measure.

(James Daniels): Well, to me as whatever I heard is that Dr. Brotman did a great job. The only thing that I would do because if I – I want to make sure that I'm just not ignorant with the process so excuse me if I go off, what I did was I concurred this to some of the other guidelines. I did, I went and compared it to U.R. to the British and then also the Japanese have a really good one I thought in – I'm not really sure who their sort of putting these guidelines out of its (four) like everyone or just the rheumatologists, but the, you know, there are questions on what really constitutes if someone has gout and if you're going to

say that they have to have an acute flare up and do you have to have a certain numbers as far as the uric acid level.

And there's some discussion on that and the number that's been put out a lot is I think it's like 6.8 and right around there because of the solubility of uric acid, but that was an in-vitro study and there's like other things that sort of affect it like pH, serum sodium that type of thing and what I saw with the Japanese, they have a range and it's almost like on who you're going to on how specific it is. So, I really like their information on how they did it. If that's helpful to the developers they'd probably already looked but I pretty much agree with everything that's been said that I heard.

Angela Franklin: Thank you Dr. (Daniels). So to your points, we do have the – Dr. FitzGerald, I believe on the call that's representing the American College of Rheumatology if you might want to speak to that?

John FitzGerald: Sure, you know, I think some of the questions about the specificity of gout, there are articles that have used to ICD-9 claims codes. Some of this we'll be looking at in the testing and the measure is specifically designed for patients who have been diagnosed with gout not cancer patients who might have been receiving chemotherapy, but it is for gout patients.

And certainly, you know, we had chosen the indication – to the prescription of ULT or a change in ULT as something to not ignore patient education or other things along those lines and those are important parts, but those presumptions that the, you know, once the ULT had prescriptions and made by the trading physicians that those other measures or those other topics would be addressed.

(James Daniels): I'm sorry doctor, what's your – that's the thing I was confused of, what's your diagnosis? Can you tell me what the criteria are, like what your diagnosis for someone having gout? How do you make that diagnosis?

John FitzGerald: Yes. (Melissa) do you want to – do you have the specifications?

Angela Franklin: I don't know if (Melissa) is on, John.

John FitzGerald: Oh, OK.

(Melissa): I am, can you hear me?

Angela Franklin: Oh, I'm sorry, great, yes.

(Melissa): OK. Sorry, I need to pull off the specifications to answer that.

Roger Chou: I mean, this is Roger, I mean, won't it be just be based on an ICD-9 code, I mean, how else, I mean, for the purpose of these measures at least …

John FitzGerald: Yes, that's in …

Roger Chou: … I'm talking about how will it be diagnosed clinically which I think is a different issue, I mean I think the – for the measure purposes it has to be based on however it's coded.

Angela Franklin: Right. It's based on the diagnosis or findings from the code, I don't have the clinical in there for how it's actually diagnosed.

John FitzGerald: Yes, it'd be ICD-9, I think we had two codes as a requirement. We do have some observational studies showing that patients with more monitoring versus less monitoring have better uric acid outcomes. We'd have to look – We'd have to re-check literature for specific interventions about specified monitoring versus the usual care. So we'd have to get back to you on that.

(James Daniels): And I don't mean to present the point if it's not rolling I'll just be quiet here, but I mean the question I would have is when you monitor, what are you going to monitor are you just coming in actually seeing the doctor makes the difference, or is it like a level you're checking and …

John FitzGerald: We were looking for a urate – a documented urate.

(James Daniels): That's all you're looking for, basically you didn't care if it was elevated just to see if they've checked it.

John FitzGerald: When there is other – there's another measure that looks at the getting to target, so this one is just if there's been a new or changed urate-lowering

therapy, is there a follow up measurement of that that changed or that initiated or, you know, the new prescription.

Roger Chou: So this is Roger again, I mean, I think my big hang up was that, you know, this is kind of like lipid levels or hypertension or whatever that sure there's an association between, you know, higher lipids and cardiovascular outcomes, but, you know, as we know they just change the lipid guidelines to say you don't really need to monitor lipids, the important thing is to get them on the therapy. And I don't know if the same is the case here that it's, you know, because some people actually have gout with normal uric acid levels, right? I mean that's actually fairly common and is it better to monitor patients clinically and increase the dose if they have recurring gout attacks or is it better to target some level or monitor at all. I don't think we know unless there's, you know, at least from the evidence that's been presented here.

(James Daniels): Yes. That's really my big concern, it's hard for me to get pass that, you know, with not of the lack, you know, I'd like to see some data showing that monitoring has some impact either that's, you know, a trial that incorporating uric acid monitoring or some kind of comparative study where they look at monitoring versus no monitoring that kind of thing. At least with what was provided in the proposed measure is just an association between uric acid levels and risk of gout.

John FitzGerald: Yes, the – I mean, you're right. The data we are presenting is a lot of the associations between uric acid changes and uric acid levels with resolution of tophi and reduction of attacks.

(James Daniels): Right. And again the question would be is that, you know, why wouldn't it be better to follow patients and see if their tophi are getting smaller? And why is – why would it – why is it so important to get a uric acid level rather than to – other than clinically. And it maybe that there's evidence, it's just that I don't see it in the proposed measure written.

John FitzGerald: Yes. The press released article showed correlation between speed of tophi resolution and uric acid levels and I forget who is the author but low uric acid levels being associated with reduced risk of recurrent attacks.

(James Daniels): Yes, yes, I understand that. It's just that we don't know the monitoring makes you get the uric acid levels down any faster is my point that the treatment …

John FitzGerald: Yes, I've got it, it's the intermediate that – you'd like more to add documentation.

(James Daniels): Yes, I mean, you know, there is another measure about getting people on treatment which I think there is stronger justification until which we haven't gone too yet, but at least for this piece I think that – at least to me it was hard to get passed the evidence part.

John FitzGerald: OK. We'll have to look at that more and see if we can find something to support it better.

Angela Franklin: Thank you. This is Angela, sorry to interrupt. I just – are we – do we have additional comments about the importance piece? Importance to measure and report? All right, hearing none, we can move on to our next criterion which is in this case feasibility.

(James Daniels): Right. With the feasibility, I mean there's – this is I guess an E-measure, there doesn't seem to be very much that submitted, I do have a four by four gird I guess that has been submitted which I don't know how to interpret. There was no narrative associated with it. It's titled Data or Elements Feasibility Scoring Table Summary and there is an addition value set which I'm not quite sure is submitted for feasibility or not, but maybe the ACR could comment on those scoring table that was submitted.

John FitzGerald: (Amy) I'll let you take that one.

(Amy): I cannot comment. I think we're going to get back to you with that one, I didn't create that table. If you have it that you can show on the screen I'm looking for – I've been trying to pick out what you're talking about exactly, I'm sorry.

Angela Franklin: We're pulling it up here at NQF but just to give some context to the committee members the purpose of the feasibility grid is to demonstrate that it was found to be – the measure developer has done an assessment and interviewed

potential users and they have or have some that it's feasible, so they're trying to display that their – this measure is feasible to use with the information submitted and I think we're pulling it up.

(Amy): So with that, the question that just sort of worked into grid focused over to a particular question about something that was on the grid.

Angela Franklin: I think the question was to – kind of an explanation of the grid and what it shows, what is meant to demonstrate in terms of showing us that the feasibility of the measure.

(Amy): OK.

Angela Franklin: So more of an explanation that would …

(Melissa): Hi. This is (Melissa), I was involved in this and I can't actually see it but I suspect I know which part of this you're referring to. It's – When it come up that will help, but it should be a high level summary of key data elements within the measures and assessing this feasibility of those data elements.

Angela Franklin: So we did put it up in the screen. Are people able to see the grid? Anyone able to see? It's in Excel C.

Male: Yes, I can see it.

Angela Franklin: Great.

Male: Yes.

(Melissa): And I'm sorry I still can't see it. So it's hard to speak to.

John FitzGerald: Yes, I'm sorry, I can see it but I'm not familiar with this table.

Angela Franklin: I can describe, there are two columns that show that current feasible with a – up to one year, the second column says future feasible in three to five years and this is regarding data elements in terms of data availability score, to data accuracy score, the data standard score, and the workflow score.

(Melissa): OK. So contained within the Excel workbook, I think that the very first tab contains an introduction that explains the questions that were asked to the four different sites and four different geographic locations with four different (AHRs to send) who were asked to assess those three data elements in those four areas. The question breaks down into the four areas that you just described. So the grid that I still can't see is the high level summary of – it's the aggregate collection of their responses and the interpretation of those responses based on the NQF score for data elements in the scale that's provided is from the NQF.

Does that at the description that you were looking for?

(James Daniels): So (Melissa) they are scored two to three, is that on a scale from what to what?

(Melissa): The scale, off the top of my head I'm not sure, the scale is actually listed in there, I can't remember if it's one to four or if it goes up to five? If anyone else knows, please chime in I can't still look in …

(James Daniels): We have – The sheet that they have here is just the Excel data table results without the other tabs.

(Melissa): OK.

(James Daniels): They might be three to five.

(Melissa): OK. Yes. I'm not sure off the top of my head, I still can't see it, so seeing just that snap shot of the workbook, I don't think it's as helpful as being able to see all the tabs because the explanation in the first tab and then you can kind of walk through the summary at the data element level for each of those data elements. I think being able to see all of that is critical to really understanding what's contained in the workbook.

Male: Maybe this can be resubmitted with some narrative with explanations and criteria.

John FitzGerald: It sounds like a result and separated from the narrative.

(Melissa): OK. I can definitely go back through the submit and resubmit.

Angela Franklin: OK, well this is Angela at NQF, we'll review what we have, this appears to be all that we have. So we'll get together with you (Melissa) and see – make sure that we have everything that we need to present to the committee.

(Melissa): OK, thank you.

Angela Franklin: Other comments from the committee regarding feasibility?

Let's move on, I'll just (call the usability).

OK, if there are no other comments on feasibility we can move on to usability and use, any comments on this from the workgroup.

Male: Yes.

Male: The comments really is that, you know, this is a new measure and therefore the testing has not taken place and all the comments from the developers that it's a new measure has not been a chance to be publicly reported or included in accountability program but ACR intends to place it in their registry. So – it's not – I don't think we're able to really comment too much on usability at this point without much more on that.

Angela Franklin: OK. Any additional comments about the measure overall before we move to our next measure?

OK. So hearing none, let's move on to measure number 2526 Anti-inflammatory Prophylaxis with ULT Therapy and I believe that the lead discussants are Dr. Chou and Dr. Dodge. So Dr. Chou if you could lead us off?

Roger Chou: Sure I need to pull that up, find it, OK. So this measure is basically in patients who are being started on uric acid lowering therapy are they also started on some kind of anti-inflammatory such as Colchicine, NSAID or corticosteroid to reduce flares which can occur when you lower the uric acid level. The sided rationale is a randomized control trial, a large control trial where prophylaxis for six months was compared with prophylaxis first for eight

weeks and fewer patients flared if the prophylaxis – the anti-inflammatory prophylaxis I should was continued for six months and then a very small trial of Colchicine versus placebo is also subsided. I think it was 40 patients when there were somewhat fewer flares in the patients who received Colchicine.

There is some evidence was provided that – I don't see it here it must be on the other sheet. There is some evidence who's provided that it's at the – anti-inflammatories are not – are frequently not prescribed when uric acid lowering therapy is given so that we're just going to be a performance gap I guess. And then, you know, the priority staff was actually similar across all the measures, it's basically the gout is common and that it causes significant morbidity. Shall I start talking about kind of a comment, some stuff related to the criteria one?

Angela Franklin: Yes, please go ahead.

Roger Chou: Yes, so that this was one where really the only direct evidence was that one trial of Colchicine versus placebo. So there are 43 patients, there's actually no data I found that was sided on use of NSAIDs or corticosteroids which were also part of this measure. The other trial even though it was very large was actually looking at longer duration of prophylaxis versus shorter duration of anti-inflammatory prophylaxis. So I don't think it was actually directly irrelevant.

So again I have some concerns about the evidence, you know, basically being based on one very small study. The, you know, and in addition kind of interpreting the clinical relevance so, you know, how I guess one of, you know, how big of a deal or it is it for someone to have a flare if you can jump on it for example quickly with the anti-inflammatories or steroids or whatever. So anyway those were my main, I guess comments about the criteria one. In terms of criteria two I guess my main concern with the specification is that, you know, with the lack of evidence about other anti-inflammatories. Should they really be – should NSAIDs and steroids really be included here if there is going to be a measure and then of course making sure that people who, you know, don't want to have prophylaxis for whatever reason aren't included in the denominator. I didn't really have any comments about the feasibility stuff,

you know, at least for me it's hard to assess those if it's, you know, if you're still stuck with the evidence piece that you didn't have.

I don't think there's major issues with the feasibility. It seems to me that, you know, it's again it's identifying somebody with gout and there's going to be a match in terms of whether they're started on uric – uric acid-lowering therapy and then on match in terms of whether they're getting one of the specified anti-inflammatory measures and anti-inflammatory drugs excuse me. So that was pretty much it for my standpoint.

Angela Franklin: Great. Dr. Dodge did you have something to add?

Christian Dodge: My main, I think it echoes the comments that are made but I think my main concern was the lack of specifically of the strategy of prophylaxis I think that it seems it would be a pretty significant diversity of outcomes based on those strategy to the (glucocorticoids), the NSAIDs and the Colchicine and there was no specific it didn't – I didn't see any specific threshold for what would be considered appropriate prophylaxis in terms of those. So I think those few things give me question about, you know, how to assess whether there's actually needing the criteria and I share some of the concerns about evidence based on that which are already common.

Angela Franklin: Thank you. Are there comments from the rest of the group?

Did the measure developer want to speak to the specificity about the strategy to address the issues and then also the specific threshold? Question?

John FitzGerald: Yes, I guess I would answer some guidance or clarity on that, you know, from the guideline there are those recommendations and they can vary a lot. And the Colchicine is 0.6 BOD but if there's comorbidity that would be adjusted, NSAIDs were specified for example (Naprocin) but there's so many NSAIDs. There's not – again looking for guidance which you'll be looking for dosage on multiple NSAIDs.

Male: I'll chime in, I guess I'm confused and you may need to edify me but as far as that the treatment I don't think of both NSAID is stopping information anymore, it's really kind of more (propane) and I know that the mechanism is

quietly different from the other two meds you're taking so that's the whole point with me on it because I agree with what the other two speaker said, that if you're going to pick something to treat, kind of that – say what it is and kind of define it. And if you decide that you're going to use the NSAID as far as I'm concerned it doesn't matter which one you use but just kind of once we can just kind of see how it's measured and then people can extrapolate, you know, if that would work will the other wouldn't work because, you know, they have kind of different half-lifes and you're going to have to kind of move things around for the patient with the renal function and all that, but – so I don't know if that helps you or not.

John FitzGerald: Yes. I can take that back to the group. Those are some good questions.

Roger Chou: Yes and this Roger again. Oops sorry, this …

John FitzGerald: You know, I just …

Roger Chou: … is Roger again. So just to be clear I think, you know, I have two separate concerns. One is that, you know, the level of evidence in general isn't very high. Maybe there's some more out there but again it's one study of 40 patients essentially. And then my second concern is all the evidence is about Colchicine or at least all the cited evidence. And is there data to support NSAIDS And/or corticosteroids for this purpose? I know it's done in clinical practice but are there actually studies showing that to support that or this all basically, you know, clinical experience or whatever?

John FitzGerald: Yes. The other trial was bigger than 40 patients but I don't remember how many it was, but …

RogerChou: That was 4,000 patients but it was – it didn't compare use of this, you know, anti-inflammatory prophylaxis versus no prophylaxis, it was six months versus six weeks, that's a different issue.

John FitzGerald: OK. Yes, I know the Colchicine better than the NSAID data so we'd have to review that. The other topic that was raised was a patient evaluation. Question about if a patient wanted to have the attacks treated with a board of

therapy with each attack rather than prophylactic therapy. That would have to be addressed or resolved as well then, yes.

Roger Chou: Yes, I mean, I am – I mean there's certainly patients who, you know, Colchicine can cause G.I. side effects that, you know, and it can cause lots of things. I think that there are certainly patients who might make ultimate decisions. I mean this is one of those things where though the clinic, you know, though it maybe desirable to offer this stuff I'm not sure that kind of rises to the level of a performance measure, quality measure whatever we want to call it, so.

John FitzGerald: Yes.

Roger Chou: So, I mean, if there's strong evidence that makes you, you know, more likely to put it forth that way.

John FitzGerald: Yes and then some of the rationale for this, is that flares after starting urate-lowering therapy or – can be high in 20 to 50 percent of patients and that site is one of the issues for adherence. We had tried to be – we'd tried to leave the various options for prophylaxis that are accepted in there. But the challenge with that is that evidence isn't – we don't have strong evidence in all of those options.

OK. All right I think the task for us on that are clear.

Angela Franklin: Thanks. Are there additional comments regarding – in importance to measuring report for this measure? If not, we can move on to the next criteria in which would feasibility. We would just note that we have a similar issue with regard to the information we happen to have on hand. And I understand from the developer that we may need to get additional information out to you regarding feasibility.

John FitzGerald: That sounds good.

Angela Franklin: Great. Any comments about use?

Roger Chou: I mean – so this is Roger, I guess just kind of one of the process. The questions I have is, it seems to me that if we have big questions about the evidence that, I mean does it – do we really need to spend a lot of time, I mean it seem premature to talk about feasibility and some of these other stuff if we're kind of hang up on, you know, the data.

Angela Franklin: You're exactly right. So for the purposes of this call, we did want to review every bit of the measure and get comments from the committee. And we won't be voting today, however, once we get into the in-person meeting where voting will occur, if we still continue to be hang up on issues or regarding evidence – I'm sorry, evidence and importance to measure and report and the committee found that they were not proficient, we would not continue review of the measure at the in-person meeting.

So today is kind of our opportunity to make sure we've looked at all pieces of the measure, raise the flags and then the voting would not reach these other criteria and if the first criterion was not met.

Roger Chou: Great thanks.

Angela Franklin: OK. So if there's no additional questions about this measure. We can move to the next measure on our agenda which is 2550 ULT Therapy, and our lead discussant is Dr. Daniels with also Dr. Dodge as our secondary.

(James Daniels): OK, I give it a shot here. Basically this measure the way I understand it is to look at the percentage of adult patient of 18 years of age with the diagnosis of gout being prescribed urate-lowering therapy. And what the – that's defined here looks like a – that's where I got – I had questions before on that. And that's been kind of talked about. And what they ever by studies that they're presenting and they had kind of tough job I think because this wasn't a huge amount there was a one side that keeps coming up a lot that the Japanese folks as a retrospective study on a relationship between the level and recurrent attack the gouty arthritis. And also that they think there's a reduction of that and that is from 2004.

Tere was another one basically using uric acid level to determine the period which is a little slightly different question but determining the levels of period

free of gouty symptoms after you withdraw a long term uric therapy that was the perspective study from 2006. And when going to asking the questions, I still am getting hang-up, you know, defining the uric-lowering therapy because there's like a couple of reasons to lower it, you know, one would be maybe because you don't want them to get problems with their kidney and that would make sense if you said, it was the levels are talking about, but as far as correlating this with their attacks I would kind of confuse the bond.

And that's kind of where I kind of got stuck on it. So maybe someone else can kind of take it from there but I went through the workbook and if you – if I went – that the questions that I put along where, you know, without these definitions, it could be non-pass about category. If those were defined, I just don't understand them. I would quote it as some evidence that would probably be raised as low at this time.

Angela Franklin: Thanks. Are there any comments from Dr. Dodge?

Christian Dodge: I think my questions had to do with the evidence supported or the evidence cited seem to suggest that, let's see. Let me post that, basically that they were advocating for a different target for initiation of uric-lowering therapy than what the evidence was supporting which I didn't quite understand why they did that which called the citation of the evidence into question. So shifting at the goal post and then also that again the criteria for how do you determine the need to initiate this therapy such in they're setting evidence such as the presence of tophi and the duration and I'm sorry the frequency of attacks without a lot of commentary about how that information was obtained, what was the context, were this patient non-compliant with other lifestyle factors, were they – were they comorbidities that sort of thing.

Angela Franklin: Thank you. Comments from other committee members?

Roger Chou: Yes, I mean this is Roger I mean I think that, you know, my I think this – my comments are, I mean I think this is very similar to the one about uric acid monitoring that just in terms of just lack of direct evidence about kind of the effectiveness of or the need for doing it. Again, all of the evidences epidemiologic evidence, not evidence about how doing, you know, this action

in clinical practice actually impacts. And again I would cite other examples like A1c targets, blood pressure targets. Lipid targets where I would say that people propose targets for quality measures that were implemented that they've had to revise substantially. Because they were too, you know, they weren't accurate or whatever. I mean, you know, that they weren't found to be helping patients and maybe hurting them in some cases.

So I think we have to be careful about these kinds of measures if we don't have, you know, strong evidence to back them up.

Angela Franklin: Thank you. Are there any additional comments from the developer?

John FitzGerald: So that the purpose of this measure is to define the indications for uric-lowering therapy. And it's derived from the guideline statements and these guideline statements the new ACR guideline (team) has really matched some of the older ULR in British statement about frequency of attacks and presence of tophi. Perhaps we didn't – sadly we didn't do a good job but it the evidence, but there are study showing that putting patients on uric-lowering therapy reduces numbers of attacks is the whole purpose of doing that in some more recent randomized trials. There's also studies that we cited here showing that urate-lowering leads to reduction on tophi. Those are observational. The – So we can try and strengthen the evidence that's been presented. The …

Christian Dodge: This is Christian, I'm sorry this is Christian Dodge, but we are also evaluating a measure that has the initiation of ULT therapy increases the frequency of attack.

John FitzGerald: It is …

Christian Dodge: So our question is this what, you know, how do we rectify this – the thing to be, you know, they're certainly related but also the evidence seems to be little bit contradictory and what is the time frame of benefit and?

John FitzGerald: Yes when you start a urate-lowering therapy there's a three to six months and it's really primarily in the first three months risk of increased attack because you're affecting the urate levels. But these are, you know, in-depth, you

know, long-term treatments and in the long term attack frequency drops significantly.

Christian Dodge: Well the question I would have to you doc, are you basically just when you define this lowering are just talking about medications you're giving or are you talking about people that may come in and they've got other issues, you know, such as metabolic syndrome and you're prescribing diet and exercise. Does that raise, I mean is that – does that affect level also?

John FitzGerald: Yes, I mean there are a lot of things that affect uric acid level diet, exercise, comorbidities, co-medications.

Christian Dodge: That's part of what I was getting confused about and it may just be because I'm not used to how, you know, what were actually trying to, you know, get to here. But, you know, I – that there's difference at least to me on if you have someone and they're coming in and you're treating about health (stalkers), life (stalkers), you know, nine times out of 10 this is a symptom of this problem with this gout and it's a symptom of a lot of other kinds of disease and we want to make sure that we're looking at the patient and not just doing a bunch of measurement.

John FitzGerald: No, no and that's, I mean that's – that was identified and specified in the guidelines that it's important to look at the patient as well and this is potentially a little off topic, but your diet and exercise can lower things and you could lower your uric acid down to, you know, by a milligram. But if it needs to be lowered more than that you're likely going to need something else. I think it would be very challenging for quality measure to find and address all the other issues about whether a patient was adherence, whether they had comorbidities that's really – if they've gotten to the point where they have erosions or tophi or they're having frequent attacks then they would benefit from being on a urate-lowering therapy.

Christian Dodge: And I get I guess that's what the thing that again I am having trouble here because what the brief measure description says for measuring patients like all of it doesn't really get into tophi. And then it kind of goes on the developer rationale that's when it kind of brings in, so a total look at the patients with

gout, with tophi as a subgroup and all the patients with gout. And I know if sometimes.

John FitzGerald: But it's not all gout, it's gout patients with frequent attacks or tophi.

Christian Dodge: OK, all I'm reading here from this thing in this – (help me) is percentage of adult patients who has an 18 years of age with gout diagnosis being prescribed uric-lowering therapy that – that's what I get. So I'm not getting this thing about tophi or is it they're having frequent attacks.

John FitzGerald: I don't have that in front of me the measure I have and the description I have includes the – at least two attacks per year or a tophus or tophi and …

Christian Dodge: But I guess maybe on this period but I look at that as the rational I though (I was supposed) to just look at the measure. And then trying to find out what were suppose if that matches what your proposing so are …

John FitzGerald: So we're not proposing all gout patients.

Christian Dodge: OK. I'm sorry I wasn't clear on that.

John FitzGerald: OK, yes we're proposing gout patients who are having complications from their disease whether it's frequent attacks or evidence of urate deposition.

Christian Dodge: And with the tophi are you measuring with ultrasound or are doing X-rays or?

John FitzGerald: That's either clinical it could be X-ray, but the X-rays are not required. But it's not advance imaging.

Roger Chou: Yes, so this Roger, so I'm sorry I was on 2549 which were looking at the serum uric acid levels target. So, sorry for if I confuse people, but to clarify about this one I mean I think there has to be studies of uric acid-lowering therapy in patients with these conditions and they just need to be cited. I mean, I just don't think that cited studies actually address the rational. They're all kind of indirect kind of things. But there has to be studies of Allopurinol or whatever and this …

John FitzGerald: Allopurinol (inaudible) older drugs is there's not the studies that you might like to see. There's definitely studies for the newer drugs, you know, (Simvastatin) and we're not including a big load of case here, but there's studies for those.

Roger Chou: Yes, but it doesn't have to be Allopurinol, I mean if you can show that uric acid-lowering therapy is effective in this population as defined, I think that would really strengthen the rationale for the measure.

John FitzGerald: OK. And we can definitely improve that.

Roger Chou: And we'll get to this with the feasibility thing. But I have some concerns about the ability to sort who has tophi and all of this other stuff. I mean I think that actually is going to be a challenge how you can actually sort out which we know how this different subgroups, if we may we can talk about that when we get to the feasibility part.

Angela Franklin: Additional comments about importance to measuring report? OK. That would move us into our feasibility discussion which I think we started a little bit already. Dr. (Daniels)?

(James Daniel): Sure. I don't want to keep apologizing, but I'm having a hard sort of time following this and I – what I got in the – on the computer where there's a bunch of list it looked like ICD-9, so I understand a little bit more now that I saw but I didn't see a four by four table early or anything that went with it. So I'm, you know, a little bit confused on how to rate that.

I think that if you're going to – if you have a defined goal on what a uric acid level is supposed to be and you can decide if you're going to measure what a gouty attack is and you have it down how you're going to evaluate the profile. I don't think that would be that hard to do. So, you know, I don't have any problem with that, if that's all are defined and that's really about all I have to say.

John FitzGerald: If for this one we don't need urate levels, we're not – it's just the –if the patient's being given the urate-lowering therapy. So it's the presence of the drug.

Roger Chou: So this is Roger. I mean, I, you know, again, these are going to – I think the diagnosis are going to have to be based on essentially ICD-9 or diagnostic codes and I don't know how you can sort out who has an acute gout attack because at least when I see somebody with gout, when I coded as gout it maybe somebody who I'm just following up their uric acid levels or just following up, you know. I may not necessarily because they are having an acute attack.

So that's one question is how – can you really identify people who are having two or more attacks per year and then the other thing I brought up is that, I don't generally code if somebody has tophaceous gout or not. Maybe I should be but I suspect a lot people just code it as gout. So how are, you know, I have some question about how the specific patient subpopulations were interested in will be identifiable through the kinds of information we're likely to have.

John FitzGerald: So those are good questions. Some of that we were – we are exploring the feasibility set. A lot of the discussion we have within our group is ICD-10 would be helping with that and a lot of the groups we're going to be casting here would be ICD-10 based. (Melissa) did you want to add comments? (Amy) or (Melissa)?

(Amy): Hi. I don't have comments. (Melissa) if you're speaking, you're maybe on mute because we can't hear you, unless you're having technical difficulties.

Angela Franklin: We can get back to you when he answers that question. All right.

John FitzGerald: Yes, we had – to try and address this we had conducted a survey which (Melissa) had led of the sites that are going to be tested as far as expected feasibility and I think that's what that table that you had put up. I think those are results of her surveys but again, that's out of context from the explanation or separate from the explanation.

Angela Franklin: Thank you. Once again, we'll try and get those – we'll pull that explanation together and provide it to the committee. Comments about use?

Male: Not really. Again, on this there's not just a lot there and I'll kind of leave at that. I don't think that once this gets defined but I think they can do it, you know. But I – after reading this, I was – I'm still – what basis what they want to use one accountability application within three years after the initial endorsement and they want to report that publicly I guess within six years.

Angela Franklin: OK. Any other comments on measure 2550? All right, maybe we can move on to measure 2549. Serum Urate Target and we have Dr. (Daniels) and Dr. Brotman leading the discussion.

Steve Brotman: OK. If you want to I can start it off.

(James Daniels): Please.

Steve Brotman: So – OK. 2549 is a titled Gout: Serum Urate Target by the American College of Rheumatology as well for the measure developer's story. Description of the measure reads that the percentage of patients with gout diagnosis that have been treated with urate-lowering therapy for these 12 months. The serum urate checked at least once yearly with the most recent results being less than 6.8 milligrams per deciliter.

This is another – a newly proposed E-measure with time limited endorsement submission and therefore, no reliability, validity or other testing has been performed with the processed measure and there are no exclusions. The numerator statement reads that the adult patients more than 18 years old to serum urate has been checked at least once per year but the most recent result being less than 6.8 milligrams per deciliter and the denominator patients with gout diagnosis who have been treated with ULT for at least 12 months. The comments related to evidence and importance really mimic the conversations that we had in number 21 and previously in some of these other measures.

Mainly that the evidence is based on ACR guidelines and based on evidences that seems to be the levels or grade C and does not necessarily design studies not necessarily address the rationale for this type of measure. This type of measure to me reminds me of a check of the box type of measure but I'm not quite sure of we've discussed this. We, you know, had previously today about lipid levels and so forth. You can have patients that are compliance, at one

point measure them. They get a great result or they're measured at a snapshot in time and then they go out and have a binge of whatever, alcohol and steak and they end up with levels that are much different.

So, having it snapshot at that point in time may or may not be a good method of – a reliable method of monitoring a patient. And a lot of the discussion related to evidence, relate the same types of questions that we've had in the previous types of measure especially in 21 but the evidence is indirect. It's based on that association between uric acid levels and gout attacks. Those cited studies compare the effective targeting levels of less than 6.8 versus other targets and it does not appear that, you know, a real evaluation has been made of the quantity, quality, and consistency of the evidence which is so empirically important to do for endorsement through this robust process in NQF.

You really have to make a case. You can't just refer to the clinical guidelines and maybe a couple citations. I think you actually have to really build your case almost like, you know, in front of the jury of this is why it's important to measure and this is the evidence supporting the quality of evidence, the consistency and with, you know, quantity of evidence that is overwhelming that we should be doing this. And again, it's mentioned that there 8 million of patients with gout but, you know, what is that population consisting of that relates to this or, you know, that relates to patients that have gout with frequent attack or tophi or based on ULT.

So, I don't want to believe there's a point, these are point that we've discussed today, a number of times I'll put it out to the rest of the workgroup to talk about as well.

Angela Franklin: Any comments from Dr. (Daniels)?

(James Daniels): No, I think he summed it up very well.

Angela Franklin: Great. Thank you. Additional comments from other members?

Roger Chou: Yes, I mean this is Roger. I think that we're on the same page too – I'm on the same page too.

Angela Franklin: Great. Thank you. Any comments from the developer?

John FitzGerald: I know, I think it's clear what we need to focus on.

Angela Franklin: Thank you.

(James Daniels): Just for the process point in – I'm going to just (make it fit) from a non-rheumatologist as far as, you know, clinically treating it's pretty rare that you're going to end up having somebody that you get the diagnosis of the gout from a test for it. You know there's a lot of issues getting that done and then even – if you get the fluid getting it tested in most, you know, areas even with hospitals either there's problems because if you don't look it right away they dissolve with all kind of issues there.

But most of the time, it's a clinical diagnosis with the, you know, the big toe gets read and you treat them and some people are kind of using the old U.R. guideline where you actually do what you were taught not to which is the check your gouts and when they're – they have the acute gout and then when they come back after its flare if it's still up and you can presumably treat if that's a reasonable thing. And if they have complications, you know, you go on but a lot of it, it seems this, you know, how do you do it and how aggressive the idea. And I think if we're trying to get it to what user-friendly for everyone that those kinds of question on how we define it and what we do will be helpful.

So get people to see a rheumatologist they've got, you know, all of the equipment there and they have it going. The other issue on this is the whole point with the levels out and one of the things that I know you've seen it but from a not rheumatologist perspective that guidelines that the Japanese had looked very good it kind of included some of these questions in it. And they used different levels depending on what the patient's symptoms were and how often they had it. And, you know, I tried to look up their resources but I couldn't get all the, you know, look at each one of the resource that they had. They had quite a few (illuminate) just from standpoint, it made it clear so I don't know if that would helpful when you go and do your re-building if that would help or not.

John FitzGerald: Yes, I know I – we – I mean there are validation studies looking at ICD-9 codes and if there – it's usually, you know, it's not dependent on them. Seeing the rheumatologist they're not dependent on rheumatology ICD-9 code. And we weren't proposing (Aspirin) or any higher grade criteria for that. The, you know, a lot of the – they're safe using likelihood ratios and it depends on, you know, Podagra increases it in response to NSAIDs and Colchicine things like that. And we can address that.

Steven Brotman: This is Steve Brotman. It maybe helpful for the group to see some of the other guidelines that Dr. (Daniels) is talking about because it probably does reference some of the evidence and it maybe useful for us to sort of – and get the background that we may not be getting from some of these.

RogerChou: Yes, so this is Roger, I mean I think that would be helpful. My understanding is that, you know, people with tophi et cetera, you tend to have lower targets but, you know, again my concern is that, you know, targets makes sense to people but in a lot of the areas they haven't hand out like we thought they would.

And I'll say blood pressure, lipids, I mean all these A1clevels, people kept pushing and pushing for lower targets and then we actually did the studies and we found that they weren't, that wasn't helping patients. And so I really do think that, you know, you do want cleared evidence that the targets are helpful. In my opinion at least that it maybe one of these cases were getting people on the therapy and following them clinically maybe kind of 80 or 90 percent of what, you know, we want people to do and what is best supported by the data.

And so, you know, that measure I think may have more kind of strength behind it than something here unless there's something that you guys have that we haven't seen yet.

John FitzGerald: Yes, this is an (intermediary) outcome. As you're pointing out we were using a patient being on urate-lowering therapy as the physician had made it the determination that the indication was there rather than going back a step which would really complicate thing by trying to include the indications and

then the monitoring and the outcome. So the rationale for this was the ULT indication was there and then, you know, we don't have evidence that the urate-lowering therapies do something to attacks or tophi in ways other than the actual urate-lowering. There's no known anti-inflammatory properties are, you know, some of the other things that we're seeing with other drugs, you know, their areas.

Roger Chou: Yes, but I guess my point is that – for example, if I had a patient who has a bunch of gout attacks, I put them on your uric acid-lowering therapy and they don't have any more gout attacks, why do I have to monitor the uric acid level? I guess that's kind of my point.

John FitzGerald: Yes. No, I understand that.

Male: It's usually a clinically indicated type of scenario, I'm assuming.

John FitzGerald: Yes, those are the indications that we're specifying in the prior measure. Frequent attacks or a tophi.

Male: And to take it fuller in some cases, you know, if they have lots of attacks then the first question you may have is, is this really gout? And it kind of gets down to, you know, how gouts diagnosed? And so, you know, the first question I have instead, well maybe I had an increased– the medicine lower the uric acid is the first question is do I really have the right diagnosis? So …

John FitzGerald: Yes, I think that would be complicated to specify in the measure, but I get the point that you're making. And that point is actually included in the gout guidelines.

Male: So, I'll leave that (build it). I was there – I guess that gets back to the gout guidelines again I'll go back, how then are you defining, you know, what a gout attack is? Like how do you make that diagnoses?

John FitzGerald: So that was done in the (ULR) guidelines that wasn't – and then there's several ways of doing it.

Male: So, I guess I'm asking the question in what are they?

John FitzGerald: For the purpose of the quality measures or for other …

Male: Yes, measures of the quality – yes, the quality or …

John FitzGerald: For the quality measures, we were just using ICD-9 diagnoses.

Male: OK.

John FitzGerald: And again my memory is most of there that we had – where we're going to use to based on other analysis that have looked at the validity of repeat ICD-9 claims.

Male: That would be a tough case to get back, to settle, to figure out.

Male: Yes I agree.

Angela Franklin: Other additional comments in this criterion?

So, that will move us to our next criterion which would be feasibility and we understand that there are some information that we'll get back to this committee about. Other comments about feasibility? Then that …

Male: I think these – that the comments are pretty much mimic what we had for 2521 at that point.

Angela Franklin: Great. I wanted to actually – I'm sorry, circle back a little bit to a request I thought that I heard from one of the members regarding for circulation of a guideline or was it circulation …

Male: There was a circulation – I think Dr. (Daniels) had mentioned here. He had looked at some clinical practice guidelines from Japan and other sources which, you know, contains evidence essentially for – either the urate levels of treatments and monitoring. And I just think it's probably helpful to ask as a group to know the totality of what exist out there so that we can reach into it or one of us is discussing it that we have an idea of what they're referencing. It's just as a very generally helpful I think.

Angela Franklin: OK. Very good, (staff) can certainly secure that and circulate it but I also let the – give the developer an opportunity if they want to address that or provide that guideline?

John FitzGerald: Yes, we can submit those.

Angela Franklin: OK, very good. Thank you. So, getting back on tracks, that'll move us to use discussion by committee members?

Any new …

Male: Again, I guess it's mentioned that the measures still being tested. They're going to be submitting for time limited endorsements and it will be finalized for a field testing in the next 12 months at which time we'll seek for NQF endorsement. But I only have any substitutes or comments on that.

Angela Franklin: Great. Any additional comments?

Well, that …

Male: OK, go ahead.

Angela Franklin: OK, (our staff) here will certainly circle back with our colleagues at ACR and any additional information we may receive, we will place on SharePoint and notify you that it's there prior to the in-person meeting. I guess they end this a bit early today since we went through our four measures. I give you back 30 minutes of your time. Actually before we end this call, we do need to take a quick pause for a public comment if there are any. And I believe the lines are open at this point, so please feel free to make a comment.

OK, so prior to the in-person meeting, staff will be completing summaries of all three workgroup calls and we'll be placing those summaries in the measure worksheet. You should have received information regarding (travel) from our meetings department. If you have not, please just send us an e-mail and we'll make sure that you do have that information. There one note I'd like to make is that I believe NQF is still working on the – finalizing the hotel arrangement

and that will be sent to you next week. So not to worry we are securing rooms but I just don't believe that context has been finalized.

But any other question before we end today's call? OK.

Male: All right.

Angela Franklin: Hearing none. Thank you for your time today and we'll be following up with you.

Male: Thank you for all your help.

Female: Thank you.

John FitzGerald: Thank you.

Female: Thank you again.

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

END