National Quality Forum

Moderator: Ann Phillips
August 21, 2014
11:00 a.m. ET

Female: Record your votes. I'll also put the link on the webinar so you can access it that way here in just a few moments.

Before we proceed, we'd like to take a quick roll call and Ann will be walking us through that.

Ann Phillips: Hi, everybody. Roger Chou. Kim Templeton.

Kim Templeton: Here.

Ann Phillips: Thiru Annaswamy.

Thiru Annaswamy: Yes, I am here.

Ann Phillips: Carlos Bagley. Steven Brotman.

Steven Brotman: Here.

Ann Phillips: Sean Bryan.

Sean Bryan: Here.

Ann Phillips: Craig Butler.

Craig Butler: I am here.

Ann Phillips: Kelly Clayton. Linda Davis.

Linda Davis: Here.

Ann Phillips: James Daniels. Christian Dodge. Zoher Ghogawala. Katherine Gray.

Katherine Gray: Here.

Ann Phillips: Marcie Harris Hayes. Mark Jarrett. Puja Khanna. Wendy Marinkovich.

Wendy Marinkovich: (Here).

Ann Phillips: Wendy? Jason Matuszak.

Jason Matuszak: Yes, I'm here.

Ann Phillips: Catherine Roberts.

Catherine Roberts: Here.

Ann Phillips: Arthur Schuna.

Arthur Schuna: Here.

Ann Phillips: John Ventura.

John Ventura: I am here.

Ann Phillips: Christopher Visco.

Female: Do we have any of our developers on the line with us?

John Fitzgerald: John Fitzgerald from an ACR UCLA is here.

Female: Hi.

Angela Franklin: And I'd like to check and see again, did we have Roger Chou?

Ann Phillips: Roger...

Roger Chou: Yes, I'm here.

Ann Phillips: OK.

Angela Franklin: OK. That's great.

There were – there's some delay with some folks getting in. Was – did anyone else – any other committee member joined that we may have missed?

Ann Phillips: Has anybody joined while I was calling a roll?

Carlos Bagley: I did, Carlos Bagley.

Female: Yes.

Christopher Visco: Chris Visco here.

Ann Phillips: Excellent. Anyone else?

Female: Nope.

Amy Miller: Hi, distant staff on from the ACR. This is Amy Miller.

Ann Phillips: Hi, Amy.

Christopher Visco: Hi, I'm not sure if you got me. Chris Visco here.

Ann Phillips: Great. Thank you, Chris.

Female: All right.

Kathryn Streeter: OK. So, now, I'm going to turn it over to Angela Franklin, Senior Director on this project and she'll be walking us through the call today.

Angela Franklin: Great. Thank you, Katie.

So – and I also want to call on our co-chairs, Roger Chou and Kim Templeton to also add what they have learned from the in-person meeting as we walk through these measures. But before you, you should have the measures that we will be considering today in the form of a memorandum, which also talks about the process for today and just to go over what the process will be.

I will discuss and raise the measure that we found from the commenting to be need – need to be considered by the committee on this call.

And just to give you a quick refresher of what the discussion was around the measure and then open the floor for the co-chairs and the rest of the committee to discuss their proposed responses to the comments that we received.

So, with that, I will start with our first measure. Are there any questions, first of all, about that process? s

Male: There sounds to be a lot of static on the line, maybe if somebody, you know, we could also unmute until necessary.

Female: Our fault, we turned on the air. We've now turned it off.

Angela Franklin: Is the sound quality better for everyone now?

Female: Yes.

Male: Yes.

Angela Franklin: OK, great, thanks. Sorry about that.

So, with that, I will dive right into our first measure. The committee might recall that we have one measure for which consensus was not reached and that was measure number 2549, Serum Urate Target, Gout. And this was a trial measure that was reviewed by the committee and the approval for this measure would be for testing only.

However, during the discussion, this measure fell into the (grey zone).

And if you can see from the memo, the primary reasons why were that they felt that it didn't meet the scientific acceptability criterion regarding reliability.

And when we're looking at the scientific acceptability, we're looking at the way the measure is constructed. And we, as a committee, had decided that

there were question around reliability and therefore, the measure ended up in the (grey zone) on this vote.

When we had comments received for this measure, most of the comments, seven in total, were in support of the measure and one comment was not supportive of the measure overall.

One commenter had noted that they felt that urate levels may not be a reliable method of monitoring a patient with gout and question the evidence around urate – the correlation of serate urum– sorry, serum urate level with the disease state. And then they also questioned the levels that were included in the measure.

So, with that, I'd like to open the floor to the co-chairs if they have additional comments about the discussion around this measure and then committee discussion.

Roger Chou: Yes. This is Roger – I'm sorry. This is Roger. You know, I think some of the discussion around the scientific applicability at the meeting at least was, you know, there were couple of issues. One was that there was no direct evidence that monitoring uric acid levels improve patient outcomes versus not monitoring.

And then I think there were number of questions about, not just the level that would be the target, but also issues about, well, if you have a patient who's on allopurinol and hasn't had a gout attack in five years, do you really need to, you know, be monitoring their uric acid levels, that kind of thing.

And I think we were hoping there might be other evidence to answer those questions, I don't think that any such evidence was presented, I think, basically, the comments were, you know, reiterating the evidence that was presented previously.

Kim Templeton: And this is Kim and I want to add. I think there are still concerns with this measure as has noted in the comments. There can be a wide range of levels at which patients may or may not be symptomatic and if we're looking at patient-centered outcome, if they have a higher level and they're not symptomatic, is

that still a medication for treatment, we don't have any good data that would indicate that it is.

So as Roger mentioned, if they're stable, but still, you know, maybe their levels are higher, what is that mean. And do we have – if 6.8 being the solubility level, is we don't really have good data that that's a cut-off point that we should be using.

Angela Franklin: Is there any additional discussion about the measure? Or, any other questions?

John Fitzgerald: Are you opening this up to developers at this time?

Angela Franklin: Yes, we can certainly hear from the developer.

John Fitzgerald: OK. Some of the discussions of the same discussions we had at the meeting, there are few issues here with this measure.

At the meeting, we had presented data showing that serum urate levels correlate strongly with probability of gout attacks and patients with low serum urate levels in the – around six have a 20 percent probability of having an attack during the year, and when urate levels go up to eight, that increases up to 60 percent or 70 percent.

The question about 6.8 versus six, the guidelines that all pick six, and we had tried selecting a less stringent measure because the data shows that a significant majority – a significant proportion of patients were put on allopurinol do not reach the six target. So we were going to try and start with 6.8. We have no objection in lowering it to six, which would bring it inconsistent with the guidelines and that was most of the critique that I was seeing in the comments.

So, I'll take other questions if there are.

Angela Franklin: Are there any additional questions – oh, go on.

Jason Matuszak: Yes, this is Jason Matuszak. I just wanted to ask the measure developers.

So, would you then still say that it has to be a 100 percent of patients across the board that that's we're treating to a target number of 6.0 versus (explain or) whatever, regardless of the number of gouty attacks that they're having at a given time. That even if they're well controlled in terms of having flares, even though their serum urate is 7.5, that that would still – even though they might not have had a gouty flare in three years, that that still would not meet the measure criteria.

John Fitzgerald: So as long as we're talking about patients with history of gouts, who's had gout attacks and had a reason to be put on like urate-lowering therapy, then yes, the measure is simply described as needing to meet the target. It – this would exclude patients who were asymptomatic hyperuricemia and really – and those wouldn't be included in the denominator here.

We can certainly, you know, through the measure testing, deal with certain exceptions and exclusions and we can look into some of those concerns about patients who aren't having attacks. The – it doesn't become problematic because gout attacks can often happen at home and not be associated with a clinic visit or chartered reported to try and find a lot of the concerns that the committee is talking about.

So, really the practical way of doing this is using the target level.

Angela Franklin: Thank you.

OK. If there's no additional discussion, we need to – our next action item would be to vote on the measure, revote on this measure.

Kathryn Streeter: Yes. And for the – oh, go ahead.

Craig Butler: This is Craig Butler. I would just (start) again, (cool up) the altitude and professionally look at what we're trying to do which is distant by the opportunity to try and get into the details of why a measure may or may not be appropriate and where the justice can be made. And I just think we need to include that as we vote.

We're not approving a measure, we're really approving a trial which (cannot) or I don't know, and address some of our questions.

Angela Franklin: Thanks, Craig, for reemphasizing that, that's very important.

Katherine Gray: This is Katherine Gray. I just – I guess I was curious if the developer might consider something like Jason mentioned, that it's, you know, no, you know, two things, not just a serum urate level, but, you know, and, you know, there's some kind of attack.

I mean, I don't know how to say that, but if you're asymptomatic and (inaudible), you know, even if you look at the correlation or predictive value of something being 60 percent, that's still not a 100 percent. So there's something kind of not right about this, so we can have a, well, an eight and you still aren't having attacks, I mean, there – so it's not just the single indicator.

So, it would seem to me that you need to join it with something else that would really add value to being able to predict this better.

John Fitzgerald: Yes. So we are collecting gout attacks through the other measure. So we can certainly collect that during this period when we're going out to the sites, we'll be, you know, going to the charts and abstracting that data. So we can look at (thing) that might go into exceptions with that.

You know, I'm skeptical that that is something that's going to be theoretically useful to apply, and it's – you know, right now, that best correlate of predicting how someone will do to uric acid level. And there's the physiologic reason for that.

We don't have, you know, good – the other predictors of having a gout attack is renal function but that's partly mediated through uric acid levels, again, drug effect is mediated through uric acid level. So, we can look into other areas, but the gout literature is really as focused on uric acids.

Roger Chou: Yes, I mean – this is Roger. I mean, I think that, you know, for me, you know, the public comments, you know, they don't really address, I think, what

to me was the biggest issue with this is that, you know, even when we see correlations like this, there are number of other disease states where, you know, and statins are the best example of this, where monitoring lipid levels probably has very little to do with whether people have reduced heart attack risk, it's more – it's much more an issue of putting them on a statin and the recent guideline is actually, basically, say you don't need to monitor lipid levels anymore and we've been treating to target perhaps unnecessarily for the last 10 years.

John Fitzgerald: (Yes).

Roger Chou: So I would be much more comfortable with this measure if we had some direct evidence that monitoring uric acid levels has an impact on patient outcomes. And I think that's, you know, that to me is the biggest issue that was discussed at the meeting even though that wasn't really brought up with the public comments again.

John Fitzgerald: So, Roger, just to respond to that, so we have presented data showing that uric acid levels correlate with outcomes. There's plenty of data through the randomized trial showing that changing uric acid levels affect outcome.

Now, you're asking a separate question and I realize that is that there's no trial randomizing patients to urate monitoring versus a non-urate monitoring, or as the specific strategy where there's a tight control versus a loose controlled problem.

And that's something where, you know, the data is not available. And I think given the other areas of the strong data showing that the uric acid is predictive and that changing the uric acid affects outcomes. I'm not sure we're not going to get a trial to test the details of testing because the marginal benefits of that, to me, would seem to be small. And I think the other people would be small.

I do object to extrapolating from the lipid literature to gout. And I think it's unfair to do that. But there are different diseases, there are different intermediaries. Lipid is only part of the problem in the event of a heart attack. The uric acid and the urate crystal really is the key focus. And while there are some other elements with the inflammatory system, the – you know, the effect

of changing uric acid is quite strong and there's good data showing that changing uric acid affects outcomes.

Roger Chou: Yes, I mean, I don't think that it's the same disease process, that wasn't the point. The point was about extrapolating from intermediate outcomes and now, it's just an example where, you know, yes.

John Fitzgerald: I think it's unfair to say, you know, look what's happened to lipids and that's a (PAS) that – I mean, certainly that's a (PAS) that may happen to gout. But I think deterrent to both the trial measure down here for that reason would be unfair to the measure, because we don't have, you know, there's good physiologic reason to think it might go differently.

Roger Chou: Well, I mean, people thought there's good physiologic reason for pushing lipid levels down as well. I mean, I think the point is that putting somebody on the uric acid lowering therapy may be more important than trying to target to a specific level. That's really my main point.

John Fitzgerald: Yes...

Roger Chou: And we don't know what the correct, you know, what's true because we don't have direct evidence either way.

John Fitzgerald: But we had also presented at the meeting that the majority of patients get written – a single prescription for 300 milligrams. They don't get urate levels checked in follow up.

And there are known problems with adherence so if there's no monitoring, the likelihood of continued attacks is high. And we see patients regularly where gout is poorly controlled and it's a disease that we have the interventions to treat as much better and it's not being done. So there are large gaps in current quality of care and this is trying to move, you know, move the way people are responding.

You know, we were actually disappointed with the (AASP) response about this measure. And we felt that that showed where there was lack of

understanding about the importance of treating gout and the steps necessary to do that.

Jason Matuszak: Well – so this is Jason again. I think we all agree that treating gout is important in making sure our patients don't have gouty flares is important. But I think I might have missed it, did you present data that showed that checking uric acid levels improve the adherence because you just said that, you know, basically anecdotally that we see that more flares happen if we just start a prescription and never check uric acid levels.

Now, I might have missed that data. What type of evidence did you have about the – about that to the specific thing that you just said?

John Fitzgerald: So all of the evidence that we had talked about at the meeting was indirect. There were – we've presented – we have presented reports of managed care groups where the portions of patients who ever had a uric acid checked starting on a urate-lowering therapy range from as few as 20 percent to – up to 60 percent.

We presented data showing that the majority of patients, and I don't have the numbers in front of me, who were prescribed the uric acid remained on the 300 milligrams without any dose adjustments that the average dose needed to get to target was 380 milligrams. So, most patients are not being titrated to target. There's reports on...

Jason Matuszak: And what – I'm sorry, I'm sorry. What percentage of those patients that were started on the 300 milligrams not checked again and were adherent to their medications had recurrent flares?

John Fitzgerald: That was not part of that study design.

Angela Franklin: Thanks. This is Angela. And not to put anyone on the spot, but I know that we have a couple of members on the call that have an expertise in rheumatology, just wondered if there were additional comments from those individuals about the measure?

Is – maybe Arthur Schuna on the call?

Arthur Schuna: Yes, I'm on the call. What I'm thinking about this is that it seems to me the goal is to keep the patient gout free not necessarily treating the patient to somewhat arbitrary uric acid level. I understand that the standard of practice in the American College of Rheumatology guidelines say we should keep – we should maintain patients with uric acid levels less than six.

And in practice, we treat patients that way. But, I don't know, should – I don't know whether that's something that you should, you know, require everyone to do in all settings. I mean, to me, the goal should be the maintaining the patient gout free.

However you do that, however the – whether the patient's uric acid is seven and you do that, or whether it's 5.0, I don't – I'm not sure that it matters.

John Fitzgerald: In my point of view, the most effective way to do that is to use the uric acid as a (numerator) step to reach that, because otherwise – the other way of doing that is you wait for a failure, treatment failures, and you titrate based on treatment failure and that just seems less optimal.

Arthur Schuna: All right. But I have a patient who's, let's say, is 82 and his uric acid is seven and he's not had a gout attack in three years, by what you're expecting here with this measure is we're – you're expecting that that's not appropriate.

John Fitzgerald: So, this is the concern I'm hearing regularly. And I think the only way we could properly address that would be with an exception clause added to the numerator to exclude patients who have documented to be gout free. And we can look at the – can we look at the data that's collecting it whether it'd be gout free since it's looking at the measure of a one-year period, I would say, gout free for one year.

Arthur Schuna: I think that would help.

John Fitzgerald: OK, because I think that – I think including that would (swage) a lot of the concerns I've been hearing.

Arthur Schuna: It would for me.

Female: And it was kind of suggestion I was saying. If you have a couple of predictors, so you'll do better, I think.

John Fitzgerald: OK. I don't know the procedure at this point how to include that, I mean, we're going to try and measure testing phase. We can certainly design that into – as I mentioned, we're collecting data on gout flares anyway.

Angela Franklin: So, this is Angela. If you are planning to make that change, if that's something you can send to us in writing, or you plan this not in writing as a follow up to this call, then that will be stipulated as part of the voting that you'll be voting, we'll be voting as a committee on this trial measure for additional testing.

And we will – with the understanding that the developer will be including an additional exclusion. Does that sound to the committee members like what we would agree to in terms of stipulating the vote?

Jason Matuszak: And just so that I'm clear again, state how you envision that being worded, so if a person has – would otherwise qualify for urate-lowering therapy, meaning that they've had multiple flares that they'll be started on a urate-lowering treatment, and then based on that initial starting, we're going to check the serate – a serum urate (inaudible) even if they're not at target, but they haven't had a flare in a year, I don't understand, I guess the mechanism where by which when you'll decide to get that serum urate and whether or not people be in compliance with that.

I mean, you're not going to do it – you're going to do it after they started and you're going to be worrying about titrating. But then they might not actually have a gouty flares, so explain that, just walk that through for me so I can hear it.

John Fitzgerald: OK, that was sort of all four measures wrapped into one, but – so, for the specific measure, these would be patients who've had – who have gout, who had gout attacks before, and are currently on a urate-lowering therapy.

The numerator part would be that they should have a uric acid checked within the last year and that it should be less than 6.8.

The exception or the exclusion would be if they've – if there's documentation that there has been no flares during the last year, then these patients would be excluded from having their urate level checked, or – and by that definition, even if it was checked, they'd be excluded from the urate target.

Jason Matuszak: So that would satisfy it for existing patients with gout, however new patients that you're – you know, just came in, their second or third flare and you're starting them on urate-lowering therapy, now, how do I proceed as a clinician. Am I treating to target because I don't have the...

John Fitzgerald: You would be treating to target because those patients would have had an attack. And anyone who's had an attack within this year would be in the denominator and would not be eligible for the exclusion.

So you would be, by this measure, one year after starting therapy – and we have it written so that the urate can be checked, there's a look back when doing a look-forward window, I don't remember the exact dates and I don't know if Melissa is on the call to give us the answer to that. But, basically, you'd be expected in a year to have a serum urate on record of being 6. – less than 6.8.

Jason Matuszak: And then after that, I can stop treating the target even after I've already treated the target in the first place and don't have any idea of whether or not they're actually going to have a gouty flare in the meantime, (OK).

John Fitzgerald: So the exclusion is given, you know, the exclusion is getting retrospectively. And so, you can't – I mean, as a clinician, you can't plan whether your patients had an attack or not. But if they haven't been coming to you and they haven't been complaining of attacks and – then they're not going to be, you know, if they're not active, they're not going to be in the redesigned definition of this measure.

But going – you know, starting on January, you can't come – you know, you would have a treatment strategy of either treating to target or not treating to target.

If you're not doing the not treatment to target and they don't have a flare, then there's no harm. But if you didn't treat to target, they have a uric acid of, you know, 8.0 and they're having attack, then you would – that would be deemed inappropriate.

Kim Templeton: And this is Kim. If I could then, you know, bring up another potential scenario, of some – of any patient does came in with a flare and their initial uric acid level is already less than 6.8, your – and you go ahead and start treatment, their repeat level most likely will still be less than, that yet they may still potentially be symptomatic.

So, are we still (how review) necessarily improve their care if they already came in of the – under the 6.8 level.

John Fitzgerald: Right. So, that – there is a proportion of patients and it's probably 5 percent of patients who have gout attacks with low serum urates.

The quality measure won't be able to move, you know, the indicator on that. And – but again, you know, quality measures can't be designed for a 100 percent, you know, for every patient. There are certainly exceptions that will fit there.

That's not someone who's going to get marked as an appropriate, it will be left as appropriate but that's more complicated patient that would need, you know, something other than the quality measure to try and guide therapy.

Male: I know the ACR guideline suggest even lower levels for patients who have flares at uric acid levels below six. So, as I recall, I think it's – there's saying five should be the goal for those patients, but I'm not – or what evidence there is that that's based on.

John Fitzgerald: So, for complicated patients, a level of five was recommended. This is, again, a little bit outside this current measure, that's – this has been something that's been recommended by the (ULearn) and British Society as well.

So, the ACR was, by in a way, (noble) in these recommendations. The data supporting that is primarily the tophus treatment data that shows a fairly linear rate with speed of tophi resolution based on uric acid levels.

But, you know, in those things, that's beyond the scope of this measure.

Angela Franklin: Thanks, (inaudible). So this is Angela again.

And correct me, I just have a quick summary of what we just discussed. And first, we were looking at the possibility of a developer and (clinics) and exclusion in the measure for existing patients. And the exclusion is general wording that I have down as the patient with a documentation of no gout flares within the last year would be excluded from the measure. And there were questions about new patients and exclusions for those patients. But there seemed to be some questions from the committee about how this might be constructed.

John Fitzgerald: I think new patients would be new patients because they're having a gout attacks so they wouldn't meet that exclusion. I mean, if it was – it'd be a hard case to imagine where – again, I think it would be the rare patients. And I wouldn't want to try and (crack) the measure around the rare patient, but someone who had had a history of gout attacks and – but had no attacks in the last year. And then someone decided they needed to be on urate therapy, urate-lowering therapy. I just don't think that's the common patient.

Angela Franklin: OK.

Jason Matuszak: So, just so that I'm clear on the process again. Now, if this does not get approved as a trial measure, now, the developers cannot submit the exact same measure again for another, what, is it three years or something? Is that right? But they could submit similar measures, so they could submit, say, a different measure for monitoring or reducing gouty flares, or something else that could be done with this other than, we either have to vote for it to be a trial measure, or it can't come back for a period of time.

Angela Franklin: Well, no, there's no bar on the measure coming back. If there's – the measure can come back exactly as is. But that we – the developer would want to include maybe additional (casting), I mean, sorry, additional evidence.

And, again, if they wanted to change the measure, of course, that would be a different measure that we'd be looking at. So there's no bar on the measure coming forward again.

We are just looking to approve it for additional testing. And the additional expenditure of resources, I guess, from the developer's perspective.

Roger Chou: Yes. This is Roger. Just wanted to pause because there are few emails from people who say they're still stuck on hold.

Angela Franklin: Oh.

Roger Chou: But I don't know what can be done about that.

Angela Franklin: Let's see here. Do we want to – before we vote, we would be able to – just do a quick (pull up) who's on the call, committee members (inaudible).

Male: We can do a roll call again.

Angela Franklin: Yes, let's...

Female: Why don't we just call the missing people?

Angela Franklin: Call the missing folks?

Female: And then, the last email I have from somebody stuck on hold was at 11:14. And I don't have any new one, I mean, so...

Female: I have one minute ago.

Female: One minute...

Angela Franklin: OK.

Ann Phillips: OK. Let me call real quick. Kelly Clayton? Christian Dodge? I know James Daniels is not going to make it. I know Puja is not going to make it. Mark Jarrett? Wendy Marinkovich?

Wendy Marinkovich: I'm on.

Ann Phillips: Good. OK. That's good.

And then who – I don't have the email from the other person who's stuck on hold. Can you tell me who that is? This is Ann.

Female: Steven Brotman.

Female: Steven Brotman.

Steven Brotman: I'm on – I've been here the whole time. Thanks.

Female: Oh, OK. OK, good.

(Inaudible)

Female: No one else stuck on – no, rather than Steven, OK.

Zoher Ghogawala: This is Zoher Ghogawala. I'm on, but I got on late because I was stuck on hold.

Female: OK.

Angela Franklin: Thank you, Zoher.

Female: That's great. Thank you.

Angela Franklin: So, at this point, I'd like to, in the interest of time, ask Roger or Kim if they have any additional comments or if we feel like we're ready to vote on this trial measure.

Roger Chou: I don't have anything additional, I think – so, I mean, for me, I think we're ready to vote.

Kim Templeton: I would agree. Thanks.

Angela Franklin: All right.

Craig Butler: So, this is Craig Butler. I'm looking at the survey monthly question that we're supposed to vote on and says, "Does the measure meet into a criteria for trial measure approval?"

Angela Franklin: Correct.

Craig Butler: I guess, I'm familiar with what into a criteria offer a trial measure approval. We used that once for...

Angela Franklin: (For)?

Craig Butler: ... the endorsement. But, is that the same? I just wanted to clarify.

Angela Franklin: It's a question about the criterion of importance and reliability and use testing. In this case, would be reliability of the specifications presented that the committee had looked at and had – was not able to reach a consensus on whether the specifications really met the reliability criterion for trial measure approval. We fell into the (grey zone). Does that help?

Craig Butler: Yes, I guess it does.

Angela Franklin: I mean...

Roger Chou: Yes, this is Roger. I think it's the same criteria that we were using at the meeting.

And again, I think where this one – where we were (running) the issues with this one was with – I mean, I can't remember what the names of them are – of the different criteria or – but, you know, you start with kind of the need for, you know, that there's a quality gap and all this other stuff. And then, which this one pass, I think we got to the point in the algorithm of looking at scientific reliability or whatever that one is call. And that's where I think we got stuck, so.

Angela Franklin: Right.

Roger Chou: But I think it's the same things that we were talking about at the meeting.

Angela Franklin: Right.

And I'll just walk through the importance criterion and the sub-criterion underneath are, whether there's a gap in performance, whether there should be a high priority, addresses a high priority issue, and whether the evidence supports the main focus of the measure. So that's what's taken to importance...

Roger Chou: Right, so...

Angela Franklin: ... which (scientific accessibility) just specifications and then looking at the reliability of the measure and how the measure is planned to be used.

Roger Chou: So, basically, the NQF criteria for trial measure approval are the same, that NQF criteria for endorsement.

Angela Franklin: That's correct, except for the testing results. We're not looking at testing because, obviously, haven't been tested yet.

Roger Chou: OK, great. Thank you.

Angela Franklin: You're welcome.

Kathryn Streeter: This is Katie. Everyone has received their link for the SurveyMonkey. I'd ask you to go ahead and please submit your vote for the measure at this time.

Male: Oh, you can submit them because it has multiple measures...

Male: It has multiple questions on it.

Male: ... so we (inaudible) with one (inaudible).

Male: All three questions we have to answer.

Female: Right.

Female: OK.

Kathryn Streeter: That's a good point. Well, actually, we will have you submit the two votes at the end of the call. And then, hopefully I can quickly read off the results because we only have potentially one other measure that we'll be voting on.

Thank you for pointing that out.

Catherine Roberts: So, just to – this is Catherine, just a point of clarification. When we vote, it's with the understanding that there will be this additional exclusion which would be artfully written in such a way that we would all eventually agree to that. But at least when we're voting for today, we would assume that, right?

Angela Franklin: That's correct. And I just want to be clear, for the voting of the exclusions for existing patients, if a developer might just clarify the language, again, just so we're clear.

John Fitzgerald: And I'm not following, existing versus what would be non-existing patients?

Angela Franklin: Existing versus new patients, I guess, was what...

John Fitzgerald: Oh. Yes, we can include that. I mean, I...

Angela Franklin: OK.

John Fitzgerald: Yes, as you get new patients, I think would fall out of the...

Angela Franklin: Right. Right.

So just be clear would be the exclusion would apply to patients with a documented history of no flares, that was a negative – double negative, but within the last year. Something along those lines?

John Fitzgerald: Yes.

Angela Franklin: OK. Is that clear for the committee?

Male: Yes.

Angela Franklin: OK.

So, please just keep that in mind. We'll be moving onto our next measure. And, of course, after we review the measures, we'll be voting on the SurveyMonkey.

So our next measure that we called out – that was called out in the measures was our recommended measure which was number 0054, Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis. And we have four comments submitted for this measure. All were supportive of the committee's decision to recommend the measure for continued endorsements.

There was one comment about the minimal gap. But the question before the committee is, do we want to have additional discussion about this measure, or any additional thoughts about this measure given the comments that came in.

Roger Chou: Yes. This is Roger. It sounds to me like there probably doesn't need to be much more discussion on this one.

Angela Franklin: OK.

Kim Templeton: Oh, this is Kim. I would agree.

Angela Franklin: OK.

If there are no others, we can move to the next measure.

And this measure is number 2523, another RA measure and Assessment of Disease Activity is the measure title.

Male: Just so we are on the same page, literally, we are on page five of Post-Comment called memo.

Angela Franklin: That is correct. That is correct.

So, we did have a comment from a commenter that technical challenges might make this a difficult measure in terms of collecting data for the measure from

an EHR to variations in workflows and physician offices, and the need to add data fields to EHRs.

So, there is some concern also about the reliability of data extraction from the EHRs.

We do have a response from the developer. And if the developer is on the call, if you could speak to your response to this comment?

(Dionisia Daniel): Hello? Can everyone hear me?

Angela Franklin: Yes...

(Dionisia Daniel): OK, great. This is (Dionisia Daniel) of the American College of Rheumatology. I think – first, I just want to acknowledge that it is a true statement that there are technical challenges. On the other hand, I think that our initial experience with our testing sites was that the challenges are possible to overcome.

And so, I think that our general strategy is that we would like to push this field forward which means, in some ways, that we have to move the EHR from being simply a billing system to actually capturing patient outcomes and a rheumatoid arthritis disease activity is among the most important outcomes.

And so, I think there needs to be a concerted effort on the part of our college and our colleagues to create the workflows to enable this.

And certainly, there are institutions, Geisinger being, probably, the most notable one that have been able to do this successfully over the last decade.

And many examples now of practices around the country, both small private practices and larger academic groups, have built the capacity to measure this outcome in a structured field. And I think one of the things that will be helpful is implementation through our national registry.

This is not to minimize, but this is an ambitious undertaking. But just to say that we would like to try to implement this to move this field forward.

Angela Franklin: Thank you. Any discussion from Roger or Kim, and then the committee?

Roger Chou: Nothing from my standpoint.

Angela Franklin: OK.

Kim Templeton: Nor from I. Thank you.

Angela Franklin: So in this case, it would be the committee response to this comment would be that the committee accepts the developer's explanation? Would that be a true statement?

Male: Yes.

Male: Yes.

Angela Franklin: OK. If there's no other discussion about that, then we can move onto the next measure.

Our next measure is measure number 2524, Rheumatoid Arthritis, Functional Status Assessment. We received a lot of supportive comments for this measure, but concerns were also raised. There was also the feasibility concern raised for this measure specifically for family physicians due to the fact that there's different functional status assessments available for you.

Another commenter was concerned about the accuracy of functional assessments and agreed while assessing pain and functional status with a validated tool is important. They were concerned that this measure may not lead to improvement in functional status as an outcome.

And we do, again, have the developer's response. If we have the developer again, would you mind summarizing your response?

(Dionisa Daniel): Sure.

With respect to the first question regarding feasibility, I think the response is similar to the one that I just gave for disease activity. I think that it is actually very similar.

In terms of the accuracy of functional status – oh, and let me just make a comment also about implementation for family physicians. As we discussed at the meeting, at this point in time, our intention is that these are accountability measures for rheumatologists. And that's actually how our denominator is specified.

And so I don't think the issue about the implementation more broadly is currently an issue, although certainly, you know, if this measure is successful and we are able to field test in non-rheumatology settings, which we weren't able to this time around, you know, maybe expand it on the future, but at this time, it's not.

In terms of accuracy of functional status assessments, I think that there is overwhelming evidence of their accuracy in terms of predicting patient outcomes and being related to a whole host of important other outcomes, for example, joint damage, health related quality of life, mortality, employment, utilizations, all of the things that we sort of consider important outcomes.

In terms of measuring functional status, improving functional status, there is no study that shows that the act of measuring functional status improve patient outcomes, but I think that might be losing the (floors) for the (trees) I think this is a key outcome that's very important to patients, has been a key outcome in clinical practice and in clinical trials in order to get away from sort of the (consults) of how a patient is doing to have a standardized way of incorporating their disease states into how we prognosticate and make clinical decisions.

And I think maybe even more importantly, as we build a, you know, learning health system or we try to do practice management, population health management, understanding an outcome that's the most important thing to patients is going to be critically important.

But I think this is an important step toward outcomes measurements. And I think that we will have opportunities to see in the future how we can actually impact the outcome itself, functional status.

I'll just stop right there.

Angela Franklin: Thank you. And this is Angela. Just to add – just to refresh the committee's memory from our deliberations at the in-person meeting, there were some concerns raised by committee members about potential technical and workflow changes for the providers.

And – but they ultimately – we, ultimately, decided by margin of – a large margin that this measure met feasibility, moderate feasibility.

Questions or comments? Roger or Kim?

Kim Templeton: Will it be explicitly stated on this that this is only for rheumatologist at this point?

(Dionisia Daniel): Yes. And, you know, we can go back and look at the materials and just make sure that that this is abundantly clear.

Kim Templeton: Thank you.

Angela Franklin: Other comments?

OK. Hearing none, I thought – what I heard from Kim is that we accept the – we might accept the explanation of the developer, but also make a note that it should be made clear that this measure applies only to rheumatologist. Is that correct assessment?

Kim Templeton: That's great. Thank you.

Angela Franklin: OK. Other comments or questions?

OK. With that, we'll move to the section of measures where the committee reached approval for trial measure approved – trial measures. And those were measures number 2522 and 2525.

On 2522, we just received comments and support of the committee's decision. I don't believe we need to have conversation about that one, unless there are additional comments from the members.

OK. All right, so moving onto measure 2525, which is Rheumatoid Arthritis, Disease Modifying Anti-Rheumatic Drug Therapy. This, again, is a trial measure.

We got several comments for this measure. Most of them are supportive of the committee's decision to recommend the measure.

One commenter suggested that this measure should only include patients who accept therapy and the provider shouldn't be (dinged) on the measure when they've documented the recommendations for DMARD. And patients elected not to take the therapy.

The commenter was also concerned about exclusions, specifically patients with comorbidities that DMARDs are contraindicated for.

And we do have a response from the developer, if the developers on the call, if you could summarize that for us?

(Dionisia Daniel): Sure. The issue regarding – let me see which one I'll take first. Oh, the patient preference.

I think in the measure development process, this was discussed at length. And in accordance with national guidance regarding preference exclusions and that (inaudible) and I quoted it here, merely indicating that patients decline the service intervention does not indicate the quality of the exchange that occurs between the healthcare provider and patient's exclusion for patient's preference, could be related to quality (inaudible) in a general discouragement from – including which things as exclusions.

We decided not to include that as an – as a denominator exclusion.

On the other hand, I think that we acknowledge and also, I think, literature supports the fact that performance should not be anticipated to be a 100 percent. And, in fact, I think at this point there are some really nice studies, some of them population based that suggest that even in the specialty setting performances in the low to mid 90s, maybe sort of a reasonable expectation.

And there is work ongoing to look at risk-adjusted performance. In other words, is there unexplained variation in DMARD use after controlling for comorbidities using validated (in disease).

And literature suggests that there are continuous to be unexplained variation even after we control for comorbidities and such. And so, I think the decision not to include a patient preference and exclusion and not to have an exhaustive list of comorbidities, but instead to say that across settings, data suggest that performance is generally between 90 – and 90 and even a higher 90s in the rheumatologist setting as an appropriate approach.

Angela Franklin: Thank you.

Are there any comments from the committee regarding the two issues that were raised?

Kim Templeton: This is Kim. To be consistent with 2522, the tuberculosis screening, although we don't – I understand the need to not put an exhaustive list of exclusions, but should we include tuberculosis within those exclusions to remain internally consistent?

Angela Franklin: Question for the developer.

(Dionisia Daniel): Yes. So, the general clinical strategy in a patient who's being started on a biologic drug is to (inaudible) TB. And, in fact, TB test is – as positive suggesting latent TB. Then if therapy for latent TB started, then most people would feel comfortable starting a biologic agent at some point after the latent TB treatment that's either initiated and even in the most conservative case where you actually complete a therapy.

If a measure (event) period is one year, that patient should still see a DMARD.

Moreover, the (inaudible) only applies to biologic DMARDs and so there are many oral DMARDs that are safe to use in patients who have latent tuberculosis.

So, to exclude that particular group of patients, which I think are going to relatively small and really the TB measures only applying to biologic DMARDs, I think it might not help us gain anything.

Angela Franklin: Thank you.

Any other comments about the exclusions or the exclusions regarding –I just want to highlight this again.

So the suggestion that the measure (link) with patients who accept therapy and patients who reject therapy should be excluded and also an exclusion about comorbidities related to DMARD.

Kim Templeton: And this is Kim again. And I understand the issues of patients not accepting therapy and, personally, I think those should be excluded, too. But it's their way with NQF policy and (fire) decisions that can happen.

Angela Franklin: Oh, that – you mean if the developer could revise the exclusion or?

Kim Templeton: Right, right. And include those – and exclude those patients that have declined therapy.

Angela Franklin: Yes. Yes. The question would be for the developer whether they want to apply those exclusions when this measure goes out to testing. Usually, when we have a fully tested measure, the question would be whether the exclusions could be added to the measure and also be supported by testing.

So, here would be a matter of whether the developer wants to do that before they go out to testing.

(Dionisia Daniel): Just – I guess the question sort to back to the committee. You know, in previous discussions with NQF staff, I was under the impression that exclusion testing for patient preferences might not be a preferable strategy.

And we can certainly – we've tested this measure in a couple of sites. But we were going to test it in an additional site. And I supposed we could add this additional piece and present that information to the committee, I think the marginal amount of work would be small. But I felt – now, I'm confused

about what sort of the preferable strategy would be based on our discussions before.

Angela Franklin: We'd actually leave it up to the developer to develop their testing strategies. So, it would be – if the developer feels like it's appropriate to include this exclusion and put it out for testing, it's definitely the developer's decision.

Jason Matuszak: This is Jason. I just had a question for the developers.

Again, what is your – just so that I'm clear in my mind. What is your target goal of percentages of patients treated with DMARDs when you don't take into account any of these exclusion things? I know that you said that if you're in the low 90s and I think that the data over the last few years has been high 80s, low 90s. So what is your goal in terms of percentage of patients that would be treated?

(Dionisia Daniel): I think the larger goal rather than being a specific percentage now that we know that this range is achievable, is to get rid of the unwanted variation which suggest that there are racial, ethnic and socioeconomic disparities in DMARD use. So, this is really a disparity sensitive measure.

Angela Franklin: Thank you.

Thanks. Is there anymore discussion about this measure, and any recommendations for committee response, further comments?

Kim Templeton: What I – this is Kim again. I'd appreciate any other comments from committee members on excluding patients who decline therapy. Is there a consensus that should be an exclusion?

Katherine Gray: This is Katherine. My one thought would be, if in the trial period, if they exclude people who decline, I definitely think they ought to ask the question why. I mean, you know, (inaudible), you know, kind of thing that's causing it or what. You know, what is the issue, because that would really tell us a lot more about why people would decline it.

John Fitzgerald: You know, I'm sure you can find that out from an electronic medical record though, are you?

Katherine Gray: I don't know what kind of technology that they have to able to – if they exclude them, if they can find out the why, if there's a way to do that. I don't know.

(Dionisia Daniel): I think this...

Roger Chou: Yes, this is...

(Dionisia Daniel): Yes...

Roger Chou: Sorry, this is Roger. I was going to say, I think – I mean, the patient preference thing, it's really applicable to essentially any quality measure. I mean, because patients can always opt out.

I think the problem with always having it is that it becomes an easy thing for people to kind of check off and say, "Well, you know, the patient didn't want it." And it's hard to verify what that really means.

So, I mean, I think that it would be probably best to be consistent with how other measures are generally approached. I know that there are probably patient preference exceptions here or there. But I'm not sure that it's compelling enough here to, you know, make the, you know, I think we just see what the – what kind of numbers we're getting and if there's very, you know, if the numbers are lower than expected for some reason, we need to – I think that, you know, we need to look and to try to figure out what that reason is.

And if there really is a big patient preference component, then I think it comes back into play. But, it seems to me that it would be better at this point at least to not try to build in that kind of stuff.

Jason Matuszak: Right. This is Jason. I agree with Roger's comments, or I think that is – well, unless we find that there are some big cultural differences between populations where, you know, where there is a significant demographics that

has entirely different feeling on this that it should be pretty consistent and, hopefully, you read into some of that disparity that the developers are looking to do.

Linda Davis: I wonder, this is Linda Davis, if some of the reasons for not wanting it are related to expense and benefit coverage differences for these drugs. There's – this is kind of a variable area right now for benefit design. And that could be contributing to it.

Angela Franklin: Are there any additional comments about the patient preference exclusion in light of the last few comments? I think we maybe (leaning) toward that committee would not recommend a patient preference exclusion.

Female: Yes.

Female: Yes, I agree.

Female: I agree.

Angela Franklin: OK.

The second exclusion about DMARDs that are contraindicated, is there agreement amongst the committee about whether that – whether or not – whether that should be an exclusion in the measure or not.

Arthur Schuna: This is Arthur. It would be – it would be hard for me to imagine that patients could – would be contraindicated to all therapies. So, I don't know that – I don't know that that would be a valid thing to include here.

Angela Franklin: OK.

Other thoughts or do we agree with that assessment?

Male: I agree.

Angela Franklin: OK.

If there are no other comments about this one, I think we have the committee's – sense of the committee on this response to this comment.

We'll move onto 2550, Gout, ULT Therapy which is also a trial measure. And we received mostly supportive comments about the committee's decision on this measure. There was one comment about the measure potentially overemphasizing pharmacologic management when dietary or educational work with the patient might be more effective at maintaining certain levels with serum urate.

And we do have a developer response. Is there – are there any comments from the committee before we move on about this issue? I know we did talk about this during our in-person meeting, other methods that might be more useful. But the committee, ultimately, approved the measure.

Male: I don't know. It seems like that's an unintended consequence that can be accepted.

Angela Franklin: OK. Thank you.

Roger Chou: Yes, this is Roger. And I think it's another one of those things where if you're seeing that there's, you know, some big gap, you might – we might need some further analysis if the gap is – because people are being successfully treated by other means, then I think the measure will need to be modified in some way. But, I think at this points, it's – I suspect it won't be a big enough issue to screw up the numbers too badly.

Angela Franklin: Great, thanks. Any other comments?

Any other comments from members?

Female: No.

Angela Franklin: OK.

In the interest of time, we'll move onto the measures that are not recommended. And we did have a comment on measure number 52 which was Use of Imaging Studies for Long Bone – I'm sorry, for Low Back Pain.

And most were in support of the committee's decision not to recommend the measure for continued endorsement.

So I don't think we need discussion there. But, moving onto measure number 0514, MRI Lumbar Spine for Low Back Pain. We did get a comment from a commenter at CMS that recommended the committee to reconsider this measure. However, we contacted the developer and had discussions with them. And the developer said that they did indeed – were indeed in process of changing the specs, several of which were responsive to the committee's comments at the in-person meeting. However, they're not ready to bring the measure back to the committee for reconsideration.

So we do have – we did have that on the ballot and we do have it in the memo as a reconsideration measure. But at this time, it's not going to be reconsidered and that's per the developer.

So you might see this measure in the future. And the decision not to recommend the measure would stand.

Are there any questions about measure 0514?

Roger Chou: Now, this is Roger.

Male: So...

Roger Chou: I – sorry. This is Roger. I think that that's fine. And I think at the discussion at the meeting just to remind everyone, I think really centered more around kind of the specifics of how the measure was going to be implemented in terms of what they were measuring. They were very non-specific about – and used all kinds of surrogate stuff to figure out the numerators and denominators. And I think that was what people had the most concern with.

So, I think if they – and to me, those are more technical than kind of scientific issues. So if they can fix those, then I think it would be reasonable to reconsider.

Angela Franklin: Thank you. That's a good comment.

So our committee (responsibly) reflect that. Thank you, Roger.

Any other comments about 514, or what we might recommend? I think we did recommend several things to the measure developer during the course of the discussion. But, any other comments?

Male: So for this measure and for any other measure that we decided not to read up or endorse, when they bring it back, is it, you know, does it have any effect on how we consider it or the process around evaluation, or just treat it as another (crash and miss)?

Angela Franklin: No, this is a refresh submission as you put it. We would be reviewing all aspects of the measure again at this point.

Male: Thank you.

Angela Franklin: No problem.

Steven Brotman: Excuse me, this is Dr. Brotman from the developer. Is there a timeframe for submission for reconsideration, or with the changes that we were going to suggest or propose? Is there a timeframe that NQF requires that the committee meet annually, or there's – we'll have to wait until specific timeframe for this type of measures to be considered?

Angela Franklin: Since it's not recommended, it would typically be out of three-year cycle before the measure could come back for a full evaluation.

If specs were submitted during the comment period, which would include the comment period, then the committee could have reconsidered the measure. But it doesn't sound like this timing would work.

Steven Brotman: So it's a three-year lag?

Angela Franklin: At this time, we're looking at three-year lag. This is the Standing Committee and we have been looking at bringing things back sooner. But at this point, it's at the three-year cycle point.

Steven Brotman: OK.

So I'll make one – and based on the comments that was just made by, I don't have the exact name but anyone of the members that said it's more technicality and there were some issues with that, be something that we could consider for – that CMS could consider to bring this before the committee and before the three-year cycle. Is that something that the committee will take into account or NQF?

Angela Franklin: At this time, we don't have a vehicle for that so I couldn't say that that would happen.

Steven Brotman: OK. Thank you.

Angela Franklin: Thank you.

Zoher Ghogawala: This is Zoher Ghogawala.

Angela Franklin: Yes.

Zoher Ghogawala: I just, you know, from a overall quality and importance perspective, (think) that if there was a way to bring this measure back after the developer had the opportunity to, you know, address all of the concerns.

This is one scenario where I think it might be valuable to bring it back before the three year – if there's any mechanism by which that can be done, just wanted to express support for that concept.

Craig Butler: And this is Craig Butler. I would agree with Zoher. I think that – I thought that was building the concept of having a Standing Committee that you didn't (inaudible) throughout these years. Or plug that in and, you know, so I just dig in (inaudible) we consider (inaudible).

(Off-Mike)

Jason Matuszak: Hello, this is Jason. But the question I'm at is, again, so that has – what I thought I was trying to ask before but I guess they get didn't get my point across the floor.

So if this measure gets not recommended, then if they want to submit the same measure with modifications, that has to wait three years. But if they submitted a brand new measure that just seemed very similar but had key differences, could that come back in a year or two years, or does that stuff wait three?

Angela Franklin: Right now, we're still within that three-year cycle for either configuration of the measure.

If they submitted specifications, the committee would have to convene to, again, assess those specifications. And it's really that convening function that we only have the three-year cycle for right now.

We are – we have them looking at the purpose of the – the purpose of putting together standing committees was to be able to speed that cycle up, but we haven't gotten that – we haven't been able to do that quite yet.

Other questions about this measure or the cycle of reconsideration, the measure review?

All right. Hearing none, we'll move onto our next measure which we did receive request from four consideration from both the developer and a commenter, the American College of Emergencies Physicians.

And in this measure, the committee had agreed that the measure did not meet the importance of the measure and report criterion. And specifically, the committee was looking at the evidence and the directness of the evidence to the focus of the measure, which is median time management or time campaign management for long bone fracture.

As you can see in the memo, members were concerned that the studies didn't link the process of measuring report in the time gap between arrival and administration of pain medication for long bone fractures to improve clinical outcomes.

They also agreed – committee also agreed that, of course, less time to administration of pain meds is better, but they pointed to the lack of evidence to support a particular timeframe for treating long bone fractures.

And it is also noted, there's no clinical guidelines addressing the specific measure of focus.

With that, I think I'll open the floor to Roger and Kim to see if they want to add some comments about this, and then we'll also hear from the developer.

Kim Templeton: This is Kim. I would just echo your comments. I guess, as we're looking at this, how do you define success? So yes, sooner pain medication is probably – maybe in some instance is better. But how short does that time period need to be if there isn't any evidence to know what targeted is that we're looking for.

Roger Chou: Yes. This is Roger. I mean, this is one, I think, we struggled with a little bit at the meeting. And it maybe one where, you know, this is a pretty indirect way of measuring, you know, quality care. I mean, if you're able to get the patient's pain down or the patient doesn't have severe pain for whatever reason, I know these are long bone fractures and they're likely to have pain.

But, you know, there seems to be more direct ways to just asses whether somebody's pain is adequately controlled rather than to kind of go through this convoluted way of looking at median time the pain medication administration.

And then I think there were some, you know, there were some concerns about whether pushing people to, essentially, treat the second a patient hit the door might have some unintended consequences in terms of kind of evaluation and other stuff, so.

Kim Templeton: Like it would make evaluation in a polytrauma patient extremely difficult if they're medicated.

Christopher Visco: Yes. Chris Visco here. That is exactly the concern of the committee with the polytrauma patient, but in addition, the complexity behind this.

The comment is really focusing on the adequacy of pain management.

The second comment, to me, is a little bit more interesting. Is that maybe this – maybe we're all together looking at this in a different light and this is more of an efficiency issue and not really a musculoskeletal measure, maybe this should fall more under care coordination, which I can't really speak to and I don't really understand the details behind that. But, again, maybe we're all together looking at this in the wrong way. But it's clearly not a good way to measure adequacy of pain management.

John Ventura: This is John. I had the same question on the one whether (inaudible) Oklahoma that suggests that this is a care coordination measure and shouldn't be a musculoskeletal project measure and could this stay at the NQF (inaudible).

(Off-Mike)

Angela Franklin: I'm sorry, we had a little bit of (inaudible). Would you mind repeating your question we had trouble hearing?

John Ventura: All right, I'm sorry, can't rid of my Bluetooth.

Yes, I just had the same question about care coordination versus musculoskeletal project measure. And the one criticism from, I believe, Oklahoma where they asked about that and I didn't understand the difference.

Angela Franklin: Sure.

So, basically, NQF has an internal process of assigning measures to the various buckets of measures, and that's done by clinicians. It's something we can consider but – in the future. But for this project, the measure (exceeded) here in the musculoskeletal project. So it's a little beyond our scope to weigh in on.

The criteria, just to be clear, should be applied consistently across committees as well. So, the linkage of evidence to the measure of focus would still become an issue and topic for discussion regardless of the committee.

Catherine Roberts: And additional comment, Cath Roberts.

Angela Franklin: Yes, please.

Catherine Roberts: So, just to add that – you know, there's a difference between a measure in theory and in practice.

So, you know, in theory, I think we've recognized that we want ED care to be timely and efficient. In practice, the way it is measure is written and how it's actually measured in coding really brings together a pretty diverse patient population which makes the metric itself less meaningful.

So, I am not sure if we gave quite as example and maybe we did it in small groups. But – so if you've got a patient in your ED and they've got a comminuted mid several fracture, they're in agonizing pain, that's pretty reasonable, that you'd like from them hitting the door in the ED to getting some kind of pain meds, you know, maybe meeting that benchmark of 34 minutes.

The problem is when they start throwing in some of the coding like fractured fibula NOS, any long bone or, you know, a long bone is any bone that's longer than it is like. Any place you have a ligament attachment, you can have an avulsion fracture, so you can have a little two millimeter avulsion fracture, so that'd be like a grade three sprained ankle. So, it's hard to put that person with a serious femoral fracture in the same bucket as someone who sprained their ankle yesterday and they're coming into the ED because they're having trouble sleeping because of, you know, it aches.

You know, and to say, you're going to treat both of those people and get them pain meds within 34 minutes, is maybe less meaningful than, you know, cleaning up some of that coding like we suggested.

Christopher Visco: Chris Visco here again. The evidence that was provided on practice gap, as well, was very much in – focused in on disparities. And so the committee was, in fact, in support of effect that there was, in fact, a practice gap with regard to, you know, race and I think it was age as well, I go back to look at it.

But, the – certainly, we were in agreement that there was a practice gap there with disparities, but not across the board, not in, you know, when combining, you know, all patient populations just looking at shared time. That's all.

Angela Franklin: Thank you.

Any other comments about the question before we look at voting on this measure?

(Arded): This is...

Angela Franklin: Yes.

(Arded): This is (Arded). Seems like this is more of an efficiency measure rather than a quality measure, and that's the – other thing I would say is, it doesn't really address, is the patient's pain treated adequately. So, maybe if they gave him some Tylenol for the pain, does that count?

I don't know.

Angela Franklin: So that's a good segue into any comments that we might hear from the developer about the measure and request for reconsideration regarding – particularly regarding the evidence.

Stacie Jones: Angela, this is...

Angela Franklin: Yes.

Stacie Jones: This is Stacie Jones. If Dale or Wanda are not on the line, I would be happy to provide some insight into a rationale behind the measure.

Angela Franklin: Great. Thank you, Stacie.

Just checking if Wanda or Dale on the line? Measure developers?

We do also point out – most of you have already seen it, we do have a letter from the developer with the official request for reconsideration that you may refer to lengthen the memo.

All right, I'm not hearing them. So Stacie, did you want to give us a quick overview?

Stacie Jones: Yes. I just wanted to briefly address part of the rationale behind the care coordination, as well as the different outcomes from some of these efficiency measures including timeliness and patient experience.

This measure was originally developed as part of the ED throughput measure sets and most of those other measures from that set were actually assigned to the NQF care coordination group.

And as many of you may know, we have our primary concerns (inaudible) emergency department is an issue of boarding and crowding in which, you know, some patients could be lingering in the hallways for hours or days, and gumming up the works so that, you know, triage of the more critically ill patients or those patients who are in more pain does become an issue to make sure that those patients are still treated timely.

And that is the rationale behind the entire measure sets.

And all the other measures in that set did recently – were recently approved for re-endorsement by that committee. And although when you look from, I guess, an orthopedic or perhaps a musculoskeletal standpoint, that there's not necessarily a change in the bone – outcome of the bone when they received timely pain medication.

But if you do – if you are waiting in the Emergency Department for pain medication and you are in excruciating pain as with the type of femur incident, those described earlier, I can guarantee you that every minute you're waiting for pain medication is going to seriously impact your patient experience in the Emergency Department.

And also, is a surrogate for ensuring that people who need timely treatment or getting at admittedly the situation with the less of your fracture that's equated to the sprained ankle, is also an issue. But, those people also deserve an NSAID or something else for their pain and that is why they're there.

So, I think that as a surrogate for high quality care, if timely efficient care is – are domains of quality and are – have been stated as domains of quality ever since the (IOM) reports originally came out. And in emergency care in particular, almost every single quality measure that we have is a timed measure toward a balloon time, door-to-needle time for stroke, this long bone pain management measure and it does not promote opioid use in anyway.

Definitely Tylenol and NSAIDs are appropriate forms of pain management for some of those less severe hairline fractures that were previously described.

So, I hope that the totality of the evidence including the fact that it was, you know, assigned in this committee that this could be reconsidered or perhaps referred to another cycle.

Wendy Marinkovich: So, this is Wendy. I guess I have one comment.

The door-to-balloon time, door-to-needle time in stroke, those are all linked directly to a patient outcome. While, time to pain management, you know, yes, I agree that during excruciating pain, you need your pain medication. I get that. But it's not linking to the outcome of a patient like door-to-balloon, so I'm not sure if that's an appropriate comparison.

Stacie Jones: Right. And, you know, by that same token, I mean, with the rest of the ED throughput set, I mean, there is a measure of just actually a patient actually getting to a hospital bed because many patients don't get to a hospital bed for hours or days.

And so, that is also a surrogate for bad outcomes. And so, this does go along that same thing.

Admittedly, it's not the same as the door-to-needle time and the door-to-balloon time as far as an actual cardiac outcome or stroke outcome necessarily. But, in general, it's a surrogate for bad quality of care when patients, basically, are not getting the care that they need.

Female: But there really has been an outcome data from an orthopedic standpoint either from musculoskeletal standpoint as far as the outcome of the eventual treatment of their long bone fracture or their long-term rehabilitation.

Stacie Jones: That's correct. And that's why this measure would be more likely to be appropriate in a care coordination type of framework such was the framework in which the measure was developed.

Angela Franklin: Hi, this is Angela. I just wanted to just clarify that we would still be looking, even if it were in the care coordination project, at the directness of the evidence to the actual focus of the measure.

So, it would still be an issue that must be raised and considered by the committee. And I also wanted to check and see if there was any, maybe, additional evidence regarding the linkage of median time to long – to treatment for long bone fracture that was presented by the developer or that you're aware of.

Stacie Jones: So, I do believe that those – the developer as well as (ASEP) cited recent studies noting that many patients with a very high mean pain score to the tune of about 36 percent of patients in 2012, from a 2012 publication, were not receiving pain medication.

And in some studies, the average was closer to 1.76 hours and that, obviously, there was a disparity in those who were receiving it versus not.

So, in addition, we did know the validity survey that was completed by our committee and – or the (ASEP) Committee which, again, is not direct evidence. But in a review of over 90 potential measures, this was the number one highest rank measure among the emergency physicians.

Angela Franklin: Thanks. We put that up on the – where in our four committee members to review.

Are there comments from the committee, additional comments on this measure?

John Ventura: And this is John. I just have a quick (inaudible) and it was pointed out earlier that the disparity evidence is pretty compelling for why this could be a reasonable surrogate measure for adequate pain management. And that it was age related, race related and ironically, the higher pain scores had inadequate pain management.

So I thought that the disparity information was purely compelling.

Catherine Roberts: This is Cath Roberts.

Just wanted to say, I heard – I hear you, I've read your comments. I understand where you're coming from. I would say, again, that, you know, some of my personal concern is that there are long bone fractures that are relatively low, acuity low pain level that are appropriately triage as being less urgent than other people in the emergency department.

So, holding those to that kind of 34 minutes benchmark door to pain meds, I just – I would have – I would – I just pause in saying that some emergency department physicians care was substandard because they appropriately triage an ankle sprain and treated that a little bit slower than someone else who, you know had a very serious injury.

So, I still have trouble with the coding of this and how you're putting those patient populations together. But I, absolutely, understand your intent.

Christopher Visco: Yes, Chris Visco here. And I just want to echo what Cath is saying and this goes back to what Roger said earlier, which is that sometimes when you measure it, it has unintended consequences and it was concern on that realm that measuring long bone fractures, you know, may have unintended consequences on other diagnoses which have a higher level of acuity as they present to the ER.

And I do, you know – and again, to what Cath said, what you're saying makes a lot of sense. Every minute that someone's in pain is, you know, a minute that they're in pain, but looking at the quartiles for which this measure has been, you know, which we have data for going back to the second quarter of 2012 to, you know, first quarter of 2013, there was no budge.

And, in fact, an increase in the number of minutes, and we've got a benchmark of 35 for measuring out at 30s, you know, 57, 59 minutes, it's only the second quartile of 2013 if there's any decrease. It's highly unlikely that extending this would change anything. So what are we getting out of measuring this further at this point?

And, you know, I think the disparities is the most compelling data that you have there. And I would say this is, you know, this is – does not make sense to vote forward at this point.

Angela Franklin: Are there additional comments from the committee, either Kim or Roger, before we close discussion?

Roger Chou: Nothing from my standpoint.

Kim Templeton: Nothing more for me, thanks.

Angela Franklin: Great.

Well, in that case, I think this is on your SurveyMonkey for voting. and the committee's decision would be whether or not – go ahead.

Female: I think that everybody gets to the SurveyMonkey.

Male: Yes.

Female: OK.

Male: Well, that just speaks for me.

Female: OK, but you're speaking for everyone.

Angela Franklin: Is everyone able to get to SurveyMonkey?

Female: Yes.

Zoher Ghogawala: (Ann), this is Zoher. This is a question.

On that survey, both questions three and four, a little confusing to me. If first ask whether we would want to revote on the measure and then number four as whether we recommend the measure we endorsed or not. How is that different?

Angela Franklin: It should be whether for this measure, number 662, whether or not we want, as a committee, to revote on this measure.

Zoher Ghogawala: If I...

Male: Yes, I think three is two, then I guess we don't even go to four.

Female: Exactly.

Angela Franklin: Is that correct?

Female: Yes.

Female: That's correct.

Zoher Ghogawala: But don't we have to vote on all of these at the same time?

Kathryn Streeter: Yes. What we'll do is if the committee decides they would like to report on the measure, I'll have to resend out a new link. I was thinking that it would work a little bit differently. But – so, I guess for now, go ahead and vote on one, two and three, or two and three.

Angela Franklin: You have to vote on four.

Ann Phillips: Oh, you have to vote on four.

Angela Franklin: Yes.

We're going to pull it up on the webinar and we'll (throw) it a bit.

Zoher Ghogawala: Do you want to just have it such that everybody says, "Yes, I would like to revote on the measure", and then just vote?

Female: No.

Angela Franklin: No, we can't do it that way for governance (briefing).

Female: Yes.

Angela Franklin: OK. So we're pulling that up on the webinar right now to take a look at it, so everyone can see what we're discussing and to vote.

This is taking a minute.

Meanwhile, we have the floor open. Are there any additional questions?

And then, just so you know, our next step after this is to review the measures that were not recommended and the comments that came in for those measures.

Typically, for the measures, unless there's something – measures that are not recommended, unless there's something that the committee wants to pull for discussion, some of those not recommended measures. We would not, typically, have a response for those measures, unless there is something that was raised regarding the committee's decision or that the committee hasn't already weighed in on.

So we've now have the webinar. The webinar is now filling the voting that we'd need to do. And I'll have Katie or Ann walk us through how we'll conduct this vote.

Ann Phillips: I would answer question three and answer question four, and it'll (tow the list). So, even if you do not want to revote on the measure, answer question four.

Angela Franklin: So, answering question (inaudible) walk us through that.

Ann Phillips: OK. Question two is the overall recommendation for trial measure approval, if we agree that measure 2549 meets the criteria for trial measure approval. We did not meet consensus previously, so this is an opportunity to vote again. That we'd like your vote.

Question number three is recommendation for reconsideration. SurveyMonkey has some limited question logic. So, everyone will need to answer question four even if they answer question three in the negative.

Angela Franklin: Other questions about the vote? You're voting live. Questions about the vote before we begin our voting on number two?

Male: I have submitted my vote a few minutes ago, will that register appropriately?

Male: Yes, me too.

Female: Yes.

Angela Franklin: OK, so.

(Inaudible)

Female: Yes.

Angela Franklin: So...

Ann Phillip: Go ahead and vote now if you haven't vote already.

Kathryn Streeter: It looks like I've – we have about 11 responses so far.

Male: While we're trying to waiting for these ones to come in, can I ask just a general question? So, after we we're done with this round here today once it maybe it's determinations, is there another report that then comes out and gets circulated back to us for approval, or is this just it for this cycle?

Angela Franklin: That's a great question. What happens if we record the committee's decisions in a voting memo that goes out to the NQF membership for voting on the committee's recommendation?

So, we – you will see a copy of that as it's going out for voting, probably, not before.

Male: And then it goes to the board for approval?

Angela Franklin: So – and then after voting comes back in, we'll tally those and we take it to the CSAC, which is the review board, Consensus Standards Committee that we have here that reviews those committee decisions of the standing committees and either, you know, (full-out) measures for discussion, or has questions back to the committee. Or more, typically, we'd look at the committee's deliberations and approve the measures for recommendation. They then go to the board which then modifies the decision of the CSAC.

On the CSAC call where the measures from this project will be considered, the chairs would represent the committee on that call, both – giving the committee a sense of each measures if there's questions, as well as any overarching things that emerge from our discussion of these sets of measure.

Male: And so when for next time that we, again, evaluate new measures again, is that next year or is that three years?

Angela Franklin: We – it's still not defined at this point. The outside dates would be three years, although it could be sooner, but three years is the outside time.

Male: So there is no likelihood of May 2015 meeting?

Angela Franklin: I cannot rule that out.

Male: OK.

Angela Franklin: Keep in mind that we do have, in this project, the trial measures that could conceivably come back before that three-year period. And there is accommodation for trial measures to come back to the Standing Committee for an ad hoc deliberation on them.

So that could happen, but we just don't know at this point.

Male: OK.

Angela Franklin: Sorry, we're just working on the voting results. I think they've come up.

Female: Yes, it is all voted and we're trying to (inaudible) the results.

Angela Franklin: OK. So, we'll have the results for you in a minute or two.

So for question number two, we had 13 members that voted yes, and four members that voted no. So, yes, the trial measure has been approved for continued testing. And, again, that's by a vote of 13 to four.

Any comments?

Ann Phillips: (Three) committee recommendation for reconsideration for measure 0662, if there's a committee wish to revote 13 yes and four no.

All right. And then do we recommend 0662 for endorsement? The committee voted 14 no and one – and three yes.

Angela Franklin: So, that result means that for 662, it remains a non-recommended measure.

Are there any questions from committee members about either of these measures or final comments?

(Marcy): Hi, this is (Marcy). My only concern is how the voting occurred? I just want to make sure that everyone felt that this– their vote for number four reflected their true vote had they have known the results of number three.

Angela Franklin: Not quite clear. You still have to vote whether you want to revote on the measure, which was the yes or no question. And then for number four, the question was whether the committee wanted to recommend 662 for endorsement. Because I just want to check, was everyone clear on that?

Male: Yes, I was clear.

(Marcy): I was clear. I just make sure everyone else was, too.

Male: Yes.

Female: Yes.

Male: I noticed it's kind of funny that 13 people wanted to revote it and that's still voted no.

Female: That's why...

Angela Franklin: I know, and I apologize I was a little change ways to kind of the voting.

Zoher Ghogawala: I'll just say – this is Zoher. I thought it was confusing.

Angela Franklin: Yes. Did you understand that you're voting not to recommend the measure when you cast your vote, or to recommend the measure when you cast your vote?

Zoher Ghogawala: I understood number four.

Angela Franklin: OK.

Zoher Ghogawala: But, I thought it was kind of arbitrary how you answered number three. So I said, "Sure, I'm going to vote because I was going to vote in number four." But I would have – if it was done in two steps, I would have voted against relooking at it.

Angela Franklin: OK. I see what you're saying. Thank you. That's very valuable input, I don't think we'll set this up in future request.

Very good. Again, apology for that confusion.

(Marcy), does that your question or did you have additional concerns?

(Marcy): As long as everyone is comfortable with how they responded to number four, I'm only concern if somebody responded to four, I'm thinking it really wasn't a vote. I thought we would vote whether to reconsider. And then if it came back that, yes, we would reconsider, then we would have another vote.

So, when I voted, I voted the way I would have voted. However, I just want to make sure everybody for number four.

Male: Yes, if your results were the opposite, if you had a majority no for the number three and a majority yes for number four, you ought to be in big trouble. But I think the way it would turn out here are OK.

Angela Franklin: Great. Thanks.

Thanks for that clarification. And I think we got some additional clarification.

Again, as we said for the measures that are not recommended, there were comments received on those. And typically, we do not have any – unless there's issues that the committee wants to raise for these not recommended measures, we would simply leave them as is. There will not be a committee response.

Are there questions about the not recommended measure 2521, Serum Urate Monitoring for Gout? 2526, Anti-inflammatory Prophylaxis with ULT therapy for Gout?

Hearing none, are there any additional comments either from our co-chairs, Kim and Roger, or the rest of the group?

OK. So just to summarize next step, Katie, could you run us through those?

Kathryn Streeter: Sure. So, actually before I do that, I just want to see if there are any members from the public that would make to – make a comment?

Operator: At this time, if you would like to make a comment, please press star then the number one on your telephone keypad.

And there are no public comments at this time.

Kathryn Streeter: OK. So, our project team here will summarize the discussion today and we'll be updating the comments and your responses to the comment and a voting draft report that will be made available for NQF members, during a voting period that will open up on September 2nd, it's a 15-day voting period.

We'll then be presenting your recommendations to our CSAC in October followed by (forward) ratification in November.

And we'll be sure to keep you posted on our – all of the steps as we progress through them.

And as always, if you have any questions or concerns, please don't hesitate to contact our project team here.

Any other questions?

I will be spending an email to the developers and to the committee members that will summarize the discussion today and include the voting results.

And if there aren't any other comments or questions, I think that will end today's call.

Female: Thank you.

Kim Templeton: This is Kim. I just like to thank everyone for the opportunity, it was fun working with you.

Female: Well, thanks to you, Kim...

Male: And (very) working with everyone. Thank you. I appreciate the great chairs, too. Thank you.

Angela Franklin: Thanks to you all...

Male: Take care, everybody.

Angela Franklin: ... and committee.

Female: Thank you.

Male: Thank you.

Male: Yes.

Female: Thanks. Bye.

Male: Excellent.

Female: Bye.

Male: Thank you.

Male: Bye bye.

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

END