

NATIONAL QUALITY FORUM

**Moderator: Adeela Kahn
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12:30 pm CT**

Operator: Welcome everyone, please note today's call is being recorded. Please go ahead.

Adeela Kahn: Thanks all, welcome to the Cancer Workgroup Call for Hematology and Melanoma. And today, we are walking through seven measures and the process will be that the lead discussants for the measures will open the discussion and give their highlights of the measure and their thoughts about the measure and any concerns and any questions they may have for the developer.

They will also make a note of those. And then we'll open it up for discussion by the full workgroup. And the first measure we're going to have up for discussion is Measure #378 and Dr. Chottiner is the lead discussant for that. And 378 is Documentation of Iron Stores in Patients Receiving - I don't know how to pronounce that.

Female: Erythropoietin.

Adeela Kahn: Therapy, thank you.

Dr. Elaine Chottiner: Okay, I need a little guidance about how exactly you want this to be done.

Adeela Kahn: Sure, if you could give your thoughts about the measure as you were evaluating the measure and your recommendation. And walk us through it and then we will discuss as a group what other people - folks on the group had to say about the measure.

Dr. Elaine Chottiner: So you want to walk through each impact and everything?

Adeela Kahn: Yes, that would be great.

Dr. Elaine Chottiner: Okay, so if we start with impact I think the prevalence of the disease isn't really well laid out here; how many patients actually qualify for supplemental erythropoietin? So I think it's moderate impact if I were guessing about the number of patients who are affected. The opportunity for improvement, I need your help. Under 1b.1 under the benefit the paragraph is totally nonsensical.

I think I know what they mean which is that if one is using supplemental erythropoietin you need to be sure you don't make the patient iron deficient. But that's not how the paragraph came out. But the problem I'm having is I don't understand the performance gap data and I wonder if you could walk us through exactly what those percentiles mean.

Adeela Kahn: Is there anyone from AMA-PCPI who can speak to this?

(Kim Chaney): Hey, this is (Kim Chaney) with the AMA. I guess I'll ask if any of our colleagues from testing are on the phone. So I'm sorry, we might be taking the calls in different locations and I'm not sure.

Dr. Samuel Silver: Because I had met -- this is Sam Silver -- I share this with Elaine. I had a very difficult time understanding the definitions of the data presented and so I really didn't understand these forms.

Dr. Elaine Chottiner: Yes, my sense from all of the measures that I reviewed is that the performance gap data all came from an analysis of what they submitted thus far on the PQRI and PQRF and that none of these data are readily available, so I need to take them at face value. I think they're saying that a certain percentage of physicians performed the measure adequately, but I don't understand how they go down in quartiles.

So I can't make any comment on the performance gap because I don't understand it.

Adeela Kahn: Okay, do any of the other reviewers understand it?

Joseph Laver: This is Joe Laver from St. Jude; I didn't understand it at all.

Adeela Kahn: Okay and Sam did you have anyone who could speak to the performance gap issue?

Dr. Elaine Chottiner: Well, I mean there are no data provided on performance gap other than those statistics that none of us understand. So I mean the question is are hematologists checking iron stores in patients who receive erythropoietin and whether that's happening or not is something we can't assess outside of the data from the 2008 measure.

(Molly): Hi, this is (Molly) from the AMA. We are trying to figure out a way to bring someone in from our testing team who can speak more to the performance data from PQRF. Thanks.

Dr. Elaine Chottiner: Okay, so if I go through that until they bring somebody the rest of the data, the citations for the data, the summary, there isn't anything there other than the 2008 and 2009 performance measures. So I guess we'll skip over that.

Going onto the evidence, the only evidence that's provided for this measure is the Clinical Practice Guideline on the one they post from the National Comprehensive Cancer Network. There's actually an American cited hematology guideline on the use of erythropoietin stimulating agents and checking on our stores is recommended, vital.

I don't know how else - I think it's the standard of care. So the question becomes I can't provide you with evidence. They haven't provided us with any randomized trials; all we really have are the guidelines.

So consistency, met benefits and that benefit isn't provided. I know what it is; it's not in the measure. And the rest of this is really something that they quote verbatim for each of the measures. It goes back to the NCCN guidelines. The NCCN guidelines use their own level of evidence and this one will fall into 2A which is based upon recommendations without a high level consensus - without lower level evidence of - but consensus.

So specific guideline recommendation, very straightforward. The use of supplemental iron in patients receiving erythropoietin simulating agents. The hard part about this measure is that it only requires that iron stores be checked. It doesn't require as the guideline would recommend that iron stores be repleted. So the measure doesn't go that far.

Reliability and validity, I think we probably need the AMA people there again too because I really don't understand how they're presenting the reliability and validity data. And I don't think it's a conflict of interest for me to say that my practice was one of the two that the AMA came out to audit to get these data. So I do know how it was done and I can tell you that if it would help the other members of the committee.

Adeela Kahn: Okay, is that in the - it's not clear in the form? Is that right?

Dr. Elaine Chottiner: I guess my - knowing how they did it in my practice, I'm not quite sure how the data were derived from that.

Adeela Kahn: Yes.

Dr. Elaine Chottiner: Because I mean basically my impression when they came to the practice was that I gave them the denominator. So I was able through our practice management system to pull out all of the patients who had a diagnosis of the myelodysplastic syndrome who had been seen in the office over the previous year who had received supplemental erythropoietin.

So those codes were easy to put together. And that was the denominator. The numerator was whether we had checked iron stores and that was somewhat difficult for them and they did go through electronic medical record and some of the hospital charts. And so that was the numerator. And I did not think that they were looking so much for our performance as they were just looking to see the data could be easily extracted.

And then after they did that part we did give them - we were able to pull the PQRI form again through our billing system so the patients where we had submitted a code and they could go back and see what we had submitted on the code was actually documented in our medical record.

So that was the process that they used, but again I don't really understand how that translates into the reliability and validity testing and it would be helpful if somebody could explain that to me.

Hello?

Adeela Kahn: I just wondered if someone from the AMA could speak to that or if they're still waiting, that's fine. You can go on with your discussion or recommendation on that one.

Samantha Tierney: (Angela), this is Sam with the AMA. We do have our testing staff, (Anne Hefford) on the phone now. So sorry, apologies for the delay. Thanks for your patience.

(Anne Hefford): Sorry that I'm late, so your specific question is about the ((inaudible)) that we were able to capture for the hematology.

Dr. Elaine Chottiner: Well, the first question is going back - how did you - what did these figures mean for the performance gap, so quartiles?

(Anne Hefford): So basically we take that information from the PQRF data and what it basically represents is the number of physicians that are actually submitting this information and whether submitting it - the performance that they're actually showing. So if you look at this particular measure you notice that most of the physicians land in the 90th percentile.

Dr. Samuel Silver: Excuse me, which paragraph - which section are you quoting?

(Anne Hefford): I'm sorry; this is Opportunity for Improvement 1b.2.

Dr. Samuel Silver: 1b.2, I see a Data Demonstrating Performance?

(Anne Hefford): Right and you asked for the gap in care, correct?

Dr. Elaine Chottiner: So the 90th percentile, what did 97.4% of physicians do?

(Anne Hefford): That basically means that 97.4% of the physicians who reported were in the 90th percentile. They basically were - 50% of the patients reported on did not meet the measure, but 97.4% of the physicians each time they were submitting accurately.

Dr. Samuel Silver: Accurately, but non-concordantly?

(Anne Hefford): Exactly.

Dr. Elaine Chottiner: Okay, can you explain how that translates into performance gap?

(Anne Hefford): Well, it's showing that there is actually a need for this measure because not everyone's actually performing at the standard or where they should be which is at 100 percentile.

Dr. Samuel Silver: So only 58% of the reporting physicians even though 97% of them gave good data, only 58% had concordant measures?

(Anne Hefford): Exactly, exactly. So 97.4% of them were actually reporting correctly, but 58% of those patients didn't actually meet the measure.

Dr. Elaine Chottiner: So they reported - the physicians reported that they did not meet the measure? Okay and then the other thing we're trying to understand on the reliability and validity data.

(Anne Hefford): Sorry, give me a moment. I'm going to flip to that section.

Dr. Elaine Chottiner: (2a.2).

(Anne Hefford): So for the Measure (2a.2), overall there was a 90% agreement that this measure is reliable based on the abstraction. And for validity, what part of validity are you referring to specifically? Which of the data?

Dr. Elaine Chottiner: Frequency distribution of ratings. I guess it's mostly the validity testing.

(Anne Hefford): Well, questions on how it works or is it the answers by the workgroup?

Dr. Elaine Chottiner: I guess it's actually the validity testing is not the issue, it was the reliability. So reliability you're basically saying that what was reported was reported correctly?

(Anne Hefford): Yes.

Dr. Samuel Silver: And how do you know that? Is that chart review or is that primary source review that you do?

(Anne Hefford): That's chart review.

Dr. Elaine Chottiner: That was what they did in my practice. They went through every single chart to see if what we told them was really in there.

Dr. Samuel Silver: So let me get this straight, the reliability depends upon your practice Elaine and then...

Dr. Elaine Chottiner: And Tim's.

Dr. Samuel Silver: And Tim's practice. So I make the comment that knowing both these practices, they were looking at reliability in practices that have incredibly high - would have a high expected rate of reliability and I don't think that that's typical.

Dr. Elaine Chottiner: And it was only 30 patients.

Dr. Samuel Silver: Okay.

Dr. Elaine Chottiner: So as to validity, I didn't have anything there. Identification - if we go down to 2b.5 then, Identification of Meaningful Differences and Performance. Again, no data other than the data from the earlier quality reporting initiative. And disparities, comparability wasn't done. Disparities in care, nothing identified here to look at disparities. The information that's provided in there is really not related at all to what the measure is testing.

Use in public reporting, again this is kind of a cookie cutter thing that they put in for all the different measures. And I mean basically I'm skipping to the end.

The problem I had when I went through this is that while I might feel that it's very important to document and to supplement iron in patients receiving erythropoietin stimulating agents, if you had me go through this form as we did in our initial conference call and judge it on the basis of impact, for impact I'm not sure I have enough data. It doesn't meet the evidence criteria simply because there's not enough presented in the measure.

And the performance gap, there's really no information other than the previous PQR data. So I have a problem with the measure as it's structured right now.

Adeela Kahn: Okay, thank you. Are there other comments from the workgroup members?

Robert Miller: Yes, this is Bob Miller. So this is a very generic comment, but I guess the uncertainty I had is since all of these measures have previously been approved by NQF. I mean, these are all reviews if you will if I'm understanding this correctly.

Adeela Kahn: That's correct.

Robert Miller: So I guess that clearly colored my review of the one measure I was assigned to in all of them that I commented on which is to say that like I think I'm hearing my fellow workgroup

members voices we had a lot of uncertainty as to whether we were simply to go by the materials presented in this one Word document. Obviously influenced by our clinical judgments fort those with us clinician.

But what assumptions are we going to make that, you know, some - like panel at NQF three years ago went through the same process and must of assumed that at some point in time these measures met the appropriate criteria, that they were of high impact and they were appropriately reliable. So maybe someone from NQF could speak to that before we go any further.

Because I made my decisions based a lot on knowing that somebody else had blessed this before me.

Adeela Kahn: Sure, what happened was this is a maintenance measure as you noted and our criteria has changed a bit in the interim. It's a little more stringent now probably than at the time that this measure was considered and endorsed initially. So keep that in mind. And the measure has to be reviewed on today's criteria.

(Anne Hefford): And we do expect that the measure developer provide all the information into the measure submission form, but we also put it before you all because we expect that you have outside knowledge that may incline you to support the measure, not support the measure. That information you may want to make the measures out there aware of if you believe that it's missing something that could strengthen the measure that would make it meet the current criteria.

Same as if, you know, the studies that are out there that wouldn't support the measure we would ask that you raise those to the attention of the developer and the Steering Committee too. Does that help at all?

Dr. Elaine Chottiner: I guess. One of the issues with this particular measure is that because the FDA has a REMS program for erythropoietin stimulating agents, the myelodysplastic syndrome fall outside that. It doesn't need to be part of that program. So we kind of picked the only area that doesn't fall under such stringent control.

But, you know, at the University of Michigan we have for the other patients a very robust program that specifically manages the anemia patient receiving these ESAs and those patients have monthly monitoring of blood counts. They've got monthly monitoring of iron, they've receive iron replacements. So there is a very good quality program in place, but it's mandated by the FDA. So I'm not sure if that really counts as a quality measure.

And I'm just no sure about the importance of taking this one separate group of patients and addressing it differently. Does that make sense?

(Anne Hefford): Yes it does and that's certainly something that we would ask you and the rest of the Steering Committee members to really weigh as you make your decision.

Dr. Elaine Chottiner: Sam, do you have feelings about this measure?

Dr. Samuel Silver: So there's a couple of things. I mean, one is that these are expensive agents given to a group of patients that do fall outside of FDA labeling criteria. That is patients with myelodysplastic syndrome.

And I think more and more because of the stringency of the FDA (REMS) criteria, I think a higher and higher percent of patients around the country are - with hematologic diseases are actually - hematology and oncology are getting ESAs because of MDS. And because these measures fall outside of the REMS, that may give it even more weight that there be some oversight about whether physicians are appropriately giving ESAs.

That is they should not be giving ESAs to any patient with MDS who's iron deficient because that would be a - using ESAs inappropriately. You know, I should say and you didn't ask for this about conflicts of interest, do you care about that?

Dr. Elaine Chottiner: Yes we do.

Dr. Samuel Silver: So I should say two things, one, I'm Vice Chair of the Board of Directors of the NCCN, a non-paid position. So maybe I - so that's one; and number two, I'm a consultant for Amgen that makes ESAs. I don't give talks, but I am a consultant for Amgen. And actually I wrote - I was co-author of the first meta-analysis that said that there could be major negative effects with cancer patients with these ESAs.

So I'm not necessarily a positive person, you know, who consults for Amgen in this light, but I thought I should say both those things. So number one, I think the very fact that this is not part of the REMS may make it more important. Number two that at least older data -- my surprise because there was 68% non-compliance with this measure -- says that there is a huge gap and inappropriate use of ESAs for patients with MDS.

I think that the measure could be further improved because looking at this document it doesn't talk at all about nor is there anything in any guideline that actually talks about the frequency of determining iron stores because you could've done iron stores two - you know, 11 months before. Is that adequate for starting ESAs? That remains unsaid and that would be considered concordant. That's number one.

And number two, I am concerned about the availability of the appropriate data and electronic health record system because even though you might be able to - you would be able to determine whether ferritin was performed or iron and total iron body capacity. Being able to determine

whether there were iron stores on an appropriately stained bone marrow aspirate might be very difficult because that would part of text in a pathology report.

Dr. Elaine Chottiner: One would hope that all that information would be available because we collect it for all the other patients getting ESA.

Dr. Samuel Silver: So I do understand that, but I don't know if it's collected in any sort of a standardized form, you know, that would be part of a electronic health record system. I don't know that answer.

Dr. Elaine Chottiner: Well, you know, when they came - our practice is a mess because our practice over there had a document retrieval system. So when they went to look for the ferritin's they had to leaf through pages of scans and laboratory tests.

Dr. Samuel Silver: But my bottom line is I think that even though this does not rise to a metric that looks at as a clinical trial. You know, we know the biology of ESAs in patients who are iron deficient. We know that they should be iron replaced before they get ESAs and that some understanding of the patient's iron stores should be measured before these expensive agents are and that there is apparently a major gap which actually surprises me.

Dr. Elaine Chottiner: And I don't disagree with him, the problem for me was when you make me go through these forms and I get to a certain checkbox and it says stop. You know, I agree that it's a quality measure. It doesn't fall in line with the checkboxes so I don't know how stringent you're going to be on those criteria.

Adeela Kahn: We would say that, I think as the previous speaker was saying, if it is good practice and it makes sense that the measure meets the patient need even without randomized controlled trials, test data and things like that and the measure is strong enough as written, that can be taken into consideration.

Dr. Samuel Silver: Now, there is a part, you know, kind of a Part B that was unsaid in this measure that I do agree with Elaine. That, you know, and it doesn't ask this and, you know, today when we were asked to deliver measures it didn't necessarily ask us to have a measure and then a follow-up Part A and Part B.

But Elaine's question is okay, so the patients, you've done the tests and the iron level is low. You know, and you give the ESA anyway. You know, you basically fulfilled the criteria of having measured it. Should there be a Part B that says, you know, if the ferritin is less than such -- I think it was 100 -- you know, if the iron over TIBC is less than 20%, if the marrow doesn't show stainable iron in the erythropoietin series, then you need to replete the iron, replace the iron before administering ESAs?

So that's not part of this and so that would be kind of a multi-part, you know, a quality measure. But that's not what was asked for initially and I don't know what to do with that.

Adeela Kahn: Okay, could we recommend a modification to the measure to say that it requires documentation of adequate iron stores within four weeks of initiating ESAs?

Dr. Samuel Silver: I think that that would be reasonable.

Male: I agree.

Male: Yes.

Adeela Kahn: Okay, we have a consensus.

Male: I'm all in. It adds in a lot more useful specificity I think. It turns this into a clinically useful metric as opposed to a curiosity.

Male: I agree.

Adeela Kahn: Is someone from AMA-PCPI, could they speak to that if that's possible?

Samantha Tierney: Yes, this is Sam Tierney. I mean, that's something that we could take back to the workgroup. You know, the measure was originally developed for use in the PQRI program which is the program that takes place on an annual basis which I think is some of the - it explains some of the reason that the measure looks at it on an annual basis if you will.

But I think that we've seen with the move of the PQRF program to registries and the use of EHR's that we have more capabilities now to define certain time frames. And so that's certainly something that we could take back to the workgroups for consideration. We do have a process by which we have to consider changes and so we have to get the clinical expert panel that originally ((inaudible)) the measures to agree to such changes.

Dr. Samuel Silver: So just so I'm not the only person from the American Society of Hematology who is talking about this, Tim what about that suggestion?

Dr. Timothy Miley: I think it's a fine suggestion, you know, if it's workable to do that. And when you look at numerator and denominator analysis, you know, I think that's part of the problem why this got hung up is that simplicity is much more workable typically and so this is - you're adding a two step process and whether that's workable under the way that they look at this I don't know.

But obviously from a clinical standpoint that makes more sense. And so just add since I got the floor just for a second, I'm unaware of gap data and Elaine and Sam are probably more in touch

with that, but just other sources, other studies that would provide this data, I think in and of itself this is an important piece of information just addressing gap information that probably wasn't known before.

So in and of itself the measure serves that function. It's just the question how does one respond to it?

Samantha Tierney: This is Sam Tierney with the AMA, if I could just add one other thing to Dr. Miley's point. I know that there was some concern related to the data that we presented for the performance gap, but unfortunately there is not any data available in the medical literature that speaks to a gap related to this particular practice.

So the only data that we really have available to us is from the PQRS program and I can certainly understand the concerns with how that was presented and perhaps we could modify it so that it's more clear. But I just wanted to make everyone aware of that and I think for many of the other hematology measures there really just isn't data available from the medical literature so we have to rely on the data from the PQRS program to support the measure in terms of a gap or opportunity for improvement.

Dr. Timothy Miley: And I mean kind of a general comment about the practice of hematology is that we, you know, see many low incidents. You have all of these small silos and we do not have a national database, you know, that looks at these things.

And so the issue of gap analysis in hematology and I would say my melanoma colleagues on the phone would have to talk about this that - and I was Chair of the Quality Committee for ASCO a little while ago that gap data for oncology in general, at least medical oncology is lacking and is being accumulated as we speak. So it's a tough issue.

Adeela Kahn: All right, any other comments about the measure? Any recommendations from the workgroup - initial recommendation on this measure?

Dr. Elaine Chottiner: Well I guess -- this is Elaine -- my recommendation would be to improve, but to recommend if possible that modification.

Male: Yes.

Adeela Kahn: Okay, all right. Thank you very much Dr. Chottiner. We went a little bit out of order. We'll go back to Measure #377, MDS and Acute Leukemia Baseline Cytogenetic Testing Performed on Bone Marrow. And Dr. Alvarnas is our lead discussant for that measure.

And Dr. Alvarnas as we talked about a little bit earlier just we would like you to just give your highlights of the measure, walk us through it a bit and give us your concerns and your initial recommendation and then we'll throw it open for the group.

Dr. Joseph Alvarnas: Great, I will - I'm sorry, I'm trying to pull this up on my computer. I apologize, I've been on the other side of campus when the meeting started and I apologize.

Adeela Kahn: We had a lively discussion on 378, no problem.

Female: If it's going to take you a minute, we can probably jump to another measure. It's up to you.

Dr. Joseph Alvarnas: It'll be okay, I'm sorry I'm just - I had been locked out of my computer when I got back into my office. So yes if we could do another measure next, that would be really helpful. I apologize for that.

Adeela Kahn: Okay, then we'll move onto to Measure 379. Is Dr. (Dale) on the line? No, okay we'll then let's move onto #380, Multiple Myeloma Treatment with Bisphosphonates. And Dr. (Fields) had already spoken to us, she's not able to join this particular call, but she did provide her comments to us and we'll read them out to the committee.

Male: So which doctor - is (Fields') first name?

Adeela Kahn: (Karen).

Female: (Karen).

Male: (Karen Fields), okay.

Adeela Kahn: (Karen Fields).

Male: Tell the whole world, you know, everybody.

Adeela Kahn: Okay. So she provided us her written comments and we'll go ahead and read those and ask the group for discussion.

Female: So for importance Dr. (Fields) - under high impact she said that it had moderate high impact. For opportunity for improvement there was high and her rationale was that the authors of the study site that this is an issue of high impact and that it affects large number of patients, approximately 20,000 patients diagnosed annually.

And under the opportunity for improvement the authors note that there is a significant performance gap in sight that during the previous monitoring period 47.4% reported did not meet

the measure. She said that this is a health outcome and when rating the evidence she said for quantity was moderate, quality was moderate and consistency was high.

She provided rationale saying that the supporting literatures of moderate to high quality and quantity with the following limitations. Randomized trials include patients diagnosed with lytic lesions and the supporting literature supports treatment in a different patient population than the study measure. And then remission does not count for the presence of only lytic lesions, but could include osteoporosis and osteopenia.

However, it is rational to administer these drugs in patients with MM, not in remission given the natural history of the disease. Several randomized trials include the use of an oral medication. Let's see, excluding criteria are the absence of bone disease, dental disease, renal disease may not always be well-documented. So in terms of the evidence she did raise that it met the decision logic.

Going looking at scientific susceptibility, she said high for reliability and validity testing and provide a little bit of rationale saying that previously endorsed measure - this is a previously endorsed measure. The interval study data demonstrated a high degree of reliability and validity with the measure. Reliability assessments of exceptions and other parameters concern the utility of this measure.

For usability, she rated it moderate. And then looking at feasibility, she said it was highly feasible and recommended the measure for overall endorsement. So we're going to open it up to the rest of the workgroup and see if they have any concerns or issues.

Dr. Elaine Chottiner: This is Elaine; I agree with her assessment. My only concern was - and again it has to do with how often you look at the measure that's giving a bisphosphonate once a year probably not meeting the measure, but that's how it's written.

I think the standard of care would be to give the bisphosphonate monthly or some people think every three months. That's being looked at in clinical trials, but once a year doesn't really meet it.

Dr. Robert Miller: I agree; this is Miller.

Female: Anyone from the AMA-PCPI? Is that a change that you could make?

Samantha Tierney: This is Sam Tierney again. So again, you know, we'd have to take that back to the workgroup for consideration. I know in the discussions with the workgroup there was, you know, agreement that once a year is certainly not enough and that this is a treatment that's usually given on a more regular basis, you know, perhaps monthly.

However, given the focus on trying to have it included in a program that assesses things annually, you know, we kind of made some modifications. But I think it's something that we could certainly reconsider and take back to the group for consideration.

Male: Okay with me.

Male: Yes.

Adeela Kahn: Okay, any other comments from the other workgroup members with the measure?

Dr. Robert Miller: I have a question, this is Miller. I have a question, this is 2b1.1 under Validity. The question is describe how the specifications are consistent with the evidence cited. So I just don't understand your answer and there were several. And I'm saying this more because this applied to several of the measures including the melanoma issue that I looked at.

The answer while I know what you're getting at is sort of non-responsive to the question. There's a difference between our measure and the evidence. Our measure focuses only on myeloma. I don't think that's - I didn't that's what the question's asking. The question is does this measure test what it's supposed to test, right?

You know, the validity testing that follows is the data that's before it's to justify that it does, but maybe I'm just totally missing this. But it seems like that's not really - the question - my understanding of validity is, is this a valid test? I'm defining it with a word, but I mean does this test show us - does this measure define what we're really getting at here?

And I don't know that I can see this from these documents which goes back to my earlier concern that since I know that this is a reanalysis of previous work that's someone's looked at, you couldn't draw that conclusion just from this 19 pageWord document. So I don't know if anyone else had the same concern, but I just wanted to share that before we got too much further in this.

Adeela Kahn: Is the measure developer there? Can they speak to that, AMA?

Samantha Tierney: Hi, this is Sam Tierney again. I guess I would just say our interpretation of that question has been different. You know, although it's in the validity section, the question seemed to us to be asking how the specifics of the measure, either the measure focus or the target population are consistent with the evidence which is actually similar to a question that's asked in the previous section.

So we have specifically answered it in the same way. I think it would be helpful if that is not the intent and NQF staff could give us further guidance of what that question actually means. I think that we had been interpreting it differently.

Adeela Kahn: Okay. In the validity section it's basically if the measure's speaking to what it's purported to measure. And that's kind of the response that we're looking for in that section.

Female: The reliability section is they're actually asking you to pull out whether the - for example, the data elements are reliably captured in a way that you specified things like that. But validity is the overall measure as it specifies capturing what it is intended to capture.

Adeela Kahn: Okay, any other workgroup comments on this one? We've already heard about - some of workgroup about some questions around strengthening the measure with the administration of the bisphosphonate. Anything else that we have to add to that?

Okay, so the overall recommendation I think that we have from Dr. (Fields) was a recommend. And I just wanted to check with the rest of the committee how they feel about the measure. Recommend with or simply recommend?

Female: Recommend with is possible.

Adeela Kahn: Okay. All right.

Female: Dr. Alvarnas, are you ready for 377?

Dr. Joseph Alvarnas: Ma'am I apologize, between a new computer and a broken foot, I think I'm ready to go. So I'll start out with a disclaimer which is in terms of conflict of interest I'm on the NCCN ALL Panel. I'm Co-Chair of that; I don't have any relationships with any pharmaceutical companies.

I thought that this measure was with respect to myelodysplastic (discriminately) acute leukemia's, an important one; this is baseline testing of the bone marrow karyotype prior to initiation of therapy. It is defined at least in the measure as being relevant to all patients with myelodysplastic

syndromes and acute leukemia's. The numerator were those who actually have that testing performed upon the bone marrow.

The denominator would be all patients with the aforementioned diagnoses. And just going through your list, in terms of the evidence for this I think this is something that is broadly supported and the levels of evidence would include not only the numerous papers that have used karyotype as an important stratifier amongst risk groups.

And those patients with AML as well as those with myelodysplasia, it's included in both of the I think most relevant prognostic scoring systems. The one based out of the World Health Organization as well as the IPSS. The karyotypic pattern is referred to in the World Health Organization classification for both of these disease entities as a way of further describing and achieving specificity in that entity.

And I think broadly throughout a number of studies including randomized trials these karyotype has played a role in outcomes differences amongst groups of patients. The other conflict of interest that I'll tell you about is that I'm a bone marrow transplanter.

And with respect to transplant which plays an important role in the NCCN algorithms for the management of both of these entities, karyotype plays I would say if not the central role, an extraordinarily important role in deciding which path of treatment, conventional dose, non-transplant therapies versus transplant therapies are offered to patients who would be otherwise considered hematopoietic stem cell transplant candidates.

So I do believe that there is a broad and relatively deep body of literature that supports this as a metric. I think that in terms of the actual measurability I would have some concerns about how best to abstract out those data amongst patients who've had this diagnosis and the assessment.

So in terms of a practical implementation I'll have questions for you in that regard, but I think this is supported.

One of the things that I was concerned about in the description of the measure is in terms of the brief description of benefits, at least as the metric is articulated in the header, it's myelodysplastic syndromes and acute leukemia's baseline cytogenetics testing and much of the body to which the metric refers, much of the subsequent supporting description refers only to myelodysplasia.

So I think one of my first concerns about this is I think we want to be very careful how we define this. If this is myelodysplastic syndrome and acute leukemia's then we're talking about a lot of different entities. Myelodysplastic syndrome, acute myelogenous leukemia, acute lymphoblastic leukemia -- all entities for which I think karyotypic evaluation plays an extraordinarily important role, but as the measure is defined it fails to articulate all of those elements.

If we want to be particular to MDS then we should define it as MDS or MDS that has evolved to acute myelogenous leukemia. If we want to apply it broadly and I would be very supportive of that because I think this is important then I think we want to be careful in all the supporting documentation that it reflects that breadth of the measure because there's some inconsistencies as this is written to whom it refers.

And I think that's reflected - that inconsistency is reflected in the differences between the title, between the articulated numerator, the denominator and then the subsequent description of the metric. So I think in terms of importance, rationale and body of evidence, I think all these things can be supported.

On the other hand I think that we have to be very, very careful how this metric is defined and I have concerns with the lack of specificity or at least the inconsistency to which the different disease entities are referred to in the body of this metric.

Dr. Samuel Silver: This is Sam Silver; I think that the point of the view of the American Society of Hematology, we wanted to include myelodysplasia and all acute leukemia's AML and ALL and not just those that derived from a previous myelodysplastic syndrome. And therefore the appropriate ICD-9 or in the future ICD-10 codes should parallel that.

Dr. Joseph Alvarnas: I agree with you and I would be extraordinarily enthusiastic about that breadth of definition because I think for all those disease entities and again I'm speaking selfishly as a transplant. I find many patients in the community in part mismanaged because their risk at the time of diagnosis was never adequately assessed due to a failure to do this very central and important element of patient evaluation.

So I'm a very enthusiastic backer of what you just articulated.

Dr. Samuel Silver: And actually that's exactly where this came from. It actually was led by, you know, more by the acute leukemia's and MDS for that very reason. I think because tertiary care centers both those taking care of just management of acute leukemia and those doing bone marrow transplant often receive patients that started therapy in the community without appropriate cytogenetics being obtained.

Dr. Joseph Alvarnas: I agree and sadly I see that way too often. I think this is a really important measure and it's one that I would with a great deal of pride be able to take to our hematologists. I think we would be very enthusiastic backers of this.

Dr. Elaine Chottiner: This is Elaine; I can tell you that there was a technical problem with them because the PQRI measures were office measures. So when the auditors came to our office and they asked me to pull from our practice management system a list of patients - Medicare patients who

had a diagnosis of acute leukemia who were seen in the office. I came up with three patients. And I think Tim you can speak, but I think in Tim's practice they came up with virtually none.

Truth of the matter is that most of those patients present to the hospital and rarely leave it aren't seen in the office very often. So I think it was not so much a problem with the quality of the measure as with capturing that patient population in an outpatient setting.

Dr. Joseph Alvarnas: Sure and I agree with you there. I think the practical implications of adequate data capture are tough, but god this is an important measure.

Male: This is something where I thought that the measure actually emphasizes MDS and not the leukemia. So the language, that certainly needs to be changed.

Dr. Joseph Alvarnas: I agree and that was my big problem is I love the header. I read it and then I got further into the body of the metric, it combed down very rapidly on MDS and I think it really would achieve its greatest importance by redefining it or changing its description to include patients with MDS, AML or ALL.

Male: So I would - if one wants to be as inclusive which I fully support with maybe putting MDS at the end because that obviously is a much broader thing.

Dr. Joseph Alvarnas: Sure, I agree with you. I mean I guess the only thing about putting MDS up front is if you're looking at the capture ability of the data you probably are getting more - a higher percentage of the MDS patients evaluated as outpatients.

Male: Right.

Dr. Joseph Alvarnas: Where as the acute leuk's will end up the ER or something. I mean maybe that was the rationale, but I agree 100% with what you just said.

Dr. Timothy Miley: Yes, this is Tim Miley from Park Nicollet with ASH. I agree with Elaine, I don't remember our actual capture rate when I first did our run, but it obviously to get your best return and to get as many of these patients involved you have to be willing to go into the notes because some people have had their genetic analysis in the past. Obviously that's typically stated it's part of their overall assessment in their clinic visit.

But that requires obviously drilling into the actual text of the reports which is more difficult than just grabbing numbers off of the lab data sheet. So if there is an accident report that exists that's unique and is part of that report then obviously it's easier.

Dr. Elaine Chottiner: A more robust and straightforward measure if it were combined to MDS. The problem on the other side, it's very difficult to collect the data.

Male: It might be more of a challenge, but I think your metric is a lot more meaningful and important if you include all the entities rather than just MDS.

Adeela Kahn: So we heard a couple recommendations about the focus of the measure and possibly setting. Is there somebody from the AMA-PCPI that can respond to those two issues?

Samantha Tierney: Yes, this is Sam Tierney. So the influence of the measure is that it would be more broad and would include patients with MDS as well as acute leukemia's. And the specifications are constructed, you know, according to that intent. You know, I apologize that the form didn't and I certainly see the comments that the form really only seemed to focus on MDS and certain instances.

So clearly we need to add more information from the guidelines for the acute leukemia's. But the actual intent is that the measure is more broad in focus. And with regards to the comment about the capturability in office settings, I think that's a good one and that's something that, you know, we can certainly confirm and unfortunately our specifications staff aren't on the phone who are much more familiar with the coding that's included in the measure.

But perhaps if we made some modifications to the codes that are included because I believe they are all codes for office visits, then perhaps it might help with capturability and some of the feasibility concerns. So that's something that we could certainly consider.

Adeela Kahn: Thanks Sam.

Dr. Samuel Silver: Yes.

Adeela Kahn: Is there - I was just saying thank you to Samantha. But is there any other discussion on this in terms of a recommendation then?

Dr. Robert Miller: So this is Bob Miller. I put (eyes) for the quantity, quality and consistency of evidence question. What does this one see? Because, you know, again I don't want to be a stickler for the rules, but none of those questions were answered in this piece of paper. I mean, first of all this is not my area of practice, but I absolutely agree with the science behind it.

You got to do this, it's important, it needs to be measured. So there's little doubt about the face validity and the usefulness. It's just, you know, if all I had was this Word document, 1c.5 is not answered at all. 1c.6 which is the Quality of the Body of Evidence is non-responsive. And 1c.7 says a statement that's true, but it doesn't really answer the question either.

So if our job as workgroup members is to analyze what's presented before us, I say we haven't been given enough information. I mean, there's no answer to quantity of studies. If we're going to require for all the measures, we should require that for this or I mean maybe we can vote not to do that and I don't want to speak out of turn. This is my first time through. But that was my concern about several of these.

Male: But I mean just having reviewed this I agree with everything you said, I thought that it needed to be augmented in the exact ways that you said because the data do exist. It's just a matter of articulate them much more fully. The document was thin.

Dr. Robert Miller: Agreed.

Dr. Samuel Silver: So this is Sam Silver, I just have to say that last night was the first time I read these documents. So I don't necessarily disagree with the need for additional information.

Dr. Timothy Miley: Yes, this is Tim Miley. I agree, I think there's more out there that could be provided obviously if required. If needed, it's there.

Adeela Kahn: Okay, thank you. Any comments on that from the AMA-PCPI?

Samantha Tierney: This is Sam Tierney, I'm sorry to be speaking so much. I guess I just have one comment in general. And this is for the Steering Committee to know for these forms, but also for other forms. We at the AMA-PCPI have a methodology of basing our measures on clinical practice guidelines.

Over the past 12 years of activity that's been our focus and primarily because we recognize that individual research studies might come out, but then later are contradicted by other studies. So

we are challenged to answer the questions about quantity, quality and consistency because all that we have to answer those questions is what is provided in the guidelines.

And the NCCN guidelines do have a rating scale, but they unfortunately don't get to the level of detail that would enable us to answer the questions on quantity, quality and consistency. So just as a general comment, you know, because of our reliance on guidelines, answering those questions when the guideline developer doesn't provide that detail is a little challenging for us.

Male: Something that may be of help is that at the end of those NCCN guidelines there's a bibliography and even sometimes the text portion of the NCCN metrics - or measures rather will have in articulation of numerators, denominators and data to support that. I'm more familiar with that with the ALL guidelines in terms of the exact papers that are cited, but for the others they're also there and that may be helpful in fleshing out the measure further.

Dr. Samuel Silver: So this is Sam, I have to agree with that. Each of these guidelines has a manuscript appended to the guidelines that often has a two or three, you know, pagedescription of probably just kind of the things that you want and, you know, what's the bibliography that goes along with important references. So it's there, you just need to jump to the manuscript section of the guidelines.

Dr. Elaine Chottiner: Okay, I might just do that. And often I couldn't find any support in the bibliography either. It wasn't directly related to the measure.

Dr. Samuel Silver: Well, so if you're dealing with the cytogenetics there might not have been a - no reference to that, but there will be, you know, discussions about, you know, 15/17 translocations. So it's an inferred about why that's important.

Male: Yes and I can tell that in the ALL guidelines that in fact that is there.

Adeela Kahn: Okay, well on this one I guess we'll ask for an initial recommendation on it and then we might be able to follow up with the developer offline about what's doable.

Male: If they want to contact me I'd be happy to help in any way if that's allowed.

Adeela Kahn: Certainly, certainly. So with that in mind I'm hearing - well I'd like to hear the sense of the committee.

Male: I guess my sense is that of this metric provides at least the skeleton for something that would be appropriate, but it needs to be more fully fleshed out prior to consideration of approval I think.

Adeela Kahn: Okay, all right.

Male: I agree, I think if we're going to require quantity, quality descriptions within the document for all the measures it should be applied to this one.

Male: I agree.

Female: Agreed.

Adeela Kahn: Great, thank you. Okay so we'll move on with that, we'll move onto #379. And that's measure, Chronic Lymphocytic Leukemia Baseline Flow of Cytom...

Female: Cytometry.

Adeela Kahn: Cytometry, sorry. I'm tongue tied today. So Dr. Chottiner has agreed to start us off with this measure and also we'll open it up to the group.

Dr. Elaine Chottiner: I mean I can go through this really quickly. I mean, some of the shortfalls are the same ones we've been talking about over and over again that are more technical. It is high impact; it is a study that needs to be done. The only concern I have again this is because the auditors came to my office is that it didn't matter when the flow of cytometry was done so we had patients who had a diagnosis of CLL because it doesn't specify new diagnosis for whom we were looking for flow cytometry reports from 15 years ago.

So it isn't really a quality measure if you're doing it that way. So somehow it needs to be for a newly diagnosed or before initiating treatment because otherwise the tests can be done a decade before the measurement period.

Male: So you're saying someone can have a normal flow ten years ago when they have a white count of 12,000 or whatever? And then ten years later someone's treating them for CLL without repeating the flow and they really don't have CLL at all, they have CML or whatever and that would still meet the measure?

Dr. Elaine Chottiner: Well yes, I mean we have patients that we follow in ten years who actually never require treatment. But if they were seen in the office in that measurement period they had CLL, we would look back and see if we did it ten years ago and we would check off the box.

Male: Okay, I agree.

Dr. Elaine Chottiner: I don't know if that's what we were supposed to be doing, but we and I suspect many others did it. So I think that if you're going to look at an intervention it should be done within the period of the reporting. Does that make sense?

Dr. Timothy Miley: This is Tim Miley, can I make a comment?

Dr. Elaine Chottiner: Yes.

Dr. Timothy Miley: I think, you know, when this program was initiated seven years ago and this metric was written, I think that probably was acceptable in some ways just for the purpose of the data capture. I think that as you move forward seven years later and it's out there and you're seeing new patients, I think that in some ways, you know, to modify it at this point may be reasonable.

Because of the nature of the disease, you know, people can present with marginally elevated white blood cell counts that need quantity to criteria before CLL can be done and it can, you know, be consistent with CLL, but decisions obviously can be made not to treat at that point. And you're not necessarily going to repeat the flow in five years when the patient finally gets to the point where you want to treat them.

So I think that it's just as valid that you did the flow several years ago as long as there's been continuity of care along the whole way. And you know what your disease is because the point of this is to make sure, number one, they've got a neoplastic disease; number two, it really is CLL and not something else that's mimicking that, so.

But if somebody was involved in this I see it's reasonable to say that - you just change the denominator then, you know, newly diagnosed individual I don't think that really diminishes the importance of what this is trying to get at.

Dr. Elaine Chottiner: If you've got a denominator though that - well, how can I put this? You've got patients that you're seeing over the course of the year and you're looking at testing that you did ten years ago. The testing was done before the period in which you're even measuring the quality of intervention.

Dr. Timothy Miley: Well, I think are we saying that we're looking for a flow that makes the diagnosis of CLL, not just that they had a flow done? Because the way it reads is patients who had a baseline flow cytometry study performed. That's it, right?

Dr. Elaine Chottiner: But if you're trying to measure quantity and how quality evolves and improves over time it's hard to give somebody credit or debit for something that they did ten years ago. There's not a time sync.

Dr. Timothy Miley: True.

Dr. Elaine Chottiner: You can't really measure improvements when you're doing it that way.

Dr. Timothy Miley: But I think the real question is whether you know what you're treating at the time you make that decision or not to treat. You make the decision to treat or not to treat. Do you know what this entity is? And again, you know, this is built such that you look once a year to see if that was done in the past and then once a year you had to respond yes or no, we know what this is.

So not having the quality is this is a person with an elevated lymphocyte count, I'm assuming this is the CLL. So I think whether it was last year or the year before it's somewhat, you know, not the question. But I can see your point in that, you know, especially where this started. It's like, "Well I did it 20 years ago so I'm going to take credit for it now." That does seem a little nonsensical I guess in a way.

Dr. Elaine Chottiner: But it's not showing an improvement in quality care really. Improvement is - I mean, over time do we get better at doing things?

Adeela Kahn: Do we have a measure developer on the line to respond to some of those questions?

Samantha Tierney: Yes, this is Sam again. I guess I'd just go back to the comment I made earlier about when the measures were developed they were developed for us in the kind of - the PQRS program which requires that the denominator be identified through like simple claims, administrative claims data. So there was no way to identify patients with a new diagnosis.

So, you know, obviously now in giving the, you know, capabilities of EHR and registries we might be able to consider modifying the measure to focus only on new diagnoses. I think the point about quality improvement over time is a very good one and certainly something we could consider.

Male: Do you know what the baseline compliance with this measure is at this time? In this document, I'm sorry maybe I missed it. So when I looked at it earlier I don't recall what the percentage is.

Samantha Tierney: This is Sam again, I'll just say from the 2009 data from the PQRS program which is the most current data that we have available, the rate of performance - the mean performance rate was 92.59%. Unfortunately data regarding the range is not available so, you know, it's difficult to say anything more beyond the mean rate which was what was provided to us.

Adeela Kahn: Okay, all right.

Male: I think at a pretty high level under your current numerator and denominator, that's going to be hard to ratchet that out.

Dr. Samuel Silver: Right, so if that indeed is a valid number, if it is that high, should this metric be retired?

Samantha Tierney: Yes and that's actually something we would composite to you all is if this measure - is there room - is there opportunity for improvement in performance of the measure?

Male: I think you've heard that rate a second ago. I mean, the measure as it stands it would be hard for us to see improvements. But how people utilize those data and whether or not they're the doing the measure or rather using this intervention prior to initiation of therapy are actually using risk profiling based on flow cytometry in terms of therapeutic decisions, that might be of more added value than something we're already performing at greater than 90%.

Dr. Elaine Chottiner: What I'm seeing on page2 of this measure is there's a gap in are as shown by the 2008 data, 38.32% of patients reported on did not meet the measure.

Male: And that's a different story then, yes.

(Douglas Tipas): Hi, this is (Douglas Tipas) at the AMA. One of the things I wanted to just say is I believe these are the average performance rates so they take the performance rate for each physician and average them where as we're not looking at the weighted average.

So if some doc has a large number of patients that they're missing the measure on or conversely, you know, one doc has a large number of patients that they're meeting the measure on, we're not capturing that sort of variability with that metric. So I just wanted to keep that in mind when we're trying to think about whether or not the measure should be retired or not.

And I believe that this program is also a voluntary reporting program. So that's in some sense, you know, not a representative sample of all the physicians who could or would be using this measure.

Dr. Elaine Chottiner: Which goes back to the fact that these are the only gap data, they're not very reliable.

Female: Just given the time I think we're going to try to move onto the next measure if we can. That would be Measure 551, Melanoma Coordination of Care.

Dr. Samuel Silver: So this is Sam Silver, I think ((inaudible)). Thank you very much for allowing me to participate. I think I'm going to sign off at this point.

Female: Thank you.

Female: Thank you. And we had Wendy Tenzyk as an assigned lead on 551?

Wendy Tenzyk: Yes, hi this is Wendy Tenzyk. And just to explain to the rest of you I don't have the medical background you do so I appreciate the fact that I got a very much less technical measure to review. I administer a health plan for about 100,000 retirees in the state of Colorado, so that is how I arrived on the Steering Committee.

So again the measure, I appreciate the fact that it's a more - a less technical one and one that is certainly we look at in terms of coordinating care. So the measure being that basically does the patient's physician get a care plan documented within one month of diagnosis? And I guess just on a very high level it sounds to me like a totally reasonable expectation. And again, it's more of a consumer or a labeler's thing.

The demonstrated impact it showed in the analysis that it affected high numbers of people and that the gap in care seemed huge to me. It showed gaps in care only 12.72% of patients. I'm sorry, that did not receive optimal care. That I guess is very adverse that the others that we've been seeing. So again, it seems like a reasonable measure. I think that all of the evidence just was rated as moderate.

There seems to be a lot of discussion about the limitations of the review on lack of high quality investigations, randomized control trials. I thought it was interesting to see that most of the studies are outside the United States where it was a single payer system. So I think that definitely makes a big difference in terms of treatment and recording.

And I did think it met the threshold and that the again a sample of things so small I wasn't personally sure about the idea of the reliability. But the testing results all showed either perfect, moderate reliability so giving reference to that I would expect that the reliability was there and that the validity was there. And again, all the results showing - was numerated as perfect.

So my feeling was that it was a worthwhile measure and ((inaudible)) should be continued. And that was the end of my review of the specific one. I guess no other specific comments on that. Because it said that the data could come from ((inaudible)), it seemed like it was feasible and reliable to get the data to record on this. So again, my overall feasibility was rated as a yes.

Adeela Kahn: Thank you Wendy and do we have - you had rated it a yes. And do we have comments and other comments from the workgroup?

Dr. Robert Miller: Yes, this is Bob Miller. I agree; I would rate it as a yes. The same comments we had all along about the evidence provided doesn't really address the specific intervention, but I think the same objection at a minor level is less so for this than the others. And I just want to raise that again, I think the - not all the questions were responsive to the questions asked on the form.

Adeela Kahn: Okay, any other? All right. All right, so we'll move onto our next measure which is 650, Melanoma Continuity of Care of the Recall System and Dr. Miller I believe you are the lead discussant.

Dr. Robert Miller: Yes, so very quickly the intervention is there, some type of reminder system, particular system that's in place for patients to have a diagnosis of melanoma from (leaves) of stage that's indicated and I'm seeing in front of me here that require - no, excuse me there's no stage.

They said the diagnosis of melanoma, the thought is that patients who have one melanoma because most risk factors there's not exposure there, but risk of second melanoma is and is reasonable to expect that early identification of a second melanoma diagnosis which occurs in 5-10% or some such figure would ultimately impact outcome.

The second and perhaps the data's a little bit softer on this is identification of an early recurrence and in transit the tasks this or other recurrence, that could be identified on the skin exam or physical exam of any type I suppose could theoretically impact outcome although it's much harder to prove since as everyone knows melanoma is a difficult cancer to treat.

So I thought that the impact was reasonable. The gap was not - I mean, the gap was in the range of - let's see it was 9% did not receive the optimal care, so almost 1 in 10. I don't know what metric we would normally use since something as inexpensive as a skin exam and a recall I'm comfortable saying that that's - that we could do better than, you know, missing 10% of skin exams - scheduled skin exams.

I think the other comment I had in terms of the evidence which is where, you know, I sound like a broken record I keep going back to where I don't know that all the information provided here was responsive as I believe Sam may have said that the references are mostly, you know, these are from the NCCN guidelines and these are where the articles or the NCCN bibliography.

However, I'm doubtful that there are - that there really is any literature that specifically looks at this particular intervention. Do you have a recall system in place or not? I'm not aware of any literature, you know, since measure developers can address that obviously that'd be great to put

in there. But I guess at the end of the day I'm willing to let those go. I think they're minor technical objections.

It's already in use and the other comment is the structure measure. So it's perhaps a little easier. Do you have the structure in place to do this? This is not necessarily a process measure, so for those reasons I advise approval.

Adeela Kahn: Thank you, any other comments from the workgroup? Okay, hearing on our last measure is #562 Overutilization of Imaging Studies in Melanoma. Dr. Laver is our lead discussant. Dr. Laver? I thought I heard him earlier.

Okay, maybe we lost him. Is there - let's see, is there someone from the group who is willing to speak to our last measure which is the imaging studies in - Overuse of Imaging Studies in Melanoma?

Male: Yes, so this is ((inaudible)). We have one minute, so I don't know about ((inaudible)). But this is one I had trouble with because of -- let me look at my notes here real quick -- my concerns about the denominator is that I just don't know how - I guess I need to hear more from - since this is in use as far as PQRS, how do you identify the denominator exception?

Okay, someone - I've got a - the point of this measure is early stage melanoma patients almost never have metastases, don't waste time in exposure to radiation risks they don't need by doing much of imaging studies which we all know happens a lot. So but the exceptions are well if they really needed the imaging study for other reasons then that's okay.

And that can be a system reason like they're on a clinical trial that requires something or some other otherwise undefined patient medical reason. They have a symptom that requires this. I just - - again maybe just being a novice here -- I just don't understand how there's any consistency with

that because if that's left up to the abstractor who I understand would probably have some kind of clinical expertise could look into that.

I just struggle with that you're going to have a clearly defined denominator - how do you know what the exceptions are to the denominator? So maybe someone could speak to that. If we can't do it today we can maybe do it at our in-person meeting. But that would be my reservation though, defer it to the primary reviewer if I'm totally off base.

Female: Sam, do you have a response to that?

Samantha Tierney: I think Diedra from our Measure Development staff is also on the phone.

Diedra Joseph: All right, this is Diedra Joseph from AMA-PCPI. So I think that the question that you've asked is with regards as to whether or not the exception are warranted. And so I'll try to explain our reason for adding the exception. So for documentation of medical reasons we have included the example that the patient has a co-morbid condition that warrants imaging.

For example, if the patient has a different kind of cancer or, you know, something like that where they need another imaging study, for this measure we don't want to present the patient for having an imaging study that they may need for a different medical condition. And then also for documentation of system reasons we have as an example a requirement for clinical trial enrollment and that the study was ordered by another provider.

And so we added - we ordered by another provider as an example because we didn't want the clinician to be penalized if they didn't have any control over the patient having an additional imaging study. If another provider ordered the imaging study there's no way that, you know, the person that's taking care of the patient for their melanoma should be held accountable for that.

So that's what we were trying to allow for. Does that answer your question?

Female: I think they're also asking how you capture those exceptions for each measure.

Male: Right, I guess my concern is that that seems very subjective and as a measure that we're trying to automate as much as possible - I mean, because it's not just the co-morbid condition, it could be what you're trying to avoid is the routine - ordering routinely various scans that the patient doesn't need.

But if the patient, the only diagnosis is melanoma and there's no other physicians involved, there could be situations where it's decided based on best clinical judgment that an imaging study is ordered. And of course everyone would agree that ought to be done. But how is that - how can you be sure that that's counting against the person meeting the measure?

Because if I see a melanoma patient, when I see them initially I know they don't need a chest x-ray, but two months later something changes about their condition that's not easily extracted from a record. And then I order a chest x-ray, is that going to be counted against me in this measure if someone's looking at it? That's my concern is how do you operationalize that?

Diedra Joseph: So it wouldn't be counted against you only because - I'm sorry I'm trying to access the form here. No that wouldn't count against you - I can't get the form up. But the basis of the measure or the intent of the measure is to present as you stated - to present unnecessary imaging and the way the measure is worded it would be any sign or symptom.

If a patient has a sign or symptom which is defined within the measure -- I know we included it there, but I don't have it in front of me -- if a patient has signs or symptoms that warrant the imaging then it wouldn't count against the clinician as ordering the imaging.

Male: Right.

Diedra Joseph: So that's the purpose of fitting that in so that we could allow for, you know, if it's necessary then the patient would still be able to receive the imaging that they need.

Male: Right, I understand. I'm just trying to figure out how that's - how you can be consistent in that assessment?

Samantha Tierney: This is Sam Tierney. I know we're out of time, but just to respond to that question a little bit more. So in a program like the PQRS program that's reportable through claims, we have a CPT-2 code that is associated with the medical, the patient and systemic exceptions that are available for the measure.

And I'm sorry, I'm not sure if they're all three. But for whichever ones are appropriate we have a CPT-2 code that would identify those so the physician would kind of be attesting that they had a valid medical reason. In an EHR world we have in our EHR specifications identified codes that - or terminologies - clinical terminologies that would match to the examples that are provided so that those patients could be appropriately excluded from the measure and the calculation of the measure.

Male: Okay.

Female: Are there any other comments on the measure? I know we're over the time right now.

Carolyn, if we could just briefly open it up for a public comment. If there's anyone on the line with a comment?

Operator: Certainly, all lines are open at this time.

Adeela Kahn: Are there any public comments at this time? So on our last measure, is there a sense of the committee on the recommendations for this one?

No, are we there? Can you hear us?

Male: So I will speak to not endorsing the measure.

Adeela Kahn: Okay.

Male: I echo that.

Adeela Kahn: All right, well thank you. If you haven't completed your SurveyMonkey or you still need to vote, please do so in the system and I'll leave it to (Lindsay).

(Lindsay): And with that, at this point we'll see you March 13 and 14 (NBC). We'll be sending out some information before that meeting, but we don't really have anything that we need you to do at the moment. And if anything comes up we'll send you an email.

Male: Sounds great.

(Lindsay): Thank you all for staying on the extra minutes; I know you're very busy.

Male: Thanks everybody.

Adeela Kahn: Okay, thanks all. Bye bye.

Operator: And that will conclude today's conference call.

(Lindsay): Thank you.

Adeela Kahn: Thank you.

END