

NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
June 6, 2012
2:00 p.m. ET

Angela Franklin: Hello and welcome. This is Angela Franklin. And I just want to check and see if Dr. Lutz has joined us. So we'll go ahead and get started with a quick roll call, and again this is the Cancer Endorsement Maintenance Steering Committee. And the purpose of today's call will be to review the comments received on phase one evaluation of the measures and the draft report and discuss the major themes that came in through the comments.

So with that I will turn it over to Lindsey Tighe who will give us a quick roll call.

Lindsey Tighe: Sure and just one little add, I will also be following up on those Phase Two lingering issues. But the roll call, I'll go ahead and begin. Stephen Lutz, Joseph Alvarnas, Eduardo Bruera, Elaine Chottiner.

Elaine Chottiner: I'm here.

Lindsey Tighe: William Dale, Heidi Donovan, Stephen Edge, Karen Fields, John Gore.

John Gore: I'm here.

Lindsey Tighe: Elizabeth Hammond, (Joseph Leiver), (Gerard Lope).

Sharon Sprenger: Hi. This is Sharon Sprenger, on for (Gerard Lope).

Lindsey Tighe: Bryan Loy, Jennifer Malin, Larry Marks.

Larry Marks: Yes, present.

Lindsey Tighe: Robert Miller.

Robert Miller: Here.

Lindsey Tighe: (Naomi Norman).

(Naomi Norman): Yes.

Lindsey Tighe: David Pfister.

David Pfister: Here.

Lindsey Tighe: Rocco Ricciardi, Patrick Ross, Nicole Tapay.

Nicole Tapay: Yes, here.

Lindsey Tighe: Wendy Tenzyk? OK. Thank you.

Angela Franklin: OK. So right now we're putting up on the screen for you our comment table.

Jen Malin: Hi. This is Jen Malin, too. I don't ...

Angela Franklin: Welcome, thank you. And what we'd like to do is go through the first themes that we have here. And I'll just run over quickly the themes that have emerged and there are a few measures that we'll call out for – were comments that we'll call out for specific discussion by the steering committee.

So the themes we've captured in our memo here is the – is a theme around reconsideration of measure number 212, proportion with more than one hospitalization in the last three base of life, to be paired with measures 211 and 213. And you can see what the overall gist of the comment was regarding this issue. Another was the concern around the understandability and usability of the palliative measures which could probably be the major theme that we'll spend the most time on today. And then there also is a request for reconsideration of measure number 0562 over utilization of imaging studies in melanoma.

So with that, let's get started with numbers – with our theme one. And I just wanted to check and see if we have also our developers on the call.

Lindsey Tighe: Operator, if you could open the lines for anyone in ASCO or Craig Earle, please.

Angela Franklin: I just want to confirm that they're on the line.

Tom Murray: This is Tom Murray. Dr. Earle was not able to join us today here for ASCO and I believe Kristen McNiff is on also.

Kristen McNiff: Yes. I'm here as well.

Angela Franklin: Great. Thanks. So, with regard to the three measures or the two measures, how much yours were (anticipating) that given the variation, the use of rooms were hospital admissions with patients in advanced stage of the illness as well as the wide variation in the intensity of care and diverse health care settings that might not be possible to understand the variation in emergency room and (inaudible) at the end of life without having data on the hospital admission.

And they all – the commenters also were speaking exclusion of patients in the palliative care unit which they thought would strengthen measure number 0212.

And with that, I will invite committee comments on this first theme and also with regular comments to the developers as well (inaudible).

Jen Malin: This is Jen Malin. I agree completely and spoke out in favor of including the hospitalization measure for these exact reasons during our initial meeting.

Male: I'm sorry. Could ...

Jen Malin: I think, you know – you know just thinking of differences, you know, an ICU admission at one hospital is very different than another. Some hospital is just a regular hospital floor can practically be an ICU. It's going to be very hard to understand variation and aggressive at the end of life if we don't have a full spectrum of measures.

Angela Franklin: Any additional comments from the steering committee?

Male: Can you just remind us the text of the measure? I'm just trying to find it. It just didn't come with the current attachments.

Male: There was a prior email that had – the email is from 3:03 on 6/4. It's by June 4th of 3:03 pm. I just – I just – I was having the same problem. I just found it.

Angela Franklin: OK. So we're looking at discussing 212 right now. I'll just run through the description. Look at the right one. It's the percentage of patients who died from cancer with more than one emergency room visit in the last phase of life, that's 211. I'm 212 with not recommended that's why (inaudible).

Male: So did we approve 213?

Angela Franklin: We approved 213 and that is the proportion admitted to the ICU at the last 30 days of life.

Male: OK. But we did not approve 212?

Angela Franklin: We did not approve 212.

Male: And we did approve 211? I thought I'd just get that nomenclature right here. So ICU is 213.

Angela Franklin: That's correct. ICU – OK.

Male: You give us – remind us what we approved and what we didn't and ...

Angela Franklin: Sure. We approved – we approved proportion with more than – let's see. We've approved proportion with more than one emergency the last days of life and that's 211. We also approved 213 which was ...

Male: The ICU and the last 30 days.

Angela Franklin: ICU in the last 30 days of life. The one we didn't approve was 212, which is proportion with more than one hospitalization in the last 30 days.

Male: They're basically saying that these things come as a set and if we approve one, it's hard to interpret one without the other. Is that right?

Lindsey Tighe: That's what the commenters take on it. Yes.

Male: That's sort of what I'm getting from reading this, is that right?

Angela Franklin: Correct.

Male: Right. That will – yes.

Lindsey Tighe: And just to remind you all the discussion around this measure at the in-person meeting; the reason that it was sort down was that a lot of people were concerned that because palliative care unit have greatly increased in number since this measure was initially developed. This measure didn't take that into account and so the results would be confounding because some patients may be hospitalized and it is actually very good quality care because they're in a palliative care unit.

Male: Right.

Male: Well, I think also the discussion was that of course there's many reasons for hospitalization. Some of which are completely beyond the health care provider's control and whereas we might philosophically try to keep patients out of the ICU or keep that emergency department. Sometimes admissions happen not just the palliative care units but to other parts of the hospital that don't reflect the lack of quality under some of that discussion.

Male: Right. That was my recollection. We control the – or the ICU or not so that made a lot of sense.

Male: Yes.

Male: And we don't really – so I guess I don't quite understand why the ICU measure is not valid without the measure of admissions or why we have to interpret that. I guess ...

Male: I agree with you. I don't get that either.

Male: I guess in the comments that link in the ER – well it is ICU. Yes. I agree, yes. I don't – I don't get it. Is the person who wrote this comment on the phone?

Angela Franklin: No. We don't have that person who wrote the comment on the phone. No. But ...

Female: I mean, I can just at least in my own experience, you know, being – working at different hospitals essentially, you know, at UCLA which is a tertiary center or quaternary center to get into an ICU. Essentially, the only way you get into an ICU is if you're on a ventilator, whereas that Century City Hospital which is a community hospital, anyone who needs a higher level of nursing care gets admitted to the ICU.

And so, you know, you will have huge variation, I think in, quote, "admissions to an ICU" just based on sort of what the level of care is in other parts of the hospital. So it may be very hard to interpret if you don't know, you know – if you're looking to one ACO and they have very high intensity ICUs and so the admission rate to their ICU is, say, 2 percent but they have a 20 percent admission on, you know, basically floor beds that are monitored in very intensive care but then, you know, some other ACO where, you know, they are actually doing a really good job but their, you know, their ICU – they put people on the ICU when they need a higher level of care. But overall, the rate across the two is only 10 percent, you could have misleading results.

Male: The definition of an ICU is variable.

Female: Yes.

Male: It sounds like the discussion on the phone today is similar to what we talked about in the in-person meeting. And I'm just reading the commenter's themes. I guess this is a distillation of NQF concerning regarding the understandability of the palliative measures. So it's just a little hard to respond to that since – I guess, I'm – I think what I'm saying is I don't – I don't agree that that's a reason to change our vote. That would be my opinion.

Happy to engage someone on the call who wants to offer some other opinion on that.

Male: I agree.

Angela Franklin: OK. And just an answer to Bob's discussion, yes, this discussion on the call does mirror what we've discussed at the in-person meeting. And the measure unfortunately failed on important measuring report.

Male: Yes. OK.

Male: OK.

Angela Franklin: OK.

Male: Do we vote – do we vote on this now or is this just a discussion point?

Angela Franklin: It's a discussion point if the steering committee feels like they would like to reconsider their vote. We can have that discussion. Did I hear that from the group?

(Naomi Norman): Not for me. This is (Naomi).

Angela Franklin: OK. OK.

Male: Not for me either.

Bryan Loy: Not for me. This is Bryan Loy.

Male: Does anybody on the call will move that we reconsider this?

Male: Hey.

Male: (Inaudible) that wasn't fun.

Angela Franklin: All right. Moving on. So the next theme that we're focusing on is the palliative measures and there were comments around the understandability and usability of the palliative measures. And we have that pulled up for you, the gist of the comments. Commenters were noting that while over treatment

of terminally ill patient is an important area, there were concerns that the measures imply that patients receiving treatments such as chemotherapy in the last 14 days of life or patients with more than one ER visit are receiving poor care.

Commenters were concerned that lumping patient population together in the measures could result in patients who are purportedly receiving said treatment being counted in the numerator and being counted against the reporting facility.

There was also a concern that the prognostication of death is limited. There's a limited ability there and in addition to being unable to determine accurately a patient's death. The measures do not distinguish patients who are terminally ill and those patients who die suddenly.

And I would like to throw it open to a discussion for steering committee members.

Female: I mean, I don't think that the intent is that this was a never event and that, you know, score should be zero percent. But at least, you know, my recollection of the steering committee discussion is there was pretty strong consensus that actually this was a measure of, you know – that going to the ER a bunch of times in the last month of life was a measure of poor quality care, that the patient didn't have an access other sources of, you know, alleviation of symptoms and care for their suffering and that treating people, you know, while it's – you know, needs to be stratified by disease. Leukemia patients are different than non-small cell lung cancer patient that's receiving chemotherapy in the last couple of weeks of life.

You know, again, it's not a never event. It'll happen. Sometimes people die of toxicity but that this was a measure of poor quality care.

Robert Miller: This is Miller. I agree with that. I also would say that I don't agree with the comment implying that we can't possibly prognosticate and that there is the ability to prognosticate should – the commenter implies that since we can't possibly prognosticate the time of death then, you can't begin to develop

quality measures. And I – that's sort of inherent in the way the comment is written.

And I'm afraid – I think that we have to draw the line somewhere and I think that the 14-day limit is a pretty low bar and I would submit that most oncologists and other physicians that take care of patients who are in the last 14 days of life – the majority of the time, do a reasonably good job of identifying this patient population. So I call into question the validity of the comment that – the implication that we can't prognosticate so we shouldn't develop a quality measure in the regard.

(Naomi Norman): If, you know – if that's the case, we – I don't think we would try to really do a whole lot of quality measurement in this area in general because it is a common problem. So I totally agree. This is (Naomi Norman).

Heidi Donovan: This is Heidi. I agree too. I think 14 days is a pretty low-bar. I think we've discussed this a lot at the in-person meeting and address some of those concerns at the meeting. And I don't think we should change our decision.

Elaine Chottiner: This is Elaine. I mean I still feel as a hematologist that this is not a measure that really applies to most of the hematological malignancies. And although there had been comments about being able to specify populations and mixes. I had the experience of sitting through a faculty meeting at the university where the data from this particular measure were presented and I could easily pick out who the hematologists were.

So then internally, I think that you can do that but if you're talking about using this for external reporting, I don't think that you can pick and choose the particular providers within a group who's focused on hematologic malignancies. And that's my major concern.

Angela Franklin: OK. Thank you. Any other comments on this group of measures. I understand we're taking them as a group. Are there any comments ...

Male: Can you – can you – can you remind me, is that measure intended to be on a per position basis where a hematologic oncologist would just choose not to use that measure, or is this based on a – you know, per group measure.

Lindsey Tighe: My recollection is it's facility level. But I'll let Tom speak to that.

Tom Murray: You know, I think the comments about the distinction between the challenges in the hematologic population and the – let's say cell tumor population, I think, Elaine alluded to is an important distinction.

Also, you know, certainly, if you're looking at the provider level, this is going to vary. But even if you look at the institutional level, one would expect that there's going to be a – I think a mal-distribution of sort of hematologic cases, let's say, between, you know – let's say some of the larger institutions to sort of focus more in that area versus other more general hospital type settings. Such that I think that comparability of the measure across those – like I don't think the presumptions that well, this is going to come out in the wash because, you know, the distribution is going to be kind of the same across institutions. I don't think the respective population is going to clearly – if that's clearly been the case.

Also, I think that, you know, we – certainly, we – predicting when someone is going to die in 14 days, certainly, it can seem like it's very straightforward. But I – you know, I think perspectively, you know, doing it in much the same way that we kind of struggle with this with (inaudible) with an eligibility criteria of – oh, then the patient is going to be alive three months from now.

It is – on a look-back measure, it seems like – well, gee, it's very clear. The person was going to die so we should have known that the person was going to die two weeks before that. But, you know, doing that perspectively is often not straightforward, plus some of the death events are not going to be clearly related to chemotherapy, toxicity or a disease but just, you know, just death that sort of aren't really related to bad quality.

Angela Franklin: I just wanted ...

Elaine Chottiner: I would just say, you know – I think this is, you know, always a difficult issue. I would point to the ones that have evidence that we have on early palliative care being the (Kimmel) study which randomize patients that was non-small

cell lung cancer at Mass General. And those who had earlier palliative care lived longer and also had lower rates of chemotherapy at the end of life.

Angela Franklin: Any other comments about the measures as a group?

OK. I just had – I wanted to call out that there were some gap areas noted specifically looking at measure number 210, proportion receiving chemotherapy in the last 14 days of life. There was a question from a commenter about expanding the measure to address radiation therapy. And I think that that was the only thing I want to highlight for the group.

And also, a question about clarifying that the therapies that are – that we're looking to curb is the use of curative chemotherapy within the last 14 days of life. I'm wondering if there comments from the group?

Robert Miller: OK. This is Miller. So I would respectfully disagree with the comment about radiation. And I think in the – in the Excel spreadsheet there was – the developer responded to that that it's not uncommon for radiation to be delivered in the final weeks of life purely palliative in (cans) with very short vaccination schedule, single dose and so forth. And that would certainly not be inappropriate or I should say, in most cases, we would not consider that to be inappropriate.

So I would submit that that we're talking about two different things here. The toxicity of chemotherapy measured against single dose palliative radiotherapy which is generally very well tolerated.

Male: I'd agree with that.

Female: I would agree as well.

Female: And I would agree as well.

Angela Franklin: At this point there's barriers to getting palliative radiation at the end of life.

Male: That's true.

Male: Oh, I'm sorry. Am I interrupting?

Angela Franklin: OK. Any other comments? I think the developer has already submitted a response. If there is any other comments from the developer. No?

Male: Is this in the same theme two in the memo we're looking at?

Angela Franklin: Yes. And we're still looking at theme two. OK. All right. I'm hearing none. We're still in theme two but we're going have a two – I guess an interim theme here. We did have some specific comments on measures related to the oncology plan of care for pain measure. That's paired with the next 0383 and that's paired with 0384 oncology pain intensity quantified.

And we're due to have some comments about harmonization of these measures with other measures of pain management including QOPI and (Assist) which specify that a plan of care be required for moderate to severe pain. And I also wanted to check and see if the measure developer for this one is on the call.

Sam Tierney: Yes. This is Sam Tierney with AMA. We're on the line.

Angela Franklin: Sam. And there is a response that – and Sam, do you want to just run through the response quickly and we'll see if there's discussion from the steering committee.

Sam Tierney: Yes. So I think this was a point of discussion at the steering committee meeting as well. The reason that the measure is constructed as it is is because it's based on NCCN guideline recommendations for the management of cancer pain in adults, which are categorized according to three levels of pain intensity; mild pain, which – with a score of one to three, moderate pain with a score of four to six and severe pain, with a score of 7 to 10.

So as a result the plan of care for pain that was – should be initiated at the lowest level of pain intensity consistent with the guideline recommendation. And I also wanted to point out that the scope of the plan of care is quite broad and it might include use of opioids and non-opioid analgesics, psychological support, patient and/or family education, referral to a pain clinic or reassessment of pain at appropriate time interval.

So one of the reasons that the plan of care for pain is so broad is to be consistent with the patient's level of pain so that the clinician can determine on an individual patient basis what might be appropriate.

Angela Franklin: Thank you, Sam. Any comments from the steering committee on this?

Female: So if I come to my doctor's appointment and I have a mild headache that day and it's not chronic pain but I report my pain as one that day because I have a headache. So the doctor is supposed to document a plan of care to see me back in the office to check to see if I have a headache again?

Angela Franklin: Sam, are you able to answer that?

Sam Tierney: Yes. I mean, I think that, you know, that's obviously a good – a good point. Maybe an example of a situation where you wouldn't necessarily want to reassess it. But I think that given the nature of this patients and their condition, it seemed appropriate to the work group that this plan of care for pain should be initiated at even the lowest level consistent with the guidelines from the NCCN.

Female: So many of the patients in an oncologist's office are going to be survivors, so they're not going to be any different from any random person. I mean, would you say that a primary care physician should have to – have a plan of care for every patient that walks into their office that happens to, you know, have an ache or a pain that day?

Sam Tierney: This is Sam again. So I think – I'm just checking, but I think the denominator is actually limited to patients with the diagnosis of cancer who currently receiving chemotherapy or radiation therapy. So it is limited to patients receiving treatment.

Female: Correct.

Angela Franklin: So just to recap. The steering committee discussion at the in-person – there was indeed the concern we've noticed that a report of pain is not (inaudible) could pollute the impact. But it still needed to be noted that a patient was

experiencing mild pain and they need to follow up on it would be sufficient to justify the measure moving forward.

Are there any additional comments about the two – 383 and 384?

Male: Can you define for me what it means to have measures that are paired?

Angela Franklin: To be reported together.

Male: So you can't do one without the other?

Angela Franklin: Exactly.

Male: And you get credit for two when you get them both or is it ...?

Angela Franklin: I understand that each measure is individually reported but they must be reported together. So ...

Male: So, yes, you sort of get double digit credit.

Angela Franklin: Two points, I guess.

Male: Two points. That's what I'm asking. OK.

Angela Franklin: So I just wanted to be sure that we had a discussion about those two. We can move on if there's no further discussion.

Male: Was the discussion to change something we voted on? I'm missing that point?

Angela Franklin: It was to discuss the harmonization question.

Male: OK. So – and have we done that? Is there – is there disharmony?

Lindsey Tighe: Yes. This is Lindsey. My take on it is that your discussion is largely inline with what you discussed at the in-person meeting unless you want to have more discussion around including patients with mild pain and measure.

Male: But currently, the stuff that we approved, are they concordant with each other or they're discordant?

Lindsey Tighe: They're concordant with each other.

Male: And that mild pain is excluded or ...

Lindsey Tighe: Mild pain is included in this measure.

Male: Included. So what we're just speaking before we're suggesting that mild pain maybe shouldn't be in – I would sort of support that. Do other people – I mean, point to good one patient is going to do is very mild pain. You know you got patient with – I don't know, whatever terrible thing going on. They get mild pain in their shoulder or whatever and normally, I just follow it and if they – if it bothers them the next – like maybe following it is the appropriate, you know, care plan.

But, you know, I think we all sort of routinely just keep an eye on things and see how the care for pain is going to get worse and declare itself and also things just get better on their own.

Lindsey Tighe: I think Sam, maybe, we will speak to this but my recollection from the in-person meeting was that simply noting that it was being followed were sufficient to meet the measure.

Sam Tierney: Yes. This is Sam. So I'm trying to pull up those classifications right now. I think a plan to passively check it another point would qualify. So the definition of the plan of care for pain is quite broad.

Robert Miller: Yes. This is Miller. I'm looking at the numerator statement in the original worksheet and it basically says, a document of plan may include meds and other things but it says – the last one is reassessment of pain at an appropriate time interval. That sounds like you can just say, we're just going to reassess this at another visit and that would satisfy the measure so it's not being ignored, I guess is the point.

Male: Yes.

- Robert Miller: And I'm – personally, I think that's fine. I think it would be hard in these type of measures to easily separate out mild versus severe pain and, you know, since there's not a single standard scale that everybody uses.
- Male: That's a good point.
- Female: And then let's just say that it would be very difficult to exclude mild pain when, you know, mild pain may be pain that was once severe that's now being well managed but you just want to continue to be following on that carefully.
- Robert Miller: Sure.
- Male: And I could tell (you) when your practice is routinely sort of deferred to the patient. You know, that doesn't sound too grand. Let me know if that continues to bother you. I don't know if that's considered acceptable but that's a pretty common thing to do I think.
- Male: Yes.
- Male: Right. You had a cough this morning. OK, if it persist let me know, you know.
- Male: So this discussion is far and wide. This discussion kind of suggests that there needs to be some sort of definition of what a care plan or plan of care is? If their – is that addressed? I'm working from a cell phone. I'm sorry. Is that addressed anywhere in the documents? And what meets the definition of a plan of care or care plan?
- Female: I was going to say that, you know, a plan for follow-up at an appropriate time period is the sort of most forgiving in those categories.
- Angela Franklin: Sam ...
- Male: I'm sorry. Can you repeat that?
- Elaine Chottiner: If the assessment – if the overall assessment in plans said, I'll see the patient back in two weeks but didn't specifically say I'll see the patient back in two weeks to reassess their pain, that would or would not meet the criteria?

Angela Franklin: Sam, do you – are you able to speak to that.

Sam Tierney: Yes. So – just that I think comments and some – someone commented about a definition. Just to clarify – so there is like a definition. It says a documented plan of care may include the use of opioids, non-opioid, analgesics, psychological support, patient and/or family education, referral to a pain clinic or reassessment of pain at an appropriate time interval.

And I'm sorry there was another question specifically to that last point but I can't recall it at the time. Could that – could you repeat it?

Male: Yes. Does the plan had to explicitly say I'm going to see the patient back to ask them about their pain or could you just say, I'm going to see the patient back because we routinely, you know, see patients with minor aches and pains all the time.

Sam Tierney: So I think that's a good question. I have to look more closely at our classification in looking at the language we have. I think it would have to be specific about pain but again, I think that has to confer with our classifications colleagues to be sure.

Male: Maybe if there was an extra clause at the end of that when you said the – you said, you know, would follow the patient back to look at the pain again or broadly give the patient – I don't know, a direction to raise the issue again if it persist or something like that. Something more vague.

Male: Yes. Just to take that to an extreme. I mean if the treatment plan was reassurance because somebody had pain and they were worried about the thing or recurrence or manifestation of the malignancy, you know, I'm not sure how that would meet those criteria that you just elaborated on. Unless you say reassurance is a treatment plan.

Tom Murray: You know what I hear from a lot of these comments is that the – there's little question that pain is an important symptom to address that's clearly – that there's evidence of under treatment of pain.

And it – you know, I think clearly documenting, making sort of documentation of the pain and the visit, I think is important regardless of the provider. But as we kind of lay out some these different scenarios and sort of say, "OK. At the end of the ..." It sounds like it's becoming an increasingly elaborate documentation exercise. Is the patient kind of incrementally better off because we did this.

To what extent is this becoming a documentation burden for the provider that where it becomes driven to be more important on documenting, doing things would probably don't make as bit – no, a huge – I'm not going to really plan the major intervention, that's my judgment but I need to document very clearly that I'm doing X,Y and Z. And it ends up being almost like time away from more directly dealing with the symptom and that we're getting kind of – that the documentation is something that sort of – is becoming the most important end point here as oppose to the person's optimal symptom management.

Robert Miller: I totally agree.

Female: Very powerful point.

Male: Right. This is – this is so far down the line from an outcome measure, right? We have an outcome measure and a process measure. This is, you know, documenting, you know, a process. I agree. Can we – can we get rid of this one? Or could we clarify it better?

Angela Franklin: Is there a question about clarifying the measure?

Male: I guess this measured passed.

Angela Franklin: It did.

Male: It did pass, right?

Angela Franklin: It did pass and they're – the committee found that the intervention did address a large population. It was needed for a patient center purposes and there was room for improvement in this area.

Male: Maybe that's the fair place to leave it which is – I think if these measures will come up for review again and I think part of what we're trying to lay the foundation for here is for those measure developers to be granular enough for measures to be meaningful but not so fixated on things that create a burdensome level of documentation for physicians and detract from the utility of that measure – to measure something that's of value to the patient.

I mean, it creates a lot of hurdles that I think new measure developers or those who will revise these measures in the future should benefit from. But I think it doesn't discount the measure where it is right now. And I think we recognize it in all of its imperfections.

Male: Except that I would say that the – I think you just had a number of comments. Unfortunately, I wasn't there for the primary discussion because I was sick. But, you know, I think what you're hearing a lot of people saying is that, let's say, there's probably little argument that severe pain, moderate pain in terms of, you know, focusing on something that people definitely knew comes with a concrete plan and follow-up on. But there are these numerous examples of kind of minor pain in a population that has a lot of minor pain that is going to lead to substantial documentation burden for things that it's – you know, you're robbing peer to pay (pawn) here.

There are only, you know, two hands at the time of these evaluations and the time you're spending documenting a detailed plan for like minor incidental pain is things you're not paying attention to – diarrhea, coordination, whatever.

And, you know, I think you've had a number of examples provided of how as is these measure isn't perfect in terms of this issue with minor. And I think revisiting this three years ago is a pretty long time for him to expect people to be measuring sort of this minor pain this way and say, "Well, it's not that big an additional burden to the provider."

Male: And just to build off of that – and perhaps there is already a measure in place that I'm not aware of but it seems to me what's missing from this conversation is a characterization of the pain. I just heard mild and moderate. I'm

wondering, you know, is there a measure that's already out there that would require documentation about the characterization, the longevity, the nature of the pain; acute versus chronic, et cetera. Does that measure already exist?

Male: It might be reasonable to restrict that the pain requiring intervention. The pain that the patient is already on pain meds, you have to address how they're doing on that. Is the pain med controlling it, it's not controlling it, they need the upping of the pain meds. That at least gives something objective that they're already getting intervention.

Lindsey Tighe: We did have a harmonization discussion of this measure with the two measures that we're discussing the palliative care project. Those measures – you're going to have a bit more of what you're discussing about intervention of pain or more severe levels of pain but they are not for the same piece and population of this measure. They only capture patients with advance cancer. And so this measure was thought to kind of cover the broad section of those patients who have cancer and who are receiving treatment who are in pain.

Female: And it can't be limited to moderate to severe pain for particular reasons.

Lindsey Tighe: That is a question for the developer.

Female: (Inaudible) any more than anything is that, you know, is the measure of quality for moderate to severe pain. But maybe the risk (inaudible) ratio for mild pain is not there. Those are too big (inaudible).

Female: Is that something in a (PCPI) to depict to?

Sam Tierney: So I think that's something that we could take back to our committee for consideration. Again, just to kind of highlight the intent. You know we base our measures on clinical practice guidelines in the NCCN panel that came up with guidelines for the management of cancer pain do have a requirement that pain – even mild pain should affective some way, they specifically say possibly consider NSAIDs or acetaminophens, consider titrating short-acting opioid or reevaluate pain at each context and as needed to meet patient goals for comfort and function.

So the measure is constructed to be consistent with the clinical practice guidelines on this topic. And the measure is limited.

Female: But I think the – I think the distinction though is the NCCN's guidelines are not talking about a single point in time cross-sectional measurements, which is what your measure is built off of. So they're talking about a clinical assessment of pain.

So if someone has – gives a history and says, "Yes, you know, I've been having this nagging pain on and off for the last three weeks." That certainly needs to be addressed. But when you're using a pain scale as an assessment like pain as a vital sign, you know, that's – you know, like taking someone's heart rate or pulse – you know, pulse or blood pressure right in that moment. That tells you nothing about whether, you know, they stubbed their toe on the way in to the office. Whereas the guidelines are talking about a clinical assessment of patient having pain as a persistent issue, that's mild, moderate, severe.

Female: Yes. I agree with that as well. I mean, it's a measure of quality is quite different and the recommendation for clinical practice.

Male: I agree. I think this is way too broad and we're making unnecessary documentation requirements on physicians that are busy enough.

Male: Yes. I agree. I think that the – that the example that was just given was a good one. But also I think that the, you know, extracting sort of what's in a practice guideline to a quality measure, I think it'd be very interesting to see what – if let's say this quality measurement was fed back to the NCCN committee and say, "Well, we took this directly. Were these what you intended to do?" I'm not sure you would necessarily get the same consensus that – if they thought it was being measure this way.

Angela Franklin: So am I hearing from the committee that you'd like to see a different – some different elements added and if that's the case how they would be added and whether the developer could do that is the question.

Sam Tierney. Yes. This is Sam Tierney with AMA again. If I could just comment and I think someone on the committee had brought this up earlier. I mean, one of the challenges in limiting this, the patients with moderate to severe pain is that then we have to define thresholds for what that is for every possible pain scale that someone may use to make the measure actually feasible and usable in any sort of program.

So I'm not saying that we can't take that back to our committee but that's just another consideration. And another comment, if I could make regarding the burden. So this measure has been used in the PQRS program for a number of years now, which uses CPT II code and it's been found to be feasible to report them and our own testing projects found it reliable to report them.

So I think as it's reported through PQRS program at the CPT II code that refers to plan of care for pain being documented. And so it's just kind of a simple note in the chart that would refer to whatever that plan of care for pain is.

So I – we haven't heard anything in our implementation of the measure related to the extreme burden of documentation. And it seems that it's quite feasible as implemented in the PQRS program, we've also worked on developing each classification for this measure which should allow for the facilitation of using this measure in more of a clinical workflow environment.

Male: In the PQRS program, what are the measures that are simultaneously are providers having to document?

Sam Tierney: I'm not – I'm not sure I understand your question.

Male: Besides addressing the pain issue, what other things are the – is being assessed at the same time that would – like you're saying, well, there's no really burden. But what else are they being measured on at the same time that they're doing the documentation for pain?

Sam Tierney: So I think there are – I'm not quite sure of the numbers off hand, but I think there are close to 200 measures in the PQRS program and for a variety of different specialties. And so it's really up to – and there are several different

reporting options. So one could report through claims, one could report through registry, one could report through EHR, depending on the measure selected.

So it's kind of hard to answer that because it really would depend on the individual provider what measures they might choose to select in the program. I mean, most of them – I think the greatest use of the program is in the claims environment and that does rely on the reporting of CPT II codes or G codes, which then there is an expectation of that in the medical record, there would be some documentation that would support the CPT II code that's being used.

Female: And has that been audited? So, you know – I mean, how do you know it's just not, you know, someone checking off when the – when they ask the patient about pain that they check off the CPT code to say that a plan was put in place.

Sam Tierney: So with regards to the auditing – I mean, my understanding is that reporting, billing codes or CPT II codes or G codes, there's an expectation that there's documentation in the medical records to support it and not doing so would be considered fraud. So I think that there is an expectation that that information is validated.

And I think that – there are also – I think some of our testing projects – I'm not sure of this particular but some of our testing projects have looked at PQRS reporting information and tried to compare that to what was in the medical records. And I think they have found some good reliability with the information that's submitted to PQRS and also in the – in the – in the medical record.

Male: To participate in the program, how many measures does someone have to pick?

Sam Tierney: So PQRS is a voluntary program that physicians choose to participate in. And depending on the options, they can participate in a wide variety of numbers of measures from one to many.

Male: So what did the people typically picked?

Sam Tierney: I don't know if that's ...

Female: Since we don't actually run the program, CMS runs the program, unfortunately, we don't have that information.

Kristen McNiff: This is – this is Kristen McNiff, can you hear me?

Male: Yes.

Kristen McNiff: From the ASCO perspective, the vast majority of oncologists report the re-measures. There is – there is not a measure group for oncology so we – you report individually. The vast majority are reporting via claims and it's really the best (inaudible), 26 percent or so of eligible physicians according the most recent data, eligible HemOncs are reporting to PQRS and 90 some of those are using claims to do so and they are reporting on three measures for 80 percent of applicable – eligible patients who meets the denominator requirements. That – there is variation but that is what the vast majority of Med Oncs, HemOncs are doing.

Male: I think that's useful information to put in perspective the comment that all the provider doesn't seem that burdensome. If let's say, the average provider basically takes well three things and I know I've got to put them up in the chart. And yet, we're entering an era where that number sounds like it's going up incrementally and I think that that – the answer to that burden question I think is going to be, you know, a very different one.

Robert Miller: This is Miller. I just want to make the contrary point and say that I'm concerned but I definitely appreciate – as a provider, I definitely appreciate the direction the discussion has been going. I'm just concerned about the unintended consequences. For example, if you're an oncology provider that is thinking of using this measure because you think you do a good job of this assessment and, you know – and I'd like to believe – that's most of us.

You know, I think it could be much more challenging to decide that you – to separate out the mild from moderate to severe pain. That implies that you have to use some type of scale and agree with what the – what the different

measures are and rate the pain on a – on a numeric scale. This is – the measure would have to be re crafted to have this distinction between trivial pain and more severe pain.

I think the point is that these measures are all voluntary. You can choose to – you can choose to do this or not. If you're choosing to do it, you may have a high enough volume of patients that have – you may have a practice of say, typically, solid tumor patients or something where this comes up a lot. I would submit it might – I would submit it might easier to know that you have to do this for anybody who mentions pain rather than the – the second step would be, I want to use this measure but now I have to determine if this rises to the level of where this measure is applicable or not.

So I just worry that that really could be unintended consequence and I'm just not sure that we're going to saving ourselves that much time by breaking it into – kind of a dichotomous variable right now.

Male: But the – is the PQRS going to be voluntary come 2014 or is it still going to be – or is it going to be required?

Heidi Bossley: Right. So this is Heidi from NQF. If you're talking specifically about the PQRS program, by 2015 there will be more of the payment based on the actual performance with more public reporting hopefully on the measures and how they are in actual use in that program.

The one thing I would like to just caution everyone is that we're really, truly asking you to talk about the measure. You need to – indeed as you're doing now, talk through what is the most – how would it play out in use and one of the primary uses as it happens to be now is PQRS.

But you need to also balance that this measure can and will be and it probably is – I don't have the information in front of me – use by others in other programs, maintenance and certification. So you need to assess the – how that measure still holds up regardless of how it's used now. And that's part of what you need to factor in, you need to look at the unintended consequences based on how the measure is specified. And the information that the developers been able to provide using PQRS is one example.

But again, just to caution that we need to make sure that this is again a balanced discussion not solely focused on issues around one program. It is one that you need to factor in but just – again, a little request that we kind of step back and think of perhaps a little more broadly.

Male: You know I appreciate it that but clearly the comment about the burden was based on the experience in that program which I think is probably instructive in terms of, you know, using it and getting that data applicable to other settings. But clearly – the (burn) data is based on that experience.

Heidi Bossley: Right. And that's exactly – so that should be part of your assessment for usability and feasibility. You're right.

Female: I mean, I guess what I worry about is when it's a completely global measure when we move to an EHR world, that what ends up happening is that there's just kind of a click box that then get's clicked. And I don't know that that really ended up reflecting anything about the quality of care that people get.

How do the other measures deal with the issue that was raised about mild, moderate, severe and how to handle that?

Angela Franklin: So we're just pulling up the information now. But when we look at what's in the palliative project and actually Lindsey could answer this question probably better than I can. But I've got the little microphone.

So those measures look at specifically hospice – it's not the screening one – hospice and palliative patients, it's using medical record data. They also do use electronic clinical data but it – the piece is the medical record data.
Correct, Lindsey?

Lindsey Tighe. We're just trying to find the specifics on the site.

Angela Franklin: So we can come back to our discussion and we'll come back to what the other measures we're looking at. So I think we left off discussing, you know, the burden and additional items that we might like to see to address that or to address how pain is screened for.

So, we're looking at how to compare this measure to the others that were in the other project. In the meantime is there further discussion on this one? So, what the – so we want to clarify, we don't have measures that actually define the pain in a way that you're looking for. We thought we did, but I don't see it in here.

Female: It's just the screening.

Angela Franklin: All we do have as patient's screen for pain.

Lindsey Tighe: The palliative measures are a little bit different because it's in-patient, so, it's most in patients in a palliative care unit where it defines a positive thing for pain as indicated by moderate or severe pain. And then cancer patients enrolled in hospice at the positive screen of any pain count, but again, this is different because it's not the out-patient patient population.

Angela Franklin: I need to pull it up for you. We put the measure number 1637 up on the – up on the screen and could you just scroll up just the top, sorry. There we go. And this explains how the denominator is handled in this measure.

So, for those who are not on the webinars, in case you aren't or I don't know how easy it is to read. So, they actually say it goes based on a positive screen and positive screen is indicated by moderate or severe pain and that is either a verbal, just moderate, or severe by the patient.

It's less than four on the 10-point numerical scale, greater than four I'm sorry or any observation or self report of moderate to severe pain. So, it's based – it's based on a number of things.

Did that help answer the question that was asked a few minutes ago?

Male: Yes, I think so.

Angela Franklin: OK.

Male: I'm sorry, I'm not on the webinar. Is this from the same metric we are talking about before? Because before we talked about mild pain or any pain?

Lindsey Tighe: Right, this was an answer to the question of how other measures that are NQF address the pain incidence and I think this one that only targets that moderate and severe pain.

Male: Right.

Angela Franklin: Yes. So, at this point, so, we want – so the Steering Committee want to reevaluate these two measures that we're looking at both the three and three to four they're reported as a pair.

Male: Excuse me, so nothing else on the – the one that we're talking about before was all levels of pain and that would be redundant with this one that we were just talking about is only severe and moderate pain.

Lindsey Tighe: Actually different because this only targets patients who are in hospice or in palliative care unit whereas the one that you're looking at in this project targets patients on our out-patient basis with cancer.

(Naomi Norman): I actually – this is (Naomi) – I actually think this is a fairly straight forward measure, see how it could be.

Male: Why should a measure be different for the simplicity stay for providers knowing what's expected of them? Should the measure not be the same in the out-patient or in-patient setting, hospice setting or not?

(Naomi Norman): It's a different population you know.

Male: Yes, but the principle is so still the same, right? I've got patient with a complaint and you want to be sure that you're addressing that complaint. Why should the physician have to remember to jump to a different hoop?

(Naomi Norman): Yes.

Male: You know what I mean.

(Naomi Norman): I agree, I think only the words only management of moderate or severe pain is targeted.

Angela Franklin: So, in the measure where a moderate or a severe pain is focused – is the focused, that's for broader population. This measure and this project is focused on oncology patient.

(Naomi Norman): Yes, a different population.

Female: Although when one thing said the population that's specified in these other measure is actually, you know, you're pre-test probability that there's pain there that needs to be managed that is actually much higher than in the measure we're discussing.

Angela Franklin: So, do we want to reevaluate the measure before which we can do by a vote, SurveyMonkey.

Male: So, this has been in existence before this measure or no?

Angela Franklin: Yes, this measure is up for reconsider – I mean I'm sorry for re-endorsement.

Male: It's been years, three years, right.

Angela Franklin: Yes.

Male: And the problems that we're raising have they – are these theoretical or they – have this problems really happening? Do we know?

Angela Franklin: (Sam), could you speak to that?

(Sam): I'm sorry, could you repeat the question? That was difficult to hear.

Male: We've been discussing the last 15 or 20 minutes potential problems with this measure and I'm asking whether in the last three years in the measures that are being used, have these problems indeed happen? Have you had complains along these lines or has this proven to be a useful measure?

(Kim): Hi. This is (Kim) from the AMA. And we do have – this is strict – this is in regards to the use of the measure in the PQRS program and our weekly calls with the measure owners and stewards. And (Pamberg) who was our CMS contractor fields all questions and issues from the public and anybody who is

reporting on these measures and we have not received any issues or concerns regarding this measure.

Male: Have people been using it?

Male: For the three years that this measure has been in used, have we learned anything in terms of the gap that still exist in the drill, the quality measure to begin with?

Lindsey Tighe: Yes. Give me – give me one second and I'll look that up for you.

Female: I actually have it in front of me. In ASCO QOPI program, they achieved the measure at 70.29 percent and then PQS for 2009, it was at 91.24 percent.

Male: Interesting, OK, thank you.

Angela Franklin: There are some specification differences between the ASCO QOPI measure and the PQRS measure though.

Male: But the measure, let me make sure I understand, the measure is voluntary. So, is that correct? You are going to report the measure if you signed up to do it.

Angela Franklin: Right and if you select it. So, it's voluntary.

Male: OK, OK.

Female: But in my QOPI measure though it's not – it doesn't include mild pain. Is that correct?

Angela Franklin: That's right. It doesn't include mild pain and it's not limited to patients receiving actively receiving chemo or radiation. Those are the differences. And it's a chart out. It's implemented. It's a chart obstruction measure instead of a claim, you know, a claims-based reporting using CPT II codes measure.

Male: OK. And that's what I heard you say I think, I heard you say was around 70 percent in QOPI was out the limitations that we described around the measure that we're now talking about.

So, across that broader base you don't have any issues arise in terms of the trivial pain or the severity problems that we're describing?

Male: I think QOPI wasn't including trivial pain. I think it was limited to moderate or severe.

Male: OK.

Male: I think we focus that.

Male: Sorry, thank you. So, then let me ask this question, how did you in QOPI determine whether how severe the pain was? Was that documented in someway or left at the viewer's discretion? How did that work?

Female: No, that is actually quite similar to the first of the paired measures that you're reviewing from the AMA PCPI where it's looking for documentation using a standardized scale.

Male: Thank you.

Angela Franklin: So, do we have other questions about these or do we – would we like to look at reconsidering the vote on this one, on this?

(Naomi Norman): I have to say I'm really reluctant to reconsider a measure that's been in the field and used in large proportions or in by a majority regardless of our reservations of it.

Male: I share the same concern.

Male: I guess I'm beaten down and I'm OK. Leave it the way it is.

(Naomi Norman): So, that would be my recommendation. This is (Naomi).

Robert Miller: Yes, this is Bob Miller, I'm also in favor of just leaving the vote as it was. Again, I fully understand that the discussion has been very illuminating here, but I fear – like I said earlier, it would be more of an attended consequences of making things worse than they might already be right now I think when it's being used.

- Bryan Loy: And this is – this is Bryan Loy. I would also be quick to say, it feels like that there is a recommendation in this discussion somewhere that hasn't been fully formed yet. But to somehow provide some guidance to the developer, to improve this measure, but I don't – I don't think we've – I don't think we've articulated that in way yet.
- Angela Franklin: This is Angela, I just want to let you know, we can put together language and include that in the report as revised that goes out the recommendations as it becomes fully formed by the Steering Committee for this measure.
- Lindsey Tighe: Yes. It would be better if there was more specification about moderate to, you know – the mild pain should not be considered.
- Angela Franklin: So, we'll include that in our recommendation of course.
- Female: I think it would also be good to have, you know, more specificity about what really constitutes a plan of care.
- Angela Franklin: I would note at that.
- Male: I would agree with that last comment because I think that it was noted earlier that the, you know, an increasing electronic documentation. I totally envision there's going to be basically a box that will get checked, that we will pass to audit which does an operational as really pain improvement at all. Just stop. It's just it feels checking a box and that would be my concern.
- Angela Franklin: OK, we're adding that.
- Bryan Loy: I hear that concerning from a payer's perspective. We kind of live with that already with this evaluation and management documentation software. So, I'm just – I know I'm not representative of the developer, but I'm just wondering, what does that need to look like in the EMR environment if it's not a checking of the box of some sort. Is there more specificity that gets to a – we actually did something for the patient versus we documented something for payment purposes or follow the assessment that we might provide?
- Angela Franklin: (Sam), did you want to speak to that or anyone from AMA PCPI?

(Sam): I'm sorry, you guys are kind of phasing in and out. Could you repeat the question?

Bryan Loy: Yes. I think what I'm hearing – this is Bryan Loy. What I'm hearing from the Steering Committee is that we have – we're somehow saying we don't want to create a check the box environment that really has no impact on the patient experience. And my comment was from the payer perspective, we live with a certain amount that I think today and I'm just wondering if we might come back to the developer and say, you know, there's a little more specificity versus just saying, you know, pain addressed or pain documented and addressed.

I'm wondering if there are some sort of elaboration or specificity that we might provide on our recommendation that would somehow improve the profitability where something is being for the patient rather than just simply checking a box to lead a quality measure or for payment purposes.

But that comment suits for a lot of ...

(Sam): Well I think some of that though comes as you – as you, you know when you – when your denominator is so broad that, you know, doing just about anything allows you to pass the indicator. The you know, checking a box becomes, you know, kind of a three-point solution and is kind of – kind of meaningless.

If your denominator is narrower so that they're actually is specific action that can be, you know, checked and you can check it again, pharmacy records or referrals or things like that, then I think you know, you're less confirmed that people are just trying to, you know, check the box to get by.

(Karen): This is (Karen) from the AMA PCPI and I'll just share with you that obviously we share your same concerns about assessments and check box measures. And we're actually working on a research project currently that are looking at best practices around those sorts of documentation not specifically for this measure but for other measures that have similar concerns so that we can

continue to provide the best implementation suggestions that we can and make sure that our measures are meaningful.

Male: Right. The comments about the check box, I mean that's true with a lot of these – a lot of these measures, you know, how they manifest that measure whatever the NQF endorses and Medicare endorses, the vendors will create and the electronic record system boxes to navigate all of these.

That's just an unfortunate reality of sort of, you know, trying to micro-manage complicated processes.

Angela Franklin: This is Angela. Do we have additional comments for – or recommendations for this measure as the Steering Committee?

OK, hearing none that moves up to theme number three which is a request for reconsideration of that measure 0562 over utilization of imaging studies in melanoma.

And this is a measure that was initially not recommended for endorsement by the Steering Committee. And the developers have provided additional evidence on the measure. And we are wanting to have discussion, additional discussion with the Steering Committee about the measure.

But before I do that, I'll let the developers walk through items for discussion. They have submitted to you a letter which is included in the e-mail to the Steering Committee. But I'll let the developers walk through the issues that they'd like the Committee to reconsider.

Diedra Joseph: Hi. So, this is Diedra at the AMA. First, I'd like to thank you all for this opportunity to present our concern and for additional discussion.

So, this measure is – was actually recently updated based on changes in evidence-based guidelines. As you know our measures are based on evidence-based guidelines. And the measure is related to improved outcomes including reduction of radiation exposure on patient anxiety and also focuses on a cost reduction.

So, the measure is – one of the issues that we wanted to address was on day one of the in person, meaning the voted way down due to evidence. And so, we just wanted to reiterate that the measure is supported by guidelines from the American Academy of Dermatology as well as the MCCN.

And the MCCN guideline specifically pulls out to be staging that – that is included in the measured denominator. We included the actual guideline recommendation in the letter there. So, I won't read that because it's kind of lengthy.

But during the – additionally during the in person meeting and the subsequent review of the measure, the Steering Committee noticed additional concerns regarding the reliability of the measure as currently specified. And the original submission of the measure did include details similar to (inaudible) ratio analysis for the reliability which demonstrated very high reliability for the measure.

Additionally there was some certain data at the data element level that was presented in the initial measure submission. On day two of the in person meeting, we did prevent additional data element level of data further showing the reliability of the measure which was requested by the Steering Committee. And that data actually pulled out two different types of – types of patients.

The current diagnostic melanoma patients as well as the history of patients and again that data showed that the measure was reliable.

And lastly I know that there was a concern from – that was expressed by several of Steering Committee members that patients with recurrent disease would not be restated at the time of recurrence. And as a result, the patients may not receive the appropriate care which may require imaging.

And the measure focused on localized melanoma patients only. So, this is demonstrated in the measure language which includes without signs or symptoms suggesting to something spread.

So, the melanoma work group does agree that patients with signs or symptoms should absolutely have imaging performed. And therefore all the patients that

have melanoma recurrence, indicating metastatic disease would display signs and symptoms and would therefore be capture in the measure.

So, I'll stop there and I'm happy to answer any questions that you have.

Bryan Loy: I don't have it in front of me, what is the measure where there's some ambiguity in terms of the entry criteria again with denominator it was initial – if I remember this right. Can somebody from the NQF could remind me what that concern was?

Female: Yes, I'm trying to remember it too. So, can you explain to us how, what the variables are in the measure that capture the signs and symptoms and recurrence and exclude those patients from the denominator?

Diedra Joseph: I'm sorry, I'm just pulling up the measure form here. So, to answer the first question, the denominator statement for the measures, all patients regardless of age with the current diagnosis of stage zero through a 2C melanoma or a history of melanoma of any stage without signs or symptoms suggesting systemic spread in for an office visit during the one-year measurement period.

So, we did include definitions of signs or symptoms, but the way ...

Bryan Loy: Excuse me, that was – if I may, I'm sorry – so, the concern I think was in that first sentence, there were two populations of patients included, initial diagnosis and patients who are coming (inaudible) a follow up. And then the NQF staff can help drag my memory back. I thought that was the thought they got and many of the members of the committee concerned about the validity of this measure.

Female: Isn't the measure – I mean aren't the patients been identified to explain?

Diedra Joseph: Yes, so – sorry. So, the patient population, the measure is actually reported through – yes, it can be reported through claims and the patient population is captured in the denominator by ICD-9, ICD-10 codes as well as CPT codes.

And again, there are CPT codes that would be also be reported to indicate the essence or the presence of the signs or symptoms and then additional CPT codes to report the stage of the melanoma.

And then just as a point of reference, that's one implementation of the measure and a particular type of program as speaking of claims. It could be used in other types of programs with other types of data sources.

Karen Fields: This is Karen Fields. I'm sorry to join late. So, I guess that the main issue was the measure was voted – it didn't pass the first criteria which was importance to measure because of our concerns about adequate amount of literature to support the measure.

I think other measures that we worked on did describe that there were – that guidelines didn't necessarily require the same amount of measures. I think that the main issue is there's never going to be any literature to support whether or not you should use – nobody is going to do a study looking out how you should stage and follow these patients or no one has done that study.

So, I guess I'll bring that back to the table for the rest of reviewers to discuss.

Diedra Joseph: So, this is at the AMAs. You're correct, there is limited evidence with regards to that, but there is – there is some existing evidence that shows that low yield and false-positive findings are frequent in staging these particular patients.

And so, if that will be helpful to provide that – those studies, then maybe the Committee might reconsider the evidence.

Angela Franklin: I mean I – remember there's a pretty strong consensus that you shouldn't (inaudible) patients to have, you know, low – you know, who fall into the low risk melanoma group or do a surveillance testing on them.

I think the concern somewhat I remember the conversation was just that the denominator was not necessarily specified in such a way that especially given a long follow-up periods of patients that you would necessarily be having strict enough criteria in the denominator. That's what I remember the concern being.

Female: That's what I remember.

Angela Franklin: Yes. I know that we voted it down, but I agree that I thought we were concerned that the appropriate patients that needed staging and follow up we're going to – we're going to – the measured discouraged follow up of appropriate patients.

Diedra Joseph: I'll just read quickly a recap of – there was a note that the denominator should be limited to patients with a new diagnosis and there was a request for additional data from the developer which they provided on new patients versus patients with a history of melanoma.

Angela Franklin: Right. So that's what I think we're all saying, the literature that we were missing was or the concern we had was, if somebody had something that we needed to follow, then they shouldn't be confused with the group of newly diagnosed patients with limited stage disease that didn't need aggressive staging in the first place. Will they say that for the group OK? Or am I saying that – describing that OK?

(Robert Miller): Well, this is (Miller), I'm sorry. I'm back. My concern was always that and maybe we're seeing the same thing but it would be the patient you're following and you needed to do a scan for some reason unrelated to melanoma but that you would be – your hands might feel tied to not order the scan.

Can I understand in the specifications it says that those things are excluded if there are some other diagnosis, but that would, you know, other clinicians, a lot of times you'll say to yourself, well, I, you know, this person has a headache and then they'll think it's not likely to do the melanoma, I think they need a brain MRI scan.

And I just found the boundaries of this, just not defined well enough and I'm just not even sure how this – how these exclusions would be handled. I have had and continue to have the greatest concerns about the denominator exclusion, so that they're not specific enough because I think that's common scenario or something that would be troubling in the routine follow up with these patients.

Angela Franklin: I agree with you, I think that's what I'm trying to say too, you're saying it better than I do.

Diedra Joseph: So this is Diedra at the AMA. Just to clarify, we have listed these actual denominator exceptions which are different from exclusions. The exceptions allowed for clinical judgment which is why we – which is why we incorporated exceptions into the measures. And we have documentation of medical reasons for ordering diagnostic imaging studies including a couple of examples that are listed there for medical reasons and system reasons.

For a medical reasons, we listed an example of patient has a co-morbid condition that warns imaging. We also allow for other medical reasons. And for our system reasons we have that the imaging is required for clinical travel enrolment or the imaging is ordered by another provider or other system reasons.

So we do allow for clinical judgment by the physicians by including the documentation of medical reasons and documentation of system reasons in the measure.

Angela Franklin: So here was our – I think our issue is this, the NCCN guidelines say further imaging only if clinically indicated. So we would clinic – we would – what we would do is, following NCCN guideline, we might have some clinical indication.

And then we might have to still follow up abnormalities on those scans appropriately even though we weren't – it wasn't part of their staging. I mean there still might not be abnormalities that we would say they had metastatic disease or symptoms to associate with what we've seen abnormalities. Do you get that distinction to the AMA?

Diedra Joseph: I understand the distinction. But again, the measure does allow for a patient who have – who are exhibiting signs or symptoms to receive imaging and the signs – the definition of the signs and symptoms is included in the form.

For purposes of the measure, the signs include tenderness, jaundice, localized neurologic signs which is weakness or any other signs, symptoms for the purposes of this measure include, cough, dyspnea, pain, paresthesia or any other symptom.

So if the patients that for any other reason needs to have imaging whether it's another co-morbid condition, an additional investigation that needs to occur because of some other complaint, that measure does allow for the patients to receive the imaging through the reporting of exceptions and through – actually through reporting of exceptions. And the definition I think helps to make that more clear or at least that was the intention.

Female: And how do patients who have relapsed get taken care of?

Diedra Joseph: So the patients – the denominator actually captures all patients with current diagnosis or history of melanoma of any stage. The current diagnosis patients are stage zero through 2C, the patients with a history above any stage are captured in this measure as well.

So if a patient has a relapse and they exhibit any sign or symptom, they ...

Female: Well, let's say they have relapse without any symptom. How would – how would they get with it?

Diedra Joseph: How would the – how would the relapse be indicated or documented?

Female: Maybe they have a chest x-ray.

Diedra Joseph: Then that would be a sign. If they say signs and symptoms, that would be a sign. Any reason that – or any measures ...

Female: Or what if someone's relapsed then they're in remission? I mean, I don't know, I mean, there needs to be a way of excluding people who – I mean that's I think where it comes down to is that, the people who – so stage refers – stage never changes. If you were stage one at diagnosis, you're still stage one when you relapse. You're just stage on but now you've relapsed.

So you have to specifically exclude people who've had recurrent ...

Lindsey Tighe: OK. Can you – can you perhaps provide an example of a person with a recurrence that your concern would be included in the measure inappropriately?

Angela Franklin: Can I ask a quick question? What we're looking at on the screen right now, is that rewarded from the last time we saw it? It was – some of this is scrolled down but we were looking at the exceptions, a couple of minutes ago. Is that different than what we reviewed before? Did you change the measure? Because I just saw a nice description of exclusions there, from that one.

Diedra Joseph: Yes, we have not changed the measure.

Angela Franklin: Then, perhaps we all haven't completely understood because I think that denominator exclusion detail addresses completely what the Committee's concerns were.

I think it says that if they evidence of recurrent disease then they're excluded and they're no longer included in the denominator.

And I think that's the concern that the Committee had. So I think just rereading that after this discussion with more clarity, I think I understand what your exclusion criteria was, so maybe the members could look at that real quickly.

Bryan Loy: Angela, this is Bryan Loy, I need to excuse myself from this call. I've got a scheduled conflict.

Angela Franklin: All right. Thanks, Bryan.

Bryan Loy: Thank you.

Angela Franklin: So, Diedra, do you mind walking us through the exclusion details? I thought you might be better.

Diedra Joseph: Sure. So, let me just get to that in my form here. So, I don't want to just read from here but I think I – it might be beneficial if I do cover all of these.

So, we do use the three categories of reasons including medical patient or system reasons. For this particular measure, we've included medical or system reasons as exception for the measures. We do provide example which is not intended to be an exhaust of list. Just examples in order to guide physicians and, you know, explaining what we mean by medical reasons or a system reason.

Where examples of exceptions are included, the examples are coded and included in the spec. Although the methodology does not require expanded reporting of more detailed exception data, we do recommended that physicians document the specific reasons for exception and let's see, we also advocate for exception rates to be reported.

So for the claims, in order to report the exceptions we would use the CPT codes here and then append a modifier to it for medical or for assistant reasons.

I'm not sure if that's what you wanted me to explain but that's what's in that denominator exception details – exclusion detail.

Angela Franklin: And then you also described all these symptoms that qualified, I thought that was a helpful list. Is that anywhere else in this document that we ...

Diedra Joseph: The signs or symptoms?

Angela Franklin: Yes. And you don't need to read it but you just told us that a couple of minutes ago.

Diedra Joseph: It's in the denominator detail.

Angela Franklin: OK. I just – it's not on the screen right now, right? OK, thanks.

(Robert Miller): So can I clarify, this is (Miller) and I'm sorry I'm in the car, I can't see the screen. Can I clarify, so the exception then must fall into one of the specified categories that you list or are those just examples of what an exception might be?

Diedra Joseph: What is listed is actually just examples and it's not meant to be an all inclusive (exhaust of list). Which is why we add the example – we have a specific example and then we have other medical reasons to allow for the physician judgment and for the physician to include any other medical reason that they think warrants the imaging.

Angela Franklin: So, Bob, it says also or any other sign or any other symptom as well. So although they gave some examples, it's also very open.

(Robert Miller): OK. So for example, if – let's just make it clean and say this is a newly diagnosed stage one patient and the newly diagnosed stage one patient says, "I have a terrible feeling that I have metastasis, I don't have any headaches, I've got nothing on physical exam. There's no lab test that's abnormal, but I have a terrible feeling that I have a brain mass. I demand an MRI scan and PET scan."

Then the oncologist says then, "Well, I'm going to listen to this guy, if I don't find anything but I'm going to order this scan anyway." Then that's considered as an exception, is that what you're saying?

Karen Fields: That's one of those cases that we – I'm sorry, this is Karen at the AMA PCPI, that's one of those cases that we talked about a lot probably disproportionate to the number of times it happened.

And other example that we used is the patient that absolutely is not going to leave the office until you give him an antibiotic for their cold. And in those cases, it would not be considered a valid medical exception. If you do something that is not a medical exception and you provide care that's not following the medical – in the accepted practice, then it is a measure of failure.

The number of instances of those patients should be extremely low and randomly distributed would be our thought.

(Robert Miller): Well, you don't know that right? I mean, there' no one ...

Angela Franklin: Yes. They'd probably not.

(Robert Miller): ... they don't know that.

Karen Fields: Yes, well, you're still making a decision as a clinician to go against your medical judgment to provide this patient with care unless they don't have a medical indication for. Does that make sense?

Angela Franklin: I guess the concern is, then we have that in the breast group which we also approved that no limited staging for stage one and two and they're going to have the same issues with that as well.

(Robert Miller): Right. And again, I think we had the discussion the in-person meeting that I think most of our heartburn was over the fact that this was not related just to the time of diagnosis.

And again I'm sorry, I miss the documentation of the call, but if that's still the case. These are the patients who have a history of stage one melanoma, it could be year 10 after stage one melanoma but it's not restricted to a timeframe of the new diagnosis, is that correct?

Angela Franklin: Yes. I agree that was part of our discussion and I don't think – I don't know that we – it sounds like what we hadn't completely incorporated in our discussion then was, were there enough exceptions so that those patients that – I mean, here's another question for the AMA then.

If those patients get out of the denominator, they're out of the denominator forever, right? If somebody had a sign or a symptom with an early stage melanoma, stage one or two and then we evaluated the sign or symptom, they no longer in this numerator or the denominator, is that a true statement or a false statement?

Karen Fields: So these measures are reported and typically there's a measurement here and they'd have to have the active signs and symptoms to be removed for signs and symptoms, does that make sense though? Like a sign and symptom 10 years ago is not going to exclude me from measure today, it has to be an active sign and symptom.

And one thing I'll just say about what I said before, you know, if you feel that the patient's concerns are a sign or symptom of care, I mean, if there's something to that, if you investigate it and you find something with the medical indication, then it can be a medical exception. Does that kind of make sense? I mean it's – I'm not a clinician but its clinical judgment.

Robert Miller: Got it. I think that makes sense but I – again, I think you're still going to weed out, you're not – the measure is not going to be able to weed out the physician who says, "You know, I really think everybody ought to get a PET scan. This is what I've always practiced and I don't like the fact that somebody is forcing us no to do it so I'm going to," – you know, it's easy to come up with reasons to order a scan.

Trust me, as a clinician, it's very easy to order a scan. And again, if this was somehow tied to the fact that this is a 0.5 millimeter melanoma that was this size a month ago, I don't think I'll have that problem. But I, you know, I don't want to keep repeating myself but I think you understand my point.

Karen Fields: Yes, no, that's fair and we have some studies of our exceptions that have been published in peer review journals, not again on this particular measure but obviously exception methodology is something that we're very interested in and we want to make sure this is being used appropriately.

And in our studies we have done chart reviews and then compared those to a list of medically acceptable exceptions that are generated by a clinical expert panel and we've found very, very high agreement between what physicians chose to document as an exception and what a panel of their peers would consider to be a clinically relevant medical exception based on evidence.

Robert Miller: And were those imaging types of studies that's comparable to that, it might be the same tumor type but it was related to overuse of imaging or some other diagnostic test?

Karen Fields: Yes, not necessarily completely relevant to this, but using the same categories of medical system and patient exception. Obviously this is – this is one more special case.

Angela Franklin: And two more questions, are patients on clinical trials excluded?

Diedra Joseph: Patients on clinical trials that are currently in the system's exceptions for the measure.

Angela Franklin: OK. Because I just can't – I can't open up the other link for some reasons to see the whole measure. And then number two, so now we've ordered that chest x-ray on the patient that had a reason for us to order it or a CAT Scan, they've got a little (inaudible) in their lung because they have melanoma and then we get worried about that but it's too small to biopsy and too small to do anything. We're going to follow those PET – those lesions serially, that counts as a sign and a reason to continue to follow the patient, correct?

Diedra Joseph: That's correct.

Male: Now when you look at your exception data, does it more commonly occur in follow up or the diagnosis or you don't have that data?

Karen Fields: I'm sorry, one more time?

Male: When you look at the exceptions that are provided, are you more likely to see exceptions provided in the follow-up population or exceptions provided at the newly diagnosed population?

Karen Fields: If I recall the rate was very, very low in both of them. I'm not sure if the NQF staff could pull that up; if that was the data that we've provided on the second day?

Lindsey Tighe: Yes, we'll pull that up in a second.

Male: Because my recollection of the original discussion here was that I – was that, and I think it's been alluded to previously was that, when you're taking – like I think there's a group, there is a reasonable comfort level with the newly diagnosed population.

But then once you get into sort this, you know, this longitudinal follow-up then it gets to be, you know, a bit more complicated and that maybe the

measure was overreached in trying to sort of address those, you know, overused at initial diagnosis and then overused in post-treatment surveillance.

Karen Fields: Yes. So, I've found that numbers here, Diedra found them for me. The exception agreement was 100 percent in the new current diagnosis population and then the exception agreement was 74.59 percent in the existing diagnosis.

Again, I'll caveat at that, those are small numbers, you know, it's a small percentage of the patients that we did abstraction on that were exceptions.

Lindsey Tighe: Hi, this is Lindsey from NQF, I guess in the interest of time and seeing as the conversation has flowed, I guess what I'll ask now is if the Steering Committee feels that they would like to revote on their recommendations for endorsement for this measure?

Karen Fields: Because I came late I don't know how many of the committee is here to have heard this discussion and I don't remember what their vote was, how close it was.

Lindsey Tighe: We'll certainly recap this discussion and the vote will be done over survey at SurveyMonkey over email, we won't be able to do it on the phone right now.

Robert Miller: If you could stop this SurveyMonkey with, do you – do you think we should revote? I don't know if that's appropriate or not.

Lindsey Tighe: If we could just get a consensus on the phone because there actually there is a quorum on the phone right now, so if we could just – is anyone in favor of voting on the measure again?

(Robert Miller): This is (Miller). I am not on favor of the revote.

Robert Miller: Anybody who'd like to propose a motion to revote?

Jennifer Malin: I would like to propose a motion to revote. This is Jen Malin.

Elaine Chottiner: I second that. This is Elaine.

Lindsey Tighe: All right. We'll send out a link over SurveyMonkey with a summary of this discussion on the call and the letter from AMA PCPI staff and I'll wait for voting. All right. Thank you.

Angela Franklin: So moving on, quickly I wanted to ask the Steering Committee if we have any additional comments looking at the comment table that was sent out. If there were additional comments where you'd like to see additional response from the developer or you do not agree perhaps with the developer response?

Robert Miller: None for me.

Male: I'm looking.

Lindsey Tighe: And on the NQF staff perspective, it's actually a comment on measure 0377, the comment number is 2265. AMA PCPI staff we didn't actually get a response from you at all on this comment which we felt required from doing a response.

Female: I'm sorry, which comment was that?

Lindsey Tighe: Its comment number 2265. It's showed on the webinar screen right now. It's calling for a further definition on the time window for the numerator.

Female: OK. Can you hold one second while I pull that up?

Lindsey Tighe: Sure. While you're doing that, the Steering Committee members on the phone, is there any comment that you wanted to pull up specifically to – please feel free to do so.

Male: Is it a Word document or an Excel document? I'm looking for it.

Lindsey Tighe: It was an Excel document.

Male: Yes, I got it.

Male: What's the subject to the measuring now, I'm sorry?

Male: Yes, what's the number again?

- Lindsey Tighe: The comment number is 2265. It's a comment on measure 0377.
- Female: So this is the same – this is the same issue with the CLL. This is the (inaudible) and I don't recall – did we not pass that one?
- Lindsey Tighe: This measure was recommended?
- Female: It was recommended. And so what they're asking for is a time window? And I think that we already discussed it with the developer. They indicated that they would be willing to modify the measure to say that it would be at the time of diagnosis which would address that. So they would only be reporting newly diagnosed (NBF) in that measure.
- Male: OK. That's OK. We like that, right?
- Female: Right. I think that's the suggestion there and I think that the developer was willing to do that.
- Male: OK. So we could, you know, potentially approve it assuming they'll do that. So we approved this already, right?
- Angela Franklin: Well, yes. Could we hear from the PCPI on that, the definition of a time window?
- Female: So I'm actually am not able to pull that up at the current moment and – but since we only have a couple of minutes, I wonder if I – is this something that we can respond to via e-mail?
- Angela Franklin: We can definitely do that.
- Diedra Joseph: OK. And the recommendation was – I'm sorry, what was the committee recommendation?
- Angela Franklin: So further definition of a time window.
- Diedra Joseph: OK.

- Lindsey Tighe: And the committee recommendation would certainly look at newly diagnosed (NBS).
- Female: Right. Because the problem is that this measure was getting reported over and over on an annual basis even though the diagnosis and the studies may have been done, four, five, six years ago.
- Diedra Joseph: OK, we'll definitely respond to those comments and recommendations via e-mail.
- Lindsey Tighe: OK. Jumping really quickly to phase two, I know you have (Tom) and Kristen on the phone, they were just going to provide a quick update of what the modifications were to the ASCO measures were going to be.
- Kristen McNiff: Yes, this is Kristen so I can quickly walk through the – starting with the breast cancer measure for 1857. We actually – there was a requested change the wording of the title, so it didn't include the word not administered trastuzumab. We actually read that out during the meeting and have submitted that, so the new title – would you like me to reread it?
- Lindsey Tighe Sure. Please.
- Kristen McNiff: Patients with breast cancer and negative or undocumented HER-2 status who are spared treatment with trastuzumab.
- Lindsey Tighe: OK, thank you.
- Kristen McNiff: And 1858 there was a request to add, to clarify in the measure title that this is in the context of adjuvant chemotherapy. So we've submitted a title change that would read trastuzumab administered to patients with AJCC stage 1, T1C through stage 3 and HER-2 positive breast cancer who receive adjuvant chemotherapy. And again, these are the same as we went through.
- Male: Sounds good.
- Kristen McNiff: Shall I continue with the other?
- Lindsey Tighe: Sure.

Kristen McNiff: OK. And then moving into the colorectal measures, there was a request for 1859 and 1860 that we provide clarification about which mutation testing is specified for this – for both of the measures so we've added some definitions they are being – they're out for review right now by our clinical experts but taken directly from the provision of clinic opinion, the guideline from which this came, it is – or we now have definitions that specify that we're looking for mutation on codons 12 and 13 of KRAS only.

We were also asked to provide a definition or an instruction about which task should be included if there are multiple test results build on the patient record. And again, that's out for review but as for our convention, right now, you know, have a statement that you would look at the most recent test result but that definitely needs to be reviewed by the clinicians.

For 1860, there was the same changes apply or the same definitions apply. There also was a request that we added denominator exclusion about receipt of the monoclonal antibody therapy as part of a clinical trial and so we have added that as well and that will be sort of resubmitted.

Lindsey Tighe: OK, thank you. Are there any comments from the Steering Committee?

Hearing none, I imagine you are all OK with those changes.

OK. And given that we are running over at this point. The harmonization is used for the ACS and AMA PCPI measures were pretty well discussed at the in-person meeting. And at least from the NQF staff perspective there was no modifications to the measures that were required.

I sent some information on materials from Andrew Stewart out, if there are any questions I'll just ask that you follow up on email about that and we can address those with Andrew Stewart from ACS and with AMA PCPI staff.

Operator, if we could at this time open up the lines, everyone's line for a member and public comments.

Operator: If you like to ask a question press star one.

At this point, there are no questions.

Lindsey Tighe: OK, great. Thank you so much. As far as briefly for our next steps, we will be red binding the stage one draft report based on today's conversation and we'll send that out to you all for review. We'll also be sending out a brief summary of the discussion on measure 562 along with a link to allow the Steering Committee members to revote on the measure.

With the respect to phase two, we will be finishing up the draft report and getting that posted for NQF member and public comment in about two weeks.

Again, we'll be following up with you all very shortly over email but thank you all very much for your participation on this call and at every meeting in the past.

Feel free to contact us with any questions and apologies to ACS and AMA PCPI staff for not getting into that agenda items today.

Thank you very much.

Male: OK.

Operator: This concludes today's conference. Thank you for joining. You may now disconnect.

END