NATIONAL QUALITY FORUM

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CANCER ENDORSEMENT MAINTENANCE STEERING COMMITTEE

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THURSDAY

MAY 24, 2012

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Stephen Lutz, MD, Chair, presiding.

PRESENT:

STEPHEN LUTZ, MD, Blanchard Valley Regional Cancer Center

JOSEPH ALVARNAS, MD, City of Hope*

ELAINE CHOTTINER, MD, University of Michigan Medical Center

KAREN FIELDS, MD, Moffitt Cancer Center

JOHN GORE, MD, MS, University of Washington School of Medicine

BRYAN LOY, MD, MBA, Humana, Inc.

JENNIFER MALIN, MD, PhD, WellPoint

DAVID PFISTER, Memorial Sloan-Kettering Cancer Center

PATRICK ROSS, MD, PhD, The Ohio State University Comprehensive Cancer Center - James Cancer Hospital

NICOLE TAPAY, JD, National Coalition for Cancer Survivorship

WENDY TENZUK, Colorado PERA*

NQF STAFF:

HEIDI BOSSLEY, MSN, MNA Vice President, Performance Measures

EUGENE CUNNINGHAM, Project Manager, Performance Measures

ANGELA J. FRANKLIN, Senior Director, Performance Measures

ADEELA KHAN, Project Analyst, Performance Measures

LINDSEY TIGHE, Project Manager, Performance Measures

ALSO PRESENT:

KERI CHRISTENSEN, MS, AMA-PCPI Measure Development

MICHAEL HASSETT, MD, MPH, Dana Farber Cancer Institute*

KRISTEN McNIFF, MPH, American Society of Clinical Oncology

V.O. SPEIGHTS, JR, DO, College of American Pathologists and Texas A&M Health Science Center College of Medicine

ANDREW STEWART, MA, American College of Surgeons

SAMANTHA TIERNEY, MPH, Physician Quality Reporting Initiative*

*present by teleconference

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(8:42 a.m.)

OPERATOR: Welcome to the Measure Application Partnership Safety and Care Coordination Task Force meeting. Please note today's call is being recorded. Please stand by.

MS. FRANKLIN: Hello, this is Angela Franklin. Welcome to the Cancer Endorsement Steering Committee meeting. This is Day 2 of our meeting, and I have with Dr. Lutz, our Chair of this Committee. And we'll start with a quick question to see if we have on the line developers from AMA-PCPI on the line?

MS. TIERNEY: Hi, Angela. This is Sam Tierney, AMA. I'm on the line.

MS. FRANKLIN: Okay, thank you. And with that, I'll turn it over to Dr. Lutz.

CHAIRMAN LUTZ: Okay. So, we're going to start with the harmonization of 220 and 387, so if we could maybe just get a

little recap and then an idea of how things have progressed with discussions about how that harmonization might go.

MS. FRANKLIN: So, in the room we have developers. And if they could walk us through the areas for possible harmonization, and we'll have the Steering Committee weigh in after.

MS. McNIFF: Good morning. Kristen McNiff from ASCO. And Sam Tierney is on the line. Measure 387 is actually stewarded by the AMA-PCPI, Sam Tierney is here, but I was involved in that work group so can speak to some of the issues, as well. How do you want to -- you want to start with --

MS. FRANKLIN: If you could just walk through the areas. We usually look at the data source, level of analysis, and numerator and denominator.

MR. STEWART: So, maybe we'll just pass this back and forth. So, the other measure in question here is 387 for which the

American College of Surgeons is the steward. I'd also take two -- I'm sorry, 220. I'm reading the wrong column, 220 for which the College of Surgeons is the steward.

I think there's some opportunity for discussion here. I don't think it should be a big issue. I think these are complimentary measures, not competing measures. We can discuss the reasons for that review and take the opinion of the Committee as that discussion moves forward.

MS. McNIFF: And, Sam, I don't want to step on your toes here, so do you want to do the introductory comments about the differences, the basic differences, or do you want me to do it?

MS. TIERNEY: Kristen, it's up to you. I know you're in the room, so it might be easier if you do it, if you don't mind.

MS. McNIFF: Okay, I will, and you can definitely jump in.

MS. TIERNEY: Okay, thanks.

MS. McNIFF: So, I'll speak to 387, but describe just broadly the kind of fundamental difference, and agree with Andrew that we don't believe these are competing. They're really getting at the same basic construct, but they're looking at hormonal therapy in two very different ways.

The 387 has been implemented for several years in the PQRS program, and certainly is used outside of it, as well. But the thought when the group was developing this was to capture a patient at any point in time between diagnosis and five-years out. And that could be any provider. And to find out whether the patient is receiving a hormonal therapy. And it doesn't need to be a prescription written by the provider, it could be a patient who they're seeing who is maintain -- still on their therapy from an existing prescription. So, the specific intention was to make sure that anyone who is caring for somebody and submitting the 174 ICD-9 code for cancer is

looking at and being thoughtful about whether the patient should be receiving their hormonal therapy, whether they wrote the prescription or not.

So, this is a physician-level measure. It's specified for claims reporting, and there are eSpecifications, as well. So, it's kind of a broader time frame for the numerator.

MR. STEWART: So, that exactly speaks to the complementary nature of these two measures. The 220 when it was developed was developed with a more singular focus on recognition eligible patients for hormonal therapy, and insuring that institutions, because the measure was developed for hospital-level reporting, that institutions responsible for those patients' care initiated care in a timely fashion. So, while 220 is more narrowly focused on the preliminary and counter diagnosis, and development and initiation of treatment plan, 387 allows that

treatment plan to be tracked or followed potentially over time. So, it's almost -- the scenario is almost one in which one measure is handing the patient off into the next. And it's that continuity issue that we believe brings complementary nature to these two similarly crafted or phrased measures.

MS. McNIFF: So, do you want us to go kind of area by area, or --

MEMBER LOY: I'm just curious. At the end of it feels like the facility is not responsible for writing the prescription, the physician is, or someone under the physician's guidance. But, ultimately, it seems like the more proximate measure is whether or not the prescription got filled, and whether it -- the pharmacy was involved or not. Have you all -- has anyone given any thought to trying to make sure that the prescription actually got filled?

MR. STEWART: I made mention yesterday of some work that we've done linking

the registered base data that we used to monitor this metric with commercial claims data. And it is possible to be able to signal that prescriptions were filled. And you can actually watch the timing of those prescriptions getting filled over a course of time. This particular measure is simply -- 220 is simply focused on did that process get kicked off.

MEMBER LOY: Could you repeat that?

MR. STEWART: So, 220 is focused on whether or not that process was kicked off.

MEMBER LOY: I'm just thinking from pharmacy claims data you probably have a referring or a prescribing physician's identifier on it. As I'm kind of thinking back to some of our conversations yesterday, it feels like when you've got a hospital or acute care facility, and everybody is responsible, ultimately, nobody is responsible. And I'm just wondering --

MR. STEWART: In our sort of

organizational construct the enterprise is responsible because of the way we laid these metrics out in front of the institutions that we accredit. We're primarily concerned about the continuity of a patient's care, so we're not so concerned about whether it was the surgeon, or the medical oncologist, or whoever it was that wrote the script. We want to make sure that that patient moves through the system successfully.

MEMBER FIELDS: Can I ask a little bit more about the process? You -- it's the tumor registry which is your tool, and you're monitoring to see that a certain percentage of women got prescribed estrogen, but your action plan is going back to the Tumor Committee, the Cancer Committee to talk about -- for them to develop action plans. And then do you re-monitor them?

MR. STEWART: Yes, we do.

MEMBER FIELDS: So, this -- how does it -- I mean, how does this quality

monitor help us with non-ACOS -- I mean, I don't understand the use then outside of ACS-certified cancer programs for this monitor. I can understand the other one a little bit more as a direct correlative to patient care, but not a lot of the hospitals are -- well, a lot are, but a lot aren't, where we worry about quality anyway.

MR. STEWART: Right.

MEMBER FIELDS: So, what's the solution for this monitor in that context?

MR. STEWART: Well, let me talk a little bit about breadth of operation, and then talk about other complementary implementations that we've been party to or aware of.

The ACS hospitals, we accredit cancer programs in about 25 to 30 percent of acute care hospitals in the country. On the other hand, those hospitals treat and manage approximately 70 percent of all ensuing cancer diagnoses in the country, specifically breast.

We have reported to us in the vicinity of 230,000 breast cases a year, which is almost 80 percent of all breast cancer cases. So, we feel that even though it's just being implemented in COC accredited hospitals, we're still casting a significantly broad national net in implementing this kind of metric.

There are other organizations that have picked up these exact same measure specifications, and leveraged them across geographic areas in which there is limited COC accreditation coverage, and attempted to implement these almost on a sort of a population-based enterprise. I can think of areas like Kentucky where this has been done, so this has developed over the past couple of years in a broader implementation possibility.

MEMBER FIELDS: It's just if this became part of pay for performance, we wouldn't have a mechanism to monitor it as easily as we would the direct provider link.

MR. STEWART: Well, understand that

cancer is a federally mandated reportable disease, so that even if the COC does not have an active accreditation program inside a hospital, cancer diagnoses are still be tracked, identified, and reported at least to state incidents and mortality registries. The algorithms that support the calculation of these metrics are in our view public domain, which is why they've been distributed very broadly in the State of Kentucky.

There's no reason why these things can't -- and we have every indication that are commercial software interests and enterprises that support cancer registry operations that actually started putting this algorithms into their software tools for the benefit of all clients, whether or not they have programs or otherwise.

MS. McNIFF: Can I just add to that. You could tell ASCO supports both these measures here. Two things. One for the 220, that measure has been recommended for

inclusion in the required PPS-exempt cancer hospital reporting, but was part of the Affordable Care Act, so that would be at the institution level. That would be a direct accountability use of the facility-level measure. And we use this in QOPI. You know, some of the QOPI data was presented with 387, and we actually look at it several different ways. But we report at the facility practice in this case, the practice level, and for quality improvement use, that's what ASCO considers to be the actionable unit for reporting, is the practice site facility.

CHAIRMAN LUTZ: Can I ask a question? When you say practice site facility, so I'll just my site as an example. We have a freestanding cancer center that I work out. We have a urology group that's separate. We're all on staff at the hospital, but they can do what they want, I can do what I want. In other words, when you're evaluating or talking about accountability, I'm trying to discern the

difference between if there's a measure that goes by physician that seems more fair than a measure that goes by facility, when we don't have any formal means by which to change the behavior pattern of other physicians in our system. We don't really have a system. I mean, this place is -- you know, like the university has integrated programs, we don't. And many places I know don't, so maybe I'm asking for education, but specifically about these two measures, how is it that the one that measures physician behavior isn't more fair than the one that measures system behavior, when I can't even tell you I have a system? Am I being clear or am I muddying the waters?

MR. STEWART: No, I think you're clear, and I don't know that we would have a clear answer for you. I mean, when -- the college's approach is at a programmatic system level. And where those systems are not functioning or don't exist, then

implementation of this and understanding how it reflects on a loosely conjoined set of practices is a much harder thing to try and handle.

CHAIRMAN LUTZ: David, I think you have something?

MEMBER PFISTER: So, these initially were basically submitted fairly independent by two separate groups. So, let's say that wasn't the process and you started right from the get-go, the two groups actually worked to come up with a measure, would you feel compelled to come up with two measures that were sufficiently complementary to do that, as opposed to this is where we are now so now we're trying to sort of come up with a rationale that -- there's a spectrum of health care where there are many, many things that we need to measure, that we need two things in this particular sort of area.

And I do think that Kristen's comment that the 220 is already part of the

exempt -- you know, the proposed measures, I think it's one of the five for the exempt centers for 2013. Right? So, I guess I'm a little visual, and I guess the table doesn't -- so, even the degree of the -- the value-added for the complementary nature isn't totally kind of coming across to me.

MR. STEWART: I'm not specifically clear on the origins of 387, but my supposition is that in both instances these developed independently because we had a dog with two different tails, so the development of those measures and the respective implementation of those reflected basically structural demands within the broader system. So, we are now where we are with what we have. I'm not sure what would have been necessarily different.

MS. McNIFF: I don't -- they were created for use at different levels and using different data sources. I don't think we would have come up with the same -- a lot of the

same people were involved in the same projects but they were fundamentally assessing the same construct in different ways, so I don't -- the 387 was developed after 220, and folks on the work group were very aware of the existence of 220, but we needed a measure that could be implemented using claims-based reporting at the physician level. That was the need.

MS. TIERNEY: This is Sam Tierney. If I could also add to what Kristen and Andrew said. I guess if the PCPI -- we've been developing measures for some time now and I think that we see that in many areas of health care, many NQF endorsed measures, there are measures that assess performance that fits the level that may be publicly reported by CMS or other institutions, but we've also seen a need to develop measures at the physician level to mostly identify opportunities for quality improvement. And also because there's a need for measures focused on the physician level at the federal reporting level, as well, such as

in CMS' PQI Program, and for maintenance of certification, as well. So, I think there really are complementary efforts.

MEMBER LOY: I wanted to ask one more question to both of you, and that would be how do you exclude each other in your universes? The patient lives in both. Right? I mean, they're in a clinician's office and potentially a facility, so how do we get passed the double counting phenomena? Does that make sense?

MS. McNIFF: It does, and you can jump in, but I don't believe they're double count -- I mean, they're reported in two completely separate ways. You wouldn't -- it wouldn't make sense, certainly, within one -- I wouldn't think it would make sense within one institution to run both measures and report both of them side by side. That doesn't make a lot of sense.

MEMBER LOY: Yes, but --

MS. McNIFF: But the --

MEMBER LOY: Well, I'm thinking a patient who say had a procedure done in a COC center, so they end up in the denominator over here, and perhaps that measure got fulfilled, the criteria got fulfilled so they met 220. But given that they met 220, they're over here in 0387. Somehow they live over here. How would 0387 deal with that? They wouldn't know that the criteria got met in 0220. Am I missing something?

MS. McNIFF: No, they are completely independently --

MR. STEWART: You're correct. They're completely independently managed, recorded and coded. The coding specifications rest in different sources and different paradigms. From that respect, they are different pieces.

MEMBER LOY: Let me ask it a different way. If I met the criteria in 0220 in a facility but as a patient I end up over in an outpatient clinic setting for whatever

reason, am I excluded from the denominator?

MR. STEWART: No, not necessarily at all.

MEMBER LOY: That doesn't -- it feels like there's a flaw in that, to me. It feels like that you're going to have an artificial false negative in that situation. And given that there's a lot of community care still out there in facilities, it just feels like we've got a mix of patients that some of which reside in a facility setting with hospital-owned physicians or affiliated physicians, and we've also got a site of care over here that's community that's very fragmented. It's not clear to me how we might interpret that data, ultimately.

CHAIRMAN LUTZ: I think Elaine has something.

MEMBER CHOTTINER: I have the same concern because I came from an excellent community hospital where we did more breast cancer than they did at the university, but we

were a private practice. We had our own EMR. And this patients who got adjuvant hormonal therapy would see us sometimes after radiation or far out from initiation of care. And so far as I know, the tumor registry didn't capture any information from our practice very efficiently. And I actually had the opportunity to review that because we became one of the NCCN sites, and we had extractors go back and in great detail pull out this information, and the discordance was very impressive. So, I'm also concerned that because a lot of breast cancer care is delivered in the community by private practices for as long as they survive that there's great potential for quality looking much worse than it is if you're looking at the facility level.

MR. STEWART: That is a well recognized soft point of cancer registry operations period, is that capturing and securing information about ambulatory and

outpatient treatment is known to be routinely under-reported for precisely the reasons you're describing, because of access to information that exists in patient and medical records outside the brick and mortar confines or sort of legal entity of the hospital in which those registries work and operate.

And we've been trying to employ a number of tools and resources to try and figure out how to facilitate better processes by which that information can be secured and brought into the registries with some success, but we know that hormonal treatment for breast cancer is admittedly an Achilles heel when you think about completeness and accuracy of cancer registry data. And it is precisely because of the way in which that therapy is provided, administered, and managed, and so forth. Usually, typically outside the immediate confines of the hospital where the patient was likely to have been surgically treated, where radiation oncology facilities

are located, et cetera.

I can say that the degree of "missingness" at least at the national aggregate level has declined precipitously in the last 10 years to less than half the proportion that we were witnessing in the mid to late '90s. That doesn't mean it's perfect. There's still room for improvement but we've made significant change in that direction.

CHAIRMAN LUTZ: Bryan and then John. You, John.

MEMBER GORE: So, just looking at the two measures it seems that the big differences are unit of measurement and one is essentially capturing recommendation or counseling about hormonal therapy, and the other is actual delivery. It seems that one is sort of documentation of quality, and the other is actual delivery.

But my question is, basically, are there a lot of centers, and I don't know if you guys have this information that have high

rates of recommendation counseling but they don't have correspondingly high rates of use? So, is there a disassociation between these two measures? Are they very concordant, in which case one can be -- one can replace the other.

MR. STEWART: We have those data. I would need to look at them and come back to the Committee with our findings.

CHAIRMAN LUTZ: Does the Steering Committee have any recommendations they'd like to make I mean either in terms of one versus the other, or both, or changes, or more information? I mean, is there any underlying theme?

MEMBER LOY: I should know this answer. Are we evaluating two measures, one of which is maintenance and the other which is new, is that -- or are they both maintenance?

CHAIRMAN LUTZ: Both maintenance.

MEMBER LOY: And is our charge here -- is our assignment to harmonize them, or --

MS. FRANKLIN: To make recommendations about where you think they should be harmonized and at what points, at what levels.

MEMBER LOY: Okay, thank you.

MEMBER GORE: I do think it would be helpful to know that then, because if there is a lot of concordance between recommendation and delivery, then it seems that one can sort of replace the other, especially because one seems to be a lot more feasibly measured. But if there is a disassociation where there is somehow some regional variation in places where it's often counseled about but women don't accept it, or it's a documentation issue then I can see the meaningfulness of having both. But if they are highly concordant, then it just makes sense to me that the one that's more feasibly measured and actually counts the actual delivery of care makes more sense, but I might be missing something.

MEMBER CHOTTINER: I still have the

concern that 220 will penalize private practices and smaller hospitals. In Ann Arbor we have community hospital which is not very well integrated and we have the U of M which is very well integrated. And I think if we're going to be using these measures for public consumption that there's potential for putting the community hospital at a disadvantage.

MR. STEWART: I don't have the data right at hand, but I remember working with it very closely. In fact, the larger referral centers seem to fair poorer than the community centers do, and it's largely because -- and this is a sociological perspective, largely because in the smaller community centers it's actually a community where patients are nearby and they're being literally treated down the road. They're not being referred off to more distant residences and whatnot. So, in our experience actually the large teaching institutions, the NCI-designated comprehensive cancer centers, they fare worse on these sorts

of measures and metrics than do the smaller community centers that we accredit.

MEMBER FIELDS: I guess the overriding theme from all of us, though, is still the next generation should also include compliance and administration of the meds. And that's, I guess -- I mean, it's true that we could penalize hospitals because you're just basically collecting the data and reporting that patients at least at one point in time got tamoxifen or AIs. And the docs at least at one point in time during the year delivered it. But the real value is there's no -- five-years of therapy is the real value, and the benefits drop off if patients aren't compliant. So that's, I think, where we need to get to with quality, because I don't know that either of us completely -- either of these measures get us there.

MEMBER LOY: So, just to take this somewhere to get you to react to, to me it feels like that what's ideal perhaps would be

more of a patient centric type of measure with an attribution to some physician, or perhaps a team of physicians where quality or the gap that is not being met gets assigned. That feels like, at least in my view, a measure that would solve some of the counting issues that we're describing. I'd love to hear your reaction to that.

And then I would say for whatever reason that's not possible, I would say at a minimum I would think in the description those would need to be of similar language. I mean, the nuances or the differences aren't great, but on one we've got considered or administered, and on the other we have prescribed. And it feels like we should have some harmonization around that.

And then I know this is subtle but Stage IC through IIIC versus Stage I, II, or III, those feel like that those could be somehow reconciled.

CHAIRMAN LUTZ: David.

MEMBER PFISTER: I think that some of the things brought up I think are not -- some of the things we talked about yesterday. And when you look at the reviews of these two measures, as I say, one of them is already picked as one exempt cancer -- these are reasonably vetted measures. And if you looked at them each individually, the discussion would probably be shorter. I think what is the issue is there's so much overlap and it seems to me with both these being not new but maintenance measures, that I think the comment made about actually looking at what the data tells us in terms of the overlap and to what extent they provide unique if any additional insights, the two of them is probably pragmatically -- if that data is getable and available, because I know yesterday we talked well, it may be available but may not be getable, that the -- I think it will change the discussion from one of like the theoretic construct, well gee, this is actually what it

shows. And they do tell us two different things that are valuable, or they don't tell us two different things, and then go from there. Otherwise, I think we're sort of -- it just gets to be a lot of judgment and opinion that doesn't -- we could talk about for a very long time.

CHAIRMAN LUTZ: I think that's a good point because I think also if they show two different things, it's easier to keep them. If they show one, it's easier to decide which one you may want to sunset out.

MEMBER PFISTER: And I think also inform that decision about how to harmonize, because I do think that -- I think based on the thoughtful framework that's been sort of developed in terms of how these measures develop, how we revisit the measures and so forth, in theory a system that is working well that we would fully expect would be robust and work well, that it would be the natural course of events to feed back the first wave of data

to sort of inform what we do next. Much the same way that revisiting the literature would inform divisions as well. But it seems to me that the -- it would be very instructive here just to see the two -- what the data tells us, if it is something that there's not a barrier to get that data.

MEMBER FIELDS: Are we going to go through each of those boxes, or are we going to just bring other disconnects between the two randomly like we're doing? Because I have some random thoughts if we want to do --

MS. FRANKLIN: No, the focus is we're going to look at -- really the focus are the levels of analysis as we noted earlier are different. The numerator and denominator details, and what --

MEMBER FIELDS: Yes, because there are some disconnects in the inclusion and exclusion data that probably need to be --

MS. BOSSLEY: I think it would be helpful to walk that through because then it

will give the developers a little bit more feedback that they can then come back to us and kind of react to. Otherwise, I think it's going to be hard for them to respond.

CHAIRMAN LUTZ: Should we start with the numerator?

MS. FRANKLIN: You also have the charts in your packet, at the end of your packet.

MS. TIGHE: And that is also - it's one of the last like five or so pages of the packets that we put out yesterday.

MEMBER FIELDS: I thought that the numerators were generally the same. I think it's the exclusions that I have my main issue with.

MS. McNIFF: If I could just make a comment about the numerator. I think the same in terms of definition, but I think this is where you get the crux of the differences of the measure that we're actually looking for two different things.

MS. BOSSLEY: In the interest of time because do have a bit more work to do today, is there anything on the numerator statement, or is there -- should we move on to -- I think it's exclusions. The denominator I would assume is the same population.

MR. STEWART: There are some very slight differences in the denominator, but if I take a liberal read of 387, their denominator principally includes a significant proportion of what we specify in 220. There's some fine tuning in 320 that we've done to make sure that we're comparing as close to an apples to apples set of population or case mixes between institutions for comparative purposes. We have eliminated certain -- patients with certain criteria, but I'm not sure that those are materially going to affect or impact a comparison of the denominator statement for the 387 measure.

MS. McNIFF: And some of the differences have to do with feasibility, too;

for instance, epithelial malignancy, limitation for the denominator statement for 220. If you look at what's available through claims, that's --

MEMBER FIELDS: I guess, naively, my big question is you have -- the tumor registry has the larger number of all the patients and who's known to be alive. How does -- and you don't make that a denominator statement so we can't tell if patients fell off for quality reasons in the denominator to 387.

MS. McNIFF: Remember that 387 is being reported with a claim, so the patient was just seen.

MEMBER LOY: Perhaps you've addressed this already, but is there any reason why the denominator statements would not be the same?

MS. McNIFF: I think the differences, as Andrew stated, reflect the source, so there's a different level,

granularity of data available in the NCDP than there is -- than can be pulled for claims. So, what you see listed for 387 with gender, ICD-9 code and the CPT codes really forming the basis of the denominator inclusion criteria within the extra codes if you scroll down quite a bit to capture stage.

MEMBER LOY: Could the known to be allowed within one year of data diagnosis be captured from claims data for both?

MR. STEWART: I think it's crucial to decide if the patient dies then hopefully you won't have that patient submitted -- having claims submitted for them after death, so that they're self-exclusionary. They will exclude themselves by a factor of death. They would fall out of the denominator in the PQRI measure.

MS. McNIFF: Yes, because this is reported with a claim. You submit a claim and that is the submission --

MEMBER LOY: Okay, so you submit a

claim, and you've got a claim with a breast cancer diagnosis, don't really know whether it's epithelial or not, or we don't know what stage because of the -- I get that. What I don't get is how do you know whether the patient either expired, lost to the health plan, or non-compliant based on the non-submission of a claim?

MS. McNIFF: You don't. This is reported with -- alongside a visit. This is tied as per the PQRS program to having a visit with a physician. If that same patient next year doesn't show up, this particular mechanism would not identify and say this patient suddenly is unreported. That's not part of the scope of PQRS. I don't know if Sam or Keri want to comment on that.

MEMBER FIELDS: So, theoretically, the main way to get survival data is through the tumor registry.

MR. STEWART: I think conceptually another way of thinking about the difference

between these two measures is that 387 is visit-based, and 220 is diagnosis and management for the primary encounter of the diagnosis of the disease.

CHAIRMAN LUTZ: So, I guess where does that leave us? Should we make some kind of request or recommendation about more -- if there's data to compare the two? I mean, that's about the only thing that sort of keeps coming up that at least gives us some means by which to decide that takes it from theory to reality maybe.

MS. McNIFF: Can we just ask for more clarity on that because I heard Dr. Gore ask for a comparison within 220, I think, about the difference between recommendation and prescription, but then -- we just need, I think, a little more clarity about what comparison you all would like to see done.

MEMBER GORE: So, I think what I was saying was that within -- kind of 387 can almost be considered to be housed within 220

sort of. Right? Kind of?

MS. McNIFF: No.

MEMBER GORE: No?

MR. STEWART: I think my opening observation was, and I think I tried to just reiterate it in a different way, is 220 has its focus or spotlight on that time period between initial encounter and diagnosis, and seeing that patient through the point where we understand that hormonal therapy has been started or at least actively considered and discussed. And then 220 essentially stops.

387 is visit-based, so that patient can show up at a medical oncologist office or a private practitioner, family practitioner for a period of up to five years afterwards, and at each individual encounter visit the claim related to that patient's condition and the continuing management of their hormonal therapy care is reported to the PQRI system using that reporting enterprise of what 220 is based around.

MEMBER GORE: Okay, that makes a lot more sense. What I was just asking for before was that one is about counseling and one is about actual delivery. And so that's what we were asking for, is could you feedback data on percent counseled, and among those percent who actually received tamoxifen or aromatase inhibitors. So, that's all we were asking.

CHAIRMAN LUTZ: Is that feasible? And then what time would we be talking about? I know we have --

MR. STEWART: Well, feasibility for me is --

(Simultaneous speech.)

MR. STEWART: -- and I need to understand what that happens to be.

CHAIRMAN LUTZ: I think we have a phone conference to tidy things up on June 6th, so I don't know if that's too quick, or if there needs to be a longer leg. But that's the only other date I think we have set up for

this Committee to talk.

MS. BOSSLEY: So, there's two options. We can either -- depending on whether they can get it in time for you to look at at June 6th, we'll get it back and it will be part of your conversation. What we've done in the past is this kind of thing takes a while for developers to look at and pull all the information needed, so we can make sure your questions are reflected in the report that goes out for comment. And then at the time of your call to discuss the comments, they can þ- - hopefully, that would give them enough time. It's roughly a month, month and a half out, give them enough time to bring it back. That's usually how we've worked it in the past, because it's very hard for developers to pull this stuff together often. And then at the time of the comment you can make your final recommendations following that.

MR. STEWART: A quick question of clarification. What's the dynamic between the

expectations for this group on June 6th, and how does that dovetail or not with your comment period and final decision making phase? I didn't quite capture that.

MS. FRANKLIN: So, depending on the response that we get back we will -- this will still go out for comment from the field, so we'll take those comments into consideration when we come back after comment. And the Committee will consider all of that, including the data that you might be able to provide, the comments from the public, and we'll make a decision at that time.

MR. STEWART: All by June 6th.

MS. FRANKLIN: No, this will -- June 6th is --

MS. BOSSLEY: At the break we'll walk through the time line with you.

MR. STEWART: Okay.

MEMBER CHOTTINER: I just have a question for NQS staff. I mean, these are both approved measures that seem to work for the

developers. I mean, how hard are we supposed to work to harmonize these? Is there a disadvantage to just letting both measures stand as is?

MS. BOSSLEY: So, this is a constant struggle that we have because it's very hard to try to ask developers to harmonize in the middle of a CDP project. We've actually, I think, come to the conclusion it can't be done, so we're actually working on how to work with developers outside of the CDP process. For what we're dealing with now, I think you should highlight the questions you have, the concerns you have, the recommendations you might have on how they could perhaps better harmonize the measures. We'll see what they can get done in the time frame that we have. If they can't, then you all will need to decide if you still agree that the measures together are useful for accountability purposes, and knowing that there are some differences. And that's always

the tradeoff and it's very hard for Committees, but that will be at the end of the day one of the questions you'll get asked probably after comment, if you have concerns.

I don't know that you will with these measures. I think the exclusions are the next piece we need to walk through, but our hope is to actually move this out of the process because it just does not -- it's not working in the process. So, hopefully, you won't have to deal with this again.

MEMBER LOY: That's very helpful. I would just ask is it reasonable to obtain the data that Dr. Pfister was referring to to let us kind of know today where we are in terms of adherence given that these measures are already in place, or is that just not obtainable?

MS. McNIFF: They were submitted þ-- presented yesterday, the most recent data we have were presented yesterday with the submissions.

MEMBER LOY: Okay.

MR. STEWART: We included some level of description of the data we have. The questions from John Gore are legitimate. We'll certainly look at those. And I think in the next week or so I'll even have more contemporary data than the submission information was based on. And we can certainly make that a little more robust and detailed, go a little more into depth around a couple of the questions and then see what turns out to be helpful and informative to the Committee.

MEMBER LOY: Is it possible to look at the adherence, not the adherence data but the data that we have side by side for these two measures?

MS. BOSSLEY: I think it will just take them a second to pull up what they can.

MEMBER LOY: Okay.

MS. BOSSLEY: But they can -- yes.

MEMBER LOY: Because it seems like while it's on our minds.

MS. BOSSLEY: Right.

MS. TIERNEY: This is Sam Tierney. I could just comment on related to the data from the measures. I think yesterday we spoke verbally to data that has been shared publicly by CMS for PQRI 2010 since the measure submissions were due, so we could amend our form just so that's kind of formally included, because I'm sure no one remembers the conversation from yesterday. But I just wanted to point that out as you maybe look at this data. I think the last data we had was from 2008, maybe 2009, but we now have 2010 data, as well.

MS. CHRISTENSEN: Sam, could you remind us what that number was, what the performance number was for 2010?

MS. TIERNEY: I'm sorry, was that a question for me?

MS. CHRISTENSEN: Yes. Sam, it's Keri. Could you just remind us what that number was?

MS. TIERNEY: Oh, sure, it was 90.7 percent was the average performance rate.

MEMBER LOY: Has that been the -- how has that number behaved over time? Is that percentage over these last three years been right around 90 percent?

MS. CHRISTENSEN: It's an interesting question to ask. It's very hard for us to know from year to year if we're looking at the same patients and the same providers. That information we're not privy to. Some of the measures for PQRS go up over time and some of them go down. It depends on if more providers start adapting it, then the providers that have been doing it for a while, their quality tends to go up would be our supposition, though we can't prove that because we don't have the data. But new providers might then bring the score back down because they haven't been working on that measure. So, it's hard to tell without a consistent population.

MS. TIERNEY: And this is Sam, if I could also add to Keri's point. The data that I said was from 2010, only 24 percent of eligible professionals were participating in 2010, and I think in 2009 only 20 percent were participating, so it shows that there is quite a bit of variation. I think the earliest iteration of the program was about 16 percent, so there's been a lot of I guess improvement in reporting rates across eligible professionals, but it would be very difficult to probably compare the rates. We could certainly provide them from 2007 to 2010, but I think we have to think about them with that caveat in mind.

MS. BOSSLEY: So, what we're going to do is Gene is going to try to do the table, but in the meantime perhaps we could walk through the exclusions while he's -- we're going to try to divide and conquer on the work here.

MEMBER FIELDS: So, I'm just

assuming that really the tumor registry data when it says considered takes into account all the reasons patients weren't medically eligible to receive the drug. And the walk -- the descriptors in the exclusions for the physician not prescribing the drug were they were already on a different drug, they had oophorectomies or everything else. I assume that's how you all harmonized when you thought you were harmonizing the two criteria. But it would be nice to maybe have in the tumor registry study, the 220, some of the obvious exclusions like oophorectomy, the patient is clearly not a candidate for the drugs, just so that you're -- it just seems to take away some of the issues that we've been talking about, the institution or the individual physician level being punished per se for not describing -- all the discussion we had in the first part of this talk.

I don't know how for us to rationalize and compare the two differences,

because clearly at the provider level there's just like these are the reasons why somebody is not getting this drug, and they're very obvious why the patient wouldn't get the drug.

MR. STEWART: The response choices in the cancer registry are actually a little more generic than you may desire. I think they fall into three bins, one in which the registry is able to indicate that consultation occurred and the physician advised against pursuing hormonal therapy because of the patient's general health condition, or other considerations without any level of specificity behind that. The second one is the indication that the patient or their guardian after that consultation declined the advised or recommended therapy. And then the third basic choice that we watch is that that consultation occurred, and for some reason, presumably one of the previous two, but they couldn't specify which, it was advised, or recommended, or determined that the hormonal

therapy was not going to be administered to the patient. So, we don't -- we may not have the level of specificity in the descriptor of exclusions that we see in 387, but in spirit they should be complementary.

MEMBER FIELDS: Yes, it would just be -- it would give you more ways to do appropriate feedback. If there were more boxes to check to prove that the patient was never eligible to receive the drug, then it wouldn't always look so non-compliant, and you'd get a little bit past the considered into what were some of the real reasons, so that we might feel a little bit more -- we might feel that there was a lot more understanding about how to use the drugs, and when to use the drugs. That's all. I don't know that you can harmonize them that well.

I do think that the physician side gives a much better description of who or who may not be eligible to receive the drug and the thought process with that, so that's all.

And I understand the limitations of the tumor registry, so I don't -- it would be nice to add more questions to the tumor registry.

CHAIRMAN LUTZ: Elaine, did you have anything? Okay, Jennifer.

MEMBER MALIN: Sorry for coming late to the party. I mean, some of it I think in addition to whatever harmonization, I think it might be a help just by having clearer titles and descriptors of what the measures are. The tumor registry measure is -- I think even more than the limitations of just tumor registries try to be consistent and still have a certain number of variables is that most of the hormonal therapy is not prescribed in the hospital where the tumor registry sits. So, a lot of it's going to depend on whether the tumor -- you know, the tumor registrar for the most part isn't going to be reading the doctor's chart who's doing the prescribing. They're going to -- if it's not mentioned in that kind of initial post op note, it's really

them calling up the doctor's office and seeing if the doctor's office responds to their survey. And they'll probably -- non-response is probably more of an issue than whether or not they get the details. So, I think specifying that that's a hospital-based measure somehow might be helpful. And then the other measure is really more about adherence than it is about initial prescription.

CHAIRMAN LUTZ: I was just trying to take that thought one step further. The one I'm not sure would be a hospital-based much as system-based because there are so many -- you know, what is a hospital system?

MEMBER MALIN: The ACOs, the current argument is oncology going to be included or not included? So, it's hard to know how --

CHAIRMAN LUTZ: It is hard to know.

MEMBER MALIN: But I think that, to your point, it's not really -- to your point it's not the individual provider, and it's

also requiring the system to do a fair amount of leg work unless there's an electronic system in place to figure out who's on the drug.

CHAIRMAN LUTZ: So, this is our summary of results. Are we getting --

MS. TIGHE: 0220 is on the left and 0387 is on the right.

MS. McNIFF: The denominator on the right, that's at the individual physician level are reporting 387.

CHAIRMAN LUTZ: Am I reading it correctly, the one on the right, the mean is 28 percent? But then right above it it says it's 96 percent.

MS. McNIFF: Giving that 20 -- something percent was giving the PQRS --

MS. TIGHE: It was 2008 PQRS.

CHAIRMAN LUTZ: Okay.

MEMBER LOY: The range is correct for reporting 100 percent.

MS. McNIFF: It's down at the

bottom for PQRS. If you can -- you can scroll back down, over to the right and down. There you go. Somewhere in there there should be --

MEMBER LOY: I thought I saw 42.

CHAIRMAN LUTZ: Yes, that was the range.

MS. McNIFF: It might be from QOPI.

CHAIRMAN LUTZ: The 28 percent is participating sites.

MS. McNIFF: Physicians. It's according to CMS, 28 or whatever it says percent of eligible oncology providers submitted PQRS measures, or submitted this measure to PQRS program.

MEMBER LOY: That's the statement that caught my eye, the 40 to 100 percent, now it's off the screen. But the performance variation, the average performance rate, that just describes those folks who are eligible not excluded in the denominator who got a prescription for tamoxifen. Is that correct?

MS. McNIFF: Those data are from

QOPI, from implementation of some measure with -- it's modified from QOPI.

MEMBER LOY: Okay.

MS. McNIFF: That shows this being used but actually I think the true use of the exact specs for reviewing if that is of a concern are the results further down from PQRS, the exact specs.

MEMBER LOY: Okay.

MEMBER MALIN: What was the rate on the CoC measure?

MR. STEWART: So, we provided two, one is a mean which falls in about 76 to 77 percent, but when we look at the 75th percentile of hospitals that are using these metrics, the mean rate among that group is 95-96 percent. What that indicates, and it speaks to the point that Dr. Malin made, and was made earlier, was that the institutional-based registries have a challenge in securing information from outpatient oncology offices. And there are some institutions which have

certainly sorted out how to achieve those ends and do that on a routine basis, and there are others that are still struggling to figure out how to make that operationalized as a routine basis.

MEMBER GORE: That's also because the CoC will be all age ranges. Correct? So, it's going to include 50-year old women, 40-year old women; whereas, the right-hand column is only going to be Medicare beneficiaries, or no?

MR. STEWART: No, it's the same population base.

MEMBER MALIN: PQRS would only include Medicare beneficiaries, but QOPI is--

MR. STEWART: QOPI is everybody.

MEMBER MALIN: -- everybody.

MEMBER GORE: Yes, I'm just trying to rectify the difference that in the Medicare patients the compliance with the measure was 96 percent, whereas in the COC -- so, does that get to a difference in populations, or

does that speak to differences in feasibility of ascertainment of the measure which would be my concern?

MEMBER MALIN: It is data issues. I mean, unfortunately, this is something I know all too much about because I did my dissertation on the quality of cancer registry data for measuring chronic care. So, essentially, I mean, without kind of extra efforts like the registrars are putting in for using this for quality of care, typically the ascertainment of hormonal therapy if it's not part of a quality program is only around 30 percent accurate, because it's resource-intensive to call up offices and find out. And they may or may not always even know who the doctor is to call up. And registries vary in staff from full-time staff to consultant, so it's sort of a very heterogenous pool in terms of the resources they put into data collection.

So, I mean, I think with those

caveats if the facilities are willing to put in the effort to use it, but I would have qualms about assuming the facilities who aren't participating in a quality program that their data accurately reflects what's really going on with the patients.

CHAIRMAN LUTZ: So, having seen that, what do we want to do? So, our request was to see those numbers, and we did.

MEMBER GORE: It just seems to me that 220 is very dependent on the ability to ascertain complex data. And you think that a counseling measure next to a use measure would have higher compliance relative to use, so the fact that it shows the concern on compliance, it just makes me concerned about the feasibility of that measure.

MR. STEWART: Well, let me speak to that. The data that we've used to provide here in the summary report are all based on retrospective exercises where the Commission tells an institution two years after the fact

what their presumed performance rate happens to be on this metric. And what subsequently happens is that a self-selecting group of institutions then scrambled to do the retrospective review to figure out if that's actually true because they tend not to believe that's the case. And then you see rates becoming significantly elevated after the fact, because we're sort of inviting them into that dynamic.

In the past year we've actually implemented a prospective reporting mechanism where we start watching these patients literally weeks to months after diagnosis, and prospectively alerting the institution and the standing cancer committee inside each of those participating hospitals about the fact that they have women about whom we don't know the hormonal treatment status. So, it's a paradigm shift. We're not comfortable living in the old paradigm of retrospective data management. We want to shift this into a prospective dynamic,

so we actually have some 250 to 300 institutions which in the last six months have self-selected to participate in this prospective reporting mechanism in which this measure is one of the six included. And I would be happy to show --to use that system to generate data that may speak to the fact that institutions are taking the time and effort to essentially do something different than I think the classic critiques of registry operations that have led us to believe the quality and completeness of data to be.

MEMBER ROSS: So, talking about the RQRS, and can you tell from the preliminary numbers? I mean you have what, you said how many have signed up for it, 200 and something?

MR. STEWART: Yes, we have 250 on and another 150 in the registration process.

MEMBER ROSS: So, has anyone actually been through enough of a cycle for you to know whether they're implementing change based on the data?

MR. STEWART: Yes, we do have evidence of significant process change occurring inside institutions that adopt the system and put it into practical use.

MEMBER ROSS: Implementing the RQRS, that's the most robust portion of surveillance the Cancer Committee has done. I think it's a very important part.

MEMBER MALIN: I just have a question on whether these measures were for accountability of quality improvement? Because, I mean, it would seem given the data issues with the first one that it might be more appropriate to use it for quality improvement if it's dependent on the data systems. And then folks who want to use it can insure that they're doing the processes to make the data valid.

MEMBER ROSS: I may have missed this earlier, I apologize if I did, but in the group of the physicians on the right, do we know -- is there any way to know, are they

represented by institutions that are part of the Committee on Cancer, the Commission on Cancer? Is there any way to --

MS. McNIFF: We have no way of -- we don't know who they are, but there is -- it's a good assumption, certainly, that some of them are affiliated with the Commission on Cancer Hospitals, or work for Commission on Cancer --

MEMBER ROSS: The number of oncology centers that aren't certified is extremely small. Right, for the Commission on Cancer?

MS. McNIFF: So, a lot of the people who will be reporting on 387 would be the med onc in private practice because that's where the majority of folks are getting their systemic treatment.

MEMBER ROSS: Right, but they care for their patients in the institution. I mean, somewhere --

MS. McNIFF: They are likely

affiliated --

MEMBER ROSS: Somewhere that patient touches the institution.

MS. McNIFF: Yes.

CHAIRMAN LUTZ: All right. We're approaching 10, so we're going to have to sum up any of our thoughts and move on, even if they're imperfect, because we have other things to go on to, including another harmonization measure coming up. Just to give you a little preview of the excitement to come. Do we have any final comments? I'm not sure we helped them harmonize or not, but do we have any final comments?

MEMBER FIELDS: We feel like we give up. You know, I think that we -- I feel as comfortable as I could with the differences. I don't know how to address some of them.

CHAIRMAN LUTZ: I believe it was Getty Lee from Rush who said, "if you choose not to decide you still have made a choice."

Do you guys want to take a five-minute break, or what do you want to do, just to clear your heads.

MEMBER PFISTER: So, we are going -- I thought I heard we're going to table this until the 6th. Is that the final - all right.

MEMBER LOY: Could you restate what needs to -- what questions need to be addressed between now and the 6th?

MS. FRANKLIN: We did have a question about data which -- comparing the two data testing results, and we did have that on the screen. We talked about that. There was a question about whether the titles should be changed to be a little more clear, and I think that one was more related to maybe 220. And then there was a question about whether staging should be harmonized.

MS. McNIFF: So, the staging is harmonized.

MS. FRANKLIN: Okay.

MS. McNIFF: There's the title

actually is raised, that one should be changed to say Stage I T1c. There's no Stage Ic, it's T1c.

MS. FRANKLIN: But the specs are correct, the specs are the same.

MR. STEWART: The specs are the same. It's just the way we expressed the level of detail of the stage group that needs to be adjusted on the 387 side. I think that's right.

MEMBER GORE: The other question that I had -- I'm sorry, I'm not trying to -- but the question I had about the data was not just the comparison of 220 to 387, but within 220. So, just to clarify.

MS. BOSSLEY: I think that is probably the -- based on the discussion we had that's the only ask given this conversation. Everything else I think -- and correct me if I'm wrong, but my take away is you all understand the differences, know that the differences have to exist now, and it is how

it is. Am I correct?

CHAIRMAN LUTZ: All right. So, is that yes to the five-minute break or dive into the next harmonization? All right. But the next two are going to be ones that have to be harmonized. So, the order will go if it's all right, I believe 223 and then 385 are the ones that are to be harmonized, so we'll start with 223. And I think our ACS folks are the presenters of it, and then Wendy will be our discussant.

MR. STEWART: Okay, so 223 is a measure assessing the appropriate delivery and consideration of delivery of adjuvant chemotherapy for patients who have resected Stage III colon cancers. The denominator criteria are consistent with the pattern we followed in the previous measures that I've discussed based on populations around which randomized clinical trials demonstrated long-term survivorship outcome benefit.

The general style, purpose,

intent, the data source, the feasibility issues that revolve around this measure are consistent and very similar to the others that I discussed yesterday. And by way of introduction I'll stop there and let the Committee discuss further.

I would also add this is also one of those three measures that have been identified by CMS for the PQS exempt hospital reporting requirements in their proposed rule for 2014.

CHAIRMAN LUTZ: Okay, thank you. And I think we have Wendy on line. Are you there, Wendy?

MEMBER TENZYK: Yes, I am. Good morning, everyone.

CHAIRMAN LUTZ: Good morning.

MEMBER TENZYK: I will go through this the way we did yesterday.

CHAIRMAN LUTZ: Okay. And I've had the request if you don't mind waiting one second. I just want to see, is there anyone

else from the Committee that's on line? I know yesterday we had some that came and went. Is there anyone else besides Wendy on line with us this morning?

MEMBER ALVARNAS: This is Joe Alvarnas.

CHAIRMAN LUTZ: Good morning, Joe.

MEMBER ALVARNAS: Hey, how are you?

CHAIRMAN LUTZ: Good. All right. Anyone else besides Wendy and Joe? All right, Wendy, I think we are ready for your take on this.

MEMBER TENZYK: Okay, thank you.

Well, this one does include some of the issues that we talked about yesterday, that we are talking about today also, but hopefully it will be a much shorter discussion than the prior one.

The chemotherapy is considered or administered, so that's one of the points that we'd struggle with, is the considering and administering. It does address the age that

came up yesterday, so under the age of 80 with lymph node positive colon cancer.

So, our first section important to measure and report. As we looked at it we t thought that it was high impact, certainly affects many patients, and that there was a performance gap so that it was something that we did want to -- that we felt because there was substantial data that there's under use and wide variation, that there was definitely a performance gap to be addressed.

And then in terms of the evidence, that there was strong evidence in this measure more so than many of the others we looked at. Evidence and randomized clinical trials, so we also felt that the evidence was strong on this one. And that's the end of point one from my standpoint.

CHAIRMAN LUTZ: Okay. Is there anybody else that was on the phone call in the subcommittee that wants to talk about the importance measures or definition? All right.

Does that mean we get to move on to a vote about that question one?

MEMBER LOY: One question. Was there any consideration given to Stage 2b colon cancers?

MR. STEWART: Not at this time. Part of the challenge was that until 2010 the ability to identify that particular subset of Stage 2 colon cancers was not routinely possible because of the way the staging systems were constructed and designed. So, we've confined ourselves to the known standard of care for Stage 3 node positive disease.

The jury is still I think out on the appropriateness of adjuvant chemotherapy for Stage 2b disease, and there are nuances and conditions there that I'm not sure that there's consensus in the GI community about whether or not there is actually a realized benefit for that particular subset of patients, so we're confining ourselves to the level of evidence through randomized clinical

trials and sticking with the Stage 3 specification.

CHAIRMAN LUTZ: Okay. Anything else before we vote on importance?

MS. KHAN: All right, voting on 1a, impact.

MS. TIGHE: Wendy and Joe, if you want to email me or speak your votes. I got yours, Dr. Alvarnas, thank you.

MEMBER TENZYK: Okay. I'll just email mine. Thanks.

MEMBER ALVARNAS: We're using the gmail chat thing today?

MS. TIGHE: Yes, I just got your vote. Thank you.

MEMBER ALVARNAS: Okay, thanks.

MS. KHAN: So, we have 11 high, zero moderate, zero low, and zero insufficient information. And voting on 1b, performance gap. So, we have seven high, four moderate, zero low, and zero insufficient. And looking at the evidence? The vote is yes, no, or

insufficient evidence. It is 11 yes, zero no, and zero insufficient. Do you want to have discussion?

CHAIRMAN LUTZ: Wendy, do you have anything to say about the reliability issue?

MEMBER TENZYK: I was just in reading the summary of our conversation, there is a note that the Steering Committee members questioned the 120 days or four months from diagnosis. And I'm sorry but I really don't remember much of that discussion.

And the other note from our conversation was that we felt that the denominator exclusions were relevant.

CHAIRMAN LUTZ: Okay. Anyone else have anything to add about reliability? Okay.

MS. KHAN: And voting on 2a, reliability. It's six high and five moderate, zero low, zero insufficient. And 2b, validity. It's six high, five moderate, zero low, and zero insufficient.

CHAIRMAN LUTZ: I think next is

usability.

MEMBER TENZYK: Okay. On usability we did feel that it appeared to be usable. And also the fact that it was -- well, it's currently in use, and that it's considered by CMS as one of their measures, so we felt usability was strong.

CHAIRMAN LUTZ: Okay, shall we vote?

MS. KHAN: And voting on usability. Seven high, four moderate, zero low, and zero insufficient.

CHAIRMAN LUTZ: I think next is feasibility.

MEMBER TENZYK: Okay, and feasibility we felt similarly, that still is strong, that the measure is in use and will be used, and that obtaining the data was doable and feasible. I guess nothing else, but like I said, we just feel strong about this one also.

CHAIRMAN LUTZ: Okay.

MS. KHAN: Voting on feasibility. We have six high, five moderate, zero low, and zero insufficient. And voting on overall suitability for endorsement, does the measure meet NQF criteria for endorsement? Yes or no? So, we have eleven yes and zero no, and the measure will pass.

CHAIRMAN LUTZ: All right. So the similar measure, we're going skip one ahead to 385, and 385 is another AMA-PCPI, and then I'll go through the details.

MS. FRANKLIN: So, do we have -- Sam are you on from AMA-PCPI or is there someone in the room who can tee up the measure for us?

MS. TIERNEY: Yes, this is Sam. I'll just offer a few comments, and then if Kristen, and I know we also have Dr. Hassett on the phone if they want to offer anything additional.

MS. FRANKLIN: Very good.

MS. TIERNEY: So, just wanted to

make a few brief remarks about 385, and I appreciate you bearing with me doing so over the phone.

This measure is intended to promote the use of adjuvant chemotherapy in Stage 3 colon cancer patients. Given its well documented efficacy and effect on survival, it is based on high-level evidence as the numerator in relevant clinical practice guidelines. This measure was designed for use in the ambulatory setting to assess clinician performance and ultimately improve quality.

Given that recent data from the VA indicates that over 25 percent of women did not receive guideline concordant adjuvant chemotherapy, there remains significant opportunities for improvement. Additionally, measure-specific data from the PQS program that I mentioned in relation to the previous measure that has become available since we did the submission forms for 2010 indicates that performance rates averaged about 93.2 percent.

We don't have data regarding variability, unfortunately, which I think would be very useful. But it's important to note, as I think I mentioned earlier, that PQS is currently a voluntary reporting program. In 2010 about 24 percent of eligible professionals participated. So, performance rates are probably not nationally representative.

The measure was originally developed in 2007 in collaboration with the American Society of Clinical Oncology, the NCCN, and the American Society for Radiation Oncology through the use of a cross faculty multi-disciplinary work group. The measure was fully vetted through a 30-day public comment period and finalized to incorporate such feedback.

The definition of adjuvant chemotherapy is reviewed regularly to be consistent with the most up-to-date NCCN guidelines. In fact, you'll see that the

definition of what qualifies is consistent with NCCN recommendations particularly in light of the current shortage of leucovorin in the United States.

The measure has been utilized in a number of national programs, including CMS' PQRI or PQRS program since its inception, and it's also included in the larger set of quality measures available for reporting in Stage 1 of meaningful use. The measure also was recently proposed for inclusion in a larger set of measures to Stage 2 of meaningful use, as well.

So, I'll just stop there with that high level overview. And, again, if Kristen or Dr. Hassett have anything they'd like to add, please do so.

MS. CHRISTENSEN: Nothing to add from me.

CHAIRMAN LUTZ: Great, thank you, you made my job easy. So, just as the discussant for this I'll say just two things

in terms of importance. One is, I know yesterday we discussed several times whether we were evaluating measures that were up-to-date on the chemotherapy, so it's nice in the numerator statement to have that sitting there. The other thing is in the denominator exclusion details, I always especially appreciate when it's separated all the way down to reasons that are medical, patient preference reasons, and system reasons. That's exactly how we think about these things, so from my perspective the importance in those specifics were very welcome.

So, does anyone else have anything to add before we move to vote on importance? Okay.

MEMBER LOY: I might just ask the question, what happens as the adjuvant chemotherapy changes over time?

CHAIRMAN LUTZ: I'm sorry, did you hear that question? The question was what happens when in our description of whether the

practitioner is up-to-date with NCCN designated chemotherapy regimens, what happens when the NCCN changes the regimen in terms of say allowance for someone to be one step behind or caught up, is there a means by which the practitioner knows?

MEMBER LOY: Or new drugs are added to regimens?

MS. TIERNEY: This is Sam. I'll just say that we currently refer in the measure to adjuvant chemotherapy, and then we provide a definition, and we say that according to current NCCN guidelines the following therapies are recommended. So, we do try to update that on a regular basis, and then would modify our specifications accordingly. And I know one of my colleagues with our specifications group is on the phone, Kendra. I don't know if she has anything to add specifically related to how that affects the specifications, but we do try to incorporate those updates as timely as

possible.

MS. McNIFF: Kendra, jump in if you're on the line. But I would just add that it is a very kind of pragmatic approach, that the actual reporting code says adjuvant chemotherapy was administered. And then the list of the current regimens recommended by NCCN is in the definition so it's easier to þ- - that can be updated much more simply in the world of PQS reporting, especially than changing the actual CP2 code that goes along with the measure.

CHAIRMAN LUTZ: So, just so I'm clear then is it the case that if the practitioner gives the chemo that's sufficient, or do they have to give the chemo with the up-to-date description of one of those regimens that's listed, and it's just plus/minus chemo and then this is just a recommendation for what's most current. Is that correct?

MS. McNIFF: That's correct.

CHAIRMAN LUTZ: Okay, thanks.

MS. KHAN: So, voting on 1a, impact.

MS. TIGHE: Dr. Alvarnas, can you send me your vote, please?

CHAIRMAN LUTZ: Okay. I guess since we only have 10 of 11, we'll have to circle back to that vote, but are we still --

MS. TIGHE: We can discuss the --

CHAIRMAN LUTZ: Okay. Pretty much my comments were for all of the number one questions, so we can go on. Okay, so go on to reliability.

I didn't see a tremendous amount of reliability data. I don't know if anyone from the -- any one of the submitters can help me out on that. I didn't see a whole lengthy description of reliability data. Was there anything I missed?

MS. CHRISTENSEN: So, this set of measures was tested using a fairly standard reliability testing protocol for us. And just

to walk you through it, we used five different practice sites that represented various types of locations and sizes, and ASCO and ASTRO helped us identify those. You can see the breakdown of what those practices are like, and the data.

We then went through and calculated inter-reliability for each measure so we have two human extractors look at the records, primarily electronic health records for these though they were visually inspected. And then we went through and calculated the percent agreement, and a kappa statistic which adjusts for a chance agreement, if you're familiar with that. And you can see there in 2a2.3 the testing results. The overall reliability as well as the reliability at the numerator, denominator, and exception levels were actually as perfect as you can get, so the kappa is non-calculable just because of the statistical thing, it needs to divide by zero.

CHAIRMAN LUTZ: Okay, that helps. All right. Now, I appreciate that. Have we reached our quorum? Should we go back and -- do we have to redo our vote on 1? Dr. Alvarnas, are you back? We can't go just the 10 that are --

MS. TIGHE: Heidi, we just lost quorum.

MS. BOSSLEY: We did? Let's go ahead and do the vote and then we can follow up with the ones who aren't on --

CHAIRMAN LUTZ: Okay. All right. So we did 1a, 1b. So, we're up to performance gap vote.

MS. KHAN: So, voting on performance gap, 1b. Can we have everyone present one more time? So, we have five high, five moderate, zero for low, zero insufficient. And going on to evidence, yes, no, or insufficient. I think we're missing one person in the room. Okay, so we have nine yes, one no, zero insufficient evidence. And going

on to reliability, seven high, three moderate, zero low, and zero insufficient. And validity? We have eight high, two moderate, zero low, and zero insufficient evidence.

CHAIRMAN LUTZ: And I think we do think the usability was high. I don't know if anyone had anything to add to that, but it seems as high as the previous measure we discussed.

MS. KHAN: So, voting on usability. We're missing one person in the room. We have eight high, two moderate, zero low, zero insufficient information. And feasibility.

CHAIRMAN LUTZ: Again, feasibility seemed good from what we could tell.

MS. KHAN: So, we're missing two people in the room. One more time, guys. We had two people missing their votes. Yes, we'll just go back. We're trying to get to ten. So, it's eight high, two moderate, zero low, and zero insufficient. And overall suitability for endorsement, does the measure meet NQF

criteria for endorsement? Yes or no? Ten yes and zero no, so the measure will pass.

CHAIRMAN LUTZ: So, with both measures passed we then need to do the comparison which since we've already had our discussion this morning about the other will go easily and quickly, and it will all be good. I don't know if anybody wants to start, but the one thing I do note is there are some similarities between the discussion of these two versus the previous two in terms of facility versus clinician, and time frames, and method of attaining information, so it is a similar series of questions, I think.

So, if we go through this in a stepwise fashion, if we go to the level where we've sort of already had the clinician versus facility discussion for the other measures, does anybody have anything specific they want to say about its different for this, or specific to this? Karen.

MEMBER FIELDS: So, the main

difference is the age group. The ACOS one talks about up to age 80, and the other one just says over age 18. And then with an exclusion later that they may have comorbidities over age 80, and not be eligible. So, was there ever any intent to reconcile that?

MS. McNIFF: We talked about it specifically with the work group who did this measure, and granted this was multiple years ago, but the group felt that they didn't -- understanding the rationale for the age limitation on the COC measure, the group still felt like they wanted to cast a wider net with this measure and be able to assess whether chemotherapy is administered or not regardless of age of the patient with the ability to pull them out through exclusion, so it was a specific conversation, a specific decision made to go that route.

MEMBER FIELDS: So, I don't know the clinical trials as well, maybe someone

else in the room does. I don't know if they exclude patients over age 80. In breast the reason it's up to age 70 is because many of the trials did stop at age 70, and then there's some separate trials for adjuvant therapy above 70, so I don't-- is the same exclusion criterion, and if so, then excluding people over age 80, is it really necessarily consistent with the-- or including people over 80, is it consistent with the literature in the adjuvant setting?

MR. STEWART: So, when we did our development work we, as you suggest, we were informed by the cohort selection that we saw in the literature from the trials. Keep in mind, however, there may be some perfectly healthy over 80-year olds who we for no reason would discourage the administration of adjuvant chemotherapy, but for the issues of say being consistent with the evidence, and also making sure that -- we also knew from our data analysis that once you started looking t

the over 80 population, you saw a quickly increasing level of variability in performance rates around this metric as soon as you got into elderly population. So, for the purposes of having complementary or like-to-like comparison cohorts between institutions that we were pushing this measure out to, limiting it to the under 80s was the most reasonable, pragmatic choice that we pursue.

MEMBER FIELDS: So, then I don't want to bring up an old comparison, but there's a growing body of data in the women over age 70 getting adjuvant therapy for breast cancer, so the open ended -- the close end of age and breast isn't consistent with leaving the open ended age when there's not much literature in the colon cancer patients. And I know there are two separate groups of studies and developers, but it seems to me that if we're literate-based in the decisions for the up to age 80, and then it's a case-by-case basis for the patients over age 80, why

would that not be consistent between the two sets of -- or the two studies?

MS. McNIFF: This is definitely -- we anticipated this would come up. And I think this is really an important discussion.

There was concern because exactly of the situation, multiple situations that Andrew mentioned about folks over 80 who certainly could be very healthy, and could be very good candidates for chemotherapy, but there was a concern among the work group members that putting something out that was going to be listed everywhere on every CMS program that said chemotherapy until age 80 would actually discourage people from providing chemotherapy to those over age 80. It doesn't -- hopefully, that wouldn't happen, but there was some concern there. And, again, the decision to account for the fact that those over 80 may -- first of all, the literature doesn't directly support chemotherapy in that population. And second of

all, to understand that there are more comorbidities, et cetera, that was handled in exclusions differently.

MEMBER FIELDS: I understand. It's just that if the literature is really the randomized trials have cutoff dates and literature to support them, then that's the big question about consistency between the two measures. And especially in the light of the other discussion that we just had where it -- there's -- at the time that that was developed there wasn't a large body of adjuvant therapy data, or there wasn't -- there was a growing body of adjuvant therapy in women over age 70 which now has shown that there are several randomized trials to support that.

I mean, it sort of gets down to we didn't include Stage IIs with the high-risk Stage IIs in this group where there's probably more inclusion -- more literature support than patients over age 80. So, I'm just trying to

reconcile when we use literature and when we don't use literature in developing these measures because this one seems a little less than literature-based.

MR. STEWART: I would just make the point that what we're doing is identifying cohorts of patients where we feel the metric can be fairly put into play, but by no means making the recommendation or suggestion that patients outside those demographic age groups don't want that level of care, consideration for that care.

MEMBER FIELDS: I'm assuming we are doing the same thing with the breast. Women over 70 get considered all the time for adjuvant therapy. And, finally, there's literature to support that, so I guess just for consistency sake, if these are more -- if these measures are what we think are the representation of the state-of-the-art and the most literature, then I'd have the cutoffs on 80 for both. That's just my consistency

observation.

CHAIRMAN LUTZ: Jennifer?

MEMBER MALIN: Yes, I just wanted to echo what Karen was saying. And I think aside from the comorbidity factors, I mean, if you go on adjuvant on line and put in 85 years old for a colon cancer patient, the amount of benefit they get from adjuvant chemotherapy is pretty minuscule even if they're healthy. And I think that's -- some people may want to undertake the risk of neuropathy and having to use a walker for that, but I think it's an individualized decision.

CHAIRMAN LUTZ: Is there -- would it be difficult to change the criteria? I can't remember which one is which, so that they both just measured up to 80. Does that create difficulty?

MS. McNIFF: The change would be to 385 in the PCPI measure and Sam, I'll have you comment on the change.

MS. TIERNEY: So, we have a

practice by which we consider changes for our measures, so it's certainly something we could take back to the work group that identified or that developed the measure and determine whether or not they agree with the change.

MEMBER FIELDS: My only question is in the future as this group anticipates how this information will be used to do studies that might lead to pay for performance or something, the risk of taking age cutoffs, et cetera, is real, that then patients might not be offered adjuvant therapy in the appropriate settings. But we had a comfort level with breast doing that. I don't understand why we aren't consistent in the colon group. So, it's, I guess, another dilemma to lay on the table.

MS. McNIFF: Although the -- I hate to even say this because I don't want to go backwards, but the PCPI hormonal therapy for breast that we looked at side-by-side does not have an age cutoff. Right? Unless I'm

misremembering. It does not.

MEMBER FIELDS: And I am talking more about the adjuvant chemo.

MS. McNIFF: Right, which yours does, both of them do.

MEMBER FIELDS: Yes. It's just if we were being -- if we were trying to harmonize, that would be my first low-hanging fruit of where does the literature stop, and then where does individual assessment of the patient begin in a group that has less data to support it. And not that I would suggest that there isn't a group that should get that therapy, it's just we know that there's more considerations in that group. And it's documented what the exclusions are, but the literature is different than that.

MEMBER MALIN: I think I just also want to -- unless there's a very specific literature-based reason that we can put on the table for why there should be different age exclusions, I think there's also a risk with

public perception if you have measures that affect women that say stop doing it at a certain age, and ones that affect both genders don't.

CHAIRMAN LUTZ: When it gets to those ends, I mean, there's a choice to request that they both stop at 80, or that neither have age restrictions at all. I mean, do you have a preference between that?

MEMBER MALIN: I would recommend they both stop at 80.

CHAIRMAN LUTZ: Okay, just checking.

MEMBER FIELDS: I would say in breast, I would say that the literature is starting to increase in that patient population, but I would say that right now those parameters are -- if that's what you're going to try to focus on, that's where the bulk of the data is right now. So, I don't have a problem in the breast. I just thought that not having the same end point for both of

these companion measures was not consistent with our last conversation of harmonization.

MEMBER MALIN: I think part of the difference, though, in the trials between breast and colon, though, is that the median age for breast cancer is 65, so just if you kind of look at the distribution of patients you're going to have fewer over 80. Whereas, the median age for colon cancer is around 75.

MEMBER MALIN: I think that's a function of when -- adjuvant therapy for breast cancer has been around for 30 years. Adjuvant therapy for colon cancer is more of a modern era when we were more inclusive about patient populations and we had more supportive care strategies in that older patient population. So, just the literature is different based on the time of the studies.

CHAIRMAN LUTZ: All right. So, I guess just to summarize, so we're saying that they could have the same age 80 cutoff, that would make it more harmonized. Is there

anything else as we look up and down the list that stands out as something we should discuss or suggest? I think there's a difference in this one as there was in the last two we discussed about the measuring time period.

MS. McNIFF: Yes. So, 385 is again capturing -- would capture patients -- anyone who had a visit, visit-based, and there was a 153, is it 153 or 154, a colon cancer ICD-9 code submitted would be eligible to report on this measure, so it could be any time between diagnosis and five years from diagnosis as long as they were still being seen with that code. And this would be documentation that they had received -- they're either being prescribed or receiving right now, or have received chemotherapy for their colon cancer.

MR. STEWART: In contrast, 223 frames the specification around the timeliness of the initiation of the chemotherapy, and suggests that chemotherapy should be started within four months or 120 days of diagnosis.

Again, this is a question of patient-centered continuity of care and making sure that that -- the right sequence of events occur in a timely and suitable fashion.

MEMBER LOY: I would just comment that I would think we would want to make sure that the definitions of treatment, and I was sort of impressed with the definition of the adjuvant chemotherapy, that we would want to extend that to both measures, would be my suggestion.

And then just another thought that comes to mind in terms of the measurement. It just seems to me it's a whole lot easier to obtain infusion-based chemotherapy data versus -- that's prescribed, or considered, or dispensed from a retail pharmacy. I don't know if you all addressed either one of those issues.

MS. McNIFF: I could speak to 385. One of the things that is just a reality but a little bit of a frustrating reality of the

PQRS program is that the provider on the claim even if they're billing for chemotherapy at that visit, they also are submitting a code that says we're giving chemotherapy to this patient, and the patient already received it. So there -- it would be -- it would cover any route of administration, but it's not -- so they are not picking up the chemo from the claim. They're picking -- well, they could be -- they're not picking up the chemo from the billing code on the claim. They're picking up the chemo from the PQRS reporting code on the claim.

MEMBER LOY: And the issue about making sure that the definitions are the same across measures, is that a problem? Well, you've got adjuvant chemotherapy definition for the measure on the left --

MR. STEWART: All right. So we have not undertaken the enterprise of maintaining a prescribed list of currently accepted regimens. We leave that -- so our measure

doesn't make that level of -- suggest that level of specificity. We just need to know that chemotherapy is started within a timely period after surgical resection. We're not monitoring the appropriateness of the regimen being administered to the patient, largely because the registries don't pick up that level of detail. It can pick up fact of administration and date, but not the agent or agents.

CHAIRMAN LUTZ: Do they pick up the difference between infusional versus oral, because I mean if someone gets capecitabine and it's a single agent as is considered standard, that can be sent from a distant pharmacy. Correct? So someone could be getting chemotherapy appropriately with single agent oral capecitabine and not be picked up by either? Okay.

MS. McNIFF: It would be picked up on 385 because there should -- unless the provider who is seeing the patient doesn't

know that -- is billing for a colon cancer visit and doesn't know they're taking oral capecitabine, which would be pretty awful.

CHAIRMAN LUTZ: Okay. Pretty unusual.

MS. McNIFF: Yes.

MEMBER MALIN: I mean, I think the registry one, basically, it's -- the issue is less -- it's less of a problem, I think, because it's probably easier for people to respond that someone is getting chemotherapy. But a lot of the chemotherapy doesn't happen at the institution anyway, they're having to call up the doctor's office to see if the patient is getting chemotherapy, so it would be up to whether the office would know, whether the physician is filling out the form and all that kind of stuff.

MR. STEWART: Right. So if the registry is able to ascertain the fact of administration, then they should be able to þ- - that would by extension capture the script

written example that you just made.

MEMBER MALIN: And most people who get capecitabine are also getting oxaliplatin for adjuvant. It really should be kind of more an unusual person that gets capecitabine alone, the over 80s.

CHAIRMAN LUTZ: All right. I think we're --

MEMBER PFISTER: It's not right in front of me, but when -- since we're talking about harmonization, my recollection is when we talked about the breast adjuvant measures yesterday that there was -- it was basically chemotherapy of any type, yes and no. Yet, it seems like the granularity at least for the one colon cancer seems to at least attempt to define the chemotherapy. And I guess while we're focused on the harmonization of these two measures, the question is when we're looking at sort of adjuvant chemotherapy question, whether we need to harmonize exactly how we ask the chemotherapy question detail.

You know, it may be limited by the data source, in which case that's a hard stop, but it's -- it just seems odd to me that we should expect more from colon that what we're expecting from breast on this measure.

MEMBER FIELDS: I think the main issue in colon is there were only a few randomized trials on a few regimens. Whereas, in breast there's a lot of -- there's a larger number of adjuvant regimens that have been tested over time, so I think that's probably the main explanation. So I think it's just a limitation of the state-of-the-art.

CHAIRMAN LUTZ: All right. Any further things on the list that we see? We went through numerator, denominator, how about exclusions? Let's see if we harmonize age, those look, I think, reasonably harmonized for the rest.

MEMBER FIELDS: We developed our comfort level from the last discussion.

CHAIRMAN LUTZ: Well, that's right.

Yes. Or we want to avoid the discomfort that we had with the last, I'm not sure which. Okay. So, are there any more questions or suggestions for the developers in terms of harmonizing these two? Okay, so I guess just the age 80 question. All right. Does that allow us to move on? We are moving on.

Next is going to be 225, regional lymph nodes pathologically examined for colon cancer. I think that's an ACS, and then I think Bryan is going to walk us through after.

MEMBER GORE: I'm definitely familiar with this topic, but I actually -- I only was able to listen to my part of the call for my measure, so I missed the discussion of this measure, as well.

CHAIRMAN LUTZ: So, we're going to count very heavily on our ACS folks that bring the measure to us, and then we'll fill in from behind.

MR. STEWART: Okay. So this measure examines the complementary activities of

surgery and pathology in the care of patients undergoing surgical resection for a diagnosis of colon cancer. And for adults with stageable non-metastatic colon disease, the measure is assessing whether or not at least 12 regional lymph nodes were pathologically examined following - from the surgical specimen.

This measure has roots in a long set of literature, as well as standard clinical references and guidelines. The principal kickoff point for this was the AJCC, the organization that maintains and supports the staging manuals used in this country and elsewhere back in the late '90s where they started to ramp up discussion about what constituted sufficient pathologic examination of surgically resected specimens for the purposes of accurate staging. And that's led to a growing body of literature looking at questions around extent and adequacy of surgical care and pathologic review of those patient specimens and the consequences -- the

potential consequences for patients who may undergo sometimes a range of adequate and quite reasonable clinical conditions, inadequate lymph node examination by pathologists.

I would add we've been watching this measure fairly -- we've been watching this metric fairly actively. It's not one that is subject to the classical challenge placed to the registries of trying to track down adjuvant non-surgical care. This is care that's being provided by and in the reporting facility, and the pathology is tied to that event. And we've actually seen fairly marked upward swing in this performance rate where we had about 60 -- we moved from a 63 to almost 85 percent performance rate compliance with this metric over the last five years that we've been watching this data across out 1,500 institutions.

At this point, that's background. Let me let the discussion follow from there.

MEMBER ROSS: I have a question right off the bat. We just heard yesterday that 21 percent of the colon cases were not staged appropriately with TNM, and yet you just said that 85 percent of the cases now have -- at least they have a nodal status report with at least 12 nodes.

MR. STEWART: Right. The cancer registry has multiple ways of describing the pathologic state of a specimen. And the fact that we've had nodes removed doesn't mean that all of them need to have been positive or negative. So, the registries report the pathologic TN elements, not the M element as Doctor Edge indicated yesterday. But they also independently report the total number of regional lymph nodes that were surgically excised, and the number that were pathologically determined to have been positive.

When you actually look at the independent field, so yesterday's conversation

was a conversation about whether or not T, N and grade, all three elements were present in a pathology report. So, that metric yesterday it was all in or out. If you were missing any one of those elements you failed the metric, and thus you have -- I actually was running data during that conversation and could verify what was being discussed.

If you look at the individual data elements in the registry, the PT and PN are appearing for surgically resected colon cancer patients, are appearing in the pathology reports as they're related to us 92 to 93 percent of the time. So, now the question is of those patients who had PN reported was the adequacy of the lymph node -- what was the extent of the lymph node examination by the pathologist?

MEMBER ROSS: I'm confused. I don't understand. The 92 to 93 percent that you just gave us is what?

MR. STEWART: If we look in our

data set in 2010 at surgically resected colon cancer patients, 93 percent of them have a PN reported. That's not quite the same metric as what we're talking about here. The metric here isþ-

MEMBER ROSS: Wouldn't I --

MR. STEWART: -- examines the nodes did they exam at least 12.

MEMBER ROSS: But I don't remember hearing about this 93 percent yesterday when we spent --

MR. STEWART: Wasn't part of -- PQRI didn't have that data -

MEMBER ROSS: And we spent an enormous amount of time talking about this.

MR. STEWART: Well, unfortunately, I didn't understand the conversation until it kicked off and I had a chance to talk to our colleagues from CAP yesterday after that conversation, and we will work on this further.

MEMBER ROSS: Steve, I hate to

bring up yesterday's news but, I mean, this is the data we were looking for yesterday when we were talking about moving that other measure forward or not, you know, what was the up-to-date staging information.

CHAIRMAN LUTZ: Which measure was that? I'm trying to recall. Do you remember which one it was?

MEMBER GORE: I thought it was the staging measure on colon cancer --

MEMBER ROSS: Because we kept hearing about the 21 percent of the patients that weren't staged appropriately, but we just heard that 92 to 93 percent of them now have normal status.

MEMBER GORE: Just to clarify, the 21 percent was comprehensive pathologic staging including T, N, and grade. So what we're discussing here is N only.

MEMBER ROSS: The other question I have is do we define how the lymph node -- the problem with the 12 is we don't know what's

normal. Right?

MR. STEWART: That's correct.

MEMBER ROSS: There's never been a study that said how many nodes in the normal mesentery.

MR. STEWART: Right. This measure unlike the others that I've spoken to is not supported by level one randomized clinical evidence. It's supported by a fairly large body of observational studies.

CHAIRMAN LUTZ: Can I ask a question about that because since those observational studies -- and I've just been looking them up. There's been several different groups that have done observational studies that have found anywhere from six to 17 to be the cut off, and there's actually a small but fairly well written observational study about the ratio of lymph nodes that come out. So, you can pull out 20, but it's a big difference in the ratio. So, I'm trying to figure out -- you know, we found this 13

number, and more seems to be better, but my surgeons who used to obsess about 13 have stopped because they figure "more is better," so if we didn't do 13 we have to change the chemo.

Is it still the case that we change chemo if someone doesn't get 13 lymph nodes out?

MR. STEWART: All you need is one positive node to initiate adjuvant chemotherapy.

CHAIRMAN LUTZ: But there was a time when if we had 10 nodes taken and they were all negative, we'd say you didn't do good enough, you didn't hit the magic 13 so chemo might be recommended, or they might have to go on trial.

MEMBER FIELDS: That's still one of the NCCN guidelines for high risk is not adequate number of nodes examined for if you have a Stage IIb or c. And one of the risk factors is not adequate number of lymph nodes

examined. So that would make you into the high risk, and that's why they are recommending chemotherapy in that group.

CHAIRMAN LUTZ: All right. But I guess the question I'm asking is is this number as a cutoff as relevant or as perfect as it seemed like it was when we were all excited about this for all those years?

MEMBER FIELDS: Well, that was my question for the group, also. There's some -- some of the guidelines I have different ranges, so including low ranges like seven positive nodes. And the other thing is -- and I'm not a surgeon but I'm frequently -- we've tried to address this at our institution, so frequently it's everybody is saying this person didn't resect enough nodes, and the pathologist didn't examine enough nodes. So, it's sort of a -- I think that's the controversy when you actually -- what we saw in a quality improvement project in Florida was that once we made this an important

parameter to measure, the pathologist started counting more nodes. That was the problem.

CHAIRMAN LUTZ: They counted more but a lot of them used this solvent that dissolves all the fat and they find one or two millimeter nodes. Is that the same thing as finding 13 --

MEMBER FIELDS: As what we're talking about. Right.

CHAIRMAN LUTZ: Right. So, yes, I don't know. It's the first question. John?

MEMBER GORE: And that brings up the structural process outcome link of the measure. And I think going back to some of the observational data, there was a prominent article by the Birkmeyer group in JAMA where -- because this is a facility-level measure, so if you take facility-level node yields there was no association with use of adjuvant chemotherapy and eventual survival. So it's I think a pretty good demonstration of the limitation of this in terms of the structure

process outcome link.

I mean, we do -- this is also an issue in a lot of other surgical diseases, and there is wide variability in how hard pathologists look. And one thing that we're looking at in bladder cancer is nodal volume, not nodal count pursuant to the issue that Steve just mentioned, so that's just my concern, is I see a limitation in the structure process outcome link.

MEMBER FIELDS: I forgot to ask my question to the developers, which was when you -- when this was developed several years ago, 12 was -- greater than 12 was the recommended number. And were there -- there's a guideline from -- where it's like a lower number, seven to 14. Is that a newer guideline since this last reporting? I didn't go back and look up the dates on that guideline. So are there --is the guideline recommendation changing in the period of time since this was developed? That's my question.

MR. STEWART: I think the most recent NCCN guideline still states 12, but there's -- but even when you look at AJCC, they have morphed their recommendation over time as they move from the fourth, to the fifth, to the sixth, to the seventh editions of their staging manuals. So we're not unaware that this is -- there's a bit of a moving target at stake here.

MEMBER PFISTER: The reference supporting that, even though it's a 2012 NCCN guide, the reference supporting is 2003. You know, I think that -- I guess consistent with some of the discussion yesterday, I think that as we revisit these measures that the -- that I think it would be a reasonable request to sort of revisit that criteria just to sort of get a sense for -- one of the things that I guess is striking is that if 90 percent of cancer is solid tumors, and most of the curative therapy for the solid tumors are surgery and radiation, the relative paucity of

measures that actually assess the quality of surgery, and so I think that just from a portization point of view that this is a measure which I think the comment about the link without comments is very well said, that this is a measure that there aren't a lot of surgical measures out there that you want to try to work with this measures somehow. But I do think that it is an appropriate expectation to kind of make sure that there's -- because sometimes guideline panels can sort of scrutinize some of these things in a lot of detail, sometimes they can kind of as part of their update maybe scrutinize in less detail.

And I guess that looking at this indication here with it being a 2003 reference, it may be that there are other things which are very relevant, but I think it's sort of reminiscent a little bit of the breast screening discussion yesterday where you don't have total harmonization of a couple of the input factors that go into this. And

that one might be placed out as a kind of well, gee, this is certainly a reasonable thing to do, but it's truly the standard thing to do. And that -- and I think that anything which goes from being -- is a quality metric is really you're implying that that is a standard as opposed to it being well, this is a guideline and you can use your judgment.

MR. STEWART: So can I make a couple of comments on that? The first comes back to Dr. Gore's comment, is that the really elegant and perhaps optimal trajectory of structure process outcome and making sure those things are all linked, I think that's optimally always our goal. But, unfortunately, those sort -- that sort of solidification, if you will, is probably only guaranteed where we've got randomized clinical trial, you know, Level 1 evidence to back up some of these measures.

As soon as any kind of measure development moves off of the -- or outside of

that sandbox, if you will, you certainly weaken the strength of the relationship between those constructs, and you enter into what is being expressed over here where you have to balance best reasonable action versus standard.

And to the Commission's way of approaching these things, we've used at least the NQF's traditional stratification of accountability measures versus quality improvement measures as a way to distinguish the potential viability of measures that either have Level 1 evidence behind them and those that may not.

MEMBER GORE: I definitely agree. And I think the link isn't always perfect, but one of the things that we do evaluate is the consistency of the evidence. And sometimes where we're faced with a measure that's based on expert opinion, what we find is that there are just no contrary evidence statements. And this is just one where there are some.

MEMBER LOY: I would ask, I was looking for it, in the submission, in the evaluation worksheet there's a reference in here from JNCI of 2007. Was there data that was evaluated in that study that you're aware of or that you could elaborate on that would inform a survival discussion based on the number of lymph nodes retrieved?

MR. STEWART: I'm going to stretch my memory. That was a meta analysis that I believe was published in JNCI in which a colorectal surgeon at MD Anderson who was the lead author, and I should know his name and it's escaping me.

MEMBER LOY: Chang.

MR. STEWART: Chang looked at the scope of available information at that point in time, basically providing a different perspective and review around the same question. And I have to go back and look at the details of that article to see if I can provide any additional direction or

recommendations.

MEMBER LOY: And the other point to be made I think that keeps coming back into this discussion but maybe not -- hasn't been surfaced today, is that one is better than zero, and the assumption that more is better than less I think is still a question, or how much is enough I guess is the better way to think about it. But the idea of having a numerator statement that would say X number of lymph nodes examined, or there was documentation that someone went back and asked that question, seems to be in the right direction. I don't know what the number needs to be to satisfy this group in the absence of data, but it certainly seems like a legitimate move in the right direction getting the most out of the material that's been submitted.

MEMBER FIELDS: I was just going to say, though, I guess it comes down to that's the current recommendation by NCCN and others, and it looks like when they went through it

they looked to see what data was there and what wasn't, and they came up with that number. So I have to agree that we have few measures that focus on the quality of surgery and indirectly on pathology, so I think we should think about adopting it for that reason given the paucity of the real literature to support it.

CHAIRMAN LUTZ: I was just going to say, if we think we've discussed it enough, we could just go for the vote. There's these handy clickers they gave us.

MS. TIGHE: Are there still Steering Committee members on the phone line?

MEMBER TENZYK: Yes, it's Wendy. I'm still here.

MEMBER ALVARNAS: Oh, yes, Joe, I'm here, too.

MS. TIGHE: Okay, great. Thank you. We're just getting the voting pulled up. You guys can still send me your votes.

MEMBER TENZYK: Okay.

MS. KHAN: So, voting on 1a, impact, we can start.

CHAIRMAN LUTZ: This is called a double-blind vote.

MS. KHAN: I think we're missing one person from the room. We're still missing one person. Okay, we're going to try that again. All right, you can start voting now.

MS. TIGHE: You can all vote again, please. One is high, two is moderate, three--

MS. KHAN: Oh, it's on impact.

MS. TIGHE: It's 1a, so we didn't get everyone's vote in the room.

MS. KHAN: So we have eight high, two moderate, one low, and zero insufficient evidence.

And going on to performance gap, it's one high, two moderate, three low, four insufficient evidence, and you can start right now. So we have five high, five moderate, zero low, one insufficient evidence.

And going on to evidence, again

it's one yes, two no, three insufficient evidence. You can start now. I think we're missing -- oh, got it. Seven yes, two no, and two insufficient evidence. Seven yes, two no, and two insufficient evidence. So do you want to discuss the reliability/validity?

CHAIRMAN LUTZ: Does anyone need to discuss reliability/validity, or did we sufficiently well to move forward?

MEMBER ALVARNAS: Let's move forward.

CHAIRMAN LUTZ: I appreciate that.

MS. KHAN: So voting on 2a, reliability, one high, two moderate, three low, and four insufficient evidence. You can start now. That's five high, six moderate, zero low, and zero insufficient evidence.

And voting on validity, it's one high, two moderate, three low, four insufficient evidence, and you can start now. That's four high, five moderate, one low, and one insufficient evidence.

And usability, did you want to -- all right. Usability, one high, two moderate, three low, four insufficient evidence. And you can start now. It's five high, four moderate, one low, and one insufficient evidence.

And going on to feasibility, one high, two moderate, three low, four insufficient evidence. You can start now. We're missing one person in the room. So we have six high, four moderate, zero low, and one insufficient information.

And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? That's one yes, and two no. You can start voting now. That's nine yes and two no, so the measure will pass.

CHAIRMAN LUTZ: All right. I believe we have two more to go, so anyone have any issues with just continuing on? Continue on we shall.

The KRAS issues for colorectal cancer, 1859. They're both ASCO, and I think

John will discuss 1859, and then I'll discuss 1860.

MS. McNIFF: All right. I feel like I've spent way too much time sitting here the past two days. All right. So for 1859 is a measure that looks at patients with metastatic colorectal cancer who are receiving monoclonal antibodies. And among that population assesses whether the KRAS testing was performed. We were asked to provide clarification about the numerator time window on the call, and so that change has been made just to make it crystal clear that the time window is the period between diagnosis with the colorectal cancer and the date of the monoclonal antibody initiation.

MEMBER GORE: Okay. So, in terms of importance to measure, the submission talks about the prevalence of colon cancer, as well as the high prevalence of metastatic colon cancer. The fact that the therapies which this measure applies to are very expensive, so this

gets to the idea not just of quality but also of value. And that there is very consistent evidence of the lack of benefit for application of these therapies for patients with the KRAS mutation.

In terms of performance gap, there was some evidence demonstrated of performance gap with this measure in terms of -- I guess that's it. That's all I have to discuss for importance.

CHAIRMAN LUTZ: Bryan.

MEMBER LOY: Can the developers comment any on the evidence basis around some of the exceptions to the mutations? I know that there was an introduction of KRAS mutation as being a predictor for some therapies, and then later on there was at least some mention of mutations where there was an exception to the exception, if you will.

MS. McNIFF: I'm sorry, I'm afraid I need more. First I thought you were talking

about denominator exclusions for which there aren't really any for this measure, but I think you're asking about something else. Can you restate --

MEMBER LOY: I am asking -- so mutations can predict response to therapy in the metastatic setting, but I believe that there has been subsequent data that came out that said that there are other mutations that really do demonstrate that some of these folks will benefit from those monoclonal antibody therapies.

MS. McNIFF: One of the things that I think came up on the call, and I'm hoping Mike Hassett is on the phone right now. Is that true? And, if so, he can comment on this more clinically. But there were some discussions about ongoing clinical trials, and that was part of the phone conversation. Dr. Hassett, are you on? Are you able to comment?

MEMBER GORE: This may be more relevant to 1860 than 1859, also. Because with

1859 all we're talking about is in patients that got the therapy, was a test done. So this may be a better discussion to table to 1860.

MS. McNIFF: And we'll still be looking for Dr. Hassett on that point.

MEMBER ALVARNAS: Although -- this is Joe. I had reviewed 1860 for my group. I mean, I think we can take care of two birds with one stone if we want to also deal with it here. Because you're right, these measures are linked, and I think a lot of the issues that we deal with in 1859 will also be dealt with in 1860. I think they're quite complementary to each other.

MEMBER GORE: Fine with me.

DR. HASSETT: Hi, can you hear me?

CHAIRMAN LUTZ: Yes.

DR. HASSETT: This is Mike Hassett. I'm not familiar with -- you mentioned a different type of mutation that predicts benefit from cetuximab that's related to EGFR. Is that the question?

MEMBER LOY: Yes. I thought that there was some subsequent data that came out that said that there may be a small population of folks who might have a mutation that would benefit from some of that therapy.

DR. HASSETT: Not to my knowledge, but I can certainly look into that. But I'm not familiar with any --

MEMBER MALIN: Yes. If there is something then perhaps it's investigational, but I'm -- there's not anything that I'm aware of that's used clinically.

MEMBER ALVARNAS: And it hasn't incorporated itself yet into the NCCN guidelines, at least in the current iteration of those guidelines.

CHAIRMAN LUTZ: Can I just say something in favor of 1859, specifically, and leave 1860 out for a second. We've talked a lot in the last couple of days about trying to get timely measures, so this is something where there's been data. You assume there's

going to be a certain uptake of a certain number of years before it becomes accepted, as is true for a lot of things. This I think timing wise is good, and for that reason the importance is actually pretty high. I mean, importance isn't always all those other measures, sometimes it's just does it fall in the right time frame. And in my mind, most everyone who's up-to-date does this, but not everyone. It's time.

MEMBER ALVARNAS: I agree.

CHAIRMAN LUTZ: All right. Does anyone have anything else to say about importance or questions for the developers before we vote on the importance of this one?

MEMBER GORE: Are we just going to focus on 1859 then, and then do --

CHAIRMAN LUTZ: I think in terms of voting we have to.

MS. KHAN: So voting on 1a, impact. You can go ahead and start now. Okay, we're missing two people in the room, or one person.

All right. We have 11 high, zero moderate, zero low, zero insufficient evidence.

And going on to performance gap, you can start now. We have six high, five moderate, zero low, and zero insufficient evidence.

And voting on 1c, evidence, yes, no, or insufficient. We have 10 yes, one no, and zero insufficient evidence.

CHAIRMAN LUTZ: Are there any points of discussion about reliability? Okay.

MEMBER GORE: I didn't have much to say. There were no concerns that I could identify about reliable ascertainment of the data, nor validity.

MS. KHAN: Okay. So, voting on 2a, reliability. You can go ahead and start now. So you have eight high, three moderate, zero low, and zero insufficient evidence.

Going on to validity, 2b. You can start now. We have eight high, three moderate, zero low, zero insufficient evidence. Is there

any discussion on usability?

MEMBER GORE: Again, the work group had no concerns about usability.

MS. KHAN: Voting on usability then, you can go ahead and start now. We're missing one person in the room.

MS. TIGHE: Can everyone push theirs one more time, please?

MS. KHAN: You have ten high, one moderate, zero low, zero insufficient information.

And feasibility? You can go ahead and start voting. Again, we're missing one more person in the room. Could everyone press it one more time?

MS. TIGHE: Can everyone keep pushing it?

MS. KHAN: It only counts it one time so you can keep pushing it until -- it's still on 10. Okay, so six high, five moderate, zero low, and zero insufficient information.

So overall suitability for

endorsement, does the measure meet NQF criteria for endorsement, yes or no? And you can go ahead and start now. So we have 11 yes and zero no, so the measure will pass.

CHAIRMAN LUTZ: All right. Then we go on to the last measure we have, which I'm not sure if it's formally paired but it's at least intellectually paired. So this is 1860. This is the basically sparing the patient if they don't fit the correct gene mutation outline, sparing them. And I think the same things could be said as were said before. It's timely.

I think the only questions I had -- actually, if you hit -- I don't want to usurp þ-- the folks who brought the measure want to give us some framework. Happy to -- I'll discuss it after. Anything you wanted to say to give us -- okay.

The two things that strike me. One is I think yesterday we had trouble passing one that was sparing someone of a drug, so I'm

not sure if we're just against it in general. I think we had -- we talked long and hard about it.

The other thing is my standard issue about wording. I like the idea of sparing someone rather than therapy not received. It just confuses me, but --

MS. TIGHE: Sorry. That was updated. It's -- okay.

CHAIRMAN LUTZ: Right. So this is the type of wording that I think is much better. It's good. So I didn't see any problems with it. I think it's just an issue of do you think it's important enough as we discussed yesterday to have a non-treatment -- an appropriate non-treatment be a measure. So I guess the question I leave open for discussion.

MS. FRANKLIN: We also have -- I think if Dr. Alvarnas is on the line, he was also a discussant for this measure.

MEMBER ALVARNAS: Sure, I

appreciate that opportunity. I think I would echo everything that's been said about this. I think you're right, I think in the abstract over-use measures are much harder to wrap our brains around because it's easier to say we should do something and measure our performance as opposed to we shouldn't do something.

But, again, speaking in the abstract, if we look at either the Institute of Medicine's Six Aims of Care or even what's been embedded in the Affordable Care Act, an important component of those measures, not that those have to be a model system in any way, but an important component would be that of overuse. And I think if we're talking again in terms of best care for our patients, sparing them futile or useless therapy does have a value. This therapy is in terms of importance -- we've talked about the prevalence of this disease and the number of patients potentially affected by it.

I think also in terms of the therapy itself, it's an incredibly expensive therapy, and rather than subject patients and our national debt to further use of futile therapy, I thought once again even though it's difficult to wrap our heads around the idea of performance judged by not doing something, I think it does get to the term of value. Does what we bring to our patients offer them value in the context of their care? And I think that there is a value in not offering futile or useless therapies. And I think this measure does speak to it.

I think the numerators and denominator are reasonable, and I think as you read through the body of the measure there is an identifiable performance gap that is troubling in light of the fact that these therapies are, again, of no use to the selected patient population, with the caveat that there may be those currently on an investigational basis for whom there are

specific mutations where it's not futile. But I think that has to be much more carefully thought through and eventually incorporated into the expert guidelines prior to being a deal killer for this particular measure. I thought, in the context of our group, we did recommend endorsement of the measure.

CHAIRMAN LUTZ: Great, thanks. David, did you have something to add on that?

MEMBER PFISTER: I think in part to sort of learn from the wisdom of yesterday's discussion, like I think there are three things worth kind of highlighting that stick out from the discussion of Herceptin versus this particular in terms of another non-treatment measure. The one issue is that, as I recall, the performance gap for that measure was a range of 80 to 100 percent with the mean being 99 percent. This is -- when you look at the performance gap data for this measure it's clearly much more consistent with there being range for improvement.

The one thing that -- the other thing that kind of came up, I suspect that it's been handled the same way for this measure, is that we know for Herceptin that there are actually clinical trials going on where people are actually getting it even though they test negative as part of the trial, so there's a formal clinical trial exclusion in this measure as there was for the breast measure.

MS. McNIFF: I'm looking. I believe there is not.

MEMBER PFISTER: And then, I guess, then the third issue is, is it handled the same way as far as if people have more than one test done, that it's the most recent test?

MS. McNIFF: One moment. I'm looking through the description to see if we put a definition for which test.

MEMBER PFISTER: Because I certainly think conceptually -- go ahead.

MS. McNIFF: We don't have it in

the instructions. We don't have that instructional statement, but we certainly can add that. And in terms of the clinical trial exclusion, Dr. Hassett, do you want to comment on that? I mean, that seems very reasonable and consistent to me to have that. Do you want to comment on that?

DR. HASSETT: Yes, I would agree. I mean, I'm also looking through the measure as we're talking, and would feel comfortable with there being a clinical trial exclusion. I think for whatever reason there's been less push to further explore the use of this agent for patients with mutations because the direction of therapy is just -- it's going in another direction. So I think when the measure was created it wasn't -- the perceived risk wasn't really thought to be there as much; whereas, with the trastuzumab example there are still I think more testing of trastuzumab, but that having been said I think a trial exclusion would be reasonable.

CHAIRMAN LUTZ: Karen?

MEMBER FIELDS: We were trying to understand, there's some literature that says there's differences in the wild type KRAS expression that may predict the subtypes of wild type that may predict for response to cetuximab. And we were wondering -- and there was apparently discussion of that on line, or with the group's meeting. We were trying to understand -- maybe that's what you just referenced, the changes in the way we approach KRAS as a predictor for response to cetuximab, and is that something that needs to be taken into account in developing this measure.

DR. HASSETT: This is Mike Hassett, again. I would say that the current measure as stated focuses on specifically gene mutations of KRAS, as opposed to variations in the expression of the KRAS protein itself. So I don't think that there would be cross-contamination, if you will.

MEMBER LOY: I was the one that

asked the question before about -- the question that is out there in terms of some of the folks that have KRAS mutations that might benefit from therapy. And I've located in the NCCN narrative, but I believe the mutation that's still a question is the KRAS T13B mutation that had been singled out. So all of that to say this, why would that be important?

If someone were to identify that mutation and prescribe therapy in light of that, then would not want them to be penalized, if you will, for not adhering to a measure.

MS. McNIFF: I don't know if Dr. Hassett wants to comment on that specifically. I mean, I will say that the source for this is an ASCO provisional clinical opinion which is based on a systematic review of the literature, very careful synthesis by experts, and that exception is not included in ASCO's recommendations.

MEMBER LOY: And it may remain a

question after. I just would ask if you've all given full consideration to that and it was somehow considered in this measure, I'd like to make sure that we've kind of gone on record as having considered it.

MS. McNIFF: I understand. Again, this was -- we rely on the guideline process, that systematic review and expert review process. And there doesn't -- we try not actually to review the science during our measure development. That is done during the guideline development. I mean, unless there needs to be an update, of course, and that's if there's new science, that's a different thing. Dr. Hassett, do you have any additional comments about that?

DR. HASSETT: No, I think your comments would be the same as mine, that we would rely on the Committee to -- for the Guideline Committee to address those issues.

I think the specific mutation that you're referring to is not made it into the

guidelines yet, perhaps because it's been viewed as preliminary data. I'm certainly happy to refer it back to our Guidelines Committee for their comments to make sure that they're in consideration of it. Although, their processes are usually pretty rigorous looking through all the data that's out there.

MEMBER LOY: Certainly seems reasonable. I guess the question would be if that Committee then -- or if that literature matures during the interim time, there's a mechanism to incorporate that back into the measure would be the question. I mean, we're dealing with an evolving body of literature here.

MS. McNIFF: And I can -- oh, sorry, Dr. Hassett, do you want to speak to that?

DR. HASSETT: I was just going to say, I think it's a great and challenging point. And one of the things that ASCO has tried to do with some of these measures is

address aspects of care that are sort of newer, and one of the risks there is that things change. And I think the organization is very committed to making sure that if there are changes, substantive changes in the evidence that would lead to a different conclusion about the way that a measure is created, that those are really incorporated as soon as they're available, again because of that very need, whether that's this particular measure, or any other measure that it's putting forward. I don't know, Kris, if you have any comments.

MS. McNIFF: I mean, because this is used in our QOPI program, it's reviewed every six months, so it does go through a review. Where things get tricky, and I think this is true for any measure development exercise is -- and is especially tricky with overuse measures is if there's one study that's not especially strong, or an observational study that suggests -- in those

cases we rely certainly on our expert methodologist to help point us in the right direction, but that can be very challenging to deal with those specific issues. And with overuse it's harder than with under-use for sure.

CHAIRMAN LUTZ: To a degree I have a sense that we have the data we have now, and we have folks that are going to have to trust that are paying attention that things change. I mean, I'm not sure. It's hard to sort of predict what might happen.

MEMBER LOY: Just to kind of round things out here. You know, I'm hearing a commitment that as things change it will be evaluated and incorporated. And I'm not sure that I understand outside of QOPI, for example, how else this measure will be used, and who else will be using that data. Is that something you all can speak to?

MS. McNIFF: And I can't predict that either. I think that's another one of

those big issue challenges. One possibility, for instance, and we don't have plans to do this but it's possible that once this gets NQF endorsed that it could be promoted for use in the PQRS program, for instance. It's possible that health plan payers may want to start evaluating some of the performance around these measures. It will just kind of be out there.

We will absolutely -- I mean, I think it's part of our contract as measure stewards to make sure that we're updating these, but we will continue to update them. And we'll provide the specs for this, and so we'll continue to provide the updated specs.

CHAIRMAN LUTZ: Are we sufficiently satisfied to vote on the first questions?

MS. KHAN: So voting on 1a, impact. You can go ahead and start. We have 10 high, one moderate, zero low, and zero insufficient evidence.

Moving on to performance gap, 1b.

You can go ahead and start. So we have six high, five moderate, zero low, and zero insufficient evidence.

And going on to 1c, the evidence. It's yes, no, or insufficient evidence. So it's 11 yes and zero no, zero insufficient evidence.

CHAIRMAN LUTZ: All right. Anything to add on reliability/validity? All right, moving on.

MS. KHAN: Moving on to 2a, reliability. You can go ahead and start. We have five high, six moderate, zero low, and zero insufficient evidence. And going on to 2b, validity. You can go ahead and start. You have six high, four moderate, zero low, and one insufficient evidence.

CHAIRMAN LUTZ: Anything about usability or feasibility?

MEMBER LOY: One of the -- from a payer perspective, one of the observations that we've seen is that there's some variance

in terms of what's being tested in terms of mutations. And it's not specific for this type of cancer, but certainly we're seeing things that I'll say go beyond the scope of the evidence that's out there. So, it's not uncommon for us to see codons and -- I'm sorry, even within the codon mutations that really aren't reflected in the literature. And I'm just wondering in your discussions have you all characterized that to the extent that you would say that that's a non-issue, that variance? Because what I worry about is the þ- - I'm not worried about where we've got science and folks are using that in a clinically sound way. Where I worry about is folks getting that information, not understanding how to correlate that with the science, and being said it's mutation positive, but outside of where the body of science would support making a treatment decision.

MS. McNIFF: Our PCO on the topic

does provide guidance about that. We don't have a measure about it. It sounds like ASCO recently published the top five. Did you follow the top five initiative at all, the top five treatment or interventions that should not be undertaken in a clinical setting without good reason to do so. And there was a lot about surveillance testing. But this particular issue was not -- it's one that I can bring back for consideration for ongoing work kind of in that area. We're developing measures around the top five.

So, we haven't, except that there is the guidance that we provide to clinicians, but I think it's a good point. We take it back.

MEMBER LOY: I take away from what you just said there's guidance, but we really don't know. We really don't understand the variance that's out there today to the extent, because I know many folks order mutations not only for treatment decisions but also for

cataloguing for potential future use or for clinical trials determinations --

MS. McNIFF: Right.

MEMBER LOY: -- for eligibility.

MS. McNIFF: And it's something that we can talk -- our colleague from CAP stepped out of the room, but it's a good --

MEMBER LOY: Okay, thank you.

CHAIRMAN LUTZ: David?

MEMBER PFISTER: The other --again, comparing and contrasting to yesterday, actually orders this particular test, so it's not like I can say how it goes in my practice. Certainly, my experience with looking at HER2 testing is -- makes it very apparent to me why they have an algorithm. So, there's this lengthy algorithm regarding like well, figuring out positive and negative equivocal results for the HER2 testing. And it seems that either because it's an incredibly robust test or it's never controversial what the result is, that for the KRAS testing it's

basically yes or no. Is it that robust?

MS. McNIFF: I don't -- I mean, I wish our colleagues from CAP were still here. They have a -- I'll tell you what it's called, "Perspectives on Emerging Technology Report on KRAS Mutation Testing," so they've really provided the guidance about the specific testing to be done, and might have more information along those lines. I just don't know. I'm sorry.

DR. HASSETT: I would say that the thing is -- doesn't make any difference in as much as it's looking for the presence or absence of a mutation as opposed to an expression profile, so it's inherently, if you will, somewhat easier to identify a cutoff because either the mutation is present or not. Whereas, with the expression profile it's how much expression is enough to set your threshold for being positive or negative.

I think the bigger question with mutation analysis is your first question,

which is to say if we expand our mutational analysis beyond the codons for the segments of the genes that are supported by evidence, how do we use the new data to inform our practice? And I guess I would say we can't if we don't have data to inform what we should do. It's going to be to some extent hard to interpret data. And I think this measure is just trying to focus on the mutations that we do have data on.

But I agree that in general I think this field of genetics is going to be a stimulus for -- but many potential problems with quality as it becomes harder to interpret test results and the subset of patients that we analyze becomes smaller and smaller.

The risks to quality in this field I think are only going to increase, and from that perspective I think that's what makes measures of quality in this field important because this is where I see some of the biggest potential risks in the future.

MEMBER LOY: I'm sure this is out of order, but it's just becoming clear to me. I'm wondering if it's a request that we can make of the developers to specify the mutations that are clinically relevant at this time in the measure. Is that an option, or have we voted -- have we gone too far down the voting?

MS. McNIFF: As a definition?

MEMBER LOY: To specify the mutations that are clinically relevant as it relates to the treatment decisions that you're specifying.

MS. McNIFF: Dr. Hassett, I think we could easily copy that in from the guideline. Do you have any concerns about that?

DR. HASSETT: No, not at all. In fact, I think it's a good idea, and to the extent that we can make this a very explicit document it's going to be that much more helpful.

CHAIRMAN LUTZ: I think the other thing it does is that if they're in there, then if there are any changes in the data you know from which you're starting. That's your starting point, so you're not starting from general, you're starting from specific and then changing as the data suggests.

DR. HASSETT: I like that idea.

MEMBER TENZYK: I think the other thing is that raises -- it's something for the NQF process and all of these measure development processes to be aware of. That there needs to be, I think, a process to update measures like this, even if the science can't --

CHAIRMAN LUTZ: Agreed. All right. Can we -- all right. There is an annual update, but I think -- yes. All right. Yes, there are measures, and actually I think we'll probably discuss those when we get to measure gaps and other things after we're done with this. So I think if I'm not mistaken we're up

to voting on --

MS. KHAN: Usability.

CHAIRMAN LUTZ: -- usability.

MS. KHAN: So, voting on usability, you can go ahead and start. So, we have seven high, four moderate, zero low, and zero insufficient information. And going on to feasibility, you can go ahead and start. So, you have eight high, three moderate, zero low, and zero insufficient information. And overall suitability for endorsement, does the measure meet NQF criteria for endorsement, yes or no? You can go ahead and start. Can everyone press it one more time? So, we have 11 yes, zero no, so the measure will pass.

CHAIRMAN LUTZ: Very good. Did we have anything else? Was there rewording from yesterday that we were supposed to bring up? Did you send me an email on that, Lindsey?

MS. TIGHE: I did forward you that but it was on the ASCO measure, so if you just want to tell them the rewording on the 1857

and 58, I think maybe. I can pull up the email, too. I've got it if you want me to read it.

CHAIRMAN LUTZ: Sure.

MS. TIGHE: For 1857, patients with breast cancer and negative or undocumented human epidermal growth factor receptor to HER2 status who are spared treatment with trastuzumab. And 1858, trastuzumab administered to patients with AJCC Stage 1 T1c through 3 and human epidermal growth factor receptor to HER2 positive breast cancer who receive adjuvant chemotherapy with a note that contraindication or other clinical exclusion such as cardiac disease has been added.

MS. McNIFF: The addition was just the specific reference to cardiac disease.

CHAIRMAN LUTZ: Very good. And then are we to go on to Measure Gaps? Measure Gaps.

MS. FRANKLIN: So, if the Committee could, we would like to get your input on what areas where you see there are gaps in

measurement that remain for this topic area.

MEMBER PFISTER: Can you be more specific.

MS. FRANKLIN: Cancer, cancer is the topic area.

CHAIRMAN LUTZ: Cancer.

MEMBER ALVARNAS: This is Joe on the phone. I guess my vested interest being a hematologist is that I think that there's still a relative dearth of measures related to patients with hematological malignancies. And although they certainly don't have the prevalence of the solid tumors, I can understand the prioritization of that, we're still talking about 60,000 people a year with non-Hodgkins lymphoma, and a significant number of people with multiple myeloma, so I would strongly encourage the development of metrics toward that.

I still see numerous people referred to us with either of those broad categories of disease who are really

incredibly mismanaged from a pathological perspective and a therapeutic perspective, so I think those areas are really ripe for process improvement.

MEMBER CHOTTINER: This is Elaine Chottiner. I'm on the Practice Committee of ASH, and we discussed this at a meeting last week. I think they are acutely aware. And I've talked with them about the change in the process, and I think they are considering now -- this is off the record - working with ASCO on some of the malignant measures, and also looking very carefully at some of the benign hematologic diseases. So, this is very high on their radar right now.

MEMBER ALVARNAS: I appreciate that. And, again, I'm both an ASH and ASCO member, and I've been impressed with the leadership, to speak very frankly, the leadership of ASCO in this area. And, again to be very frank, appalled at the lack of leadership that ASH has at least overtly

shown. So, as an ASH member, I've been particularly troubled by that, so I'm glad to hear that.

MEMBER CHOTTINER: I second that.

MEMBER ALVARNAS: Thank you, again.

CHAIRMAN LUTZ: David?

MEMBER PFISTER: Just to reiterate the comment that I made before, that if we're going through this exercise with the metrics looking to at the end of the road basically improved cancer control, that I think that in looking at measures that need to definitely be developed in terms of the gap is look at those things that ultimately impact the major outcomes of cancer in terms of cancer control, which for most cancer that's going to be surgery and radiation. Yet, when you go through the menu of metrics it's perhaps significantly weighted to a lot of systemic questions, in part I guess the randomized data there. But I think we really need more measures looking at surgery/radiation both in

terms of their role as part of curative therapy for solid tumors, and also in terms of some of the value and efficiency care issues that are related to that.

CHAIRMAN LUTZ: And I appreciate that. I can say actually on the record that ASTRO, now that they've had the experience once through here with this Committee last time we met is very excited, and has the staff to do just that. And one of the things I've been remiss in, they've asked me to brainstorm with them the ideas that we could take back. I just haven't had time to yet, so if you think of anything specific radiation-wise, I'm all ears. I think Bryan, and then John.

MEMBER LOY: From a payer perspective, I would just say we have an interest in survivorship. And I know that's very broad, but there's a lot of variation that exists out there in terms of survivorship, and I'll give you some specifics. Just smoking cessation for those

folks who have gone through lung cancer, or are going through lung cancer treatment experience is an area of interest to us.

I would also say that just maintaining nutritional status and going back in for ongoing surveillance, which would also point me to that there's a lot of variation that exists out there in the surveillance experience, as well. We've talked a little bit about that over these past couple of days in terms of under-treatment and over-treatment, but as a payer we're trying to figure out what it is that's the right level of care, making sure that the patient that's going through a cancer journey remains engaged in the system to minimize the probability of recurrence, but at some level adhering to some evidence-based standards.

CHAIRMAN LUTZ: And, actually, if I could just say one -- just sort of echo and maybe add to that concern. One of the issues I've noticed is I've heard for years that

follow-ups do or don't help. I know we had that discussion yesterday about breast cancer. I've heard well, they're going to cut off payment for all follow-ups, or it's very important, we need to keep doing it. Follow-ups are -- this is going to sound wrong, but they take a -- I don't want to say clogging. They take a lot of the time of oncologists right now, and I know a lot of follow-ups for prostate cancer are unseen by a radiation oncologist or urologist any more, they're seen by a nurse practitioner or a PA. I don't know that that's wrong, but there seems to be a lack of consensus about what are we supposed to do for those 10 million cancer survivors in follow-up. It's very frustrating. John, I think you're up.

MEMBER PFISTER: Yes. I think this surveillance area, although again we -- at the last meeting we talked about, I remember -- I think it was a melanoma measure that had to do with like over-imaging. It wasn't surveillance

setting, but oftentimes we suffer a little bit for an evidence gap in those areas. But I think what happens in the evidence gap is that there's a little bit of a default to image, or to do something. And I think that it's not that there's necessarily any additional veritas to justify the decision, just I think that there can be a certain centrifugal force toward a greater burden to say why you didn't do something as opposed to why you did do it.

CHAIRMAN LUTZ: Great. John, then Elaine, then Karen.

MEMBER GORE: I had two comments. One is a little redundant with something I said at our last in-person meeting, which is that when you look at some of the surgical diseases, it's very difficult to discriminate surgical quality. And I think with our last review we had a chance to look at what the Society for Thoracic Surgeons was doing where they were really trying to drill down into some intra operative things that might be

associated with different surgeon quality. And I know that they spent years and money building up their registry, but I think that is a good model for something to feed back to the representatives of other surgical societies, at least trying to do something to link surgical quality with outcomes.

And then I also -- just a comment. I feel like I'm -- as more and more agencies are bringing metrics to the NQF for consideration of endorsement, and then thereby potentially to payers or to organizations, I think counseling measures are just very hard in terms of feasibility, so in terms of burden of work to facilities or systems, so just the notion of counseling for something I think it's -- as people are faced with trying to prioritize the different measures they use to track the quality in their own system, those are just hard measures.

MEMBER CHOTTINER: I'm new to the quality process, and I may be somewhat naive,

but one of the issues I see is that it's very difficult to develop quality measures for young people. So, when I talk to ASH about this, because ASH is notorious for not having a lot of evidence-based guidelines, but they do have them for Sickle Cell, they are excellent guidelines out there for hemophilia. But there isn't the will to develop those because right now everybody is concentrating on PQRS, because that's where the penalties are going to come in. So, the answer is always well, Medicare isn't going to be interested in those, so that's not what we're going to work on. So, it affects the young people with chronic diseases. It has a real impact upon survivorship in young people. And I think it's a major obstacle.

CHAIRMAN LUTZ: Agreed. Bryan?

MEMBER LOY: Just one more thought comes to mind. I would just challenge the folks who are in the laboratory space to come up with some quality measures around those

laboratory tests that really are not being held to a standard of laboratory validity and clinical utility.

We're starting to see some movement around the companion diagnostics with some of the introduction of the latest drugs and targeted therapies, but there's a whole universe of laboratory developed tests that are out there that are being provided that methodologies are changing. We've got next generation sequencing coming in. There's a translational component. Physicians who have not been trained in those areas that are getting information and trying to figure out how to take probabilities and assign them to a clinical situation, so there's a translation component. There's a consumer component for those folks that are getting predictive testing that maybe does not have a context set around it.

It just feels like that there's a very broad opportunity to get after some

existing practices that are out there and demonstrate their quality in a place that really doesn't have governance over it.

CHAIRMAN LUTZ: That's a good point.

MEMBER FIELDS: I guess the other thing that was disappointing for all of us to see is some of the things that people were bringing back, but no next generation thoughts about the measures. So, for example, making þ- - although I guess it's sad to also see for hormonal therapy for breast, that's been around for 30 years, and there's lots of data that that's our role. When are we going to get to be able to do the studies that said okay, women now all get AIs appropriately, but we need to make sure that they're not breaking their bones.

CHAIRMAN LUTZ: Right.

MEMBER FIELDS: Or when are we going to get the study that says they took the AIs for the appropriate period of time.

Because I think there's literature to support how to manage all of those things. So, maybe -- I guess we aren't at a point in our -- nationally to be able to say that we're meeting all the standards of care and, therefore, we're stuck with pretty low-lying fruit. But it would be very nice to see that developers bringing back the next question that goes with the last question, how to integrate that.

CHAIRMAN LUTZ: That's one thing I think also, you know, with these last couple of KRAS issues, I mean, they fall right into the -- there's been data but it hasn't been fully accepted yet. We had some issues about are we too far ahead of the curve? Is there a subset of the wild type? But the fact of the matter is they passed pretty easily. I mean, there's a whole window of things that are coming out with biologicals and everything else that we just don't have any. There's not much there.

MEMBER FIELDS: Just to some of the rest of the discussions we had, but it's still the reality. When you talked about people get needle biopsies, then they get a core biopsy, then they get an incisional, that's actually happening. It's not just like you have one example of that, so when are we going to be able to -- and we're also -- many of us are used to working in big comprehensive cancer centers where there's this level of peer review. That doesn't -- maybe the measure should be how many patients got presented at an interdisciplinary care conference with the right level of expertise so that we knew that they weren't going to be doing what you talked about.

How often do we see in the community sentinel node biopsies not being done appropriately in breast cancer, yet that's been the standard of care for years. There's -- I just think we haven't gotten to the very -- like are the people using the

studies, and the data, and the therapies appropriately. And then not necessarily over-utilizing the system in an inappropriate way. And it's still disappointing to see those things.

CHAIRMAN LUTZ: And, actually, I'm glad you said that because you just convinced me of what I should tell ASTRO. You know, someone gets certified by an outside like ACR to do radiation, you have to prove you're doing QA on every patient within a week of when you start, and that saves lives. Unless you do the outside certifications, you know, that's one thing I'm not sure what the equivalent would be for surgery, but yes, we can absolutely convince ASTRO to bring a measure that says you have to QA within a week of starting or else. That would be a great one.

MEMBER FIELDS: I thought ASTRO's measure they brought the last time was a great example of what it is that I'm talking about,

which is the variation in how many times you need to radiate a painful bone mass. And then, obviously, the way that the system has increased resource utilization and cost in an unnecessary fashion.

So, more things like that for these kinds of measures would be what I would hope would be the next generation. Yet, I guess I'm also struck with if we've known for 30 years women should get tamoxifen, and only 70 to 80 percent of the women get tamoxifen, we've still got a lot of improvements to go. So, I guess the state-of-the-art is still somewhat disappointing when you think about it.

CHAIRMAN LUTZ: Is there anyone on the line that wants to add anything?

MEMBER ALVARNAS: Nothing else comes to mind.

MEMBER TENZYK: I just want to echo what's been said about cost, measures being updated and more specificity than just does a

patient get chemo or not, or hormonal therapy or not. I think the ability to do quality measurement is a long way in the last 20 years, so the measures should be able go with the clinical science at this point.

And the thing is, you know, I agree with my colleagues here that malignancies -- most of the measures are basically focused on breast, lung, and colon which even though they're the most common malignancies, there are still a lot of others, so it would be good there, as well.

CHAIRMAN LUTZ: Good points. Good points. Is there anything else on the Measure Gaps before we open up for member and public comment? I guess, Arnika, can we check and see if we can open the phone lines for public comment, please?

OPERATOR: At this time, if you would like to ask questions press star then the number 1 on your telephone key pad. We'll pause for just a moment to compile the

Committee roster. Again, to ask a question press star then number 1 on your telephone key pad.

CHAIRMAN LUTZ: Any public comments, anyone?

(No response.)

CHAIRMAN LUTZ: All right.

OPERATOR: At this time there are no questions.

CHAIRMAN LUTZ: Thank you very much. I think Angela is going to talk about next steps.

MS. TIGHE: Okay. For next steps, there's a phone call scheduled for June 6th I think from 2:00 to 4:00 p.m. Eastern Time. At that point we'll be considering the comments received on the Phase I measures and draft report. We received 111 comments largely supportive of the endorsement recommendations. Those comments have been pushed to the measure developers who are working on their responses to them now. We hope to be able to send you

their responses and some proposed NQF responses late next week.

Also on that June 6th call we'll be handling any follow-up from this meeting, so if the developers can get us their changes or the requested information, we'll discuss it at that point.

Phase I is scheduled to go up for vote I believe June 12th, and this Phase II report is scheduled to go up for public and member comment June 18th, I believe, so a lot happening in June.

(Off microphone comment.)

MS. TIGHE: The ASCO conference ends on June 5th. And then other than that, we'll be in touch by email, but you probably won't ever see us face-to-face again, unless it's on another Committee, so I'm sure people are okay with that. Thank you very much for your attendance.

MS. BOSSLEY: Thank you again to everyone.

MS. TIGHE: This has been a marathon.

MS. BOSSLEY: Yes, we really appreciate your time and dedication.

CHAIRMAN LUTZ: Thank you.

MS. FRANKLIN: Thank you, Arnika. We're completed.

OPERATOR: You're welcome. Ladies and gentlemen, this concludes today's conference call. You may now disconnect.

(Whereupon, the proceedings concluded at 12:28 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cancer Endorsement Maintenance Steering Committee

Before: NQF

Date: 05-24-12

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter