THE NATIONAL QUALITY FORUM

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STEERING COMMITTEE ON
NATIONAL VOLUNTARY CONSENSUS STANDARDS
FOR PATIENT OUTCOMES

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MEETING

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WEDNESDAY
APRIL 21, 2010

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The Steering Committee met in Salon 1 in the Marriott Bethesda Hotel, 5151 Pooks Hill Road, Bethesda, Maryland, at 8:30 a.m., Joyce Dubow and Lee Fleisher, Co-Chairs, presiding.

MEMBERS PRESENT:

JOYCE DUBOW, MUP, CO-CHAIR
LEE FLEISHER, MD, CO-CHAIR
RUBEN AMARASINGHAM, MD, MBA, MEMBER
LAWRENCE M. BECKER, MEMBER
E. PATCHEN DELLINGER, MD, MEMBER
ANNE DEUTSCH, PHD, RN, MEMBER
BRIAN FILLIPO, MD, MMM, FACP, MEMBER

LINDA GERBIG, RN, MSPH, MEMBER
EDWARD F. GIBBONS, MD, MEMBER
LINDA GROAH, RN, MSN, CNOR, FAAN, MEMBER
PATRICIA K. HAUGEN, MEMBER
DAVID HERMAN, MD, MEMBER
DAVID S. P. HOPKINS, MS, PHD, MEMBER
DIANNE V. JEWELL, PT, DPT, PHD, CCS, MEMBER

DAVID A. JOHNSON, MD, FACP, FACG, FASGE, MEMBER
IVER JUSTER, MD, MEMBER

MEMBERS PRESENT (Cont'd):

BURKE KEALEY, MD, FHM, MEMBER

PAULINE McNULTY, PHD, MEMBER

LEE NEWCOMER, MD, MHA, MEMBER

VANITA K. PINDOLIA, PHARMD, BCPS, MEMBER

AMY K. ROSEN, PHD, MEMBER

BARBARA YAWN, MD, MEMBER

ALSO PRESENT:

HEIDI BOSSLEY, MSN, MBA, SENIOR DIRECTOR,

PERFORMANCE MEASURES

HELEN BURSTIN, STAFF

HAWA CAMARA, STAFF

SARAH FANTA, STAFF

SEAN O'BRIEN, MD, CONSULTING STATISTICAL

REVIEWER

REVA WINKLER, MD, MPH, PROGRAM CONSULTANT

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9:01 a.m.

CO-CHAIR DUBOW: So we were very productive yesterday in terms of doing heavy lifting, not to say that we don't have hard questions to deal with today, but it will be shorter.

It's nice everybody moved around.

I think the Committee as a Committee worked very, very effectively yesterday. So that's really great.

So today we have a couple of cardiovascular measures left to consider. And then we have the GI measures and the cancer measures. And that's it.

And we're going to try to be out of here by 2:30. Okay.

Could the folks on the phone just identify yourselves, please.

MEMBER GIBBONS: This is Ted Gibbons for University of Washington.

DR. WINKLER: Hi, Ted.

CO-CHAIR FLEISHER: Hi, Ted.

DR. PATTON: Mary Patton.

CO-CHAIR FLEISHER: Could you repeat that?

DR. PATTON: Mary Patton.

CO-CHAIR DUBOW: Mary Patton.

CO-CHAIR FLEISHER: Yes.

CO-CHAIR DUBOW: And anybody else?

DR. DAVIES: This is Cheryl Davies from the AHRQ development team.

CO-CHAIR FLEISHER: Great. When you speak today, if you could identify yourself, even if you had previously. Then the person who is actually transcribing this can attribute it appropriately.

CO-CHAIR DUBOW: Yes. And please use a land line if it's possible, but certainly not a speaker phone because the connection is not always clear. So it would be best if you had a land line, we would appreciate that.

DR. BOTT: John Bott with AHRQ.

CO-CHAIR DUBOW: Hi, John. How are you?

DR. BOTT: How's it going?

CO-CHAIR DUBOW: All right. We're going to start with the cardiovascular measures.

CO-CHAIR FLEISHER: Okay. Reva?

DR. WINKLER: Okay. The first measure we're going to talk about this morning is measure 010-09. This is acute myocardial infarction, AMI mortality rate. This is from the folks at AHRQ.

CO-CHAIR FLEISHER: Page 149?

DR. WINKLER: Yes, page 149 in your PDF document.

This is a measure of number of inpatient deaths among cases 18 years and older with a principal diagnosis code of acute myocardial infarction. So this is an inpatient mortality rate for acute myocardial infarction.

This is not the first time NQF has

dealt with measures of mortality for AMI. In fact, we have previously endorsed two measures:

(1) An inpatient mortality measure from the Joint Commission, and;

(2) A 30 day mortality measure from CMS.

So this is not exactly new ground.

This measure, however, is different and unique in a couple of respects. This measure, unlike the 30 day mortality which was reported by CMS and the Joint Commission, this includes all ages. The measure that CMS and Joint Commission report only include patients over age 65, but it is a 30 day mortality rate.

This measure is similar to the endorsement measure from the Joint Commission in that it is in-hospital mortality for anyone regardless of age greater than 18. However, this measure uses claims as its data source, whereas the Joint Commission measure uses the

more typical Joint Commission data abstraction methodology. All right.

CO-CHAIR FLEISHER: So just a comment with regard to harmonization of measures: If we approve this, does that occur at a different stage or do we have to be concerned about harmonization?

DR. WINKLER: At this point we need to evaluate this measure on its own merits. The other measures, for the most part, the definition of AMI is fairly straightforward. The age criteria is very straightforward. The things that are different are the way the risk adjustment models are created.

MEMBER HOPKINS: So, Reva, are you saying it's not our job to worry about best in class and this measure versus others that are similar measures?

DR. WINKLER: Well, I think you can but there are a lot of elements about how to make that decision that make it quite

difficult. Differences in data source is one issue.

MEMBER HOPKINS: Yes.

DR. WINKLER: The other is just looking at what specifications you can, I don't know how the two best models would compare. I don't believe there's been any head-to-head comparison. So it can be challenging to do that.

MEMBER HOPKINS: So you're saying if I hear you, NQF could live with this measure being alongside the ones that are already endorsed?

DR. WINKLER: I think if the reason is because it's used as a different data source, that would be fine.

MS. BOSSLEY: I think the only thing I would add is at maintenance it will come up when both measures come forward they will then be looked at probably head-to-head, side-to-side. And data source may again be the reason why both are continued, it may not

be. Yes. But if you look also, they included on page 165 the one difference between the two measures. So they did address the differences in how they exclude or include transfers.

DR. WINKLER: Right. That's right, the transfers.

MEMBER DEUTSCH: And there's some difference to the rest of this?

DR. WINKLER: Yes.

MS. BOSSLEY: Yes.

CO-CHAIR FLEISHER: So, Ted, do you want to make any comments from the TAP's perspective?

MEMBER GIBBONS: Well, I think it is important to emphasize that our perspective here is this is more inclusive, and its versed with individuals that deserve, perhaps more attention as it relates to excess morbidity and mortality with AMI, particularly the description of gender differences and rural versus urban of AMI.

And so it is unique in its

analysis when compared to the CMS measure. So we were interested to see that that give some insights into looking at quality measures.

CO-CHAIR DUBOW: Yes. Is the Joint Commission measure widely in use?

DR. WINKLER: After the TAP met, I asked the Joint Commission what the status of their measure was. They publicly reported on their website from 2004 to 2007. But at the time that the CMS 30 day mortality measure became available and was publicly reported they did not want to put both measures up for confusion, whatever; there was a decision. So they only publicly reported the 30 day measure. However, they continued to collect data from hospitals and provide feedback to hospitals on the inpatient measure.

MEMBER HOPKINS: Would you say that their measure is also 65 and older?

DR. WINKLER: What? The Joint Commission?

MEMBER HOPKINS: Yes.

DR. WINKLER: No, not their inpatient measure.

MEMBER HOPKINS: Oh, CMS' measure?

CO-CHAIR FLEISHER: So any comments from our colleagues from AHRQ? John?

DR. BOTT: No, I don't have any other comments. But I think Cheryl's on the phone and I believe Patrick Romano is there in person. They may have comments.

CO-CHAIR FLEISHER: Patrick, do you want to -- I don't if we have a spot at the table. But why don't you come up while we discuss it.

So, any comments from the Steering Committee? Barbara?

MEMBER YAWN: The distinction of not having people whose MI is while they're in the hospital seems to me to be a little bit difficult from discharge data. Could you just comment on that?

DR. BOTT: This is John Bott.

I believe, and correct me if I'm

wrong, I believe it's being discussed in the TAP and at that time the way in which AMI was defined is in the same group that AMS defines AMI with its denominator for the 30 day mortality measure.

DR. RAMANO: That's correct. It's defined based on the principal diagnosis. Our definition is the diagnosis that's responsible for occasioning the admission of the patient to the hospital for care.

MEMBER YAWN: A lot of times they come in because they're having symptoms of chest pain and they're not admitted for an AMI. And it turns out that, of course, it is an AMI. It captures those also?

DR. RAMANO: Yes. It's under coding rules it's a retrospective determination that's made by the coder after discharge based on review of the entire medical record and the physician's impression of what was the underlying diagnosis that caused the admission of the patient. Now, of

course, in occasional cases there may be confusion about that.

MEMBER YAWN: There's always occasional anything.

CO-CHAIR FLEISHER: But I think what it does is eliminates the perioperative MI and peri-procedural MI, which is a good thing.

Lee?

MEMBER NEWCOMER: So if I'm reading this TAP comment on page 164 correctly, we are missing one-third of the MIs if this correct. So could someone from the TAP just explain how they work that through from a scientific and usability standpoint? That's question one.

Question two is I notice that if discharge diagnosis is missing or if disposition is missing, the case is excluded. Do we have any idea how many abstracts come out with missing disposition?

DR. BOTT: Well, I could address

the first issue about one-third of MIs being missing. But since these come up in the TAP and really reflect the definition of the MI and the coding with the definitions that were brought out in 2007 of the universal definition of MIs the seven criteria and the public allegation it appears that some MIs made the list because that the majority that was defined as the medical condition applied to in the admission would be included.

The measure developer may have another perspective of that, but we didn't see that as an obstacle.

CO-CHAIR FLEISHER: Can you comment, Patrick? Can you comment?

DR. RAMANO: I had a little trouble understanding the telephone comments.

Yes, I'd reference the point, yes, it is definitely true that a significant chunk of MIs occur in the hospital, particularly in the postoperative settings, somewhere in the range of 30 percent. And these are omitted

from all of these AMI mortality measures.

And the basic rationale is that it's a fundamentally different set of events. These events are picked up, obviously, very quickly when they occur in the hospital. And they have a lot of variety of predisposing circumstances, particularly in hospitals that do a lot of cardiac surgery and cardiovascular surgery.

So, all of us have excluded for the sake of homogeneity these in-hospital events. But it is perhaps an area for future measure development.

CO-CHAIR FLEISHER: So can we record that for future measure development we should look at an in-hospital secondary diagnosis MI and potentially mortality. It used to be, at least perioperatively, 30 or 50 percent of these patients died. The recent data suggests in the 12 to 15 percent range for prospectively collected data. That would probably be an interesting question between

hospitals.

DR. RAMANO: You could also address the second question that was raised. Missing discharge disposition is extremely rare in most of these datasets, less than a tenth of a percent. The more significant issue relates to the patients who are transferred to another hospital and may expire at another hospital. This measure definition excludes those patients because the ultimate outcome is unknown when you don't have linked data. And that is clearly a superior feature on the CMS 30 day mortality measure. Of course, that measure does require a linked dataset as the Medicare claims dataset.

CO-CHAIR FLEISHER: Patricia?

MEMBER HAUGEN: Yes, just a comment relative to this issue that a third of them are missing from a patient perspective. I'd just like to add some weight to the need to further explore this type of measure. Because from a patient perspective the fact

that there was an AMI, mortality AMI on an inpatient basis even if the admission wasn't AMI, is a serious mortality event that needs to be measured and would affect a view of the quality in an institution provider.

MEMBER DELLINGER: Don't you think that a lot of those would come up under the individual surgical quality measure? Because that's where they're captured is a 30 day mortality rate. And so they would be actually captured but maybe not specifically defined under a AMI or --

MEMBER HAUGEN: Well, I can't speak not being a measure developer that for all conditions it's going to be captured in some other measure. I don't know, I couldn't speak to that.

CO-CHAIR FLEISHER: So actually, the NSQUIP, the ACS measure yesterday would capture not AMI, but capture those complications with 30 day complications?

MEMBER HAUGEN: As a new measure

if it ends up being --

CO-CHAIR FLEISHER: Absolutely. You're correct.

MEMBER HAUGEN: I mean, there's a long road to go through to make sure that that would be in place.

MEMBER KEALEY: So I wanted to support Barbara's contention about possible MIs that get admitted, unstable angina. In my experience a third of MIs happening in the hospitals is incredibly high. So it just doesn't seem right to me. It just doesn't pass the gut check. And so I just want a little clarity that we're not missing all these people whose troponin comes back eight hours later and positive and then we say they have an MI.

CO-CHAIR FLEISHER: So I guess as someone who does a lot of coding is the diagnosis code, could that be expanded for Burke's comment?

DR. RAMANO: In previous work we

have looked at how many patients have a principal diagnosis of unstable angina, for example, ventricular tachycardia, ventricular fibrillation, cardiac arrest; other conditions that might be a consequence of the MI but they have a secondary diagnoses of MI.

So we have looked at that situation. Don't quote me on the exact number, but it would modestly increase the denominator size. I'm remembering numbers on the range of 3 to 5 percent, but it certainly wouldn't account for the majority of the cases with a secondary diagnosis of MI.

MEMBER KEALEY: So as I look at it we have kind of the MIs that are associated with things we do to people; so these are the surgical procedures mostly. And then we might have MIs that, say, happen to somebody who is there with pneumonia, some other medical cause. Do we try and sort those two out? Because it does seems like I can understand how you'd want to look at those differently.

But the second, the ones that are just associated with other medical conditions, seems like it ought to be counted just like a regular MI.

DR. RAMANO: It's a good question. I've personally taken care of patients who came in with hip fractures and other trauma who had MIs while awaiting surgery. So they weren't postoperative MIs. So I think it is an important question and it's one that we haven't fully explored.

CO-CHAIR FLEISHER: I wondered if as we vote whether we need that clarification or ask for that data as we go forward? Because it's sort of, Patrick, you're giving us your Gestalt but maybe that can be addressed more formally as a question to the measure developers to get us that data of the other diagnosis codes for the comment period. Would that be something you'd like to say?

MEMBER HOPKINS: Did I hear correctly, though, that the other measures

that are out there, CMS and Joint Commission, also exclude this group?

DR. RAMANO: Yes, that's true. And obviously those deaths would be captured under other NQF approved measures, for the most part for pneumonia mortality, heart failure mortality, hip fracture mortality, et cetera.

MEMBER HERMAN: You know, it may be worthwhile somewhere along the line to do a crosswalk of all these measures to find out where everything's being picked up. Because taking them one piece at a time is likely going to have a lot of overlap and a lot of administrative burden that are going to cause us to make poor decisions down the line because we're going saying there's just so much administrative burden we don't want to measure this.

So if we could get a crosswalk maybe somewhere this year to look at the CMS measures, the JCAHO measures, the NQF

measures. Because when I look at the stuff that I get every month from the Mayo Clinic standpoint, all this stuff is in there someplace. So in the hospital 30 day mortality we break it out what's due to MI, what was the admitting diagnosis; all that stuff.

So a crosswalk and an overall, you know 20,000 foot view of this, might help us as we develop measures in the future.

MEMBER GIBBONS: This is Ted Gibbons on the TAP.

Just coming back to the issue of usability, the other thing that we discussed in the TAP was the fact that individuals who have a secondary myocardial infarction related to a whole variety of things, arrhythmia, sepsis, pneumonia, renal failure where the diagnosis is often made retrospectively based on laboratory data rather than clinical symptoms, it's more difficult to interrupt we thought the timeliness of application of

entrance-based AMI care such as aspirin beta blockers for what they're worth now and other principals of management that are often instituted within minutes, within an hour of presentation.

So interpreting the timeliness of management of secondary myocardial infarctions we thought was fraught with quite a bit of difficulty. And that's why we felt that even if it was a significant number of MIs, that they're not being counted in terms of mortality, that the data was perhaps more interpretable just including the primary data.

CO-CHAIR FLEISHER: Barbara?

MEMBER YAWN: But as a primary care physician I'm going to suggest that some of those people who are called pneumonia, they have pneumonia but they also have symptoms that vary MI which haven't been recognized. And so to say that it's hard to interpret, perhaps. But it might also make us look a little beyond what, you know, oh yes they have

a pneumonia and a chest x-ray and that's all your focus on and you forget the rest of the patient.

So I'm not convinced of that argument. I understand postoperatively it may look a little differently.

My other question, though, is about the crosswalk between coding and looking at the medical records. And I believe you have some data about that.

We did a study was published about -- oh, it was probably published almost ten years ago, and we were missing, oh somewhere around, I think 17 percent of the MIs from coded data versus medical record review. And I can't remember what you tell us when you check that.

CO-CHAIR FLEISHER: I think that was addressed to, Patrick. No?

DR. RAMANO: Let me look that up. I'll be back with you in a minute.

MEMBER YAWN: Thank you.

CO-CHAIR FLEISHER: Any other questions? Yes.

MEMBER JUSTER: Yes. This is just a coding question.

Would there be any circumstances under which a patient would receive a principal diagnosis on discharge of AMI, but it was because of an MI that actually occurred once they were hospitalized or is that code only to be used for people that that was the reason they presented to the hospital? In other words, might there be some reasons to code it simply because it reimbursed better or something?

MEMBER YAWN: Yes, and that happens regularly.

MEMBER JUSTER: And they really had an MI, it just wasn't the reason they were admitted?

MEMBER YAWN: Yes. And we just finished auditing a large number of records to see if the coders ranked the diagnoses in the

same matter in which the physician did. And pretty consistently they did not.

DR. DAVIES: This is Cheryl Davies.

Patrick, you can tell me am I right. I just want to note that technically a principal diagnoses must be present on admission for it to be valid as it comes for diagnosis code. So that would be actually the incorrect coding because a postoperative AMI or an AMI that occurred in the hospital as a principal diagnosis?

DR. RAMANO: Yes. I would add that there clearly are going to be variations in the sequencing in the diagnoses. But the principal diagnosis is really kind of sacrosanct because it is the diagnosis that drives the DRG. So actually, it would be fraud for a hospital to claim that an MI that actually occurred after discharge was present on admission. You know, some hospitals may do that, but it would be fraud.

MEMBER YAWN: And I think sometimes you'd be hard pressed to prove that the MI occurred after admission if it's 12 hours or 10 hours. So, you know, what's an evolving MI versus -- you know. But I do think that no one intentionally approaches it as fraud. They intentionally approach it as how do we get the best DRG with what has been available for patient diagnosis.

CO-CHAIR FLEISHER: So, I will ask that we move on from this particular topic because of the issues -- I understand, Barbara. So as we vote on this, we can consider the issues of coding. And I would actually suggest that CSAC and the crosswalk, they consider the validity of the different approaches in determining what is the best measure in the end to harmonize against.

So, we'll go on from there.

Dianne?

MEMBER JEWELL: Well, it's my impression we're not, whichever way we slice

this whether we're talking about how its coded or who, it doesn't sound like we're talking huge volumes of patients here from anybody's description.

So, if it's not creating an unstable measure, I'm not sure that picking out these very narrow slices really helps us make a good decision about the measure.

CO-CHAIR FLEISHER: This is the traditional approach with coding. But I think it is valid to ask NQF to look at these issues that we have great concern about to see what's the best approach.

Other comments?

MEMBER YAWN: The only one of our narrow comments that I don't think it is, the methodology, the using codes versus using medical record abstraction. I think that does affect the scientific validity and other things. And so I don't know how narrow it is.

CO-CHAIR DUBOW: It effects feasibility.

MEMBER JEWELL: So let me try again. I think that these kinds of issues come up with every single measure we have.

I appreciate the relevance of all of the comments, I just am not clear that they are so different in this case that it's helping me, at least, make a better decision about the measure. So that's really why I'm saying that. It's not that I don't think they're important; believe me, I do.

CO-CHAIR FLEISHER: Thanks.

Vanita?

MEMBER PINDOLIA: But I think on that same point, the other measures they've actually gone and done chart reviews compared to their claims and had data to show that it was X percent similar. Their data, the 2b reliability, it was done with 25 patients and found to be 90 percent.

So, it is 90 percent but it was with 25 patients. So that is concerning of why -- actual it was 100 percent but their

claims data showed 90 percent to have AMI.

CO-CHAIR FLEISHER: Any comments?

DR. RAMANO: Yes. So in section 1c, I apologize. Some of the information here is not really properly in the right section.

But anyway, in section 1c about four paragraphs in there's some information regarding the agreement in the identification of new MI cases with more recent data, two studies. One indicated 93 percent, the other 98 percent agreement. So that's the best current evidence that we have.

CO-CHAIR FLEISHER: How many numbers?

DR. RAMANO: What's that?

CO-CHAIR FLEISHER: Do you know how many numbers of patients that represented?

DR. RAMANO: The study from California was roughly a 1,000. And I don't recall the other study offhand.

MEMBER ROSEN: I think there was a study also done -- it's just escaping me right

me. But Laura Peterson looked at the reliability of AMI coding and found it was quite high in VA data looking at the medical records.

CO-CHAIR FLEISHER: Other comments? Okay.

Any public comments?

DR. KAY JEWELL: Hi. Kay Jewell, no disclosures.

The only thing I would comment is the usability in terms of if Joint Commission has not been publishing theirs because they are concerned about the confusion with the CMS measure. This measure and the Joint Commission are both 18 and over in-hospital mortality. So I'm not sure that effects the usability issue.

CO-CHAIR DUBOW: Heidi reminds me that the cardiovascular measures come up for maintenance this year and that means that if this measure were endorsed, it would be put to a head-to-head comparison with the Joint

Commission measures. So we're looking at a very narrow time frame for resolving these issues.

CO-CHAIR FLEISHER: Ready to vote? Reva?

DR. WINKLER: All right. We need to go through the four criteria.

So in terms of a measure of in-hospital AMI mortality. Important to measure and report? How many would say it's yes?

Oh, great, I got to figure out where everybody is now. All right, that's everybody.

CO-CHAIR FLEISHER: And Ted.

DR. WINKLER: Okay. Plus Ted, that's fine.

MS. BOSSLEY: Twenty.

DR. WINKLER: Twenty. That's okay. We'll be 21 but Brian is not here right now. Okay. Got it. All right.

Scientific acceptability of the measure properties for this measure as

specified. So how many agree it meets the criteria completely? Thirteen.

Partially? Seven. Okay. That's it.

Usability, completely? Seventeen.

Partially? That's the remaining three.

Feasibility completely? Seventeen.

Partially? Three. Okay.

All right. Recommendation on the measure.

CO-CHAIR FLEISHER: Any conditions?

All those in favor of the measure? Twenty.

DR. WINKLER: Is that everybody?

MS. BOSSLEY: Everyone.

CO-CHAIR FLEISHER: Yes.

DR. WINKLER: Okay. Got it. All right.

Ted, are you going to send me your

votes like you did last night?

MEMBER GIBBONS: I certainly am. I can tell you that I support the measure right now.

DR. WINKLER: Okay. Thanks.

MEMBER GIBBONS: I'll send you a written one.

DR. WINKLER: Thank you.

CO-CHAIR FLEISHER: Next measure.

DR. WINKLER: The next measure is measure OT1-012-09, coronary artery bypass graft procedure and postoperative stroke during the hospitalization or within seven days of discharge. This is a measure from Ingenix.

Okay. What do I want to say? I'm just trying to find it. There it is. Okay.

Again, this is not the first measure that NQF has evaluated and endorsed for postoperative stroke after CABC procure. This is one of the measures from STS that is endorsed both independently and as part of the

composite that you discussed yesterday. This measure approaches it somewhat differently looking at the time frame of hospitalization plus seven days out. Okay.

Did Ted want to say anything?

CO-CHAIR FLEISHER: Ted, any comments?

MEMBER GIBBONS: Yes. The TAP was concerned on several levels.

(1) That it was already a measure that was included in the STS composite. I'm wondering whether that --

CO-CHAIR FLEISHER: We're losing you again, Ted.

MEMBER GIBBONS: Sorry. I'm actually on the land line connected to the wall. So I don't know if it's the connection.

The TAP was concerned about several issues.

(1) That it was already a part of the STS composite and it did add a separate meaning.

But more importantly, the definition of stroke was of concern because it really depended on who made the diagnosis of stroke; was it the surgeon, was it a consulting neurologist, was it based on an imaging scan. And it was felt that the reliability of making the diagnosis of stroke was of significant concern.

And on that basis, because it arose from the data different from the registry of the STS, we wondered whether it actually added a value.

CO-CHAIR FLEISHER: Any comments on risk adjustment? Ted?

MEMBER GIBBONS: No. Well, the risk adjustment was there weren't any specific comments on it. But I would have to ask whether the Steering Committee felt that it was adequately looked at.

CO-CHAIR FLEISHER: The issue was that there was no risk adjustment, correct?

MEMBER GIBBONS: Yes, that's

correct.

CO-CHAIR FLEISHER: Okay. Can we have any comment from anyone from Ingenix.

DR. SCHWEBKE: Is there anything in particular you would like me to comment on?

CO-CHAIR FLEISHER: The risk adjustment would be the first question.

DR. SCHWEBKE: Okay. So this is Kay Schwebke from Ingenix.

As far as risk adjustment, we do not have any specific methodology. We do exclude from the denominator people that have had pre-existing strokes and we do take into account that people who are going to undergo coronary artery bypass or surgery to some degree have already been self-selected. So beyond that, we do not take administrative pains to try to further risk adjust.

As far as the first concern, does it add value? One of the unique features of this measure is that it really improves authorization of what STS is trying to

accomplish.

And I apologize. I'm sure that the FM music makes it difficult to understand.

MS. BOSSLEY: Can you hold on.

CO-CHAIR FLEISHER: Okay. Why don't --

DR. SCHWEBKE: Great. Thanks. Thanks.

CO-CHAIR FLEISHER: Why don't you start at the beginning again.

DR. SCHWEBKE: Okay. So as far as risk adjustment, we do not have any specific methodology currently that's risk adjusting. We do pull out of the denominator individuals who have a previous CBA. In addition, we do take into account the fact that people who are undergoing coronary artery bypass procedure to some degree have been self-selected.

Beyond that our concern has been the ability of administrative claims to otherwise really completely risk adjust. We have not built in any methodology. We're

certainly open to suggestions and feedback about that.

With respect to, you know, does this add value, I certainly appreciate the STS measure and this measure was built off the STS measure because we appreciate the value of this measure. What's different is that the STS measure really focuses on a registry and a category 2 coding approach, which unfortunately we have found is not taking off and is really reducing the feasibility of measuring and identifying this important gap in care.

What this measure does is actually takes administrative claims data. So it really operationalizes the measure to a greater extent that I think would allow us nationally to probably do a better job looking at large numbers of people and truly trying to capture this information.

I think a few points, you know, diagnosis of CBA, you know it's really

difficult to address that one. If petitioners aren't able to accurately diagnose a CBA, then it doesn't really matter how that data is collected; if it's collected through the STS approach, if it's collected through using a face-to-face encounter with an administrative claim that identifies a CBA.

So to me, I don't really see that argument particularly if this is a measure that's already supported by STS and is using exactly the same codes.

CO-CHAIR FLEISHER: Comments from the Committee? David.

MEMBER JOHNSON: The questions I had was on the seven day extension. Where did that come from? Why pick seven days, why eight days? And was the captured percent of postoperative CBAs, and where's the science behind that?

DR. SCHWEBKE: Yes, that's a great question. You know, our original measures I mentioned was built off the STS measure. And

in that measure we did a good job defining certain characteristics. For example, what's bypass procedure or what's the code for CBA.

What they did do was specify time frames. And so as we were conceptually trying to kind of mimic their measure of CBA, we also appreciate that they didn't have a specificity that we really needed from which to built a more precise measure. So we actually took input from our external consultant to try to define that time frame.

So almost without any data, it is really a consensus import from an external consultant, Panlow Specialist that included neurologists and surgeons and cardiologists. However, that's another area where we're certainly open to feedback and modification if people thought that that was a significant issue.

MEMBER JOHNSON: So the point, I guess you were registering, is that there's so much variability here because if the length of

stay is extended for one patient, seven days beyond that gives you whole different time frame for capture. And why not just stick with a 30 day rule which would really harmonize across other measures of postoperative complications within particular CABG 30 day events?

DR. SCHWEBKE: So just so I make sure that I'm clear. So you're suggesting to be consistent rather than looking seven days out, look 30 days out? Is that a correct summary of your statement?

MEMBER JOHNSON: Yes.

DR. SCHWEBKE: Yes, we'd be certainly open to that. And I certainly appreciate that that would at least bring some standardization to the approach.

CO-CHAIR FLEISHER: So you're willing to change it if we put a condition on it, is that what I'm hearing?

DR. SCHWEBKE: Absolutely. We would be very open to that.

CO-CHAIR FLEISHER: Okay. Joyce?

CO-CHAIR DUBOW: Could I come back to the risk adjustment and ask our methodologists, or anybody else for that matter, about the -- oh, Sean's on the phone?

MS. BOSSLEY: Sean should be on the phone.

CO-CHAIR DUBOW: I'm just interested in your take on the explanation about the lack of risk adjustment that we just heard?

CO-CHAIR FLEISHER: Amy?

MEMBER ROSEN: Is Sean on the phone?

MS. BOSSLEY: I believe Sean is on.

DR. O'BRIEN: Hi.

CO-CHAIR FLEISHER: Sean?

DR. O'BRIEN: Hi. This is Sean O'Brien.

I think I definitely, I shouldn't comment. Actually I was asked to reviewed

certain measures, as other measures I did not review. I'm involved with the American College of Surgeons, and there's a conflict here. So I think I can't comment on this measure --

CO-CHAIR DUBOW: We appreciate that. Thank you.

DR. O'BRIEN: From the comment standpoint, I didn't really review this measure and I can only comment on the kind of address measure.(Inaudible due to failure of house audio system)

There's a risk model using clinical data for the end point in STS and the model that has that model discrimination that it's clearly identifiable risk factor that are associated with that higher risk of CBA, even among patients without CBA, this risk measure did not approve patients with prior CBA, but among the patients without CBA that sets that comparability present in the package (Inaudible) is associated with 50 percent

increased likelihood of stroke and peripheral vascular disease, as well, at 30%, so there are well established risk factors that could potentially (Inaudible).

CO-CHAIR FLEISHER: Thank you, Sean.

Can you hear us?

DR. O'BRIEN: I can hear you fine.

CO-CHAIR FLEISHER: Okay. And I would ask anybody on the phone to not put us on hold since we got music last time.

Amy, comments?

MEMBER ROSEN: I missed 95 percent of what Sean said. But I think that risk adjustment is very important in this kind of modeling. In looking at stroke I think that there are from the literature lots of risk factors for stroke that it's really critical to include in a model.

Also, I'm concerned that patients with prior strokes with evidence of history of stroke are excluded from the denominator

because it seems to me that that variable would be an indicator of severance. So I'm unclear why patients with prior stroke were excluded unless there's some diagnostic coding issue there.

DR. SCHWEBKE: Yes. This is Kay Schwebke again.

That's a good point. Usually that was because we wanted to make sure that if it was coding for a CBA after the procedure, it was a higher likelihood that that CBA coding face-to-face encounter was truly related to a CABG and wasn't kind of a follow-up code for an individual who has a stroke in the past and now was just being addressed as part of a longstanding chronic situation versus an acute episode. So that was one of the big reasons why we thought that we really needed to exclude a prior CBA from the denominator.

MEMBER ROSEN: I appreciate that comment. I would still think that one of our recommendations might be to include those

patients, and also to encourage Ingenix to think more about developing or applying a risk adjustment model for this particular measure.

Also, it's my understanding from looking at this that there's only face validity. This hasn't been empirically tested, is that correct?

DR. SCHWEBKE: That is correct. I'm sorry, if what you're asking is, is there a chart review validation process that's been tied to testing this specific measure, that is correct.

Now we do provide in the measure application a summary of more global chart review comparison to administrative claims, a validation that we have done. And actually in that setting we found that measures like this which are looking predominately for ICD Diagnoses Codes are actually quite accurate and sometimes were actually better than chart review if we truly it a gold standard.

MEMBER ROSEN: I was looking more

as these statistics are some evidence of model performance, empirical performance. Does that appear? I don't see it.

DR. SCHWEBKE: Could you give me an example of specifically what you're looking for, and maybe I can answer that question?

MEMBER ROSEN: Is there a key statistic, you know r squared or something where you've basically developed a model to look at an outcome of stroke?

DR. SCHWEBKE: Okay. We do not have that information as part of our testing.

MEMBER ROSEN: Okay.

DR. SCHWEBKE: Thanks for clarifying that.

CO-CHAIR FLEISHER: Other comments? Yes.

MEMBER GERBIG: Yes. I have just a technical question back to the seven day follow-up. At least for the Medicare population those short, fast readmissions are rolled back into the original admission and

billed as a single bill. So those codes appear on the original bill, not as a separate admission. And I was wondering if since we'll have essentially two different measures for the under 65 population and the over 65 it won't appear as a readmission, it'll appear as a continuation of the original admission which would speak for spreading that out to the 30 days. I'm just wondering from a purely performance improvement aspect if we'll get the information from the measure that we really need to drive improvement?

We'll certainly see a postoperative stroke. There's no doubt at all that it would appear to have occurred within the admission rather than, perhaps, the patient was discharged too early or with improper follow-up and returned with a stroke because they didn't take their medicines, they didn't see a physician. I was just wondered if that was considered?

DR. SCHWEBKE: You know, that

wasn't considered in our time frame. You know, really the reason we had developed this shorter time frame because we wanted to be more confident than less confident that if a CBA occurred, that temporally it was a higher likelihood which related to the recent hospitalization for the CABG procedure. But again, you know, we'd be happy to consider to extending it out to a 30 day time period based on the feedback that has been shared today.

CO-CHAIR FLEISHER: Dianne.

MEMBER JEWELL: So after the risk adjustment question, you know Amy brought up the point about prior stroke. And I would think that that would be a reason to risk adjust, the presence or absence of that.

But also the wide age range here, 20 years to infinity. The measure identifies patients 20 years and older?

DR. SCHWEBKE: That's correct. And that actually is the original age group that was in the STS measure.

Now STS has actually modified their measure from the original one, and I'm speaking now to one of the CMS PQLI measures. And it actually extended that age group even further, which is now 18 years of age and older.

So, you know, we were really trying in good faith to replicate as best we could that STS measure that was NQF endorsed at that time and so didn't want to stray from the age group that they had defined.

MEMBER JEWELL: And actually, I'm not debating the choice of the age group. I'm actually more just raising the point that it seems to me with such a wide age span, that's another argument for having some risk adjustment in the measure.

CO-CHAIR FLEISHER: Other questions? Other comments? Okay.

DR. WINKLER: Okay.

MEMBER NEWCOMER: So point of clarification. I have to recuse myself,

Ingenix is a subsidiary of United Health Group.

DR. WINKLER: Thank you, Lee.

All right. For this measure the CABG procedure postoperative stroke. Importance to measure and report. All yeses?

MS. BOSSLEY: We're back to 20.

DR. WINKLER: We're back to 20 now?

CO-CHAIR FLEISHER: Well, we're back to 21 a least.

DR. WINKLER: But Lee's recusing himself, so he's not. Okay. So we still got 20.

All right. Scientific acceptability of the measure properties. Completely meets criteria, how many? Zero.

Partially meets criteria? Eight.

Minimum meets criteria? Twelve. That's 20. Okay.

Usability. Completely meets criteria? One.

Partially meets criteria?

CO-CHAIR FLEISHER: I think it's two.

DR. WINKLER: Oh, okay. Sorry. Sixteen.

Minimally meets criteria? Not at all?

MS. CAMARA: I think we had 17 for partial.

DR. WINKLER: Okay. Seventeen for partial. All right. That adds up now.

Feasibility? Completely? Two. Okay.

Partially? Seventeen there.

Minimally? Okay.

CO-CHAIR FLEISHER: Okay. As far as the vote, is there any conditions? Or we want to include a condition on time frame or no? Ruben?

MEMBER JOHNSON: I believe that was the same.

CO-CHAIR FLEISHER: It's David,

okay.

MEMBER JOHNSON: The extended time frame, the 30 days seemed to be kind of consistent with other measure capture. The risk adjustment I think has been raised by a number of people and I'm not sure that we get that in a condition.

CO-CHAIR FLEISHER: Right. So I wasn't going to put the condition of risk adjustment because that's a different measure, correct?

DR. WINKLER: I think that's a significant change in the measure. You've heard a willingness to change the time frame to a 30 day. So you can vote it that way.

MEMBER JOHNSON: My point is I think it's too complicated to show risk extended time frame with the elephant being the risk adjustment. And I think it's counterintuitive to make that a condition.

CO-CHAIR FLEISHER: Yes?

MEMBER HOPKINS: I'm seeing a

problem here. Suppose they agree to extend the time frame and we do mean from admission, so it's actually that change as well, then aren't they going to get hung up on the testing requirement because that measure would not have been tested?

MEMBER AMARASINGHAM: I would propose that there's too many deficits to have a condition and ask for to vote.

CO-CHAIR FLEISHER: Okay. Very good. We will go to all these in favor of approving this measure. All those opposed.

MEMBER GIBBONS: I oppose.

Ted Gibbons.

DR. WINKLER: So it's 17.

CO-CHAIR FLEISHER: No, it would be 18.

MS. BOSSLEY: Eighteen because we had Ted.

DR. WINKLER: Well, okay. Yes. Okay. Seventeen plus Ted. Because I haven't got him in all of them.

CO-CHAIR FLEISHER: Okay. Thank you.

We're done the cardiovascular and GI.

CO-CHAIR FLEISHER: Okay. Thank you.

Are the measure developers on the phone for the GI measures.

DR. WINKLER: Actually, they're the same group as the previous.

CO-CHAIR DUBOW: Yes, it's AHRQ and also Pfizer. Is there anybody from Pfizer on the hone.

DR. WINKLER: I doubt it. Okay.

CO-CHAIR DUBOW: Can we do that one first?

DR. WINKLER: Yes, that's the one.

The first measure is OT2-014-09. This measure was submitted by Pfizer. It's opioid-related symptom distress scale. And one of the issues was the incompleteness of the information that was provided in the

submission despite numerous attempts to get greater information.

When this went to the TAP they felt that they didn't have enough information really to do an assessment of the criteria. So disposition is ultimately in your hands, but--

MEMBER JOHNSON: I'd like to move that this be denied. Not considered for review because there was no input from the TAP and that we felt that we were hindered by this process. It shouldn't even be discussed beyond a no vote if it goes to a vote.

CO-CHAIR DUBOW: Is there a second for that? Any discussion at all?

MEMBER McNULTY: Just one question. I mean, I know that with GI that, you know, opioids can cause GI side effects. I guess you have no background information so I'm asking questions you probably can't answer. Why is was specifically submitted for a GI?

DR. WINKLER: The one thing I can tell you is when you look at the tool because they did give us the references that it's based on, it was applied to like gallbladder patients for pain management. That was its primary application. So that seemed to be its use.

MEMBER McNULTY: Okay.

CO-CHAIR DUBOW: Okay. And we don't have the measure developer on the phone, is that correct?

Okay.

CO-CHAIR FLEISHER: There's nobody on the TAP call either.

CO-CHAIR DUBOW: We don't have any information.

MEMBER HOPKINS: It came in late?

CO-CHAIR DUBOW: No, it just --

DR. WINKLER: Not late.

CO-CHAIR FLEISHER: Did Pfizer call into the TAP?

CO-CHAIR DUBOW: No.

DR. WINKLER: No.

CO-CHAIR DUBOW: So apparently the measure developer is not interested in this measure. Okay.

CO-CHAIR FLEISHER: Maybe the drug development changed over the course of the time frame. Can I --

CO-CHAIR DUBOW: All those in favor --

CO-CHAIR FLEISHER: Can I move that we thank them for saving us a lot of time?

CO-CHAIR DUBOW: We have a motion on the table to deny the measure.

CO-CHAIR FLEISHER: To deny.

CO-CHAIR DUBOW: So this is in denial. All those in favor of denying consideration of this measure?

MEMBER DELLINGER: Let's vote it down.

CO-CHAIR DUBOW: Okay. Then you want to change your --

MEMBER JOHNSON: The proposal is that this be a no vote on the measure.

CO-CHAIR DUBOW: Fine.

MEMBER HOPKINS: What if they wanted to legitimately submit at another time? It wouldn't be fair to say the measure was considered and turned down or denied.

CO-CHAIR DUBOW: Well, David, the measure developer didn't provide enough information to consider it.

MEMBER HOPKINS: So let's not consider it.

CO-CHAIR DUBOW: So you just want to table it?

MEMBER JOHNSON: We can't. Based on the data that it provided, we're evaluating this for a yes or no vote. We've already said that it was incomplete. So you don't have information. It's a yes or no vote.

CO-CHAIR DUBOW: So Helen correctly points out that we didn't have adequate information to consider this.

DR. WINKLER: It's a condition for consideration that that is a full submission. And I think we should just say it's not considered, period.

CO-CHAIR DUBOW: It was not considered a full submission. The measure was not considered.

DR. WINKLER: It's not considered.

CO-CHAIR DUBOW: So, okay. And there's unanimity, I see, not to consider the measure. Okay. That's it. But we finally got it out.

Okay. The next measure is the AHRQ measure ion gastrointestinal hemorrhage mortality rate, 009.

DR. WINKLER: Yes. This is measure 2-009, gastrointestinal hemorrhage mortality rate from AHRQ. This is the number inpatient deaths per 100 discharges with esophageal hemorrhage as defined within the measure.

David, the view of the TAP?

MEMBER JOHNSON: The TAP felt that this was certainly an important outcome to measure, although it wasn't clear that this was going to be gained through the measure that was provided. The developers of the measure did an excellent job of giving us the stratifications that would be used in this, but recognizably it had not been validated. It's certainly impossible to corroborate that that process for extraction then walleyed be accurate.

The TAP felt that this was a very complex populations and that complications inherent from esophageal hemorrhage may be very much more stratified for risk for death from other causes that may not be attributable and may be attributable to disease, particularly to cirrhosis and complications from cirrhosis.

So the overall feeling from the TAP was that this was, perhaps, too diffused to really validate this as a measure.

CO-CHAIR DUBOW: John, are you still on the phone?

DR. BOTT: Yes, I'm on the phone.

CO-CHAIR DUBOW: And Patrick too?

Does either of you want to respond to the TAP's observations?

DR. BOTT: Well, if I can first backup a little bit. I don't the degree of which this would be significant or not. But in the TAP's deliberations something occurred I guess extracting our measure submission form it providing it to the TAP and there was a lot of discussion about the denominator not being thoroughly defined in the submission form that the TAP had.

It wasn't on the online form, and for some reason again, it was during Committee--

MEMBER JOHNSON: It was recirculated then after the call, so that was complete.

DR. BOTT: Okay. But I was just

referencing it because the Steering Committee in the packet they estimate did not have that. I don't know, Heidi brought that and was able to distribute it.

One other just logistical about this, it was a wrong phone number to call in today, which I called NPS and got the right number. So I'm not saying Pfizer tried to call in, but if there are some people you expected on the call today, that could be due to that.

Clinical, as far as a clinical response, I differ to Patrick for the comments made from the petition representing the TAP.

CO-CHAIR FLEISHER: Patrick?

DR. RAMANO: Yes. I will say that this is a measure has really just been revised because of feedback from users and stakeholders. That the original definition of the gastrointestinal hemorrhage mortality measure, which was never an NQF endorsed measure, the denominator definition was too

broad in that it captured all types of gastrointestinal hemorrhage. And so the feedback that we received was to narrow the denominator to patients who were admitted related to esophageal hemorrhage and variceal hemorrhage because that's a subset of patients for whom there are more clinically defined interventions.

But I will say that the measure has not gone through full testing in the sense of validation with chart review and so forth as a result of the fact that these changes have been made recently.

With respect to the other points in the memo, the only thing that I would just slightly correct is that the logic does not involve CPT codes. So it is strictly based on ICD-9 CM diagnosis codes.

MEMBER JOHNSON: The TAP felt that this is an inordinately strong end point that ends to be looked it, but it just by the present measure this is captured -- HRQ

captures an all VI hemorrhage measure already. That there was too complexity in this space with a claims base measure that the outcome of death is really within a specific hospitalization, but the complexity of the patient population made it somewhat difficult to really be accurate that this is related to the GI hemorrhage and in particular cirrhosis and alcohol related death is multicomplex variables that could contribute to this.

So that, and the lack of a validation testing really made it too much of an issue for the TAP to really endorse the measure.

CO-CHAIR DUBOW: Any other comments?

MEMBER DELLINGER: Is there any risk adjustment in this?

MEMBER JOHNSON: There is, but within specifics of other multiple. Because it's a claims based extraction, it makes it impossible to really be -- we felt until you

have validation testing to be an accurate assessment. We didn't want to speculate on how accurate the assessment would be.

MEMBER DELLINGER: So do they, in instance, risk adjust between alcoholic cirrhosis and viral cirrhosis?

MEMBER JOHNSON: No.

MEMBER NEWCOMER: And clarify for me is there a difference in the outcomes and the natural history of those sets of patients by the time they make esophageal varices --

MEMBER JOHNSON: Absolutely. Because the comorbidities associations with alcohol can be a lot more complex. Clearly you can get pulmonary disease and cardiac disease both from cirrhosis. But in an alcoholic you have multiple other variables that play into end- organ damage. So the answer is there's just no question that alcohol related diseases can be a lot more complex.

MEMBER NEWCOMER: So there's

evidence for that or --

MEMBER JOHNSON: Yes, there's evidence for that.

MEMBER NEWCOMER: Okay.

CO-CHAIR FLEISHER: And, David, the TAP brought up the issue of withdrawal of support?

MEMBER JOHNSON: As far as end-of-life decisions?

CO-CHAIR FLEISHER: Right.

MEMBER JOHNSON: We actually didn't discuss it specifically a withdrawal of support conclusion. But, again, as a claims-based measure you wouldn't be able to capture that decision in part of this. It's a great point, though.

CO-CHAIR FLEISHER: So the risk adjustment wouldn't capture the fact that there may be some decisions with regard to that this patient's probability of dying independent of this event, this may be the way that the patient actually chooses to withdraw

support?

MEMBER JOHNSON: Yes. As a claims-based measure there's just no way to harmonize that decision into an extraction.

MEMBER YAWN: I don't remember what this one does about patients referred. Is this only for the primary hospital that admitted this person or is it also for referral?

MEMBER JOHNSON: This was another element of potential stratification bias against complex patients being shifted to a center that is really tertiary referral center because it's too complicated a patient. So that was an element raised as far as some of the extractions as well, that there may be an inherent downside for just referral by it's--

MEMBER YAWN: So that it did not account for that referral?

MEMBER JOHNSON: Did not.

MEMBER YAWN: Thank you.

MEMBER HOPKINS: I asked whether

transfer are included or not included in the measure.

DR. RAMANO: Yes, so transfers are included in the measure, that's correct. They're included in the denominator.

They're also included as a factor in the risk adjustment. So the odds ratio associated with those transfers in is 1.64 indicating that we account for basically a 64 percent higher risk of death for those patients who are transferred in from other centers.

I should also just clarify that the risk adjustment does include, well it's based on the APR DRG system and so it does include specific factors for alcoholic liver disease including more severe alcoholic liver disease as well as less severe disease. This is, of course, captured with ICD-9 CM codes. And so there could be room for argument about whether those codes would accurately capture the patients who actually have alcoholic liver

disease.

MEMBER JOHNSON: Patrick, and I guess the other question is how those numbers came be of the risk adjustment? Where they were validated as far as previous data and maybe you can expand on it, and if there is any data?

DR. RAMANO: Right. Well, this the situation for a patient who is admitted with esophageal varices would be typically that the coders are required to identify the underlying cause of the varices. So they would be expected to code whether the patient had underlying liver disease of course is the most common cause of varices. But we have no separate validation regarding the accuracy of the assignment, whether the coder assigns alcoholic liver disease versus viral liver disease in that field, so to speak.

MEMBER JOHNSON: And more specific, I guess to get to Barbara's comment, was really the transfer validation of that

risk adjustment of 1.6. Is that where that number comes from? It may be right. I don't know the science behind, you know at least in our discussions there wasn't -- that may be correct but it, again, hadn't been validated as far as an accurate prediction of a transferred mortality related to esophageal hemorrhage.

CO-CHAIR DUBOW: So that raises the question for me to the staff about the time limit endorsement and the complexity of this measure with respect to how we would handle a time limited endorsement given what has to be validated. How do we do that? Does it fall within our purview to do that?

MS. BURSTIN: Yes. You know this project began before the new Board directive came down to narrow the scope of time limited measures. So I think if you think it's an important measure.

The other thing is AHRQ has a track record of testing the measures and

bringing them back. So I don't think there's a lot of concerns about the timeliness of the testing of the measure either. I think it's really for you to determine. I think it's an important enough measure to add to the portfolio that you would be willing to take it in while its tested.

CO-CHAIR DUBOW: Alternative to ask AHRQ to bring it back when they have more data as opposed to doing it that way.

MEMBER JOHNSON: Can I say, this is an incredibly important measure to capture, but the science behind it right now is just to me and to the TAP was too premature to endorse this and there's just too many stratification biases that they're inherent to the measure as it stands. No question that it's important.

CO-CHAIR DUBOW: I think the importance is quite clear. I mean, I'm concerned about an endorsement for a measure that really does need to be flushed out with better data to support it. And I have doubt

that AHRQ will do that. And the issue is whether it can find a home as soon as the data are available and ready for us to consider it again.

MEMBER JOHNSON: Joyce, one of the places we thought it might find a home at present if you look at ICU mortality and that this might not stand up to a best in class if you looked at an outcome of an ICU mortality kind of a crosswalk, as David was talking before on other measures that may capture a short term consequence in a more synthesized and harmonized way.

CO-CHAIR DUBOW: You said it would not?

MEMBER JOHNSON: No, it would. It would potentially if you looked at like an ICU outcome. As far as mortality in an ICU, this would come into at least some coverage in the short term, albeit I think it gets more granular if you specifically assign it to GI hemorraghes as a long term measure.

DR. DAVIES: This is Cheryl Davies from the development team.

And I apologize because I had to step off for just a minute there and I think I missed.

We have run some additional data analyses. So if there's specific data that you're interested in. Specifically we looked at information involving more tabulates by transfer status. I'm happy to see if we've actually run that data already to inform the discussion today.

CO-CHAIR DUBOW: So do you have the data that David discussed from the TAP perspective? I mean, what do you have? Show your cards.

DR. DAVIES: Show my cards? Okay.

DR. RAMANO: Cheryl?

DR. DAVIES: Yes.

DR. RAMANO: This is Patrick.

Yes, I think the question was specially related to data about validity based

on chart abstraction, which I don't think we have. We have data with respect to the performance of the risk adjustment model and the bias with respect to variables that are in the risk adjustment model as well as data on the issue of the transfers. But those are all based on analyses of secondary data, administrative data.

CO-CHAIR FLEISHER: So I would ask David one of the options we're debating up here because we're concerned that this may not be endorsed, but we haven't taken a vote yet, is that if it's deferred do you think the TAP would want to see the data, and would that change the recommendation from the TAP?

MEMBER JOHNSON: It might in the time frame that we're talking about for a month or two. I'm not sure you can get validation data. So I don't think the answer is, it's a fair measure to propose at this point. The gaps are too severe

CO-CHAIR DUBOW: So the second

question is finding a home for it in a subsequent review when the data might be more readily -- Patrick, do you have any idea when you'll have these reliability data? Is that a fair question?

Well, anyway I'm asking you.

DR. RAMANO: I'm a contractor to AHRQ. I advise AHRQ.

CO-CHAIR DUBOW: AHRQ, John, Cheryl, what do you have to say about that? Do you have any idea?

DR. DAVIES: I'm a contractor too.

CO-CHAIR DUBOW: Well put John --

DR. BOTT: Yes. We're all contractors on the call, actually. I work under contract.

I just don't know if that's in the forthcoming fiscal year to perform such analyses. I can't commit to that data either.

DR. RAMANO: I would just say that recommendations from NQF do carry some weight in AHRQ's decision making about how to invest

resources in validation efforts.

CO-CHAIR DUBOW: Barbara?

MEMBER YAWN: One of the things that I think we've heard about this measure that I haven't heard about any of the others is that this specific one is coming from feedback from users of their full GI hemorrhage measure. I think that ought to carry some weight with us thinking about is this something you'd be willing to do as a time limited, given the opportunity to get the validation that you've asked for. And if they don't get it, and it's not acceptable, it goes away.

CO-CHAIR DUBOW: It is being considered as a time limited endorsement. It doesn't meet the criteria for a full fledged unlimited endorsement. So it is a time limited endorsement.

MEMBER YAWN: Well, and I think that's very important to bring out --

CO-CHAIR DUBOW: Okay. Okay.

MEMBER YAWN: -- and think about in our discussions.

CO-CHAIR DUBOW: All right.

CO-CHAIR FLEISHER: So one of the questions I actually have for Helen is can we define what we think should be obtaining that data. As Patrick sort of suggested if NQF eventually says this is the critical data, if we do decide to endorse this time limited, can we say this is what needs to be done during that time?

CO-CHAIR DUBOW: Absolutely. Right. And from I hear it doesn't sound as though there's an easy home for it anytime soon.

So I think to Barbara's point we should pursue consideration of this measure as a time limited measure. Is it 12 months or 24 months, the new rules?

MS. BURSTIN: It's your preference.

CO-CHAIR DUBOW: We prefer 12

months. Okay. And we will communicate that to AHRQ.

David, do you want to make one more point?

MEMBER HOPKINS: I have a totally different question.

So I just want to explore the usability criteria here. And I'm trying to understand how an individual consumer patient would use this measure. Because if I get what this measure is, it's that something happened in the hospital and they handled it better or worse then some other hospital. I didn't enter with this problem, correct? So how would I know --

DR. BOTT: No, you entered with it.

MEMBER HOPKINS: Oh, I did enter with it a GI hemorrhage? I thought it was occurring in the hospital.

DR. BOTT: Well, because it's a principal diagnosis.

This is John Bott.

MEMBER HOPKINS: Okay. But it's probably emergency surgery so I wouldn't have a chance -- all right.

MS. BURSTIN: I think that it may have some -- it's just I think another of the suite of the patient's safety indicators. We've endorsed a series of a couple of composites around it. I guess the question is if the measure worked, is that something that you would -- do you consider it a safety measure?

CO-CHAIR FLEISHER: It's almost like a failure to rescue measure, I mean it's in that way in that someone comes in with a major complication and is the patient rescued or do they die.

MEMBER JOHNSON: And this should be helpful just so we understand, are there ICU measures that cover mortality and ICU performance measures that are endorsed --

DR. WINKLER: The first group that

you did in March, remember it was an ICU mortality measure

MEMBER JOHNSON: So don't we have -- you know, we're saying we need to have something to give this a home. We have an ICU mortality measure.

CO-CHAIR DUBOW: The idea of a home is that it would be subsequent home. Because that ICU measure sits in this home.

MEMBER JOHNSON: Right.

CO-CHAIR DUBOW: And it's under consideration now. So it doesn't help. They live in the same place.

MEMBER JOHNSON: No, but I'm talking about as far as patient safety and defining risk, you've got a measure that captures what we're talking about until you refine the specific granularity of this measure; that's where our TAP was that you would capture this as a best in class by some other measure right today.

MEMBER YAWN: I don't think that

you do have a full measure of it by looking at only ICU mortality. Because as somebody who is from the rural hospital world, I want to know did I send the patients fast enough and make decisions quickly enough and things like that. And that won't be captured in just an ICU mortality if they don't use transfer and all those other things.

So this is I think different than some of the other ICU mortality because it's going to look at what I did in the first hospital and what it had to do with the second, as I understand it. And I think that's an important way to look at it.

CO-CHAIR FLEISHER: But I would actually argue my biggest concern because we spend a lot of time now talking about preventable mortality in the four quadrants, as opposed to someone who ended up on hospice and then expired. And I'm very concerned about the robustness of this measure because if they chose hospice because their end stage

liver disease, that's not a good measure of quality.

MEMBER JOHNSON: How would you assign the rural hospital assessment of management when it gets transferred? Was it that you managed them too poorly before you transferred them or you held them too long, or they managed them poorly when they got there? See, that's what I'm saying is it doesn't capture when you got to a claims-based extraction of this measure.

No question this is important and all this information needs to be ascertained, but just at present point it just doesn't seem to be accurate.

MEMBER YAWN: So Patrick and I agree, it's a discussion starter.

CO-CHAIR FLEISHER: So I'm just actually curious. Is there a way to use any kind of hospice codes in this measure to pull out those patients? Because that's one way to actually change the measure.

DR. RAMANO: Yes, it's an important question. And the problem is that there are hospice codes that are available in Medicare claims data in certain claims datasets. But the hospice eligibility code is really tied to Medicare eligibility, and therefore it's not available in other administrative datasets.

There is a palliative care V code which vendors are using as the basis for exclusion or stratification. But we're very concerned about using that because palliative care can cover the waterfront in terms of a wide variety of different services. It doesn't necessarily translate to terminal or end-of-life care.

DR. BOTT: Yes. This is John Bott.

When I was on the CSAC this very question came up with CMS 30 day measures about can we through codes address folks receiving palliative care. And CMS' positions

and the documentation that CSAC had was that that palliative care code is just too unstable to consider on risk adjustment.

A couple of other thoughts is beginning the first of this year a point of origin code was introduced to identify folks coming from hospitals, and I think that just partially addresses the questions. So it's an exciting opportunity to build in the point of origin code to remove people from probably primarily mortality measures. So, you know, to count somebody who came in or who is from an active hospice care program.

And the one other thought is often times when people go from receiving active care in a hospice to now be cared for in a MLA situation, a discharge claim is generated and the person is transferred to assume that. And now that discharge phase view is ending, so they don't actually appear in a discharge hospital claim as a death. It's noted as a transfer out, and then admitted to that

hospital or admitted elsewhere into a admission home.

Just a couple of thoughts.

MEMBER JEWELL: David, can I just get some clarification? Are you making a case for not even endorsing it on a time limited basis? I'm trying to get a little clarity on your perspective there. Because I think what I'm hearing you say is that the measure is currently specified, the validity testing included, is still not strong enough to get at what we need to get it. Am I understand you property?

MEMBER JOHNSON: Yes.

MEMBER JEWELL: Okay.

MEMBER JOHNSON: Yes.

CO-CHAIR DUBOW: Are there any other questions. Is there any discussion? Helen?

MS. BURSTIN: I'm sorry. And I apologize, I missed the beginning since I was with the nursing home group.

So this current GI hemorrhage mortality is part of the endorsed composite that NQF has endorsed of mortality for selected medical conditions? So I was just checking just so I don't make a strange disconnect here.

So, I guess my question is regardless of sort of what you do with this as a stand-alone, we'll also just need to update this measure for the sake of this composite, which I believe is also intended for posting at a hospice center.

MEMBER HOPKINS: What's the composite? I'm sorry.

MS. BURSTIN: I'm sorry. It's a composite of mortality for selected medical conditions. These are the IQI composite. Correct me if I'm wrong AHRQ folks or Patrick. But it includes AMI mortality, CHF mortality, acute stroke mortality, GI hemorrhage mortality, hip fracture mortality and pneumonia mortality.

MEMBER JOHNSON: But, Helen, this is specifically esophageal hemorrhage.

MS. BURSTIN: No, I get that. That's why I was doing a little sidebar review. But I'm trying to understand is this measure essentially to replace what's in this composite then, Patrick or John, do you know?

DR. RAMANO: It is true that the two measures that are currently in the NQF endorsed composite that off not been separately endorsed, are the two measures under consideration today. But of course, you know, NQF is still free to make its own decision about these as stand-alone measures.

The GI hemorrhage mortality measure is undergoing revision. And so we submitted the definition which is the anticipated future definition and not actually the current definition that's included in the NQF endorsed composite.

So we apologize for that confusion. It's a versioning issue.

CO-CHAIR DUBOW: Okay. But then the measure in the composite is not what we are now considering?

DR. RAMANO: Technically, no.

CO-CHAIR FLEISHER: But it will be.

CO-CHAIR DUBOW: Well, it will be. But this is not -- this is the updated measure that they want to fold into the composite?

DR. RAMANO: Right. Depending on the NQF process for annual updating, for example, we would have to present the changes to the NQF endorsed composite --

CO-CHAIR DUBOW: Right.

DR. RAMANO: -- to the NQF. And one of those changes would be that the GI hemorrhage mortality component of the composite would be redefined in this way.

CO-CHAIR DUBOW: And when is that composite going to be maintained?

MS. BURSTIN: It was just endorsed.

CO-CHAIR DUBOW: Yes, right. But do we have a calendar for -- I'm only looking for a home again.

DR. RAMANO: John knows the calendar.

CO-CHAIR DUBOW: No, no, this is an NQF question.

MS. BURSTIN: This wouldn't link for you as a measure change. You'd have to get review --

CO-CHAIR DUBOW: Right.

MS. BOSSLEY: Right. It would go through an ad hoc review.

CO-CHAIR DUBOW: Anyway, so --

MS. BURSTIN: You know, the question would be either way we're going to have to do this as an ad hoc review because it's part of an existing composite regardless. So we're going to have to get on this sooner rather than later because I believe it's intended -- I'm just pulling up the list of measures intended for Hospital Compares. If

it's included in the Hospital Compare in its old iteration, then it's pretty important that this group look at it in its new iteration and feel comfortable with it.

MEMBER GERBIG: Yes. Those preview reports were posted. I just looked at that.

MS. BURSTIN: Yes.

MEMBER GERBIG: Just what? About a month ago. And they're due to be posted on Hospital Compare sometime during the fourth quarter of this year. Yes.

MS. BURSTIN: So I'm just saying the timing of this would suggest that we should do this sooner rather than later. So I guess it might just be a question back to AHRQ of who --

CO-CHAIR DUBOW: If it's a little bit later, would you have had time in the later to answer some of the issues that we are posing now so that when it comes back for that composite review, it would be more complete

with respect to the data? Do you understand? You do. I know you understand what I'm asking.

DR. RAMANO: Yes. I mean, obviously, I can't speak to -- I think it's unlikely that we would have information to address the validity issues that the TAP has raised within a few months. So there you have some issue of reconciling the previous endorsement of the overall composite with the fact that we are moving to a new version of this component to the composite based on more recent research as well as input from the users and stakeholders.

CO-CHAIR DUBOW: I don't understand having a time limited measure folded into the composite. I mean, I think this is a question for the staff to tell us what to do, frankly.

MS. BURSTIN: Yes. I actually think this is a discussion we need to have offline with AHRQ and figure out what our options really are.

I mean, literally the composite is intended, not this individual measure. I just looked it up. This individual measure is not intended for posting on Hospital Compare. But this particular mortality for the selected medical conditions is slated to be on Hospital Compare in December 2010. That's pretty soon.

So I guess as long as we have this brain trust here, I'd like to see how much of this we actually could get done and get the measure looked at.

It's also not clear to me what's going to be posted in December of 2010; is it the old one or the new one?

So I just think that there's enough uncertainty that possibly we could just take this offline and bring it back to the group.

DR. BOTT: Well, this is John Bott.

What is being calculated currently to be tested in Hospital Compare in December

of this year is the version 4.1 version of all these measures contained in the composite which is currently out now.

MS. BOSSLEY: The old one or the new one?

DR. BOTT: I'm sure what you mean by "old one" or "new one." It's the version that's presently out that users had access to run in the two tier measures working on right now.

I think that the version that you have in your hands today is a potential future version.

CO-CHAIR DUBOW: I think that regardless of the outcome of any decision we make today, when this goes to public comment this has to be very clear to the public because they need to know what they're voting on. And it's hard to imagine that the timing issue is not going to have an impact on some of the comments. That's my personal observation.

So, what's staff's druthers? That we vote on this now? That you have a conversation offline with AHRQ?

We have had a conversation, so that if we voted on this, we could vote on this on email. Because we have had the discussion and it's now just a matter of reaching a decision.

How does that grab you?

MS. BURSTIN: I just think it would be better if we talked to AHRQ directly, have an answer that all the contractors feel comfortable with that we can share with you and then make the decision.

CO-CHAIR DUBOW: Okay. So we will just defer consideration of this, unless there's any objection to the contrary. And we will hear from staff shortly.

MEMBER JOHNSON: Do you think maybe we would resend it to the TAP first so we sensitize it before it's presented back to the Steering Committee?

MS. BURSTIN: That would be great.

CO-CHAIR DUBOW: That's a great idea.

MEMBER ROSEN: Can we be clear what we're asking from AHRQ in terms of further testing? I hear they're changing the denominator. I mean, this will come up next time. We would want the empirical testing --

CO-CHAIR DUBOW: On reliability.

MEMBER ROSEN: -- of the -- yes. Reliability of the new measure. And in terms of validity. And we're looking at comparing the administrative data with medical record review, is that correct? And are there any standards for that? I mean, are we looking at 100 records, 200 records? I mean, do we have any sense of what we're asking?

I don't know if there's precedent on that.

MEMBER JOHNSON: I think that there's got to be a pro forma for validating testing that they use standardly, I would say,

but other standard means --

MEMBER AMARASINGHAM: Will the resubmission or the return of this measure include the DNR care aspect?

CO-CHAIR DUBOW: We could ask them.

MEMBER JOHNSON: I'm not sure you can get a DNR in a claims-based extraction.

CO-CHAIR DUBOW: Well John mentioned that new code.

DR. RAMANO: Yes. That was for patients who are actually --

CO-CHAIR DUBOW: In hospice?

DR. RAMANO: previously in a hospice.

CO-CHAIR DUBOW: Yes.

DR. RAMANO: And admitted from type of hospice program.

MEMBER AMARASINGHAM: Yes.

CO-CHAIR DUBOW: Right.

DR. RAMANO: So it doesn't fully address Dr. Fleisher's concern that there is

some patients that go into a terminal care program during a hospital say when it's that the variceal hemorrhage is a manifestation of terminal liver disease.

CO-CHAIR DUBOW: And as I understand that issue, the concern is that we want to avoid needlessly aggressive treatment for terminal patients.

CO-CHAIR FLEISHER: But the question is whether your risk model captures that sufficiently. You said 66 percent increase risk. I mean, that gets to the transfer of risk adjustment and where did that number come from based on your data analyses from previous data of transferring comorbidities.

DR. RAMANO: Well, it's based on the admission source variable, which can be validated. But it's really two separate issues. So the issue of patients who are not admitted from another hospital but they're simply recognized to be terminal care during

a particular hospitalization for GI hemorrhage I think is a more difficult issue that we wouldn't be able to effectively address.

MEMBER JOHNSON: But again, the odds ratio that you designed at 1.6 for a risk adjustment for a transfer. So what we were struggling with was just dumping patients and referral bias of being the super sick tertiary referral center.

CO-CHAIR DUBOW: I think that we should continue the conversation offline in terms of exactly what questions we have. I think you have a general idea. But we can be more precise in conversations with staff and with you, David. And we can just expect to see this come back to us by way of email so that we can vote.

Okay. Can we move on to the two bariatric surgery complication measures?

Is Ingenix back on the phone or still on the phone?

DR. SCHWEBKE: Yes. This is

Schwebke. I'm still here.

CO-CHAIR DUBOW: Hi. Okay.

DR. WINKLER: The next two measures are virtually identical with the exception of the time frame. 2-008 is bariatric surgery and complications during the hospitalization or within 180 days of discharge. The second measure, 2-012 is bariatric surgery complications during the hospitalization or within 30 days of measure. So, essentially it is identical except for the time frame.

Again, this was discussed by the GI TAP.

MEMBER JOHNSON: So important to measure consensus of the TAP. The 180 days we felt was really the real kind of conundrum because it was such a broad net to cast. Recognizably, too, all the data that were presented are non-Medicare patients. So we have a focus of where the data analysis has come from.

The complication rates, no question. Important to capture for any surgical intervention.

But the 180 days, the weakness of the time frame was really troublesome for the TAP because there are just so many comorbidities and complications that can occur just in the at-risk population and we didn't have any balance for that against the norm of risk complication against that population, which are typically comorbid metabolic syndrome type patients.

And then how that was captured was still another question. Because they're identified by the claims code, so the definition and standardization of those diagnoses wasn't really as clear.

Management among different populations, too, and different systems would be an issue because patients may come in on one system and be captured in another, in particular if it's a referral system. And the

accuracy of attributable risk adjustment for that to the system that really created the problem is still the question.

So the 180 day rule was very much of a trouble for us. The 30 day rule we felt more accurately within the same context of what we do with 30 day risk adjustments for other things that we've considered here and already endorsed.

There's some issues that's still in the comorbidities and complications that were troublesome, and in particular as gastroenterologists they didn't include GI bleed and the other one was hernias, which is a very common complication postoperatively. In the interpretable complications we would say that is a significant complication that requires frequently another intervention. Both of those were at least lacking from the definitions of attributable complications.

CO-CHAIR DUBOW: I just wonder whether we want to hear a response from the

developer before we go to you, Patch.

Kay?

DR. SCHWEBKE: Yes. I am here.

And would you like me to address this as the 180 day measure or you want me to address this more globally?

CO-CHAIR DUBOW: Yes, both.

DR. SCHWEBKE: Okay. Okay. Just a little bit of history. Initially we had built in, like this measure has been used for a couple of years now as the 30 day measure. And surely the comment that came forth from the technical advisory group about the 180 measures is appreciated.

The reason we had extended it to 180 days was because of some research that came out from Encinosa, et al. that had basically demonstrated that there may be different patterns of complications in shorter time periods versus longer time periods. And of course, the whole goal was to identify these folks for possible preventative

interventions as well as ability to offer disease management services. And in light of that article we realized that there might be value from our perspective of having a 180 day measure. So we wanted to bring both measures forward for you to consider. But certainly appreciate the limitations that have been articulated about the 180 measure.

As far as additional complications, we did look at the Encinosa article to expand our original complication list. We actually did not include the hernia and GI bleeds because based on that article those complications were relatively lower-prevalence, although we certainly had the ability and have the codes that actually were used in that study to add those complications if desired.

Also, we were really kind of focused on complications where there might be opportunities to prevent these complications. For example, DVTs and the known data about how

to use prophylactic measures to prevent the deep venous thrombosis.

So hopefully that addresses the 180 day measure, but also might capture some of the things people might be thinking about the 30 measure also.

MEMBER JOHNSON: Recognizably as gastroenterologists GI bleed is not an infrequent diagnosis in post-bariatric patients.

In hernias it may be limited because of laparoscopic surgery, so they may be less than in typical abdominal surgeries. But still, a frequent complication.

The other thing is, and maybe you can update us, but the validation testing on the 180 days extraction was still pending at the time of the TAP.

DR. SCHWEBKE: The 180 day complication was 19.1 percent.

MEMBER JOHNSON: The reliability testing of your 180 day extraction?

DR. SCHWEBKE: Well reliabilities remain, again looking at a gold standard, like a chart review.

MEMBER JOHNSON: You told us at the time, I think there's a 12 million extraction analysis that was pending at the time of the TAP. Maybe you could just give us an update?

DR. SCHWEBKE: Yes, I'd be happy to. That is still pending. We're going to have our new updated benchmark projection. We'll end being closer to 15 to 18 million database, and that should be available sometime this summer, hopefully end of July.

MEMBER DELLINGER: Just a comment. I would think the 180 days would be very important if you could accurately capture all the information about the patients. And I have a strong skepticism that you could possibly get accurate capture of 180 days except for Medicare patients. And if you made this a Medicare patient measure, then you

walleyed in fact have a chance for accurate 180 day capture because you would have all the claims data available.

And while that's variable around the country, I know in our medical center half of our bariatric surgery is Medicare. So it's certainly a very significant patient population.

DR. SCHWEBKE: Yes. As part of the inclusion criteria we do require that people have active medical enrollment throughout the entire period. So I'm not worried about our ability to capture as individuals. If those individuals don't have the amount of enrollment eligibility that we need, then they actually are eliminated up front from the measure.

And also I just want to be clear that although the testing database that we use is a commercial database that is on these individuals younger than 65, I just want people to be aware that this certainly is a

measure that we believe could be used in a Medicare population 65 and older.

MEMBER DELLINGER: Well, almost all the bariatric Medicare patients are under the age of 65 anyway.

DR. SCHWEBKE: Yes, I would agree with that.

MEMBER DELLINGER: But another question I have is whether there is risk adjustment for band versus bypass and laparoscopic versus open? Because if there isn't, I think the measure is completely unacceptable. The risk of a band procedure is literally one-tenth the risk for a bypass procedure, even when they're both done laparoscopically. And there's no way I could consider this if there's not risk adjustment.

DR. SCHWEBKE: That was an issue that was actually addressed in the Encinosa study, which was actually published in May of 2009.

And in this study we were seeing

trends and the differences of complications for the different types of procedures that were being used on bariatric surgery. But it still wasn't entirely clear from their research that there could be a definitive statement said at this point about which was the best procedure.

And I think one of the points in their article was that it we would need to compute to understand complication data because it really is missing from the national arena despite the fact that bariatric surgery is really significantly increasing as a procedure. And so the ability to capture complications and then to look at things like the type of procedures that was done, I think will actually contribute to our knowledge and we can stay with clearly identifying the best approaches.

MEMBER DELLINGER: That's absolutely right, but the point is the procedures are radically different.

The band is much less dangerous and much less effective. And unless you report them separately, your data is expletive deleted.

DR. SCHWEBKE: And my only comment is that I say that generally the literature is trying to define what you just stated.

MEMBER JOHNSON: The other question that the TAP wrestled with those, your definition of background risk in a high risk population with comorbidities for assigning what you call as a complication, how did you attribute those?

DR. SCHWEBKE: How did we attribute those? This measure is does not have attribution relating to the measure itself. What we do with our measures is we develop the methodology for identifying certain aspects of care and then we provide actually several output files that identify different ways that users could attribute the measures. For example, we can identify who

the surgeon was that performed the procedure, who had the greatest number of contacts with the patients. We basically provide those options to our users because our users have different needs. And then the user can select their own attribution methodology.

So that itself is not built into the measure so that the customers have the flexibility to do that how they're planning to use this measure.

CO-CHAIR FLEISHER: I have a question slightly different than Patch but along the same lines.

I mean, bariatric surgery at our different centers as well as the bariatric center in the suburbs who do 250 pound patients versus 600 pound patients. And that's very different. And the odds of having complications are hugely different.

So you can forget about the type of surgery, but without weight-based risk adjustment how do you compare the place that

advertises on the Jersey Turnpike to the major medical centers that are taking care of the 600 pound patients? Have you addressed that at all since there's no risk adjustment?

DR. SCHWEBKE: Well, we certainly about this as being an elective procedure. And as an elective procedure there is going to be some inherent risk adjustment that's going to take place.

We also appreciate that data is really limited on complications that are taking place which also means that there is data limited on selection of patients that might reduce complications.

So this is really a first national effort to capture some of this information so we can start defining some of the issues that you just raised.

CO-CHAIR FLEISHER: So I also thought the American College of Surgeons has a registry. Because I mean bariatric surgery done in the suburbs that's a 24 hour stay or

even outpatient and monitoring the heavy patients, and you have very different populations. So I'm wondering do you know as far as ACS how does this compare to the ACS registry that's being developed?

DR. SCHWEBKE: Yes. I can't comment on that because I haven't seen that information published in any peer review journal. If I did have access to that information, you know I think we'd all be very interested in that.

CO-CHAIR DUBOW: Pat?

MEMBER HAUGEN: Yes. Just comments relative to the 180 day question that we've discussed. And I can't comment on the rest of the things. But I think from a patient perspective I think 180 days is important. And especially with the advent of direct-to-consumer advertising for this.

And as we know, these patients come in with they are a whole series of issues and complications coming in the door. So if

there is a complication within 180 days, I think it needs to be reported against the intervention. Now all the other specifics need to be taken care of. You can't say well this one was more serious than the other, maybe the weight and type of thing. But I think from a patient perspective 30 days is not adequate. 180 days is. And I think anything that happens within that window.

I mean, if you look at from a cancer patient, you know an AML patient that goes in for a transplant are monitored and looked at as a total patient for at least 180 days to make certain they survive. And I think this patient population is a little different.

CO-CHAIR DUBOW: I think the meaningfulness of the longer window is clearly obvious for patients.

Barbara?

MEMBER YAWN: And I think we might be mixing some terms with risk adjustment and

perhaps stratification.

I do not want to risk adjust. I want to say okay, patients that are three times their ideal body weight versus two times, perhaps, verses something.

So I don't think any of you really mean risk adjustment. And I have no problem if they report that and we can look at that. And if they report what kind of procedure and we can look at that. But I want to know the whole thing because you chose to do that 600 pound patient. I believe you are there and responsible for whatever happens with that person.

And I know you're not trying to dodge that. But we keep getting into all these funny things.

CO-CHAIR FLEISHER: Stratification would be ideal.

CO-CHAIR DUBOW: But can you get those data elements from claims? Can you get weight from claims?

MS. BURSTIN: Just one additional question. I mean, what if the measure could at least be stratified as a starting point? And again, there are no measures in this area and it's a huge growth area. If you could at least stratify the codes by a laparoscopic procedure versus surgical procedure, would that be a reasonable points or are there still additional --

MEMBER JOHNSON: No. They're virtually all start intention is laparoscopic, and there's just no way to stratify data.

MEMBER DELLINGER: That's actually not true. There are plenty started open if you sit in a referral center where they send the cases that can't be done laparoscopically.

CO-CHAIR DUBOW: So it sounds as though we're entertaining a possible condition here, or at least a question to ask the developer whether a couple of these variables can be reported in a stratified way. It sounds as though one of the important ones

that we mentioned around weight cannot be, though, because claims data don't have weight reported in them. But the nature of the procedure certainly is available.

DR. SCHWEBKE: Actually, all claims are identified differently in categories. I think the question would be whether or not those are reported. And it might be that who are doing bariatric surgery because some of the requirements that you need follow to validate the fact, that this is an actual an individual who meets certain requirements. So, you know, we could certainly look to see the frequency of submission of these calls in our bariatric surgery population.

And then as far as procedures, my understanding is that granularity for the type of procedure is there. That if there were kind of groups of procedures that we wanted to identify for the purpose of stratification, that's certainly something we could explore.

MEMBER YAWN: The other thing that a lot of, and I think most -- I can't talk about all the suburban ones, but most of them have bariatric registries now and you can get weight from the bariatric registry.

And I understand. I'm just saying that this is something we may make a comment back to the developer that in addition to adding as a condition I'm going to say add the ability to stratify by surgical surgery, we comment back to them we think it walleyed be very important to be able to stratify by weight category in some way. And we would suggest that they figure out how to do that as they update their measure.

DR. SCHWEBKE: And I think this is some great recommendations.

CO-CHAIR DUBOW: The one other question that I would pose to the Committee is whether we think that the testing is adequate for a non time limited endorsement. I'm seeing a lot of -- I'm hearing a lot of nos.

So when we consider this measure it sounds like it's the Committee's pleasure to consider this only for time limited endorsement and with conditions attached would include stratifying by weight and by procedure.

Is there anything else?

MEMBER HOPKINS: I think we said by procedure for sure. And they would try to come up with a way to do it by weight, but they may not be able to.

MEMBER YAWN: Yes.

CO-CHAIR DUBOW: To qualify the condition, recognizing that --

MEMBER HOPKINS: You know, BMI might be easier to capture this way. That might work

MEMBER JUSTER: You can't get it from claims data.

MEMBER HOPKINS: Even for these surgical patients?

MEMBER JUSTER: No.

MEMBER JOHNSON: See, Joyce, I just have to take a gut check from the TAP. The point is, is that NQF has very strict and high quality assessment processes to evaluate measures. So to respond to we need a measure in this space and put a measure that we think potentially has so many inaccuracies and stratification biases undermines, I think, the credibility of the NQF process.

And so I'm much more comfortable in saying let's capture it appropriately and correctly under surgical measures or other parallel processes rather than to say we need something to have it on a checklist for bariatric surgery.

CO-CHAIR DUBOW: So I think that's something to consider as we vote. I mean, you know I think that's an important consideration and we have the TAP's review. But I think in terms of considering it, we have that.

Iver?

MEMBER JUSTER: Under what

circumstances would we put forward a measure that required using -- I mean, there are codes for BMI ranges. I don't know if they're fine enough for this. But let's say they were. So the measure can only be used if you include the codes, and therefore we are encouraging using the codes: Under what circumstances would we put forward a measure like that?

CO-CHAIR FLEISHER: One of the problems I have is actually ACS has the registry. And Barbara is correct. So if there's actually a better way to do this that has not been submitted, it would unfortunate to endorse a less than best in class.

MEMBER YAWN: This is what we have.

CO-CHAIR FLEISHER: We're going to ask you to vote on this.

MEMBER NEWCOMER: There also is no guarantee that the ACS would ever release that data.

CO-CHAIR DUBOW: This is a measure

that we have before us. It would be nice to have another measure with a different data source. That's not what we have right now.

MS. BURSTIN: And just to respond to Dave. I'm not saying that we want to bring this in if it's low quality. I think the issue would be if there's additional information you would gain by, in fact, seeing what they could come up with the stratified measure, it would go back to you again to take a look at based on the conditions. It wouldn't be a slam dunk. Conditions means they have to bring it back. You take another look at it and see if it works. If it doesn't work or if they can't do it and satisfy the remaining concerns that you've listed, it won't go through. But the question is are you interested enough to at least be able to see if they stratified the measure by type of procedure, would it maybe something that you think would be a good starting point, at least to something that you could grab in the

interim since there's nothing else currently publicly reported in this space.

MEMBER JOHNSON: Stratification of the measure --

MS. BURSTIN: Type of procedure.

MEMBER JOHNSON: -- open versus laparoscopic.

MS. BURSTIN: Yes.

MEMBER JOHNSON: And I will tell you, despite Patrick's comment, it's not uniform and it reflects institutional bias on how these things are done.

We screen over a 1,000 bariatric patients a year, due 450 of the operations. And our intention, we just wrote a book on bariatric issues. It's not standard. So that would be a selection bias against an institution.

So if you took that as your intermediate assessment of BMI or other parallel risks, I think you've made a major assumption which is probably not present.

CO-CHAIR DUBOW: Amy?

MEMBER ROSEN: So I'm not sure where this puts us, but I have two concerns about the measure.

One is that I understand that it's important from a patient perspective to look at 180 days. But I think from a claims data perspective we're just having too much lead time in there to be able to control for all the many things that may be associated with complications. That when we look back at the bariatric surgery there may be just a million things that have happened to the patient that we can't control for.

So I think 180 days I'm really not comfortable with that as an outcome, per se. I'd be more comfortable with 30 days of raising claims.

So my second point is that I guess maybe I'm alone in this, but I do feel that some type of basic risk adjustment for this outcome is appropriate here. Because it's not

just the type of procedure that may affect the outcome, but it may be patient related factors that are really important.

MEMBER JOHNSON: It's highly important, yes.

MEMBER ROSEN: So I'm sort of echoing that. And I think that we could garner from the literature some patient related factors that would be appropriate to use from claims data.

So I would make those two statements.

CO-CHAIR DUBOW: I heard the developer say in his introduction that they didn't comfortable with easy ways to risk adjustment administrative data. So I don't know whether that takes it off the table from their perspective or not, but that's what I heard in response.

MEMBER ROSEN: I heard it too.

CO-CHAIR DUBOW: Yes. Okay.

Patch, and then we need to wrap

this one up.

MEMBER DELLINGER: I'm actually -- if we could get an adequately stratified and possibly risk adjusted measure, I would strongly support the 180 days. And while these are complicated patients to which many things can happen in 180 days maybe not related to the operation, differences would be important.

CO-CHAIR DUBOW: Yes.

MEMBER DELLINGER: You know, a stratified group from one area that has a high rate and the same stratified group from another that has a lower rate, I think that would be significant.

There are always going to be some complications that are not necessarily --

CO-CHAIR DUBOW: Okay. So am I hearing that voting on this, and we need to vote on the 30 and the 180 separately, is that right?

DR. WINKLER: Correct.

CO-CHAIR DUBOW: So are we adding I think a third condition now to go back that we do want to ask the measure developer to entertain the addition of some kind of risk adjustment ---

CO-CHAIR FLEISHER: And stratification.

CO-CHAIR DUBOW: No, no. This is the third one to see what they can do to address the patient factors that we've heard.

MEMBER DELLINGER: There are data you can get from administrative data that walleyed effect risk: Diabetes, sleep apnea, pulmonary hypertension.

CO-CHAIR DUBOW: Okay.

MEMBER DELLINGER: These are things that we see routinely in this patient population that at least should be looked at, I would think.

CO-CHAIR DUBOW: Okay. So the case heard that conversation. And so I hear stratification on the basis of procedure, risk

adjustment for patient factors and the third one was --

MEMBER JOHNSON: Weight. But BMI, actually.

CO-CHAIR DUBOW: Yes. You think that would be wrapped in? Okay.

CO-CHAIR FLEISHER: Comorbidities may be the way to actually get around the fact that you probably can't get weight. So if you actually looked at the number of comorbidities, that may --

MEMBER JOHNSON: I'm not that you can say that there's not a threshold effect for comorbidities and then beyond that you super select risk. So you have a 300 pound that's got sleep apnea, diabetes, metabolic syndrome but is that patient at 600 pounds more a risk for DVT, pulmonary complications.

CO-CHAIR DUBOW: Okay. So the developer has heard the conversation. We are going to vote first on the 180 day criteria and I think let's go.

MEMBER HOPKINS: So you're going to remind us what the conditions are that we just--

DR. WINKLER: Well, let's do the criteria first.

CO-CHAIR DUBOW: Okay.

MEMBER HOPKINS: Was it presented or what?

CO-CHAIR DUBOW: Criteria are risk adjustment for patient factors.

MEMBER AMARASINGHAM: This is a significant revision to the measure.

CO-CHAIR DUBOW: Right. Okay. So should we vote the measure as it is and then consider some recommendations for the developer? Okay.

DR. WINKLER: So for a measure of complications after bariatric surgery for 180 days. The report is to measure and report. How many yes? Nineteen. And Lee you're recusing

MEMBER NEWCOMER: I'm abstaining.

Yes.

DR. WINKLER: Yes. Okay. Scientific acceptability of this measure as specified as submitted to you. All right. So completely meets the criteria. How many?

Partially meets the criteria? Three.

Minimally meets the criteria? Fourteen.

Not at all? Oh, that's right Brian's gone. Okay.

MS. BOSSLEY: But we have 19 on the list and now we have only 18.

DR. WINKLER: Lee's not voting. All right.

Let's try usability. Completely meets the criteria? No.

Partially? Fifteen.

Minimally? Three. Okay.

And not at all? Okay. That's the 18. Okay. That's where we're at.

Feasibility. Completely? One.

Partially? Fifteen.

Minimally? Three.

And not at all, is there anybody? Okay.

All right. Did you want to do the--

CO-CHAIR DUBOW: Oh, you want to vote?

DR. WINKLER: That's what I'm asking you.

CO-CHAIR DUBOW: Yes. Is there any public comment before we go for a vote. okay.

All those who are in favor of recommending for endorsement the 180 day bariatric surgery measure as-is. Right. As-is. All in those in favor?

MEMBER KEALEY: Are we doing time limited?

CO-CHAIR DUBOW: This is just as-is. No, this is as-is. It came as a non time limited. So this is straight. We could do

that separately.

All those in favor of the 180 day measure as it was specified and as it's presented?

MEMBER KEALEY: Sorry. Just a little clarity. So I'm in favor of a time limited. What do I vote now? What do I do now.

CO-CHAIR DUBOW: Do you want to separate this vote as a time limited one or not?

MEMBER YAWN: We voted on 09, we voted yes for the measure and then said for conditions.

CO-CHAIR DUBOW: Yes. That's exactly right.

MEMBER YAWN: And so I was now saying yes with no conditions is the vote at the moment.

CO-CHAIR DUBOW: Yes.

MEMBER YAWN: And then you're going to say yes with conditions if it's voted

down.

CO-CHAIR DUBOW: Yes, that's right. This is the measure as it's specified and it is not a time limited measure as it is specified.

So all those in favor of this measure as it appears in our materials? And all those who are opposed?

DR. WINKLER: I assume everybody else? Is there anybody abstaining.

MEMBER YAWN: Lee.

DR. WINKLER: Well Lee is recusing, right.

CO-CHAIR DUBOW: Okay. We have to the conditions.

DR. WINKLER: How quickly you forget.

CO-CHAIR DUBOW: Okay. SO do we have a vote on the conditions?

MS. BURSTIN: I think you need to vote just that you want to see a series of recommendations to bring the measure back.

And again, this is a pretty heavy lift condition. So I don't know if the measure developer can do it, but at least the question is do you want to offer it. And since it is a significance difference, definitely that include, that measure would then truly have to be time limited and be tested.

CO-CHAIR DUBOW: So you'll get if we see a response from the developer in a way that modifies the measure in accordance with the discussion, then it would be a time limited measure and then you'll have the opportunity to vote that way.

So I think staff has a pretty good handle on what it is, but you know we're talking about stratification under certain circumstances, risk adjustment for demographic factors. We're talking about trying to get weight in some way.

MEMBER JOHNSON: Type of procedure.

CO-CHAIR DUBOW: Type of

procedure. That's what I meant by stratification.

Is there anything else that I --

MEMBER HOPKINS: Actually, I'm worried we're being overly prescriptive here.

CO-CHAIR DUBOW: But we're not being prescriptive.

MEMBER HOPKINS: We want the developer to address risk.

CO-CHAIR DUBOW: Right.

MEMBER HOPKINS: Yes, he's heard all the conversation about it, it's got to there.

CO-CHAIR DUBOW: Right.

MEMBER HOPKINS: I don't want to build in right now that we're going to stratify by procedure, because I actually heard a good argument against it.

I don't want to build in that we're going to stratify on this and adjust on that. But they've got to address these issues and these factors.

CO-CHAIR DUBOW: I know the developer has heard the conversation and I know that the staff understands that. And we will see this conversation reflected back in the measure if it's possible for them to respond. So I think that's clear, David.

Okay.

MEMBER YAWN: Do we have to vote that we would want to even send it to them, or we just want to ignore it.

CO-CHAIR FLEISHER: Because then it would be a form of that would allow it to come back, right? if we affirm the vote?

CO-CHAIR DUBOW: All those in favor of making those recommendations to the measure developer?

CO-CHAIR FLEISHER: And then if they re-evaluate.

CO-CHAIR DUBOW: Well, if that happens as a matter of course.

CO-CHAIR FLEISHER: Iver, yes or no?

CO-CHAIR DUBOW: Okay. And no opposition. Okay. So let's do the 130 day -- the 30 day.

DR. WINKLER: We do need to break.

CO-CHAIR DUBOW: As soon as we finish this measure we are going to have a break. So the quicker we do this, the sooner we'll have a break.

Reva, please.

DR. WINKLER: Yes. All right. On the 30 day bariatric surgery measure importance to measure and report. How many yes? Is that everybody?

Scientific acceptably of the measure properties. Completely meets criteria? Zero.

Partially meets criteria?

PARTICIPANT: Excuse me. We can't hear.

DR. WINKLER: This is the 30 day bariatric measure, scientific acceptability of the measure properties completing meeting.

Right, with zero.

So partially now.

MEMBER JOHNSON: Do you want to just go back for a second. There was a couple of issues for the TAP just on the 30 day versus 180.

CO-CHAIR DUBOW: Yes, I apologize. That would be a good idea.

MEMBER JOHNSON: Okay. I'm sorry. There were a couple of issues. The TAP felt much more inclined with a 30 day measure which was a lot more attributable to the surgical intervention.

The reliability testing for this measure was also still pending at the time, so maybe the measure developer can address that as well. The key issues was the number of key morbid disease states attributing risk. And then the extraction based on all the factors that we've just discussed as far as patient selection, what type of intervention they had and the biases that were already pertinent and

relevant to the 180 day discussion.

CO-CHAIR DUBOW: So similar concerns except less so about the shorter period of time.

MEMBER JOHNSON: Yes. Just wanted to qualify that their reliability testing for the 30 days measure was pending at the time as well. So just maybe the measure developer could address it.

CO-CHAIR DUBOW: Kay? That's who hung up.

MEMBER YAWN: They may have gotten cut off.

MS. BOSSLEY: We're checking it.

CO-CHAIR DUBOW: Patch, do you want to say something?

MEMBER DELLINGER: Just, I mean I think this measure is equally flawed and equally important as the 180.

MEMBER HAUGEN: Yes. It's the same importance.

CO-CHAIR DUBOW: Let's continue.

DR. WINKLER: All right. We're back on scientific acceptability of the 30 day bariatric surgery measure. Completely meets criteria. Zero before any changes.

Partially meets criteria? I get nine.

Minimally? That's seven.

Not at all? None.

Is anybody abstaining, not voting.

MEMBER NEWCOMER: I'm still out.

DR. WINKLER: Right, you're still out. Brian's still out. And Amy's out. There's it. Okay. Yes.

Usability. Completely meets criteria for usability? Seeing zero.

Partially meets criteria for usability?

Minimally meets criteria? Three. Okay.

Not at all? Okay.

And now Amy's back. Okay.

Feasibility. Completely meets

criteria? One.

Partially meets criteria?

Seventeen. Okay.

Minimally? I don't think there was anybody. Okay.

So recommendation to you.

CO-CHAIR DUBOW: Okay. So we'll vote up or down and then vote on making the same conditions, okay?

All those in favor of recommending this measure for endorsement as it is presented? All those opposed?

DR. WINKLER: That's everybody.

CO-CHAIR DUBOW: All those who favor making the same relevant recommendations to the developer?

DR. WINKLER: That's everybody. Is there anybody not jumping in on this? Okay.

CO-CHAIR DUBOW: Okay. So we've earned a break, right? And we'll reconvene, I have 11:10, is that -- so we'll be back at 25 after 11:00? Okay. Thank you.

(Whereupon, the foregoing matter went off the record at 11:13 a.m. and resumed at 11:37 a.m.)

CO-CHAIR DUBOW: And the Chair of the cancer tab is Lee. So we have the imaging measures -- I mean the timeliness measures and then we have the FACIT, is that how you pronounce.

DR. SCHWEBKE: Excuse me. This is Kay Schwebke from Ingenix. Are we done with the bariatric surgery measures.

CO-CHAIR DUBOW: Oh, I apologize. Yes, we are done.

You got cut off, I think.

DR. SCHWEBKE: Well, I was when I was told there was a break. So I wasn't sure if you were coming back to it.

CO-CHAIR DUBOW: Okay. Sorry. Well, you're welcome to listen to the discussion of the cancer measures.

DR. SCHWEBKE: Okay. Thank you. Thank you so much.

CO-CHAIR DUBOW: Okay. So the first one we're going to do is 002-010 which is the imaging timeliness of diagnostic mammograms. Okay.

CO-CHAIR DUBOW: Did he say okay honey?

MS. BOSSLEY: Heidi.

CO-CHAIR DUBOW: Oh, just checking. I was going to have a talk with David.

MS. BOSSLEY: Okay. Am I red? Okay.

So this measure is imaging timeliness of care. It measures the time in business days required between the diagnostic mammogram which identifies a suspicious lesion and the day that the biopsy actually occurs.

Just in general, the TAP had a discussion primarily on importance and whether this measure really, first of all, had a demonstrated link to an outcome because they all agreed this was not really an outcome

measure. So one of the biggest concerns was there was no evidence provided that it impacted survival or mortality, nor did it address disparities in care, didn't even look a whether or not it reduced anxiety if we had the time frame shortened.

So based on that, they actually did not move beyond the importance criteria. They all agreed that it did not pass that piece.

Lee, do you have anything you wanted to add?

MEMBER NEWCOMER: No. I'd just emphasize that even anxiety we had no evidence to show whether a shorten period would alleviate anxiety, which was the principal effort behind this measure. So we stopped right there and moved on.

CO-CHAIR DUBOW: Pat?

MEMBER HAUGEN: And I was on that committee also. So just to comment I guess on this and overall, it was extremely

disappointing the quality of measures that were submitted considering the issue of cancer. And this certainly wasn't an outcome measure, and no evidence to the measure itself.

CO-CHAIR FLEISHER: Boy, that put the group on a downer.

CO-CHAIR DUBOW: Barbara?

MEMBER YAWN: I do want to say that this is a measure that lots and lots of clinics use for themselves. And I think that if there is something that could come out of the comments that would be useful to go back, I think that would be very helpful.

And we were discussing it, and it's not so much exactly how quickly its done, it's are there barriers to getting the next step that is much more important. And if we could somehow have that come out in a comment or a discussion or something, I think that would be very helpful for all the people who choose to just measure it, including our group

I realize, in a very quick and dirty way.

I'm just hoping for comments?

CO-CHAIR DUBOW: Is the measure developer on the phone?

MEMBER NEWCOMER: He was during the actual subcommittee meeting and did get that feedback. We actually had a very good discussion with the measure developer on this and the next measure with exactly that feedback.

CO-CHAIR DUBOW: Okay. Is somebody from the National Consortium Breast Centers on the phone? Okay.

So it's good, Lee, that you remember that conversation to call it to our attention.

All right. Is there any further discussion. Okay.

Should we go through the -- we should vote on the importance, right? Well, I think that's a good question whether this is out-of scope or whether it's

MEMBER HERMAN: It's nonresponsive.

CO-CHAIR DUBOW: Yes, which is out-of-scope.

So is it the pleasure of the group to consider it nonresponsive and out-of-scope rather than bringing it even it to the first point? Okay.

All those who vote that this measure is out-of-scope for this project -- everyone. Okay. So there are no nays. Okay.

Can we go to the next timeliness one, which is imaging timeliness?

MEMBER NEWCOMER: It's actually biopsy timeliness.

CO-CHAIR DUBOW: Right. Sorry.

DR. WINKLER: This is identical to the conversation that I think was identical to what we just talked about. Nothing was different I don't think, unless Lee and Pat have something to add.

MEMBER NEWCOMER: The measure

looked at the time from initial needle biopsy to definitive surgical therapy. And again studies have been examined looking at impact on outcome with this and there isn't any until you get out to the very, very long time frames. So we had the same opinion about this one that it just didn't make the importance measure and stopped at that point.

CO-CHAIR DUBOW: Pat?

MEMBER HAUGEN: Also there was a discussion that could be unintended negative consequences of this measure from a patient standpoint because there is no evidence that it impacts outcomes. And by kind of the rush to procedure, the patient does not have timing for informed decision making looking at alternatives, reconstructive surgery, second opinion, et cetera. So, I mean it's a very poor measure from a patient-centered perspective.

CO-CHAIR DUBOW: Did you all have that opportunity to discuss that with the

developer as well?

MEMBER HAUGEN: Yes, very much.

CO-CHAIR DUBOW: Was there any response to that?

MEMBER NEWCOMER: It was taken into consideration and actually I'd call it almost a mentoring session with the developers. They hadn't considered some of those and were very interested in pursuing something later. I think you'll see something again.

CO-CHAIR DUBOW: Yes.

MEMBER HAUGEN: The thing that I was concerned about, and again I'm not an expert in this, but because of the source of the measure looking at breast centers that you have to be careful that my intent is not to keep the patient within my own circle of influence. And that's what I'm measuring to versus the care the patient gets, if that makes sense.

CO-CHAIR DUBOW: Yes, it does.

MEMBER HAUGEN: So the source of the measure needs to be considered in the potential intent of the use.

CO-CHAIR DUBOW: Right. Not a patient-centered approach.

CO-CHAIR FLEISHER: So I'm not a mother, but I am a husband. And not all positive mammograms are cancer. And I was concerned in this measure in having looked through it the decision of whether or not watching waiting versus going to biopsy, and that other decision process took a while. And I would not want somebody to rush into it because we had one opinion that was watch relating.

MEMBER NEWCOMER: Actually, just on the technical end this measures the time from the initial needle biopsy. So the decision about watch relating precedes this measure.

CO-CHAIR FLEISHER: And that's the other measure.

CO-CHAIR DUBOW: Yes. Right.

MEMBER NEWCOMER: That was my thought on the other measure, right. Right.

CO-CHAIR DUBOW: Right.

MEMBER YAWN: I just don't want to give this measure developer the idea that we don't think it's good that they tried, they just didn't think of it broadly enough. I mean, they were using a poor proxy for making sure the patient wasn't having barriers, I believe. And I think that's what they were trying to do.

So, I don't want them to think we think your awful, and I know you guys didn't do that.

CO-CHAIR DUBOW: Although I think Pat's point about the fact that this is not patient centered is very important to be the point to be in our report that:

(1) We are very concerned about the dearth of cancer measures generally that came in. These, in particular, don't have a

patient-centered focus that we obviously are looking for. And I think the measure developer will hear that.

MEMBER YAWN: I think you just have to be very clear about what you mean by not patient-centered. Because I think they will believe they were being very patient-centered.

CO-CHAIR DUBOW: Well, I'm teeing up on Pat's comment.

MEMBER YAWN: Yes, but if there are any other peoples besides who were there at that meeting reading, I just would urge you to be more explicit in what could be patient-centered --

CO-CHAIR DUBOW: They will have a chance to review it.

MEMBER HAUGEN: I guess, you know some points that could be made. When I look at some of the values that are important to a patient, is the value of having adequate information, the respect for their opinion,

the process of decision making; those things were not considered at al when you look at this rush to timing. And just the lack of outcome evidence here, this is an outcomes measures, that is of concern did they think through what this was about.

CO-CHAIR DUBOW: Vanita?

MEMBER PINDOLIA: After reading this I had a suggestion that if we could try to help them to try to figure out where maybe there are gaps related to breast cancer, the mammogram and then the needle biopsy.

We have so many now that are diagnosed at such an early stage, like DCIS, and there's so much confusion because they're not really considered cancerous, so they don't get a medical oncologist assigned to them. They have their surgery, and then their discussion on radiation therapy, which most of them end up going through because of the 13 percent versus 9 percent recurrence rate, et cetera. Then you're given a one-time fill for

your tamoxifen. And then you're kind of on your own.

And so there really is a need for a patient care plan to either be passed out to the internist or assigned to an oncologist, or something to make sure the six month follow-up whether it's a MRI, is done. And then the 12 month mammogram. And then on top of that the gynecological appointment that they have to keep up because of the -- and if that could be as an illustrated example of where something similar to what they're thinking there really is a gap right now.

CO-CHAIR DUBOW: Yes. Dianne?

MEMBER JEWELL: So Lee's point a moment ago that it almost being a mentor session. You know, as I referenced yesterday the bone and joint TAP didn't receive any measures. I guess the eye group didn't either, right?

So in our conversation about why the bone and joint TAP's conversation about

some possible reasons why we didn't receive measures, this issue of really not understanding, particular because we were asking for outcomes measures. And this patient-centric and how that's truly reflected in the measure isn't something we specifically highlighted. But as you're speaking to it, I think it is a key point. I think this speaks to the larger concern about groups not truly knowing how to do this.

And so I don't want to lose that thought.

CO-CHAIR DUBOW: Any other discussion?

So are we entertaining --

MEMBER YAWN: I move that we do exactly the same motion that we both --

CO-CHAIR DUBOW: We missed it, Barbara. You didn't have your mic on.

MEMBER YAWN: Oh, I'm sorry.

I move that we consider exactly the same motion for the 30 day that we did for

the 180 day.

CO-CHAIR DUBOW: No. You're back.

MEMBER YAWN: I'm sorry. I'm sorry. The imaging -- yes, you know the needle biopsy to surgery that we did for the other --

CO-CHAIR DUBOW: Right, that it was out-of-scope.

MEMBER YAWN: Yes. That it's out-of-scope.

CO-CHAIR DUBOW: Right. That it was out-of-scope. Okay.

All those who believe that this measure is out of scope for this outcome project?

MS. BOSSLEY: Seventeen.

CO-CHAIR DUBOW: Anybody who disagrees? Okay.

MEMBER YAWN: Do we get to make recommendations to NQF also? About maybe a meeting or sponsoring other workshops. I know you do some already, but about outcome

measures that would particularly target some areas that we know are gaps like bone and joint and eye and cancer. And trying to think of how to get those people to come and talk with some of the others that have figured it out a little better.

MEMBER HAUGEN: But let ask a question. With cancer being as much money as we spend in health care on cancer and all the people that are working on cancer, why don't we have measures for cancers coming forward here? I don't understand it. And they're inadequate. This is just embarrassing.

MEMBER YAWN: There are more.

MS. BURSTIN: Yes. I'm sure Lee has something to say about this as well. But, you know, I did call some of the luminaries in outcomes research in cancer at the time we were doing this and there was a lot of discomfort about what really is an outcome for cancer. So much of the way its measured is about life span or those appropriate.

So maybe, Lee, you want to have further thoughts about that. But I was fascinated. I tried and they just went no.

MEMBER NEWCOMER: Well, the nation does have probably the best outcomes measure collection of all specialties, and that is the National Tumor Registries where we have survivals recorded in nearly three -- actually, I'm sorry. Four thousand hospitals with survivals by stage and prognostic factors breast, cancer, colon, all the major cancers. But the American College of Surgeons will not release that data.

Each hospital can release it themselves if they choose to. And there are a few institutions that do that, but very few. And so until the ACS decides to open that treasure chest, if you will, we're blind.

CO-CHAIR FLEISHER: But Medicare has their SEER Medicare.

MEMBER NEWCOMER: But SEER doesn't help anybody. It's de-identified. And you

can't get the hospital names. It's also limited to six markets. And it's the Medicare population. So a fair number of cancers fall off quickly.

CO-CHAIR DUBOW: Lee, do clinicians know how survival relates to the care that's provided?

MEMBER NEWCOMER: Well, I would answer that they do. That those folks getting -- we know oncology is very rich in studies that have shown difference in outcomes for various regiments. So we know that good standard care will produce prolonged survivals.

CO-CHAIR DUBOW: That makes it -- I'm asking whether there is indeed an opportunity to develop measure then along those lines.

MEMBER NEWCOMER: Measure 1 would be let's release the cancer registry survival data. That would be very simple. It would be simple in methodology, not politically.

MEMBER HOPKINS: I so agree with Lee on this. Is there anything NQF can do?

MS. BURSTIN: We'd be happy to have conversations with ACS. I think it's a good discussion. Bauer is in the back of the room, I don't know if you have any thoughts on this, but go for it. Bauer is from ACS.

MEMBER HAUGEN: You know, not understanding. Coming in to this from a patient that is an expert on this, I mean this is where the definition of what is proprietary data and what should be publicly available data when it's about patients, and much of that has been paid for with public funds. I mean, I think this is a big issue here. And I don't know who wrestles the bear with it. But if we can't even develop good outcome measures in a health reform context because data is being viewed as proprietary when it's about me, I mean that's a big issue.

MEMBER AMARASINGHAM: I had a quick question to ask Lee.

You know, for these measures so there's the issue of the measure definition and there's the issue of the data to get the cutpoints. Can the measure definitions at least be endorsed without having the ACS data?

MEMBER NEWCOMER: Yes, I believe that's very possible.

CO-CHAIR DUBOW: So could you elaborate on what that would mean?

MEMBER NEWCOMER: I think you could create cohorts very simply based on staging information and a few other prognostic factors for a large number of cancers. And simply set up a measure that looks at their overall survival. It should be fair.

Defining that measure was relatively simple work.

MEMBER HOPKINS: Can you think of another source of data?

MEMBER NEWCOMER: Our conflict of interest all over here. But I have now collected staging information comparable to

tumor registries on 10,000 patients which we are combining with claims data and then creating a medical record to do survival measures. But we're not ready to come in and test yet at this point.

And it's a non-randomized sample. It's volunteers who are submitting the data. So it wouldn't be ready for this group, whereas the registry is all patients and is of the rigor that would allow the kind of measures here.

CO-CHAIR FLEISHER: So, Lee, I mean we have the surgical complication issues, we have comparative effectiveness and some of those hundred are actually comparing different modalities of treatment in the top 100 IOM priorities. I'm thinking of robotics, I'm thinking of prostate cancer with, you know we're a proton therapy unit now.

Do you think that we can get anything in that domain of looking at different treatments? Even at six month, you

know, bariatrics the 180 day window, but trying to treat prostate cancer and looking at complications. Because there's a cancer that you shouldn't do treatment unless survival is long term.

MEMBER NEWCOMER: There's some very good recent work from the -- up at Boston on prostate looking at brachytherapy, IMRT and radical prostatectomy which showed basically no differences except cost between the treatments and complications.

The proton therapy folks -- well, wait a minute. I don't believe there were significant complications. Not significant. Yes. Not significant.

Proton folks, Sean Tunis, the CMPT group has tried for almost three years now to begin developing measures with them, and they simply refused to participate.

CO-CHAIR DUBOW: Linda?

MEMBER GROAH: You know, the ACS has a new Executive Director, Dr. Hoyt, and he

may be very open to working and looking at opening some data. I understand he's a basic scientist so he may have a different view on their data than what we've had responses in the past.

MEMBER McNULTY: Can I ask a question? What do they actually do with the data that they're collecting if they don't release it to the public? So is it just storing it and not doing anything, or they actually doing something with it?

MEMBER NEWCOMER: You do get your data back as a hospital and you get a blinded comparator. So you will be able to see how you do against your peers. But there's no further -- none of that data is allowed to come out to the public.

CO-CHAIR FLEISHER: But research, I mean they use it for research purposes.

CO-CHAIR DUBOW: Yes, and hopefully for quality improvement.

MEMBER NEWCOMER: I've seen

nothing that suggests there's an organized quality improvement effort or any publications that have shown quality improvement from that data yet.

MEMBER HERMAN: You know, we should probably ask the patients what they think is important. Because we can all kind of sit around the table and say this is important and this is important. But if you could get a form to find out what the patients think are important and then find a way to measure that as an outcome, and then you can do that. Because there's a lot of things that are important, just not in survivability, certainly that's important, but there's a lot of things along the way that are just as important from a quality of life standpoint.

MEMBER YAWN: And that's exactly what I was going to say, too. I think that when NPF thinks about their outcome forms, they ought to bring people in who don't say they're health care professionals who can say

we'd love you to figure out how to measure functionality, quality of life, all kinds of things. And nobody's talked about any of the mental health complications today.

CO-CHAIR DUBOW: Yes. And there is, you know, the Foundation for Informed Decision Making does have a module on breast cancer, because this is in terms of modality, there is a shared decision making component here. And that does exist already.

So there's a way to being. But I think it's hard to imagine that some of the cancer groups haven't --

MEMBER HAUGEN: But the thing that you also have to make certain, this is a very complicated topic and you need to also make sure that that consumer patient is an educated, people that understand this. So this is some of the things, at least I've seen, where many times there's patient involvement, and the involvement is I want to be satisfied. Well, we know very well you

could be satisfied with poor care based on its being delivered. So that one has to be very cautious as specific and thoughtful about how that process occurs as anything else that's done in the quality area.

MEMBER HOPKINS: So this brings up another huge gap area, since we were talking about that. And our work here which is when we had our first meeting, I think we all agreed that quality of life, functional health were really important outcomes, particularly to patients. And we've come up so short.

We've got a couple, I realize, the last couple of measures are going to address little pieces of that. But that's just one little slice. We don't have what we need for the broad population.

CO-CHAIR DUBOW: You know, I think that I'm going to use that as a good segue to get the last set of measures that we need to address. And then our concluding conversation should be about the gaps and the concerns, and

the outstanding issues that we want to identify for the report.

DR. WINKLER: There are box lunches right out that door.

CO-CHAIR DUBOW: Why don't we do that now and then we will proceed to talk about FACIT and then we will get to the last agenda item. It's noon, so we should have plenty of time. Everybody, just take five minutes, okay. We just had a break.

(Whereupon, the foregoing matter went off the record 12:01 p.m. and resumed at 12:07 p.m.)

MS. BOSSLEY: Is there anyone from FACIT on the phone, Lauren or Jennifer?

PHONE OPERATOR: This is the operator.

MS. BOSSLEY: Wait a minute. What was that?

PHONE OPERATOR: This is the operator. There's only one on the line.

MS. BOSSLEY: There is somebody on

the line?

PHONE OPERATOR: Just Ted Gibbons from the University of Washington.

MEMBER GIBBONS: I'm still here. This is Ted Gibbons.

DR. WINKLER: Ted, you get the prize.

MEMBER GIBBONS: Well, it's snowing in Seattle.

CO-CHAIR DUBOW: Well, we're just trying to reach the measure developer to see if we can have them walk us through this. Otherwise, we'll proceed.

Okay. While Heidi's finishing the email, we are going to the FACIT-G, 19. And that's because that's kind of the stem for the other -- just a second. I'll tell you the number in a minute.

DR. WINKLER: It's OT2-019-09. So it starts on page, I think, 165.

MS. BOSSLEY: They should be bookmarked, but they sometimes disappear.

CO-CHAIR DUBOW: Functional assessment of cancer therapy, general version.

MS. BOSSLEY: So just in general what you have before you are four surveys, questionnaires. We're talking about the first one, which is the general one that is the functional assessment of cancer therapy.

These are a collection of quality of life questionnaires targeted at the management of chronic illness.

There are multiples in existence. I actually have lost track of many they have. And they have been translated into multiple languages. But they have been using primarily these surveys for clinical trials to assess how cancer patients feel about how true certain symptoms have been for them. So it truly is assessing patient's experience with care.

And again, it primarily has been with clinical trials to date.

The TAP discussed this and all

agreed that these surveys were well described, well validated, and have been proven as excellent tools in clinical trials.

You definitely can determine the differences in the quality of life for patients in one therapy versus the other with these tools. And it can be used to guide patients in therapeutic interventions.

One of the key concerns that was discussed was how does this measure or this tool translate from clinical trials into point of care. And that was one piece that they grappled with.

The other was how do you take this tool and really use it to determine an outcome. So this measure really assesses at the patient level for clinical trial how it worked for them.

The TAP was unsure how that would then translate into a measure that would be publicly reported as its written now.

So that was primarily what they

discussed under importance.

When you look at the scientific acceptability, again the tools have been well tested for their use as it stands right now. They have not necessarily been tested to look at clinicians performance or practices performance on treating patients. They felt that risk adjustment and exclusion should be considered if, again, you're going to look at it as a quality of care measure.

For usability they felt that it was unclear, again, how the measure would inform patients when its publicly reported as its written now. It's been used as more of a static tool, not necessarily for reporting out how it has worked across a patient population.

And feasibility. Again, felt these have been widely used, widely demonstrated across multiple practices targeting different disease types. One question was how would a small practice or perhaps an indigent community be able to

implement these measures.

And they're primarily available by paper, but they're also starting to be available electronically with a few.

Lee or Pat, did I miss anything?

MEMBER NEWCOMER: I think I would add one comment that particularly in quality of life, we are looking at the general measure here. But you could have wide variations in your scores depending on what part of the treatment process you were in. So the classic example was a patient who begins radiation therapy , good functional status in radiation therapy, significant drop in functional status, 30 days later higher than usually before they started.

So as you think about an outcomes measure where patient would compare, you'd have to be at a very similar process in the therapy in order to have an apple to an apple. And it again made it very difficult to discuss how this measure could be used as a patient

outcome without controlling for those types of issues and getting, basically, homogenous therapy between patients.

MEMBER HAUGEN: From a patient perspective as we look at this as a public reporting, that that was the intent, the developer hadn't put any effort into thinking through how would you take this and use it for public reporting. And I couldn't as a patient.

If these quality of life surveys are very important in the context of research studies and clinical trials or in particular environment such as that, but to understand how you would use this in public reporting as an outcome measure, would you just say this group of people, they feel better than this group of people, or at some point in time, or how would you use this to evaluate an outcome.

The other concern is, I mean if you look at some, like one of the ones that's on fatigue, was used in, how do you say it,

the erythropoietin trials where you could have an outcome that would have said fatigue had been addressed fabulous and the real outcome of that, as we know, that there are other complications due to some of those intense therapies.

So in isolation, none of these really me what I would view as important or usable from a patient's perspective.

CO-CHAIR DUBOW: Did the TAP have the opportunity to talk to the measure developer? So did you ask about what their plans were for public reporting or did they just misunderstand what we mean by public reporting?

MEMBER NEWCOMER: They were on, Heidi. I don't remember a response to that. Do you?

MS. BOSSLEY: No. I think they were approached by a group to put these forward because they are really good tools to measure this. I don't think that they then

had taken the next step, nor has it been something that they've been actively looking at: How would you then take it to public report it.

MEMBER HAUGEN: Where would you take this to mature it --

MS. BOSSLEY: They were not response in the materials we had.

MEMBER HAUGEN: They were not responsive.

CO-CHAIR DUBOW: It seems they answered a different question from what we intended.

MEMBER HAUGEN: Yes.

CO-CHAIR DUBOW: And I just wondered whether they understood what the intent of public reporting is. Okay.

Vanita?

MEMBER PINDOLIA: I think where it would be useful, and I don't know if this could be done, I haven't read the details, is their data collected and if they could

stratify by age groups and the different tumors and where they're at in their disease states when they took this. For new patients coming in and having to make difficult decisions and then they can glean from previous patients who had a breast cancer, and then they had to deal with the radiation therapy, what were their outcomes. And if you have an aggregate of, like, at least a 100 or 200 it might bring some value for that new patient to feel more comfortable or help a decision if they're actually on the fence.

CO-CHAIR DUBOW: Sounds like a new measure.

MEMBER PINDOLIA: Yes, I know.

MEMBER HAUGEN: Yes, that's another one.

MEMBER PINDOLIA: But that's where I think a tool like this could be useful.

MEMBER NEWCOMER: You would actually have to look at the differences in the functional status or quality over time

because everybody's starting in a different point.

MEMBER HAUGEN: Yes. Right.

MEMBER NEWCOMER: So it would be the different thing you get.

MEMBER HAUGEN: Yes, you would.

MEMBER JEWELL: So, my impression is that when it comes to functional status measures, whether they're a physical activity or fatigue, or whatever, that there's such disparity and variation of use at the clinical level for individual patients. And so part of the push, I could imagine in this case, again it's not the intent of the NQF, but nevertheless there's a real effort to try to get clinicians just to adopt standardized clinical measures like this. You know, vigorously self-report patient-centered outcome measures.

And when you have tools like this that have a wealth of data behind them demonstrating their responsiveness, et cetera,

I can envision that the desire would be well if we get some kind of seal of approval, that will firm up their use. Now that doesn't fulfill our mandate, but I think that speaks to the state of where we are. And so we have to understand that that's another sort of message to help people.

CO-CHAIR DUBOW: I think one of the challenges that we have at NQF that we have to come to grips with is the notion of taking a patient level tool and converting it somehow for purposes. So it's not necessarily this tool, it's all of them.

We had a little bit of this conversation in the HOS measure that is rolled up to the health plan level. You know, that's how NCQA has dealt with that. And yet we had a discussion about the challenges with that particular measure.

So I think it's a broader policy question about how we do it. Because we clearly defined outcome, functional status and

quality of life as an outcome that we're interested in.

Pauline?

MEMBER McNULTY: Yes, I think this is the conundrum. And for me working in the area of patient reported outcomes and mostly in clinical trials context, sometimes in the context of observational studies, I think you've hit the nail on the head. There's a huge amount of measures that are out there that could potentially be used, but it's the question of well how do you take them from the use that they currently have to public reporting kinds of use.

But one of the things that I was curious about, and I don't know if Lauren Lent or somebody else from FACIT is on the line right now, but I did see in here somewhere that they talked about AHRQ, not just the use of the FACIT measures in the context of clinical trials, but also at cooperative group clinical trials, and also AHRQ. And I'm

thinking that maybe they might be looking at some of the upcoming comparative effectiveness types of research. And if they are, then they have to be thinking about these issues of how you kind of jump from the clinical trials intervention kind of studies and following patients over time, as Lee talked about. Because these measures are commonly used and very, very useful in those context.

So I just think, again like everybody else is making a plea, that we really ought to be looking at the wealth of measures that are out there for a variety of diseases and seeing how we can bridge from one kind of use to the kind of use that we're talking about here.

I would hate to see all of the effort that has gone into these measures not somehow being able to be pulled into a quality initiative.

MEMBER HAUGEN: Just to add to that, some of these comments. I think that is

exactly the issue: How do you take it from a patient level to something that's meaningful on public reporting? And urging clinicians to use this is one thing, but from a patient perspective it isn't enough to just a yes or no do you use it. Because the issue is how is it used? How does it inform your care and the work you're doing with the patient? How does it inform the patient?

So it's a big issue. It isn't just whether you use it or not, but how and in the context.

CO-CHAIR DUBOW: Dianne?

MEMBER JEWELL: Well, and I think you're absolutely right. I mean, it's not intended to be a process thing anymore than the rest.

I think the issue that you all raised related to measures like this for patients undergoing cancer therapy of any kind is a particular conundrum because the therapy often makes you feel worse before you feel

better. Whereas, many of the other measures are being implemented in situations where, you know, and so I'm the beneficiary of this in my world -- I mean, I can make somebody feel worse, too. But generally speaking the rebound is quicker. And so I think that that's also something. I think that the cancer experts that you -- at least where these kind of outcome measures are concerned. So for me I could see there being a gap related to management of more the long term implications that we're starting to have a better understanding of that. I have no idea what that would look like. But I think that's a conversation that's almost unique to cancer and similar kinds of diseases where the treatment is almost as bad, if not worse at times than the disease, at least in the short turn.

MEMBER HAUGEN: Yes. And long term you may not feel as good. You may survive but you may never feel as good or the

same. And so then that's an issue of survivorship and managing -- you know minimizing that in survivorship which is totally different than what some of these tools are even trying to get at.

MEMBER McNULTY: Can I just say something?

That has actually been recognized by the FDA, for example because they put out their final guidance on patient reported outcome measures for labor claims. It was one of the things that they noted was that they really would like companies to not just look at kind of the standard time period that you have that's protocol driven in terms of you measure the beginning and in between and at the end. But they really want the companies to start looking beyond that to see what the effects are beyond the end of the treatment especially, as you said, in oncology. And I think it's really, really important. But there are other disease areas that it could be

important in also. But they really kind of put it out there as almost a challenge to companies to really start collecting data beyond the treatment intervention period.

CO-CHAIR DUBOW: But I think Dianne's point also makes the point that we made before, and that is that we need to be sure that we're able to make apples-to-apples comparisons when we public data, which means everybody has to be sort of at the same place when we start.

Barbara?

MEMBER YAWN: And I like that, they have to be in the same place. But it is not necessarily always at the end of therapy. Because you can make a difference to how a patient feels in the middle of therapy. And I would love to have that also be one of the patient driven outcome measures. Because if you have lots of support and help, and explanation, and education most people do feel better then if they're just kind of stuck over

in a corner with their IV chemo going.

MEMBER McNULTY: And that's actually where electronic data collection can be really, really useful. Because when you think of the worlds that that opens up that you can have more continuous data collect.

MEMBER YAWN: Yes.

MEMBER McNULTY: Again, if you've got a protocol, the data collection is very much driven by the time points that a patient comes back in.

MEMBER YAWN: Yes.

MEMBER McNULTY: But as to your point, Barbara, it may be between baseline and where they come back at week 4, you've lost a whole wealth of information about what's happening in that patient's ability to feel and function.

MEMBER YAWN: Yes.

CO-CHAIR DUBOW: Who is the telephone?

MEMBER YAWN: Ted is.

CO-CHAIR DUBOW: Oh, it's Ted. Not that we're not happy for it to be Ted.

Ted, we're looking for the measure developer.

MEMBER GIBBONS: Well, I can't help you there, but I'm still holding.

CO-CHAIR DUBOW: No, I know. We're happy that you've stayed with us.

Okay. So we still don't have the measure developer on the phone. But I think that if there's no further discussion on the FACIT-G, which is the 019 measure, we should start out -- do you want to walk us through the vote?

MS. BOSSLEY: Sure. So we're going to have you vote on importance first.

So, again, we're doing the FACIT-G, so number 19.

So all who think yes it meets criteria? Oh, this is importance. I'm sorry. Importance. Yes.

DR. WINKLER: Twenty-two.

MS. BOSSLEY: So next for scientific acceptability. First for completely? No one.

Partially? I have 12. Twelve. Okay.

Minimally? Eight. Is that everybody? Are we 20?

Anyone for not at all?

CO-CHAIR DUBOW: Did Ted vote.

MS. BOSSLEY: Oh, there we go.

CO-CHAIR DUBOW: You really want us to work at this.

MS. BOSSLEY: Next is usability. Completely?

Partially? Two.

Minimally? How many did you have? I had 14. Okay. Got it. Okay.

So minimally? Did we do -- I'm sorry. Which one? I lost track.

DR. WINKLER: You just did minimally.

MS. BOSSLEY: We did. Okay.

Not at all? There we go. Four.

So last but not least, feasibility. Completely?

Partially? Seven. Seven.

Minimally?

DR. WINKLER: Twelve.

MS. BOSSLEY: And not at all? Two. Okay. All right.

CO-CHAIR DUBOW: So we're ready to vote up or down?

MS. BOSSLEY: Yes, vote up or down.

CO-CHAIR DUBOW: All those in favor of the functional assessment of cancer therapy general version FACIT-G?

DR. WINKLER: Anybody abstaining? Okay. Vote by subtraction.

CO-CHAIR DUBOW: Okay. Which is the next one you want to do --

MEMBER HOPKINS: Can I just what we just did? Is we said no to this measure because of various points that were raised,

most of which had to do with how its used, or the survey instrument is used, right? I didn't hear anybody say it was a bad instrument or didn't accomplish its purpose.

So I'm having a little trouble interpreting --

CO-CHAIR DUBOW: Although we didn't respond to the TAP point that there's no testing on using this measure reporting. It's only a validated instrument in a clinical trial.

And, Lee, do you want to --

MEMBER HOPKINS: So I'm wondering if there isn't sort of a condition that we attach to it. I mean, otherwise we just lost our only functional status measure

MR. HERMAN: It a great tool, but it's a bad tool for the job.

MEMBER NEWCOMER: It's very reliable and valid. Everybody agree with that for its purpose in clinical trial. No dissent on whatsoever. But it is the wrong tool for

this purpose.

MEMBER HOPKINS: So is there a better tool out there?

MEMBER NEWCOMER: No, I would agree there's none, but that doesn't make this tool better, either.

CO-CHAIR DUBOW: And I assume that, David, to your point I know I'm inferring that there's some wish on your part for NQF staff to get back to the measure developers to tell them why this didn't prevail.

MEMBER JEWELL: So just for clarification. We did approve for time limited endorsement, if I understood what we talked about yesterday, the CRQ for the COPD population which is a functional status measure. So we will have --

MEMBER HOPKINS: But, see, we're not giving the developer --

MEMBER JEWELL: Let me just finish my thought.

But the difference in that case was that the measure developers had in fact thought about how this would work for public reporting and be used, they just hadn't tested it yet. That's in my mind what's different here.

MEMBER HOPKINS: But, see, we're not giving the developer a chance to respond to that. Because of --

MEMBER JEWELL: Well, I thought that the TAP did in fact talk to them about the issue of public reporting and how would you use it for public reporting. And they have not responded with that information.

CO-CHAIR DUBOW: And I don't think it's fair to say we haven't given them a chance.

MEMBER JEWELL: Yes, right.

CO-CHAIR DUBOW: I mean, that's not fair. You know, they had the opportunity to be on the call. We've tried to contact them. I don't think that's a fair statement,

David.

MEMBER NEWCOMER: Yes. Our call was just last week. So it's a very short time frame.

CO-CHAIR DUBOW: Right. So I think that that's -- we have to be reasonable. But I think the message will be clear about what our needs are and maybe they'll be able to think about this. And we also discussed the need for NQF to think more about how you translate patient level measures into reportable measures.

MEMBER ROSEN: And I think it's really important that we give them very clear feedback that. Because it's really important for testing purposes to understand what the measure would be like for public reporting and to give them time to do that. But not the time limited endorsement at this point.

MEMBER DELLINGER: And we've sent a very clear message by voting unanimously that this was important. It's just that it

doesn't do what it needs to do.

MEMBER McNULTY: And just to add to what Pat just said. Again, as somebody who works in this area I would make a plea to all of us to figure this out how we can really piggyback on all of the work that has been done, whether it's these measures or other measures for other disease areas, that we somehow figure this out.

MS. BURSTIN: And just a general point on this. We've been coming up with a list of what I think are essentially white papers or sort of thought pieces that we need for this next generation of measurement that we're all sort of, I think, wanting to enter into. And one at the top of that list is how do you use functional status measures for performance measurement? What's the science of the delta, for example?

I mean, I think this is at the cusp. I just don't think we've kind of gotten over the hump with the exception of perhaps

the functional status delta measures around physical therapy, which we've endorsed and now the COPD measure.

MEMBER HOPKINS: Isn't there a huge literature that from the SF-36 studies of 30 years ago or something?

MS. BURSTIN: But again, other may know this very well. But at least my understanding is the deltas really happen when somebody had a major life event. So, for example, hip surgery gave you a really significant change in your physical functioning score. But there's very little about understanding the interventions across an episode, for example. If somebody enters the hospital, leaves the hospital. Or a lot of interest has been about using the SF-12, or even like this beginning of cancer therapy, end of cancer therapy.

We need to understand those deltas and how to use it. It's absolutely the right place to go, particularly with PHRs coming on

line, the ability to get patient reported outcomes. I just want to make sure we understand how to use it best.

MEMBER McNULTY: And just, David, to your question about the SF-36. Yes, there are normative data not just for the general population but for particular diseases as well. So you can look at diabetes patients, patients who are depressed and there are normative data for all of those patients. And you can benchmark against the general population to see how a particular disease population is doing. And you could do that in the context of a particular health care plan. You can do it on all kinds of basis. But I think the fact is that the SF-36 has had a 30 year advantage and has put a lot of thought into how these kinds of data might be used in other ways other than in clinical trials. And I think that that's where a lot of these other developers need to go to figure that out.

MEMBER HOPKINS: Nobody ever put

it on the table.

CO-CHAIR DUBOW: But you know in terms of measure --

MS. BURSTIN: We tried and they refused because of the intellectual property issues. I mean Reva and I had several phone calls with them and they would not play.

DR. WINKLER: That's it's their business model. I mean that's what they've got to offer as a product.

CO-CHAIR DUBOW: I know that there is money in the new bill for measurement development that is being considered in Congress, the authorization is being considered. Because it has to be funded.

MEMBER AMARASINGHAM: How is it funded?

CO-CHAIR DUBOW: It has to be authorized first. Well, it has to be appropriated. It's authorized. So it's to do measure development.

MS. BOSSLEY: Let's just around

the table once more and then we can move on. And the measure developer is going to join us.

Lauren, are you on the phone?

MS. LENT: I am, yes.

CO-CHAIR DUBOW: Great. Okay.

So we just completed our discussion of the general version. And we are about to move -- do you want to give us any introductory? Lee, do you want to --

MEMBER NEWCOMER: Well, Joyce, I just wonder as a matter of procedure these subsets are going to be exactly the same discussion.

CO-CHAIR DUBOW: I know. Right.

MEMBER NEWCOMER: I'm happy to have a talk with the developer now that they're on the call. But I think all we're doing is being redundant by going through the measures.

CO-CHAIR DUBOW: I know. But we still need to record our votes for each of these measurements. So --

MEMBER NEWCOMER: Could we move the same votes for all measures?

CO-CHAIR DUBOW: I think that's something we can entertain. But I think we should give the developer a chance to say something, if she wants to.

MEMBER NEWCOMER: Yes.

CO-CHAIR DUBOW: If that's okay.

MEMBER YAWN: Did she hear our discussion. I think she needs to respond to what we've said --

CO-CHAIR FLEISHER: Yes. Please your mics.

So why don't we let Lee sum it up and so the developer respond, if that's appropriate.

MEMBER NEWCOMER: Sure. So who am I talking to?

MS. LENT: My name is Lauren Lent. I am a senior administrator at FACIT.org.

I'm going to apologize in advance that I'm not a scientist. I did answer the

questions for the NQF, but I did prepare those answers with significant input from our biostatistician, Jennifer Beaumonth who was on the previous phone call, as well as Dr. Stella, who is actually the developer and the copyright holder.

I'm pleased to answer questions I can. But I do want to be clear that I'm not a scientist and I'm afraid I won't be able to answer any scientific questions with any legitimacy.

MEMBER NEWCOMER: Well, no apologies required. And I'll apologize because I'm not a scientist either, I'm a doctor.

So I think what we discussed here, Lauren, I'll try and be brief, is that there was uniform agreement that the FACIT measures are both reliable and valid in clinical trial work where they've been well tested and are considered to be gold standard.

The issue here was that we didn't

believe there was enough evidence or information about converting this tool into an individual patient outcome measure; that it instead applied to populations and these populations had to be quite comparable in terms of disease states and progress through therapy.

So the reason that we voted this, our vote reflected that this was an important thing for us to be measuring but we were concerned that this was not a right tool to measure an individual patient outcome.

MS. LENT: Yes, sir. I will say a couple of things to that.

Jennifer gave me a brief rundown of the previous phone call that occurred with the TAP committee. Please forgive me if I've gotten that incorrect.

MEMBER NEWCOMER: Right.

MS. LENT: In any case, and she said that there four parameters that you all were reviewing in terms of making the decision

about whether our questionnaires would fall into an approval category for what you all are doing.

And I think the bigger issue -- let me just say this. There are cases in particular with the lung module, the FACIT-L. And I apologize, I can't speak to the others. Oh, that's not true. The fatigue module which I'm not sure if you guys are reviewing today. I think actually the fatigue module is being reviewed by a different committee.

But the fatigue module and the lung module are very usable on an individual patient basis. They have been proven to be reliable clinical indicators.

I'm going to give a Reader's Digest condensed version of this. Again, I apologize. I'm not a scientist.

But the lung cancer module in particular is being used by oncologists for treating lung cancer patient as a parameter for when treatment can be halted and period of

care being.

And the fatigue module is used with a wide variety of individual patients with different chronic illness in terms of the changing quality of life score.

So, I'm not sure I'm prepared to answer critiques on the FACIT-B module for individual indicator. In fact, I know I'm not. But I can say pretty confidentially that the lung and the fatigue module are used on an individual patient basis.

I do agree with your synopsis that Jennifer gave me as whether these questionnaires can be used as a quality module and/or quality indicator. I am afraid I can't defend that statement.

And when Jennifer told me that that was one of the bigger reasons why you guys were not sure if you were going to be able to vote for it, I have to be honest with you, I kind of agreed with that. But I do think that on an individual patient basis that

Dr. Stella, if he were on the phone, could absolutely make a case for that being an acceptable use of these questionnaires.

MEMBER NEWCOMER: And, Lauren, yes we're also in agreement about that portion, the individual. But it's the quality component, the individual quality component. So you might be able to tell in an individual's fatigue score where they are at a given moment, but it wouldn't be a good quality outcome measure for others to compare one provider versus another or one treatment versus another because of the multiple --

MS. LENT: I agree with that.

MEMBER NEWCOMER: Okay.

MS. LENT: Yes, sir.

CO-CHAIR DUBOW: Okay. Was it Lee who was going to make a motion that we consider--

MEMBER NEWCOMER: I was going to move that we use the same set of votes for all of the subset measures since the issues are

exactly the same for all of them.

CO-CHAIR DUBOW: Okay. Is there any disagreement with handling --

MEMBER HOPKINS: Was there nothing different about the chronic illness therapy measure because it applied to a broader population? The same issues

CO-CHAIR DUBOW: Okay. Okay. So we are going to consider 017, which is the assessment of cancer therapy, the 016 -- I'm going backwards, lung. The first one is breast, lung and the fatigue. The functional assessment of chronic illness therapy-fatigue, which is 015.

Since nobody has any concern about looking at these three measures simultaneously, should we just go through the criteria for the three of them?

MEMBER HOPKINS: Or just take the previous vote.

CO-CHAIR DUBOW: Or take the previous vote?

MEMBER HOPKINS: I think that's Lee's--

CO-CHAIR DUBOW: Okay. Okay. I guess should we just ratify that through?

All those in favor of doing that? Okay. That's great.

Okay.

MEMBER NEWCOMER: While the developer is on the phone, I want to reemphasize the fact that everyone at this table believes that in the place where those measures are used, they are very reliable, very valid gold standard measures. So please don't take that as a --

MS. LENT: Thank you, sir. We feel the same way.

CO-CHAIR DUBOW: Yes.

MS. LENT: No, we understand. We understand. We're all about measurement, so we understand if it's not measuring what you're trying to measure.

CO-CHAIR DUBOW: Yes. And we all

thought that this area is extremely important. And as soon as you have a publicly reportable measure, please come back fast.

Okay. Thank you very much for joining us.

We have completed our review of the measures. Is there public comment?

Okay. No comment. Okay.

We did a lot of work very efficiently, so I think you. I know Lee thanks you. We think this is going swingingly.

We have one outstanding issue, and that's to discuss gaps and recommendations. Right? Okay. So the floor is open.

DR. WINKLER: I was going to say, it's a huge thing to throw at you.

In terms of the second deliverable for this project, it is an assessment of gaps where specific direction as to measure development to fill those gaps is needed. And we've been collecting your comments and the TAP comments along the way.

What I'm intending to do is use as a framework the types of outcome measures that we talked about yesterday that were on the slide, take the measures that have been endorsed previously and are being recommended in this project, kind of plug them in if you will, and look at the empty spaces.

We can begin to start populating some of those empty spaces based on comments and conversations that have been ongoing through all of these. I think that once we have those a little bit better setup, we didn't want to give them to you now when you have all this other work to do. We'll be able to provide that to you a little bit later. We'll have some opportunity for you to make the suggestions.

And the granularity of suggestions is great. There are a lot of efforts around looking at gaps, but they're kind of big picture: We need more measure about some big topic. That's lovely, but could you be a tad

more specific of what those might look at.

And our charge is to try to be more specific about what outcome measures would look like for the various types of outcome measures that we have in the various topic areas that we've outlined. So we are going to have a fairly significant deliverable around this.

I do think, however, that at this point as sort of a close to the considerable work you've done in the last two days, is think about general issues. What are some of the big picture issues around outcomes measures, around getting the kinds of measures we would like and don't have that you could make recommendations around? Because not only do we have those specific little framework thing, I can envision several pages of very general recommendations around approach for outcome measure.

Hey, Ted, how you doing?

MEMBER JOHNSON: So I think that

was a comment we need veterinary measures included.

CO-CHAIR FLEISHER: Barbara?

MEMBER YAWN: Well, one of the things that I think I have heard us sort of wrestling with back and forth is the idea that all of these measures have to go back to something that we could easily attribute problems to this or that. But on the other hand, we've kind of moved beyond that, which I think is wonderful, that we have the whole patient problem. And you don't have to be able to immediately attribute it, you need to think about it.

For example, we're go to bariatric for second. The fact that somebody chooses to operate on patients that weigh 600 pounds versus they don't, those patients are going to have many, many more risks and you have to think about that as a whole patient so you look at all cause morbidity, mortality for a long period, not just what happened because

you didn't clamp some little artery or something.

So, I think -- I know, it's a big deal. I understand. I'm trying to speak as a non-surgeon, and I am a non-surgeon.

But I do think that we have made that comment with several of our recommendations that we are looking at much broader problems and some of those problems are whole system problems, some of those are our lack of system problems. And we'd like that the measures would address that issue and recognize that issue.

CO-CHAIR FLEISHER: Good. David?

MEMBER JOHNSON: So there are a couple of things that I thought that begins with uniformity of definition for outcomes and to make sure that they're standardized as far as across the system that's assessing the outcomes and that's appropriate.

The second thing that I really saw as an unmet need is longitudinal outcomes.

Because we go to snapshot analyses. And to your point about bariatric surgery and we had this discussion a little earlier, people stop the outcome assessment at 30 days, or that's a surgical outcomes or 180 days. But for some of these interventions they're really life long manifestations that the outcomes and the pass-off of the transition of care is critical for the ultimate outcome and assessment longitudinally, particularly if we talk about bariatrics, metabolic nutritional consequences. It may not even manifest for years after the initial surgery.

So I think the longitudinal assessment of outcomes is really an unmet need. That I think if we put out a plea, that would be really a key one for me.

CO-CHAIR FLEISHER: So I would actually for the procedural aspects, you could actually add in appropriateness and how does appropriateness criteria mesh without outcome? So to address Barbara's original question: Is

there a way? And there are, particularly the American Heart and the American College of Cardiology has developed appropriateness criteria. You know, could we some develop an outcome that says it's both appropriate for the Rand-type studies and has a good outcome?

Path?

MEMBER DELLINGER: Yes. I would agree that appropriateness is important. But I also point out that it's incredibly complex to take an example already on the floor. You choose to operate on that 600 pound patient or you choose to let that 600 pound patient stay at 600 pounds, gaining with all the comorbidities and say I'm not going to do anything for you.

CO-CHAIR FLEISHER: Iver?

MEMBER JUSTER: I'm thinking even further into the future. And I suppose the Medical Home and ACO organizations and so on are thinking about longer term, more longitudinal outcomes including the community

as part of the system. A lot of times what the community does might be more important to the health of more people than what the so called health care system does. Well, we don't have the information systems necessary to link our neighborhoods and communities to our health care system. But thinking in this forums might drive the future building of such systems.

CO-CHAIR FLEISHER: That could also incorporate our concerns that we didn't capture some of the novel approaches to taking care of patients remotely or through nursing outreach.

MEMBER JUSTER: And the other thing, I don't know where I found this on the web the other day, the National Happiness Index. And I suppose happiness is an outcome. The ability to be happy with whatever you've got is itself an outcome, although not necessarily of health care.

DR. WINKLER: I just want to make

a comment to Iver that there are other aspects, particularly in the child health part of our outcomes projects where we actually are looking at the influences of community and like, for instance, schools and things like that particularly as NQF is broadening is looking to populations and population-based measures. So this is a growing area that we are beginning to move into. So it's definitely on the agenda.

And to the degree you can help me craft the recommendation in a way that is useful, I think it's totally appropriate and a very good one to put in there.

MEMBER McNULTY: Reva, one thing that just has come to my attention in the last few weeks that might be worth taking a look at in terms of this idea of looking at populations and the health population, especially from the patient's own perspective, in the U.K. the National Health Service now has actually already instituted a mechanism

for collecting PRO data from all patients in the National Health Service who come through the system.

They're looking at right now, I think, at four different elective surgeries like hip and knee and varicose veins, and whatever. But they're talking about extending this out to other disease areas and so on.

It might be worth looking at what they're doing in the U.K. I'm still trying to find out more about it because one of my big questions is well they're going to collect all of these data, but what are they actually going to do with them? I mean, how are they planning on analyzing them? Because I think they'll face some of the same problems that we talked about here just a little while ago with regard to the FACIT measures. So I'm trying to find more about that and see what's going on. But at least they are down the road of thinking that they want to collect lots and lots of data on a population level.

CO-CHAIR DUBOW: You know, apropos of that, the issue of population medicine is clearly important, but I think we need to grapple with how we translate that into these measures of accountability that can be used in decision making for patients, which is one aspect of our care. I mean, we need to look at broad -- and that speaks to accountability, which comes back to Barbara's point about systems and about shared accountability, and about community responsibility for patient outcomes.

But I think we need some guidance to help us to figure out how to think about these of things.

The other point I wanted to talk about really speaks to the issue of longitudinal measurement, and that is to think about the episodes, thinking in the context of episodes. And NQF has done a lot of the bubble diagram and that kind of stuff.

DR. WINKLER: Right. I was

planning on using the bubble diagram.

CO-CHAIR DUBOW: Yes. Showing it. Because that really graphically very nicely describes what the episode is. And I think that we need to start doing is to begin to define the episode, you know, longer period of time so that we get the whole scope of it.

MEMBER JOHNSON: And, Joyce, just to expand on that further. To harmonize the outcome assessment for success. So you're a bariatric patient, you lost weight. Did you harmonize the success based on management metabolic syndrome that effected diabetes, hypertension and other risks that if you snapshot, you might miss. And so I think that's a -- as I would encourage long term assessment of risk and harmonizing. Because one outcome may not be the predictor of success. And it's really harmonization of that outcome that really defines best quality.

CO-CHAIR DUBOW: An we need to include marriage, as you pointed out.

CO-CHAIR FLEISHER: Then divorce.

MEMBER JOHNSON: No. One of things, a sidebar conversation we had with Joyce, is one of the major complication that patient don't realize when they go through bariatric surgery, a very significant complication is divorce. And that some programs now actually have marital counseling.

CO-CHAIR DUBOW: So we're branching out.

MEMBER ROSEN: Well, Walter Pories is the godfather of this. But he would not even operate on a patient until they went through marital counseling. And the divorce rates were in excess of 40 percent.

CO-CHAIR FLEISHER: I will go around the room. Why don't we go around and see if people had a last comment. And you can just defer, if not. But that way we can get everyone if they have a thought, it can be collected.

So Amy?

MEMBER ROSEN: So just a couple of thoughts from the discussion over the last two days in terms of methodological thinking.

So we had concern about our thinking about process measures. And I think there should be some sort of TAP or steering committee that looks at trying to link process and outcome measures. Because until we do that, we're really not going to be able to understand what's effecting the outcomes that we're talking about. So to look at outcomes in a vacuum, I think it's important to come up with a clearly defined set of outcomes. But I think the next step and important gap that the literature certainly has been facing is the ability to link process measures with outcomes. And very few empirical studies to date really are able to do that. The data just don't seem to be able to do that. So I think that's important.

The other thing I heard is that while administrative date, you know sometimes

don't cut it. But then we have clinical data from registries or from medical record review, and that's very expensive and very labor resource intensive. So one thing would be to encourage some sort of crossbreeding so that we could test outcomes in both emerged administrative-type database along that has some clinical data elements.

And I know that AHRQ and some other groups are trying to develop those kinds of databases. But those might be good sources for us to start to think about developing outcome measures that incorporate both clinical and administrative types of elements.

The third thing was to think about risk adjustment and to think about ways in which we can enrich that as we think about outcomes measures. And one important ingredient I think that's really been brought out here today is the patient-centered view and perspective on care. And I think as much as we bring patients-center measures into a

risk adjustment framework would be great. And I know that's going to be hard to do. We tend to rely on either administrative or clinical data. But trying to broaden our perspective on risk adjustment would be great for thinking about comparing outcomes across providers.

Those were three thoughts I had.

CO-CHAIR FLEISHER: Any comment? I mean, you can defer.

CO-CHAIR FLEISHER: Yes, I agree with Amy.

MEMBER JUSTER: I'm also a vote for linking process to outcomes. It's not the same thing to say that people who are randomized to take a statin, for example, have better heart outcomes than the 20 percent, let's say, of some group that ought to be taking a statin is not. And you convert ten of them, ten of those 20, we don't really know whether outcomes improvement follows exactly the same pattern as the randomized trials upon which those guidelines were based. So

the more we can do that, the better.

And other than the National Happiness Index, I'm fine.

CO-CHAIR FLEISHER: David?

MEMBER HOPKINS: A couple of things.

For Reva. When you do your gap analysis, and I wasn't sure if you were expressing this or not. But it strikes this that you've got one dimension right there. But the other dimension that may be is the 20 priority conditions? Is that what you said?

DR. WINKLER: Yes.

MEMBER HOPKINS: I'm sorry I missed that.

DR. WINKLER: It's the major conditions, right.

MEMBER HOPKINS: Okay.

DR. WINKLER: That this project is oriented around.

MEMBER HOPKINS: And then this process look at outcomes, I just want to

express a somewhat perspective.

Yes, where we know what processes lead to good outcomes, we should do that. But I learned a long time ago when I was at Intermountain Healthcare that it's perfectly okay to collect data on outcomes when you don't know what processes lead to better outcomes, because that's how you find out. And that leads to clinician innovation. And Intermountain Health Care's story has been there for 20 plus years, and that's proof.

MEMBER DEUTSCH: This is Anne.

So just wanted to mention for functional status, there are measures out there in rehabilitation, but I did approach the developer and I guess they didn't submit. So probably a copyright issue. So it's similar to what we've talked about before.

CO-CHAIR FLEISHER: That might be an issue of how do we get around copyright issues in the future.

MEMBER GROAH: We'll let the

lawyers dig that out.

MEMBER DEUTSCH: Yes. But it's come up three different times, three different issues today.

And I just wanted to support Pauline's comment about there's a lot of people who developed instruments and test their reliability, validity. But they don't understand the outcome quality measure issue, and maybe not even the risk adjustment issue and how important that is. So I think that's really important.

And that's it.

MR. HERMAN: We had a lot of smart people that submitted things to us that we dismissed because they were out of scope or they weren't relevant to what we were talking about. And I'm not sure we clear enough when we asked the question of what we wanted them to preform to. So we spend a lot of time talking about it now, and maybe we an crystallize those things together, and the

next time we ask this we can be a little bit more specific so that people can be a little bit more responsive.

I also think that we spend a lot of time talking about well if we can't get at -- we understand the limitations of administrative data, but we don't have any other place to go. We're spending a lot of money in the next five years across this country how do we design our information systems to actually collect the information that we need to pull out at the end.

And then particularly with the bariatric surgery and things like that, we talk about risk adjustment, we talk about stratification. But I think it's important from a quality thing to be able to stratify before and then risk adjust afterwards. Because we can't apply everything to everybody. And you have to understand who this is important to apply it to before you start, and then risk adjust at the end.

Because I'm afraid we're going to have a lot of places out there taking our recommendations and taking a hammer to them and trying to fit them in and spending a lot of money on something and not getting a lot out of it.

So any guidance that we can provide as far as that stratification before about who are the patients that we should really apply this to, I think we'll make a lot better investments as we move forward.

MEMBER GROAH: I support the process and the outcome, and as well patient-centered movement. And also I'd like to bring up again is the remark that David made about the crosswalk. I think that would really serve us well and help in the future.

MEMBER NEWCOMER: So my points have also been made, but I'll underscore the two.

One is the use of combined databases. I've had the opportunity to do that now with the Ohio Tumor Registry,

WellPoint and us putting all of our claims data together with information. And we got more information about cancer in that state then we dreamed possible. So I think we can't do this enough.

The second is I also would agreed with David that I think we should worry more about outcomes and not worry about process linkage unless we have some clear -- but the outcomes in real world are not what we see in most of the studies with the process attachment. So I'd rather measure outcomes, use that, inform that information with the processes we know about but not be dependent on it.

MEMBER PINDOLIA: I agree with what everyone said, and especially that last part you said, Lee.

Reva, thank you for mentioning about childhood diseases because that was one of my comments that we haven't talked about childhood obesity and depression.

Looking at disparity, I know on my Medication Management Steering Committee and this one, it's listed but every time there's no information. And with looking at the U.S. and the whole focus on disparity, infantile mortality, asthma, I mean there's mammograms, colorectal. I mean, there is so much opportunity for someone who has collected tons of data between RWJ and everyone else, that they should be able to develop one outcome measure for racial disparity , whether it's women keeping their OB/GYN appointments, something as simple as that that we know could help. But I mean just to give some ideas to someone for motivation.

And I was really surprised if we get come feedback about like smoking cessation. In the U.S. more and more states are becoming nonsmoking states. So are these smoking cessation programs really useful or is just that people are paying for something and they're still not helping them. It'd be a

really good outcome for patients to know which ones are working and which ones aren't.

So those are just some of my suggestions.

MEMBER HAUGEN: I think most of my points have been also. But just two areas.

You know, having grown up in the information systems business, the data problem in this industry is just -- it's appalling and inexcusable. So it's so behind, but the message that it is a barrier to a quality care and delivering quality care, and the investment through health reform in electronic health records isn't the answer. That's part of the answer. Because as we listen to this, there's issues: Is the right data being capture, do I have access to it? The issue with proprietary data, the ownership of it. And it is a barrier to delivering quality care because we can't even assess it.

So I think from a topic moving forward as far as something, you know is there

a central message source for that is critical.

And then the second is this point of development. If outcomes are important, then the development of good outcome measures by groups that are used to doing process measures, how does one make that transition? And from a patient, I'd rather have a real simple thing. How many breast cancer patients recurred in the first five years? Well, maybe that isn't fair and I don't want it attributed to me, but it would begin to tell you something if people dig into it, wouldn't they?

So I think it may be simpler clarity, and I can get the information, maybe that's something that needs to be kind of a criteria as one looks at measures.

MEMBER YAWN: Well, I think my comments follow-on to that.

I'm really interested in more work being done on how we present the information to people, how they use it. And then I'd like

to know what the outcomes are from us presenting this information to the public.

DR. WINKLER: Impact?

MEMBER YAWN: Pardon me?

DR. WINKLER: You're talking about an impact, right?

MEMBER YAWN: Impact. I mean, yes, we keep saying this is great, let's do this. But I haven't seen a lot of outcome saying this is the impact of talking to patients. But part of that is I don't think we know how to talk to them or describe the information.

You think it's been done?

CO-CHAIR DUBOW: No. You know, there is evidence that at the present time given the measures that we have now, there is evidence that most consumers don't use the measures.

MEMBER NEWCOMER: Yes. Right.

CO-CHAIR DUBOW: But we know that there is an effect anyway because providers

are using it. So there is value to public reporting whether or not consumers themselves use it. And I don't think we should ever lose sight of that.

CO-CHAIR FLEISHER: And actually, if you look at the Kaiser data, it's changed over time.

MEMBER YAWN: And I wasn't wasn't suggesting we shouldn't do it. I'm just saying that we said there were two parts. One was for the systems and health systems and one is for the consumer, if you want to call it.

CO-CHAIR DUBOW: I know. But I just think we have to remember that there is value to publicly reporting regardless of who the --

MEMBER YAWN: I would never arguing that.

CO-CHAIR DUBOW: I know. I just want to say it.

MEMBER YAWN: I just want to do it better.

MEMBER FILLIPO: I think most of my points have been made. I just want to underscore again the discussion about process indicators.

Again, I'd love to be able to identify process indicators that are true intermediate outcome indicators and tied to the outcomes we're interested in. I just think that most of the processes of care that we're trying to look at are far too complex for us to bogging to understand what are the real important process indicators. And we go ahead and identify process indicators and health care systems and providers then work to those process indicators. And we've done nothing to improve outcomes of care. And in a lot of those case I'd prefer identify structural indicators. You know, structures of care that we know are tied to outcomes.

MEMBER BECKER: So a lot of great work has been done. We should never forget any of that. Given health reform, given the

environment, given costs I think we're going to have to move a lot more quickly. And it seems to me that one of the things we should be thinking about is what's our desire to state, what do we want, what measures do we need, what do we have and what are the gaps? And then once we figure out what those gaps are, we need to become more prescriptive about saying this is what we want developed. Because we've got to start to fill in those holes. We've got to start moving in a direction.

When we talked about cancer today, maybe it's about filling in cancer and putting most of our energy towards that to get that one done, or another condition. But getting pieces done so that we have the most impact in health care cost and quality that we can. Because maybe we can't do it all at once, but we got to focused and finish.

MEMBER JEWELL: So I think NQF as a bit of a conundrum to wrestle with, and I'm

guessing you already have started down this discussion. And that has to do with the fact that there is such a wide range of understanding across the different groups about what is needed.

So to your point about identify what we need and become more prescriptive, I could see some greater clarity in saying these are the kinds of measures we need and these are the specifications. But the variety of level of understanding is such that there is in my estimation is such an educational need that I'm not clear that NQF can maintain its neutrality as a endorser and provide the level of education that's required.

And I've been down that road in my own professional organization relating to credentialing processes that we have. And this incredible demand for a level of experience and detail that at some point we had to draw the line and say we can't teach you and endorse you at the same time.

So I'm sure you're well aware of that. But I just wanted to call it to everybody's attention. Because my sense is that even with more prescription like you're describing, there's going to be some significant cadre of people who don't know what it means to take a measure from a patient level up to an advocate level and to develop a registry in order to do that, and to do the risk adjusting and decide empirical versus clinical. I mean, that's huge amount of stuff.

MEMBER GERBIG: Well, I'll be interested to see the gap analysis. Because my sense is that we've missed a lot of things.

We've really been down in a lot of minutiae, a lot of measures and we might be shocked when we look at the gap to say how did we miss this one. And then the fact that you have two customers. You have the patients, the public that we're trying to provide them useable information and also the providers.

And I'm sure payors, too, are interested in the data. And have we met both of their needs and will we even ask a group of patients what are we missing and what would you like to see, and is this understandable.

I really like the fact that we're beginning to look at measures longitudinally. Because to the degree that we push measures beyond the hospital event, we really serve the data purposes for patients and get off of our own internal purposes as providers. And it's really uncomfortable because we don't have good methods for doing that, but that's what we want. We want to push people beyond their comfort zone because we'll rise to do what we need to do.

MEMBER McNULTY: I think it's really important, not just that we look at patient- centric measures, but that we also actually get the voice of the patient, him or self in there, hence the patient reported measures. And I'm just really pleased that

that is beginning is happen.

I think it's the beginning of a long journey. And other people have talked about that, but I would just really encourage us to move forward in this path and to see where we can go. Because I think from one the customers, i.e. the patient's perspective on this, it would be good for them to know how their own reports of how they either survived, or they feel or they function is really important information for them to know. And to translate that somehow into a quality measure is something I really want to see happen over the coming period of time. And I don't know how long it will take us to get there, but I think it's a really worthwhile endeavor.

So that's kind of my little piece.

MEMBER KEALEY: I want to make sure that we, as we look at measures, that we continue to use strategies that keep the heat on people to get better. Some examples, we

saw in the diabetes all or none versus the DRP, which was partial credit. We definitely know that the all or none may seem unfair to some people, but it really keeps the heat on and it makes sure that people are getting better. So I propose that.

I do like the measuring systems. We've seen a tendency for some of these measures to really try and focus down on a procedure done and my responsibility with that procedure and not think about the team or the system of care in the measures.

And the last thing as a non-statistician, I guess I just want to say that the whole idea of risk adjustment does concern me. Because I do think that it can obscure the reality of what's happening in our facilities. And so I think it can explain things away and turn the heat down, which I want to keep the heat up.

MEMBER JOHNSON: So two areas just for final comment.

One is the implications of how these measures are developed and how they're used. Because these things will all be used to single out individual or health systems, be it good or bad. That's what's going to be used. Payors and even the consumers are looking for discriminance in choosing one course of action or another. And there are just so many unforeseen consequences of these measures when you start to talk about reporting bias stratification risk. And you really run the risk as we put these systems through to really maintain the mentality of are we adding something that's truly better. And on the same side, are we burdening a reporter that we may hinder their care or cost them in their practice in imposing something that really is justifiably better. So that remains my consternation on this process.

We don't more measures, we just need measures that really work. And so as we look for things and say we've got gaps in

measurement, the easy thing because everybody feels good about quality. Nobody could argue quality. But if it's quality that matters, that's really I think the jurisdiction of what the NQF really needs to rein in and keep perspective on that. Not that you haven't, but just the concepts of going forward I think that becomes even more of a growing emphasis of need.

I remain concerns, too, with the accuracy of the assessments that are judged then by cross validation and looking at ways that these are truly reaching the right measures and the validity and how these things are reported. Because until everybody's on a uniform system with electronic records, it's very burdensome for any organization to go in and validate to make sure that these measures are really reported accurately by intent or just by misdirection.

The second area that I really wanted to focus on, this silo mentality, and

I've alluded to this to some degree. But when you look at an outcome and you can say for a bariatric patient they lost X amount of weight or you look at a colonoscopy patient and say I found X number of polyps. And outcome is very easy to report. Or you talk about an ICU mortality and you say the 30 day mortality in the ICU patient was at X percent. But if we looked at the data on that ICU, maybe 50 percent of them went out on dialysis with pegs, they're brain dead and they went to a nursing home.

So the context of silo mentality I think is the other challenge for the NQF. That we harmonize these outcomes across the myopic focus that I think that a lot of us tend to practice in, because that's our snapshot of the episode of care.

So anyway, I'm not sure what the answer is, but that's really the assessment over time.

MEMBER AMARASINGHAM: That's

great. I just have a few additional comments myself.

I think that this conference has clearly illustrated how difficult measure development is and the importance of sort of national leadership with respect of funding for this. And I also think that if there is federal funding for measure development, there absolutely has to be stipulations that it's going to be a variable. And if you have groups that are developing measures like the American College of Surgeons or even the SF-36 work is just for the academic credit of the investigators. And it clearly needs to be doing that.

The other thing is for research that's been funded, federal funding for research that primary intent may not have been measurement development but for which a measure was developed, should also released. Just like we have data sharing agreements from federal funds.

I also think that, you know there's only 1.7 percent of U.S. hospitals have electronic medical records. And this is absolutely critical, obviously, to developing e-measures. And we maybe ought to consider if there's only 1.7 percent of U.S. hospitals that are going to be the ones that are sort of all oriented development in this area, the question is whether we should think about the feasibility standards, the threshold being slightly lower. Just to encourage IT measures.

CO-CHAIR DUBOW: The Meaningful Use Regulations are actually to produce that.

MEMBER AMARASINGHAM: To put that up. So, obviously, you know we hope that we move from 1.7 to 20 percent. But still the vast majority of hospitals do not have electronic medical records.

We also for the longitudinal data, this absolutely critical. There's no doubt about that. But one of the questions with longitudinal data is if you're not an

accountable care organization, your patients are staying with you hopefully for five years, but there's a significant turn within the community. So let's say that the work that I do at my hospital is responsible for what may be real benefits in five years. But let's say if the patient goes up to a different hospital, and then measure is then attributed to that hospital.

I think there's an emerging area that we should encourage which is outcome and profiling at the community level. So imagine for Dallas, you say what's the readmission rate for Dallas and that hospitals are potentially in the game together on this. And while we're computing hospitals need to come together and say what's your admission rate in Dallas, and you'll all be penalized to some extent if that readmission rate is too high. I think that that's radical, but it's something we should consider.

CO-CHAIR DUBOW: We'll start in

Dallas.

MEMBER AMARASINGHAM: I have another Dallas partner here.

CO-CHAIR DUBOW: We'll start in Rochester --

MEMBER AMARASINGHAM: That's right. That's right.

And I think there is areas that clearly have been doing this. I think it would be real interesting to see this work in highly competitive markets.

CO-CHAIR FLEISHER: Philadelphia.

MEMBER AMARASINGHAM: Philadelphia, Dallas, you know Boston.

And I think that some ideas about the NQF supporting conferences on this. Because I think there is a large amount of sort of lack knowledge of how do you move strictly health services research methodology to more public reporting. I think there's health services researchers that are very intelligent, but many may not require a lot of

guidance to move into thinking about how their work could apply to public reporting.

MEMBER JEWELL: Or to at least train them.

MEMBER AMARASINGHAM: Okay. I'll be more charitable.

CO-CHAIR FLEISHER: So I'm actually thinking of the end user. I think NQF needs to go to AHRQ or some -- and actually get something upon what will actually move the public. What way of reporting does the star method actually influence how the public thinks.

I know Kaiser's analyzed this, but nobody's actually trying to change the way, see how different reporting systems make a difference to the patients themselves.

And the other thing is I think there's a lot about integrated outcomes versus subcategories of outcomes. We've actually approved a lot of broad outcomes, and how important is it to look at specific outcomes

versus the more general.

It's been a tremendous experience for the last two days. This is an amazing group. I've learned a lot. And it's been a real honor.

I wanted to thank, unless you have other comments, thank Helen, who is not here, and in particular Reva who has led us through this, and Heidi. And whole NQF staff.

CO-CHAIR DUBOW: Also Hawa and Sarah.

(Applause.)

CO-CHAIR FLEISHER: And Hawa and Sarah.

And despite putting us in two different hotels, it's been tremendous. Thank you.

CO-CHAIR DUBOW: And thank you to you all. This has been a really terrific group. I mean, for doing this kind of work we've really come together.

I just want to say a word about

next steps.

MEMBER YAWN: Before you do that, we just want to say thank you to the two of you also.

(Applause.)

CO-CHAIR DUBOW: It has been a real pleasure. Thank you for that.

DR. WINKLER: Can I make a comment?

CO-CHAIR DUBOW: Yes, please.

DR. WINKLER: Okay. In terms of next steps, you know this only so long, it's not goodbye. We're going to continue to be friends for a while now.

As we referred, David is always asked me for a copy of the slides that have the timelines for the two parts of this project going forward. And so I'm going to distribute that, send them out to everybody. You guys can take a look. Those will be the timelines.

This particular group will go

through the same process that we're embarking on for the first group, just lagging about four to six weeks behind. We will be first wrapping back with the measure developers you asked us to get responses on and get back to you. We'll try and do it electronically. If it looks like that's not the best way to reach some conclusions, we may have to organize a conference call. We'll have to see how that plays out. We'll work with Joyce and Lee to determine that.

Then we will be drafting a report. As I mentioned, we have drafted the ones for the first 12 measures. And now that you've kind of put this behind you, we can send you some more documents to take a look at. Lucky you.

But the summaries from the two conference calls as well as the draft report, like we said, we'd be happy to circulate with you. We'll send them to. So realize that that's those first 12 measures.

We're going to be preparing exactly the same set of documents based on this after we do the discussion with the measure developers and kind of sort through some of some of these pending issues that you've left us. So that's sort of the immediacy for us.

So both of these draft reports will go through public comments periods. So a 30 day public comment period. You are certainly welcome to submit comments, should you want. Encourage your friends, colleagues, whoever else you'd like. It's available and open to everyone.

We have at times see highly voluminous numbers of comments come in. And we will have to deal with those.

We will schedule a conference call during the period where we're responding to comments to wrap back with you all to see how we're going to respond them, does it change your thinking, might it change your

recommendations? This is the opportunity for the folks that you're really acting as a proxy for. You know, how does it play out there? How does your work reflect what they're really thinking? And so this is a nice feedback loop.

Revisions to the document or your recommendations will be finalized into a voting draft. It goes out to NQF members for voting. Those results ultimately go to the CSAC.

Now just to tell you, David and Joyce sit on the CSAC. They don't get to go away from this at all.

And then ultimately to the Board for final endorsement.

The time period for endorsement is looking to be September, October, November of next fall. So it's moving quickly. There is a lot of stuff. You've seen lots of volume. So we'll be in constant contact with you. We don't anticipate any more in-person meetings,

but certainly a minimum of two conference calls, possibly more as issues could arise that we need to check in with you all to help us make the decision necessary to go forward.

So with that, questions?

MEMBER HOPKINS: So does our work persist beyond the current realm measures, or is that it?

DR. WINKLER: Well, essentially for each project steering committee, yes. Once we reach the endorsement phase and we kind of finalize the deliverable, the work of this committee as constituted this group of people, is pretty much at an end.

MEMBER JEWELL: Trying to give us lifetime appointments, David.

DR. WINKLER: Yes.

MEMBER HOPKINS: No. But after a discussion about gaps, you sort of wonder how you're going to handle that and are you going to re-educate a whole crew. I mean, think about that.

DR. WINKLER: In terms of -- you're saying next time we look at outcome measures?

MEMBER HOPKINS: Yes. Not that I'm looking for more work.

CO-CHAIR FLEISHER: I think he's volunteering.

DR. WINKLER: I get the feeling -- yes.

CO-CHAIR DUBOW: You know, I just want to mention one thing about the public comment period. Because I think to emphasize what Reva said about commenting and having colleague comment. I think it's really important.

I think we just made some recommendations that deserve a lot of scrutiny. And I think that the CSAC would benefit from a lot of input from the public to ratify the decisions we made, to disagree. I'm sure there'll be a lot of that too. But I think that it's a good idea.

It's the part of the process that really does allow for public input. And I think it's very important to have that information available when the CSAC makes its recommendation to the Board. So I really encourage you to work that part of the process.

So it's time to wish everybody safe travels.

(Whereupon, at 1:28 p.m. the Steering Committee was adjourned.)

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