NATIONAL QUALITY FORUM

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CANCER ENDORSEMENT MAINTENANCE STEERING COMMITTEE

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WEDNESDAY
MARCH 14, 2012

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., Stephen Lutz, Chair, presiding.

PRESENT:

STEPHEN LUTZ, MD, Chair
JOSEPH ALVARNAS, MD, City of Hope
EDUARDO BRUERA, MD, FAAHPM, University of Texas, Anderson Cancer Center
ELAINE CHOTTINER, MD, University of Michigan Medical Center
HEIDI DONOVAN, PhD, RN, University of Pittsburgh School of Nursing
KAREN FIELDS, MD, Moffitt Cancer Center
JOHN GORE, MD, MS, University of Washington School of Medicine
ELIZABETH HAMMOND, MD, Intermountain Healthcare
BRYAN LOY, MD, MBA, Humana Inc.
JENNIFER MALIN, MD, PhD, WellPoint
LAWRENCE MARKS, MD, FASTRO, University of North Carolina School of Medicine
ROBERT MILLER, MD, FACP, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
NAOMI NAIERMAN, MPA, American Hospice Foundation

ROCCO RICCIARDI, MD, MPH, Lahey Clinic Medical Center
PATRICK ROSS, MD, PhD, Ohio State University Comprehensive Cancer Center
NICOLE TAPAY, JD, National Coalition for Cancer Survivorship
WENDY TENZYK, Public Employees' Retirement Association of Colorado

MEASURE DEVELOPERS:

MICHAEL COHEN, MD, College of American Pathologists
KERI CHRISTENSEN, MS, American Medical Association
AMARIS CRAWFORD, American Medical Association
NADINE EADS, American Society of Radiation Oncology
CRAIG EARLE, MD, MSc, FRCPC, American Society of Clinical Oncology (by teleconference)
JAMES HAYMAN, MD, American Society of Radiation Oncology
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KRISTEN McNIFF, MPH, American Society of Clinical Oncology
CAROL POLISARIAN, MD, ActiveHealth Management (by teleconference)
MARJORIE RALLINS, DPM, American Medical Association
FAY SHAMANSKI, PhD, College of American Pathologists
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ANUSHREE VICHARE, American Society of Radiation Oncology
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EMILY VOLK, MD, College of American Pathologists
EMILY WILSON, American Society of Radiation Oncology

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HEIDI BOSSLEY, MSN, MBA, Vice President, Performance Measures
EUGENE CUNNINGHAM
ANGELA J. FRANKLIN, JD
ADEELA KHAN
LINDSEY TIGHE, MS

ALSO PRESENT:

MAUREEN DAILEY, American Nurses Association
TOM MURRAY, American Society of Clinical Oncology

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P-R-O-C-E-E-D-I-N-G-S

8:00 a.m.

CHAIR LUTZ: So, if you've noticed, our first seven measures are all being brought by the same developer and they're all variations on a theme.

And I believe one of the important members that will be on the phone to help us from the developing crew is only going to be available for the first certain number of minutes.

So if we could, we're actually hoping to see if the developer might be able to give us an overview of all seven. And then we'll go one by one for discussants.

But I think if the developer is comfortable just giving us a bigger picture, and then we'll work through one by one after that.

DR. EARLE: Sure, okay. Craig Earle here on the line. Can everyone hear me? Hello?

CHAIR LUTZ: Yes, you're good, Craig.

DR. EARLE: Okay, great. Yes, these are a series of measures that largely get at the idea of overuse, over-treatment among cancer patients near the end of life.

They were developed over several years from NIH-funded grants and started off, I won't go into the development of them, but what you'll see is, as you said, they're variations on a theme.

The first one, 0210, the proportion of patients receiving chemotherapy within the last 14 days of life. The idea here is that, in general, there's a time to transition from active anti-cancer treatment towards more palliative and symptomatic approach towards the end of life.

And when we looked at practice patterns, trying to identify a cut-off related to outlying practice in national data sets, it fell at around 14 days of life with

identifying tenth percentile outlying practice.

And so, that's been developed and evaluated in several different areas where there's found to be huge variation in this type of measure, and that there's been some indication that measuring and reporting back has led to an improvement in this measure, meaning that the proportion of patients still receiving chemotherapy very near the end of life has been able to decrease.

Similarly, the next four, I guess, proportion with more than one emergency room visit, more than one hospitalization, or admitted to the ICU, or dying in an acute care setting. These are all things that, again, can raise a red flag of practice that's not appropriately planning for the end of life.

And as a result, whether because of ongoing aggressive treatments, inappropriate patient selection, et cetera, end up with patients having to be managed in

an acute care setting. In particular, ICU is a prime example of this near the end of life.

And so one overlying thing with all of these is that these are not never events, meaning that there are obviously always going to be situations where someone ends up being hospitalized near the end of life.

But there is quite a bit of data showing that the majority of patients prefer not to have this sort of care towards the end of life. And similarly, the majority, although not 100 percent, but the majority prefer not to die in an acute care setting.

The next two, then, relate to hospice utilization. The proportion not admitted to hospice, and the proportion who are admitted only for the last three days of life.

And so again, that's the idea of not availing of the end-of-life resources to better palliate as death approaches.

And one question that's come up several times is that the model of care in this regard is starting to change with palliative care, palliative care physicians, et cetera being involved, and in some cases, providing the care that otherwise would be identified with hospice.

And indeed, when this measure's been operationalized in Canada, where I am now, we are able to identify palliative care physicians and other forms of palliative care in administrative claims, and that's how it's been operationalized.

Currently, though, in most cases, Medicare claims, et cetera, the data infrastructure hasn't caught up to that. And so at this point, all of the work that's been possible has been to focus on hospice.

And in general, it still seems to identify important practice variations that resonate with people. I'll stop there.

CHAIR LUTZ: Thank you, Craig. I

appreciate it. And do we understand we only have you for a limited time this morning?

DR. EARLE: Right. Unfortunately I have to travel to another meeting, which is at 9:00. So about 8:50, I'll have to ring off.

CHAIR LUTZ: Okay, then if you don't mind, even though we haven't gone over them individually yet, I'll just see if anybody in the room has a general question to ask you before we do start to go through them one by one. Is there anybody that has a question for the developer?

MEMBER ALVARNAS: Hi, this is Joe Alvarnas from City of Hope. One of the questions I have for you is that I'm a bone marrow transplanter, so my view, I guess, of hematology oncology's really incredibly skewed.

So when I look at some of these metrics, many of the metrics that we've looked for have looked for optimum performance where

you're either achieving a minimum performance standard, or a maximum performance standard, or even a maximum or minimum process-based standard.

In this case, given the nature of what we do, part of what you're seeking may be to optimize the care of the patient. But how do you know what that ideal number is? What is the -- how do you know when you've achieved ideal performance?

I mean, for instance, in the setting of an allogeneic transplant, patients may have received chemotherapy within 14 days of the end of life.

I hate to contemplate that, but that does happen. And I think that wouldn't necessarily represent a deviation from standard accepted practice.

I think we also care for patients with acute leukemia for whom we're performing inductions, and while the induction-related mortality, thankfully, isn't massive, it's

still a real number.

So I think for most of the metrics that you've espoused, it's an asymptotic figure that represents some optimum degree of performance. But I have no idea, first and foremost, what that number is.

And I guess the second question I have for you is, how do you know that. I mean, based upon three years of data, can you give us some projections of what might represent optimum performance?

And I guess the other practical implementation question from my point of view is, given that this is a fairly broad based metric and given that some of the nature of our practice may be very, very specialized, and in my case, particularly skewed, how do you judge one's performance adequately using these metrics.

I think that's the kind of push back I'll get from the physicians with whom I work. And I guess the question that comes

based upon our specialty.

DR. EARLE: Yes, sure. And so the answer is, first of all, as I said before, these are not never events, so you're right. It's absolutely true that each of these things have happened to my own patients.

So you know, they're not never events. The idea here is, are your results on these measures outlying when compared to your peers.

So in your case, if you were to look at bone marrow transplant practices across the country and find that, you know, in your case, or in a particular center's case that there were a lot of people dying in the ICU or having chemotherapy very near the end of life, whether because of prolonged treatment of incurable disease or higher toxic death rates during induction or things like that, that it's a red flag to say, you know, we need to look at this and try to tease apart what the underlying reason is.

So it's always to be comparing as much as possible like with like and look at outlying practice.

MEMBER ALVARNAS: Thank you very much.

CHAIR LUTZ: Craig, this is Steve Lutz. Just a quick question.

You know, if you're gone and off the phone and we start getting deep into these seven measures, now that you've, you know, set these up years ago and have maybe more idea of which ones are more likely to tell us the things that we need to tell us, do you have one or two favorites where you say boy, this one seems to ring true?

And I think it's important to sort of, you know, if we end up with seven and we're kind of floundering to sort of know from your perspective, I assume you have more knowledge about how these are working or will work than we do.

Are there any that just seem to

stand out versus the others?

DR. EARLE: Yes, and in particular, it's ones that do resonate the most with people.

And that would be receiving chemotherapy in the last 14 days of life, lack of admission to hospice or very short admission to hospice. So those two would sort of go together.

And the proportion dying of cancer in an acute care setting. And especially when I start talking about this, one aspect of all of these, when we've done evaluation, it's not just about physician practice and attitudes or things like this.

One of the things that comes out time and time again is that these also reflect the capacity in the local healthcare system.

And so for example, if you're in an area where there's less availability of hospice services, you're less likely to be admitted to hospice, and more likely to be

receiving chemotherapy within the last 14 days of life.

So you know, you can get into chicken and egg arguments about why that exists, but they also can indicate deficiencies in local medical resources.

CHAIR LUTZ: Great, thank you. I think Doug Marks has a question.

MEMBER MARKS: Quick question. Is the intent, the denominator looks like it's all patients. It's not just, for example, the chemotherapy within 14 days.

I would have thought it might have been patients receiving chemotherapy for non-curative intent. Patients receiving palliative chemotherapy which would get at Joseph's concern.

DR. EARLE: Exactly. So these have been operationalized in different ways. And in some situations where, for example, stage of disease can be ascertained with high accuracy. That's one of the ways that they've

been operationalized.

In many situations, however, it's much more difficult to infer whether something is given with palliative intent versus not.

And so in those situations, we've also had to look at all comers, assuming that, comparing, you know, one outpatient practice to another or something, that the proportion is not going to be dramatically different of palliative patients versus adjuvant patients, for example.

And so the relative rates that are measured would still have meaning. A lot of it depends on how accurate and precise the data you have are.

CHAIR LUTZ: All right, let's see. Does anyone else have any questions for Craig? Bryan?

MEMBER LOY: Just a curiosity question. As I look at these topics, I'm wondering, did your group consider a measure that reflected the presence or absence of an

advanced directive, because that seems to be at the root of all of this.

DR. EARLE: Yes, these started off as things that could be evaluated. We were looking for things that could be evaluated in administrative claims data, and depending on how you define administrative claims, if it's things like insurer claims, Medicare, et cetera, the advanced directive is not something that could be operationalized. Maybe I'll just stop there.

CHAIR LUTZ: Okay, anyone else before we move on to the first one and let Dr. Bruera? Sure, Jennifer?

MEMBER MALIN: I just wanted to comment on the advanced directive issue, which is it's kind of a very basic first step.

You know, I recently did a study in the VA where we looked at a lot of these measures.

And we had, essentially because the VA has a reminder system, 100 percent

presence of advanced directives in people's charts. And that didn't necessarily correlate with very high outcomes on these measures.

DR. EARLE: Yes, that's what I stopped myself from saying. Joan Teno, for example, has looked at this.

And the advanced directive, while it's a great idea, in practice hasn't really been demonstrated to affect things.

MEMBER TAPAY: Hi, yes, this is Nicole Tapay. I was on the workgroup, so benefitted from some of this discussion.

But I just wanted to add, on the advanced directive front, having gone through that under Ohio law with my mother, you know, frankly it's not specific enough to address these situations. And it's still requires the kind of conversation.

CHAIR LUTZ: All right, let's see. Anyone else before we let Eduardo get started? All right. Let's go. The first one's 210.

MEMBER BRUERA: Thank you. I

would like to thank first, Dr. Earle and certainly the ASCO team that took over some further information that was provided to this team about this measure.

And I think the committee in general felt, the working group felt generally that the tool was very well crafted, that it is extremely simple, and that's perhaps one of the wonderful aspects of it, it's easily retrievable.

Some of the concerns that were expressed so far were addressed, and that is that we should make sure that we compare apples to apples and pears to pears rather than, you know, people receiving allogeneic bone marrow transplantation versus adjuvant chemotherapy for breast cancer and put everything in the same package with regards to last 14 days.

That was very well, I think, addressed initially in the SEER's data then in the Dana-Farber data. And basically, it was

highly reassuring to find that those elements are there.

And perhaps the most important aspect of the discussion was around the never event. This is not like operating on the wrong side or basically giving the wrong agent.

This is like a c-section that per se has nothing wrong, it's not Monday quarterback, it's not saying this person, in hindsight, should not have received it. It's looking at the frequency.

And there was a wide distribution that was measurable in frequency of this process happening. So for that reason, it was felt to be reassuring.

So there was a general feeling that this is reliable, it's good, and ASCO proposes this to be a good quality measure.

So in general, as some of the comments were added there, and I think I will leave up to other members of the committee or

the working group to say if they had any other concerns.

CHAIR LUTZ: So anyone else from the working group, the smaller working group have any suggestions? All right, should we open it up to everyone?

MEMBER FIELDS: Is the developer still on the line?

DR. EARLE: Yes.

MEMBER FIELDS: I wanted to ask a couple of questions. I understand the never concept, because obviously it wouldn't be acceptable if we didn't -- be able to account for acute leukemics might die with leukemia even though they had curative potential.

But what was the intended use of this data? How is it getting used in Canada where you're working, because I think that that's one of the things that makes a measure like this a little bit more challenging.

And this one you chose a threshold of less than ten percent as the target. How

did the group come up with that target?

DR. EARLE: So how it's being used in Canada, as elsewhere, is as one of the, I guess relatively few overuse measures in oncology, which is, I think, one of the reasons why people have been interested in it. That, you know, in general in oncology we're looking at well, you didn't get this, you didn't get that.

These are starting to actually look at or recognize that, you know, at times we provide care that goes on too long or is overly aggressive or in patients who are not well selected.

So it's reported as rates and comparing different jurisdictions within Ontario, for example.

This is the type of thing, you know, when I speak to my colleagues, often when you take a weekend of call for your colleagues, you get a sense of there are some of them who maybe are more aggressive than

necessary.

Regarding the tenth percentile choice, this was a decision made a long time ago when first developing them, trying to operationalize the concept and chose that as a threshold for looking at the outlying practice.

We used something called method of achievable benchmarks of care. And there's some references that I can give related to that.

But it's finding a threshold that can be used as an initial benchmark in a particular group of patients and then over time, practice can evolve so that there's the opportunity, in fact, to even shift the benchmark if practice sufficiently changes.

MEMBER FIELDS: So there's not randomized trial for that benchmark or data, there's just that benchmark was just sort of a arbitrary number?

Or it did look like in some of the

other measures, you actually showed the variation around the U.S. and then chose those numbers. It doesn't look like that's what happened in this measure.

DR. EARLE: It was the same, actually. So the 14 days marked when we looked empirically at Medicare data, the tenth percentile outlying practice were patients receiving chemotherapy within 14 days of life. So the 14 days is what marks the tenth percentile.

MEMBER ALVARNAS: Question for you. And again, I'm not as familiar with this literature. It sounds like you're looking at those patients who represent outliers in their population by virtue of that ten percent number.

Has anyone done a deep dive in terms of auditing those data to ascertain what portion of those patients are receiving medically inappropriate care as opposed to represent outliers for biological reasons?

DR. EARLE: Yes, there have been analysis that have been trying to look at a bit of that.

In particular, looking at things like, it's less for this particular one, but for some of the hospitalization ones, finding that there is a proportion of patients for whom comorbidities, comorbid conditions are important drivers of that sort of care at the end of life.

Now it begs the question of, is decisionmaking particularly appropriate if you're treating people with a lot of comorbidity and, you know, having them end up in the ICU. But that was one area, in particular, where this has been looked at.

MEMBER BRUERA: I think that's to address this issue. Not in this cohort from SEERs and the Dana-Farber, but in other previous research, there has been some documentation of this fact.

Perhaps, one of the points that we

felt was strong is that it proposes the measure, but does not propose a rigid ten percent.

So it would not be saying that if in a certain institution you have a certain fixed number, that would be considered operating on the wrong side.

I think it would have to have a more complex quality analysis to it. The same as C-sections might be different in a place that has high risk pregnancies as compared to an area where the pregnancies are suburban and higher middle class.

So that's where we felt it was more robust than simply trying to come up with a one size fits all.

CHAIR LUTZ: I think we'll do Jennifer and then Robert.

MEMBER MALIN: I wanted to just speak a little bit into how these were used as part of a VA national assessment of the quality of lung cancer care.

Several of these measures were included amongst a set of measures that included things like receiving adjuvant chemotherapy or palliative platinum-based chemotherapy.

And then the individual results for each of the 138 VA medical centers were fed back to those facilities.

And then for facilities that were scoring lower on some of these measures than other facilities, they could see their adherence to these measures compared to their peers.

And then that gave the facility director and the oncology departments in those facilities the opportunity to look into their own data to try to understand, you know, why were their rates of referral to hospice lower than the facility on the other side of the state?

MEMBER MILLER: So, just a question for Dr. Earle. This is Bob Miller

from Hopkins.

Regarding the numerator and denominator just say patients with cancer, and I just wanted to clarify, are pediatric patients being explicitly excluded, because lower down on target population, it looks like it says adult elderly.

But I just want to make sure that that was the intent was to exclude pediatric oncology patients.

DR. EARLE: That's right. We've never looked at this in pediatric patients.

CHAIR LUTZ: Larry?

MEMBER MARKS: A slim clarification. Help me on this business of we're going to normalize it depending on the type of practice or the institution or the socioeconomic, you know, of the clientele of the patients that are being seen.

Isn't it the idea to have sort of one standard that's across institutions and across all providers?

So how does one operationalize this to deal with transplanters differently or advanced cases or for different people's practices. I don't understand that.

DR. EARLE: I think the analogy to C-section rates, although it may not completely address this.

But it's the idea that if you were to compare transplant centers with transplant centers or VA hospitals with VA hospitals, that looking at relative rates on these measures to identify outliers. That's the purpose. To identify outlying practice is the purpose of the measures.

MEMBER MARKS: I guess when this committee approves, I thought the criteria's sort of rigid, you know?

We make a criteria, you know, the pathology report should always have the grade if there's dysplasia. Or there should always be, whatever, a completion of summary at the end of radiation.

It's not, you know, figure out what's in your state or your environment and then if oh, completion notes are done 70 percent of time in your environment, well that's considered the gold standard. So I'm not sure how you operationalize this.

DR. BURSTIN: Just a brief response on this, this is Helen for Craig on the phone. We do have other measures that look at rates that people don't know what the right value is.

For example, C-section rates, the rate of episiotomy, things that are in clinical practice people consider probably should keep an eye on this rate. But we actually don't truly know what the optimal rate of C-sections are in the United States.

And yet, I think the measure has moved forward. There has been an attempt to at least identify the patients most appropriate for it.

So I think there are other

examples like that, where rate measures don't always have an absolute known value of what it should be.

But I think at times, getting these measures into use, we get a much better sense of what that benchmark is.

MEMBER FIELDS: Well, I guess C-sections aren't. We've done a huge public education activity. But how do we use some of these data for public reporting, then, because the scenario I can imagine is, come to our hospital, we'll give you less chemotherapy sooner.

And you know, whereas we've really looked at C-sections because there's health advantages to the mother and the fetus and we've educated our public on that.

So I just didn't know how we're going to use this data. That's my other question.

DR. BURSTIN: And Craig has had a fair amount of experience with this in Canada

in using the public reporting.

But I'll also point out the discussion with the obstetricans was identical around the C-section measure, in fact, because a lot of moms, in fact, choose that and want that. So it's not as clear cut as, perhaps, we think.

CHAIR LUTZ: Well, do you get a sense, also, in your practice? I mean, there are a lot of individual patients that struggle with whether or not they should get active chemotherapy or radiation if they're close to the end of life.

But there's not really anything for them to hold onto if there isn't an individual discussion. And so I think the time might be ripe for such, you know, measures and discussions.

MEMBER FIELDS: Yes, I mean, I think all these measures, I think all of them are really important measures.

I don't know which one we should

choose because I think that what we see, whoever said it, is when you're on call that weekend and you see the variations in practice, it's really more about how to we get to the point where we are realistically communicating survival-ship data and really having truly that quality of life discussion with the patient.

And so trying to be rigid and put a number of 14 days is the number, when we know that lung cancer we should have probably stopped 60 days before when there's only a couple of lines of therapy.

I'm sorry, there may be lung cancer, or you know, other kinds of solid tumors have less second kinds of salvage therapy versus a woman with breast cancer now, in this decade, has about ten different kinds of salvage therapies that she might go through.

So I think these measures are important and I think the patients ask for

this kind of information. It's just been hard for our healthcare system to give this kind of information. And I don't know if this is necessarily the way to do it.

CHAIR LUTZ: Thank you. Elaine and then Joseph again.

MEMBER CHOTTINER: I have a couple concerns. One of them is that the measure focuses upon physicians and how physicians handle this.

And I think it would be very important to look at the patient population, because a lot of this is driven by cultural things, by education.

And I think a lot of us, even though we have these discussions, are dealing with patient populations that don't really understand.

The second is that our institution uses this measure and presented it at a faculty meeting. And some of the differences were striking.

And I think they have to do, in academic institutions, people who do a lot of Phase 1 and Phase 2 trials are always going to look bad even though they might be within the same sub-set. So I think you need to look carefully at that.

MEMBER BRUERA: And I think, to echo those comments, the 14 day initially, in some of the initial studies from Zeke Emanuel and some of the comments made by the Institute of Medicine, it went as far as 30 days.

The 14 days reflects some reasonably good data about the tenth percentile issues that Dr. Earle made reference to.

And I think with regards to the variation in practice, there is good data out there showing that randomized control trials have shown that when patients access a collaborative practice with a supportive care and palliative care team, these numbers do change.

So that suggests a little bit of what you were so well describing, that there are patient-related cultural issues, communication issues that are more important than the pure biology issues that drive many of these decisions that are measurable and can be followed up over time.

Even within Phase 1 practices, there is wide variation, and we have data on that, for our institution between physician and physician.

So even if you look at a focused group, you would have significant variation in patterns of practice suggesting that, once again, it is more related to this communication than to the pure biological aspects that is driving some of this outcome.

CHAIR LUTZ: I think we were Joe and then John.

MEMBER ALVARNAS: I guess my question speaks to that is because, I mean, we're a center that does a lot of Phase 1

trials.

So you're right, I think if we use this measure, particularly in that population of patients, our outcomes would appear to be concerning.

And I guess I don't know with measures of this ilk, those that are more look at yourselves more closely rather than you're doing a bad job, is there some guidance that can be built within the measure that can articulate that point that this is maybe something to be used for self-reflection and direction of where to do deep dives in terms of quality analysis, because I think the problem with telling physicians that the metric is chemotherapy within 14 days of life, for example this one, is that there will be a great deal of push-back, that that simply articulated as a metric lacks enough nuance to be meaningful within the context of our care.

And again, you've seen these comparable types of metrics in other settings.

Is it feasible to integrate within the articulation of the metric how this is used, or some direction as to how it's implemented, because I think this is very different than, you know, you chopped off the wrong arm or you've done something which is egregious and you shouldn't do that.

I think that given the extraordinary sensitivity with which we, as physicians, approach the issue, I don't think anybody takes life or death issues lightly.

So when we raise questions of either medical futility or even at which point we reach diminishing returns in the use of aggressive chemotherapy, radiation therapy or Phase 1 agents, I think that probably we have to approach that with more finesse then we would otherwise.

And I just worry that the the way that this is written and articulated is that it fails to do justice to those questions, because I think we don't want people to feel

like you're being made to look bad because your patient really, sincerely wanted to be on a Phase 1 trial.

And it just seems to, as this is articulated, lack the nuance that lets us, as physicians, to be fully advocates for our patients without feeling like we are somehow contravening a nationally endorsed metric.

That's my concern and my fear. And that is the push-back that we'll get from our physician population.

CHAIR LUTZ: John?

MEMBER GORE: Just to build on what Dr. Marks was saying, you know, one thing that just strikes me is that we talked about how most of our measures are zero or 100 percent is what we're going for, and this is not something like that.

I think it's, in some ways, analogous to the thoracic surgery measure looking at morbidity and mortality.

But what, I think, is very

different between that and this is that it seemed like they went through a very rigorous process of case-mix adjustment for the thoracic surgery measure.

And there's no effort to adjust by case mix, whether the case mix is the type of cancers you treat.

I mean, the analogy to lung cancer, that's a very specific patient population. And so you should see some homogeneity of practice behavior. But this is just all cancers across all institutions and I wish there were more of an effort to achieve some kind of case-mix adjustment in looking at this outcome.

DR. EARLE: Maybe I'll just speak to that. As opposed to case-mix adjustment, just because maybe, unlike the thoracic measure you're mentioning, this is much less about, you know, age, stage, performance, status, LDHs.

And the type of things that come

into case mix are more what is the disease, what was communication like, what are the resources available in the community regarding palliative care and things like that.

So it's something where you couldn't really case mix adjust and rather than doing that, stratifying to compare, you know, as much as possible similar patient populations is the approach that we've taken.

MEMBER TAPAY: Hi Dr. Earle and others. This is Nicole Tapay from NCCS. I mean, I just wanted to highlight one of the workgroup's points of data that was in, actually, the materials, and it just reflects some of the discussion here.

But specifically around breast, ovarian and leukemia as being kind of exceptional cases in the sense that chemo is given in a higher percentage of that population.

And I can speak from personal experience because my mother, she lived four

months with advanced ovarian after the last chemo. And there was a very frank discussion that I was a part of with the provider about this likely being futile.

And I don't know, frankly, if that added to it or not in terms of when she died. And I think, you know, there's a lot of conversations that obviously go on about endpoints and at what point you're adding months or days, et cetera.

But I think just to echo some of the comments that have been made about what is the right practice, and also saying that that may reflect cultural and other norms where frank conversations weren't being had.

I was part of some really frank conversations at NCI in the last year of her life in a Phase 1 or 2 trial, 2 I think. Yes, sorry I forget. But as well as this final conversation with the provider before, and she did go into hospice in the last month.

So I would just say from the

patient perspective, I think I'm a little torn, because she falls into, with that type of cancer, one of the types where it is more the norm to give it in the latter part.

And where I do believe, actually, that both the NCI early phase trial as well as this last chemo may have extended her life to at least a significant degree that is not minimal, and I also would imagine somewhat representative.

So I would echo the thought of if there's any way we can add any kind of nuances to the measure while recognizing as being part of the workgroup, I also was convinced, after listening to the experts who worked on this for a long time that it has a validity and a usefulness.

But I think, you know, we're treading a fine line, in my opinion,

CHAIR LUTZ: So we'll go Larry, Karen and then Jill.

MEMBER MARKS: I think these

metrics are very good. They're clean, they address relatively straightforward ideas that I think we all sort of agree with.

And every provider doesn't need to use every metric, right? So if you're a transplanter, you can choose not to use this metric, I guess. Right?

In my center and other places I've worked, you know, if I wanted a patient to get more chemotherapy, I knew who to send the patient to. There are certain doctors that tend to view more aggressively, and then the patients would seek them out.

So are these metrics are all on a per doctor basis, or can they be on a per group basis?

DR. EARLE: Well, like everything else, it all depends on reasonable sample sizes. And so, in general, I would say the way it's been operationalized has probably got down to the level of an individual practice such as in QOPI or Jen was just talking of the

VA hospitals.

That's probably the level that it's gotten down to. When you get down -- you could look at individual physicians, but you would need to have enough patients to make it reasonable to do that sort of comparison.

MEMBER MARKS: So I think it's more valid if you don't go down to the physician basis. There might be practices where one person is doing the Phase 1s, the other person is not. So overall the group might have what would be an acceptable rate when there might be individual practitioners who might appear to have an unacceptable rate.

DR. EARLE: Exactly. And that's where it also can reflect the resources in the health system in that area.

MEMBER FIELDS: I just wanted to clarify. When we're talking about treatment, it's really only chemotherapy.

And are we talking about only intravenous chemotherapy, because there's some

oral agents or other antineoplastics that might actually be very helpful for palliating patients with pain.

And also, obviously, radiation therapy's probably still useful at the end of life for pain control. So it's really just chemotherapy is the measure?

DR. EARLE: Right. Cytotoxic chemotherapy, not necessarily restricted to intravenous. But that's what the measure is about.

MEMBER FIELDS: Okay.

CHAIR LUTZ: And just a quick update, actually, from the radiation side, we are looking into other similar types of measures, fractionated and also the end of life.

You know, if you are trying for pain relief and it takes some months to get full pain relief, do you really benefit if you do it within a week of the end of life? So we're looking at all those things. Elaine?

MEMBER CHOTTINER: Recognizing that we can't propose changes, I would say that this measure should exclude patients who are on clinical trials because those patients are vetted to have a reasonable performance status, and it also encourages the use of trials for people with advanced disease instead of just using what's available.

DR. EARLE: Yes, that's fine, as long those patients can be identified in the data set that you're looking at. Most clinical trials require a three-month estimated survival at the start, as well.

So, you know, I think even in clinical trials, most people are not aiming to have chemotherapy right to the bitter end.

But yes, there's no problem making any of these sorts of exclusions, as I say, in an attempt to stratify and compare like patients to like. And it depends on the data available with which to do that.

CHAIR LUTZ: All right. Does our

silence mean we're headed toward a vote? Or do folks need a minute to gather their thoughts? It's a good discussion, it's a very good discussion.

MEMBER LOY: Are we voting on a exclusion of clinical trials for all of these measures, or just this first measure that we're talking about? And what types of clinical trials are we excluding?

CHAIR LUTZ: No, I think we'll not vote -- yes, voting on as-is.

MEMBER MARKS: Again, if a practice has a lot of patients on clinical trials, they could choose not to use this metric.

DR. BURSTIN: And I just want to clarify one thing, though. NQF endorsement means the measure is appropriate for quality improvement and accountability.

It doesn't necessarily mean public reporting. But it could be used in board certification, it could be used in pay for

performance, it could be used in a variety of mechanisms.

So I don't want to have this, it seems like there's a little bit of an assumption that, just, it's okay internally. This is a measure that would be, and again, if somebody picks it up for that purpose, could be used in those other applications as well.

And I guess the question I would just have for Craig about clinical trials is I just don't know how well clinical trials are coded in ICD-9 coding and it would just be a concern.

Again, we've seen, certainly when things like this are put into measures over time, the coding improves, if people are concerned about making sure they get the exclusion. But just a question for Craig if that's been looked at at all.

DR. EARLE: So clinical trials are generally not identifiable in administrative claims like Medicare claims. And so that's

why I say it completely depends.

If you're in a system that is able to identify and exclude those patients, then that's perfectly fine in an attempt to compare like to like.

If you're not, then, you know, if you're comparing Dana-Farber to Sloan Kettering, you presume that there's going to be a similar proportion.

CHAIR LUTZ: Jennifer?

MEMBER MALIN: I was just wondering, not kind of at this point, but sort of over time if it would be something where it might be feasible to look into obtaining a G code to identify people who are on trials?

I mean, I think that could actually be useful for probably adjusting a number of measures.

MEMBER BRUERA: And I would echo that. Our data and I think there are some other data suggests that even for clinical trial accrual, the results can be dramatically

different.

And these results over three months can be sometimes not estimated in a very accurate way by some people and very accurately by other people.

So even within those cohorts, it would be of some usefulness to have some data. Not to just consider it just because there are criteria one would 100 percent exclude that practice, but perhaps make sure that one compares apples with apples and pears with pears.

CHAIR LUTZ: Okay, anyone else? So you want to do a vote?

MS. KHAN: Voting on 1A impact?

CHAIR LUTZ: Sorry. It's the first measure. We'll go one by one through, although I assume many things will apply throughout. But we're voting on the first Measure, 210. Chemotherapy in the last 14 days of life.

DR. EARLE: Yes, and unfortunately

I'm going to have to ring off in a couple of minutes. I think, as you just said, that the issues are pretty similar for all of them.

And if there is a specific question, Tom Murray, I think, is in the room and could email me. And even though it's bad form, I could be trying to check my BlackBerry in other meetings throughout the morning.

CHAIR LUTZ: All right, since we just had Naomi join us, are we going to vote again on that? Is that what we're doing? Okay. Now that everybody has a voting thing in their hand, let's go for it.

MS. KHAN: Okay, it's 1A on impact.

MEMBER BRUERA: It's not working.

CHAIR LUTZ: Maybe while we're waiting, since I think Naomi, you were not able to join us yesterday, correct?

MEMBER NAIERMAN: That's right.

CHAIR LUTZ: So we were hoping to give you the opportunity to introduce yourself

and tell us if you have any conflicts of interest and do whatever else you can do to entertain us while we're trying to get this fixed. We would appreciate it, whatever you do, you know, imitations or bird calls.

DR. EARLE: And actually, I'm going to turn into a pumpkin.

CHAIR LUTZ: Thank you so much, Craig. We appreciate it.

DR. EARLE: Talk to you later. Thank you. Okay, bye.

MEMBER NAIERMAN: I'm the CEO of American Hospice Foundation. And what we try to do is look out for consumers, dying people and grieving people.

And one of the things we're doing right now is designing a hospice public report on quality of care.

Fortunately, NQF just endorsed, actually re-endorsed a set of measures, PHEC measures and we're about to go in the field and see if they're actually meaningful and

accessible to consumers, those who have never really experienced hospice indirectly through family members, and those who have, only because they've only been tested in the past with people who have just finished a hospice experience as family members.

And we do have a design already that Shoshanna Sofaer has actually developed for us and a public report is on our website.

But we have since learned that there are other features, like customization, that could improve it. So we're on our way. We're hoping, actually, to build the first hospice public report, hopefully in California.

We just did a survey of all California hospices to find out if there's a substantial number, a critical mass of them that would report the PHEC measures voluntarily. And indeed, there are.

You may know that in California, there's been a lot of bad publicity, even

fraud cases, brought against some hospices that have a presence in California.

So the other is a feeling, a shadow cast over them. And they are eager to share their PHEC data with the public. And the question is how best to do that. So that's one of the things that we're doing.

We're also doing workshops all over the country on pain and dementia. That's a topic that has hardly been addressed in the past. So we have a grant for the Purdue pharma to do that, among other things.

CHAIR LUTZ: Thank you. Are we good to vote?

MS. KHAN: Yes, I think we are.

CHAIR LUTZ: We think we're good to vote.

MS. KHAN: I think so.

CHAIR LUTZ: Yes, we're doing question 1A for 210.

MS. KHAN: So you can go ahead and start. There we go. We have 12 high, four

moderate, and one insufficient. 1B, performance gap? So we have nine high and eight moderate. And looking at 1C, evidence? We have 13 yes and three no, one insufficient.

So going onto scientific acceptability and reliability? Nine high, six moderate, two low. And validity? We have four high, nine moderate, three low and one insufficient.

And going on to usability. We have six high, seven moderate, two low and two insufficient information. And feasibility? We have seven high, six moderate, two low and two insufficient.

And overall suitability for endorsement: does the measure meet NQF criteria for endorsement? So we're one person short. We were doing so well. All right. It's 15 yes and two no. So the measure will pass.

CHAIR LUTZ: All right, so the

next one is 0211, which I think I have now.

Oh, it's Eduardo as well? Okay. So 0211 is proportional with more than one emergency room visit within the last days of life.

And since I think Craig already gave us a general overview, if you want to, Eduardo, you might as well just go ahead.

MEMBER BRUERA: Yes, this adds to the same tone as the other conversations that took place. So I think it's not a significant departure from the issues that had been discussed.

The data is based on similar cohorts from SEERs, Medicare and the Dana-Farber. And again, they showed considerable variation.

These measures are all intended to be seen as measures for the purpose of comparison rather than yes or no measures, and therefore, useful measures for monitoring.

It is clear that emergency rooms

are highly distressing and generally undesirable. And for that reason, although they need to happen in many cases, monitoring the frequency of these events is very useful.

And so, therefore, there was a general feeling that this was a useful measure and should be brought up to the full committee for consideration.

So unfortunately we don't have the developer. But I think it's the same discussion on the same cohorts and I wonder of some other members over the group would like to make some comments.

MEMBER MALIN: I think this is a useful measure of access basically to, you know, other sites of care. And really resources that are made available to people so that they don't, you know, have the emergency room as their only option.

And I think the other thing I just wanted to say is, I think the three different measures: emergency room visits, admissions to

the hospital and admissions to ICU, I think in some ways need to be considered together because ICU differs from hospital hospital in terms of what constitutes kind of, you know, high acuity care.

But if someone gets admitted to the ER, they may not show up as a hospital admission. And so I think we really need to be able to understand the three together to make sense out of the data.

CHAIR LUTZ: I agree completely. In our practice, we have two very busy medical oncologists, each of whom are not particularly good at having end of life conversations and probably overtreat and overadmit people.

One who always sends people to the ER, and the other one who always does direct admits. So unless you have them paired, I think, you know, you're going to have a hard time figuring out what quality really is.

MEMBER FIELDS: Although I think this measure and the other ones are much more

reflective of how to increase resources and activities around the disease, because I think this much more reflects than -- 14 days of end of life reflects physician practices a little bit more and maybe the system.

This reflects the system. If you don't have adequate support systems, so I think this is a more useful measure about how to really improve a regional care pattern than the other one.

CHAIR LUTZ: We'll do Bryan, then Naomi?

MEMBER LOY: Yes, I also share the concern that was expressed about looking at the system rather than the components independently.

The other concern, and I'm just curious if your workgroup spent any time talking about unintended consequences here.

You know, access to hospice care and other care can be troublesome in some areas of the country and I worry about, you

know, what the intent of the visit to the ER was.

If it's, you know, unmanaged pain, I worry that we might have some backward pressure because of a measure that would say, you know, it's not desirable to go to the ER or have someone seen at the ER or sent to the ER.

CHAIR LUTZ: Well, and I will say actually, I think all these measures were first brought up in the end of life steering committee last July, I believe.

We spent a lot of time talking about exactly that, unintended consequences. And even several months later, I still have some of those arguments going on in my head. Naomi?

MEMBER BRUERA: I think one of the points that were brought up that in our group, in our working group and before in those discussions, as is very well pointed out, these unintended consequence requires that it

be understood that this is after death, Monday morning quarterback.

And therefore, one should never have a yes or no, 100 percent or zero percent. But clearly, a comparison and basically, including the referral to hospice or the bounce back from a hospice might refer much more to very poor hospice care rather than the oncologist's treatment of that patient.

And that is also something to be nicely monitored. And I hope Naomi's group will, you know, use their machine guns to make clear that that measure not only reflects on the practice in cancer but on the practice in hospice for these patients.

Perhaps the one that was a little bit more clear-cut was one that will come later is the ICU, because from the Institute of Medicine to everybody else including ASCO, that is considered to be much more tragic in terms of the suffering component as a one.

But these ones, like referral to

hospice or the access to the emergency center reflect a complex system interaction. We know that hospices see cancer as bad business.

So they run away from 85 percent of their business to about 35 percent of their business. In many regions, there's some concern or reluctance to take cancer patients by some hospices.

And I hope this is going to be a major item into the future. So your point is very well taken, and it was considered in the unintended consequences discussion that these had to be seen in a wider context than being assessing only an oncology practice.

It was felt to be a very useful measure. But the interpretation of it had to be a little bit more systemic rather than thinking that it's only the practice of that particular oncology group that resulted in this outcome.

CHAIR LUTZ: Naomi?

MEMBER LOY: Oh, I'm sorry. I

just wanted to respond.

CHAIR LUTZ: It's okay.

MEMBER NAIERMAN: Go ahead.

MEMBER LOY: I would just say, and I failed to make this point, I think I would worry much more about an ICU patient that had been an acute admission that was referred from the ER that was a result of an EMT call than I would be for someone that showed up in an ER for unmanaged pain that, you know, maybe was at day 13 or day 29 in this case.

So it feels like that there is an egregious side to this continuum versus an acceptable medical care. And trying to sort through all of that individually seems far less valuable than looking at it collectively. So I guess that was a point I didn't make. And I'm sorry, go ahead.

MEMBER NAIERMAN: That's okay. Well, I think it's really important to remind ourselves, in all of these measures under palliative care, that what we're looking for

is patterns.

Yes, there are going to be unintended consequences for some of the patients. But if we see patterns such as the patterns we see now in the Dartmouth Atlas of huge variations, geographic and otherwise.

And in this case, it'll probably reveal variations among practices if there's an unusual number of patients who die in the ICU, emergency room and so on, then I think that's what we're looking for.

We're not looking for the occasional patient that might need emergency refuge. The other thing I wanted to address is what you said about hospices resisting cancer patients.

As far as I know, the reason is that the cancer patients are very often referred very late, which is ironic because one can believe that, can assume that cancer is much more predictable than most other conditions that a person dies of.

But the patients that hospices don't resist are those who come in for three days. And by the way, that's the mode, three or less days is a number a huge number of patients that come to hospice.

Not only is that stressful for the staff, it's terrible quality for the patients. So I would imagine that hospices would prefer cancer patients, say, to dementia patients who are not communicable and one doesn't know when they're going to die, and consequently may have to be readmitted to hospice.

So that is a system issue. If you get cancer patients into hospice for a couple of weeks, or enough time to really get them the kind of care that hospice can deliver, then that's a totally different picture.

But 30 percent of patients in hospice are there for less than a week. And most of those, I would imagine, aren't cancer patients.

So I think it's the resistance and

reluctance on the part of the physicians, that's my guess.

CHAIR LUTZ: I don't know if Robert or Karen wants to -- go ahead.

MEMBER MILLER: Sure. So, you know, as an informatics person, unintended consequences is what keeps me up at night the most.

So I guess I worry about, a little bit about, I want to make sure all these measures are as precisely specified as possible.

And I keep reading, first thing I've gone to in all my analyses has been the reliability section, because that's where unintended consequences can really bite you.

And I don't have any huge concerns with this. But, you know, I worry about, this is a measure that really is going to rely almost exclusively on administrative data, if I'm understanding this correctly.

And so if you look at, if anyone

is following along, it's 2A 1.7. But the denominator details, this requires that cancer be listed as the cause of death in the death registry.

And again, as a clinician who's filled out these forms, you know, I know it's only as good as the data that goes in. And then I start to think, you know, how is an ER coded? Is every ER visit, is there a standard code for that and so forth?

And, you know, I could envision a single glitch in the coding in one hospital where the place, and Jennifer may know this better than I, because I think you've just done the research, but you know, are we sure that that's the same code in every place that's going to be looking at this data set?

I mean, you know, maybe certain centers or certain hospitals call their ER something else, and so forth. And so, those are just the small things.

And this could apply to any one of

these, so I'm not trying to hijack this just based on this one measure.

But these are the kind of things I think could -- we better just be absolutely certain we're all comfortable with that, because I, like I said, having filled out cancer registry forms on my patients before, you know, I know how hit and miss it can be.

So maybe that's more of a rant then a question.

CHAIR LUTZ: Karen?

MEMBER FIELDS: Two comments. First, I agree with Dr. Bruera that regional variations in hospice are tremendous, including accessibility to inpatient facilities.

In many parts of the country, there's not even adequate access to inpatient facilities.

And as long as that's going to be the way we've distributed our resources, it's going to be very, very difficult to address

some of these kinds of activities, because that's why the patients end up using more expensive inpatient kinds of facilities.

So I think we can't understate the importance of improving the quality of hospice. So I don't really think patients don't get referred to hospice because of doctor's reluctance.

I think that there's a huge variation in the ability of hospice to help with end of life. And I think you probably have lots of experience because you see patients coming from all over, and you've seen the regional experience. I have as well.

Number two, my other question is that benchmark. Less than four percent is a low number. But I still don't completely understand how we get to those kinds of numbers.

Again, they described it as the tenth percentile. But if less then ten percent is the best, and this one it's even

more dramatic, I think. If the tenth percentile reflects the practice, and you don't have adequate inpatient hospice facilities to deal with all of these issues around the country, then how can you compare a city like Los Angeles to a city like Las Vegas where there were 14 inpatient beds for 2.5 million people?

It's a very dramatic difference in accessibility. And I think I can't stress how important it is for us to understand what these benchmarks really mean and how they'll be used.

CHAIR LUTZ: Elizabeth?

MEMBER HAMMOND: You know, I think one of the blessings, actually, that's a way of helping our society change is if it turns out that when we measure this that we see a lot of variation, then in one place or another, there will come evaluation of those differences and maybe societal changes in those places.

But without measuring, we're never going to find that out. So even though, there will be those differences and there is differences and problems with patients in various places, I think that measurement is in and of itself an important aspect to help us make changes in society and make changes in areas that will help patients.

MEMBER BRUERA: Yes, and that was exactly what our group felt that this is a measure that is a very useful patient-based measure, very hard.

Reassuring Dr. Miller's comments, we found that the retrieval of these, at least in studies that we're doing in a number of places, including studies that we did in the Houston region and so on, is quite reliable because for hospice referral, there's a specific Medicare access code that is reasonably easy.

And for billing from emergency room is also very good from the billing

perspective.

But the interpretation of these would be extremely useful because a patient who goes to an emergency center might go to an emergency center from the oncology practice, or as we see very, very frequently in cancer centers, from the hospice practice.

And that would reflect on who is doing a reasonably good job or not doing a reasonably good job. So it would be a very useful measure of both aspects of care.

CHAIR LUTZ: Jennifer?

MEMBER MALIN I wanted to touch on some of Karen's concerns. And I think, you know, I was first introduced to these measures probably close to ten years ago.

And I think initially, you know, I shared many of the same concerns. And I think part of it is, as clinicians, it's hard to be held, I think, accountable or to have our care assessed when it involves a lot of structure that we don't have control over.

And I think that's the issue with these measures is that it's not just kind of the process, like what we do in the OR or where we give people chemotherapy, that we feel, relatively speaking, we have control over.

It involves lots of other parts of the healthcare system. You know, many parts that we need to change.

And so I think -- I mean, I guess over time I've become just more comfortable with that and see it as, you know, by adopting these kinds of measures it shows our willingness to take leadership in terms of, you know, pushing the kinds of change that need to happen in our communities.

You know, it really shouldn't be okay to have a community where hospice isn't accessible to patients.

CHAIR LUTZ: Karen?

MEMBER FIELDS: Yes, and I used to have an average referral date of like 60 days

or something. I used to be the leader in my community. I've always used and accessed it.

However, the difference, I think, is another unsaid difference which is we have for-profit and not-for-profit hospices around the country. And I think that makes everything very, very cloudy in accessibility for our patients.

And you know, so when you talk about accessibility, I just lived in a community where you couldn't easily get access for your patients if they weren't insured. And we had a huge uninsured population.

And, you know, so it's even more dramatic when you add some of those other kinds of consequences. And it's not the same thing as you walk into an ER and there's a law that says we have to treat everybody that comes into the ER.

If you can't access a good, decent hospice facility for a patient, until we start to address some of those kinds of things, it's

going to be very hard for us to address the systemic problems.

And that's why my big concern is, like, if we're going to hear you announcing that these could be endorsed for pay for performance later or things like that, then these thresholds are so variable around the country, it's very, very difficult for us.

It should give us some pause about that measure when there are so many systemic issues that interplay. And this has such a low threshold or target threshold.

And I understand, when I read it the first time, I got a little more excited about it.

When I read more than one, that makes it a little bit more reasonable, because hopefully somebody would intervene better if there was one ER visit.

But I still think this one is so reflective, and the other ones that we're talking about being paired with it are so

reflective of a systematic problem.

And it gets hard for me, as a physician, in the end, to understand that we'll be measured with a threshold on really things we don't have a lot of control over.

So unless we got to the place where we were going to say, you know, every hospice has to do a better job of taking uninsured or unfunded patients, it's really not the same thing as accessing acute care facilities.

CHAIR LUTZ: Helen?

DR. BURSTIN: Just one response, and those are great comments. The inclusion of the benchmark is not technically part of the measure specifications.

That's really from Craig's research, empirical data they've used so far. So that's really, I just want to make that clear, that's not part of the specifications.

MEMBER FIELDS: You're just telling me our goal will be, as a country,

we'll just start measuring.

DR. BURSTIN: Exactly.

MEMBER FIELDS: And pay for performance, how would we interpret that in a pay for performance?

DR. BURSTIN: Again, I don't think we know that yet. I mean, and there's no guarantee that it'll get picked up. I mean, usually there's a period of time during which people will start to use NQF-endorsed measures, oftentimes internally first.

They will then gradually be used for other purposes. They don't necessarily on, you know, Day One get picked up and get put into a program.

I mean, ASCO maybe is already using them as part of QI. Maybe other efforts, perhaps, you know, maintenance and certification.

Those are considered accountability applications as well. So it isn't always just going directly to public

reporting. But again, some of those could be picked up for those purposes as well.

Yes, exactly. It could be picked up anywhere along that path. So I just need to be honest that that's certainly a possibility.

But it would not include this benchmark of less than four percent. That was their internal work, it's not part of the measure itself.

MEMBER FIELDS: Thank you, because that, to me, when we looked those benchmarks across that are included, or target benchmarks, if we don't know what the measure is and we've got target benchmarks, that's terrifying to think that we have absolutely no control over big chunks of this pie, which is accessibility for our patients and inadequate resources.

MEMBER BRUERA: And this was part of an extensive discussion about the unintended consequences.

And it was quite clear, and I think I appreciate the comments from the NQF team because we clarified very well that the importance here was the actual conduct of the measure and the monitoring.

And then, your point, Karen, is very well taken. In Houston we have 47 different hospices that are registered. And you have from extremely good to a disaster ones.

And therefore, measures might be useful to monitor that aspect of the equation, too. So in other areas where you only have one, because they have a monopoly, then it might be a very easy measure to see how they're operating.

CHAIR LUTZ: We'll go Heidi and then Naomi.

MEMBER DONOVAN: So I agree with much of what Karen said, and feel like actually that becomes an argument for the measure.

That we have measures that represent, sort of, patient, provider and systems-related measures of quality.

And that what we're talking about here, really, is healthcare disparities and systems-related contributions to healthcare disparities.

And this, right here, is a measure that can really tap into that, and as Elizabeth said, may really be a measure that could drive policy-related decision making to reduce healthcare disparities, which I think much of this is what we're about.

I mean, we have talked about other measures that are sort of individual level measures of quality. But this right here is really a systems level healthcare disparities measure.

CHAIR LUTZ: Naomi?

MEMBER NAIERMAN: I think that if you think about the patient, there's one thing we know for sure, and that is most Americans

want to die at home. And if they're in a nursing home, then that's their home.

And if there is, in a particular region or a particular city, a high incidence of dying in emergency rooms or ICUs, then it's terrible care. It's not just obvious, it speaks for itself that it's terrible care. We know that it's not what patients want.

So if nothing else, it could be a red flag. And I think that, of all the things we're considering, we should be looking for spots in the country where there's a lot of people who die in these situations that none of us want to be in in our last few hours or few days.

So pay for performance, I understand, but as a red flag to look for where we're failing from a systems point of view, this is very important to monitor.

CHAIR LUTZ: We'll do Larry and then Karen.

MEMBER MARKS: I'm a little

confused. I thought the goal of these metrics were to drive reimbursements or some quality metric for the government to decide who's providing good and bad quality care, I thought.

So yes, it's a red flag, could be a red flag, but it could have all sorts of unintended consequences.

So imagine if this is made as a metric, so it's not too far-flung to say okay, Medicare will stop paying for admissions that happen, or ER visits. They just won't pay. Never mind pay for performance, that just will not be covered.

And that doesn't quite seem right if that's sort of out of the controls, all these societal things. Yes it's terrible that the infrastructure is bad, but it's sort of, I don't want to say it's not the doctor's fault.

But these are doctor-specific metrics, I think. Not health system, you know, the City of St. Louis or the City of

Cleveland. These are doctor-specific, and so much of this is out of our control.

I don't feel comfortable with this. Much of the chemotherapy orders, as was said before, the medical home's writing an order. They have control over that. They don't have control over whether there's a hospice, whether the family has good support, et cetera, et cetera.

I understand there's a motivation to maybe measure it, it might be a red flag. But that's not exactly what our charge was, I don't think.

MEMBER BRUERA: Yes, I think our group looked at some of those important issues. The outcomes are going to be mostly patient outcomes, patient-based outcomes rather than purely a practitioner-based outcomes.

Now, they might reflect the side of us in the cancer center, they might reflect the side of the hospice center that received

the patient. But it would be reasonably easy to tease that out.

The data would be very robust to be able to tease out those aspects and predominantly to look for variation within groups. It's not so much to look at yes or no for reimbursement.

It would be likely that UnitedHealth, that has said they're going to pay for performance. They might say: you might be in the outlier group of C-sections, rather than we're not going to pay for a C-section whenever you do it.

I don't know if that makes sense. If you happen to be in the five percent lower, then CMS might have some general practice.

So the use of these measures is likely to be based on cohort data and it's very, very unlikely that any of these measures would ever be used on individual case basis, unless you're able to, as Dr. Gore's outlined

so well, become so sophisticated in the stratification of each of the prognostic factors that you might get to a situation of no, no. But that's not likely to happen for a huge number of time.

CHAIR LUTZ: Well, and not to play devil's advocate, and it's not exactly a correlation, but there's an anecdote where I had someone paid by Medicare call me and say: We've looked at cases three years ago. We don't like that we paid you this money; we would like it back.

They didn't pay me. I was part of a system. Someone else in the system had been paid the money, they wanted it back from me, because it was the most convenient and that's what it said on their sheet.

Twelve months and several conversations with the Attorney General of the State of Ohio later, they just stopped. No more requests. No "sorry," or "this is how we messed up."

So there can be retroactive, unintended system failures that are placed on an individual when that individual not only didn't have any say in it, but didn't even get the money. It happens. It happened to me.

MEMBER FIELDS: I think these are very important measures and I think we do need to get to a place in our country where we've got adequate resources.

And we've come to some conclusions about how we're going to manage patients at the end of their life, and what the definitions of quality are.

I just worry about how this data will be used. And that's a good example of how the data could be used versus what we really need, which is more and better hospice care at the end of life for our patients.

MEMBER NAIERMAN: I have a question. You mentioned earlier, Steve, that your practice has a couple of physicians that have variation among them.

So what would happen if these measures, these three measures were instituted and there was going to be some monitoring going on?

CHAIR LUTZ: I think if there was no monetary difference, nothing would happen. If there was a monetary difference, then the one that sends people through the ER to become admitted so they don't have to come in and look at them first would just send them direct admit.

But I think both would inappropriately admit up until the last days of life to avoid having the conversation that they need to have with the patient. I don't think it would change anything.

MEMBER NAIERMAN: So money would drive it?

CHAIR LUTZ: Absolutely.

MEMBER NAIERMAN: Okay, so that argues for pay for performance, right?

CHAIR LUTZ: As long as you can

measure the performance. I mean, you know, it's like trying to block water. If you dam up this way, is the water going to run around a different way to get to the --

MEMBER NAIERMAN: Yes, I understand. But the three of you; you've got two other physicians and yourself?

CHAIR LUTZ: They're not in my -- they're two separate medical oncologists from each other and from me, but yes.

MEMBER NAIERMAN: Yes, but there are three of you kind of in the same system. Hospices are generally available.

CHAIR LUTZ: Very good hospices.

MEMBER NAIERMAN: So how are we going to make those two physicians accountable?

CHAIR LUTZ: You know, you and I looked at all these back last July, and I have struggled in my mind ever since about whether any of these would change those behavior patterns.

We're not supposed to compare. I only found two that might. We've already passed one. This isn't the other one.

MEMBER NAIERMAN: I'm sorry?

CHAIR LUTZ: Of the seven measures.

MEMBER NAIERMAN: Oh, yes.

CHAIR LUTZ: I don't think this is going to change, I mean again, it's a local --

MEMBER NAIERMAN: It's just the money, the reimbursement or the disincentive?

CHAIR LUTZ: Yes.

MEMBER MARKS: Could I respond to Naomi's question? And I guess in that scenario, the right metric should be: did the doctor make a referral to hospice? Or, if the hospice wasn't available, did the doctor write in their note "I would refer them to hospice if hospice were available?"

That is a direct measure of the physician's actions, rather than the patient went to the ER because there was no support

structure and they had no family and hospice wasn't available.

It's just more proximate to the physicians actions to say: did they refer to hospice?

MEMBER NAIERMAN: But if you have, in the same area, physicians who do refer to hospice next door to physicians who send their patients to ER, then you know something.

MEMBER MARKS: I agree there's something there. I'm just trying to figure out what the right metric is to measure the physician's actions more directly.

MEMBER NAIERMAN: Yes, I would be looking for the outliers like those two physicians, yes, in the same community.

CHAIR LUTZ: Heidi, are you still --

MEMBER DONOVAN: No, I'm all right.

CHAIR LUTZ: Just checking. All right, another good discussion. Anyone else?

DR. BURSTIN: Question for Tom, actually, since we lost Craig. Tom? Sorry. Don't want to surprise him.

One of the issues that keeps coming up is the level of analysis. Is the level of analysis for this measure at this point physician, or is it physician group, or is it higher?

Do you have a sense of it? I was just trying to find it on the form. It just lists out everything, and I was curious what level of analysis was intended.

MEMBER BRUERA: It's cohort data. That's what you're asking? How the SEERs data was analyzed and the Dana-Farber?

DR. BURSTIN: No, I understand the testing that was done and the level of analysis. But they put forward the measure, and checked all the boxes.

This was an issue -- Dr. Fields raised another about what level of analysis would you use for this measure? And it

currently says, thank you for providing it, clinician, group or practice, facility, health plan, integrated delivery system, it goes all the way up.

MS. BOSSLEY: Helen, it's not individual clinician, though. It's just group. How the taxonomy is, it's group and higher.

DR. BURSTIN: Oh, it's only group or practice. Okay, so I was trying to understand that, okay.

So group or practice. Some people have brought up issues about individual docs, and this is not at the individual doc level. Okay.

CHAIR LUTZ: All right, time to vote.

MS. KHAN: So 1A, impact? So we have ten high, four moderate, one low and one insufficient. And 1B, performance gap? We have ten high, three moderate and three low.

And 1C, evidence? Eleven yes,

three no and two insufficient. And going on to reliability? We have seven high, three moderate, five low and one insufficient evidence.

Validity? We have five high, five moderate, five low and one insufficient. And usability? We have five high, four moderate, six low and one insufficient information.

And feasibility? We have six high, seven moderate, and three low. And overall suitability for endorsement: does this measure meet the NQF criteria for endorsement? We have ten yes and six no, so the measure will pass.

CHAIR LUTZ: Okay, Naomi?

MEMBER NAIERMAN: I just want to say something, sort of an overall comment. There is definitely a majority of the folks here who are voting on these measures are clinicians, that's my guess.

And I'm just wondering that when you're voting on these, maybe you can split

yourself in half and think about, as a clinician, but also as for yourself or your mother or your grandmother as to how you would view or what you would like to see in the system improve, assuming that it's a valid and scientifically strong measure, because what I hear, and what's predictable is that as clinicians, we would try to, or as providers we would try to make sure that there are no unintended consequences and that we won't be held accountable for things we don't have control over.

But on the other hand, they're very important to measure from a patient-centered point of view.

CHAIR LUTZ: Well, I can only speak for myself, but I think I'm hearing mostly conversations about patient issues. I think unintended consequences for patients or patients being denied care. I think that's being taken into account by everyone.

All right, I think we've made it

up to 0212, proportion with more than one hospitalization in the last 30 days of life. And I think Dr. Bruera is carrying a lot of water this morning, he is.

MEMBER BRUERA: I don't know why there is zero comment about that one. But the concept was pretty well identical to the ones that were discussed before.

The cohort is the same, the second cohort is also the same. And so I am not sure I can add any more comments to this one. I don't know if any of the people in the group would have any other specific comments. But it's basically the same as the other ones.

MEMBER MARKS: It's closer to the ER one than the chemotherapy one, correct?

MEMBER BRUERA: I would completely agree that that's more likely to be, yes.

MS. FRANKLIN: Bryan?

MEMBER LOY: Just from a payer perspective, what are the issues that I think about?

Many claims that get processed by payers, if they are admitted as part of an ER, depending on how the contract's written, they'll ultimately show up as an admission and not as an ER visit, when in fact, it may have touched both points of care.

And I'm wondering, you know, in terms of reliability, usability, I think the one thing that we don't want to promote here is, I think, it was previously stated that you don't want folks saying oh, I don't want to be in the ER now, I want to go straight to an admit to avoid this.

I'm just wondering, was there any thought given to how the data could be interpreted in a usable way given all the constraints that we have around claims?

And then I think the other claims related issues is I was listening, I think it was Helen that mentioned that this is at a particular level.

And as I think about how folks

contract with payers, you know, many times you'll have an individual tax ID number for one group, and that group has a lot of flux in and out.

And as I think about what's going on in our nation in terms of oncologists, you know, coming together, being purchased by hospital systems, it makes me think, boy, this is a real confounder in interpreting the data.

There's a flux and then there's a synthesis of practices. Any thoughts on how that --

MEMBER BRUERA: Yes, thank you very much. And that was one of the points of reflection.

Certainly, the Houston community has seen exactly your point in which doctors have gone from 65 percent private practices to 35 percent in only five years by the ACOs and all that.

And therefore referral patterns, particularly when the patients become very

ill, have dislocated completely in a short period of time.

The interesting part of this measure is that it measures more than one hospitalization, meaning by that, it is not one shot.

Is the repetition of the pattern when perhaps that hospitalization within the 30 days would have helped kind of decide the trajectory rather than resulting in two, three, four, five, six during the last 30 days.

So from that perspective, it was perceived as being reassuring the fact that that is more than one. And that's what, perhaps, might help.

The second point was, as it happened in the other measures, this was felt to be an important measure for monitoring, not for a yes or no decision as to if the second or third hospitalization occurs, then you will not be eligible for a certain level of

reimbursement, but rather appropriate comparison of cohorts.

That is, perhaps, the most important issue. In Phase 1 or bone marrow patients, it might be a percentage of 30 or 40 percent that becomes an outlier, while in other areas, it might be a much lower percentage that results in becoming an outlier.

So we think that unintended consequences, as Stephen very well pointed out, can occur even in the most successful and ethical practices.

But it provides a very useful measure for monitoring on an ongoing basis. But the interpretation, we unfortunately cannot completely control.

CHAIR LUTZ: Naomi, are you, oh you're fine. Bryan, did you have something? Oh, okay.

The only question I was going to ask, and this is an informational question

because I'm ignorant to these issues because I don't admit.

But I keep sitting through physician staff meetings, in fact one last week that was very lengthy and dealt with, you know, patients, are they hospitalized, are they 23 hour admit, are they observation? Can we push them over to the SNF, can we bring them back from here?

I mean, I'm just asking for information, can you get all this data and figure out, you know, whether someone's truly hospitalized or not, because I'm confused about what being hospitalized means anymore, increasingly so.

And, you know, as an outside observer, but can someone help me with that, or is there no helping?

MEMBER LOY: From a payer perspective, we can't always know for all the reasons that you just said. And, you know, Medicare has their own rules. Private payers

have their own contractual agreements that they have.

So as I said, you know, an ER for one group, an ER visit that gets admitted within a time period gets coded as an admission.

And, you know, we're blind to whether or not it was actually an ER visit in the claim or not. So you would have to go to a chart review there.

And as I think about, you know, your other statement about admit versus observation, there are particular rules around that, both that are distinct for Medicare versus commercial payers.

So all that being said, you know, there are confounders and if I back away and pause and say, you know, is this a desirable measure to understand, I would conclude yes, it's desirable.

When I start to think about what's being done with the data, my mind still goes

back towards, although we may not have the benchmark, we're going to have variation.

And in the user's hands, what to do with that variation, you know, I think is still yet to be determined. You know, trying to drive towards some central tendency may appear to be desirable.

But I think that's only desirable if we've gotten to a root cause and a thorough -- not a thorough -- an understanding of why the variation exists to begin with. And if it's quality and delivery of care, then some underlying systemic or systems based problem, then I would say great.

If it's a function of coding and the way a claim is processed, then I would say better be careful to understand that.

MEMBER FIELDS: My question was a little bit like yours, as well. The cost of an ICU admission, the cost of an ER visit are very high.

I don't know how to put it into

perspective, but the cost of a hospitalization might not be as high because if you're putting a patient in for management of symptoms with a DNR status and you're not going to spend lots of resources, necessarily, and you're going to target pain and palliative care, especially in an environment where there's not adequate outpatient resources or inpatient hospice beds.

That, and the dying in the hospital one, to me still would help, you know, those ones bothered me a little bit more just because that might be still an appropriate use of resources verses we don't necessarily want a lot of unintended emergency kinds of admissions or aggressive interventions.

And I think it goes back to your spectrum of how does a patient really get into a hospital? An ER visit, straight to the ICU with not a lot of thought in between.

Did the committee ask the question

about where the real expenses were? Or from a payer perspective, where are the real expenses on the end of life interventions for patients?

Or am I just naive about being in a hospice with the appropriate level of communication with the providers would be less expensive. Is that a naive answer?

MEMBER LOY: Restate your question.

MEMBER FIELDS: Well, I mean, does it cost more? If I put a patient into the hospital for two or three days for symptom control, with the right expectations on the chart, and is that outrageously expensive, because I know the ICU visit is not our goal and is very expensive.

So is this really a measure that still doesn't reflect on quality at end of life? Or dying in the hospital, if the family system and everything else can't support that, are dying in the hospital with appropriate expectations, is that outrageously expensive?

MEMBER BRUERA: And I think one of the comments that came to us is that you are absolutely correct, Karen, that that was considered. And I think that's an important issue.

ER and ICU are well clear cut. The inpatient admission is much less clear cut than an ICU for the obvious reasons of extreme suffering associated with some of those issues like ambulance to the ER and nobody knows you and all those things.

And then, of course, the ultimate is the ICU. So the point is very well taken that there are differences in the size of the problem, independently in the size of the financial burden.

There's also the physical and emotional burden that differ quite dramatically. And therefore I think there would be slightly different in their impact.

CHAIR LUTZ: Larry?

MEMBER MARKS: Yes, just Karen,

I'll, if I can, try to answer that a little bit. I mean, it's very hard to know what something costs, because what the payer is paying for the hospital side is a DRG.

What it costs the health system to provide that care is totally in the hands of the physician's pen and how much stuff that we order while the patient's in the hospital.

And in many instances, there not paying for that admission because maybe it's under a bundle of a prior admission.

So, you know, I share Bryan's pain. You can't answer that. It's really hard to do. And the minute that ER patient gets admitted, you're right. The ER charge goes away. Now it's an admission charge.

The health system cost went up. We took the patient out of the ER, put them in a hospital bed. New sheets, another nurse, new doctors involved. But the insurance carrier's cost just went down because it's not an ER visit, it's now a hospital stay.

And if they're out in a day, then it's a very complicated, unfortunately. But the main point I wanted to make was, I mean I share your concern. These are all very arbitrary, where's the ER.

But again, it's the physician's decision to give chemotherapy. It's the physician's decision to put them in an ICU bed, all right?

It's one thing to say here's a patient. They have no family support, there's no hospice. I've got to admit them, it's compassionate care to do.

But putting them in the ICU is something a physician makes that active decision to do.

So I think putting them in the ICU, giving them chemotherapy, those are things that the physician has much more direct control over than are they in the hospital, did they go to the ER?

CHAIR LUTZ: I think Nicole was

very excited to tell us something. She was tearing it up over there.

MEMBER TAPAY: Did not mean to draw attention in that fashion. But I mean, just to add, you know, the patient perspective on some of these similar questions.

And also, maybe not that cost isn't valuable but maybe to bring that a little bit away from this particular conversation because I think that irrespective, I mean clearly ICU is more expensive.

In most cases, I would imagine hospital is more expensive than hospice. I think, you know, that's data that is out there.

But I think it really may depend on the kind of cancer as well as you mentioned, all the different family situations.

And also just keeping in mind what Dr. Earle said earlier to all of us, that out

of all of these standards, this may be one that he might think could fall away for some of the nuance reasons that Dr. Bruera mentioned.

I mean, you know, again, to bring it back to personal experience here. But there was family support. We did have hospice admission.

But there was some valid reasons to consider hospitalization, at least in the prior months. I don't think it was the last 30 days of my mother's life.

But, you know, and again, in the case of an ovarian cancer patient, there's some pain relief that can be brought on by some draining and other things that can happen in the hospital.

I mean, it's very specific, I would imagine, to other kinds of cancer as well. But this one, again I'm not necessarily arguing against it, but I think apart from the cost issues, and whether there's a family

support system.

There are things that a family can't do at an at home hospice setting that could happen in a hospital that I think might be worth at least considering.

CHAIR LUTZ: Okay, we have Bryan and then Naomi.

MEMBER LOY: Yes, I'll just synthesize some of the things to try to answer Karen's question and I'll probably butcher it anyway.

But you know, in the continuum of trying to get after the desirable, I think Naomi's already pointed out what the goal would be. And that assumes that you've got resources in a community that are accessible and they're quality.

So from a health plan perspective, if someone didn't have access to a quality hospice experience, you know, then what you just said early on, you know, may be an appropriate use of resources in that

particular community.

And in terms of the expense, I think Larry eluded to a lot of things in that, you know, once you're in the system, you know, all sorts of things can happen.

You can have things ordered that you may not have otherwise for a variety of reasons, inexperience with the patient, inexperience with understanding what the values of the patients are, et cetera.

But, you know, from a health plan perspective, we're absolutely interested in the quality of the delivery of the experience that's available. So trying to get that in the right setting given the resources is a desirable goal.

I would also say that the costs that are associated with each one of those sites of service are different, depending on the contractual relationships.

So some have said DRG, so if there's a case rate there and you go in for

one day, you know, and you're going to get paid as though that case rate was resourced for three to five days, it's very expensive.

And if it's, you know, per diem, then maybe comparable to a one day hospice visit versus a percent of charge type of contract. So there's so much variation that exists within there, hard to really answer the question definitively.

MEMBER NAIERMAN: I just wanted to point out a couple of things. One is the reimbursement in hospice is structured as a per diem cap. So it's fixed and in a way it's kind of a fixed price.

And the payer doesn't have to worry, it's usually medicare. But doesn't have to worry about whether there were going to be any extra charges.

Whereas in hospitalizations, it's all about charging whatever the physician -- it's less predictable. So probably by definition, the cost to the system, hospice is

less expensive. A lot depends on how much went on before you went into hospice.

But the other thing is to keep in mind that the continuum as you mentioned, is that you take care of the patient at home if at all possible. If it's not safe, or if their symptoms are complicated, then you consider an inpatient hospice facility.

Sorry, either it's a free standing facility, or it may be a unit in a hospital. Or it may be a bed in a hospital.

But if those dedicated hospice units are not available, then it seems to me the next best option to take care of people who are not safe at home and have complications is the hospital.

So it's kind of a natural continuum, based on the hospice philosophy. If they're not safe, it's too complicated and there's no hospice option, then it seems to me from a quality perspective, yes, hospitalization makes sense, especially if you

say if the expectations are understood.

CHAIR LUTZ: We'll do Dr. Chottiner and then Dr. Ross.

MEMBER CHOTTINER: I'm concerned about the 30 day window. Drawing on my experience as a hematologist and reluctant oncologist at a community hospital for 20 years, most of the inpatients were newly diagnosed, the sick oncology patients.

And so that was our first encounter with them. And, you know, the transition to palliative care is a journey.

And so it's often very difficult when a patient's in for the first time to have that conversation, to get everything in place, to make all of those decisions.

So having a patient bounce back in the first 30 days was not uncommon, and I don't think it reflects any quality issue. So I just think it's a bad time window.

CHAIR LUTZ: They would end up being in twice, because the first

hospitalization counts. And then the second one, and usually at that point, you can move people forward.

But it's very difficult to have those conversations and make those decisions in the acute care setting when a patient's first diagnosed. And they often come back for symptom management or, you know, other complications early on.

CHAIR LUTZ: Pat?

MEMBER ROSS: I have a couple of concerns. I think this is not at all as clear cut as the emergency room or the ICU.

And we're discussing these concepts as if exquisite oncology care and supreme hospice care is the standard in every town in this country, and it's not.

And, you know, the fact is is that I do 900 operations a year. I have a busy practice. And I will tell you that when a patient or the family want to be in the hospital, they will shop around to get in the

hospital.

So they don't come to Ohio State, necessarily. They might go three hours away to a small town they live in in Kentucky or West Virginia where there is not the same level of understanding about all these things we're talking about, go to their family doc, go to the local emergency room.

And that engenders two things, either an admission there, and then a transfer to Ohio State. Or an admission right from their emergency room to our emergency room, which means no one gets paid for anything.

Or ultimately just a direct admission from that emergency room to our hospital. And, in fact, you may have the best high quality discussion with this patient and the family when they leave during that first last hospitalization of the 30 days.

And then they go to their local town and go back in for their second hospitalization, which results in that bounce

back.

I think that this one is cumbersome. I think it's complex. I don't think that it necessarily addresses a quality issue. I think that there are so many factors involved that you can't dissect them out in the way it's going to be measured.

And I think that I'm confused also about yesterday's discussion and today's discussion, because yesterday, I don't think I heard the word finances at all. Okay? I didn't even hear economy come up.

I didn't hear about we're controlling healthcare costs. So yesterday it was okay for a general surgeon, and all due respects to my surgical colleagues, it was okay for a general surgeon to do a chest surgery in their local hospital even if a shorter length of stay was available at a regional facility.

And we didn't talk about that as a quality issue. But today, we're talking about

economics. So I would like to know when the agenda changed, and what are we here to say?

Is it doing the right thing for the patient every time? Or are we mixing quality and cost into one confused discussion this morning?

CHAIR LUTZ: I would say you brought us just right back in quality. Thank you. We'll go Jennifer and then Karen.

MEMBER MALIN: I mean, I, you know, agree with most of what's been said. And I think that there's a lot of, you know, this measure has a lot of baggage.

You know, the VA facility that I practice in has an inpatient palliative care unit. So, you know, people would be getting admitted for palliative care. And it would be virtually impossible to tease that out.

That being said, I think it will be very hard to obtain usable information from the indicator, you know, the measure we just endorsed. And from the ICU admission

indicator, if we don't have a measure of hospitalization as well.

CHAIR LUTZ: Karen?

MEMBER FIELDS: Yes, my main concern is outpatient hospice care uses generally one modality of palliative care, which is medical interventions.

And I think that palliative care is a broader concept. I think Nicole actually described some examples of very appropriate palliative care that should be part of the spectrum of care, like managing ascites, managing pleural effusions for symptom control and things like that.

And unless we make sure that we think very broadly about palliative care, and we take out really what would be the appropriate place to do appropriate palliative care interventions like an inpatient setting.

Then even if we've got inpatient hospice, we're still only looking at one aspect of palliative care, which is medical

interventions. Pain meds and everything else.

There's pain pumps, there's nerve blocks, there's a lot of different ways to palliate patients.

Until we have adequate resources and until, even inpatient hospice isn't going to deal with good palliative care of some of the symptoms that are very important to the patient.

Ascites is painful and difficult. A large pleural effusion that could be drained appropriately for a very short of breath lung cancer patient is a quality of life indicator.

And we don't have any place to deliver that kind of palliation if we --

MEMBER MALIN: Well I guess I want to follow up on a couple of things. I mean, it's rare that, at least in my practice, we don't do thoracenteses and paracenteses as an outpatient, or put in PleurX catheters for people so that they can get that without having to require a hospital admission.

That being said, I agree completely that there is a role for hospital admissions, whether it's to an acute palliative care unit, which isn't, you know, what I was describing, it is not a hospice unit in our hospital.

It is a palliative care unit for people to get admitted with acute pain crises that aren't being managed even on hospice. So that they can get, you know, the types of interventions that maybe can't be delivered.

Again, I would argue that, you know, for most patients, they would be much happier to be able to have, you know, 20 minutes in an outpatient radiology suite to get their ascites tapped than to have an admission for that.

MEMBER TAPAY: I mean, I just want to bring it back a little bit to the regional variations. I mean, I have kind of looked at some of these questions with the Dartmouth Atlas and everything.

And just in our own personal experience, even in Cincinnati, Ohio with a good hospice and some good availability, you know, not every hospital has those kind of offerings that you're talking about, Jennifer.

And so I just worry about that. And then I guess I just want to ask a question, maybe to the NQF staff about the cost component, because in the benefits of some of these standards in some of the materials, the cost benefit and resource savings was considered as a benefit that was legitimate for the working group to consider.

So if you could maybe explain, kind of in general NQF standards how the cost benefit can weigh in, that would maybe help us.

DR. BURSTIN: Sure. So to date, NQF has done a measurement framework a couple of years ago making it very clear that cost, in and of itself, is not quality and should not be looked at in isolation. But value is

very fair game.

And so I think the question here, and the comments Naomi and others raised about the value to patients of not dying in a hospital I think is the part you're balancing. So just to, you know, respond, I think, in some ways.

If this was a pure utilization measure, just you know, without the sort of balance of why you would actually be measuring this, it probably would not be appropriate.

But I think this was specifically put forward and tested because of the concerns of people not wanting to spend that time, more than one hospitalization in the last month. So for your consideration.

CHAIR LUTZ: So any thoughts before we get to a vote? A very good discussion this early in the morning. It was a good one.

MS. KHAN: 1A, impact? We have four high, ten moderate and two low.

Performance gap? Four high, eight moderate, three low and one insufficient. And evidence? We have six yes, six no and four insufficient. So we stop, correct? Evidence? Yes.

CHAIR LUTZ: All right. Yes, anything else before we move on to the next one? No, all right, so we're up to number 213 is proportion admitted to the ICU in the last 30 days of life.

MEMBER BRUERA: Craig, well this is, I think, much more clear cut than the other measure and resembles more the emergency room.

And we know that it's based on the Institute of Medicine having issued more than ten years ago a serious concern about the increasing number of deaths in the ICU setting as a very uncomfortable setting.

And basically, the data showed that this is a reasonably easy outcome to measure because it's highly reachable. And also that there was considerable variation

both in the SEERs database, as well as in the Dana-Farber based.

So our group felt that it was reasonably clear cut, perhaps one of the most clear cut ones. And therefore, the decision was to bring it to the full committee for voting.

The data are the same as we discussed before. And so we thought that the ASCO proposal was reasonable.

CHAIR LUTZ: And so I would just echo what Larry said. I think we talked a about this a little bit in the last one, that this is, if someone is consistently sending their patients to the ICU and in situations where they should probably have the lengthy discussion, that is a measure that should come to light and be changed.

Is there anyone else, either from the smaller workgroup or the big group that wants to comment either way? I think we're benefitting time-wise from the fact that we've

already discussed virtually all seven of them in the first one or two of these.

Well, that said, does anyone have any great need to think further, discuss further before we vote? Okay, let's vote.

(Off microphone comment)

CHAIR LUTZ: Oh. Well, one went to a meeting and we can give John a minute to come back. All right, the NQF staff says we can keep going.

There's John. Nobody had anything to say, so we were curious, we were going to start voting, we didn't want to leave you out. We are complete.

MS. KHAN: Okay, 1A, impact. I think we're one short. We're supposed to be at 16. So 14 high and 2 moderate. And performance gap? Eight high and eight moderate.

And evidence? We have 16 yeses. And reliability? Twelve high and four moderate. And validity? Eleven high, five

moderate. And usability? We have nine high and seven moderate.

And feasibility? We have 13 high, three moderate. And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? Sixteen yeses, so the measure will pass.

CHAIR LUTZ: All right. So this, I think would have been the point where we would have taken a break.

If you want, we can continue on and see if we can get through the next few because we've already discussed them mostly. Or we can take a break. It's fine to do any of the above.

(Off microphone comments)

(Whereupon, the foregoing matter went off the record at 10:13 a.m. and went back on the record at 10:28 a.m.)

CHAIR LUTZ: The next one is proportion dying from cancer in an acute care setting. I think I have this one. And we

have obviously discussed these things at great length.

I think I will only start the discussion by saying for all of the reasons we've talked about it seems reasonable to minimize the number of patients whose site of death is somewhere they would rather not die.

And I think the hard part is, like we had mentioned, some of the questions about what is an acute care setting. It doesn't even say hospitalization now. It says acute care setting and I'm even more confused about that.

The only thing I will say in favor of this, I've seen some data and Naomi could probably help us, but I think in 1900 virtually everyone died in their own home. By 1970 that was down under 15 or maybe under ten percent.

And it's only been with the hospice movement sort of helping us out that we're back to a more reasonable number. But

it's still a pretty high number that die in the hospital, from my understanding. Anyone in the smaller group want to clarify more than that?

MEMBER BRUERA: The database used for this is, again, the same. The proponent is again ASCO and basically the data easy to collect. They're basically simple outcomes. And I guess what supports this measure is the same evidence that existed for the other ones.

And I guess some of the concerns have been expressed. This is a harder outcome insight because it's death in the acute care setting. So all the caveats that have been mentioned are, I guess, similar to this cohort.

The group, the team felt that it was reasonably simple and well outlined. And it might be nice to bring it for wider consideration.

So I don't know if anybody in the group wants to bring any of the items that

were discussed but there was very limited need to debate it in great length at that point.

CHAIR LUTZ: Naomi, do you have any deep thoughts about dying in the acute care setting at the end of life. I was quoting numbers about, historically, what's been true or not been true.

And you can probably do better than that. I was saying 100 years ago everyone died at home. And that became very untrue in the late 70s. I don't know if you have any --

MEMBER NAIERMAN: We know that we spend almost 30 percent of the Medicare dollars in the last year of life. And most of that goes to aggressive treatment that happens in the ICU and acute care hospital.

So not to mix in the cost issue, it's just that's where the resources are going to. And I think it speaks for itself, I don't think any of us want to die in the ICU. So it's obviously a patient-centered measure.

CHAIR LUTZ: I think this one's dying in the hospital, we're --

MEMBER NAIERMAN: Yes, in the acute care center. But that's where a lot of the resources go and therefore there's very high use of it. Nobody actually has a way of measuring futile care but there are more and more measures around waste. And I would imagine a lot of that goes on in ICUs.

CHAIR LUTZ: Robert?

MEMBER MILLER: I'm just going to disagree a little bit and say I don't think it's true to say that nobody wants to die in the hospital. I have family members that clearly said that's where they want to die.

I know when I used to practice in California we had a large population of Southeast Asian patients, Hmong and other Laotian patients, and they absolutely weren't going to die at home. The spirits would come back if they died at home.

So again, those are the

exceptions. I agree that the higher number, where the money is, is the people that shouldn't be dying in the hospital.

But I think we do have to be cautious. And this applies to the last two hours of discussion for all these things. I think there's going to be this variation. And so --

CHAIR LUTZ: I think they want to hear on the mic.

MEMBER NAIERMAN: That's true of the Chinese population as well. So if you're measuring in San Francisco then you're going to see different patterns for a good reason.

CHAIR LUTZ: Bryan?

MEMBER LOY: I'm curious. How do we define acute care setting? Did that include hospitals and long term acute care centers, et cetera? Is there a definition?

MEMBER BRUERA: The definition is acute care facility. So acute care hospitals.

MEMBER LOY: Okay, so did that

include long term --

MEMBER BRUERA: Long term, or LTACs and --

MEMBER LOY: Thank you.

CHAIR LUTZ: Karen?

MEMBER FIELDS: I will say that this benchmark is a little bit different. It's less than 17 percent compared to less than four percent. So to me that made it more helpful to account for regional variations and access and cultural differences.

But I also disagree strongly that all patients want to die at home. I think all patients want to die with the end of their life being treated and their symptoms being managed in an appropriate setting.

CHAIR LUTZ: Okay, anyone else? Bryan are you still, just checking? Elaine? I keep missing Elaine to my left. Sorry, Elaine.

MEMBER CHOTTINER: I would just go on record as saying if you work in an urban

community like Detroit the definition of family has changed, which is probably some of the reason you don't have large extended families.

You have people without the social supports, you have uninsured. And although we do have few in-patient hospices a lot of them don't take Medicaid. So this may not be a measure of care for the under-served.

CHAIR LUTZ: That's a good point. Does anyone have a response to that or anything else they want to bring up?

MEMBER MALIN: I agree it's a complex issue. And I guess the question that we'll need to get sorted out is whether it reflects real disparities that can be met with some other resources from the healthcare system or whether it just reflects changes in society.

I know, certainly within the veteran population, I know there are a number of very isolated veterans that don't want to

die at home. But them having in-patient hospice facilities provides maybe a more desirable option. It's just that they are very, very few beds available.

CHAIR LUTZ: Heidi?

MEMBER DONOVAN: Can you remind us the three measures that Craig thought were most valuable?

CHAIR LUTZ: Correct me if I'm wrong, but the three were proportion receiving chemotherapy in the last 14 days of life. And then he said the two hospice, either not being admitted or being admitted for a short time.

And then he went on to say this one is his fourth one. So he did mention this. The last three we evaluated were the only three he didn't give his stronger preference to.

MEMBER TAPAY: I would just emphasize from having participated in the work group that it isn't a never event. I would agree that there could perhaps be some

discussion. And I don't know, Dr. Breura, if you want to add a bit about the 17 percent benchmark.

Because I think the point about the under-served, when you're looking at a country with 50 million and we don't even know if the healthcare reform bill's going to be upheld by the Supreme Court, is no small context in certain areas, particularly with high Medicaid and other populations.

But that being said, I think to look at this as a process measure, that it could be informative and helpful in improving care, is also an important thing to think about.

CHAIR LUTZ: All right, anyone else? Or have our discussions earlier in the morning led us to what we believe? Are we good to vote?

MEMBER MARKS: What's the rate currently of people dying in the hospital?

MEMBER BRUERA: For cancer it's

about 52 percent.

MEMBER MARKS: Fifty-two?

MEMBER BRUERA: Yes.

MEMBER MARKS: And we're about to endorse a standard that say's it should be 14 percent, 17?

MEMBER MALIN: I think we're just endorsing the measure.

(Simultaneous speaking)

MEMBER MALIN: I mean the benchmark is just --

(Simultaneous speaking)

MEMBER MALIN: I think the benchmark just reflects what was observed in the Medicare population. So it's a benchmark in one population. It might be very different in a Medicaid population or --

MEMBER ROSS: But we have that benchmark of 17 percent in here, right?

DR. BURSTIN: It's not part of the measure though. The measure specifications do not include the benchmark. The benchmark was

just provided as background information.

MEMBER BRUERA: Yes, those benchmarks are created for the purpose of the data analysis to see the outlier versus non-outlier group.

But it doesn't become an established measure that one would like to use. It's left completely open to different healthcare systems, institutions and hospitals to decide.

MEMBER MARKS: Just to clarify, there was a prior measure. I forget what it was. But somebody made a comforting comment about a prior threshold. I think, Karen, you said this is okay because there's a four percent number, or something.

MEMBER FIELDS: And I said that the ER visits, and the hospital stay as well, had more than one ER visit in the last 30 days. So I felt that, okay, if we're going to endorse something it's not inappropriate to realize that we haven't necessarily determined

the setting for adequate emergency interventions.

I didn't like very many of the benchmarks. They're all very, very low thresholds. But this one was a little bit better because it was 17 percent, so one in five patients, essentially.

If we actually get more people enrolled in hospice that'll be -- if we do the other two we can maybe get to this one in a reasonable way. But that's all. It's better than the less than four percent.

CHAIR LUTZ: Elaine?

MEMBER CHOTTINER: I guess my concern is that this measure is built on the assumption that people would prefer to die at home. But I think the assumption should be that people should want to be comfortable and cared for. And if the hospital is unfortunately the only place that can happen, then it's not a bad thing.

CHAIR LUTZ: Naomi?

MEMBER NAIERMAN: The part that bothers me is the word acute. We were talking about a population that needs palliative care. And so the mismatch there, is there an alternative, is there a sub-acute, is there a nursing home, is there something that is more of a match to the patient's needs?

CHAIR LUTZ: I guess do the folks that submitted have any thoughts about the choice of the wording because --

(Off microphone discussion)

CHAIR LUTZ: Sorry, the question was whether the phrasing of this death in the acute care setting, whether that was less appropriate than some other phrase like dying in the hospital setting. Or is there a reason that phrasing was chosen or --

MEMBER FIELDS: My concern though is very few cities and regions enjoy the opportunity to have a decent palliative care program. So I think acute, I understand what you're saying but there's not a lot of Dr.

Brueras in programs like that around the country right now. We could clone him.

CHAIR LUTZ: You don't want to do that. Heidi, are you, just checking. See, I don't want to ignore you. Anyone else or are we headed for the vote? All right, everyone's picking up to Dr. Ross's vote.

(Off microphone discussion)

MS. KHAN: All right, 1a Impact, it's seven high, eight moderate, and two insufficient. Performance gap, we have six high, seven moderate and four insufficient. And evidence, you have six yes, six no and four insufficient evidence. So we're going to stop.

CHAIR LUTZ: All right, then I think we move on. The next one is 0215, proportion not admitted to hospice. And I think, Naomi, I think you're up to be the first discussant for the next one.

MEMBER NAIERMAN: I think it will be wise for us consider, at least in the

discussion part, both of the next ones, that's proportion not admitted to hospice and proportion admitted in less than three days.

A lot of what is appropriate was already discussed. It's obviously the converse to the previous three is, if you're not going to go to ICU and acute care and emergency, then hopefully you can get admitted to hospice with a caveat that hospice is available.

We were just talking about certain cities like Louisville, Kentucky, where hospice is terrific, by all measures that I know of.

And it's under utilized. So we have both extremes and it really depends on where you live and what state Medicaid programs allow for it.

But not being admitted to hospice in frequency, in high incidence, obviously shows that either there's no hospice facilities around or you just haven't had the

conversation or haven't figured out, like the two physicians that Steve talks about, how to actually use the resource.

So I think to me that's a very strong indicator of quality of care, patient-centered. Because in the end hospices are supposed to be the specialist on end of life care.

And less than three days, if I may just discuss that briefly, that's what I said earlier. To take care of someone in hospice care, regardless of where they are, home or in-patient facility or nursing home, to do it in three days or less totally compromises the quality of care you'd otherwise get.

So I think those two really are well paired together. And our committee, actually, unanimously voted to pass those two with high marks all the way across to board.

CHAIR LUTZ: Karen, Are you, just checking.

MEMBER FIELDS: But I will

comment.

(Laughter)

CHAIR LUTZ: So you subconsciously were, that's very impressive.

MEMBER FIELDS: I just think, again, that hospice, not admitted to hospice, I think is still a reflection of the physicians and the provider's knowledge of the local, regional hospital facilities and everything else.

So it's hard. I was trying to look again. I hadn't written it down this time what they thought that the benchmarks should be. But the data right now is less than 45 percent of the patients in one of the studies was admitted to hospice.

So I do think we have a ways to go for improvement of that. I just don't think, again, there's enough consistency and quality in the hospice availability for our patients across the country. So it makes it hard to measure, that's all.

CHAIR LUTZ: Robert?

MEMBER MILLER: Actually two questions, one is are we considering the two measures together? Or are we just going to talk about this one first, I think, is all.

The second question or comment is in looking through the detail, the assessment form on 0215, on this one, one sentence caught my eye. It's 1c8, which is page six or seven if anyone wants to look.

But it says, net benefit, it's under the evidence section, net benefit, there is no known harm to hospice enrollment. So I look at that and the word harm is defined in various ways.

And I'm not sure I agree with that because I think, for some patients, they do perceive that there's harm. And let me just say for disclosure I was a former hospice medical director in a previous life.

And so we occasionally had patients who felt they were railroaded into

hospice by their families, who didn't reflect their true desires. So again, I'm just urging caution here. I'm not opposed to any of these measures.

I like the next one better than this one, to be honest with you, because I feel like the next one says if you're going to do hospice you do it right. And you don't do it for three days.

But I just urge for the discussion and thoughtful reflection on comments like there's no harm because I'm not sure I agree with that.

CHAIR LUTZ: We'll do Pat and then Bryan and then Jennifer.

MEMBER ROSS: I think these are two very discrete measures. The next one, as you say, addresses a quality issue of if you're using hospice are you using it appropriately.

This one addresses, globally, a system issue that may not always be available.

Or it does not address the fact that some physicians may, in their practices, do the equivalent of that palliative care and end of life care without utilizing hospice.

So I think these are two very different things. One of them is a true quality measure, the other is trying to mandate a type of practice that I don't think we should be mandating.

CHAIR LUTZ: Bryan?

MEMBER LOY: Building off the previous comment, I would have been a little more comfortable if I'd seen an enumerator or the measure had reflected patients who died from cancer and had not received a palliative care and/or hospice consult within three days rather than an admission.

Because I really don't know what an admission means, if it's in-patient or out-patient or if there was an evaluation. It just left me with a broader definition than I was comfortable with. And I'd appreciate your

comments if you all had deliberated on that.

CHAIR LUTZ: Actually we brought that up last summer when this first came up. And one of the things that Craig Earle said, and I hate to speak in his absence, but he had said that these measures were first submitted and tried a great number of years ago before one would have considered palliative care to have been penetrated enough into the system to really be a reasonable option.

And so I think they had some -- somebody pointed out to them the patients were dying without hospice. And they said, well, let's just make it that simple. And it's become more complex in the years since.

I don't know if that helps but that's what he told us. I think we'll do Jennifer and then Joseph.

MEMBER MALIN: So a couple of things, first I just wanted to mention that in the VA, when we looked at this in our lung cancer population, and the VA's spent millions

and millions of dollars over the last ten years developing their hospice and palliative care program.

And the facility-to-facility variation on this measure was tremendous. It ranged from 20 percent to 90 percent. So with fairly comparable resources and allowances, in the VA you can get concurrent chemotherapy while you're on hospice. So it's fairly generous hospice benefit.

The second thing is I just wanted to caution that, without this measure, there's I think potential for unintended consequences with the second measure.

Because you could avoid sending someone to hospice because you were worried that they were going to die in the next three days. And so that's an issue.

And then the final thing just has to do with the growth of palliative care, which I think is really important. But currently, within claims, there's a code that

identifies providing palliative care for a patient.

But it's not provider specific. So it's hard to know how long we'd use that and what one would define as a palliative care consult.

And if you look at the data that's available from the Association for Advancing Palliative Care, essentially currently it's what's available. And it's not universally available, it's in-patient palliative care consultation.

So I think these are measures that are going to hopefully be in transition. And we need better ways of identifying and providing access to palliative care.

CHAIR LUTZ: Let's go on to Joseph, Nicole and then Elaine.

MEMBER ALVARNAS: Thank you. One of the things that struck me about a lot of the metrics that we reviewed thus far is the degree of nuance that's been used in the

definition of the enumerator and denominator.

And in listening to the other members of the steering committee speak with respect to this, what's most striking about this is the lack of nuance and how this is defined. It's not clear to me what's being measured.

I know that if we're looking at the value that we want to bring to a patient I would imagine that the value that we're trying to confer through a metric like this is respect for patient autonomy, to some extent offering them appropriate choices and then respecting their choices.

Unfortunately given the regional differences, the ethnic differences, the cultural differences amongst our patients as well, are differences in scope of practice.

It makes this broad denominator definition so, in fact, inclusive as to be almost meaningless. And I'm not really sure, at the end of day, what we're actually

measuring or that this metric conveys something that's of value in assessing our practice.

If the denominator were defined as something like out-patients who are interested in hospice care, or who should have been offered hospice care, palliative care, or something far more narrow, then I think the enumerator versus the denominator provides us with something that adds value in our understanding what's going on in our institutions.

But once you add in all these variants of ethnicity, scope of practice, patients' preferences, what's available as regional resources, I would think that it so dilutes out the value of this metric so as to make it virtually meaningless as a number, and something that would be impossible to apply as any sort of national or even regional benchmark.

That would be my concern with

this, is that it's ill-defined. And I see that in quite significant distinction to a lot of the measures that we've looked at thus far.

CHAIR LUTZ: I think you're up, Elaine.

MEMBER CHOTTINER: I think there's an underlying threat here that cancer is a progressive, predictable process. And that's really not true. Patients die during the nadir of chemotherapy for a potentially palliated or curative therapy.

Speaking as a member of ASH, our hematology patients die during induction therapy for acute leukemia. Our bone marrow transplant patients die of, one of the biggest causes of death in cancer patients is thrombosis.

And that's unpredictable and it can occur at any point in care. So I think that the idea that hospice has to have a place in this process is probably not valid.

CHAIR LUTZ: I think we're at Nicole, Jennifer, and then Terry.

MEMBER TAPAY: I just want to preface these comments by saying I'm a firm advocate of hospice. My family benefitted from it and also working for Senator Wyden, who I just have to admit my personal bias, he was a huge advocate for it on behalf of the Oregon movement.

So that's where I come from professionally and personally. But that being said, obviously there are decisions that have to be made. And there were decisions to forego curative care that I know in my mom's case she did not want to do, point blank.

We ended up actually having to only allow hospice in the home when she went into organ failure because she didn't want to sign the form. And they made an exception. That just was her choice.

And so when you talk about patient

preferences, especially in the context which I believe now has changed under Medicare law, but when you had to give up, since '03, the curative option, that affects a lot of patients' preferences.

I think the assumption, that I'm hearing in some of the comments here, that this is absolutely the standard of care. And just to kind of echo what Bob said about the railroading, I don't think that's an argument against promoting the care of hospice.

But I think it's something that we haven't actually thrown out here. And I just wanted to put that out there because not everybody is willing to take it.

CHAIR LUTZ: Karen?

MEMBER FIELDS: I have two comments, first to echo Joe's comment. When you looked at the data that was presented in the application about sensitivity and specificity of the measure, they reported that the sensitivity was 0.24 percent

compared to specificity of 0.96 and an accuracy of 88 percent.

And their statement was medical records don't often document referrals to hospice or enrollment to hospice. So I don't know if we have a good way to measure it. So if we can't even pick up the measure with a lot of sensitivity, it's hard to even determine what the value was.

And I'll add another comment about the openendedness of the timing of hospice referrals leads to some other discussions about for-profit and not-for-profit hospices.

This for-profit, the sooner you get enrolled into hospice, and in some of these capitated systems for payment, the more profitable it is to take care of patients in hospices.

So I don't know that this is as clean and pretty as it looks when we look at it. There's different modus for enrolling patients into hospice.

Now having said that, I agree the hospice service issue be available and accessible for patients. And I also agree, patient autonomy and choice.

Because again, we'll go back to the I don't agree that all patients want to die at home and all patients want to be enrolled in hospice. I think that that's a problem.

But I don't know that we can even easily measure this if the sensitivities only 0.24 percent. All the other measures that they gave us when they reported their data were in the 0.9s. So that's an observation of the data.

CHAIR LUTZ: Good point, anyone else?

(Off microphone comments)

MEMBER FIELDS: When they did their reviews, when they did their first studies and they went back, this is what they reported in their application.

They did chart reviews in retrospective analyses. And they said that the sensitivity of finding the hospice referral, so therefore potentially the reliability of the data was 0.24 percent.

They presented their data in a different way than some of the other measure authors did yesterday. We saw a lot of a different way of presenting sensitivity and specificity. And so they broke down 0.24 percent.

And then a statement, which is not, medical records don't often reflect hospice referrals. And that was the method that they chose to do it.

So unless there's some other measure that we can easily capture hospice referrals and hospital enrollment, we might be measuring something that we can't reliably define.

And whereas the specificity is if there was documentation that there was a

patient, then it really was a hospice referral.

CHAIR LUTZ: Heidi?

MEMBER DONOVAN: All right, I just have to do my internal struggle externally here. So I think we can always come out with examples of individuals who didn't choose to do hospice.

But I'm really reluctant to say that means we shouldn't include admission to hospice as a quality measure. So I think there's good evidence that people who die on hospice have a better death experience than those who do not die on hospice.

And I think we have pretty good evidence that admission to hospice in a community or within a system, or maybe low rates of admissions to hospice, is an indicator of poor services within a community and places where we need to have an active change.

And I'm having a hard time. I'm

really struggling with the idea that admission to hospice is not a quality measure, at a very broad swipe, in that the percentage of patients within a hospital or a practice or a system, that low rates of admission to hospice is not an indicator of something going wrong.

I don't think that everybody should be admitted to hospice. I think this is one of those rate measures that is a pretty good indicator.

MEMBER FIELDS: My point was mainly it looks like we can't easily capture the data from the data that they presented.

DR. BURSTIN: Just one clarification to that, the measure is put forward as a claims-based measure. So actually being able to find it in their medical record is actually not as cogent for this particular measure.

Because they're only using claims where it was actually quite accurate. It's

hard to find in charts but that's not what they're using as the basis of the measure.

MEMBER FIELDS: So I guess I don't understand then the data that they presented to talk as preliminary data.

DR. BURSTIN: I think they gave two different kinds of data. They tried to just say it was part of their analysis to go back in and see. We try to do parallel forms, reliability, things along those lines.

And I think in this instance, we often consider the chart the gold standard. And I think the point they're making here is in this particular instance a claims-based indicator hospice status is probably the gold standard.

A little bit later on you'll actually see there's further data of their testing of the Brigham, which has higher levels. It goes a little bit further down.

CHAIR LUTZ: You guys can help us with that?

MS. MCNIFF: That was the measure specified for claims. They're actually seeing that you are able to find better data in claims.

And I would comment also, in response to Dr. Alvarnas' comments and a few others, that when part of the presentation I think you heard this morning, about use of these measures in ASCE's QOPI program, and I would just say that is based on medical record review.

That's not the specifications that are presented for you today. But participants in that program have found the data regarding hospice enrollment rates to be incredibly impactful and important for quality improvement.

We see a lot of quality activities that have happened around that. We do collect several other measures related to hospice and palliative care as well.

But hospice enrollment, in and of

itself, has been the impetus for collaborative quality improvement projects, for local improvement projects certainly has been impactful.

MEMBER MILLER: To go back to the measure specification worksheet under the 1c, or the quantity and quality of evidence, the quantity of studies is listed as five although they're not specified. Maybe they were alluded to or mentioned earlier.

But under the quality of evidence, and anyone who's following along this is Page 9, ASCO put forth the studies are observational and use administrative data, consequently there are limitations to the quality of the data.

And I guess my question is, and I don't know if you guys can fill in the blanks at all, but I guess I'd like to hear more than that.

I'd like to know more than just saying that the studies are observational and

use administrative data, to me that's the whole crux of this.

If you can show me some data that says that there's more of a connection between this process measure and outcome, several of us have been saying we know of exceptions.

We're focused on exceptions. I'm struggling with the exceptions. Others are saying yes, but this measure speaks to patient autonomy and maybe that should be the driver.

But, I know Dr. Earle's not on the line anymore. But I don't know if there's any more information about the quality of the evidence or if there are studies specifically looking at how -- I'm not sure what I'm asking -- how was autonomy respected and what are the outcomes relative to meeting patient preferences.

Because I think that's where, if I'm going to go by the book, that's where I'm

having trouble with, matching up what's on the paper here.

MEMBER MALIN: I think in terms of a process outcomes link I can't imagine an IRB that would approve a randomized control trial of hospice.

So I think because of that we're limited to observational data for hospice, per se. I think there was a recent randomized control trial of early palliative care that showed improvement in quality of life, and life expectancy actually.

But I don't know that it's fair to extrapolate that to hospice. But I don't think we're ever going to be able to justify a randomized control trial of hospice.

And so I think good observational studies that show that patients have better quality of life, that family members' bereavement process is improved with hospice, are valid outcomes.

MEMBER MILLER: And you're saying

there is a literature to support that?

MEMBER MALIN: Yes.

MEMBER MILLER: There's a robust literature to support that.

CHAIR LUTZ: Karen?

MEMBER FIELDS: I did have my question/answer about sensitivity. If we couldn't measure it, it wasn't going to be helpful.

And I will say that the benchmark that they gave was less than 45 percent for this. So it's not a very high benchmark of enrolling patients into hospice.

Although I have trouble reconciling that with they wanted less than 17 percent then to die in the hospital. Because if you're not enrolled in hospice that equals 55 percent.

But we're voting on them separately. But these two applications included a study rating the quality of life and of the impressions of the family member.

And that's pretty well documented about whether they were enrolled or not. So it wasn't a randomized trial but it was a comparative trial.

So I think they actually provided more data in this one, that hospice actually improves quality of the family perception.

MEMBER BRUERA: I think one of the questions is the evolving nature of this field and it is evolving reasonably rapidly.

On one hand you have palliative care emerging. And on the other hand the monolithic concept of hospice is cracking. And therefore, you have an evolving field in which an outcome that 15 years ago could have been seen as acceptable, like hospice referral, now becomes which hospice, in which area, how good is it?

And it's a good change in a sense because we don't talk about orthopedic surgery as a field. And therefore there are good and bad orthopedic surgeons.

For 15 or 20 years people talked about hospice as a monolithic concept of goodness. And we know that some hospice providers are in jail right now. So basically things are getting a little bit more shades of gray.

On the other hand, in-patient is not always bad, as it has been so well stated in these discussions. And perhaps what we have now is a reasonably low hanging fruit that allows us to collect some meaningful data about what is happening right now with a need to update it and to perhaps control for variables in different areas.

So to me that's not different that much from the other outcomes, in which the monitoring process will be very important. And perhaps it might be perfected down the line.

It is a good effort and I think the QOPH data seems to support somehow that it can be implemented reasonably well. But

all the comments are very fair. It's an evolving field.

CHAIR LUTZ: Elaine?

MEMBER CHOTTINER: I just need to make one last plea for hematology because I always find I'm in the minority wherever I go. The problem I'm having with it is cancer.

And I think at some point in time, and we can't do it today, we need to look at the hematologic malignancies differently. And if you look at the evidence for this measure, it's going to be for things like small cell lung cancer.

It's going to be for the predictable, progressive diseases where you don't want them dying in the hospital. You want hospice intervention.

But the hematologic malignancies are high acuity patients with effective treatments. And at the university we rarely have more than six patients on our oncology

service. And we usually have upwards of 20 on our hematology service. So I think broadly including this in cancer doesn't really fit well in the measure.

CHAIR LUTZ: That's a very good point. Anyone have thoughts about that or any other thoughts to add? Naomi?

MEMBER NAIERMAN: I just add one more thought. The palliative end of life care steering committee convened not too long ago.

And among the hospice measures that it endorsed is comfort within 48 hours, meaning if the patient enters hospice with pain, what was the outcome at the end of 48 hours in terms of making that patient comfortable, and other symptoms as well.

So even as we're talking about how hospice is an evolving field, that measure is something that CMS, that particular measure, is starting to collect from hospices uniformly.

And so we will know, at some point along the line, how effective hospices are in at least managing symptoms in the first 48 hours. And that is chart-based, by the way, data.

CHAIR LUTZ: John?

MEMBER GORE: I was just going to say the same thing I said before, building on what Dr. Chottiner was saying. It was that it should be possible to adjust these for the type of cancer that people have. It wouldn't even be that hard.

And I think these measures just have a very broad swath to them without an effort to consider some of those issues. And they're issues that would be very easily addressed.

And so I just don't understand why there's not a little bit more specificity in how they define the numerator, not that I disagree with it.

CHAIR LUTZ: Another good point.

anyone else have anything to say.

MEMBER MALIN: I would say the only thing is that for some of the outcomes measures that were risk adjusted that we looked at yesterday were things like mortality. I think it's really hard to understand how to interpret a risk adjusted proportion, which is what this is as a measure.

MEMBER GORE: But I don't even mean risk adjustment. I mean adjusting for the demographics, the cancer specific demographics of the patient population at the institution.

Different centers have different rates of, for example, hematologic versus solid organ cancers. And so if use of hospice is very responsive to the type of cancer, at least that could be accounted for in how that proportion is presented. That's all I mean.

MEMBER MALIN: I think the challenge is, my guess is if you polled all of us in the room we'd each have a different set

of the cancers that we thought should be included or not. And I'm not sure we'd reach more consensus.

And I think the other thing is that the, except if you're looking at specific practices that have a unique focus, in general the hematologic malignancies are much rarer.

So if you're looking at a hospital base, compared to lung cancer, if you're looking at hospital systems and comparing them, or large multi-specialty practices, these should be relatively rarer events in terms of the overall impact on score.

CHAIR LUTZ: Karen?

MEMBER FIELDS: Well, speaking as a reformed bone marrow transplanter, I agree with you that it's a different spectrum of disease. But to have a threshold of less than 40, what was it, 55 percent of the patients are enrolled in hospice, it is hard to stratify by disease.

I think that's a different topic

than where they might die. Because you're talking about, frequently MDS is a disease of the elderly, myeloma is a disease of the elderly, lymphomas are common in a variety of age groups.

So we can't say that we shouldn't be enrolling hematologic malignancies into hospice. And the 45 percent threshold's a very low bar for whether or not we're going to refer our patients to hospice.

It's true that they frequently need to be cared for in an acute setting but I think that's a different topic than how would we utilize and access hospice.

And so I don't think any of the diseases can claim that their patients aren't going to die. We haven't cured all of our patients yet.

MEMBER MILLER: And again, the provider is free to use or not use this metric if it doesn't meet their practice. If they're treating a bunch of young people that have

acute leukemia then maybe they don't use this metric.

MEMBER FIELDS: Although her statement was we don't necessarily get that choice about using or not using if other places pick up that as a measure and a benchmark. So I think that's a little bit of a different topic than how would we improve our own practices.

MEMBER MALIN: I don't think pediatrics is included in the measure.

CHAIR LUTZ: All right, anything else before we go to a vote.

MEMBER MALIN: It doesn't say age so I didn't know. Is there evidence that it doesn't say --

(Off microphone discussion)

CHAIR LUTZ: Microphone.

MEMBER MILLER: 2a1.5, I just searched the word adult in the word document.

CHAIR LUTZ: All right, shall we vote?

MS. KHAN: So 1a Impact, ten high, three moderate, two low and one insufficient evidence. And performance gap, nine high, five moderate, one low and two insufficient evidence. And evidence, ten yes, two no and five insufficient.

Going on to reliability, four high, nine moderate, three low and one insufficient evidence. And validity, six high, seven moderate, three low and one insufficient.

And usability, I think we're missing someone, six high, five moderate, three low and three insufficient. And feasibility, we're still missing someone, six high, eight moderate, two low and one insufficient.

And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? Eleven yes and six no. And we'll move on.

CHAIR LUTZ: All right, then the next one is the measure we've already

discussed a little bit, proportion admitted to hospice for less than three days. I think it is Nicole is the discussant.

MEMBER TAPAY: My thanks and please others on the work group provide backup. But as we discussed before, this perhaps is a little less, some of the same resistance that we discussed around the previous measure.

It's a process measure because I think the work group really agreed it addresses the high priority issue with high impact. I think if you do go into hospice, if you would get the maximum out of it in three days it's likely not going to be enough on that.

There's 11 percent of patients are in for less than two days, 28 percent for less than seven. And in addition there's some upward trend, not super extreme but in the 90s, from the beginning to the end of the 90s, from 12 percent to almost 15 percent that are staying for less than three days.

So there's a concern. This is around the adult elderly population so it wouldn't include children and is dry for Medicare data. And the work group unanimously, I believe, supported moving forward.

CHAIR LUTZ: Does anyone else from the smaller work group have anything to add?

MEMBER NAIERMAN: Only that it was unanimously approved and there wasn't a whole lot of resistance on our part in any case.

CHAIR LUTZ: John?

MEMBER GORE: I just wanted to ask, was the three days selected based on that ten percent rule, just like some of the other benchmarks? How was three days selected?

My only experience with hospice care is for urologic malignancies. And we have seen some increasing use of hospice for patients dying of GU malignancies but it's all mistimed. It's all patients within the last seven days of life.

So I don't know how three days was selected but there seems to be increasing use of hospice, at least for urologic cancers, but too late. And so, that's my only question. I'll stop rambling now.

MEMBER MALIN: My recollection is just more that's going to be bare minimum, like lowest bar. When we operationalized a similar measure in the VA the consensus of our expert panel was seven days, actually.

CHAIR LUTZ: So if my memory serves, I think Craig said there was some data that came out when they were first making this that suggested that there was a meeting of three days for some scenarios. So they picked it, again, five, six, seven years ago based upon a study that came out then. I think that's what happened.

MEMBER NAIERMAN: I think seven days, anecdotally, is better for quality of care, to put your life in order and so on. But three days, for a long time if not still,

was the mode, three days or less. So I think that's probably why they honed in on that.

MEMBER FIELDS: So their threshold, and this one is a benchmark of less than eight percent. That would mean more than 90 were admitted for more than three days if that was their benchmark. Or am I interpreting that wrong?

So that means that we're meeting the goals but we still have about, and right now currently it says it's about 14 percent. So we have about ten percent of the patients that get enrolled in the hospice get enrolled very late.

So it sounds like we're actually using hospice pretty well. But we could do better, three days, we should have a lower threshold, unless I'm interpreting that data wrong, that's how they presented it.

MEMBER ALVARNAS: One of the articles, I guess, cited here as evidence was looking at process outcome length. It looked

at patient satisfaction with end of life care.

And they seemed to use that three day threshold. And it shows some outcome differences. So that seems, although maybe from a personal preference, seven seems good.

I don't know of a paper, and perhaps someone in your small group does, that can justify a different threshold. But at least you've got some data that argues for the importance of three days. So there seems to be some rationality to that.

MEMBER TAPAY: Are you looking at the 2b5.2? Because I just found that, which actually talks about it --

(Off microphone discussion)

MEMBER TAPAY: Oh, okay. Well then, there's two things because also, just to add I found the benchmark was established to identify the outlying ten deciles. So I guess this is outlining ten deciles for the three days? Does that correspond with Dr. Bruera, do you remember?

MEMBER BRUERA: I think I pointed out it's regarding the cut-off that was resulting in significant variation. And so it is a good cut-off from that perspective.

The initial data from the NHPCO study was looking at something like a seven day cut-off. But the outcomes for that were not very reliable because it was only using already referred patients and this voluntary reporting by hospice organizations. So there were a lot of limits in that seven day cut-off data.

CHAIR LUTZ: Does it make it less important if there's just one measure that has some number of days so that it's brought up as something greater than zero. Because lack of predictability for survival at that point anyhow might be low. There's more to it than that. Yes, Naomi, one of those two medical oncologists I had, two days, absolutely.

CHAIR LUTZ: You know what, actually from the description from my hospice

group, it is hours. It's almost like he doesn't want to deal with the dying discussion. So it is literally hours for many, yes. So that's a greater than zero number, helps. Is there anything else before we vote?

DR. BURSTIN: It's just that all very reasonable questions are posed to Dr. Earle. And we could have him come back with that information of three versus seven to show you later.

(Off microphone discussion)

CHAIR LUTZ: If you want we could table it if it's important enough. If you want to wait to have Dr. Earle come back or you want to --

MEMBER FIELDS: So I guess we're asking can we lengthen the number to a higher number? I would think we should vote on the measure as it is.

Because at least when we're talking about a threshold of less than eight that

means more than 90 percent of the patients would actually be enrolled, or greater.

So it would be nice if we moved the bar even farther down. But at least I think somebody's trying to present something and they presented some rationale for that less than three day number.

So I don't know that they're going to change their measure, unless we believe they might. It sounds like Dr. Bruera's group thought that three days seemed like a more reliable minimum threshold.

CHAIR LUTZ: So does anyone want to try and lead us toward waiting or, okay, I guess we have a vote.

MS. KHAN: Voting on 1a Impact, 14 high and three moderate. Performance gap, 13 high, three moderate and one low. And evidence, 16 yes and one no.

Liability, 14 high and three moderate. And validity, 13 high and four moderate. And usability, 11 high and six

moderate. And feasibility, 12 high and five moderate.

And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? Seventeen yeses, so the measure will pass.

CHAIR LUTZ: All right, so we made it through those seven and we have one more to go before lunch. This will be a new one. And I had mentioned in my initial disclaimer that this is one that I did not help form but it is based upon the guideline that I wrote.

So I might actually, even though I'm going to be the first discussant, I'll probably step off a little bit in terms of having strong opinions after that. Because I'm not that emotionally invested. I'm interested in whatever you guys come up with.

ASTRO is the submitter. And then I'll give a couple of words after they do their part. This one is entitled external beam radiotherapy for bone metastases.

DR. HAYMAN: So I'm back, thought you were done with me but I'm back. You're not. So this is a new submission of a measure that was developed by ASTRO, the American Society for Radiation Oncology.

So we're seeking a time limited endorsement. This is actually the first measure that I believe we've developed ourselves, internally. And I'm here with ASTRO staff, Anushree Vichare and Nadine Eads. Thank you.

So the denominator for this measure, which is focused on external beam radio therapy for bone metastases, is all patients with painful bony metastases and no prior radiation to that site were going to receive external beam radiation therapy.

And the numerator is those patients who receive one of the recommended fractionation schedules, which range from 30 gray and ten treatments over two weeks down to a single eight gray fraction.

This measure is based on a guideline that ASTRO recently developed along this topic. So just to step back a little bit in terms of impact for this topic we would suggest that this is a high impact area.

There are certainly lots of patients with advanced cancer who develop painful bony metastases. And those metastases significantly impact their quality of life.

In terms of opportunity for improvement, this is an area where there's been a wide variation in practice over the last several decades with a number of studies demonstrating a significant proportion of patients receiving more that ten fractions, so upwards of 20 to 30 percent of patients. And there's really no support for that in the literature.

And then to speak a little bit in terms of the quality, quantity, and consistency of the evidence over the last several decades, there have been, I want to

say nine randomized studies that have addressed the issue of shorter courses of radiotherapy versus longer courses of radiotherapy.

And they've all shown pretty consistent results, in terms of similar pain relief with no differences in toxicity, leading to a number of meta-analyses and systematic reviews which have suggested that lower, shorter courses of treatment are more appropriate than longer courses of treatment.

And that's what, in fact, led to ASTRO developing a guideline around this topic and to the development of this quality measure.

So this also is a measure that falls into the category of an overuse measure. And so we would recommend that you endorse this measure. Thank you, anything else you want to add?

CHAIR LUTZ: So just a little bit of background, there was a survey a couple

years ago that suggested that for this one simple clinical condition of painful bone metastases there's over 101 different commonly used fractionation schemes.

There are a slew of well done prospective randomized trials, all of which show a remarkable similarity between any of the four fractionation schemes listed here, virtually the biggest ones all showing a difference of less than one percent in pain relief between all of them.

The only real difference being a little bit of higher rate of retreatment to the same site if you do a single fraction, but that's more commonly used for folks in hospice or heading toward the end of life.

The prospective randomized data has swayed physician behavior very little. The guidelines have come out and we've not had time to know if that's going to change physician behavior.

But it sure seems like one of the

areas that we know in our specialty, where there is a wide array of behavior, there's data. And that data is not being particularly followed.

And so it just seemed like a sensible thing to bring up as a possible measure. Anyone else in the small work group have thoughts?

MEMBER FIELDS: I just had one question for the experts. So you had the wide range in, I think it's a great measure. And obviously there's plenty of literature to support it.

The practice patterns vary so much. Did you anticipate in the end we'd get down to one fraction or did you anticipate we'd get to more of the three fraction group? Because the retreatment failure rate to me seemed of concern.

And we're talking about palliative care and having to retreat patients. So I didn't know what you had as your gold

standard. I agree that it's probably pretty obvious when you would do it or when you wouldn't do it. But I didn't know what your real number was, just less than ten was good and that was the answer.

DR. HAYMAN: Well, I think a lot of the literature would support the use of the single fraction. There's no doubt about it. But we also want to, there is this retreatment issue, which it runs around 25 percent in most of the clinical trials.

And also there might be situations where a longer course of treatment may be appropriate. So I think that this is a place to start, honestly.

Because there are clearly, when you look at SEER-Medicare data or other data there's a significant proportion of patients that are getting more than ten treatments. And there's just absolutely no justification for that.

MEMBER FIELDS: I saw a patient

recently that got IMRT for a bone lesion. So there's such variation it's really amazing.

DR. HAYMAN: Right. So I think that this is a place to start.

CHAIR LUTZ: Jennifer, did you have something?

MEMBER MALIN: I think that the issue of hypofractionation often gets discussed in the context of overuse. And it clearly has implications from that standpoint.

But I really see this as a patient-centered care measure. The VA system centralizes its radiation therapy so the VA West Los Angeles provides radiation to people as far away as Las Vegas.

And I just find it cruel that people come and spend three weeks at the end of their life to get their palliative radiation.

CHAIR LUTZ: Larry?

MEMBER MARKS: Couple of comments, the retreatment rate is something, as Jim

said, about 25 percent. That means the rate of failure to control the pain has got to be even higher than that.

Because most of the patients don't want to come back, or are afraid the doctor will send them back. So I would estimate, I don't know, maybe it's 40 or 50 percent.

And that difference, at the higher retreatment rate -- correct me if I'm wrong, Jim -- it was mostly in the eight gray times one versus the three times ten.

I don't think there's any data that the three times ten was any worse than 250 times 14 or two times 20. So three times ten already, in many of these studies, is already considered the long version.

And there are the exclusions in here for the reasonable things of spinal cord compression in retreatment, those areas where you could make a cogent argument it should be longer.

But even there the exclusion is

actually generous. So I think we should support this. This is a very rational, reasonable thing to do.

CHAIR LUTZ: Pat?

MEMBER ROSS: Yes, I have a question on the exclusions, actually. So if we're saying that this is the best palliation, which I think is what I'm hearing, I don't do radiation oncology, then why do patients decline? And why do we have patients declining it as an exclusion?

And the other is we have the economic variables. So why are patients who can't afford to get it, which is how I interpret that, excluded from the denominator. Wouldn't we want to stratify that out as a potential quality issue?

DR. HAYMAN: So I think that the patient exclusions that are listed are ones that are routinely cited, I believe, by the AMA PCPI in terms of patient reasons for exclusion. So I think that's

where we got them from. People think that they're inappropriate. I don't know if anyone from the AMA staff wants to --

MEMBER ROSS: Well, for example, on the hospice we didn't exclude patients who didn't want to go to hospice, right?

MEMBER MARKS: The denominator has patients who get radiation. So if you look at --

MEMBER ROSS: No, it says the reasons for denominator exclusions. So if the patient says they don't want radiation then even though you had the lesion it was --

MEMBER MARKS: Then they're not in the metric. The metric is of patients who get radiation do they get a long versus short course. It's how I read it, Jim.

(Off microphone discussion)

MEMBER FIELDS: It's on Page 10 where the allowance for the patient exclusions. And they do say patient declines, economic, social or religious reasons.

But that implies that it's part of all patients that, I don't know how you could exclude them if you're only looking at all the patients that got treated. They would have never been excluded.

MEMBER MARKS: But those exclusions don't make sense there.

MEMBER ROSS: They don't make sense if we're offering them --

MEMBER MARKS: Unless there's a patient who's declining a short course and insists I want 15 fractions, I want 20 fractions. That's likely to happen.

MEMBER ROSS: I think that they shouldn't be in there.

MEMBER MALIN: The measure specified using claims data so I don't see how those could be captured in the data set.

DR. HAYMAN: We were just caucusing over here. We don't think that there's any reason why we couldn't remove these exclusions. So maybe there's some unintended

issue that I'm not thinking of while speaking on my feet. But I think that if people are comfortable we could certainly consider that.

CHAIR LUTZ: Bryan, did you have something?

MEMBER LOY: Yes, I was listening to your comments about retreatment metrics. That just seems to be the missing element of it, for me. I agree it's a good start and narrowing the range feels like, incrementally, a good place to go.

But adequacy of control, this result of the treatment, either measured through some instrument or through retreatment rate seems to be a missing component.

CHAIR LUTZ: So the retreatment rate is actually, if you look at the compendium of the studies, it's about 20 percent get retreated at the same site if they get a single fraction. About eight to ten percent get retreated if they have multiple fractions.

So it's not a 20 versus zero. There's a difference between, so it becomes an issue of whether someone wants to have a slightly higher rate of retreatment.

So one plus one is still less than four, less than six, less than ten. So any of these four are still considered appropriate. What's excluded is any of those other 97 that might be four weeks of IMRT or something.

MEMBER LOY: Okay, then I misunderstood. But it still gets at the adequacy of pain control. That piece feels like it's missing.

CHAIR LUTZ: I think, since it was equal across all four of these, I think the initial pain control is considered equal across and then it's a trade-off in terms of retreatment rate versus amount of effort put in the first time through.

MEMBER LOY: Okay, thank you.

MEMBER MARKS: Just to clarify, the immediate response rate is the same for all of

them. It's the relapse rate that's a little bit higher in the eight gray times one. Am I saying that right?

MEMBER MALIN: Do the studies say what's the median time for retreatment for people who get retreated?

CHAIR LUTZ: They're very specific. First off you can't be considered to have been retreated if you get that retreatment within the first month. So it's any time after one month and before death.

And one of the arguments that's made, it's a little bit deep, but it may be more dangerous to the normal tissues to retreat after you've given the full ten days than it is after giving one.

So you have the option to retreat after a single fraction, in some cases, more safely than you might if you had given the full ten days. And so it's even more complex than just, oh, one leads to more retreatment than the other. There's a lot more factors in

there. Larry?

MEMBER MARKS: Just to clarify it, there's nothing in here that prevents a practitioner from giving ten fractions of IMRT, right? So you mentioned IMRT in there. That's not in here.

CHAIR LUTZ: Right, that's not in there.

MEMBER MARKS: So there will still be people out there doing ten radio surgery fractions and ten IMRT fractions.

MEMBER FIELDS: So should we get proton beam in there too?

(Laughter)

DR. HAYMAN: Be nice.

(Laughter)

CHAIR LUTZ: There actually are open trials for IMRT and stereotactic body for spine. And there is data that should be -- right, and this is bones, bigger picture. So there may be more data to come to refine this. One would hope.

MEMBER FIELDS: Yes, I was assuming that this was of the hip, IMRT is what my little reference was. But I'm assuming that you're adequately removing the patients that really would benefit from targeted therapy, targeted radiation.

So my first question was just what's your real goal? Is it to get down to one or is it to get to the three? And it sounds like as long as we're less than ten that would be our standard. And that sounds reasonable.

DR. HAYMAN: There's not any data that justifies more than ten. I think that you can have a rational discussion about wanting to, it's really at this point in time, but more than ten, again, I would agree with what Dr. Malin said. It's unconscionable.

MEMBER MARKS: The other comment I'd make is as the aggressiveness of systemic therapy goes up and there's new agents, et cetera, et cetera, whether it's rational or

not, I get worried about doing eight gray times one, four gray times five, brain mets, three times ten even, in a patient who's gotten all sorts of modern drugs, almost none of which were included.

So you get on these studies, they were pretty palliative patients. Systemic therapy was not routinely being given. So I get uncomfortable with a 40 year old with bone mets who's getting a lot of chemotherapy doing a fast fractionation scheme, which is why I'd hope that the threshold is not going to be a zero.

There shouldn't be a never event, or should it be? I don't know, that's debatable. Should a cohort of younger patients being aggressively treated otherwise, who've had a long disease free interval, getting newer agents where one shouldn't treat them too rapidly.

CHAIR LUTZ: Good point. Anyone else have thoughts, suggestions?

MEMBER MALIN: Again, I think the bar is set rather low at just less than ten.

CHAIR LUTZ: Essentially ten or less, I guess is the way it stands.

MEMBER MALIN: Yes, ten or less.

CHAIR LUTZ: Yes, fractions.

MEMBER MARKS: But the target, I wouldn't think, would be 100 percent of the patients. There are some patients who, or is that supposed to fall under the exclusions?

The exclusions don't have in there concurrent treatment with some experimental whatever, which does happen. Patients are getting some weird agent and they're having pain.

And they're going off study but they begin this agent for three weeks and now they have pain. This does happen. And I don't know if that should be included as an exclusion?

CHAIR LUTZ: What do you think, developers?

DR. HAYMAN: I think that there's a number of different, probably the rate shouldn't be 100 percent from what it is. There's research being done right now around the issue of stereotactic body radiotherapy.

The RTOG, the Radiation Therapy Oncology Group, has a randomized status two study that they're doing that may or may not show benefit for higher dose stereotactic treatment versus eight gray times one for painful bone metastases.

So I think that there always has to be some room for clinical judgement. But I think when the standard is more than ten I think that denotes poor quality. And we see that in various --

MEMBER MILLER: So I would just speak to being cautious about adding any denominator exclusions. Because when I first read this I missed that this was for patients who already the decision had been made to give radiotherapy.

Because if you start bringing in any systemic issues then it gets very muddy because you could say it's very tumor type specific. I may have a patient with breast cancer that I'm going to rely on hormonal therapy.

I don't want to radiate away their marrow, like the way we talk. And so I wouldn't go there. I'm comfortable with the way it is without mucking it up too much, just my two cents.

MEMBER FIELDS: I just mostly have a process question then. Since this is a new measure, we're voting for a short evaluation? It's a little different than the one we did yesterday. So what are we actually voting on?

MS. FRANKLIN: This one is for full endorsement.

MEMBER FIELDS: Okay.

MS. BOSSLEY: They presented testing information too. You have reliability and validity in front of you. So we may have

something wrong on our agenda, but it's the actual vote.

CHAIR LUTZ: So this is not time limited? Oh, okay. All right, anything else? Shall we try and earn our lunch by voting?

MEMBER ROSS: I'm sorry, so Steve, you would address the exclusions, is that what we're talking about? Okay.

CHAIR LUTZ: Except for those exclusions so--

MEMBER ROSS: Again, sometimes you're thinking on your feet and there's something you're not thinking of. But I don't see any reason why we wouldn't be able to deal with that.

CHAIR LUTZ: Karen?

MEMBER FIELDS: I just wanted to say I would applaud ASTRO for trying to decrease overuse in this area. I think it's a great measure. And it was one of the best palliative care ones that we had.

DR. HAYMAN: Thanks, some of the

measures that we talked about yesterday were first generation measures. And I see this as a next generation measure. And it's something that I'm certainly more enthusiastic, enthusiastic about all of them, of course, but this is something that we're excited about.

CHAIR LUTZ: All right, let's move on to vote.

MS. KHAN: So 1a Impact, 15 high and one moderate. And performance gap, you have 13 high and three moderate. And evidence, you have 16 yes. And reliability, you have 13 high and three moderate.

And validity, 11 high and five moderate. And usability, I think we're one person short. We have thirteen high and three moderate. And feasibility, we have 14 high and two moderate.

And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? So we have 16 yeses and the measure will pass.

CHAIR LUTZ: All right, so that's the last one we had before lunch. But Angela's been kind enough to remind me not to forget the public comment this time. So can we check and make sure if there's anyone that has any comment from the public?

OPERATOR: And at this time there's no public on the phone.

CHAIR LUTZ: Anybody in the room that has comment or suggestions?

Well, that was going to be the next question. Anyone have any knowledge of when lunch might be getting here because that's the biggest question of the morning.

Want to keep going? Because they said it's supposed to be here any minute, like literally --

MEMBER MARKS: Do we know how many people are leaving now and what our schedule should be for the afternoon and should we car pool together to the airport, those sorts of things?

CHAIR LUTZ: I'll say I think we do have several people leaving earlier. If people want to stop and grab lunch real quick and then work through lunch that's good, because yes, I'm one of the early leavers so I'd appreciate it. Shall we stretch, grab our lunch, come back to the table and keep going?

Let's see, do we have everyone we'd need for the next one? I think the next would be 0382 Radiation Dose Limits. Am I looking at the right sheet, AMA?

All right, then we'll invite Dr. Hayman back.

DR. HAYMAN: Should I go ahead?

CHAIR LUTZ: All right, so you can go ahead. This is Number 0382 Radiation Dose Limits to Normal Tissues.

DR. HAYMAN: So this measure actually fit with the other oncology measures that were presented yesterday. So these came out of the ASCO/ASTRO/AMA/PCPI Oncology Workgroup that I was involved with.

And so this measure is a process measure that had time limited endorsement by NQF in 2008. The denominator for this measure was all patients regardless of age who had a diagnosis of pancreas or lung cancer, who received 3D conformal radiation therapy.

And the numerator for this measure is that radiation dose limits to normal tissues were established prior to the initiation of the course of radiation for a minimum of two tissues, two normal tissues.

So for example, for lung cancer it might be the dose to the lung and dose to the spinal cord, whereas for the pancreas it might be the dose again maybe to the spinal cord or to the kidneys.

And in terms of impact, you know, lung cancer, obviously there's a very high incident of cancer. Probably about, oh, I guess around 30 percent of all patients with lung cancer get treatment with radiotherapy, and the majority of pancreas cancer patients do

as well. So I would suggest this is a high impact topic area.

In terms of opportunity for improvement, there's some data, again unfortunately we don't have any data about variability but we have some data from PQRS in 2009. For the physicians who participated in reporting this measure, 89 percent rate of meeting the measure, which isn't that similar so as part of the validity and reliability testing that we did around this measure.

Again this is just for a select number of centers, 91 percent of centers were meeting this measure. But there was a relatively wide, I think around 25 percent standard deviation, so it's not something that's being done routinely.

And then in terms of the quality, quantity and consistency of the evidence, there's no, again, no randomized studies suggesting that this should be done, but it's certainly one of these processes of care for

which there's lots of data suggesting that if you exceed normal tissue constraints to these structures you're going to have an increased risk of complications. So again I think that the literature around this is very consistent in that regard. And I would suggest that again this is a process that's closely linked to outcomes.

So I don't know if there's anyone has anything to add. Again this is a measure that we would recommend that you approve for endorsement. Thanks.

MEMBER LOY: I think Dr. Marks was our primary discussant.

MEMBER MARKS: Thanks. And so the committee discussed this and we found there general consensus this was a very reasonable thing to do. That wasn't unanimous, it was close to that. That setting one's dose limits before you treat a patient is the equivalent to checking somebody's PFTs before you take out the lung or checking their ANC before you give

them chemotherapy. so I think it's just sort of one of those things that should be done.

It's almost hard to believe that it's not being done in every patient but it appears not be done, so I think setting it out as a quality metric will heighten awareness and hopefully bring this, this should really be a never event.

CHAIR LUTZ: Does anyone else from the small group that discussed have any suggestions or comments?

MEMBER GORE: I think we all agreed that this was important and considered this a never event. The only concern I think that was voiced in this small group was that compliance is very high, it's like 90 percent. So this is a performance measure with a lot of room for improvement, but I think the conclusion was that it should be 100.

CHAIR LUTZ: Bob?

MEMBER MILLER: Can you clarify about the minimum of two tissues? Why two

tissues and does that read different between the lung and pancreas?

DR. HAYMAN: At the workgroup there's a lot of discussion around this issue. I think that, you know, because in certain settings, again depending upon this might be more appropriate for lung rather than not for pancreas, but depending upon where the disease is you might be interested in dose to the brachial plexus or to the spinal cord or to the lung or to the esophagus.

And so, you know, a minimum of two, at least two seems appropriate. There are certainly situations where more than two might be appropriate. But for instance, if you're doing say stereotactic body radiation therapy for an early stage lung cancer and that lesion is more posterior but central in the lung, then at least the dose to the lung and say the spinal cord might be appropriate. But anything beyond that probably actually isn't necessary.

MEMBER MARKS: And you could

almost imagine scenarios where, you know, a peripheral lung lesion, not near the esophagus, not near the spinal cord, not near the chest wall, it's only lung. So in that setting I mean we sort of have defaults in the back our mind, you know, the esophagus should be below this, the cord should be below that. We don't maybe right it down because it's sort of self evident. But this maybe shouldn't be self evident, we should write it down.

But two is a reasonable, I mean, you can almost imagine this being applied more broadly to every patient getting conformal radiation anywhere in the body. I mean in the prostate it's rectum and bladder. In the brain it's the eyes and the brain stem, you know.

MEMBER MILLER: So in your estimation there's not likely to be many exceptions where it's only one tissue. The peripheral lung is --

MEMBER MARKS: The only one is that I can think of is peripheral lung, and I

guess in this setting --

MEMBER MILLER: Yes, I would agree. I mean we also had, you know, some discussions about other sites during the workgroup discussion. And part of the discussion, I think, also it just sort of revolved around picking diseases that are common where there would be at least two dose constraints, and also just some acknowledgment of the issue of feasibility.

MEMBER MARKS: And I think it was brought up on the call, even though the peripheral lung lesion we just assume OGO to worry about the esophagus and the spinal cord, that's just where we get in trouble. That's just when you get in trouble, right. That's just when physicist or the surgeon puts in through the spinal cord. You don't look at the spinal cord dose because it's seems so far from the spinal cord you don't think it's an issue, but then the planting system since you didn't specify it goes ahead and puts dose through it.

So it's probably more specifying even in those. It would encourage us to be more explicit, which is a good thing.

CHAIR LUTZ: Yes, Jennifer?

MEMBER MALIN: I just had a question in terms of the specification of 3D and this just reflects my ignorance, to limiting the denominator to just to conformal radiation therapy and not, you know, I guess no one uses external being without really conformal and more so, we don't have to worry about that.

I mean is it just not relevant to the other forms or, you know, why was that specific modality chosen?

DR. HAYMAN: So for 2D, which is usually palliative radiotherapy, then these sorts of issues aren't as important. I wouldn't say they're not important at all but they're not as important, because the doses that we're using can relate, you know, are not above a normal tissue at those limits.

But the reasons, you might wonder why IMRT isn't listed. And the reason for that is actually that specification of normal tissue dose constraints was required as part of the billing for IMRT.

So if you're billing for IMRT and you're not doing that, you're committing fraud basically. And so that's why it wasn't -

MEMBER MALIN: So when, basically it sounds like, based in your other statement that really across the country really conform loads in the -

DR. HAYMAN: Yes.

MEMBER MALIN: -- standards so there aren't rural places that are using other -

DR. HAYMAN: I don't think so.

MEMBER MARKS: Also if you don't do conformal 3D therapy you don't have access to the data. So if you put on a set of two dimensional beings, you don't know what the lung doses are. You can guess, an educated

guess. But you don't really -

MEMBER MALIN: Okay.

MEMBER MARKS: See you can't specify it because you can't measure it.

MEMBER MALIN: That's helpful, thank you.

CHAIR LUTZ: Does anyone else have any questions? Should we proceed onto the vote then?

MS. KHAN: So 1A impact? So 12 high and four moderate. And performance gap? So we have two high, 12 moderate, and two low. And evidence? So 14 yes and two no.

And reliability? We have one more person. So we have 11 high and five moderate. And validity? We have seven high and nine moderate.

And usability? Ten high and six moderate. And feasibility? Eleven high and five moderate.

And overall suitability for endorsement, does the measure meet NQF criteria

for endorsement? We need one more person. Okay, 16 yes's and the measure will pass.

CHAIR LUTZ: All right. So the option is open if folks want to take a break long enough to grab lunch, and stretch legs, and then get back to the table.

Is that what I'm hearing, since many of us have early leaving times? And we're one time special offering of the food to the other folks in the room as well.

(Whereupon, the meeting in the above-entitled matter went off the record at 12:18 p.m. and went back on the record at 12:39 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:39 p.m.

CHAIR LUTZ: All right. Measure 0388 has been retired. So that's the quickest one we've done all day. We've got that going for us. So I believe that leads us up to 0389, which is --

MEMBER MARKS: Jim, do you want to.

CHAIR LUTZ: Jim, can you tell us, how did 0388 get pulled? We just become passe?

DR. HAYMAN: So I think this is sort of a relic, actually, of the claim states reporting primarily. So the measure was looking at use of either, for prostate cancer, 3D for IMRT versus 2D radiotherapy. And 2D radiotherapy is really, even when this measure was developed back in 2007, I think it's relatively uncommon now.

I think it's even more uncommon for definitive treatment of prostate cancer. So the workgroup decided there was no reason to

continue with this measure. That it had put a subset in.

CHAIR LUTZ: Okay. So I guess we move on to 0389, which is a prostate cancer, avoidance of overuse bone scan for staging low risk patients. And I think Dr. Gore is our first discussant after the presenters give us the overview.

DR. HAYMAN: Sure. So these next two measures came out of a prostate cancer workgroup that was sponsored by AMA PCPI, with the AUA, the American Urological Association, taking the lead. And the American Society for Radiation Oncology, or ASTRO, being an active participant in that workgroup.

So I believe there were about one-third of the participants were urologists, one-third were radiation oncologists, and one-third were individuals with other backgrounds, such as medical, oncology, primary care.

Some input from the payer and the patient community, as well as pathologists. So

it was a multi-disciplinary, cross specialty work group.

And they had approved, the PCPI approved these measures in 2007. And then they received time limited endorsement in 2008 from NQF.

So with that background, the first measure is a overuse measure, looking at the use of bone scans for patients who have low risk prostate cancer.

So the denominator for these patients, I'm sorry, for this measure, are patients with prostate cancer who have low risk disease, which is defined as a PSA of less than or equal to ten, and a Gleason score of six or less, and clinical stage T1c or T2a disease, who are receiving either prostate brachytherapy, external beam radiotherapy, radical prostatectomy, or cryotherapy.

And the numerator for this measure is patients who did not have a bone scan performed at any time since the diagnosis of

prostate cancer.

There are some exclusions for this measure. Patient exclusions including if the patient had documented pain, if they were undergoing this therapy as part of salvage therapy.

And then there's also an exclusion for system reasons, dealing with if the patient had a bone scan ordered by someone other than the reporting physician.

So in terms of the other aspects of the measure, impact. I think there are over 200,000 patients diagnosed with prostate cancer each year. And Dr. Gore would probably know this better than I.

But I think about 40 percent are estimated to have low risk disease. So it's a significant patient population. There are data that demonstrate opportunity for improvement.

So in a number of published studies, including one from the VA, showing 25 percent of patients who had low risk prostate

cancer undergoing bone scans.

Also data from SEER-Medicare looking at a larger cohort of patients, in whom about 40 percent had undergone bone scans.

There's also data from a quality improvement project that was initiated in the Midwest at Michigan, Ohio, and Indiana, were showing 25 percent. So I think that there's pretty consistent evidence for opportunity for improvement.

In terms of the quality, quantity and consistency of the body of evidence, I'm not aware of any randomized data that are available for this process measure.

But this is a measure that is derived from best practice statement that was developed by the AUA, as well as a clinical practice guideline from the NCCN, which are consistent in their recommendation that patients who are low risk, in a low risk group, should not undergo a bone scan unless there's some clinical reason to do so.

So I would suggest that the potential benefit to the patients outweighs the risk. And therefore, would recommend that you endorse this measure.

CHAIR LUTZ: Okay. Thank you.

MEMBER GORE: That was a terrific summary actually. It's hard to add to that. I mean, I think going through how we evaluate these in terms of importance, this is a very large population.

It's the most common cancer in men. Low risk prostate cancer accounts for the majority of newly diagnosed, clinically localized cancers. It's about 60 percent of the clinically localized cancers. So 40 percent overall.

And the kind of structure, process, outcome link is really mainly that there's no link between obtaining the bone scan and any definable outcome.

I've never seen a study that showed that there's a remotely reasonable

positive bone scan rate for low risk prostate cancer. Most published series are zero percent, or maybe one out of 200 patients.

And so it's really an unindicated scan that has substantial expense. And so with technology being a big portion of rising health care costs, I think it's an important measure. And there's no contrary literature.

In terms of feasibility, the only concern that our workgroup expressed was the fact that it requires assignment by the physician. So that when you do this for PQRS, it requires the physician to code the risk stratification.

So they have to be familiar with the risk stratification, although it's a commonly employed risk stratification scheme. But other than that it's very gleanable from claims and from EHRs.

It exhibited strong validity. And, you know, I think ideally this would be a measure that would be eligible for retirement,

but the data shows that it's a persistent quality problem. So I think our workgroup summary was to re-approve.

CHAIR LUTZ: Anyone else in the workgroup, or in general? Karen.

MEMBER FIELDS: I'm not in the workgroup. So the NCCN guideline says less than, or a low risk patient is less than 20 PSA. And the guideline's for less than ten. So I just wanted to hear the discussion about --

MEMBER GORE: That's actually, the NCCN guidelines are less than ten as well. The risk stratification is based on what we call the D'Amico classification. And so low risk universally is PSA less than ten, Gleason six or less, and clinical stage T2a or lower.

MEMBER FIELDS: So there's probably been a typo in the --

MEMBER GORE: Yes. There must be. Because the NCCN is also less than ten.

MEMBER MARKS: Do we know what

percent of patients have false positives? or what the patient harms are from this?

MEMBER GORE: I don't think that was presented. But I think we all see, you know, the bones scans with positive rib things related to old rib injuries, or humerus things related to old arm injuries.

And so, you know, bone scans aren't perfectly specific. So they're definitely, I mean, it definitely leads to other plain radiographs.

MEMBER MARKS: My point was, it's not, clearly not just the expense, right? It's the patient harm.

MEMBER GORE: Absolutely.

CHAIR LUTZ: We'll go Jennifer, and then Bryan.

MEMBER MALIN: I wonder, it seems like the issue of PET scan is not addressed. And so I wonder if this measure is really also kind of dated.

I mean, even one of the

publications that's submitted as evidence talks about PET scans done inappropriately. And it seems people are often doing PET scans now instead of bone scans. And so your numerator is probably incomplete.

CHAIR LUTZ: I don't know all the details, but I think it is hard to get a PET scan approved for a prostate situation. I may be wrong about that. But I don't know anyone who's done it.

Even those who would feel it would be gaming the system, or unintelligent to know why they shouldn't do it, they can't get it. I may be wrong about that, but --

MEMBER GORE: I actually, I don't even remember seeing something in the evidence review about PET scans. PET scans are never even on our radar for prostate cancer.

CHAIR LUTZ: Jennifer are you -- Jennifer, we'll come back if you find it. Let's go Bryan and then Robert.

MEMBER LOY: Looking at the

exclusions, and I was noticing the comment about exclusion including a bone scan ordered by someone other than the reporting physician.

And hearing your comments about it should have been retired because, almost to the point where we would expect to see 100 percent or higher number.

And I'm just wondering, in your analysis, was there any attention paid to that group of folks that were ordering bone scans outside the ordering physician, to make sure that this measure kind of gets at the root cause?

DR. HAYMAN: I think the thought, you know, this wasn't the workgroup that I was directly involved in. But I think the thought was, you know, it's an issue of attribution.

So, you know, if I'm a radiation oncologist, someone's referred for me for, you know, definitive treatment for prostate cancer and the -- Well I'll pick on the urologist. We love to do that in radiation oncology.

So the urologist, you know, who diagnosed the patient, ordered a bone scan. Then the thought was well that, you know, shouldn't be counted against me.

Because, you know, I'm not the person who ordered it. Even though I'm reporting, say, on this measure. So I think that was the thought.

MEMBER GORE: I think it would be great. Oh, sorry. I interrupted. I think it would be great to figure out a way to attribute the bone scan to the ordering practitioner.

But the index that triggers this being captured is the treatment. So the index is either the radiation therapy, the brachytherapy, or the surgery for their prostate cancer.

And so that's why it's done that way. And I know a big concern for practitioners is specifically that. That we shouldn't be penalized for a bone scan that was ordered outside, potentially by someone other

than the urologist.

CHAIR LUTZ: Did you find it, Jennifer?

MEMBER MALIN: Yes. So maybe it's not applicable. But at the bottom of Page 2, under 1a-4, citations for evidence of high impact. The second reference by Oyama, et al is see acetate PET imaging of prostate cancer detection.

MEMBER GORE: Yes. I'm not familiar with that reference.

CHAIR LUTZ: Well I think interestingly, it doesn't it say for recurrent disease? So essentially --

MEMBER MALIN: Yes. I doesn't look like it, so maybe it's not relevant.

CHAIR LUTZ: -- I'm not sure it's even there. Yes.

Okay. Larry.

MEMBER LOY: Just to round that out though, it just seems to me that that's a necessary piece of data that would inform this

discussion, to make sure that the measure is addressing the issue that we're trying to get after.

If, in fact, we've excluded the folks who are the root cause of the inappropriate bone scans, then this measure won't get after that.

MEMBER MALIN: I guess just to speak to it as well from a validity standpoint, it's just as easy to identify PET scans and claims data, as it is bone scans.

And it seems that the argument for not doing it, because you can't get through the system currently, is a reason why it's not, the measure is valid without it.

CHAIR LUTZ: Well can I answer that though? I have not seen a prostate patient get a PET scan in my career. But every single patient with low risk prostate cancer has a bone scan from my urologist, after ten discussions.

So I mean, the biology is such

that probably prostate cancer is not likely to be picked up on the existing PET scans, unless they use newer tracers of some type.

So we're projecting a newer type of PET scan. It's not just rejected because it's not yet been accepted. It doesn't seem to pick up disease. It grows too slowly. You can --

MEMBER GORE: Bear in mind that cancer's in general are not active at avid cancers. So we don't use PET for really anything except for some cases of testicular cancer, and some rare cases of urothelial cancer.

We don't use PET in urology. So it's just not a concern. We're not trying to discriminate against PET. It's just not used in prostate cancer.

MEMBER MALIN: -- does include PET in their version. But endorsed by an expert panel of urologists and radiation oncologists.

MEMBER MILLER: Well I'm also

surprised to hear that. I'm not doubting it, but I never ordered a PET scan in my previous life, ever, for anyone with prostate cancer. Because I just was always taught that it doesn't help. It doesn't play anything.

CHAIR LUTZ: What do you think, Larry? Were you going to discuss this or something else?

MEMBER MARKS: Well I agree, we rarely order the PET scan. So I don't know how much of a concern that is. I want to speak to this issue of the exclusion for somebody else ordering it. I think it's a very reasonable exclusion to put in.

Maybe the staff could help me out here. Is there a reason for consistency? So the patient got admitted to the hospital. But I didn't admit him to the hospital. I didn't put the patient in the ICU. That was the family practice doc who did that.

The same things apply. And we didn't address it there. So I don't know what

the right answer is. I'm just pointing out the potential inconsistency. I haven't thought it through. But I think the exclusion makes sense, but we didn't exclude the others.

MEMBER GORE: The one thing I would comment about that is, typically when your patient, for example, going with the palliative care analogy. That's a patient sort of treated in your system where there's a decision made within that system.

Here, you're talking about a patient who got their bone scan outside of your system. And so I think it's a little more relevant to this than the other.

One question for PCPI though is, because, you know, when you denote the system based reason, and that's the number one, two and three reasons for denoting the system based modifier for a low risk patient getting a bone scan. Is that something that's tracked?

So for example, that's something that could alert PQRS to the fact that there

still are a lot of practitioners out there ordering bone scans for low risk prostate cancer. And there could be a search for the UPIN of the provider, or who ordered the bone scan.

MS. TIERNEY: Yes. So with regards to the exceptions, first I just wanted to mention, I don't know if you all noticed it in the submission form.

But in our testing project, and granted, that was limited to a few sites. The exception rate for this measure was 6.4 percent. So it was used, but on a fairly limited basis.

But with regards to your question about the exceptions being reported out. So we do advocate for the reporting of the performance rate, as well as the exception rate. So that physician could be aware of anything that would seem unusually high.

And I'm not sure at this point if CMS publicly reports. I mean, they provide

information for measures at a very high level, just a overall performance rate. And I'm not sure if they also put exception rates.

But we encourage them to at least report those to the individual physicians who are reporting on this measure. So they can have that information to help inform their quality improvement up.

CHAIR LUTZ: Bryan.

MEMBER LOY: Probably need some help then. Just listening to the explanation around the exclusion. And still not real clear on whether the majority of the folks that are not meeting this measure today are either radiation oncologists or urologists.

And I'm not even debating that aspect of it. But I guess I'm still struggling with A, how will we know whether this measure has a good patient focused impact, unless we know that information of who's ordering those today. That's point one.

And then number two, in that

definition, I'm now asking myself the question of, this someone other than the reporting physician. I don't know who the reporting physician is. Is that the radiation oncologist? Or is that some other person?

MEMBER GORE: That's the person treating the prostate cancer. So if it's radiation, it's the radiation oncologist who's treating the prostate cancer. If it's surgery, it's the urologist who's performing the surgery.

MEMBER LOY: What if it's both?

MEMBER GORE: Then that probably wouldn't be a low risk prostate cancer.

MEMBER LOY: Okay.

CHAIR LUTZ: When we do brachytherapy are we both, I mean, are both specialities considered to be treating? Because we technically are surgeon and co-surgeon. So I guess that's a --

MEMBER GORE: That actually, that's a great point. And I don't know. I

actually, I mean, I have to report on this measure.

But I don't know what they do for brachytherapy. Maybe it's just whoever books it. It usually goes to the OR, so maybe it's the urologist that books it.

CHAIR LUTZ: Jennifer, do you have anything else to add? You still have your -- I was just checking. And Larry, are you? Just checking, okay. Any other thoughts? All right. Do we get to vote?

MS. KHAN: And we're voting on 1a impact. Eight high and eight moderate. And performance gap? Seven high and nine moderate. And evidence? Fourteen yeses and two no.

And reliability? Nine high, six moderate and one low. And validity? Seven high, eight moderate and one low. And usability? Six high, eight moderate and two low. And feasibility? I think we're missing one person. Six high, eight moderate and two low.

And overall suitability for endorsement, does the measure meet NQF criteria for endorsement? We need one more person. Fifteen yeses and one no. The measure will pass.

CHAIR LUTZ: All right, 0390 is also a prostate cancer measure. It's adjuvant hormonal therapy for high risk patients. It's still our AMA presenters. And what do you have?

DR. HAYMAN: So this is a measure that came out of the same prostate cancer workgroup. And it was a measure that was approved by PCPI in 2007 as well. And also has NQF time limited endorsement in 2008.

So this measure is looking at all patients with a diagnosis of high risk prostate cancer. So that's defined as PSA greater than 20, or a Gleason score between eight and ten, or T3a disease, who are receiving external beam radiotherapy to the prostate. So we're just talking about one modality.

And the numerators are those patients who receive adjuvant hormonal therapy in addition to their external beam radiation therapy. So again, this is a measure that has a high potential impact.

I would assume about 20 percent probably of localized prostate cancer is high risk. So, you know, we're talking about tens of thousands of patients.

The opportunity, in terms of opportunity for improvement, this is, there's some data from the PQRS system suggesting that this measure may not be met in about 20 percent of patients.

And that is similar to some of the data that ASTRO collected along with the AUA, as part of the testing for this measure. About 25 percent of patients actually didn't appear to be receiving adjuvant hormonal therapy.

Actually, I should have mentioned that there is an exclusion for this measure for medical reasons as to why a patient may or not

be prescribed adjuvant hormonal therapy.

So it's not surprising that that's, you know, there's going to be some patients that aren't going to get it. But that number should be relatively low.

In terms of the quality, quantity and consistency, of the body of evidence supporting this data. There have been at least two randomized trials in this patient population.

The randomized studies use slightly different definitions of high risk. And some of the studies are older, even in the pre-PSA era.

But with the addition of hormonal therapy to external beam radiotherapy demonstrated, especially in the EORTC study, was clearly an improvement in survival, along with biological pre-survival, and regression pre-survival. But even an overall survival benefit.

So that has led to clinical

practice guidelines from both the AUA and the NCCN, which are consistent in their recommendation of the use of hormonal therapy in this patient population.

The AUA guidelines list it as a standard, which is their highest level of recommendation. And even the NCCN has a Category I recommendation, as opposed to their 2A recommendations.

So there was consensus based on high level evidence that this intervention should be used routinely in these patients. So based on that I recommend that you consider this measure for endorsement.

CHAIR LUTZ: Okay. Thank you. I think, John, you're up again.

MEMBER GORE: So I think that's another terrific summary. I think in terms of importance, you know, although the number of high risk patients is definitely smaller than the number of low risk patients, it still represents a large number of patients.

And frankly, these are the patients at risk of dying of prostate cancer. So whereas with the low risk patients we're worried about over utilization, this population is actually prone to under utilization.

And actually, I may have misinterpreted, but my reading of the 2008 PQRS data was that adherence to this is actually pretty terrible. Did I read that wrong? Because it looked like the adherence to that was actually 20 percent, not 80 percent.

So this is a measure that has substantial room for improvement, and a pretty large performance gap. The evidence underlying it, as Jim said, is all Level I evidence.

It's not just overall and disease specific survival, it's also progression of clinical metastases, which is an important outcome.

In terms of reliability, feasibility, it's very easily ascertained from the medical record. It does require, much like

the bone scan measure, assignment of the risk category.

So the risk category for high risk is PSA greater than 20, Gleason score eight or higher, or clinical stage T3a. So you feel like the cancer's going outside of the prostate.

But it requires someone to assign that risk. And so this is a measure that's to be completed by the treating radiation oncologist. But is easily incorporated in the EHRs.

And in the PQRS reliability and validity testing performed very well. So actually this was an easy one for our workgroup. And we, I think unanimously, approved this. I might be wrong. But I thought we unanimously approved this.

CHAIR LUTZ: Okay. Anyone else in the workgroup, or just in general? Comments? Suggestions?

MEMBER MALIN: Sorry, what's the

time window in this? It doesn't seem to be stated.

MS. TIERNEY: So I think it's supposed to be reported each time the procedure for the treatment of prostate cancer is performed.

So the external, each time the code for external beam radiotherapy would appear, there would be an execution that this measure would be reported on.

MEMBER MARKS: Was there a claim for adjuvant? Or there's a G code for adjuvant?

MEMBER GORE: There are J codes.

MEMBER MALIN: It's a G code?

MEMBER GORE: J. J as in John, for adjuvant hormones.

MEMBER MALIN: Right. But a G code means like the provider's practice checks the box, as opposed to using J codes for --

MS. TIERNEY: Yes. So there's a CPT-II code associated with --

MS. JOSEPH: The radiation treatment management. There's a CPT-II code of 77427. And then you also report an additional CPT-II code for the high risk.

MEMBER MALIN: That's for the denominator though. How is the numerator scored?

MS. TIERNEY: The numerator is through a CPT-II code, for use in the PQRS program in a claim system.

MEMBER MALIN: So that's the 4164F?

MS. TIERNEY: That's correct.

MEMBER MALIN: Sorry. I'm just trying to understand how -- So basically the treating provider has to document. So if the urologist prescribed it, the radiation oncologist has to know that it was done, essentially, and vice versa if they're reporting on it.

MEMBER GORE: Sorry. That's actually a great point. And so I actually

don't know how that's delineated. Because oftentimes that does not happen concurrent with your visit for another radiation treatment.

And so actually, I don't know that. But that's important. Oftentimes, at least in the practices I'm used to, the radiation oncologists give the hormones.

But I know in the community it often happens that the urologists give it in their clinic. And so I don't know how that gets captured.

CHAIR LUTZ: Okay. I think we go Robert and then back to Karen.

MEMBER MILLER: So just for the clarification about the patient you supply. So you said the high risk is, you said was defined as T3a, Gleason eight, or PSA 20. And are some of these prostatectomy patients who are getting post-op radiotherapy? Is prostatectomy excluded then?

MEMBER GORE: Salvage radiation, which is, I mean, you would consider adjuvant a

salvage, and that's an exclusion.

MEMBER MILLER: That's an exclusion.

MEMBER GORE: That's a denominator.

MEMBER MILLER: This is primary. So as I understand it, the literature supports in the radiotherapy plus hormones. But certainly much weaker for anything else. Is that correct?

MEMBER GORE: That's absolutely correct.

CHAIR LUTZ: Karen.

MEMBER FIELDS: A couple of questions. Why did you exclude like brachytherapy? Would none of these patients be a candidate for that? And also, proton beam is frequently used. So that's my first question.

And then, other hormonal therapies besides LHRH agonist versus, and including surgical anti-hormonal therapies. Because that's still used occasionally.

MEMBER GORE: Yes. I don't know actually. When you look at the codes for delineation of hormones. I mean, at least in, for example, SEER-Medicare analyses, they typically include codes for orchiectomy.

So I would hope that those would be captured for the measure. And maybe the stewards can address that. In terms of brachytherapy, all of the Level I evidence is with external beam.

We had this discussion about the 3D measure, which got pulled. That basically these are all forms of external radiotherapy. And so I would hope that they would be included. But I'm not quite so sure.

Brachytherapy is rarely used in isolation for high risk prostate cancer. It's typically used with external beam radiation therapy boost. And there's not as much evidence there for use of adjuvant hormones. So that's probably why that was excluded.

MEMBER FIELDS: And proton?

Because I think that's pretty common in parts of the country, if I recall.

DR. HAYMAN: So it's a code that's used to define the denominator, it's a physician code that would include proton beam therapy. It's for any external beam radiotherapy.

And then just to echo what Dr. Gore said, the data for the use of adjuvant hormonal therapy is an external beam treatment. And then brachytherapy as monotherapy, would be not recommended, you know, typically in high risk patients.

MEMBER FIELDS: And it doesn't look like the measure includes other kinds of anti-hormonal manipulations. So I didn't know if --

I'm sure that's getting to be farther from the standard of care. But I think that it's still used in patients, elective still.

MEMBER GORE: You mean like

antiandrogens?

MEMBER FIELDS: Well no. I mostly mean orchiectomy. Because in parts of the country you still see that. Usually you see it more in metastatic disease. But my only --

And I don't know what the standard of care is anymore. You're the urologist that can answer how often that happens. It's just that that's still an appropriate anti-hormonal therapy.

MEMBER GORE: But it's irreversible. And so that's why it wouldn't be used in this situation. So with external beam radiation therapy, you typically get a couple of year course of hormones.

And so the problem with orchiectomy in that clinical scenario is that it's irreversible. So I would be shocked if it were ever used for this clinical situation.

MEMBER FIELDS: And no other anti-hormonal therapies are used? Medical anti-hormonal therapies?

MEMBER GORE: The big other category is antiandrogens. And I don't know of any evidence of use of antiandrogens concurrent with radiation therapy. And so the measure really applies to the studies which have all used LHRH agonists.

CHAIR LUTZ: Okay. Jennifer, Robert, either one still? Okay, fine. I don't want to ignore anyone. Anyone else? Any thoughts?

MEMBER FIELDS: Can I ask the urologists and the rad oncs, then why aren't the patients getting treated? That's only, it's an NCCN Category I recommendation.

It's like one of the few Category I recommendations. And only 20 percent about are getting this kind of therapy, when you look at the way the data was presented to us.

Is it because of the question of the handoff, between the urologist and the radiation oncologist? Or are we reading that data wrong?

DR. HAYMAN: It may be that the PQRS data is, you know, more of a reporting issue, than it is a medical issue. That would be my, when I look at those numbers.

Again, we have a little bit of data from our own, you know. And admittedly it's a small, you know, sample. But our own testing would suggest that it was around 25 percent.

And I think actually, this has been studied. And I can't quote you the study right now. But I have a vague recollection that this has been, you know, that number sort of fits with some other studies that I've looked at. This issue, that are in the published literature. I don't know if Dr. Gore might be more familiar with that.

MEMBER MARKS: There's a time disconnect also, right? The data presented here is like 2008. When did the randomized studies come out? How long ago?

MEMBER GORE: There's some dating

back to the nineties.

MEMBER MARKS: Okay. But some of them are more recent. The ones, I think one was the survival benefit. Wasn't that just recently?

DR. HAYMAN: It's been updated, I think on two separate occasions. So I think the most recent update, I want to say, was in and around 2009. But there were earlier publications. But you're right. Over time the survival benefit has become more obvious.

MEMBER MARKS: This one it was disease specific survival, metastasis fee survival, and then it was more recently overall by, I don't know the literature that well.

MEMBER GORE: Yes. I mean, I think at the latest, because there was a D'Amico JAMA paper that was just challenging length. So by then it had already been established.

And that paper was from like 2005. So it's pretty, I mean, it's pretty old

evidence, I mean, relatively. Definitely relative to 2008.

CHAIR LUTZ: All right.

MEMBER MALIN: So I guess that my question is, does the fact that the PQRS data have such a low rate of adherence to the indicators suggest that there's validity problems with the measurement? That the way it's specified isn't really capturing the use?

MEMBER GORE: Yes. I think that would be the concern. Who knows if it's because there's a problem with education. I mean, this may be a problem with how it's specified in the requirement for CPT-II codes. I don't know.

MEMBER MALIN: And I wonder what the need for CPT-II code is, when you could just use a J code. It seems like it's more straightforward.

MS. TIERNEY: So if I could just speak to that for a second. So the measure denominator is a little complicated in that it

will require an ICD-9 code for prostate cancer, the code for radiation therapy, and then also a CPT-II code to identify the patient as high risk. And then the numerator could be reported, and the PQRS could be reported through a CPT-II code as well.

So I think we found, with our past experience with the PQRS program, that measures that have those extra components in the denominator are more complicated. And it takes a little bit of time for the physicians reporting on them to report properly on them.

Because although we try to create documentation that would help with the reporting, the measures that seem to have the most difficulty with reporting have those extra elements. And the first year this measure was introduced in the PQRS program was 2008.

So I would suspect some of the low rates may be a result of confusion about how to actually properly code the denominators for the measure, and identify patients eligible for it.

MEMBER GORE: Would it be possible to get more contemporary data about that?

MS. TIERNEY: So I do have this, PQRS did make available the data from 2009. And the rate for 2009, the mean performance rate was 71.84 percent, among 485 reporting physicians. So, you know, and there's, the PQRS data is somewhat sparse.

But there's also more information in this report about certain measures that had more difficulty with reporting. So I guess I would say that it seems like the reporting problems for 2008 might have resulted from the complex denominator.

I think also the numerator's confusing. But physicians have to report on this measure any time they have a patient with prostate cancer, who they are treating with radiation therapy using that code.

And they have to report whether or not the patient is ineligible. So they are low risk or medium risk. And then if they are

eligible for the measure, they have to report high risk, which just adds elements of confusion in the PQRS program.

MEMBER MALIN: What's the rationale for using the CPT-II code for the numerator, when you can get more directly evidence that they received the drug?

MEMBER GORE: I think, I mean, at least I don't know about the rationale for the drug. But they have to do it for the risk stratification.

MEMBER MALIN: Right. For the denominator. But the numerator you should be able to just use the J code.

MS. TIERNEY: So certainly for reporting and, you know, just a claim system that could look at that information. We could add that element to our specifications. And some of our specifications have those available.

The PQRS program though, requires a physician who's reporting on the measures to

use a quality data code, which is a G code or a CPT-II code in order to report the measure. So it's a requirement of the PQRS program.

MEMBER GORE: At the very least, the changes between 2008 and 2009 indicate that at least some of those reliability and validity concerns may be obviated. Maybe.

MEMBER FIELDS: Two questions. How easy is it then to find out which patients declined? It's one of the exclusions. But there's probably a substantial number of patients that decline anti-hormonal therapy.

So that might also explain the difference. We're not getting it out. Because it would have to be a chart review for that one, right?

And then number two, just like we talked about bisphosphonates yesterday, we talked about the measurement period included one time administration. And we made the assumption that that meant that the patient was being described.

But it doesn't really, I didn't completely understand if that was the same kind of, we're going to determine at one time within the measurement period. I assume the measurement period was one year, and we just determined it one time.

MEMBER GORE: Well I think that gets to the issue of this requires physician codes. So rather than ascertaining that numerator through the J codes, it's ascertained through the CPT codes.

So it's not an issue of how many times there's a code for hormones. Although that would be an interesting performance measure too.

Because there's a minimum length of these, that we know now is associated with better survival. So actually that could be a follow up measure, frankly. But that's why. I'm sorry, what was the first question?

MEMBER FIELDS: Patients declined --

MEMBER GORE: Oh, yes, yes. That's actually a huge issue. My gestalt impression of that would be patients that don't want to get hormones oftentimes select alternative treatments. So patients often get surgerized.

DR. HAYMAN: From the testing data we collected, I think the use of exclusions is around three percent. So at least in that small sample it wasn't happening very often.

CHAIR LUTZ: All right. Anything else?

MEMBER MARKS: Just a quick question. The PQRS data that's been gathered in the past. Is that just people doing it for MOC? They're not doing it for financial reimbursement reasons, right? Correct?

DR. HAYMAN: They are participating for --

MEMBER MARKS: They are participating. So there is the incentive. The data should be accurate. I'm trying to --

DR. RALLINS: Excuse me. I just wanted to add one more point, that we've also provided coding for an electronic health record, in anticipation of PQRS requiring the HR data. And it will be interesting to see what the results are like.

We anticipate a less complicated coding and reporting. That's what we anticipate. Although it will be interesting to see what the data looks like when we receive it.

CHAIR LUTZ: All right. Anything else? Are we up to the voting stage?

MS. KHAN: So we're voting on 1A impact. I think we're missing some people. So 12 highs and four moderate. And performance gap. Nine high and seven moderate.

And for evidence. Let's try that again. One more time. We're one vote short. So 16 yeses. And going on to reliability. And there's seven high, eight moderate and one low. And validity. You have four high, 11 moderate

and one low.

And going on to usability. You have 11 high, four moderate and one low. And feasibility. Six high, nine moderate and one low. And overall suitability for endorsement. Does the measure meet NQF criteria for endorsement? Fifteen yes and one no. So the measure will pass.

CHAIR LUTZ: All right. I think the next measure is 0625, also a prostate cancer measure, cancer surveillance. Right. And so who's our measure developer? Active Health, is there anyone from Active Health on the line?

DR. VIR: Yes. This is Bani Vir from Active Health. We actually have a whole team of clinicians on the line with us.

CHAIR LUTZ: Well that's impressive. We appreciate that. You guys ready to give us sort of a thumbnail sketch? And then we'll work from there.

DR. VIR: Sure. Should I go over

a brief description of the measure?

CHAIR LUTZ: Sure, please. Yes.

DR. VIR: Okay. This measure, briefly, this measure is looking to measure the percentage of men with definitively treated prostate cancer, who had at least one PSA level done within the past 12 months.

The numerator consists of men who had at least one PSA in the past year. And in the denominator we have men who had localized prostate cancer who were treated with curative intent.

CHAIR LUTZ: Okay. And I think our primary discussant is going to be Dr. Ricciardi.

MEMBER RICCIARDI: Thanks. Sorry, I was supposed to do another process measure. But just found out about this. But I'll do my best to summarize the thoughts of the group during the conference call.

As was stated by the measure developers, the aim was to identify a

percentage of men with definitively treated localized prostate cancer, who had at least one PSA level in the past 12 months.

With respect to importance, the measure developers indicate that relapse after definitive therapy increases the risk of dying from prostate cancer, obviously. And thus early detection and appropriate therapy is important to treat those who still have options for salvage therapy.

The measure developers described a number of treatment modalities that are available to patients who have prostate cancer occurrence. And they also describe some data to demonstrate a survival advantage to salvage radiation therapy for PSA detected relapses.

They also point to NCCN guidelines indicating that serum PSA levels should be measured every six to 12 months for the first five years. And then rechecked annually for patients initially treated with intent to cure prostate cancer.

There were a number of concerns of the workgroup during the conference call. And I think almost all of them revolved around documentation. Although there were some other issues as well.

I'll try to be brief. First, the measure developers documented little evidence that surveillance care is a significant problem in prostate cancer care. Or that the management of recurrence is associated with a high resource use.

Although one would logically think that they would be. They do indicate that 20 percent of patients lack surveillance PSA levels within one year of their treatment.

But they do not document the lower level of care or worse outcomes for that group. The measure developers provide low level evidence that delay in detection of recurrence was associated with adverse outcomes.

Again, one would assume that there's likely a relationship between

surveillance and outcome. One of the biggest concerns was the paucity of data presented on reliability and validity of the measure.

The measure developers detailed a testing database for reliability and validity testing. But don't describe results. And the workgroup felt that the testing database was inappropriate for evaluating reliability and validity for prostate cancer, because of the young age of the cohort, and so forth.

There were several other questions related to measure implementation. Which provider is the responsible provider? How that's determined? Whether the PCP, urologist, oncologist, and so forth.

When in the post treatment course does the measure become measured? And what is the time line? When does it become irrelevant?

With respect to denominator exclusions, the rationale was not clear for several. And as I already mentioned, there is some difficulty in ascertaining them from

administrative claims data.

I would say in summary, that the group thought that although surveillance care and survivorship care are important areas for measuring quality, that the measure seemed to have a difficult time demonstrating a link between process and prostate specific outcome, prostate cancer specific outcome.

And in addition there were substantial issues related to lack of data documenting the reliability, feasibility and usability of this measure.

CHAIR LUTZ: Thank you. Anyone else from the small workgroup want to elucidate or add to that?

MEMBER GORE: I was a vociferous critic of this measure. And I think Dr. Ricciardi did a great summary of all of our concerns.

You know, I have concerns related to, as was stated, who is the -- you know, this is sort of a patient centered measure. So it

seems like it's going to be measured at the patient level, rather than being some measure of performance.

And so I don't really understand kind of the unit of measurement. And I don't understand a lot of the denominator exclusions. Because those exclusions are actually patients who require more rigorous follow up, and more rigorous surveillance.

And so there's a lot about this measure that doesn't make sense. According to this measure, if you had a radical prostatectomy ten years ago and have never had any evidence of recurrent disease, you should still be getting a PSA every twelve months, which doesn't make any sense. And so I have issue with the measure, and in general.

CHAIR LUTZ: Does the, do the presenters of the measure have any response, or clarification, to help?

DR. VIR: Yes. Actually, we first of all would like to apologize. We were unable

to attend the preliminary discussion that you all had.

And I think had we had the opportunity to be there a lot of this would have been clarified right on the spot. So my apologies for missing that meeting.

But we would like to address these concerns one at a time. And give you adequate responses for each concern. So if you don't mind, we'll start from the first one. And perhaps if you could just give us that item, and we will address it.

CHAIR LUTZ: Do you remember what your first concern was?

MEMBER GORE: Me? Okay. Number one, who is the attributing provider? So is this going to be mark of the urologist, the radiation? Who are you actually measuring.

DR. VIR: That's a great question. We have a very complex rule algorithm that allows us to attribute a provider with a patient.

In this particular case what we use is, what we look for is an overlap between a patient and the providing physician who may have requested or performed the procedure that's indexed within this rule algorithm.

MEMBER GORE: So if a patient --

DR. VIR: By tying the physician to the procedure. And thereby tying that procedure to the patient we feel that we can get to an accurate level of provider attribution.

MEMBER GORE: So if the patient has their surgery, and two years after their surgery the surgeon and the patient agree that the patient's going to continue their survivorship care with the PCP, the surgeon still gets penalized for the surveillance that the patient receives.

DR. VIR: No. Actually the way that our rule algorithm works, it looks for the most recent care for the patient. The most recent procedure, the most recent diagnosis

tied to that procedure.

So if there's no longer a procedure on record, it would ordinarily then go back down to the diagnosis level. And remember that we're only looking in the past 12 months.

So if the patient had a frequency of diagnoses from a particular provider, with no procedures on record, then it would get assigned to the provider who was coding for the diagnosis.

MEMBER GORE: So if a primary care physician just simply notes that their patient, in addition to their diabetes, hypertension, whatever, has a diagnosis of prostate cancer, that primary care physician is now responsible for the 12 month PSA.

DR. VIR: If there is no longer any procedure on file, meaning there's no specialist performing any care for this patient, yes, it would go to the PCP.

MEMBER GORE: So I think the next

concern. And I don't mean to preempt you. I think the next concern was the time limit. So there's no time limit denoted on the measure. So basically this is sort of an indefinite measure.

Sort of analogous to what we discussed for melanoma yesterday, but with melanoma it's a life long surveillance. Whereas with prostate cancer, it doesn't necessarily need to be. At least not this rigorously.

DR. POLISARIAN: Yes, hi. I'm sorry. I'm Carol Polisarian. I'm new to the, you'll just have to bear with me as I try to explain to you.

I'm a medical oncologist. And when this measure was first endorsed by NQF I wasn't part of it. But I did kind of help write it this time, and adjust it appropriately to what we think we know about prostate cancer now.

The reason I left, the

surveillance is lifelong is extrapolating a little bit by what we think we may know about prostate cancer as a hormone sensitive cancer.

And I just want to take you back for a second to why we continue to do surveillance for breast cancer for many years out.

Because in several cancers, we think that if you're at five years your risk of dying of that cancer being metastatic. If you haven't died by that point you're not going to. And you're essentially cured, so to speak, if you can use that term.

But we know that with hormone sensitive cancer, like breast, your risk of dying actually continues to increase year after year.

So your risk at 20 years is higher than it was at five of dying of that breast cancer. So prostate cancer is likely to be the same.

We don't know that for sure. So

current guidelines really don't stop. Because we don't know when that risk ends. Does that make sense to you guys?

MEMBER GORE: I would actually disagree with a substantial portion of that. I would disagree that guidelines don't discriminate between the follow up time.

In fact, if you look at both the AUA best practice guidelines and the NCCN guidelines, the interval between PSA testing does increase with time. To the point where it becomes optional.

The other thing is, if you are a prostate cancer survivor, your lifelong risk of dying of prostate cancer is three percent. And that's mostly among high risk patients.

And in fact, if you are five years out and disease free, your lifelong risk of dying of your prostate cancer is less than .5 percent.

So it actually does not increase with time. And in fact, the longer you're out

from your diagnosis, it actually astronomically decreases.

DR. POLISARIAN: Yes, I know. I hear you. And I do understand that in the NCCN guidelines they say that you should be checked for every six to a maximum of every 12 months for the first five years, and then annually after that.

And certainly your risk of dying from the disease depends on your PSA doubling time. So it's not just your PSA, but it's your PSA increasing over time.

I think that you make some good points there. If you, you know, it's certainly easy to put a time deliminator on it, such as five years. If that's something you would recommend, that would be easy to do.

CHAIR LUTZ: Well we have a couple other folks here that were going to comment. So I think maybe they can either help us with that, or even further. So I don't know, Bryan, were you next?

DR. VIR: Can I interrupt for one second? I just wanted to note one thing that Dr. Polisarian touched upon. We are open to any suggestions that the NQF may have for a time delineation based on best practices.

We're trying to be very careful not to make assumptions, you know, using guidelines or position statements. And using best evidence for this medicine. But if you all feel that there should be a time delineation, we are open to any suggestion that you all have.

CHAIR LUTZ: Very good, very good. Thank you. Bryan, did you?

MEMBER LOY: First of all, I need to disclose that my company has a working relationship with Active Health Management. So I don't know if that presents a problem or not. Okay.

And second, what I'm hearing is that Active Health Management is articulating a measure that they are able to execute upon in

their proprietary rules engine.

If I'm misstating that, folks on the phone please let me know. If that's true, I'm wondering, was there any discussion given to the reliability and validity of this measure in a non-proprietary rules engine type environment?

DR. VIR: So for that answer, I'm going to defer to one of our -- I'm sorry, could you repeat the question one more time?

MEMBER LOY: Yes. What I thought I heard was that there was a reliance of attribution and, I'm asking the question about validity and reliability of this measure in a non-rules based engine environment.

DR. VIR: Unfortunately, we use, this rule algorithm is typically used in our rule, in our rule engine, and not outside.

MEMBER LOY: Thank you.

CHAIR LUTZ: Okay. Karen.

MEMBER FIELDS: I wanted to ask some questions about the exclusions. You

alluded to the exclusions, but I didn't really understand most of the exclusions.

So some of them I assume you are still looking for the patient that was more than, had definitive therapy, and they were more than a year out.

So I assume exclusion number one, surgical treatment in the past year, meant that they had their definitive therapy. But I didn't understand if that's what you were seeking.

Drug treatment, some of the patients will be on active drug treatment, even for localized prostate cancer. So I didn't understand that exclusion.

And radiation, I'm assuming you mean that we're looking for the second year for the PSA. And the other, four and five I assume means that they had other definitive assessments for evidence of recurrence of their prostate cancer. So I wanted to comment on that.

Also, I would also add a little caveat. Ninety percent of recurrences in breast cancer are within the first five years. And then the recurrence rate drops off dramatically. So I think that that's the same for prostate cancer as well.

DR. VIR: Thanks for your comments. I just want to address them in general. We do look for people who had, did not get definitive treatment within the past year.

We're looking that they had surveillance beyond that initial year of treatment, where they're probably under observed care with a physician.

And as far as the prostate biopsy, again, that's a level of surveillance. The prostate MRI we do want to point out, we've noticed that that's a typo. Those people are actually counted in the completion, and not an exception. And we can go in and edit that at any time.

MEMBER FIELDS: So my question is, are the exclusions, are you mainly trying to develop something for the primary care provider to follow these patients?

And you're assuming if they're getting any of these other tests they're being followed by a sub-specialist? I still don't understand the exclusions.

DR. VIR: The measure is going to be attributed to the treating physician at the time. So if you were to look at our rule algorithm, you'll see that a lot of the rule details revolve around tying a patient, or diagnosis, with a procedure.

So if a patient has both a diagnosis of prostate cancer and a procedure for say radiation treatment, it will be assigned to that provider that coded for that treatment.

If that treatment isn't coded for, and we're looking back in the past 12 months, and we don't find that kind of procedure code,

we will attribute it to the last physician that coded for this patient with some frequency. Does that clarify things?

CHAIR LUTZ: Yes. I appreciate that. I think, John, are you still?

MEMBER GORE: Yes. I mean, I don't know if we need to continue going through a lot of the other criticisms. But another question I had was, with regard to your reliability testing.

You know, there's a lot of testing on the health plan data. And so, you know, one of our workgroup's criticisms was that, you know, for example, you present an average age of your population at 37 years, and a 51 percent female population.

And so do you have data on reliability for this actual patient population? Or is it just data on your ability to abstract from your health plan sample?

DR. VIR: I would just like to clarify, we get more than just health plan

samples. But we tested this measure on a total population of 20 million lives, or people.

Forty-nine percent of this 20 million were men. Out of that 49 percent, 39,386 fulfilled the requirements to fall into the denominator for this measure. And from that we found a compliance rate, or numerator, of 80 percent.

CHAIR LUTZ: Okay. Thank you. I think --

DR. VIR: We can also get ranges and more reliability information, if required in the future.

CHAIR LUTZ: Okay. I think Robert was next, and then Larry.

MEMBER MILLER: So in terms of the connection between process and outcome, this is in your primary worksheet in 1c.1, which is on Page 4. You say that local recurrence can be cured by salvage therapy. In addition the therapy for metastatic disease depends on the burden of metastatic tumor identified.

However, I don't think those are statements lacking in controversy. Certainly the second one. So I'm just, the studies you cite, the SEER data and the other guidelines, I'm not seeing that they address those.

Related question is, if I'm understanding correctly, the type of local therapy doesn't seem, you're looking for both types of primary local therapy, radiation and surgery.

So one might argue that the salvageability is quite different between those two, if there's relapse after radical prostatectomy, where salvage is certainly a reasonable consideration with radiotherapy and reverse sequence is much more controversial.

So maybe you could just address the question? Or you're looking, I gather you're looking for any type of patient who's had primary therapy. Not just the prostatectomy patient that can be salvaged with radiation. Is that correct?

DR. POLISARIAN: Yes. Yes. This is Carol Polisarian. And I completely concur with your statements about several of the things that you said. What was discussed, the question you want me to address first is the question about salvage therapy. Is that?

MEMBER MILLER: Well, yes. The only really question was, the other was a statement. You just addressed the question about salvage therapy. Are you intending salvage therapy to be irrespective of the type of primary therapy delivered?

DR. POLISARIAN: Yes. And maybe I could just take a second to explain my thoughts of, you know, when this measure was written it was looking, and was endorsed by NQF.

I wasn't here. I've only been here a short period of time. And I rewrote it to at least try to take out some of the controversy surrounding this whole issue about following prostate cancer. And who's going to die of prostate cancer versus the vast majority

that die with cancer.

And the way that it was originally endorsed, it was taking all men who had a diagnosis of prostate cancer and following them yearly, making sure they had a PSA annually.

And with all the data showing that many men with low risk breast cancer, or even if they have prostate cancer, don't need to be treated, or shouldn't be treated.

I pulled back on that measure and I thought, well if we want to try and identify men who maybe are going to end up being the ones that die of prostate cancer, is it still the number two cause?

And we should take men who somebody identified as needing definitive therapy and just apply the measure to them. Thinking that at least if we apply the measure to them you will get an estimate of what their PSA doubling time is.

If they had radiation therapy first, we know that those men might be

salvageable, possibly. Or if they had surgery first, they could definitely be salvaged by radiation therapy, because it's much easier.

And then my second comment is really relating to the ability to get men into clinical trials. Because that was where I mentioned that there are these therapies, like immunotherapy that you have to get men early with low burden of disease.

And maybe we could get them enrolled in the clinical trials if we had regular PSAs. Is this making any sense to you?

CHAIR LUTZ: That's good. You answered the question. Let me check and see here if we have anyone else that has any further questions.

DR. POLISARIAN: So the measure is really more specific and really pulled back than what it was before.

MEMBER GORE: I just want to clarify one question. This has not been previously endorsed. Is that?

DR. POLISARIAN: No, it has.

MEMBER GORE: Really?

DR. VIR: What our goal here was with the NQF's new focus on more evidence based medicine, we really revamped this measure to fulfill that criteria and make it a much tighter measure.

So that we weren't erroneously holding physicians liable for measuring PSAs unnecessarily. We really wanted to focus in on the right population of men who needed this kind of follow up care.

MEMBER MARKS: And it's worth saying, the potential harm to patients is very high, right? You have a disease for which screening in general is debated. And you have the screening for relapse.

And certainly a lot of the patients that get radiation are not surgical candidates. So there really isn't a salvageable option.

If they're asymptomatic you can

make a very good argument not to follow them at all. And the potential harm to these patients I think is potentially very high.

DR. POLISARIAN: Yes. I hear you. And certainly if they have surgery first and if they relapse maybe they're candidates for a clinical trial. You don't know that, of course, unless you know that they've relapsed.

MEMBER GORE: I'm not sure that clinical trial is really as much on the radar for this measure as you're presenting it to be.

You know, I can conceptualize a structure, process, outcome link for a measure like this. Because there is sort of some evidence that early treatment of local recurrence can be salvaged.

And there actually are salvage therapies available for post radiation recurrent prostate cancer. But we don't even know if those treatments are associated with improved survival.

And so I think that the question

of unintended harm is a real question. There's a significant over-treatment of prostate cancer patients for secondary relapse, just as there is for primary diagnosis. And so I think the harm issue is a real issue. But I don't think clinical trials are as much on the radar for this measure.

CHAIR LUTZ: Okay. So we're looking around the room. Does anyone else have any other questions or thoughts. So we proceed to vote. All right.

MS. KHAN: We're going to vote on 1a impact. So we have two high, one moderate, eight low, and five insufficient evidence. So we will not be moving forward.

CHAIR LUTZ: Okay. I appreciate that. Thank you for your help. We'll move on to the last one, which I believe is 1853, radical prostatectomy.

I'm sorry, last one, plus one. Radical prostatectomy pathology reporting, presented by CAP. And then after they present

I think Elizabeth will be our first discussant.

DR. VOLK: Hi. It's nice to be back. Thanks for having us. We're asking for a time limited endorsement of the radical prostatectomy pathology reporting measure.

This is the measure that was mentioned yesterday where we have as the numerator is the radical prostatectomy pathology reports that include the PTPN category, the Gleason score and the margin status.

In the report the denominator is all radical prostatectomy pathology reports. Exclusions would include any documentation for whatever medical reason there might be for not including this information. For instance, the specimen originating from another malignant neoplasm or secondary site prostate carcinoma.

And this is a measure that was developed by the College of American Pathology, performance measure working group. And it is currently in play with PQRS. And we

anticipated feedback from its performance from PQRS. And this is also endorsed by the AUA.

MS. FRANKLIN: Okay. Thank you. Elizabeth, I believe you're next.

MEMBER HAMMOND: Yes. This measure is a measure dealing with pathology reporting. Let's see here. I've got to go back to the top here.

The numerator statement is those pathology reports that include the staging information, the grade and about the margin status. This information can be gleaned from CPT-II codes.

The denominator statement is all radical prostatectomy pathology reports. Exclusions include the ones, specimens originated from other neoplasms, TURPs and secondary sites. The data source is administrative claims data and paper records.

The workgroup looked at this measure and felt that prostate cancer represents a major health hazard, as we've

already talked about. It's a very prevalent condition.

And I think the majority, what this measure really represents is another example of a staging measure like we talked about yesterday, where there's a lot of evidence that shows that staging information in prostate cancer is very valuable.

The stage and the Gleason score are the most important measures to define the treatment of the patient. And also the prognosis of the patient. And there's a lot of data about that particular aspect.

The quality of the evidence is as has been stated before, when we've talked about staging is, obviously we can't run randomized trials with or without Gleason scoring and staging in this patient population.

And so the majority of the evidence includes two large trials that consistently show, as well as a lot of other data that shows that staging and grading are

very valuable.

It's likely that the, but this is not grade one evidence by any means. There is a protocol that's evidence based, that has been put forth by the College of American Pathologists on prostate cancer, that is now used as a means of recording for the Commission on Cancer.

The reliability of the measure is likely to be good, because the data is readily available. But there has been no testing, so we can't really talk about the reliability or the usability, or the feasibility at this point. Because that information is about to come forth.

So we, there was a split about whether or not we felt that the criterion should be met for endorsement. I think it's basically in the same category as the ones we talked about yesterday.

Whereas we're talking about a floor of measurement that we feel it needs to

be started before we can assess, whether or not measures like this are going to be valuable.

There have been studies that have been performed that show that there's about 11 or 12 percent of patients who do not, I mean of pathologists who do not provide this kind of reporting as they should.

And yet, it's believed to really be a never event. All prostate cancer reports should include all the elements that have been specified, including the stage and the grade, and the margin status.

This is up for a limited time endorsement. So I'm not sure what else the workgroup needs to know. Do the other workgroup members have comments?

CHAIR LUTZ: Let's see. Are there any other comments from the smaller workgroup?

DR. FINCH: I think we need to vote.

MEMBER GORE: Yes. I think that's fine. I would just echo what I said about a

measure yesterday, where I do think this is important in general.

But also just in terms of reporting to cancer registries, which are an important component of just quality of care research in the U.S.

CHAIR LUTZ: Another question I could ask is, if someone has a better recollection when, you know, I see patients all the time who have had surgery and are being considered for either adjuvant or salvage radiation.

And I pull out the NCCN guidelines where it talks about risk factors. Does this cover it? Or is there something that's not there, that is in --

MEMBER GORE: So there is Level I evidence for adjuvant radiation therapy post prostatectomy for high risk for recurrence. And positive surgical margin is actually one of the factors. And T status is one of the factors influencing that. Yes. Those are the

two. Yes, which is reflected in the T.

MEMBER HAMMOND: Right. This guideline was endorsed by the AUA as well. This measure, sorry.

CHAIR LUTZ: Any other questions or thoughts? We're voting that quickly.

DR. BURSTIN: Just a quick reminder, since I don't think you've had very many untested measures. These measures can't be rated highly, obviously, on reliability or validity.

So the only think you get to actually indicate is how you feel about the precision of the specifications. And there was a second element that will show up on the slide.

But in general untested measures can never be considered superior to any other measures. And, you know, we would expect testing results within one year. But for now, it would go forward without that information.

MS. KHAN: So 1a, impact. We have

nine high and seven moderate. And performance gap. We have three high, 12 moderate and one low. And then evidence. We have 15 yeses and one no.

And the potential exception to empirical evidence, 1c. If there's no empirical evidence. All right. Oh, untested, sorry about that.

So foundation for reliability and validity, measure specifications, the numerator denominator exclusions are unambiguous and likely to consistently, 1) identify who is included, excluded from the target population. 2) Identify the process condition or events begin measured. And 3) compute the score and reflect the quality of care problem and evidence cited in support of the measure focus.

So we're going to be voting one for yes and two for no. So we have 16 yeses. And we're going to go on to usability. We have nine high and seven moderate. And feasibility. Twelve high and four moderate.

And overall suitability for endorsement. Does the measure meet NQF criteria for endorsement? And we're one person short. Here we go. There's 16 yeses. So the measure will pass.

CHAIR LUTZ: Thank you. And I think mention was made, was there one that we did not finish voting on yesterday?

MS. KHAN: Yes. 0379.

MS. TIGHE: No, that was 0562.

CHAIR LUTZ: 0562, which we'll have to remind ourselves. Because I don't recall.

MS. TIGHE: Yes. 0562 was the measure discussed yesterday. That was overutilization of imaging studies in melanoma.

And you all had asked for information on patients with a new diagnosis of melanoma versus patients with a history of the reliability testing for that. The measure developer has provided that. I can pull it up in my email to put it on the screen, I guess.

One second.

DR. BURSTIN: 0562 in melanoma hem.

CHAIR LUTZ: All right. I'll admit, I don't have my sheet to remind me who was the first discussant of 0562.

MEMBER MILLER: I was the pinch hitting discussant.

CHAIR LUTZ: How very fair to ask you a day later again to pinch hit. So Lindsey, can you remind me again what we asked them for? Because I don't recall. I mean, I see some --

MS. TIGHE: Sure. So the denominator, I think for the patient, or for the measure includes patients with a new diagnosis of melanoma and patients with a history of melanoma, who are asymptomatic. And they should not be receiving imaging.

And the question that was asked yesterday was whether the reliability testing indicated that the patient populations

essentially behaved in the same way for the measure, for reporting of the measure.

And they wanted to see whether the new patient group and the history of melanoma patient sub-groups were able to be combined into one measure.

MS. CHRISTENSEN: So what we did is we took the patient sample that we had quick access to. And we divided them into two patient samples, one for the new diagnosis, at initial diagnosis.

And then one for the patients who had had a previous diagnosis and care for the condition. And I think they're working on showing them there.

But what we actually found was that the new diagnosis patients were more reliable on these measures than the existing diagnosis patients.

Not hugely. And I won't lie. I did not run a statistical test to see if they're statistically significantly different.

But eyeballing it, it's about ten percent improvement for the new patients.

The old patients were somewhere in the high 70's for the reliability. And the new patients are, as you can see, between about 89 percent and 100 percent reliable.

MEMBER MARKS: When you say reliable, that's just the percent of the time that they're currently complying with --

MS. CHRISTENSEN: No. So this is --

MEMBER MARKS: What do you mean?

MS. CHRISTENSEN: Good question. So the reliability testing that was done in this one, to take you back to yesterday, was a registry versus manual review, re-abstraction of the records.

MEMBER MARKS: Okay. Thank you.

CHAIR LUTZ: So pinch hitting, can you remember if this helps us move forward, Robert?

MEMBER MILLER: Actually, I don't

think it makes me feel a lot better. Because I think the concern that I know I had, and several of us had on the workgroup call, was that it still spoke to the issue of the denominator exclusions.

I understand this is a way of, I'm trying to look at that. But I still don't know how you account for the other medical reasons why these imaging studies may appropriately be done.

When you're looking at a patient, I think the examples we used clinically were if you're a clinician following a patient with a "history of melanoma", any symptom could in your mind reflect something related to the disease.

So you may be more prone to ordering imaging studies. As opposed to what I think the measure was trying to get out. Just like the bone scan measures from today, and the prostate cancer was.

You don't want to order a PET scan

on someone with a .9 millimeter thick melanoma with the negative axillae, or something. So I continue to have that same reservation.

MEMBER FIELDS: Yes. I thought our real question was to get rid of the patients that were already in the system. Because they weren't necessarily surveillance testing, which was the question.

Were we going to do surveillance testing on newly diagnosed low risk patients with melanoma? And so the group posed a question about, if you had an abnormal CT scan, then you'd be following that. Well then that met the diagnostic threshold for appropriate follow up.

If they have an abnormality in their CAT scan you're supposed to follow that up. That's different than routine surveillance on patients that shouldn't have had scans in the first place.

MEMBER MILLER: Or stage. I think you mean staging, initial staging versus

monitoring.

MEMBER FIELDS: Right. Excuse me. So, yes. So they probably need, they just need patients diagnosed in that period. Did they get staging?

More than a physical exam and pathologic exam? Then patients that are in the system that already have melanoma don't need to be in that study period, I would think.

MEMBER MARKS: I think that point was that in both those settings they shouldn't be getting routine scans at diagnosis for early stage disease, or in follow up for any stage disease.

MEMBER MILLER: That's true. But I think we were saying that the latter is much more prone to clinical variability. And it would be much reliability.

My question was more reliability, that how reliable a measure is this going to be? How do you account for, I know comorbidities was included as a denominator

exclusion. But I'm just saying practically I don't see how you can account for that consistently. So I'm --

MEMBER MARKS: It's a validity thing on the comorbidities that's got -- You know it gets so that every time you order a radiographic test, and you put down reason, you just put down a cancer diagnosis.

That shouldn't be the reason. It should be they got a cough, they got a pain. But we don't do that clinically, right? We all just write down the cancer diagnosis.

CHAIR LUTZ: Okay. Any other thoughts?

MEMBER FIELDS: It depends on how good your police in your institution are for making -- No, I'm just kidding. But it's true. It's not helpful unless you give an indication.

CHAIR LUTZ: So is this something we're waiting to get the information to vote? So we're going to vote? Is that where we are

in terms of --

MS. TIGHE: We actually started voting on this yesterday. And it was voted down on 1c, under the importance criteria. So I guess the question is if we want to re-vote, based on what was presented.

MS. FRANKLIN: Go ahead.

MS. CHRISTENSEN: So if I can -- Wow, that's really loud, sorry. So if I can just clarify, just to make sure everybody's understanding what we presented today.

If you were to look just at patients that were newly diagnosed, that's that top set of numbers. So the overall reliability would be 88.9 percent of the measure.

Validity against the goal standard, that's what we're talking about for reliability there. The exceptions, there were very, very few exceptions.

There's only two in the patient sample. But they were found 100 percent reliability. It's just very low patient

sample.

MEMBER MILLER: How big was the sample?

MS. CHRISTENSEN: There were just two patients that were exceptions.

MEMBER MILLER: What was the size?

MS. CHRISTENSEN: We only looked at 148.

CHAIR LUTZ: So I guess it's for us to decide whether the new information changes our perception enough to want to re-vote and see if we get beyond 1c this time.

So I guess we're asking if we want to vote as to whether we want to re-vote. I mean, really that's what it is. Anyone want to make a strong argument either way. Are we too tired to make a strong argument?

MEMBER MILLER: I'll move that we re-vote.

CHAIR LUTZ: Okay. All right. Sound fair? Let's do it. All right. Basically this is, new information was brought.

And the suggestion is we re-vote based upon that new information and see if it changes anything. And just basically this is new information, we go forward again and see.

MEMBER MALIN: We never got to the point of discussing reliability and validity. We voted it down before we got there. So I don't see what the additional data does.

I mean, at this point I don't remember all the stuff we discussed that led to the votes on the first three criteria. So without delving back into it again, I wouldn't feel comfortable voting on them.

CHAIR LUTZ: Joseph.

MEMBER ALVARNAS: I think kind of skewed down are two issues, which were the imprecision of the population. Because we were talking about people not only recently diagnosed with this early stage melanoma, but also following them indefinitely without a cap on that.

So I think one of the concerns was

along the way was if somebody breaks a bone, develops pneumonia, life happens to them. Then all those appropriate imaging studies, which may not have been coded properly in terms of the diagnosis for justification, end up being a hit against the practitioner. Perhaps inappropriately so.

And then I think the second issue that Bob talked about, again, speaks to that attribution issue. It's difficult to achieve a level of precision in the attribution with respect to physicians or practitioners ordering in order to give the metric the sort of teeth and robustness that actually gives it meaning in this context.

I mean, if the intent is to keep people from ordering inappropriate staging studies for somebody who doesn't need them, then it's not clear that even with those refinements you achieve that.

So I guess that's kind of why we stopped yesterday, was that the metric didn't

have the capacity to discern what it's supposed to discern.

MEMBER MILLER: I just suggested the re-vote since we took the time to ask for more evidence, more information. I mean, I certainly understand the part.

I was closest to it because I had to present it. But I'll defer to the chair in whatever parliamentary procedure we want to do.

CHAIR LUTZ: Actually I looked at the NQF folks. I mean, you guys go through this a lot. Do you have any thoughts about? I mean, it seems as if what you're saying is the information that was brought doesn't change the part that we voted down. Am I hearing correctly?

So then it doesn't sound like we should re-vote. If we basically stopped short of that part, and that doesn't change why we voted no, then okay. Karen.

MEMBER FIELDS: Were we mostly asking whether or not the measure could be

modified? Is that part of the discussion. Because I'm -- And get rid of that one denominator. We're talking about just newly diagnosed melanoma.

CHAIR LUTZ: I don't recall.

MEMBER ALVARNAS: I think the question was, when it got sent back, was if you got rid of all the patients who had been diagnosed more than a year out, does it clean up the population enough to make it more precise? And it doesn't sound like the numbers, I mean, maybe they do skew out a little better, but it didn't sound like it.

MEMBER MILLER: Well I think we did ask that question, whether we could, you know, there's the whole amendment question, which I still don't know that I understand yet, whether we can amend something or not.

But I don't think that's what was presented to us today. This isn't an amendment. This is just saying, I think the presenters are saying it doesn't look that

different on our very small sample size, using the process that we used. So I agree. I just raised the question of re-voting in fairness more than anything else.

CHAIR LUTZ: If we pretend the presenters are not in the room, the ones that brought it to us, I mean, does it seem like we're being unfair to them if we say, well we voted no on 1c and we're done. Does it seem unfair? All right. Then I guess we're done.

But we're not done, done. Although actually, although I am. I will take my leave in about 60 seconds here and thank you all. And say it's been an honor. I have to head out in a minute. So we'll pass it on to the staff to finish up. But thank you.

MS. BOSSLEY: So I think that there's just two things. And correct me if I'm wrong. One is to discuss the measures that we said might need to be harmonized, that we mentioned yesterday related to pain. And then the other thing is gap.

So I don't know how many people are staying, or could stay for the -- I don't think it's more than a half hour at the most. I don't know when people's flights are. But some people are ready to go, and that's fine.

MS. FRANKLIN: Right. So it's just the -- Okay. So we're putting -- All right. So the first things we had up were, we're looking at measure number 0384 from the oncology set.

And that's pain intensity quantified. And it's paired with number 0383. And we're looking to walk through harmonization with number 1628 and 1634 that are up on your screen.

MS. BOSSLEY: Why don't we have Lindsey walk through it? Because she knows these very well. Because they were in the palliative project that she staffed. Lindsey, that good?

(Off microphone comments)

MS. TIGHE: Okay. Measure 1628

and Measure 1684 both went through the palliative care project. Both of them address pain screening for, one for cancer patients and the other for hospice and palliative care patients.

The numerator statements for both of them reference a quantitative standardized tool, which measure 0384 which was discussed yesterday, asks for patient visits in which pain intensity is quantified using standard instruments, which is why we raised these to discuss any harmonization issues.

Measure 1628 and 1634 were harmonized with each other in the palliative care project. And the way that that was done was that the quantitative standardized tool was defined in the numerator details.

It was defined as, screening may be completed using verbal, numeric, visual analog, rating scales designed for use of non-verbal patients, or other standardized tools.

Essentially we're asking you to

look at that definition, and look at what is used in measure 0384, and see where you want to refine the specificity of either of those. It would help if you guys could see what I was talking about. We're working on that issue. Sorry about this.

MS. BOSSLEY: So I've lost my copy too. So I think that the big question is when we talk about related measures. Because I would assume we would not classify these as competing.

Competing would be same target measure focus, same population. And there's overlaps. But again, I think everybody would agree it's slightly different.

You really are looking at your numerator population, more than anything else. And how they define, I think it's more assessment of pain. And two of them, as Lindsey said, are harmonized.

The RAND measure that looks at advanced cancer screen during outpatient

visits. And the other one looks at hospice and palliative patients.

They have, and again, you may look at this and decide that the way they're written, they may be written slightly differently. And that may be worth thinking about whether it's --

But they may measure the same thing. So I think we may need to talk through exactly what that is. And again, it's very hard I know, because you don't have it in front of you.

But the ones that were just endorsed, not the ones before you, do look at, it uses some scale. That could be verbal, numeric, visual, or some, and it has to be a standardized tool.

What you have with the PCPI measure really looks at something very similar. It says pain intensity should be quantified using a standard instrument such as, zero to one numerical, rating scale, categorical scale,

or the pictorial scale.

So once you see it, you can take a look and see whether the wording for users might be -- If I was going to implement it, and I had to implement across all these, one question might be, it may measure the same thing.

And it almost sounds like they are, I think. But is the wording better to be the same? So that everybody understands yes, it is intended to be the same.

And I think that could be a recommendation that could go back. And we need to have all three developers discuss this.

Or you can say they haven't quite met what you think should be included in it. So I think there's a couple of things we can discuss. But if you need to wait until you see it, that's fine.

MS. TIGHE: No. We just created the document yesterday afternoon. Sorry about that.

MS. BOSSLEY: Gene, did you put it on SharePoint?

MEMBER DONOVAN: And our role is to make a recommendation? And then the implications of that recommendation are what?

MS. BOSSLEY: So there could be a few. And it all depends on the level of perhaps concern, or harmonization you think is required. In this instance it's fairly minimal.

We've had the steering committee say that they expect the harmonization occur before they could give them all the way through the comment period and say we're giving them time

But it needs to be done by the time you evaluate all the comments and make your final recommendation to the Consensus Standards Approval Committee, or CSAC.

You might say it's something that would take long enough that it's acceptable that they bring it back at the next annual

update, which is in one year. Or at the next maintenance cycle.

Again, I'm not sure that in this instance that's quite where you are. But that has been a couple of the avenues that they have taken, the committee has taken in the past.

So Gene, if you could blow it up a little bit bigger. And it's the numerator statement and the numerator detail. And we have hard copies.

MR. CUNNINGHAM: And we also emailed it to everyone just now too, if you want to open it on your own machines.

MEMBER MILLER: So, I'm sorry. I kept trying to find the document we were talking about. So we're not just harmonizing 0383 and 0384, we're harmonizing 0384 with previous measures. And the previous measures are these first two columns that somebody else has already gone to the trouble of making them the same.

MS. TIGHE: The first two are the

same.

MEMBER MILLER: I just want to make sure I've got all this.

MEMBER FIELDS: The main difference that we understand is these people gave examples. Whereas, the first people left it.

MS. BOSSLEY: That's how I interpret it.

MEMBER FIELDS: So you want the discussion to begin? So I would think that they're both essentially the same. And it just gave an example of, and it's a standardized tool.

So you could leave the example out. But I would say that's pretty much the nationally accepted standard already, that they're just describing better in example three.

MEMBER MALIN: I mean, I think from an NQF standpoint, if it's better to have in a similar measure have the same wording, and

have the wording harmonize. That's probably more just going back to the measure developers and saying, would you accept this as a synonym.

MEMBER GORE: They're slightly different patient populations, aren't they? Slightly different. So do we need to harmonize the patient population it's relevant to?

MS. BOSSLEY: I think that's another good question to take a look at. And they do overlap. If I can find it here. It's probably more 1628 and 0384 that overlap the most, I think. And the data sources are similar.

So one uses electronic clinical data, using registry and paper records. And then the one you've discussed is administrative claims, electronic clinical data using electronic health records, and the registry, and paper records. So there is overlap between the data sources as well.

MEMBER FIELDS: Can I ask a question though? I mean, without having

reviewed 1628, what recommendations are we to make? Because somebody's accepted 1628, and we've only reviewed 0384. So with lots of discussion, if I remember.

MS. BOSSLEY: I think one of the questions we could ask, because what we have here I don't think provides enough information to tell that they used the same say ICD9 coding.

The visits may also overlap. It's a potential. But I think it's just go back to the developers. We can ask for more clarification and bring it back to you.

MEMBER MALIN: I don't know. I mean, I'm actually pretty familiar with the measures. And I don't know that we really need to harmonize the denominators.

I mean, I think, you know, there's other patient populations that this measure could apply to as well. And I can envision other, you know, other groups that you'd want.

And so having the numerator, if

it's supposed to represent the same type of care, which I think it is, be consistent. But then, you know, if you, you know, the difference between, I mean, the middle one obviously applies specifically to hospice as a site of care.

I think the difference between the RAND one and the ASCO measures, the ASCO measure really, I mean, it doesn't say it explicitly. But it says it's for patients on treatment with chemotherapy and radiation therapy. It's really designed to be for cancer providers.

And the RAND measure is more holistic basically. It takes more of an integrated health system perspective. Or basically any of the key providers, from primary care on, who are caring for the patient. So, you know, I think they can all be useful in different settings.

MEMBER DONOVAN: So if it comes down to just wording of the numerator, it seems

to me that the other two measures are clearer in their specifications.

So in the measure that we looked at yesterday, it confuses intensity and severity. So it uses both intensity and severity. Whereas in the other two it's specifically severity. And I think that's important.

Often severity is the most common representation of intensity. But you can see that people might change that a bit. And then the types of measures that are presented as possible for use are more inclusive in the RAND scale.

So it seems like a superior description to me, and not a difficult change, and not changing the intent whatsoever. So I guess I would make a recommendation that we adopt these previous measure's descriptions.

MS. BOSSLEY: Bryan.

MEMBER LOY: Are we on numerator details also as part of the discussion? I'm

looking at 0384. And I'm looking at the time window. And it says, at each visit within the measurement period.

But I'm not clear. It seems to me there needs to be some though and discussion about how we might get that clear. Because it's a cross multiple site service.

And I'm looking at the RAND one, and I like it a little bit better, because it's one site of service, the setting. And it says at the time of outpatient visits.

I think now that I see that, I think the 0384 kind of raises the question of, okay so you go to different providers. Is each one of them required to do that, required to assess? So it seems like there's some need for some harmonization across the time window piece.

MS. BOSSLEY: Yes. I actually think they do measure the same thing. So at every visit within that 12 month window. They're both 12 months.

MEMBER LOY: Across every site of service? So if I went to a radiation oncologist and a primary care doctor and a cardiologist, every one of those is responsible for filling out a pain assessment across all those different providers, in order to meet that measure?

MS. BOSSLEY: Assuming, right, yes. Assuming they see multiple providers, yes. That's very similar to all the measures. Many of the measures we have, it's very agnostic to the provider and the number of people who would be assessing it. More patient centered in that way.

But I think they are measuring the same thing. Same visits. Potentially, if they go see different providers, and they're all within, yes. Does that make sense?

MEMBER FIELDS: So in the past when you've had the same target population and the same question, you approved both of those measures?

And then the external bodies that might use them for whatever, then choose which one seems more applicable? Is that how you resolve that? Or do you don't accept a measure that's so similar to a previous measure?

MS. BOSSLEY: Well that is one option for you, to decide that you have before you a measure that is looking broader, and captures the patient population that you want.

And if that's the case then you would say that we defer, and prefer this measure. And then either recommend or remove endorsement from, removal of endorsement of the other one.

The goal is, from NQF's perspective, is to identify the measures that cover the broadest population where it's appropriate.

So if there is one in here that you would say does do that, then I would recommend you put that one forward. I'm not sure.

And again, it's been a while since I looked at the other two. I'm not sure how much of this is a total overlap of patients versus the fact that some of it captures different.

One is advanced cancer. And I don't remember how they define advanced cancer. The other one looks at the two treatment, the ones receiving the treatment modality.

MEMBER MALIN: All right. I think that, I mean, the hospice one is the hospice one. The ASCO measure basically it would be any cancer patient that only, while they're on active treatment essentially. Defined as chemotherapy and radiation.

So for example, someone who was end stage and getting palliative treatment only, theoretically wouldn't actually be eligible for that measure the way it's defined.

I don't know how broadly the, it's 12 consecutive months. So I guess maybe they would fall within that window still. And then

the RAND measure is limited to basically Stage IV and metastatic advanced patients. But it's agnostic to the site of care basically.

Any provider who's taking care of someone with metastatic cancer should be assessing their pain when they see them. Essentially that's the intent of that measure. And it's agnostic to what kind of treatment people are getting.

MEMBER GORE: And to clarify, the palliative, the hospice palliative care is not cancer specific. It's basically like the one on hospice.

MEMBER MALIN: Right, yes. And it's within admission to hospice. So anyplace else, it wouldn't --

MEMBER LOY: But now I'm listening to what you're saying. 0384 just feels like a sub-population of 1628.

MEMBER MALIN: Well there are overlaps. So 0384 includes people who don't have metastatic disease. So if someone post

thoracotomy for Stage II lung cancer, who's getting adjuvant chemotherapy would be captured in 0384.

Whereas someone with metastatic disease who's not, you know, who falls into the next year of measurement window, wouldn't be captured, but would be captured by the other one.

MS. BOSSLEY: Right. So one recommendation you could have is a gap area, which is one of the other things we had talked about, is the fact that you'd like to see a measure that goes broad, so that you capture the broader population. Rather than having these more slices, where you do have some overlap.

But the question is, is there potentially one that you think supercedes the other because it may capture more patients? Or is it the state of where you are right now, as long as the numerators harmonize, you're comfortable having the three?

MEMBER FIELDS: I think it comes down to what our goal of measuring pain was. And our goal was to improve quality of life. And patients with Stage I, II and III can have pain from side effects of therapy, or surgical pain.

So I don't think, I think they are exclusive. But I do think they should be harmonized. I think the goal was, we were going to try to make sure that we assessed what the patients perceived as their most important problem, which was were they having pain, and were we addressing it?

And so not having seen the first one, it's hard to make a recommendation that they harmonize them and come up with just one measure. But just sitting here having the discussion, it sounds like they need to harmonize them and just have one measure.

So I don't know. Our committee is filled up with a lot of people who haven't done this before. And we don't know what kind of

recommendation to make.

MEMBER MALIN: I mean, I think, you know, so the challenge is you want to have a broad population. But at the same time, you know, if I'm seeing a breast cancer survivor to refill her Anastrozole, do I necessarily need to screen her for pain?

I mean, I guess, I do ask her about joint, you know. But no, she wouldn't fall into any of these measures currently. Because she's not on chemotherapy or radiation. And she doesn't have metastatic disease. So currently she would not be in the denominator of either measure.

MEMBER FIELDS: The public comment yesterday asked us to consider oral meds.

MEMBER MALIN: Well they said oral chemotherapy. So, I mean, whether --

MEMBER FIELDS: Then again, well the problem was we had problems with the fact that what's appropriate. I mean, a Stage II woman with massive lymphedema and pain needs to

have us be assessing that.

MEMBER MALIN: Right. But I think this is more of a systems issue, right? Because in order to implement this you have to have your front office staff screening patients, you know, or something in general. I mean, you could do it on a case by case basis.

MEMBER ALVARNAS: It sounds like there's some issues related to harmonization. Like it would be easier like having a common pain scale versus others of greater complexity, like figuring out whether or not the discreet metrics actually add value, given the more discrete.

I think the former issue is probably easier to discuss in this forum. The latter, given that we haven't really examined the other two measures in as much depth as probably would be necessary to so justice to them, might be a little outside our time constraints, and best left to the three sponsors to work out amongst themselves.

MEMBER LOY: I was going to ask, what can we do with this? Is that an option? What --

MS. BOSSLEY: So I think to ask for one measure that addresses all of it is probably out of the scope of what we can ask them to do now. Because that does potentially change a lot of information, be a lot of re-work.

But I think you could set that as a request that they collaborate, or one or both of them come back with a measure that is broader the next time around.

And then your initial would be can they harmonize? So that you are saying things the same way. 0384 be more specific about the severity not the intensity. Those things now may be the best way for you to go. If that makes sense to everyone.

MEMBER MILLER: So I'm not convinced that we need one measure. I'm going to speak to keeping the measures as they are.

And part of that is laziness and ignorance.

But in all seriousness, I do think, as we've been saying, these are different populations. And I'm not convinced, from a systems standpoint as Jennifer was saying, that we really want to set out as a standard of care that every cancer patient who ever had cancer at any time, in every system has to be asked about their pain.

Because it's curatively treated. Patients with Stage I breast cancer, who aren't on any therapy for decades may not apply. But I agree, I think we just ought to fix the little technical things here, and just keep it this way.

MEMBER MALIN: And I think the issue is, you get to a point where if you're at that point -- You know, maybe we should just have a measure that says every patient who walks into a doctor's office, regardless, should get screened for pain. And then we don't have to worry about the denominator.

MEMBER GORE: It's kind of funny that none of these measures apply to post--surgical patients, where pain is certainly an issue.

MEMBER FIELDS: Well, I think it was, the other problem that we don't even know how to reconcile is then the paired study with this one was to try to have a plan for that pain. And so we don't know if there's a paired study for this one that might actually make this a reasonable question.

MS. BOSSLEY: There is. And maybe I think we need to get you back on one conference call to discuss those little remaining things.

And we can provide those to you. Because there are ones that go further, and Naomi may remember. This is where they look at more intervention.

MS. TIGHE: Well, 1628 was a stand-alone. And 1634 was pain screening with treatment.

MS. BOSSLEY: It was paired.

MS. TIGHE: Yes.

MS. BOSSLEY: Yes. One of them was paired. So we'll get that for you so you can take a look at that the next time. But it sounds like right now we'll just ask PCPI to take a look and see if they can harmonize their language, how they describe it.

I'm assuming it won't be too much of a challenge. But I'm not going to put them on the spot and ask them now. And have them bring that back, and you can take a look at it. But otherwise, it sounds like there's no desire to go any further than that right now.

MEMBER FIELDS: I'd make that motion the way you said it.

MS. BOSSLEY: We'll pull it from the transcript. Great. Okay.

MS. FRANKLIN: Moving on to our next item on the agenda, we will discuss measure gaps. And we wanted to, at this point, we wanted to get from the steering committee

gaps that we identified in our discussion of the measures before us.

And we do already have from Jerod Loeb a note that he unfortunately is not able to make it today. But he had noted the need for a measure capturing PSA screening for patients diagnosed with prostate cancer. And he noted that as a gap area for future measured development.

And at this point, we wanted to get from the steering committee other areas for future measure development that they have observed in our discussions. So Elizabeth?

MEMBER HAMMOND: I would like to just make a general comment that I think I made before. And that is: I think it would be very valuable if, I would like to really encourage NQF to get a new process where we can evaluate measures when they're in the concept stage and make suggestions to the developers.

So that we can have measures that have better specification when we come down to

voting. I think that would really help both NQF. It would help the developers of the measures. It would help us. Because then we would have more productive discussion.

If we talk about things that we could do to improve, I think people in this room had a lot of good ideas. But those things basically fall on deaf ears, because the measures are already out there. So I would just like to -- I think that's a serious gap that we have.

MS. FRANKLIN: Thanks. Dr. Fields.

MEMBER FIELDS: Yes. I think one of the main things was on pathology reporting. And it would be nice to go back to CAP and just ask them why they don't want some specific reporting details for across all tumor types.

On pathology reporting, why didn't they have standardized pathology reporting across all tumor types. So we saw that multiple times.

We also had treatment summaries. Why were we looking at just radiation oncology, and why not medical oncology, or some other kind of thing?

So I think there's a lot of areas that we identified yesterday. But those are the two striking ones where we got very disease-focused.

And perhaps they were sort of general issues. If we felt we had to measure quality on path reports, it wasn't probably just in esophageal biopsies and prostate biopsies.

MEMBER HAMMOND: Definitely not. It's in everything. I mean, half the soft tissue tumors in the United States are not graded. And that's the only important factor.

MS. FRANKLIN: I think it was Joe and then Bryan.

MEMBER ALVARNAS: You know, from a national perspective, CMS has highlighted the four tumor areas, you know, prostate, lung,

breast and colon as areas where they want to see metrics developed, implemented and used as measures for assessing effectiveness of healthcare interventions.

I mean, we get that from the healthcare reform legislation and all. I guess my perspective is, I think we want to look at what's done in those fields. Identify opportunities based upon where we see true deviations from the standard of care in ways. And I think we can bring that forward to this forum through our expert organizations.

Then I guess on a selfish level, being a malignant hematologist rather than a solid tumor person, if I look at what I think is most under represented in terms of the NQF metrics, or metrics related to hematological malignancies and advanced malignancies, while there are only 6000 people per year diagnosed with acute lymphoblastic leukemia, that's a disease where, if you make mistakes in the first six weeks of taking care of that patient,

then your capacity to salvage them is over.

I mean, salvage therapies for that disease are particularly egregiously poor. I mean, they're about to present the standards of care practice guidelines in Florida in three days. And unfortunately, once you get past first line therapy, second line therapy is not that good. So I think our best opportunities are up front.

So I think, given the resource-intense nature of the hematological malignancies, as well as, I think, the irrevocable nature of some of the decisions that are made early on in the care of patients, that that might be an avenue of focusing, in terms of lives saved by decisions that I think can be articulated into discrete metrics. So I think that would be an area that I'd very strongly urge be evaluated for future metric development.

MS. FRANKLIN: Thanks.

MEMBER FIELDS: I don't know if

it's our prerogative, but sort of along those lines. We don't, none of the measures really address enrollment in clinical trials at appropriate times.

And I think that we all agree that we're not curing all the cancers we should cure. So I don't know what kind of measure could be developed.

But are appropriate patients offered clinical trials, I think, is a critical question. I don't know if we can measure the quality of the trials themselves. That's another topic, but we didn't even address that in any of our studies.

MEMBER LOY: The one topic that I heard today was when we were in our hospice discussions. I think there's a possible measure, or a gap to made around palliative care and/or hospice consults.

MS. FRANKLIN: Thanks. Dr. Gore.

MEMBER GORE: I think there's a huge black box of what happens in the OR that

has yet to be well unlocked. And I know that AUA has been very involved in generation of some of these measures.

And if you look at all the prostate cancer measures, for example, they are all radiation-related. And the only one that isn't even really applicable to urologists is overuse of bone scans, which is a clinic measure.

And so I think we should feedback -- you know, I definitely commend the STS for what they have done for this iteration. And I think we should feedback to all the surgical sub-specialties, the ACS, the AUA, the STS, all of them, that they should make an effort to try to figure out what can be measured with surgical processes, because it's currently overlooked.

MS. FRANKLIN: Thanks. Over on to Jennifer and then Robert.

MEMBER MALIN: I was going to -- you know, I'm struck by how almost all the

measures come from the professional societies. And I think that one of the challenges is that then you get a fairly narrow viewpoint.

And so I think providing feedback to try to engage stakeholders in identifying what the important areas are to measure. So it's not just the medical oncologists looking at what we think we like to measure, but to get broader input.

MEMBER MALIN: Well, and also I think broader. You know, we tend to play a lot with other oncology specialists. And ask others, radiation oncologists in the room with us.

But we don't like get the primary care providers engaged, who might have another, you know -- especially on the issue of PSA surveillance. I think some primary care providers might have a lot to say.

MEMBER GORE: And I think advocacy groups. I think, you know, in building upon what you're saying, there may be a role to

engage, you know, patient advocacy groups are heavily involved in issues of policy.

They're very interested in quality performance. And so engaging them, or at least encouraging the specialty societies to engage them, I think, would be great.

MEMBER MALIN: Yes. And I think it may, you know, I think it's great that the professional societies have risen to this challenge. But there's also no substitute for public funding for doing rigorous measurement development.

And so maybe, you know, there could be some funding from AHRQ to have some more multi-disciplinary efforts that get stakeholder involvement.

MS. FRANKLIN: Thanks.

MEMBER MILLER: So let me say, I completely agree with Jennifer about the need for a more multi-disciplinary approach. But I'm going to say something that's completely the opposite of that, which is very specific.

Which is that I think we also, you know, the four letter word, cost, we danced around a little bit. But clearly one of the biggest rising costs is in expensive new targeted therapies.

And so we could pick the tumor type where this is becoming relevant. I would be thinking about lung cancer, for example. There have been several targeted therapies which have been introduced in the last few years.

Tarceva is a little bit older, but crizotinib and a few others that -- these are all very expensive. Most of them, require that a specific target be identified.

And thankfully, I think the payers are holding our hands to the fire a little bit. Because they're so expensive they're not paying for things where the marker's not done.

But I think this is an area that is only going to increase. And I think it might be good to cut our teeth a little bit on

encouraging someone to bring forth some measures specifically to target the therapy in the solid tumor type.

And, you know, lung comes to mind. But I think there may be some measures for colon like KRAS testing, I was going to say. And, you know, there's several others. But I think there's opportunities.

MEMBER GORE: Kidney as well.

MEMBER MILLER: Kidney, absolutely. Yes, kidney.

MS. FRANKLIN: Dr. Fields.

MEMBER FIELDS: We didn't see any on prevention or screening. And when you think about some of the access problems around the country, like mammograms outside of a metropolitan area, or colonoscopies. So it was striking.

And then, you know, we'll also have to deal with CT scanning for lung, since there's some data in there. So it will be interesting to see if we could get more into

the prevention and screening and early detection.

Because, although it was important to spend a lot of time on end of life as one of the most important quality interventions. We didn't really address trying to not have the problem of end of life needs in early diagnosis and high risk patients.

MS. FRANKLIN: Did you have another comment?

MS. BOSSLEY: I will add though, we do have some. And we'll provide them to you so you can see what's in there.

MEMBER FIELDS: Well, that's what my other question was. Do you have another place where you address these?

MS. BOSSLEY: They currently live within our prevention workgroup. But we're in the process of actually -- I think we're going to move all of those screening more into the clinical area.

In part because then you get a

sense of the whole suite of measures that are in the endorsement portfolio for cancer, rather than just seeing the slice of just treatment. So you will see, we'll provide it to you.

And that is where we think we're heading next. We won't have a separate group that looks at it. It will be integrated into the different review committees in the future.

MEMBER FIELDS: So a good example of new screening modalities for breast that then yield lots of overutilization of other resources. Like when do you use MRIs, et cetera? And now we'll have tomosynthesis, which is going to change overutilization potential even more.

MS. BOSSLEY: So hopefully, it will then allow you to be able to better identify the gaps and where measurement should head next. But we'll provide it to you. We'll send it to you so you can see it.

And then if there's anything additional to the gaps discussion, this isn't

the last time you can discuss this. It will go out for comments. And we often get a lot of comments back on what other gaps are out there.

So as you think of things, you can send them, email them to Lindsey or Adeela, and they're happy to collate all of it.

MEMBER ALVARNAS: And the one other thing that came out yesterday in our conversation in evaluating one of the metrics, is that, if you look at all these metrics by themselves they're kind of interesting. But I think unless you turn them into some sort of coherent whole, you're missing out on a very large opportunity. I mean, payers and accountable care organizations will be looking towards these metrics as giving them some direction as to what constitutes measures for assessing their own performance.

But I think developing, either as a committee, or more broadly as the NQF, a strategic plan for how you seek to develop metrics, how you seek to empower them so they

actually grow in robustness and relevance over time, and are refined over time.

And then, when people are hitting their marks well, to be able to retire those metrics and then invoke new ones. But I think instead of doing those on an ad hoc basis or one metric by one metric, developing a strategic plan for the growth, evolution, development, implementation, and, you know, whatever happens after that, of metrics, I think would be invaluable.

Just to be able to coordinate efforts across disciplines and achieve kind of levels of creativity that you might not now, when you look at these things on a one by one basis.

MS. BOSSLEY: And ironically, tomorrow there's actually a group who's starting to look at it a little bit. There is the Measures Applications Partnership, which I think we told you about during your orientation.

But they're the group that is advising HHS on what measures should be appropriate for the federal programs, with the hope that it then translates into other uses as well.

They're discussing cancer tomorrow. So they've put together a set, and I'm happy -- when it goes up for comment, we'll be sure you see it.

And they are challenged by exactly what you've been talking about. That it's narrow slices and it doesn't, they don't have a nice suite of measures that could be used in a payment program or for public reporting or anything else.

So they did take a lot of the measures that you are looking at now and will look at in the future, and try to determine that. But when that goes out for comment, we'll be sure to send that to you so you can see it.

MEMBER NAIERMAN: When we were

discussing today the more than one admission to acute care. I can't remember exactly what the words were. It occurred to me that it is so connected to the whole issue of readmission.

It was just huge with CMS, which is now under total scrutiny, and actually, the hospitals don't get paid for readmissions in some cases.

And so I thought we really probably should have talked about it in that context. And, as I recall, we actually voted down that measure, yes?

MEMBER ALVARNAS: One of the things that's fascinating, when you look at that 30 day readmission metric -- not ours, but the broader one. That was one of the first metrics I read.

I think I almost had an aneurysmal bleed from reading it. Because the number of corrections in data, it's really painful to read through that. But, I think, valuable to have all those variables articulated. But it

makes those sorts of things difficult beasts.

I mean, to some extent they're being evaluated under value-based purchasing formulas, to which we're not yet beholden. But I think this is part of a broader part of a conversation which I think would be worth exploring further.

MEMBER FIELDS: The main kind of feedback that we're not going to get, though, is -- in this it talks about the siloing of a committee like this.

I think what came through the most for hospice is inconsistent access for patients to high-quality hospice in our entire nation.

And that's one of the reasons that it was really hard to have that conversation. Because we can't make the assumption that hospice is hospice is hospice, when we're trying to make sure that we're accessing it.

So how do you harmonize this committee with other committees? I mean, this NQF with other organizations to really improve

access and quality across our entire healthcare system?

This is still sort of a siloed group of people making some recommendations about quality. But we can't really solve the quality problem.

MEMBER TAPAY: I mean, if I could just interject, as someone who actually -- my focus in my professional career has largely been around the access and coverage issues.

And so I'm, you know, in new territory here, that I firmly admit. But my perception of NQF, you know, and I was involved in some of the early stages of the health reform legislation and other debates dating back to the Clinton reform. I'm not old.

You know, it's a group that really is pretty well-respected. They think about incorporating them in legislation and regulation quite frequently.

And so I actually don't think that's necessarily -- at least, I'm giving you

an inside the Beltway perspective. That's how it's perceived.

MEMBER FIELDS: No. But is our hospice services -- if we prove that we're still not adequately accessing hospice services, are we going to solve the problem if there's not a good funding scheme for hospice right now?

So we're going to demonstrate that we don't have quality or we don't have consistency in utilization. But the underlying reason is because the healthcare system doesn't support end of life care consistently across the nation.

So that's my question. It's different than, you know, how this group is perceived. It's more about what actions come from this.

MEMBER ALVARNAS: And I guess what would resonate in my mind is, it seems like we're touching upon a lot of areas that the IOM and the IHI all talk about in their various

work.

And I guess the two questions that arise in my mind from that are: where does our responsibility or scope end and where does theirs begin? And what opportunities to leverage knowledge across these entities, plus all the others that are participating in this discussion, how do we move that forward without remaining so siloed that we miss potential opportunities to actually help people who need it out there throughout the country?

MEMBER DONOVAN: I guess I'd make a push to try to generate more creative measures that tap into patient-reported outcomes, care coordination, and patient/healthcare provider communication, which I think a lot of what we've done over the last two days is really tried to tap into the low-hanging fruit that we've talked about, that might be able to let us infer or draw conclusions about communication without actually tapping into communication.

And I think, again, bringing in advocacy groups, bringing in other healthcare professionals, with a different area of expertise will do that.

Bringing in, you know, I know the Oncology Nursing Society is working to develop some nurse-sensitive outcomes that might be an indicator of quality as well. And I think those will be very interesting to see as they come through.

And then I think, you know, as electronic health records become more ubiquitous and we start to see more creative use of electronic health records, especially in terms of getting patients tapped into the electronic health record on their own, and generating data, delivering data to the records. We may find other ways to be creative in this manner.

MEMBER GORE: I don't actually have my own ideas. I just build upon other people's. But I think that's a great point.

And that sort of builds on what Jennifer was saying about, you know, feeding back to organizations like AHRQ to put more effort behind performance measure generation.

You know, a great resource for that would be PCORI. Their public reporting period is over for research foci. But they would be a great funding source for performance-measured, measurement around patient-reported outcomes.

MEMBER FIELDS: Not a gap in measures, but maybe a gap in makeup of a committee. Unless I didn't understand, I didn't hear anybody representing nursing or oncology nursing, or some of those other kinds of --

Oh, okay. I didn't understand that. I'm sorry I missed that. But I mean, I don't think we still got to all of the potential providers that touch oncology patients. And everybody has such a unique perspective. It was nice to see pathology

participating, since if we don't diagnose it right in the first place, we're not doing ourselves any good. But diagnostic imaging, we didn't have as much representation across the board. And one nurse probably isn't enough.

MS. BOSSLEY: Yes. It's always a challenge to get, especially in these areas, to get the breadth and still keep it to be a reasonable group. But it's not always perfect, we will admit that, or ideal. We'd like to have more.

MS. FRANKLIN: Okay. Thank you. I guess our next steps are up next. And after this meeting we'll have a call in approximately two weeks to follow up on any issues that were unresolved during this meeting.

We will be sending you materials related to that. And then also please be aware that we have a Phase II of this committee meeting, and it will be focused on breast and colon measures.

And we will be tentatively

scheduling an in person meeting to discuss measures on May 22nd and 23rd. And we'll be sending those materials out to you as well. At that same meeting, we also intend to follow up on any -- and the voting -- we'll follow up, on our follow up conference calls, with additional details about Phase II.

MEMBER NAIERMAN: Did you say May 22nd and 23rd in person meeting?

MS. FRANKLIN: That's correct.

MEMBER NAIERMAN: Usually there's only one in person meeting, right?

MS. FRANKLIN: Yes. That's right. We had to break this out in two phases. And so we'll have that second in person meeting for this.

MS. TIGHE: So if you're all willing, we'd love to have you back again.

MEMBER NAIERMAN: Is that set in stone?

MS. TIGHE: It is not. And we had intimated at that, and honestly couldn't think

of a good way to do a full evaluation of the measures without two in person meetings.

MEMBER NAIERMAN: Yes, I won't be able to attend that. I'm going to another conference.

MS. TIGHE: We haven't set the date in stone yet. And we'll be calling you all for availability.

MEMBER NAIERMAN: And when is the next conference call, you said?

MS. FRANKLIN: Approximately two weeks from today.

MS. TIGHE: Yes. We'll look to schedule that probably in the next day or two.

MEMBER NAIERMAN: All right. So as soon as possible we'll have that information.

MEMBER MALIN: Backtracking a little bit, and maybe this is all there and I just didn't notice it. But do you guys routinely collect information on who's funding the organizations that submit measures?

MS. BOSSLEY: We don't. Although typically, we know who does. I mean, for the most part the ones that you saw today were either developed with internal funding from that group, or a lot of them actually were developed through contract with CMS, especially the ones with the PCPI, quite a few were, several years ago. But for the most part we don't ask, but we usually know.

MEMBER MALIN: I mean, I think that's relevant information in sort of understanding the stakeholder perspectives.

MEMBER FIELDS: I also wanted to compliment Humana, the third party payer, for being here for this discussion. So I didn't expect that. That was very nice. But I mean, just from the commercial payer perspective. Are you from a commercial payer? You said from the VA.

MEMBER MALIN: No. I left the VA.

MS. FRANKLIN: Put the microphone on.

MEMBER MALIN: I used to practice at the VA.

MS. FRANKLIN: Say it again.

MEMBER MALIN: I left the VA about four months ago full time. I still volunteer there and maintain a small practice there.

MEMBER FIELDS: Just having that perspective is so important for these discussions. Because we can talk all day about what's important, but without people actually participating in that discussion makes this meaningless. Because they're the ones that actually have to help us solve these problems.

MS. FRANKLIN: Who are you with now?

MEMBER MALIN: WellPoint. It's basically the enterprise organization for a number --

MS. FRANKLIN: Do you have your microphone on?

MEMBER MALIN: Sorry, yes, it's on. Mostly under the name Anthem BlueCross

BlueShield, although some states have a different name.

MS. FRANKLIN: Heidi, did you have a comment, or are you done?

MS. BOSSLEY: I get the feeling we're kind of done.

MS. FRANKLIN: We're done. Well, thank you all. And with that, we'll adjourn the meeting. Nicole, we are completed.

(Whereupon, the meeting in the above-entitled matter adjourned at 3:20 p.m.)