NATIONAL QUALITY FORUM

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PALLIATIVE CARE AND END-OF-LIFE CARE

STEERING COMMITTEE

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WEDNESDAY

JULY 20, 2011

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The Steering Committee met, at the Capital Hilton, 1001 16th Street, N.W., Washington, D.C., at 9:00 a.m., R. Sean Morrison and June Lunney, Co-Chairs, presiding.

PRESENT:
R. SEAN MORRISON, MD, Co-Chair
JUNE LUNNEY, PhD, RN, Co-Chair
RUSSELL ACEVEDO, MD, FACP, FCCM, FCCP, Crouse Hospital

EDUARDO BRUERA, MD, FAAHPM, The University of Texas, MD Anderson Cancer Center
DAVID CASARETT, MD, MA, University of Pennsylvania School of Medicine
ROBERT FINE, MD, Baylor Health Care System
RICHARD GOLDSTEIN, MD, FAAP, Dana-Farber Cancer Institute

SARAH HILL, MA, Ascension Health
PAMELA KALEN, National Business Group on Health
NAOMI KARP, JD, AARP Public Policy Institute
MICHAEL LEPORE, PhD, Planetree
SOLOMON LIAO, MD, University of California, Irvine
STEPHEN LUTZ, MD, Blanchard Valley Regional Cancer Center
HELENE MARTEL, MA, Kaiser Permanente
NAOMI NAIERMAN, MPA, American Hospice Foundation
DOUGLAS NEE, PharmD, MS, OptiMed, Inc.
KATHLEEN O'MALLEY, California HealthCare Foundation
TINA PICCHI, MA, BCC, Supportive Care Coalition
TRACY SCHROEPFER, PhD, University of Wisconsin-Madison School of Social Work
DOUGLAS WHITE, MD, MAS, University of Pittsburgh, Department of Critical Care Medicine

NQF STAFF:

HEIDI BOSSLEY, MSN, MBA
HELEN BURSTIN, MD, MPH
ERIC COLCHAMIRO

CAREN A. GINSBERG, PhD
ANN HAMMERSMITH, JD
KAREN PACE, PhD, RN

LINDSEY TIGHE, MS

ALSO PRESENT:

SYDNEY DY, Johns Hopkins University

CRAIG EARLE, The Ontario Institute for

Cancer Research*

LAURA HANSON, MD, MPH, University of North

Carolina Chapel Hill*

CAROL ROTH, RAND*

MARTHA TECCA, Deyta

JOAN TENO, Brown Medical School

NEIL WENGER, RAND*

*Participating via teleconference

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9:10 a.m.

CO-CHAIR MORRISON: Good morning, everybody.

Actually, the first thing, Debbie, I think you're our operator. Could you open up the public lines for us?

THE OPERATOR: Yes, one moment --

CO-CHAIR MORRISON: Thank you.

THE OPERATOR: -- and I'll get you transferred in with them.

CO-CHAIR MORRISON: So, as I look at my agenda, the first thing is welcome. I guess that's our role. So, let me take this opportunity to just say a couple of words.

First of all, to thank all of you for being here in beautiful Washington. Fortunately, I gather, we are inside today and not outside.

But I really wanted to thank all of you for being here, for going through the review process, and for your participation.

This is an incredibly-important meeting. As many of you know, the field of palliative care and end-of-life care has been lagging behind the rest of healthcare in terms of quality measures. It is fundamentally important as we move forward to have those quality measures to improve care for our patients and their families.

I particularly want to thank the National Quality Forum. Helen Burstin and I were talking about I think we started talking about this process two years ago, Helen? At least. At least.

And it has really just been extraordinary to see the NQF put this on their priority list, move it forward in a very, very exciting way, and get to the point right now where we are really at the cusp of looking at and approving measures to improve care for patients with serious illness.

So, I really wanted to thank Helen. I really wanted to thank Lindsey, who

has been the person at NQF who has been coordinating this all along the way; Caren Ginsberg, to my left, who you are going to hear from, and Heidi -- where's Heidi? -- who have really helped steer this process forward.

Just a couple of words and, then, I am going to introduce June, to my right, who is my Co-Chair.

Why is this so important. Really, from my perspective, and I think from the field's perspective, there are three reasons why we are gathered here today. The first is, obviously, improving quality for our patients with serious illness in their families, to have distinct measures so we can, as Joan Teno keeps telling me, know what we are doing because, if we can't measure, we can't improve it. And I think that is a critical aspect, moving forward.

The second us that we in healthcare are being increasingly held to standards by our payers, by our providers, as

to what is it that we're doing, what type of services that we are providing. And I think this really gives us an opportunity to say to people and to the public, "What is that palliative and end-of-life are really does?

And third key reason that I think we are here is, as many of you know, all of the new provisions of the ACA require the measurement of quality. So that any new accountable care organization, the new medical homes, any new healthcare delivery system has to have NQF-endorsed measures as part of that package.

And if palliative care does not have a set of measures that can be utilized, we will not be part of any of the new healthcare delivery systems. So, it is critically-important for this panel to (a) recognize that and (b) to think very carefully as we move forward, is this appropriate evidence? Are the standards there? And can we endorse this for the new payment systems

moving forward? I think that is part of our mission as well.

I am delighted to be co-chairing with an old friend, June Lunney, who many of you know was instrumental in moving palliative care into the forefront of NINR, and NINR is still the lead Institute focused on palliative care.

And, June, comments, welcomes?

CO-CHAIR LUNNEY: Thank you.

I believe that I have the privilege of being Co-Chair with Sean, who really knows the process, really understands what we are doing today, and I'm the novice.

That can be an advantage in the sense that I think that novices sometimes ask questions that really people who are too deep into the system don't see. They have blinders on. And that will be my role.

I also bring a balancing perspective, I think, in that I have always had a little trouble understanding how we can

provide palliative care to people who don't know they have serious illness. They have multiple chronic illnesses. They're falling apart at the seams. They're reaching the end of their life, but they don't have that single diagnosis or even one of their diagnoses hanging over their head as life-limiting.

So, I think I bring a perspective here that I am still struggling with what's this concept of end of life. I define it much more broadly than most. But that's the perspective that I bring today as well.

CO-CHAIR MORRISON: And I made the first mistake. Everybody, when you speak today, if you could turn your mics on, because it is being recorded. Thank you.

MS. BOSSLEY: And there will be people on the phone as well. So, from time to time, we will do public comments. So, you will hear us ask the operator.

But, again, I just wanted to say thank you very much. We know that you are

taking two days out of, hopefully, where you were cooler and you're going to be somewhere quite hot. So, we are very sorry about that, but, unfortunately, it's D.C. and that's what happens. So, thank you so much for coming. We appreciate it.

CO-CHAIR MORRISON: And Caren?

DR. GINSBERG: Sorry, I already forgot (referring to microphones).

Welcome. We are glad you are here.

Actually, it's probably hotter where you came from than it is here. Welcome to the dome of high pressure.

So, we would like to get started first with Ann Hammersmith, our NQF General Counsel, who will ask some routine questions and talk about disclosures.

MS. HAMMERSMITH: Is this mic live? Can everyone hear me? Okay. It's on.

For this part of the meeting, we are going to go through the disclosures of

interest. If you recall, several months ago, we sent you a form that asked you some detailed information about your background and what your involvements are. You very kindly filled out the detailed form and returned it to us. We went through them carefully.

Now what we would like to do is have you orally disclose any interests that you believe are relevant to your service before this Committee. I want to emphasize that just because you disclose something does not mean that you have a conflict of interest. We are doing this in the spirit of openness and transparency.

We don't expect you to recount your CVs. We know you're all quite qualified and talented. So, we don't need to know every article you ever published.

What we are looking for, in particular, is disclosure of consulting relationships, research support or grants that are relevant to what's before the Committee.

I also want to remind you that you serve on this Committee as an individual. You do not represent the interests of the organization that you work for or for any organization that may have nominated you for service before the Committee.

So, with that, I am going to ask you to go around the table, identify yourself, who you are with, and let us know if you have anything to disclose.

And I will start with the Co-Chairs.

CO-CHAIR MORRISON: So, my name is Sean Morrison. I wear a couple of professional hats. I direct the National Palliative Care Research Center in New York City. I am a professor of geriatrics and medicine in the Department of Geriatrics and Palliative Medicine at the Mt. Sinai School of Medicine. And I am the Immediate Past President of the American Academy of Hospice and Palliative Medicine, which means that I

still serve on their Executive Committee, as a disclosure.

In terms of disclosure, I receive research funding from the National Institutes of Health and from 15 different private philanthropic organizations, none of which are related to industry, device manufacturers. They are all 501(c)(3) organizations and several individual philanthropists.

CO-CHAIR LUNNEY: Again, I'm June Lunney. I am supposed to be retired.

(Laughter.)

I do work on a very, very part-time basis for the Hospice and Palliative Nurses Association. I also receive funding, I guess you could say. I am co-PI on an RO1. I have no salary support and I have no funding from any other private source at all.

MEMBER GOLDSTEIN: My name is Rick Goldstein. I am a pediatric palliative care physician at Dana Farber Cancer Institute in Boston and Children's Hospital, Boston. I am

also the Massachusetts Center for SIDS and Child Bereavement Medical Director. And I have no conflicts to report.

MEMBER ACEVEDO: Hi, everybody. I'm Russ Acevedo. I am a multidisciplinary intensivist from Syracuse, New York. I'm a clinical professor of medicine at the Upstate Medical University. I am also on the American College of Chest Physicians' Quality Improvement Committee. So, I guess that is one of the hats I'm wearing today. And I have nothing financial to disclose.

MEMBER PICCHI: Good morning. I'm Tiny Picchi, and I'm the Executive Director of the Supportive Care Coalition, which is a national coalition of Catholic healthcare organizations to promote excellence in palliative care. And I have no disclosures.

MEMBER HILL: I'm Sarah Hill. I'm System Manager for Palliative Care Initiatives for Ascension Health; also, a Supportive Care Coalition Board member, but no financial

disclosures.

MEMBER KARP: Hi. I'm Naomi Karp. I'm with AARP's Public Policy Institute. I work for the 501(c)(4). AARP is three different entities. I don't work for the for-profit entity, and I have no financial disclosures.

MEMBER KALEN: Good morning. I'm Pam Kalen. I'm with the National Business Group on Health. I'm representing a purchaser perspective, and I have no financial disclosures to report.

MEMBER BRUERA: Hi. I'm Eduardo Bruera. I work at MD Anderson Cancer Center in Houston. It's a State of Texas institution. And I have federal grant funding, but I do not have any funding that is directly or indirectly related to industry.

MEMBER O'MALLEY: Good morning. I'm Kate O'Malley. I'm a geriatric nurse practitioner and a senior program officer at the California HealthCare Foundation in

Oakland, California. And I have nothing relevant to disclose.

MEMBER WHITE: Hi. I'm Doug White. I'm a pulmonary critical-care-trained physician, and I direct the Program on Ethics and Decisionmaking in Critical Illness at the University of Pittsburgh. I am also the Chair of the Ethics and Conflict-of-Interest Committee of the American Thoracic Society. And I have research funding from the NIH and the Greenwall Foundation.

MEMBER CASARETT: Good morning. I'm Dave Casarett from the University of Pennsylvania, where I hold a faculty appointment. And I'm also the Chief Medical Officer for Penn's Hospice and Palliative Care Program. I receive grant funding from foundations and from NIH, no industry sponsorship.

Two non-financial conflicts or potential conflicts I wanted to raise. These have been reviewed by NQF staff, but I wanted

to share with the group.

First of all, as some of you know, I used to work in the VA and was involved in some of the early phases of the development of one of the measures that we will be reviewing, the Bereaved Family Survey. But, as I explained to NQF staff, I have not been involved in that in its national rollout. I have not been involved in the VA in the last year.

The second is I work as a paid consultant Medical Director for the National Hospice and Palliative Care Organization, which has at least one measure under consideration, but was not involved in the development of that measure for this group, nor the creation of the proposal.

Thanks.

MEMBER MARTEL: Good morning. I'm Helene Martel. I am the Director for Eldercare and Palliative Care at Kaiser Permanente in Oakland. And I have no

financial disclosures.

MEMBER LIAO: Hi. Solomon Liao from the University of California, Irvine. My only consulting work that is relevant is with the U.S. Attorney General's Office.

MEMBER FINE: Hi. Bob Fine, Baylor Health Care System in Dallas, and since 1994, a founding member and Co-Chair for the Clinical Corporate Ethics Committee for VITAS Hospice, a for-profit hospice agency.

MEMBER LUTZ: Steve Lutz. I'm a radiation oncologist; also, Board-certified in hospice and palliative medicine and serve as, I guess, the unofficial liaison between the two specialties.

No financial disclosures, but in terms of a perception disclosure, my brother is the Director of the Agency on Aging, and had better be working pretty hard this morning about a couple of hundred yards from us.

(Laughter.)

MEMBER NAIERMAN: Hello. My name

is Naomi Naierman. I am the CEO of American Hospice Foundation, and we represent the consumer's perspective. No financial disclosure of any relevance.

MEMBER SCHROEPFER: Hello. I'm Tracy Schroepfer. I'm an associate professor and Associate Director of the School of Social Work at the University of Wisconsin, Madison. It's a land grant, State-funded. And I have RO1 funds, but I have nothing to report.

MEMBER NEE: My name is Douglas Nee. I'm an independent consultant pharmacist in palliative and hospice care. I have nothing to disclose.

MEMBER LEPORE: Good morning. I'm Michael Lepore. I'm an investigator in health services policy and practice with Brown University. I'm also Director of Research for Planetree, which is a nonprofit membership organization and partnering with the Veterans Administration to support person-centered care and provides consultation for person-centered

care in other healthcare settings.

MS. HAMMERSMITH: Okay. Are there any Committee Members on the phone?

(No response.)

No, Lindsey? Okay.

Thank you for those disclosures.

I now want to give you the opportunity to discuss anything amongst yourselves that you would like to talk about, any questions you have for each other, based on the disclosures that have been made this morning.

(No response.)

Okay. Thank you. Have a good meeting.

CO-CHAIR MORRISON: Thanks, Ann.

We are now only five minutes behind. We've already made up 10 minutes, guys. So, this is really good, and we will make up time.

What I would like to do now is turn things over to both Heidi and Caren, who are just going to walk us through a little bit

about the project overview and the process for measurement evaluation that we are going to be going through today.

I'm not sure who's -- it will be that screen, and it will be Heidi. Caren's going to do it? Okay.

DR. GINSBERG: No, just me.

CO-CHAIR MORRISON: It's Caren. Okay.

DR. GINSBERG: I want to talk to you about a couple of things this morning before we start talking about the measures. I wanted to review the purpose of this project and the scope of this project and the timeline. And you have seen these slides before, but I just wanted to review them again.

And I also wanted to mention some related activities within NQF and elsewhere that focus on palliative care and end-of-life care.

So, again, the purpose of the

project is to identify and endorse measures for accountability and quality improvement that address the quality of care for patients that receive palliative care and end-of-life care. And we are also going to be reviewing previously-endorsed measures related to palliative care and end-of-life care that are undergoing their maintenance review.

This project will seek to endorse performance measures that focus on assessment and management of relief of symptoms, psychosocial needs and care transitions, and patient and caregiver and family experiences of care.

So, we talked earlier about your role as a Steering Committee Member. I would like to just remind you again of what that entails.

You are acting as a proxy for the NQF multi-stakeholder membership for this project, and you are working with us to achieve the goals of this project. So, as you

know, you are evaluating submitted measures against our formal criteria for evaluation. And you will be making recommendations to the National Quality Forum membership for endorsement.

You will respond to comments that are submitted during a review period, and the Co-Chairs of this meeting will represent you at a followup project webinar and at our Consensus Standards Approval Committee meeting.

So, let's review the timeline. We are at the July 20th to 21st in-person meeting. Following this meeting, there will be a draft report produced for member and public comment. The comment period will be September 7th to October 6th.

Following that, you will be responding to comments on or around October 14th. Then, there will be a followup project webinar sometime in late October.

A draft report will be produced

for the NQF membership voting. The voting will be in late October or early November. The CSAC review and approval is in December.

Then, our final endorsement by the NQF Board is in January of next year.

And some of these dates, as you can see, are tentative.

Any questions about any of that?

(No response.)

Okay. I would like to just talk very briefly about some related activities at NQF and our National Priorities Partnership and our Measure Applications Partnership that focus on palliative care and end-of-life care.

Let's talk a little bit about the National Priorities Partnership first. NQF provides annual input to Health and Human Services on the National Quality Strategy. We do this by identifying goals that map to the NQF priorities, NQS priorities, and providing input on measures to track those goals.

There is not a specific priority

related to palliative care and end-of-life care. But, as you will see, there are opportunities to incorporate goals and proposed measures into the identified priorities.

Oh, and I would like to say also that their work is done in Work Groups in a consensus fashion around each specific topic.

So, an identified priority is to ensure person- and family-centered care, and a proposed goal that has been identified is to improve patient, family, and caregiver experience of care related to quality, safety, and access across settings.

A proposed measure to meet that goal is patient-centered hospital pain management. They have also, under the NQS priority to promote effective communication and coordination of care, have identified, proposed a goal to improve care with a care plan that addresses pain and symptom management, psychosocial needs, and functional

status with proposed measures of hospital patients not receiving care consistent with end-of-life wishes and the Care Mortality Followback Survey of Bereaved Family Members.

Okay. Let's talk for a minute about the Measures Application Partnership.

This activity provides input to Health and Human Services and CMS on selection of available measures for public reporting and performance-based payment programs. They identify gaps for measure development and endorsement, and they encourage alignment of public and private sector programs across care settings.

so, the MAP projects that are relevant to our work consist of projects on post-acute care and long-term care facilities, hospitals, and hospices.

The Work Groups for these projects identify core sets of available measures, including clinical quality measures, patient-centered cross-cutting measures, and

population-based measures. They identify critical measure development and endorsement gaps, and they provide input on measures to be implemented through the federal rulemaking process that are applicable to these settings.

So, the recommendations for measures are due next year in February for the post-acute care and long-term care and in June for hospital and hospice.

We talked briefly about the quality reporting mandates of the Affordable Care Act. As you know, CMS is identifying a framework for quality reporting that is aligned with those National Quality Strategy goals. So, I wanted to just mention how our work relates to theirs.

Their recommendations will be considered by the MAP. The measures that you will be talking about today and tomorrow and endorsing for this project will be considered for subsequent years by the MAP.

So, we just identified, we just

mentioned the word "framework", and I would just like to bring that word back for a second to talk about frameworks for developing a report for our work here today.

And so, there have been a couple of frameworks that have been introduced, one by the Long-Term Care Quality Alliance, another by CMS for their work. And we will discuss that further tomorrow, when we talk about writing our report.

So, if you have thoughts about that, please save them for tomorrow. We are happy to talk about them.

Again, to introduce the project staff: Heidi Bossley, who is Vice President for Performance Measures; Lindsey Tighe, Project Manager; Eric Colchamiro, who is our Project Analyst, and I'm Caren Ginsberg.

Thanks very much.

I am going to now, on the agenda it says we'll talk about measure evaluation, criteria, and review. For this, I will turn

the floor over to Karen Pace, who will lead off with a discussion of our first measure.

DR. PACE: All right. It's nice to see everyone in person.

CO-CHAIR MORRISON: I'm sorry, Karen, just before you start -- Helen, could you introduce yourself because I realize we went all the way around and Helen Burstin didn't get a chance to introduce herself, who will tell all about her wonderful qualifications. But, in my mind, her greatest qualification is she is the sister of my pediatrician, who has been fantastic for 18 years.

(Laughter.)

DR. BURSTIN: Hi, everybody. Just to add my welcome, Helen Burstin. I'm the Senior Vice President for Performance Measures at NQF.

So, if you have any specific questions about those, sort of big-picture questions about how what we do relates to

those other issues, I would be your person.

Karen Pace will be speaking next, as our lead measure methodologist, the person most steeped in our evaluation criteria, how we look at our measures.

As I told the Co-Chairs earlier, you are a bit of a guinea pig for us, one of our first Steering Committees to use our updated evaluation criteria on evidence and testing. So, we thought it would be useful to have Karen walk through the first measure with you, raise some of the issues, kind of get you ready for the evaluations to follow.

Again, we are still always trying to, in the guise of continuous quality improvement, tweaking our process. So, if there are elements of this that don't work, we will continue to try to improve it. But Karen will walk you through that first measure.

DR. PACE: Okay. So, this measure is 0213. I am going to bring up the preliminary evaluations.

As you know, you were assigned a group of measures for an in-depth review of the measure, but everyone will participate in the final voting on these measures in terms of rating the criteria and, ultimately, whether you feel it has met our criteria for consideration for endorsement.

So, you need to enable macros for the calculation to work.

So, this is the measure of the proportion admitted to the ICU in the last 30 days of life. Basically, it is a measure of the percentage of patients who died from cancer and were admitted to the ICU in the last 30 days of life.

So, what we ask you to do, for the person that will be introducing the measures is to really kind of look at the group of preliminary vals, kind of summarize what the ratings were and identify any issues that were raised during the various Committee reviews of this measure.

In addition, as Helen said, I'm also going to provide some perspective, just from the perspective of what the Task Force and Board and CSAC intended with some of the guidance on evidence and measure-testing, and we will kind of work through this.

So, on this particular measure, under importance to measure and report, the ratings were fairly high, were high and moderate for high impact and, also, opportunity for improvement.

Then, on evidence, we will talk about it a little in just a moment.

One of the things that I will point out, I think this is a good measure for us to kind of go through together because it presents a variety of challenges that you all may have identified. As Helen said, we are just now implementing those two Task Force guidance recommendations in terms of how we rate these criteria and, ultimately, how that factors into a decision.

It is new for our Steering Committees as well as our developers. So, I think some of the submissions reflect the developers also feeling their way through some new areas.

And having said that, I will also mention that, although our guidance has been made more specific, the criteria themselves have not changed. So, NQF has had a criteria on having evidence to support the measure focus since the beginning of NQF. We have had criteria about reliability and validity.

So, the criteria have not changed. We are expecting more rigor in terms of what is submitted and how that is evaluated. So, I think that is probably the main thing to keep in mind.

And I think the Committee ratings were fairly high on these, but what I would note is that there was one reviewer who indicated insufficient evidence. If we look at this actual measure submission form, there

really is very little data that was actually presented for any of these categories.

So, one of the questions that we will talk with you about is rating the measure based on what was submitted versus substituting your own knowledge in the field, and we are going to have to have some discussions about that, so that we're all on the same page.

For example, under impact, they make the comment that decrease in ICU use would save resources and improve the quality of death. Generally, for all of our criteria we are asking for some actual data. This one is probably more evident. But, in general, we would be looking for some data about what percentage of patients have these ICU admissions or what that cost is overall, what the impact is on quality of life.

For opportunity for improvement, which is criterion 1b, again, we are asking for some actual data. And for a measure that

is undergoing endorsement maintenance review, we are actually asking for some information on the measure as specified. So, in this area a new measure, what they present there in opportunity for improvement may be from the literature, from studies in the literature, from population data, et cetera.

When a measure is coming back for endorsement maintenance, we would like to see what the performance is on that particular measure because it has some implications for whether that measure should be continued to be endorsed.

So, in this particular case, they didn't really provide any data, either in general or for this specific measure. So, again, both of these areas in terms of impact and in general the opportunity for improvement are things that the Steering Committee probably has a lot of knowledge about. We can go back and talk about that in a minute.

So, when we get to evidence for

this particular measure, again, we are asking now for the submitter to summarize the body of evidence related to the quantity, quality, and consistency of the evidence for a specific measure focus.

So, the real goal is transparency. Our Task Force, and this really came at the impetus of a lot of our membership, our Board, and our CSAC, that we even had a Task Force to look at evidence, but the idea was to be real transparent about what evidence does or does not exist.

And all else being equal, NQF would like to endorse measures that are based on the best quality evidence. Now we know that that can vary according to the particular area and the type of research that can be conducted, but, in general, the idea is to know what the evidence is and to make some decisions based on that.

So, I think in terms of what was presented, there were some conclusion

statements presented, but, really, no actual evidence, in fact, not even any citations for evidence.

So, again, this may be an area that you, as a Steering Committee, have some knowledge of the evidence, and that's what we were talking a little bit just before the meeting in terms of how to proceed with -- this is probably not the only measure that is in this shape in terms of what you have reviewed. I haven't reviewed the full set of measures. So, some of this will apply to other measures and some not.

So, the way our Task Force -- and this has some very important implications -- based on our rating scale for evidence, evidence has to meet certain criteria in order to pass evidence. And all three of the criteria, high impact, opportunity for improvement, and evidence, must be met. All three of those need to be met in order to say that the measure meets our criterion for

importance to measure and report.

And they must pass criterion, meaning that if a measure does not meet that criterion, it is not further evaluated and would not even be considered for potential endorsement.

So, we are in this little bit of a quandary here because, based on the ratings, I am assuming that the Committee Members are thinking this is an important issue that should be measured. I would just like to point out that we have certain criteria about what meets our criteria for importance. I am not saying this doesn't. It is not clear in the submission form that it does.

So, one of the things that we will want to discuss with you is how we should proceed in this kind of circumstance. But I will just kind of run through the other criteria maybe, if that is okay, and we will come back to that.

So, in this particular submission,

if we move on to scientific acceptability and measure properties, reliability and validity, again, the reviewers basically thought that this measure met those criteria at a moderate and high rating.

And I will just point out a couple of things that we may want to discuss. I am going to hold off and just talk about the measure specifications for a moment because we do consider those kind of a foundation for having a reliable measure.

One of the things that you might want to look at as you are looking at measure specifications, the main question is, if you had these specifications, could anyone implement this measure? Would they be able to identify the patients that are included in the denominator and who would be included in the numerator?

And so, one of the things that I noted is that this measure is based on claims data, but no codes were provided. So, it is

just a question that we might want to see with the developer if there are more specifications, so that anyone would be implementing this exactly the same way.

So, in terms of reliability and validity, the developer noted under reliability that they looked at their claims data and compared that to chart data. I know this gets into some very specific issues regarding what's reliability and what's validity.

But in terms of data element level, and we allow for testing at either the data elements that go into building a measure or looking at that performance measure score. There are different kinds of testing of reliability and also validity, depending on what level you're looking at.

So, they basically were looking at the data element and they were comparing the information from claims to a medical record review. We would actually classify that as

validity because you are kind of looking at the data you are using in the measure and comparing it to an authoritative source.

Even given some of the limitations of medical records, those are typically considered the authoritative source. So, we would consider that a test of the data element validity. And actually, our criteria do indicate that, if you are doing data element validity, you don't have to do an additional reliability testing at that data element level.

So, I would agree with the reviewers that, in general, this would be sufficient. The question that it raises for me, however, is I don't know exactly what data elements they compared. They mention one statistic, the sensitivity and specificity. So, my question would be, sensitivity and specificity of what? Was it sensitivity and specificity for identifying ICU use in that 30 days? Or was it for identifying cancer

patients? I don't know because they haven't really described it for me. I mean the actual number is good. I just don't know what it applies to.

And so, the same way, with validity they kind of just presented the information in different ways, saying 95 percent accurate. But, again, I don't know what. Are they saying, on average, all the data elements were 95 percent accurate? I'm just not sure. So, we don't actually have as much information as generally we would like.

Okay. So, the other thing that I will point out is under 2b5, identification of meaningful differences in performance, we actually would like some information about, if they have it, which also gets back to opportunity for improvement, but what has performance on this measure been? What's the distribution? What's the average, et cetera?

I'm not sure, and maybe some of you understand this, they mention that a

benchmark target of less than 4 percent of patients being admitted to the ICU in the last 30 days of life. They said benchmarks were established to identify the outlying 10th decile of practice.

So, I'm not exactly sure. I'll just stop there and ask if anyone else is maybe more familiar with this that understood what they were saying here. I don't know if they were saying --

MEMBER GOLDSTEIN: My reading of this is that they were willing to accept something like two standard deviations from the norm as a tolerable level of ICU use. But, more than that, they were trying to at least measure, you know, introduce it into the measure as something to compare.

DR. PACE: Right. So, I believe the way the measure is set up is just coming up with a rate. So, it is not really meeting a specific target, which some measures do incorporate that into the measure. I mean

they may just say, when they looked at the distribution, the rate at the 10th percentile was less than 4 percent. I'm not sure, but I think that is perhaps what they were looking at.

Okay. So, in terms of usability, then, we will move on. The usability was rated high to moderate from the reviewers.

One thing that we are interested, again, for our measures that are undergoing endorsement review, maintenance review, is, are they in use, and specifically, are they in use for public reporting and quality improvement? Basically, they say that this is being used for public reporting in the Cancer Care Ontario's Cancer System Quality Index.

Okay. And, then, feasibility, I think everyone is okay with the feasibility for this particular measure.

So, I just went through the whole review first. What we are going to do, as we go through these measures together, and maybe

now we will kind of go back through that, is after we discuss each criterion, we are going to have a vote on it. Then, that will decide whether we go on to the next criterion.

So, maybe we will go back and talk about some of the issues about importance to measure and report, see what questions you have, and how we might want to proceed. Then, we will vote on that criterion and, then, talk about whether we move on to the next.

And actually, because of the way the Task Force guidance is, we are going to have you vote on each of the subcriteria under importance to measure and report because, then, that ultimately rolls up to whether it passes the criterion.

So, before we have any more discussion, let me just stop here and just see what your thoughts are about this particular measure or, in general, some of the comments I made, how it applied to measures you reviewed. We thought we should kind of lay

this out, get on the same page of how we might look at these as we are going through the rest of the measures.

MEMBER FINE: I don't mind starting. I'm thoroughly confused now.

(Laughter.)

I had called Dr. Ginsberg during this process trying to understand even the basic questions. For example, is this measure an outcome or a process? And I noticed that the six of us who turned something in, two of us said it was an outcome and four of us said it was a process. And I would have said it was an outcome until I talked to Caren, who said, "Oh, no, this is a process."

And I also notice that five of the six people who turned things in thought the evidence was anywhere from moderate to low. Russ I think got it right and said, "No, there's insufficient data there."

I just need some help understanding how you all are answering these

questions. What you just did was fine, but I am still confused. Sorry. And if I am the only person confused, I withdraw my confusion.

(Laughter.)

MEMBER ACEVEDO: Well, this was very helpful for me because, when I first looked at this and saw I was the outlier there, I was getting a little worried myself.

(Laughter.)

I found the first block more difficult than the second block because these were measures that had already been approved. I almost got the sense that, when they submitted their reapplication, they knew in their heads they had collected this data. It's out there. But they never put it on paper.

And if I am asked to judge something that is put on paper in front of me, that is what I have to judge against. Because I went to the Canadian website; I went to try to look to see if I could find some

justification. Because I figure at least if they gave me the website, that is something to go on. But even then, I wasn't going to find much evidence to put my hat on.

CO-CHAIR MORRISON: Did you have your mic on? Oh, Bob still. Okay, sorry.

Let me try to frame this a little bit, if that would be helpful for people. The first, I know many of you in the room. I met some for the first time. Is everybody comfortable with just using first names? Okay. I just want to clarify that. Some people are not. And if not, then we can do that.

So, let me try to frame this, sort of frame this process a little bit for people who are not familiar with it, which I think is most of us and, also, because it is a new process.

So, first of all, I think, Russ, you're right. I think some of the measure developers are going through this (a) for the

first time or (b) have already gone through the process and are not quite sure about the new evidence guidelines.

And I think what differentiates this Steering Committee from, for example, an NIH study section or review panel, which many of us are familiar with, is that although we had what was in front of us to review coming up to the meeting, the purpose of this meeting, and, indeed, the purpose of having the developers in the audience -- and many of them are going to be here, and I'll talk about Craig Earle in a minute -- is that those types of questions can be answered both by the developers or by people within the audience who are familiar with the body of work and the evidence behind it. And you should feel free during the course of the discussion to bring that forward.

I would encourage very strongly, to the extent that you can, to try and separate out passion, belief, experience from

your knowledge of a body of evidence when you present it. Because when it is going to come to a vote, the Committee is going to vote on both what they have seen in front of them, what they have heard from the developers in answer to specific questions, and what they have heard from the Committee.

As we move through this, I think it will get a lot easier. Part of the issue about going through criteria-by-criteria is that, in order to meet endorsement, it has to be approved on all the criteria. So, as we go through, if there is one that doesn't meet criteria, we just stop and we move forward.

Okay? That measure will not be moved forward for endorsement. So, that is why we move through it for very carefully.

I think the other summary statement that I think is really helpful is this is the first time that this field has put forth measures like this. I think there is some confusion and some difficulty about what

might be a process, what might be an outcome, and what is structural.

Clearly, NQF, and I think all of us, would really like the majority of measures to be outcome measures. As we have talked about over the past couple of years, our field is not at that stage yet. And so, we may need to look at process measures that meet the criteria.

And I would encourage everybody not to make the perfect the enemy of the good here. If this Committee moves forward with zero or one or two measures ready for endorsement, that is what is going to happen. It will be a while before new measures come forward. This was the first call for palliative care and end-of-life measures, and this is the opportunity.

So, I would encourage people to be broad in their thinking. Think about what the evidence is, but also not to make the perfect the enemy of the good.

I would also say that, working with NQF over the past couple of years, everybody at NQF is aware of the limitations of the current system. Everybody is aware of how the current endorsement process doesn't match well.

For example, with our field, you will see there are measures that have been developed in one population that might be well extended to another. Well, that can't happen per se under the current -- and NQF is really working hard on that.

But does that help a little bit, folks, in terms of framing it?

Naomi?

MEMBER NAIERMAN: Sean, just to clarify, are we allowed to ask a developer who may be in the room to clarify some information that we might seek?

CO-CHAIR MORRISON: Absolutely, and, in fact, I would encourage, if somebody does have a question, particularly if it is a

question that may lead to endorsement versus non-endorsement, please, please raise that. Raise it with the developer. Bring it forth to the table.

My understanding is most or all of the developers will be here when their measures are being addressed except for Craig Earle. That's the hard part. The measures that are being stewarded by ASCO, which we are discussing first, Craig will be available by conference call from 12:00 to 12:30.

So, June and I are making a list of questions. I have already got two to ask Craig.

If you have a question, please make sure that we get it, and we will really spend 30 minutes moving forward at that time to see if we can get that clarified.

Unlike the other measures -- correct me if I'm wrong, Karen -- but if we have open measures on this, will we come back for a vote on it? Or do we have to move

forward without the information?

DR. PACE: Well, one of the things that we talked about is, you know, maybe as we go through this first measure, we will find a way to address this, but one thing we could do is ask the Committee if they are aware of evidence, a body of evidence. I think Sean's caution about separating knowledge of a body of evidence from your personal experience or passion for the area, to be clear about that. The Committee can then vote on this.

I think if there's really insufficient evidence according to our criteria, it would not meet that criterion, it would not go further. If we think it is something that the developer could supplement, we may make the decision at that point to continue evaluating the rest of the criteria and then ask the developer to provide that. Or, you know, if the Steering Committee essentially agrees that, yes, the body of evidence supports this, but we are going to

have to document that both from the Committee's standpoint and, also, what we might ask the developer to come back with to really provide that documentation.

I think you're right, this is a new area of measurement. The caution I will give you is that everyone is expecting all measures to meet the criteria, and measures that were endorsed previously, when maybe our criteria were not applied as stringently, at the time of endorsement maintenance are expected to meet the criteria.

But, Helen, I don't know if you want to make any comments about that.

DR. BURSTIN: Yes. This has been a big issue that CSAC has been talking. CSAC is our Board-level Committee, the Consensus Standards Approval Committee, that reviews all of the measures following you that Karen talked about earlier.

We have actually had extensive discussions about how do we handle sort of

emerging measures in new measurement areas where the evidence may not be quite as robust, where the information and the testing may not be quite as robust. And do we sort of modify the way we bring measures forward?

I can't say we have complete clarity. We just had this discussion just last week on some measures for pediatric end-stage renal disease, where, for example, some of the thresholds and outcomes, the evidence just isn't there. So, how could you move towards an outcome when we can barely get past the process measure?

So, I think you guys should just indicate what you think. I think you are still very early in the process. There's a long opportunity for comment. We get hundreds, 300 to 400 comments on every project.

You will get a chance to get a sense of what the larger community thinks about this. We will, then, bring it back to

the CSAC. So, I think you have a good opportunity here. I think what you need to do is, just as much as possible, we need to document the justification and the logic of the decisions you are making.

If you are rating evidence high, and, in fact, the evidence, technically, the way you would construct it on quantity, quality, and consistency is not, we need to just be very, very clear that you used a different lens to somehow come to that decision. We would prefer you just vote it as it is, but our concern, though, is we also don't want these measures to die on the vine in importance because, then, we won't review the rest of the measure.

So, I think we are going to try to work with you today, see what we can do, document everything, document your justifications, and just see what's possible.

MEMBER O'MALLEY: And I just have a question in terms of process. The voting we

do these next two days is not the end word on this. I mean if we, through the comment period, learn more that substantiates the value of the measure, then there will be a revote to reconsider new evidence?

DR. BURSTIN: Yes. So, essentially, what will happen is, after this process, you will have an opportunity for a little bit of back-and-forth with the developers. They could give additional information beyond what they gave you today, present additional information. You may even have a chance to revote or reconsider then.

But what would happen is, after the comment period, particularly for a measure that you either didn't recommend or did recommend, you would have the opportunity to reconsider, based on what came in a comment, and make a different decision prior to the measure going out for a vote.

CO-CHAIR MORRISON: Could I just a quick clarifying question? For those of you

who have more experience in Washington, could we do the tent thing for questions because it is really helpful for June and I to figure out who turned their mic on and who has a comment? So, if you have a comment or question, if you will just flip your tent card up, and that way we can keep track and make sure that we include everybody.

And, Solomon, if you could please be less clumsy at that, it would help.

(Laughter.)

Yes, so I've got Rick. I've got Stephen. I've got Solomon. I've got Doug.

MEMBER GOLDSTEIN: I'm wondering if someone could speak directly to whether, as part of understanding evidence, how the measure appears compared to all the other measures that we have had to review, should be factored in.

For instance, when I reviewed this, I thought it was actually a very clear measure in comparison to the others, even

though when we break it down criteria-by-criteria, it has its deficiencies.

DR. PACE: I was going to say I'm not the one that can answer that. But our process is really to evaluate each measure against the criteria without considering the other measures.

If there are related and competing measures, then we look at those at a next phase. But maybe someone else wants to comment.

CO-CHAIR MORRISON: I mean all of you, I think, received a package, a letter from the NPCRC, the National Palliative Care Research Center, that looked at, tried to put together and look at, as a process with the developers over the past year, look at all the measures and how they might harmonize together.

I think there's two answers. And, Helen and Karen, correct me, Heidi, if I'm wrong. The first is that every measure

probably you should evaluate independently, based on the quality.

But I do think that, as we are going through the day, because of -- how should I say this politely? -- because of the limitations of the process right now, that you should also think about how these measures harmonize with others.

Because, for example, if we approve a specific pain measure for cancer, that would be applied only for cancer. If there's a harmonizing measure that looks very similar that is in another population, you should also think about how those two relate.

Because the way the measures are framed now, they are population/setting-specific. And we recognize that people with serious illness both transverse settings and have multiple different and existing conditions.

So, thinking about how they relate to each other, Rick, I think is also an important way to evaluate them.

Is that okay, guys? Helen, I'm looking to you for guidance.

DR. BURSTIN: Yes. Measures are to be individually evaluated. You will have the opportunity to look at competing and harmonized measures when the measures have passed the criteria. When you feel like different measures -- for example, those three or four different measures of pain, if you feel like three of them have met the threshold, the three of them will be looked at for harmonization, once you think they have met that threshold.

But I do recognize the fact that, again, you may not -- I mean we have got some of the cardiovascular measures that have been around for a decade. Some of those submission forms were small tomes. I mean they could report pages and pages of some of this.

I think what you need to factor in -- and this was the issue that really came up at our discussion last week with the CSAC --

is sometimes when is the evidence, particularly I think the evidence, when is the evidence on these forms lacking because it doesn't exist? As opposed to when the evidence is lacking because the developers didn't really pull it together and explain it to you in a way that makes sense. That is an important distinction.

I think in the first instance the evidence isn't there, and you are inferring, based on what is there. That is something only to document, justify, and bring forward through the process.

But I think it is different to say there's plenty of evidence out there; they just didn't cite it, in which case I think we need to go back to them and get additional information.

DR. PACE: And just one other thing about that. You know, actually, it is very difficult to work into any kind of algorithms. But the Evidence Task Force

report really did identify that there may be cases where there is no body of evidence, and, then, it would rely on expert opinion.

Generally, expert opinion is not considered evidence.

But I think that speaks to what Helen is saying. If there is no evidence, then, you know, hopefully, there would be some clinical practice guideline that already exists based on expert opinion. But, then, it would default to, I guess, your expert opinion.

So, that's why I think we should vote on the subcriteria under importance. And if it really is insufficient evidence, then we need to stop and have a decision of, well, is it because there's evidence, but it just isn't here or is that there is no body of evidence for this particular aspect?

I just wanted to comment about the process outcome. I think that was an interesting observation, also. Sometimes it

is much more clear, but even in some of Donabedian's writings about structure, process, and outcome, he identified that sometimes it is not always clear.

I think some of it depends on your perspective. But, in general, we tend to classify things as process if it is about treatment or intervention of the patient, and outcomes tend to be more either the end-result outcome or some intermediate clinical outcomes.

And depending on your perspective, you could probably put this particular one in either bucket. I think the developer presented it as a process outcome, and I don't necessarily have any quarrels with that. But I think that this is one of those areas that, depending on how you looked at it, might be viewed in different ways.

The other question about body of evidence for this is, because they didn't really clearly delineate, because we asked for

what are the kind of structure/process/outcome links. So, what outcome would this process be related to? Is it about quality of life? So, being in the ICU in the last 30 days represents poor quality of life. I think that they alluded to it may represent patients' wishes not being followed.

So, I guess that is a question about what would the body of evidence even be about. Would it be about, are there studies that have shown a relationship between ICU use and that wasn't the patient's wishes? I don't know. And that would be a question.

Because we don't really see this as strictly a resource use measure or a cost measure. What's the quality aspect of it? Is it that it is just inappropriate use or inappropriate level of care? So, is the evidence about futile care? And at what point is doing aggressive care considered futile and not the right approach to care?

So, I think this particular

measure presents a lot of challenges. We talk about no evidence here, but my question is, what are those relationships, or at least the concept of why is this an indicator of poor quality. What are those things that would, you know, what would be in the body of evidence as it existed?

CO-CHAIR MORRISON: Could I take the moderator's privilege here and just ask, Solomon, Stephen -- and who else do I have? -- oh, Doug, are these questions that you guys think will be clarified as we move through the first measure? I am a little conscious of where we are on time.

Helen?

DR. BURSTIN: The first measure always takes --

CO-CHAIR MORRISON: Yes.

DR. BURSTIN: Don't sweat it. It's really okay. I think it is probably better off just to kind of get some of these issues cleared.

CO-CHAIR MORRISON: Yes.
DR. BURSTIN: And it will be smoother sailing later.
CO-CHAIR MORRISON: Yes. Actually, my concern on time is actually getting Craig on the phone. He may be on the phone by the time we get there? Okay.
So, I have Solomon, Stephen, and Doug.
MEMBER LIAO: My question has already been answered.
CO-CHAIR MORRISON: Oh, you put your tent card down? Thank you very much.
MEMBER LUTZ: I have one general thing and, then, one thing specific to this measure.
The first general thing, I would ask the question, essentially, what were we thinking for some of these that didn't have much data? To answer the question, I am usually pretty hard-core about data. But when I called and Lindsey said, "Oh, this is not

nearly the final vote," I said, "You know what? I will make the bar the lowest I've ever made, and we'll get to it later." So, it wasn't meant to ignore the fact that there are some questions about almost all these measures.

Specific to this one measure, though, one of the things that concerns me, at least from a devil's advocacy position is that I think the intended consequence of this should, hopefully, help physicians have discussions about whether cancer patients should be placed in an ICU in the final days of life.

One of the potential unintended consequences you can perceive is that it may be the case that, if someone thinks they are going to get dinged for putting a cancer patient in who may unexpectedly die in the following 30 days, it will perhaps put a pall on ICUs ever receiving cancer patients. I am not saying is it right or wrong, but the

unintended consequence has to be something to be, I think, measured as well.

CO-CHAIR MORRISON: I think that is a really critical point. I think that certainly comes up in the discussion, that probably comes in the discussion of the importance of the measure. I think I would, again, when we discuss the importance, both the intended and the unintended consequence of the importance of the measure.

Doug?

MEMBER WHITE: Yes, Doug White.

I fully agree with the concern for unintended consequences here. I might frame my comments around the concept of validity in that I think there are probably three different kinds of validity that are crucial to this measure being accepted, and that if any of them is missing, then I think it is, in my view, a dealbreaker.

I would say that the validity is around the numerator, the denominator, and,

then, criterion validity. So, I will just take each one.

Numerator is this question of, did the patient die in the ICU, and 30 days prior to their death? I think that is pretty easy. I suspect that is what they are telling us, that they were able to measure that easily.

The denominator of how many cancer patients, how many patients died of cancer, I suspect it is hugely difficult to measure in a valid way because cause of death is notoriously variable from doctor to doctor.

Actually, as an intensivist, I don't know what it means to die of cancer. People die of sepsis or acute respiratory failure or hematologic failure, but I rarely put as a cause of death cancer. So, I would really want to scrutinize how they determined whether they are measuring the death of cancer accurately.

And, then, the third, and for me the most important, validity is the criterion

validity. It seems like this measure is set out to get at, is the care patients are receiving consistent with their wishes? I don't know of any data that really has shown this to be, whether you die in an ICU to be a reliable proxy for whether your wishes were followed.

In the absence of that, especially with the unintended consequences that Stephen raised, I have a healthy degree of skepticism for the importance criterion.

CO-CHAIR MORRISON: Naomi?

MEMBER NAIERMAN: A quick question. Are we now talking about just simply documenting patients' wishes rather than wondering if the outcome is meeting those wishes?

CO-CHAIR MORRISON: You know, I think right now we are actually delving into the specifics of the measure rather than general questions. So, I guess I would ask is we hold that until we move forward, and if

there are other general framing questions before we move forward, we take them.

I hear what you're saying, Doug. I hear what you're saying, Naomi. I think that is going to be coming up very soon.

Other questions, comments?

(No response.)

I'm sorry, Lindsey, help my aging brain, but do we have Committee Members on the phone?

MS. TIGHE: No.

CO-CHAIR MORRISON: No? So, I don't have to go to the phones. Okay.

Karen?

DR. PACE: So, maybe we can now proceed through this measure as we would go through the measures.

CO-CHAIR MORRISON: My thoughts exactly.

DR. PACE: Okay.

CO-CHAIR MORRISON: Could we proceed through the measure as if we were

going to -- actually, we are going to proceed through the measure, not as if we are, but we are going through the measure, as an example of how we are going to proceed through subsequent --

I will generate a list for Craig, and Craig will join us by phone at noon.

Karen, could you take us through the measure?

DR. PACE: Okay. So, I'm not going to repeat what I said about the subcriteria, impact, opportunity for improvement, evidence. So, you have heard that.

And we should see if the other reviewers want to add anything to that discussion. Then, we ask for other Committee discussion. So, primarily, probably the big question is about evidence and the body of evidence.

But, first, let's see if any of the other reviewers want to make some

comments, since they delved into this measure, about impact, opportunity for improvement, and evidence, because those are the three things under importance that we want to address right now.

CO-CHAIR MORRISON: I would just say that I am told that I can identify -- should I identify reviewers? So, the reviewers from this have been Bob, Helene, Stephen Lutz, Russ, Eduardo, and Michael. So, if any of those have key thoughts that I would like to add to Karen's, feel free.

MEMBER FINE: Well, I'm still confused. The first time I went through these, almost all of them, kind of like Stephen, I just said, well, there's not a whole lot of data here. But if I mark them all insufficient data, then I didn't get any further through the process.

So, I kind of went back and agreed with what Sean said. I don't think we want to make the ideal the enemy of the real. I think

we won't get out of here with any metrics if we are not careful, just as I have looked and tried to spend a fair amount of time thinking about this stuff.

If we took just this whole issue of high impact and we looked at the six in terms of opinions, we've got one moderate, one insufficient, and four highs. I would just like a discussion of that, so I understand how people are thinking about this.

My own thinking was intuitively I kind of agreed with the submitter; there's high resource use when you deal with this. I thought their summary of the evidence, though, was insufficient. I don't think we know that ICU use near the end of life indicates a lack of discussion about advance directives. Maybe it does; maybe it doesn't. In my shop, it means all kinds of things, not necessarily a lack of discussion about advance directives.

But, with that in mind, what I want to understand is I still think it is high

impact or potentially high impact. Can I give it a moderate? Or several of you all gave it a high. Or because I think that their summation of the evidence is non-existent, should I rate it insufficient? That's what I want to understand because this changes how I think about almost everything I evaluated.

I would like to get us very specific as a group discussing this. What do we really think as a group is evidence of high impact? And I would personally like to just kind of go through each one of these.

DR. PACE: And we are going to vote on each one of these categories and discuss them.

So, the question here on high impact, and this may be an area where it is very easy for you to substitute your knowledge for what is not here, so high impact is a fairly easy criterion to meet. It means that it affects a large number of people, high resource use, quality problems have a high

impact.

And so, you all, as experts, may very well be able to, based on your own knowledge, rate the impact criterion.

MEMBER FINE: So, if under the definition in these metric evaluation criteria that we were sent, high impact, "The measure focus addresses a significant national health priority identified by DHHS or the National Priorities Partnership convened by NQF."

So, that makes it high impact?

DR. PACE: Well, that is one component, but the rest of it says "or" --

MEMBER FINE: Right.

DR. PACE: -- it addresses a high impact aspect of healthcare.

MEMBER FINE: Right.

DR. PACE: So, that is where the data would come in.

MEMBER FINE: But if it meets that first one, then you don't need data, as I have read that because it is an "or"; it's not an

"and". Did I interpret that correctly?

DR. PACE: In terms of the Committee's decision, we asked the submitter not to identify that because, generally, most of the submissions identify -- we asked them generally for data.

Yes?

MEMBER WHITE: I wanted to make sure I understand this. Conceptually, it seems like you could have something that is hugely impactful that we just don't know how to measure, and that would be a non-starter. Is that fair to say? The topic is usually important, but we don't know how to measure it?

CO-CHAIR MORRISON: That is correct.

MEMBER WHITE: Okay.

CO-CHAIR MORRISON: That is correct. Well, because they wouldn't then submit it. Right.

Yes, we are charged with

evaluating what is here. Tomorrow we will have an opportunity to identify gaps that will help guide further measurement development.

But we are charged -- is that what you are asking for?

MEMBER WHITE: No. Yes, that's a slightly separate question. Mine is I think, even looking at a measure, you could still at the end of your evaluation of the measure say, "Gosh, this is a hugely important topic," and I still don't think that they or we know how to measure it.

DR. PACE: That's fine, but that is what the other criteria are.

MEMBER WHITE: Perfect.

DR. PACE: So, we are starting with importance.

MEMBER WHITE: Yes. Good.

DR. PACE: And it may pass importance, but when you get to scientific acceptability, you may decide that there's no evidence that it can be a reliable and valid

measure as they have constructed the measure.

MEMBER WHITE: Yes.

DR. PACE: So, yes, that's what each of the criteria --

MEMBER WHITE: Good. And one last, quick question. Is there an easy, little, one-page cheatsheet about the criteria and how they are organized that we could all just look at as we are going through the measures?

DR. PACE: Sorry. It is hard. We haven't found a way to put it on a one-pager.

(Laughter.)

But I don't know if we can --

DR. BURSTIN: You will see shortly --

DR. PACE: Yes, right.

DR. BURSTIN: -- Lindsey is going to be showing you the voting slides. We have actually made the voting slides, included the subcriteria on them. So, at least you will be able to see as you are going through them at

least a quick summary.

DR. PACE: Yes. Right, right.

DR. BURSTIN: So, for example, it is actually listed up above as it comes up what we mean by that. So, it is a little bit of that, if that helps.

DR. PACE: Right.

CO-CHAIR MORRISON: I am feeling a lot of tension and uncertainty about a new process. As Helen reminds me, there always is. And I will tell you it is not a perfect process, and over the course of the two days there is going to be a lot of uncertainty. But, folks, we are in a field that deals with uncertainties. So, get used to it.

(Laughter.)

Yes, let's move forward. Karen, are you going to walk us -- do I walk you through or does the developer walk you through? I walk us through? Helen walks us through. Okay.

So, we are going to start with 1a

-- oh, I've got to do this -- which is the impact, which is, does this address a specific national health goal priority or was data submitted that demonstrated a high impact on healthcare? So, we're voting on whether that does.

Clickers. Clickers, everybody.

MS. TIGHE: Yes, everybody should have a clicker.

CO-CHAIR MORRISON: I'm sorry. Sorry, Lindsey.

MS. TIGHE: We gave you a quick, little cheatsheet of how to use the voting tool.

Briefly, this is the voting receiver. So, aim your tools at me.

And, then, if you are voting high, moderate, low, or insufficient, it is one, two, three, four as it corresponds up there.

If you push a number and decide that you want to change your vote, push the Caution symbol, put in your new vote, and then

push Send. Once you have hit Send after pushing in the number, you can't change your vote, though.

I will click the little red thing on this screen. It will start a one-minute countdown timer. So, you have one minute to complete your votes.

And I think that is it, unless you have any questions.

MEMBER FINE: Can I ask a question? Sorry.

So, is there a specific national health goal priority around this or a National Priorities Partnership convened by NQF?

DR. BURSTIN: There is; palliative care was one of the National Priorities. In addition to that, in the National Quality Strategy, although not separated out, on its own it is clearly described as being a high priority within the National Quality Strategy.

MEMBER FINE: So, that alone makes --

DR. BURSTIN: Correct.

MEMBER FINE: -- it high impact? I am just making sure I understand on which ground we're voting. Because it seems to me, at least as I understand the evidence tables, there wasn't necessarily, the number of randomized controls on that wasn't there.

DR. PACE: That's evidence. This is just about impact --

MEMBER FINE: I understand.

DR. PACE: -- in terms of numbers of people, resource use, quality --

DR. BURSTIN: General topic, yes.

DR. PACE: Yes.

MEMBER FINE: So, we are voting on this because there is actually a specific articulated goal, not because we, as a group, happen to think it is important? That is what I am trying to clarify.

CO-CHAIR MORRISON: Let me clarify quickly. Then, I have Michael.

Let me encourage everybody,

please, to use tent cards because, otherwise, it is going to be very difficult.

The National Priorities Partnership has identified palliative care as a national priority. Palliative care is a priority. I can't remember who did the presentations. Pain and symptom management, transitions of care, and improved health services delivery for people with serious illness has been identified as a national priority, and there have been multiple statements from multiple stakeholders at the federal government, including the IOM, which has identified this as a national priority.

So, I would really like to put that on the table, that we are here because everything you are identifying is a national priority. I am hoping -- hoping -- we're not going to debate on that one.

Michael, I'm sorry, you have been waiting patiently.

MEMBER LEPORE: Well, I'm glad

that part is clear. There is a slight difference that I think gets at a lot of the differences that I see between Russ' scoring and the scoring of most of the other reviewers. I think it comes up right on this slide.

When I look at the criteria that we were provided, we are looking at if the measure addresses a demonstrated high-impact aspect of healthcare. And here, we are looking at if data was submitted that demonstrates -- the idea that data was demonstrated is a little different.

CO-CHAIR MORRISON: I think the question here, and it may be less relevant, and I will clarify this again, is that for other Committees, because this stands across, if it has not been identified as a priority, it allows the developers to provide evidence that it is a national priority. Again, this has been identified as a national priority.

Solomon, a quick question before

we move, sir.

MEMBER LIAO: All right, real quick. So, if every one of the measures we are looking at meets this criteria, can we make this meeting more efficient by skipping this step for every measure?

(Laughter.)

MEMBER ACEVEDO: I second that motion.

CO-CHAIR MORRISON: I turn to my NQF colleagues because I think -- that's fine? That's fine. Then, yes. Yes, we can.

DR. BURSTIN: However, it would be really useful to just do this one, so you get used to your little clickers and make sure you all know how to do it while it's not an important vote. How about that?

(Laughter.)

CO-CHAIR MORRISON: Can we click, Lindsey?

MS. TIGHE: Okay, and if you guys could keep clicking? It won't count your vote

twice, but there are 20 of you who should be voting. So, I just need that last vote to get in.

(Whereupon, a vote was taken.)

All right, got the last one.

CO-CHAIR MORRISON: I will read these for the first go-round and, then, not after that, guys. Okay?

So, the importance of the measure, the question is performance gap. "Do the data demonstrate a considerable variation or overall less-than-optimal performance across providers and/or population groups that is disparities in care?"

So, we are voting on the performance gap of this measure.

DR. PACE: Does anyone want to discuss this? I mean this was an area where we really --

CO-CHAIR MORRISON: I'm sorry. Right.

DR. PACE: -- did get information.

So, maybe you want to --

CO-CHAIR MORRISON: Thanks, Karen.

DR. BURSTIN: And just to point out I did pull up the Ontario Cancer Care website. Some of you may have done that who reviewed it. That is actually where that threefold regional variation and increase over time directly comes from. It is from the Ontario experience. It is not very well cited, but that is, in fact, what he is referring to.

MEMBER CASARETT: Just a quick question for those of you who looked at this more carefully. So, is that variation adjusted for case mix? In other words, how much do we know about whether that variation might be due to case mix versus differences in practice?

DR. BURSTIN: I think that is probably going to be a question for Craig. All that is on the Cancer Care Ontario website is the percentage of Ontario cancer patients

admitted to ICUs in the last two weeks of life varied significantly. Seven percent of patients were admitted to the ICU in the last two weeks of life, an incremental increase from 2004, is what he is pointing out, with a variation between 3 percent in the Northwest -- and you're a Canadian, by the way, so you probably know these places better than me -- and 8 percent centrally. So, they are at least showing a 3-to-8-percent variation regionally in this rate, although it would have been nice to have more of --

CO-CHAIR MORRISON: It has face validity.

DR. PACE: But the question about case mix is something that we would address and definitely ask Craig. Again, this relates to whether you consider this a process or an outcome measure. So, case mix maybe doesn't make a difference in terms of ICU use.

So, anyway, we'll get to that in scientific acceptability.

CO-CHAIR MORRISON: Other questions? Russ, did you have a question?

MEMBER ACEVEDO: No, I was just going to mention they do say later on there is no risk adjustment as part of the measure.

CO-CHAIR MORRISON: June?

CO-CHAIR LUNNEY: So, if we don't move this, I mean if we vote insufficient data here, we are stopping this motion?

CO-CHAIR MORRISON: Karen, how are we going to handle that since Craig's not here?

DR. PACE: Well, I think probably, because each of these subcriteria would stop the measure, I think if the reason it would be stopped is because of insufficient evidence, I think we would want to get a sense from you that you think that there is evidence of that that they could provide. Then, we could continue on.

We don't have to do a hard-and-fast stop. We can definitely continue on if

that is the will of the group. But I think what Helen mentioned to you, although it wasn't put in their application, the more detailed does provide data on demonstrating a gap in performance, that there's variation in this quality indicator, which is what we define as opportunity for improvement, that there is either a variation or that there is overall just bad performance or low performance.

CO-CHAIR MORRISON: So, Kate?

MEMBER O'MALLEY: The question I have is, if it is based on international data, does that color how we look at that when we are looking at performance of our own healthcare system?

DR. BURSTIN: It's an excellent question and one that doesn't come up a lot. We don't have a lot of international submissions, although Canada doesn't feel terribly international.

I think it is probably not that

different than looking towards the evidence, for example, and pulling out a rate of variation that comes from a single paper or several institutions. To me, it is just another example of a body of evidence. I don't know that location matters terribly. But if you think the experience in the U.S. is incredibly different, then that is something to consider.

CO-CHAIR MORRISON: I would also suggest, Kate, if there's variation in the single-party payer with a unified healthcare system, there is probably variation within the United States.

Naomi?

MEMBER NAIERMAN: It seems to me this is an interesting measure to consider with respect to self-evidence or in a sense of what our expertise might be. To think that there is consistency and no room for improvement in this particular measure I think would be quite foolish. I mean it seems to me

it is pretty clear or at least reasonable to assume that there is inconsistency in the way that last wishes are documented in the ICU.

Expertise can play into this with some --

DR. PACE: Well, this measure is not about documentation of wishes. It is about actual use of the ICU in the last 30 days. And we do have data from the Canadian experience about that.

MEMBER NAIERMAN: Right. Okay.

CO-CHAIR MORRISON: So, let me just come back because, remember, we're really focusing on performance gap. And I guess the question, the issue for the group is they have presented data from Ontario across cancer centers that demonstrates variation. I have a question here about whether the variation was adjusted for case mix for Craig, which I've got on my list of additional questions for him.

Oh, I do see a tent card.

Solomon?

MEMBER LIAO: So, I just want to ask the people in the room because I suspect there may be people who know this answer already, but isn't the usage of ICU beds dependent mostly upon the number of ICU beds regionally?

MEMBER WHITE: I think you have to be a little careful about "mostly", you know, explaining the proportion of variance from bed availability. When you look at the studies, it is not a "mostly"; it is not 70 percent of the reason explaining ICU bed use is the number of beds. There's a small statistically-significant effect, but it is not the major driver of it, especially in the U.S., where there is not that -- I mean there is a good deal of variability in the ICU beds per region, but with ambulant services, et cetera, that is superable.

MEMBER BRUERA: Eduardo.

I think there is very good data,

even from American sources, on ICU deaths and variability. So, I don't know why we have this -- we have published some data, and it is peer-reviewed data. So, there is considerable variability, and it is well-documented, and there's reviews by the Institute of Medicine and others.

So, independently of what Craig is sent -- I don't know why he went to Canadian sources. I have great respect for Canadian sources, as our Chair probably does, too.

(Laughter.)

But there is very good data. There is no concern.

CO-CHAIR MORRISON: I've got Russ. No? And, Naomi, are you still up or are you down? You're down. Okay.

Doug, I've got you.

MEMBER WHITE: Just very quickly, variability in and of itself doesn't show a problem, though, right? There's patient-centered variability that reflects differences

in patients' preferences and there's non-patient-centered variability that reflects financial incentives, et cetera.

So, to say that there's a clear gap, you need to know that that variability reflects care that is not consistent with the patient's preferences, but that would be the problematic variability.

CO-CHAIR MORRISON: Other comments, questions? Naomi?

MEMBER KARP: Well, just to address what Eduardo said, I don't think the measure is about where they died, is it? It's about whether they were in the ICU during their last 30 days.

CO-CHAIR MORRISON: That is correct. Thank you.

Seeing no more comments, Lindsey, can we vote?

(Whereupon, a vote was taken.)

I guess that means we move forward, right? Excellent. Okay. Onwards

and upwards.

So, the next item is the importance to the measure in the report, and this is 1c, which is evidence or outcome. "Is the measure a health outcome with relationship to healthcare structure, process, intervention, or service?"

And it's a very simple yes or no. Open for discussion.

Karen, you looked like you were dying to say something there.

(Laughter.)

DR. PACE: Well, this is a complicated one. So, basically, if it is an outcome, then we just need to have a good relationship or a good rationale that it is related to healthcare structure, process, intervention, or services.

If it is an outcome, then you are going to have to deal with risk adjustment and scientific acceptability.

But I guess they have presented it

as a process. It is a use of service. I don't know. Some of use of service is used as a proxy for outcome, such as hospitalization or readmission is a proxy for deterioration in health status.

That's why kind of a conceptual framework is important here because, is this seen as inappropriate care? Is it seen as poor quality for end-of-life care? I don't know, and I guess that is what we are looking to you for.

But I think, from what little is in here, it seems to think that it is related to inappropriate care or not reflecting patient wishes. But I guess if someone sees this as an outcome, I guess maybe we should hear that other side.

CO-CHAIR MORRISON: That helps. That helps a lot. Thank you, Karen.

And I am struck because I am staring right at Joan Teno for this entire meeting. So, I am just going to highlight

this really carefully, folks.

When we are evaluating outcomes, I think it is really critical for this Committee to make sure that they are directly linked to structure and processes that could be modifiable, that we could hold somebody accountable for changing the outcome. Because if we don't have that link, then we may have some unintended consequences.

And I do remind people this was submitted as a process measure, not as an outcome measure, by the developer. But Karen is absolutely right; we should hear whether there are strong arguments from the group as to why this should be treated as an outcome.

DR. PACE: So, essentially, if we are all on the same page about this being an outcome, we can skip this question because this question is, if it is an outcome, is there a rationale that it is really linked --

CO-CHAIR MORRISON: You mean a process --

DR. PACE: I'm sorry. Yes.

CO-CHAIR MORRISON: Process. Process, I'll try to say "process". Sorry.

(Laughter.)

DR. PACE: Okay. So, we can move on to the evidence part.

CO-CHAIR MORRISON: Okay. Evidence. So, 1c is the importance of the measure and the report. That is, is there evidence or are there data and the quantity of studies and the body of evidence to support the measure?

Again, I would say that this is both based upon what has been presented by the developer. If he or she is here, we can ask clarifying questions or open-ended questions, or to recognize that this is a very diverse Committee with people who have a lot of experience in measurement development, a lot of people who have experience in using the measures and the feasibility. So, if you have, bring that experience to bear on the

discussion.

So, open for discussion.

Naomi?

MEMBER KARP: This isn't really discussion. And at the risk of sounding really experienced on this, which I am, could somebody -- maybe one of the NQF folks -- could you just give us a statement of exactly, it's evidence of what? Just so we know we are evaluating it from the right perspective.

DR. PACE: It's a good question. Generally, that's why this measure presented multiple challenges. So, I am going to give you a different example first and, then, we will take a look at this one.

So, if a process measure of, for example, patients with pain should receive an analgesic -- I know you are going to be looking at pain measures later on. So, what we would be looking for is evidence, what's the evidence that giving analgesics for cancer pain is effective? And there's a lot of

evidence about that. And that's what we would be looking for.

So, what we are looking for, if it is a structure or process, evidence that it links to desired outcomes. So, if it is a treatment, an intervention, a service, what is the evidence of providing that treatment, intervention, or service to the outcome that you are trying to attain, which would be patient comfort, et cetera?

And you could also have measures that are about poor quality and what's kind of the bad consequences linked to it. So, in this case, it is ICU use. Normally, what we ask for at the very beginning of 1c, which is 1c1, is for the developer to tell us what's the structure/process/outcome linkage.

So, if this is a process of ICU use, what desired outcome or undesired outcome is it linked to? So, is it ICU use is linked to patients having stated that it's against their wishes, that they really didn't want

that care? Or is there evidence that ICU use really is not effective in changing the course of the illness? And so, it is kind of represents that futile care concept.

So, they didn't really delineate that. Maybe you and the Committee know, but that is the question: what would the body of evidence be for this measure? Why is this an indicator -- I assume it is an indicator of poor quality. Higher ICU use in the last 30 days is representing poorer quality.

So, what is that around? Is it because it is not effective in controlling symptoms, extending life? Or is it that it represents -- or a combination of those things?

So, I'll stop there and see what you think.

CO-CHAIR MORRISON: And I've got you, Russ.

The quality of the body of evidence that has been presented, a structural

-- oops, I'm reading the wrong one. So, I'll go to Russ and I'll grab it.

Russ?

MEMBER ACEVEDO: Yes, I would agree with what you said. I looked at this as the evidence that a cancer patient admitted to the ICU in the last 30 days of life represents poor quality or poor performance because this is a performance measure. We are saying that, yes, that's positive, that indicates poor performance.

And so, the next question would be, well, what's the quantity of evidence that this represents poor performance? What's the quality, poor performance? That's how I look at those questions.

CO-CHAIR MORRISON: Eduardo, and then Rick, and then Solomon.

You've got to keep them up (referring to name tents) because I'm going to work on it. But I just want you to know that I do see you.

MEMBER BRUERA: Thank you.

I think the question is the average oncologist knows that a patient is going to die about a year before the patient is going to die. There's good data on that. We have published data on that. That is all over the primary tumor, and so on.

So, basically, the question that Doug very appropriately asked is, when do you say that a patient dies of cancer? Well, it is very easy to say when somebody is going to die of cancer. You cannot say it a month before. You cannot say it two weeks before. But you can easily say the year before, a year and a half before.

So, nobody with cancer dies of cancer. Everybody dies of sepsis, organ failure, and thrombosis and arrhythmias, but they die because the cancer is there, and we know the person is going to die of cancer.

And therefore, the measure has a considerable body of evidence behind the fact

that -- and I think that is why ASCO is supporting it, is because you know that person is going to die much better perhaps than you know for other chronic conditions.

So, to me, what guides this is there is a very strong body of evidence guiding the fact that this person is facing end-of-life. Now what is the percentage? The Canadians were looking at 5, 6, 7 percent. It's about 50 percent in the United States.

So, we're talking about huge numbers, considerable variation, and knowledge of death before.

Basically, you might say, well, what is the percentage which is consistent with my wishes? I don't think that data is known for almost any condition, not just for cancer, but for any condition.

So, if you are going to tie it to some kind of a discussion, you're in trouble because you won't have that for anything. I mean I don't know that any NQF criteria has

ever come out that we'd be able to tie it with that because we know those conversations are not happening.

So, is this a marker of good/poor quality of care? I would say it is very hard to find one that would be more effective in finding that you knew exactly that this was going to happen a year before, and now it did happen.

CO-CHAIR MORRISON: Thank you, Eduardo. That was extremely helpful.

Oh, Kate went down. Rick?

MEMBER GOLDSTEIN: So, I just really have comments in parallel to that. So, the pediatric research is that it is three months ahead of parents' understanding of prognosis that doctors recognize that children are going to die.

My other point is just that my understanding of this measure is that it is really trying to attack the issue of regional variation. Maybe it is helpful to think of

this as a monitoring measure and an incentive to at least make the process more rational. And so, think of it purely as a quality measure rather than embedding too closely into the care of individual patients, might make it seem to be a more reasonable kind of a measure.

CO-CHAIR MORRISON: I've got Solomon, and then Russ, then Doug.

MEMBER LIAO: Mine is a followup question to Naomi's and is a much more general question, not just specific to this measure, but our general approach.

So, since, like you said, Sean, at the beginning, ours is a relatively-young field and there is very little research specifically for palliative care, how much can we or should we consider the, quote, "circumstantial" evidence, I mean the research that is published by the critical care folks and oncology, and so forth, that doesn't specifically address the question at hand, but

really is the underlying foundation and support?

So, if you consider that greater body of evidence, then the numbers are much larger than what the developer may be giving us. So, as we approach this, how broadly do we spread the net and how much do we consider the circumstantial evidence?

CO-CHAIR MORRISON: I'm going to let you guys tackle that one.

DR. PACE: It's a good question. I think the problem is there is no one answer for it.

We want to start with things that are evidence-based. So, the question here is, is there a body of evidence that supports this and it's just not provided? So, that's the first question.

And if there is a body of evidence that supports it but not presented, then we can ask the developer to provide that or you could make some suggestions to the developer

of what that is.

If the collective wisdom of the group is there really is no body of evidence to support this, but that it is an appropriate indicator based on experience in the field and experts, then we can proceed with the measure on that basis. But we wouldn't want to say that it's got high evidence, high rating of evidence. We would want to say there is insufficient evidence, but the Committee identified there is no evidence and this is an appropriate measure.

So, I think the key is not to change the rating so that you get the results you want. It is to be realistic about what the evidence is, but, then, to make a decision that, in spite of the fact that there's no body of evidence, this is a reasonable performance measure and this is the reason why.

MEMBER LIAO: Well, my question is not whether we ignore this subcriteria. My

question is how widely do you consider that. So, when we're asked how many, the number of studies that support this, if we include all the critical care and oncology data, and not just palliative care, I mean the number will be greater than five.

DR. BURSTIN: And I think you need to just look at the body of evidence that is relevant for the measure. It doesn't have to be tied specifically to the name of this Committee. If it is appropriate to the measure focus, you should look at it.

DR. PACE: Right, right. Exactly.

CO-CHAIR MORRISON: Who do I have next? I'm sorry. Russ, Doug, and then David.

MEMBER ACEVEDO: Okay, it's time for a true confession. I do admit patients at the end of life in my ICU. And there are appropriate reasons for doing so.

Many times, one, they may be a cancer patient, and we make the diagnosis at the end of life in our unit. We'll get dinged

for that.

I have a hospice service that is not very -- I want to be polite -- they just don't do palliative care as well we do. And there are times I will have to bring somebody down into my ICU to get good symptom management.

I'm not trying to change the course of their disease process, but I know I can't manage their symptoms upstairs. I can bring them down to the unit, manage their symptoms. They go up and die more peacefully upstairs. I'll get dinged for this.

Steve brought up before the unintended consequences. Well, if this goes through, the question is, will I have to think twice before doing that? Again, I just don't know, those patients who are admitted at the end of life in the ICU, is it because that they're being treated against their wishes or at times the resources in an ICU may be helpful to improve their end-of-life

experience?

CO-CHAIR MORRISON: Let's see. Doug?

MEMBER WHITE: I fully agree with that. I think that that is one of the issues that is really important here.

I am not sure what the right approach is here to go beyond that, except to say, if the goal of this measure is about patient-centered care, it is not clear that dying in an ICU is not patient-centered, especially because we don't have the prognostic certainty that would really require that.

I mean I would ask us, what is the goal, what is the outcome that we are really trying to effect here? I know that we are supposed to consider each measure in and of itself, but I would also sort of alert people that there are many other measures that we are considering today that will achieve the same purpose of driving towards patient-centered

care that are much more focused on the process of conversations and preference documentation that don't get us into this nasty little thicket of, is it objectively normatively bad for a patient with cancer to die in an ICU? I'm sorry. To die around the time of, to die within 30 days of being in an ICU ethically, and I think that is part of why I was asked to be here, is to sort of comment on some of the ethics of it. That is a sticky topic. Is it wrong to be in an ICU a month before you die? That's very difficult.

CO-CHAIR MORRISON: Karen?

DR. PACE: I think that is a question to add to your list: what is the kind of goal or what is the process outcome link here? Because although they alluded to patient preference, I think people have talked about a body of evidence about the appropriateness of ICU-level care for patients at that stage of the illness.

And so, that really is a central

question when you are talking about the evidence: you know, is it about patient preference or is this about ICU level of care being appropriate at that stage of an illness?

MEMBER WHITE: That is a hard question. It was something I was reluctant to bring up, but when I looked at the charge of this group, it didn't seem to be about resource allocation. It seemed to be about patient-centered care, good palliative care, et cetera.

Maybe can we just have a little conversation about that issue?

DR. PACE: Well, I think, in general, that is the charge of this group. But, then, you have to look at individual measures. So that every measure doesn't have to be specifically about patient-centered care. We obviously want measures that indicate that, but some measures are about patient-centered care. Some measures are about clinical effective treatment. Some

measures are about resource use. So, I think we want a variety of measures for any area.

CO-CHAIR MORRISON: Bob?

MEMBER FINE: So, I think the question before us is on the quantity of studies. The proponent of this says, "I've given you four studies." They're not randomized, controlled trials. They're really observations of what goes on. He has shown, at least in Ontario, there is this discrepancy.

It seems to me we have gotten way off target here with what we are discussing. If I am understanding what we are supposed to be voting on, at least according to the charts you gave us, these are non-randomized, controlled. There are four of them. If two of them are flawed, there's still two. It seems to me that puts us in a moderate evidence category, moderate quantity, and we could move on.

CO-CHAIR MORRISON: David, Tracy,

and then Naomi, and then Doug.

MEMBER CASARETT: So, thanks.

I have maybe a response to Bob's question. So, maybe this fits in a weird way.

In terms of thinking about the quantity, Solomon said earlier that there are lots of studies out there. But based on some of the conversations, I thought it might be helpful to refine what we mean, what goes in that basket of quantity of studies.

Because it seems to me that using the pain management example that somebody brought up earlier, what's the evidence that pain management is good? It's effective, it's associated with better quality of life, and it's something that patients want. For that measure, those would be studies we would include.

So, it seems like the quantity of studies here, we would also need to include evidence that ICU admission in the last 30 days is ineffective, meaning it doesn't work

to prolong life, or that it negatively impacts quality of life, or studies that ICU admission in the last 30 days is inconsistent with patients' preferences to a degree that we could make it a quality measure.

So, if I understand it right, those would be the studies we should be looking for in adding up how many studies there are, not just what's here, and not just everything that is out there, but studies that fall into those buckets.

Is that right?

CO-CHAIR MORRISON: That is absolutely correct. So, actually, David, I was going to try to summarize that, but you did it beautifully for me. So, thank you.

I am going to try to take just a couple of more questions -- Tracy has been really patient and hasn't said anything -- and, then, try to move on just in terms of moving us forward.

MEMBER SCHROEPFER: So, in

listening, I still come back to the issue, earlier issue. That is, when looking at 1a3, it says ICU care is expensive and uncomfortable and generally not appropriate for the dying patient. So, there is evidence for that.

Then, later, when it is looking at the studies for the data for the performance gap, it talks about African-Americans receiving aggressive treatment. I guess this gets back to the point of what we should in the data is that African-Americans request aggressive treatment.

So, to me, it gets back to this issue. I am not saying that is good or bad, but that is their preference. And there are many reasons for that, and those are documented, too.

So, I just get concerned over voting for this. It gets back to, what is this measure? Is there an assumption that, this measure assumes, then, that dying in the

ICU is not a good thing? It just seems like there's assumptions for this, and this is not a clear measure to me as to quality of life or provision of care.

CO-CHAIR MORRISON: So, let me take that point to just sort of summarize a little bit of what I am hearing because this has been a very intense discussion. I am conscious of the time, but I think it is, as Helen reminds me, the first one always takes twice, three, four, five, six times as long . I think we get these issues on the table now and we will get them later.

So, what I am hearing is comments that have been made about that this is a population that there is a very clear prognosis very, very clearly defined, and that there is a belief that critical care may not be beneficial in terms of prolongation of life and sort of clinical outcomes in a population that has a prognosis well-defined.

I am also hearing comments from

people that this type of measure doesn't take into account care preferences, that this type of measure sort of sets a bar that we don't quite know what the right level of intensive critical care is for a population at an individual level. And I am also hearing comments from the group specifically along the lines that there are data that suggest there are different preferences in different populations, but we don't know why those preferences exist.

I think that in terms of evaluating this, which was put in as a process measure, I think it is up to the individual Committee Members to sort of think through how you weigh each of those facts in terms of the evidence, to come to the conclusion of, is there enough quantity of studies in the body of evidence to support using this specific measure as a quality indicator for appropriative palliative and end-of-life care?

And I don't think that there is

going to be a hard-and-fast answer, but I think each individual, you have to weigh what you have heard from the experts. You have heard differences, not so much differences, but different body of evidence that you need to weigh.

Does that make sense, folks? Can we go to a vote? Are you comfortable with that?

And again, these are issues that are going to come up with us over and over again.

Kate, unless there is a really burning question -- okay.

(Laughter.)

(Whereupon, a vote was taken.)

Just come right up here, Helen, and take over, would you? June and I would love it.

So that means we move on, right, Karen?

DR. PACE: Even if you think that

there is a body of evidence, do we have information about the quality of that body of evidence and consistency? And this may be where you decide that it insufficient at this point, but want to continue on and just get more information.

But why don't we see if anyone has another thought? Just go ahead.

CO-CHAIR MORRISON: I was going to make the motion just to go ahead and vote.

Sean?

MEMBER WHITE: Just a quick question about, if the quality of evidence is poor, then we give it low or we give it insufficient?

CO-CHAIR MORRISON: If the quality of evidence is poor, then give it low, not insufficient.

MEMBER WHITE: Okay.

Now I vote on consistency. That's easy. Consistency then?

(Whereupon, a vote was taken.)

Okay. Not even close.

DR. PACE: All right. So, the question is, because we have these unanswered questions about the evidence, we really can't say it meets that criterion. And the question is, is there any objection -- well, I guess the question is whether we should have you continue on and evaluate the rest of the criteria with the condition that we ask the developer to supplement some information on the body of evidence, so that we can substantiate. But I don't know.

CO-CHAIR MORRISON: Heidi, did you have a comment?

MS. BOSSLEY: No. I mean I think we consider this preliminary because I think you have a lot of holes that you don't have answers to.

So, what I think we are already planning on doing is scheduling another call and make sure that the developer for these measures is on that call, and he will have

provided additional information at that point.

So, if that helps you kind of weigh whether you want to move forward on any of these measures, I mean keep that in mind. Staff is already working on that. So, I just throw it out there.

CO-CHAIR MORRISON: Naomi?

MEMBER NAIERMAN: Just a quick question. Is it possible to come back to this measure after we have heard from the developer this afternoon?

MS. BOSSLEY: I don't know that having him on a 30-minute call is going to give you everything that you need to come back in the afternoon. It may be that we are going to definitely have to do another call.

CO-CHAIR MORRISON: I have a feeling that, given that there are 14 people in this room who said insufficient evidence or low, that 30 minutes is not going to be enough to bring that forward, I'm afraid.

DR. PACE: Do people think that

that can be answered? It sounds like the various experts have identified actually even different bodies of evidence that could support this measure. So, it sounds like there's a body of evidence that could be supportive of this measure.

If anyone has a differing opinion, state it now. But, otherwise, if that is the thought, then I would say let's continue on and look at reliability and validity. Because if it is not reliable and valid, then we will end there.

CO-CHAIR MORRISON: Yes.

DR. PACE: But does that make sense?

MEMBER FINE: Just my observation, just listening to people talk, including the colleague from ethics, it seems to me that, Doug, what you were saying was not that there was necessarily insufficient evidence, but great concerns -- and I have heard it here -- about the meaning of the phenomenon of people

spending at least time in the ICU during the last 30 days of life.

That, to me, is very different from evidence. I just, again, wonder if we got a little bit offbase. We were given this table for how to evaluate what was submitted, and randomized, controlled trials are great. They hardly exist in this field, and then other types of studies.

Just as I listened, there were a lot of concerns about what does it mean if we say this is a quality metric? But that is not the same as a question about evidence.

MEMBER WHITE: I might argue that that is a question about evidence because it relates back to criterion validity. Does this thing measure the outcome that we think is important to measure? And we are all wondering, does this really get at the thing that it's -- first, what is the thing it is supposed to be measuring? And second, does it measure it?

CO-CHAIR MORRISON: Guys, I'm going to take the Chair's prerogative. Actually, I think what we would like to do is we are going to move forward. I would like to move forward with this measure because I am hearing enough diversity of opinion that I think it would be very helpful to have Craig on a conference call to make his case and ASCO's case as to the body of evidence, because I don't think it is here for us to evaluate. And I am hearing enough difference of opinions on the Committee that I think we need to have that and, also, because 10 people voted for insufficient evidence rather than low evidence. I am hearing a lot of passion in people's voices.

But is that all right with folks?

Eduardo?

MEMBER BRUERA: Yes, I guess we need to be aware that, you know, having done about 200 or more randomized, controlled trials, many of the most important questions,

as John Lynn used to say, cannot be answered with randomized, controlled trials because it would not be ethical to design some of those randomized, controlled trials.

So, when we are looking at the evidence, we need to be aware that sometimes the evidence needs to be different from the one that is brought up, and we have to do a little bit more with thorough work into finding out if an admission to an ICU is a source of terrible suffering for patients and their families, for which there is a huge body of evidence.

And if we knew that the person was heading to that cliff, for which there is a strong body of evidence, and we decided to do nothing about it, then that is called considerable suffering.

The question becomes always, is it going to be 100 percent versus zero percent? Well, this is like the story of the C-section. The C-section is not inherently bad, but, you

know, there are situations in which the C-section can be terrible. If we are going to have to look for evidence for yes or no, 100 percent, then that makes no sense because, later on, we are going to look at chemo. Well, you know, most of the time chemo 14 days is ridiculous, but sometimes you didn't know the person was going to die 14 days later.

So, it is the usual standard, not the outlier, because we are not going to find strong evidence to back up outliers by any means. So, if we believe the evidence for suffering is very strong, the ability to know we are heading to that cliff is very strong, then that is the evidence we are going to have to judge, not the presence of a study in which a randomized sampling to ICU versus not, because that's never going to be there.

CO-CHAIR MORRISON: Solomon? Yes, sorry, Karen.

DR. PACE: I just want to make one clarification. That is an excellent point,

that we are not comparing these things to zero percent or 100 percent. It is looking across providers and what the norm is.

But the other thing about criterion validity, that is handled under our criteria of validity. So, evidence is about the specific focus of the measure. When we get to reliability and validity, it is about the measure as specified.

So, this is where, if you have issues about, well, maybe the concept is a good concept to measure, then the question under reliability and validity is, how the measure is constructed, is that a reliable and valid indicator?

So, your question about should there be any exclusions to make it more valid, you know, that's where that would be addressed. So, I know it is getting used to how we have kind of separated things out. But certainly we want evidence for reliability and validity, but what we were just talking about

is the focus of measurement in general, what's the evidence that that intervention, service, treatment is linked to outcomes?

CO-CHAIR MORRISON: Solomon, is this a burning question before we move forward that's going to stop us?

MEMBER LIAO: Just a short comment or concern on the standard that we are setting ourselves up for. So, out of these last two votes, if we are saying this has insufficient evidence, I mean the other measures that we are going to be discussing later on have even less evidence than ICU and cancer care. So, I am just concerned of what we are setting ourselves up for as a Committee.

CO-CHAIR MORRISON: I think let me take a crack at that. Part of the issue here is that the developer is not here to answer these questions. I think if the developer were here, if Craig were here, a lot of this would have been, a lot of these things could have been clarified. I think what you are

hearing is uncertainty from the Committee rather than -- at least that's what I am hoping.

David?

MEMBER CASARETT: Very focused, yes or no. The question that Doug raised earlier about denominator issues and coding of death, does that go under this question, reliability, or is that a vote on the issue? Because I think it is a serious one; I just want to know where we should code it.

DR. PACE: Well, I guess it can apply to both. In this case, they basically did one study of the records to the chart. So, it is primarily using the same information for reliability and validity. So, I guess at this point I would vote the same way on reliability and validity.

But I think you should probably -- let me back up. Where we put the issue of exclusions is under validity. I mean reliability is whether it can be reliably

obtained. But if it is an issue that you think, an exclusion that is in there or an exclusion that is not there, really affects the validity of the conclusion you can make about quality, then that would be a validity issue.

MEMBER CASARETT: Sorry. I really do think it was a yes-or-no question.

(Laughter.)

DR. PACE: Yes.

CO-CHAIR MORRISON: You're forgiven.

MEMBER WHITE: Sean, can I just say one thing? I promise, first of all, I won't be talking nearly as much. I might not say this much for the rest of the two days.

One question about reliability here. They have studied this in Canada. This is claims data. There's a very different claims system in the U.S. As a Canadian investigator --

DR. BURSTIN: He left Dana Farber

and went to Canada. So, the actual specs are on Medicare MEDPAR data, yes.

MEMBER WHITE: Okay. Helpful.

CO-CHAIR MORRISON: Okay. You know, I am trying to figure out, honestly, if we need to break now because of people's biological needs or whether we can push through this. I am going to try to push through it. I think that will keep the conversation a little more focused.

(Laughter.)

So, we are going to be voting on reliability. Are there precise specifications and is the testing appropriate? Is there appropriate method and scope with adequate results?

(Whereupon, a vote was taken.)

Okay. Validity?

Oh, yes, I'm sorry, go ahead.

Karen gave a good definition. I don't need to read this one.

(Whereupon, a vote was taken.)

MS. TIGHE: Okay, we still need four more. So, if you could just keep clicking? It won't register your vote twice. But we are missing four.

CO-CHAIR MORRISON: Okay. What do I do with that guys?

DR. BURSTIN: Actually, could you go back one slide, Lindsey, just to show?

It would be helpful, just as you look at those subcriteria under validity, you guys all raised several issues on that. Again, as we think about our conversation with Craig, it would be helpful to know why people voted it low. Was it because of the risk-adjustment issues that were brought up? Are there other issues you want to tee-up for the conversation with the developer?

CO-CHAIR MORRISON: Questions, guys? I know it is secret vote, but you can ask questions wherever you voted, just in fairness to the developer and to the steward.

MEMBER WHITE: These are the

questions we would like to ask him, is it? Okay, so I think the questions would be along the lines of: what was the validity testing? Did you test only how accurately you can figure out whether they were in the ICU in the 30 days prior to that? Or did you also test how reliably that statement, that adjudication of cancer death was measured? And, then, also, criterion validity, what's the evidence that dying within 30 days of an ICU admission correlates closely with a bad health outcome?

MEMBER CASARETT: Could I add on a related question to the cause of death? I would also, I guess, want to know there was an interaction between site of care and determination of cause of death. Specifically, I could imagine a concern that patients who get care in an ICU may have more complex illnesses, may have other codes, compared to patients who receive care in other settings, and may, then, have a secondary cause of death, like sepsis or thrombosis,

coded, when another patient who wasn't in the ICU wouldn't have.

CO-CHAIR MORRISON: Great. Move forward? Let's move forward, guys.

Scientific acceptability and measurement properties. If the disparities in care have been identified, do measure specifications, scoring, and analysis allow for identification?

I think what you have heard from many people in the group is the variability in admission to the ICU within 30 days of death, both across the United States and in the population that was developed. And the question is, do they allow for identification of this variability at -- let me just stop there.

Oh, go ahead.

MEMBER WHITE: Sean, as part of this, does it allow for identification of the appropriate outliers of people to be excluded from the analysis?

CO-CHAIR MORRISON: That would be your interpretation. Yes, if you have concerns about that, I would put that as your interpretation, yes.

MEMBER LIAO: I'm sorry, I still don't understand. Identification of what?

CO-CHAIR MORRISON: Disparities in care. Remember, this is about improving quality. So, are there disparities in care? For example, if you have differences in admission to an ICU within 30 days, if you assume that that is a quality indicator, does the measure identify that?

(Whereupon, a vote was taken.)

Next, usability. This is my fault because I should have brought this forward before. So, this I think is the crux of the question here that everybody is really struggling with. Is this measure usable? That is, is it meaningful? Is it understandable? And is it useful for public reporting? That is, based upon the measure

that you have in front of you, is the admission rate to intensive care units within 30 days of death, as specified by the measure developer and specified within the context of how it is going to be reported, is this going to be meaningful, understandable, and useful for public reporting and -- that's an "and", right, guys? It's very important, "AND", capital letters, meaningful, understandable, and useful for quality improvement. So, it is not an either/or; it's a both.

DR. BURSTIN: The only qualification, just one qualification of that, we have been doing a lot of work about this concept of, is public reporting one element of broader accountability functions? And we really landed on the idea that what we are really talking about is broad accountability beyond just simple, not simple, often very complex, internal QI, but what else would you use this measure for? Pay-for-performance, using it for incentives, things along those

lines, also fit into this lens of public reporting accountability.

CO-CHAIR MORRISON: Yes, that's very important, Helen, because this does have implications both for quality, but, also, for payers.

Eduardo?

MEMBER BRUERA: I would just like to clarify that figuring out that somebody died of cancer is the easiest thing. There is no "ifs" or "buts". Tumor registries have done it for decades and decades.

So, I would like to put to ease the fact that the reason why that person died was cancer, it should not be a problem for us to address at this point.

Yes, cancer causes thrombosis or causes arrhythmia or causes infection, or causes whatever, but it is cancer underlying and it is a progressive, incurable disease. So, from the perspective of evidence and perspective of usability, that is zero

problem.

Admission to an ICU, it is the easiest thing because you can see that is a huge red bar in the billing system. There is not going to be a missed ICU admission in the last 30 days of life because no institution, no third-party payer, nobody misses that one.

So, I would like to clarify these points because, yes, there's a lot of other issues that happen. You may have ERDAs. You may or may not get mechanical ventilation. But I think the measure is more simple than that. The evidence for those two is reasonably easy.

CO-CHAIR MORRISON: Stephen?

MEMBER LUTZ: I agree with that. I think the question, though, is the data that is going to be pulled out. Other people who enter what someone died of on a death certificate or in whatever manner it needs to be entered, are they thinking in those terms?

In other words, I have actually

had a woman call me and say that her husband died from radiation side effects. We lined him up and had never treated him. Cancer was never listed on the death certificate. It was listed as a radiation effect.

I mean it is the extreme case, but I don't think it is always the case that whoever is filling out the death certificate is thinking as clearly or as in-depth as we are. I know many places where it is not the physician who fills it out. Sometimes it is the ward clerk.

CO-CHAIR MORRISON: My feeling is I've got this as my question to ask Craig, a real specific question. He'll give us an answer.

Are we okay voting?

I see Naomi going up.

MEMBER KARP: I guess I just want to know if something is relevant to usability. So, the whole discussion we had before about what does this measure really mean and what

does it mean about quality, and is it really identifying something about quality, is that relevant to usability or not?

CO-CHAIR MORRISON: I think, unless Karen corrects me, it is incredibly relevant to usability. I think you need to think about this is the question that talks about how this measure is going to be used. And as Karen pointed out, it is going to be used by individual institutions. It has the potential to be used by payers. It has the potential to be used by providers and systems. And it has the potential to be used by CMS. So, yes, this all comes into that discussion.

Russ and Doug.

MEMBER ACEVEDO: Yes, I just want to make the comment about I don't think it is that clear as far as admission to the ICU. You could have a cancer patient who has a life expectancy of two years come into my ICU for acute pulmonary embolism and die in the ICU. I will dinged with this measure, even though

this person is not at the end of life, but comes in with a life-ending illness and just happens to have the diagnosis of cancer.

CO-CHAIR MORRISON: Yes, I hear that. I think Doug was going to say something like that. It's separate? Okay.

I'm just going to reframe that, think broadly about it's not about specifically deaths. Think broadly about the fact that this is going to be a population measure. I do think it is important to think about perhaps the unintended consequences from an individual provider's perspective, but we need to think broadly about that, too.

Doug?

And we're looking at rates, guys. I mean this is not about all or none.

MEMBER WHITE: All right. This usability one raises a slightly different twist on it when you bring in the question of pay-for-performance, too, and the publicness of this, especially around the idea of paying

to not admit cancer patients to ICUs. You know, politically, this gets a little touchy.

I wonder, because we have other less-politically-charged ways to measure concordance with care preferences, whether this becomes an issue of usability. Will this really raise concerns at the political level?

CO-CHAIR MORRISON: Let me clarify a couple of things. First of all, these measures are going to be NQF-endorsed. There is no direct link from NQF endorsement into pay-for-performance or other organizations or other faith-based organizations or faith-based measures in ACOs. There is no direct linkage.

They will be NQF-endorsed. And I think that you need to think about them not so much from the political ramifications, but would this be an acceptable quality measure for a variety of audiences, which might include payers? And I include CMS and the VA as payers. I think you need to think about that as a broad context, but please don't try

to get this into the pay-for-performance lens.

Helen?

DR. BURSTIN: And unintended consequences is actually in feasibility. So, you will have a chance to specifically weigh-in on that. And obviously, you could extrapolate where you think it is going to go, but at least at this point that is not something on the table.

DR. PACE: And just to point out, it is not a measure of patients who die in the ICU. So, my understanding -- and, again, this would help to have a little more detail here -- but they start with cancer patients who have died. Then, they look back at the prior 30 days to see if there was ICU use. So, that is the context.

CO-CHAIR MORRISON: Are we okay voting, guys?

I'm sorry, Kate.

MEMBER O'MALLEY: This pairing public reporting and usability for quality

improvement gives me a problem because I would probably rate this low for public reporting and high for quality improvement. So, putting the two together I think is troublesome. And I would like some guidance on how to think about that.

CO-CHAIR MORRISON: I think it is really simple because Karen has beaten this into my head. It's an "and". It really, truly is an "and". We may disagree with that, and we may argue that that is not appropriate. I can't tell you. You know, you have to vote your conscience. But the way that the properties have moved forward is that you have to think that it at least meets some criteria for both, and how you weigh that is your individual conscience, Kate. But I was told pretty specifically that the semicolon is an "and", not an "or". And so, you've got to think about both.

(Whereupon, a vote was taken.)

June reminds me -- we're going to

move quickly --

CO-CHAIR LUNNEY: You can quote me.

CO-CHAIR MORRISON: June says there's going to be a puddle in the middle if we don't move quickly.

(Laughter.)

All right, feasibility. I think we've talked about this. Can you get it? Are there electronic sources? Is it susceptible? Can the data collection be implemented?

(Whereupon, a vote was taken.)

Okay. Onwards and upwards. This is pretty straight. Okay. Is that it?

Lindsey, are we here? Overall?

I want to defer on this, yes. Yes, I definitely want to defer on this.

All right. Strong work, guys. Very good. We're only an hour-plus behind schedule, which is great.

We are going to take a 9-minute break.

(Laughter.)

(Whereupon, the foregoing matter went off the record at 11:37 a.m. and resumed at 11:53 a.m.)

CO-CHAIR MORRISON: So, everybody, I am conscious that when a meeting facilitator says that was a great discussion, there may be a hidden message there. But it was a very good discussion because I think one of the reasons that we had that discussion was I think a lot of these comments are going to resonate throughout the day.

We have been talking a little bit about what should be the next step, and I think the first measure was particularly problematic because we didn't have the developer on it.

So, what we would like to propose to the group is the following strategy: in the next 10 minutes, we are scheduled to go through one, two, three, four, five additional measures from the same developer and from the

same steward related to the same issue. I don't think we can do that.

I think that, in fairness to both Craig Earle and to ASCO, we need a lot more information. So, what I am going to propose is, for the next five to ten minutes, I am going to ask the reviewers of these specific measures -- we'll go through them just one-by-one quickly -- are there specific questions, comments that you need clarification from Craig and from ASCO that would help inform your decisionmaking?

We are going to put forth as many questions as we have to Craig in the next 30 minutes, when he is on the phone, in terms of clarifying. And after the meeting is over, we will reconvene by phone, rather than coming down to Washington in August, and vote back on the ASCO-stewarded measures. Because I think then we will have the information that we need in order to really carefully consider them.

I do want to highlight to

everybody that, from my understanding, the developers for the rest of the measures we will be discussing will be with us, either by phone or in person. So that the questions that we had this morning, which I think a lot could have been easily answered, could be clarified.

Does that work for people? Most importantly, it works for Helen, who is nodding her head at me because she suggested it.

Well, you know, if it wasn't going to be okay, Helen, I was going to say that you told us we had to do it.

So, just very briefly, my notes, and then I just want to summarize what I have already. Then, we are going to quickly go through the other measures.

So, for the first measure, which was related to the proportion admitted to the ICU, people had questions about whether there has been coding developed for the claims data

capture. They wanted detailed around the comparative data elements for reliability testing. There were questions about variation adjusted for case mix. What's the process/outcome links here with that particular measure. There were questions about insufficient data, questions about validity. What was the validity testing? How reliability was the adjudication of the cancer data from the medical record review?

There was a question whether dying in the ICU was really a bad outcome and how they define that as a bad outcome. And, then, questions about site of care and determination of cause of death, is what we gathered.

So, what I would like to do is, then, go on to Measure 0214. The measure proposed is the percentage of patients who died from cancer dying in an acute care setting. This is very similar to the measure proposed above, except that the fact is, did you die in a hospital; if you had cancer, did

you die in a hospital?

I guess from the people who reviewed that and others, are there specific questions that we should pose to the developer when we get him on the phone that would help in terms of you've now seen what the discussion looks like?

Cards? Russ? Oh, I'm sorry. Kate, I see your card. Oh, I'm sorry. Yes? Russ?

MEMBER ACEVEDO: I guess the one thought that went to my mind, looking through this, is this an access issue or a practitioner issue? If you have limited hospice beds or hospice services in your community, you may not have the option of dying elsewhere besides a hospital or acute care setting.

CO-CHAIR MORRISON: So, this comes down to the link between structure, process, and outcomes. Are there adequate structures that would support changes in the outcome? Is

that what you're saying?

MEMBER ACEVEDO: Yes.

CO-CHAIR MORRISON: Okay. Where am I? I'm sorry. Solomon?

MEMBER LIAO: Well, I don't know about others on the Committee, but for me it would be personally helpful if we could actually successfully go through the process we just did with a measure that we actually have a developer personally here.

CO-CHAIR MORRISON: We are going to be doing that this afternoon, Solomon. The problem is Craig is only available at noon today. So, I would like to get some of these questions available for him.

MEMBER LIAO: Oh, I see what you mean. Okay.

CO-CHAIR MORRISON: Doug?

MEMBER WHITE: The link between the P and the O.

CO-CHAIR MORRISON: The link between the P and the O? Okay.

Eduardo?

MEMBER BRUERA: Yes, I think, is there anything else he can shows us that is reasonably new? He has very old information.

For example, he doesn't have palliative care units. And certainly, David's data, it is very compelling, and our data at Anderson is that, you know, if you have a palliative care unit, you may die way better than alone in the community with or without hospice twice a week or a nursing home. And there is no evidence whatsoever in that older data that there is a difference.

So, unless there is something new that he knows about that he can use to support that setting-based issue, that is going to be very weak.

CO-CHAIR MORRISON: So, Eduardo, I just want to make sure I have this. Unlike the ICU, which you argued very articulately is a bad outcome, that hospital death may not be a bad outcome, given the resources in the

community and the presence of hospital-based palliative care teams, right? Is that what I'm getting?

MEMBER BRUERA: Especially if you happen to be poor, old, sick, minority, and home ain't good, and you don't have a little family around, and there is good data on that. But the question is, what is the data that that says about outcome? The old, old data he has probably is not that good.

CO-CHAIR MORRISON: Any last questions before the next measure?

MEMBER NAIERMAN: Is it too much to ask him as to whether he might have some information about patient preferences with respect to this particular measure?

CO-CHAIR MORRISON: It's not too much to ask.

MEMBER NAIERMAN: Okay. Well, I'm just wondering if it is self-evident already that he does or doesn't. That would be a good question to ask, it seems to me.

CO-CHAIR MORRISON: Measure 0215, the measure here -- I'm sorry, Stephen, I didn't see your card. Okay.

The measure here -- and I do want to sort of focus this particularly on Eduardo's comments before -- this is specifically focused on a cancer population. It is not all comers. It is specifically a cancer population.

And the measure is the proportion of cancer patients not admitted to hospice, yes.

So, I've got Stephen, who moved really quickly, and then Rick.

MEMBER LUTZ: So, this is one I was to have looked over. Obviously, the same question. Older data; is there anything new?

In terms of reliability, described as sensitivity of .24, which doesn't sound particularly enticing. I was checking to see if there is anything else that he could give us that was better than that.

A benchmark target of less than 45 percent of patients not enrolled in hospice at time of death. Is there a reason they picked that? Or is that just it sounds better than it has been? In other words, is there some data or some quality that would lead us to believe that is better than any other number?

DR. EARLE: Hello. Craig Earle here. Can you guys hear me?

CO-CHAIR MORRISON: Hi, Craig. Welcome.

DR. EARLE: Great. I dialed in a moment ago, but it seems like no one could hear me. So, I had to dial in again.

CO-CHAIR MORRISON: Well, Craig, my understanding is we have you for about 30 minutes. Is that correct?

This is Sean Morrison.

DR. EARLE: That's correct.

CO-CHAIR MORRISON: So, Craig, actually, I am going to ask as we go through -- Craig, the Committee has been reviewing the

measures that you submitted and ASCO submitted. There were a number of -- first of all, we understand that this is a brand-new submission process, and we, as a Committee, and, also, have experienced that the developers, you know, struggle with meeting the new guidelines.

So, in the review of some of the measures, there were a number of questions that the Committee had that we just didn't have available on paper in front of us. What we hope to do is use this 30 minutes of time to have the Committee have some clarifying questions for you across the ASCO measures, so it will help the deliberations of these measures in the future.

We felt that we didn't really have enough information to adequately consider them, and we hope to be able to get some clarifying information from you, and, also, to reach out to you after the meeting for some others to help us fully evaluate.

Does that make sense.

DR. EARLE: Sure. Sure. Absolutely.

CO-CHAIR MORRISON: Fantastic.

So, is the Committee okay with me just going through some of the questions that have arisen, and then I will open up to the other Committee Members for clarifying questions that came forward?

Craig, I am going to start with -- there are some questions that I would consider to be sort of in the weeds and some which are 30,000-foot view pictures. We are going to start with sort of the 30,000-foot view picture because I think some of the more technical and detailed questions we can do by email with you.

Is that all right?

DR. EARLE: Sure. Yes.

CO-CHAIR MORRISON: Okay. So, one of the big questions that came up around, I think, both -- and tackle them separately --

the 0213 and 0214 measures, which is NQF-speak.

But the first measure was the proportion admitted to the ICU in the last 30 days of life. One of the questions the Committee was struggling with is (a) is this a process measure; (b) is it an outcome measure? And if it is an outcome measure, is being admitted into the ICU within 30 days of death a bad outcome for cancer patients? There was some question about what the data were to support that.

DR. EARLE: Off the top of my head, I can't remember if I put process or outcome.

CO-CHAIR MORRISON: You put process.

DR. EARLE: I seem to recall that it was pre-populated when I went to submit these. So, I probably just went with whatever was there.

But it is probably conceptually

more a process measure. So, I will just take a step back.

Where all of this came from was an NIH grant about 10 years ago with the idea of creating or developing quality measures for advanced cancer care, in particular, that could be evaluated with administrative data.

And so, the first step in that was review of literature, et cetera, but, then, getting together focus groups with patients with advanced cancer, bereaved family members, et cetera, to come up with topics. There was also an expert panel of clinicians.

It wasn't our initial intention that these all be about aggressiveness of care, but that was what ended up coming out of the focus groups. And it turned out to be, you know, I think there has been a lot of interest in these because I'm an oncologist myself, and, in general, in oncology we consider poor quality when not enough is being done. You know, we are not giving enough

chemotherapy or we are not doing enough scans or something. And here, these are things actually looking at the idea of doing too much and being too aggressive. So, we then operationalized them in Medicare claims and published a few papers looking at trends over time and things like this.

So, getting to your question about ICU or hospitalization or death in hospital, and some of these concepts, it is not that any one instance of that occurrence is necessarily a bad outcome. The idea is looking at what the overall pattern of practice is.

And we have seen this quite nicely in geographic variation as well as, for example, in some of the ones that have been operationalized in QOPI measures, that from one practice to the next there can be huge variation in whether patients are receiving chemotherapy very near death or very different rates of intensive care utilization, hospitalization, et cetera.

And whether that is to do with the practice of individual clinicians or the culture in that group or area or lack of availability of services to allow things to happen in different ways, it is not clear. But, overall, the idea is, is there outlying practice that could be a red flag for more aggressive care?

One of the things that we have found in doing these analyses is that the more available hospice is in a region, the less likely these measures of aggressive care are able to occur or tend to occur. So, for example, you had mentioned the preference for dying in a hospital versus at home. Absolutely true that there is a proportion of patients, in most surveys, in fact, in all surveys that I am aware of, not the majority, but a significant proportion who, for whatever reason, cultural, they're too sick, no family, whatever, don't want to die at home.

But if a particular practice,

institution, area, et cetera, is one where 70 percent of patients are dying in acute care settings as opposed to others where it's 30 percent, well, that makes you wonder if there's something about that system or that setup or that practice style that is leading to that.

CO-CHAIR MORRISON: Thank you.

A couple of other questions; then, I am going to open it up to the Committee, Craig, if that is okay.

One of the questions that came up this morning was, have you -- and we didn't have the data on this -- observed unintended consequences, particularly around the ICU measure in your work in Ontario?

DR. EARLE: Unintended consequences?

CO-CHAIR MORRISON: So, for example, I think the question was raised about somebody with advanced cancer who might have had a reversible pulmonary embolus that might

have been appropriately admitted to the intensive care unit, but was not admitted to the intensive care unit because of the focus on measuring ICU utilization in people with advanced cancer?

DR. EARLE: No, I'm not really aware of that ever happening. You know, in most cases -- there was a nice quote, one of the first papers from this, from the expert panel. It was actually an oncologist who said, "You know, for most of us, if our patients end up in the ICU, it is a failure." It is a failure, meaning that we haven't talked about where things are going in the bigger picture with treatment or we are giving aggressive treatments to patients who can't handle it.

There are definitely scenarios where it is completely appropriate for cancer patients, even near the end of life, to end up in the ICU or to die in the ICU. And in fact, I have often said, when I was doing the

analyses looking at how accurate the claims were for these various things, my practice was included in the claims, et cetera, that we were looking at. Basically, all of these things have happened to my patients as well. So, these things definitely can happen.

But, again, the idea is to look at outlying patterns of practice as opposed to individual institutions. I am not aware, I have never heard of anyone saying, you know, there was this appropriate ICU admission that was denied because people were worried about how this measure would end up looking.

CO-CHAIR MORRISON: And, then, just moving on to your measure about the percentage of patients who died from cancer in the acute care setting, one of the questions that was raised was the data that were presented were really done before the advent of, the growth of hospital-based palliative care programs, and whether there were newer data that you might have available that looked

at people dying within palliative care programs or hospice units within hospitals rather than just an acute care death, because that might be considered to be a different type of outcome than somebody dying in a regular hospital bed.

DR. EARLE: Right. Exactly. And so, that becomes more an operationalization issue. So, we were able within Medicare claims, as I recall, to tease out things like inpatient palliative care settings, at least when they weren't part of an acute care setting, an acute care hospital, so nursing home palliative care and things like that, and not include those.

So, it just all depends on your ability within claims to separate those out and tease them out. Because I do agree, conceptually, that is a different thing than the patient who is taking up a bed that should be for post-op surgical care or something like that.

CO-CHAIR MORRISON: And I guess just a followup question, Craig, which you may not know the answer to, but it might be helpful. Do you know, is it going to be possible to be able to gather those data moving forward and to segue those people out? And I know you are not working down in this healthcare industry anymore. You're actually working up north.

DR. EARLE: Yes.

CO-CHAIR MORRISON: But just is it going to be possible in terms of the feasibility question?

DR. EARLE: Off the top of my head, I am not sure how that is being billed or filed in claims right now.

CO-CHAIR MORRISON: Okay. Other questions for the Committee for Dr. Earle about the measure around dying in the acute care setting? Then, we can go on to the four other additional measures that he and his group submitted.

And if you could identify yourself when you are talking, so Craig knows who is responding, that would be really helpful.

Okay. Seeing no tent cards, I am going to move on to --

MEMBER WHITE: Sean?

CO-CHAIR MORRISON: Yes. Oh, I'm sorry, there is a tent card.

MEMBER WHITE: We're talking about dying in the acute care setting or either?

CO-CHAIR MORRISON: Either of the first two measures. I tried to summarize, I tried to put together the big-picture questions that came up on the first two measures. And there's a couple of smaller ones that I have that I think Craig can answer by email, but I am conscious of his time.

MEMBER WHITE: Can I just ask a quick question?

This is Doug White from Pittsburgh.

It is a little hard to get your

head around a measure that requires a retrospective look at dying. Do we know anything about patients with cancer who are admitted to the ICU sort of in the middle of their stage of cancer who end up surviving and making it out? You can imagine that some patients who have gotten chemotherapy get septic, have a 50 percent mortality rate, but half of them survive.

So, I worry a little bit about, are there patients who should be going to the ICU with cancer if they have an imminently-reversible thing who aren't in the very latest stages of cancer? And, yet, we may not be able to tease those groups apart.

DR. EARLE: Yes. Absolutely. There are studies that have been done. I think in the ICU literature and the ICU profession there has been more of an acceptance that I think if you went back a decade or so, they saw cancer and didn't want anyone coming into the ICU. I think attitudes

have really changed for that appropriately.

And so, yes, it is absolutely true that people getting anti-cancer therapy, even if it is not curative, can have reversible things for which a trip to the ICU is completely appropriate.

Again, this is all about, is there outlying practice? If you are able to compare similar practices, are you ending up with people in the last weeks of life in the ICU because no one has had advance directive type of conversations with them?

And similarly, depending on how you define an operationalized measure, you may end up with a few people who are in the scenario you just described who end up dying in the ICU. That makes you look bad, even though the initial trip to the ICU may have been appropriate. It can still be a red flag if you are an outlier. Is there something about how you are giving chemotherapy that is making a higher proportion of your patients

end up in the ICU or not survive the visit or selection of patients for aggressive treatments, et cetera?

So, it is all just to raise a red flag, not to look at any specific instance of care.

CO-CHAIR MORRISON: Naomi?

MEMBER NAIERMAN: I want to know, was there consideration given to looking at cancer patients dying in ICUs versus spending time there?

DR. EARLE: So, that can be looked at as part of the death in hospital. As I recall, when we operationalized these in Medicare claims, I am not sure we could tell whether people died in ICU versus were in ICU, got out, died on the floor, et cetera. Because you can know how long they were in ICU during a hospitalization, but the exact dates of the ICU visit was not necessarily known.

So, it is an interesting point and subquestion to look at, but, as I recall, in

Medicare claims there were some difficulties operationalizing that.

CO-CHAIR MORRISON: Yes, and in my expertise, yes, you cannot tell in Medicare claims where people died in the hospital.

Questions around the measure proportion not admitted to hospice? And again, this is patients with advanced cancer. Questions from the Committee for Craig?

(No response.)

DR. EARLE: So, again, this is one that is sort of a combination of the practice patterns of the providers as well as the availability within a system, and you try to break out reasons differently. But it is something where, again, we see big variation in practice.

CO-CHAIR MORRISON: So, a question from Rick Goldstein.

MEMBER GOLDSTEIN: So, in pediatrics there is a survey of ACOG providers, and only 60 percent of them had

hospices to make referrals to. I am just wondering whether that would make children a risk group and somehow the information should be stratified or whether you thought about that at all.

DR. EARLE: Sure. Now we have never looked at this specifically in children, but it is true, it sounds like they absolutely are a risk group. And again, that is a great example where this sort of measure would highlight something more about the resources available in an area and highlight something that needs to be done about that, as opposed to what the physicians are doing.

CO-CHAIR MORRISON: And, Craig, correct me if I'm wrong, but your -- and I know this -- but your denominator population is adults?

DR. EARLE: That's right.

CO-CHAIR MORRISON: Yes. So, I've got Stephen, David, Kate, and Naomi.

MEMBER LUTZ: Hey, Craig, this is

Steve Lutz.

Just a quick question. You know, again, sort of variation on a question on a previous measure, but since these data are fairly old now, especially with regard to patients who may have palliative care intervention, given that there is a fair number of patients who have very active and appropriate palliative care intervention, either inpatient or outpatient, who never quite make it to hospice, is it harder now to just simply make it a measure of patients who do or don't get to hospice before they die of cancer?

Because I have a lot of patients who I think die very reasonable deaths who are in the palliative care service and the word "hospice" comes up once, and that's it; they never get there.

DR. EARLE: Yes. Again, that is a question of operationalization because I think, conceptually, that that is something

that is important to put into a measure like this. It is whether you can actually identify palliative care providers and physicians accurately, because a lot of different people do palliative care.

I am aware of a group in the Midwest somewhere who is interested in trying to do that and trying to develop and validate an algorithm to get at that part. As our data systems get better, that is something that we would try to include.

Now in Canada we actually were able to look at some of that, but it is all related to what is available in the administrative data sources.

CO-CHAIR MORRISON: David, you're down or up?

Kate?

MEMBER O'MALLEY: I have a question. This is Kate O'Malley.

I have a question related to the usability of the measure. I tried to find the

measure as described on ASCO's QOPI website. It didn't appear to be accessible to the public.

So, I was wondering how you see the measure, since it has been around for quite some time, where it is being used and how it also meets or addresses the issue for public reporting of this measure as well.

DR. EARLE: And I'm sorry, which measure are you talking about?

MEMBER O'MALLEY: This is proportion not admitted to hospice.

DR. EARLE: And you say it wasn't accessible to the public?

MEMBER O'MALLEY: I looked for it. It was referenced as being available on ASCO's QOPO website. I didn't see it there. It may have been operator error, but I wasn't able to find it.

And also, that website appears to be a member website. I was just wondering how that makes it available for public reporting

and for people to use the measure from the public and, also, from a QI measure. I would just like to know a little bit more about its usability.

DR. EARLE: So, you mean accessible to the public. I am probably not the best person to speak on accessible of QOPI data.

It is true, I think, as I understand it, that participating practices see both their own and aggregate data. Aggregate data has been presented in several fora, including a few publications, meetings like ASCO and other presentations. I can't tell you exactly, though, whether they are really available. Actually, I think they are not, but if there is someone there from ASCO or someone who knows, they can chime in on that.

So, they are available to a certain extent, but I don't think the practices' performance is publicly reported

there, but I am not entirely sure.

CO-CHAIR MORRISON: I've got Naomi, and then I've got Sarah.

MEMBER NAIERMAN: I'm wondering why it was presented as a negative versus a positive. That is, the percent of people who were referred to hospice versus not referred to hospice.

DR. EARLE: I'm trying to remember reasons for these sorts of things. I think it was more just to make it more comparable to the other set of measures. I can't really recall. And certainly, the inverse could be presented as well.

CO-CHAIR MORRISON: Sarah?

MEMBER HILL: I have one question and one comment. My question is, admittedly, your sensitivity was low due to the lack of documentation of hospice admission. Since this is already in use, and it seems like it is something you are still currently collecting, my question is, has there been any

action taken to ameliorate this issue in the current collection? So, have you been working with people to make sure that it is now in the chart, and that medical records do show election of hospice?

DR. EARLE: I can't say I've been specifically involved in those sorts of things, aside from just the general idea of things being measured and reported and getting your rates back as being an impetus to document things better.

But this was one where the claims were better than the records because people get referred to hospice in all different ways. You know, a phone call comes in that someone is not doing well. So, hospice gets arranged, and it never involves a visit. And when there isn't a visit, there isn't a note.

And so, it ends up not being clear documentation. There's documentation, you know, in a hospice record, but not in the record of the provider necessarily who was

involved in it.

Yet, because of things like the hospice benefit, there ends up that people are getting paid. So, there ends up being good measurement in administrative claims.

MEMBER HILL: Okay. And, then, my concern was just I think currently this was listed as a process measure, but a concern would be if it would become an outcome or quality measure.

I work for Ascension Health, and we have 77 acute care facilities. My teams report that, no matter how well they address goals of care or talk about hospice, how wonderful they make it sound, there are many patients who culturally will just not choose it.

So, that is a concern of mine with this one, that no matter how well our teams do in presenting it, it still might not be chosen.

DR. EARLE: Yes, and like

everything else, that is absolutely true. But we have seen in the QOPI measures just dramatic differences in presumably similar practices in patient populations where hospice is involved early, and in the vast majority of patients and others where hardly anyone gets hospice care.

So, again, it is a red flag. There are definitely patients who do not want hospice. I remember a patient who said, "So, will there be a van that says `hospice' that comes outside my house?" You know, there's lots of reasons for that.

CO-CHAIR MORRISON: I've got you for about five more minutes, is that right?

DR. EARLE: At the most. I was just paged a few minutes ago.

CO-CHAIR MORRISON: At the most. I've got a number of tent cards up. There are three other measures that were submitted: chemotherapy in the last 14 days of life, emergency room visits in the last days of

life, and more than one hospitalization in the last 30 days of life.

What I would ask the Committee is to sort of self-evaluate. If you have a burning question, put your tent card up. Keep it really short, really fast, and we will try to get through this. We will connect by email on others.

So, Stephen?

MEMBER LUTZ: Craig, actually, given the number of those competing measures, I was just curious, if we get charged with the task of picking one of these, one or two that seems the most relevant, in your experience or your thoughts, which one or two of these, if we end up picking one, is your favorite or is the one that you think is the most useful? Because they are all semi-related. I mean they are all good, but they are all semi-related. Do you have a favorite?

DR. EARLE: Yes. I think the ones that have had the most traction are the

chemotherapy in the last 14 days of life and the short admission to hospice, short or no admission to hospice. Those are ones that I think there's a lot of traction because there just ends up being a lot of face validity to this.

When I give talks on related topics and I'm speaking with oncologists, it is sort of like, you know when you take calls for your group who the ones are that keep chemotherapy going to the last minute because you are getting calls from people who are having complications and toxicities who really should be having a different focus of care. And you know that that tracks with certain practice styles rather than others.

So, those are the ones that are my favorites.

CO-CHAIR MORRISON: I've got two more questions on the table.

Doug White from Pittsburgh.

MEMBER WHITE: I've heard you say

a couple of times the term "red flag", which I am hearing as a little bit different than a quality measure. I am hearing you say it is a red flag and it is something that might warrant more investigation.

And we are here today sort of working through whether the relationship between the thing and health outcomes is strong enough to endorse it.

So, maybe could you share with us the best cast you have for the link between the process measures that you are proposing and the validity of their relationship to health outcomes?

DR. EARLE: Yes. I think the thing is they were developed with benchmarks, and the benchmarks were identified, were set to try to identify the 10th decile of outlying practice.

We've in one of the papers looked how consistent over time is this, meaning if you look really aggressive one year, but the

next year you don't, and various things like this. And there's a lot of consistency when you look at these.

So, again, though the concept is that any particular instance of these measures doesn't necessarily mean bad quality care, having outlying practice, especially if it is confirmed to be continuously outlying practice, does suggest that there is something potentially overly aggressive going on.

CO-CHAIR MORRISON: Thanks, Craig.

And, then, the last word goes to the gentleman from Houston.

Eduardo?

MEMBER BRUERA: Thanks, Craig.

I wonder if you have looked at more recent data. There is no doubt that cancer care has changed dramatically with the development of targeted therapies and patients are getting later access, and they are getting therapy longer, not just inappropriate, but also quite appropriate.

And I wonder if these hospice referral numbers are changing, and if you did include the other big change that has been the development of acute palliative care programs. And like Stephen was saying, things have changed in two ways. On the one hand, you have people getting options of care that were not available 10 or 15 years ago. And on the other hand, you have a fully established setting of acute-care-based palliative care.

So, how does that change the numerator and the denominator on the percentage of hospice access that you are proposing?

DR. EARLE: Yes, exactly. So, I have not personally looked at those issues, but I am aware of people who are. They are doing it more in the sense of academic research studies as opposed to trying to do methodological development of these things.

You're right, the targeted therapies that have little in the way of

toxicity might have a different pattern of usage. And I guess it is debatable in some cases how appropriate that might or might not be.

And similarly, as I said before, if we are able to incorporate good palliative care, can that take the place of formal hospice? And I think it can. And it is more an issue of, can that be operationalized? In Canada it can, and it is actually more the model.

So, these are things that can be developed and looked at in the future. They're both great points.

CO-CHAIR MORRISON: Craig, thank you so much for your time. We'll be back in touch by email, and really, really appreciate it very much.

DR. EARLE: My pleasure. Thank you so much. Bye.

CO-CHAIR MORRISON: So, folks, what I am going to propose we do is we are

going to take 15 minutes to get our lunch. Then, we are going to come back and we have a 15-minute public comment session we have allocated for public comment, both from people on the phones and those from the audience.

Then, we are going to move to the afternoon session, where a little different from this morning, we have the developers here, and we are going to sort of move quickly through the process of the endorsement process.

Anything from my NQF colleagues or June?

(No response.)

We're good? Okay. Lunch is outside.

Oh, I need to do this NQF announcement, which I hate doing, but I'll do it, so I don't blame them.

Lunch is reserved for people who are sitting at the table here. Is that right? She's the boss. Is that right?

Yes, I didn't want to put them in the position, but they have to say this because it is their dime. Lunch is, quote/unquote, "reserved" for the people sitting around the table, but I don't eat a lot. So, if somebody wants my lunch, they can have it.

(Laughter.)

So, we are going to come back here in 15 minutes, which brings us up to 12:50, in which case we are going to open things for public comment.

So, please get your lunch and bring it back here.

(Whereupon, the foregoing matter went off the record at 12:35 p.m. and resumed at 12:52 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:52 p.m.

CO-CHAIR LUNNEY: It is time for us to reconvene with a public comment session. So, we will begin that public comment session by first opening the floor to the public in the room, in other words, people who are sitting outside of the square table, to see if there are any comments that any of those members of the public would like to contribute to this discussion for the record.

I think we have to do a show of hands because we don't have table tents. Thank you.

Joan?

DR. TENO: I just want to make some suggestions --

CO-CHAIR MORRISON: Joan, could you identify yourself?

DR. TENO: Sure.

CO-CHAIR MORRISON: Sorry.

DR. TENO: Sure. I'm Joan Teno.

I am very thankful for the fact that NQF let me have lunch.

(Laughter.)

Anyway, I just want to make some suggestions to Craig and, also, just to talk a little bit about what the U.S. experience is.

We have had a cancer cohort that we have been following between 2001 and 2007, and there has been a 50 percent increase in an adjusted model controlling for a fixed effect in the use of ICU among a cancer cohort. We have been identifying the cancer cohort based on the published criteria of Dartmouth, based on the diagnosis in the last six months of life.

So, there has been an increase in ICU use over time to the fact that I think it is about 11.7 or 11.8 percent of cancer patients, people with Medicare who have a cancer diagnosis have an ICU stay in the last 30 days of life. This varies tremendously

across the U.S.

No. 2, I would hope that Craig in his response also cites the growing evidence to the family bereavement and post-traumatic stress disorder outcomes, based on having a loved one in an ICU.

Then, I guess, to argue with myself to the contrary, I think it is really important to take into account the criticism that Bach published in JAMA in 2004, that you might need to consider that the cohort is clearly defined as someone who would not benefit, either, by developing the cohort at a set time period prior to it.

CO-CHAIR LUNNEY: Thank you.

Is there anyone else? Can you raise your hands if you would like to make a comment from the public present in the room?

(No response.)

Then, Debbie, can we open the line for any public comment from people who might be listening in?

THE OPERATOR: Thank you.

Ladies and gentlemen, all lines are now open.

CO-CHAIR LUNNEY: There is a time now on our schedule for this meeting to invite public comment. So, any of you who are listening into this meeting who have comments or issues they would like to bring to the table, this is a good time.

(No response.)

I'm hearing none.

Then, we'll move forward. We are skipping over the measures that come from ASCO, which means that, according to your schedule, we are now at the 12:45 slot and we are only 10 minutes late. It is known as sweeping it under the carpet or something like that.

And specifically, we are going to change the order in this session because we have two measures developed or being stewarded by RAND, and we have the opportunity to have

Karl Lorenz on the call at one o'clock.

So, I would suggest that we start with Measure No. 1617.

Carl, are you present on the phone now? And if so, do you have a limited time with us?

(No response.)

All right. Laura, are you present on the phone now?

DR. HANSON: I am.

CO-CHAIR LUNNEY: All right. Well, then, we will go in order and start with 1634, and the presenter for that is Pamela.

MEMBER KALEN: Hi. Okay. So, Measure 1634 is the measure that is called hospice and palliative care, pain screening. This measure looks at the percentage of hospice or palliative care patients who are screened for pain during the hospice admission evaluation or the palliative care initial encounter.

So, basically, do you want me to

go through the numerator and the denominator?

DR. HANSON: This is Laura.

I'm having a lot of difficulty hearing you.

MEMBER KALEN: Okay. Let me see if I can bring the mic a little bit closer.

DR. HANSON: That would be terrific. Thanks.

MS. BOSSLEY: One thing we could do, Laura, do you want to just give a little background on the measures perhaps, just generally? I think we have to briefly discuss them, and, then, why don't we move to the evaluation.

MEMBER KALEN: Okay. That will be great.

DR. HANSON: Yes, I can give just kind of an overall background.

There are five submitted quality measures that are proposed to be stewarded at the University of North Carolina, Chapel Hill. And I am the primary contact for those

measures. So, I will just give kind of a general background that will be relevant to all five of those as they come up in the discussion.

All five of the submitted quality measures have been developed and tested in two project phases. They were first developed as part of the PEACE Project which was initiated under contract with CMS in preparation for the QAPI requirements for hospice organizations that were issued in 2008.

And CMS contracted with the Quality Improvement Organization, the Carolina Center for Medical Excellence, in order to develop an instrument package with quality measures that could utilize existing quality measures with existing data or generate new data and new quality measures for use in the hospice population.

This 18-month-long project resulted in recommendation of a total of 34 potential quality measures that were derived

from comprehensive literature review, review and discussion with a technical expert panel, and initial pilot testing of 60 potential measures with 126 patients from 22 different hospice organizations.

And all of those quality measures were highly specified with operational definitions that were developed, and then nurse abstractors in hospices were trained to utilize them. That generated the initial data for these measures that, as you go through them, you will see identified as hospice in origin.

The TAP reviewed all of these quality measures as well for important scientific soundness, usability, and feasibility, and only the highest-rated measures were included in the initial group of 34. Among those are the five that are included here for NQF.

In the second phase of the project, when the PEACE Project was first

developed, the requirement was that the quality measures be initially tested in hospice, but that they be broadly applicable and potentially be useful in the broader palliative care population.

So, we have subsequently expanded testing of those measures in a hospital-based, seriously-ill patient population in order to extend that denominator population beyond hospice. We have done testing of the feasibility, inter-rater reliability, both face validity and construct validity, and, then, some clinician reflection on usability, with 17 measures that, again, include the five that you see before you.

That project was done by abstracting medical record data from 460 seriously-ill patients for whom the clinicians agreed palliative care quality measures were relevant, but these were individuals without specialty palliative care, and, then, for 102 seriously-ill patients who had received

specialty palliative care.

These patient populations were purposely selected to represent a diversity of hospital-based patient services that included a wide range of underlying diagnoses. And you can see some detail on that in the application material.

The measures from that two-stage process were further winnowed down through the process, the consensus process that Sean Morrison led, that I assume he has introduced to the group, but, basically, making sure that the five measures that were selected out had even broader endorsement and support and background evidence.

So, that is the general background, and I think the discussion here starts off with two paired pain measures.

CO-CHAIR LUNNEY: Any questions for Laura in terms of this general background?

DR. HANSON: Yes.

CO-CHAIR LUNNEY: This is June,

Laura. I was just trying to see if there were any questions from the panel.

(No response.)

And seeing none, then, I think we will move to evaluation, and Pam will be the presenter for the first measure.

MEMBER KALEN: Okay. So, this first measure, as I said a moment ago, is really looking at screening, pain screening, for patients who are admitted to hospice or at their initial palliative care encounter.

In terms of some of the criteria -- do you want me to just present it or as we go through the voting --

CO-CHAIR LUNNEY: I think you want to do a sort of --

MEMBER KALEN: Overview?

CO-CHAIR LUNNEY: -- overview, but, in other words, sort of what Karen did on the much abbreviated version of it.

MEMBER KALEN: Okay. Okay. So, this measure really addresses, the pain

screening measure addresses pain for patients with a high severity of illness and risk of death, including seriously- and incurably-ill patients.

There is a lot of research on the care of patients with serious, incurable illness and those nearing the end of life that shows that they experience high rates of pain along with other physical, emotional, and spiritual causes of distress. This is something that has been identified by the National Priorities Partnership, palliative and end of life, as a key national priority.

And one of the goals of this priority is to ensure that all patients with life-limiting illness have access to effective treatment for pain and other related symptoms, such as shortness of breath. There is a large number of people with life-limiting illnesses who are receiving hospice care.

So, this measure is really, it is a process measure, the purpose of which is to

really identify who in these populations is identified with pain. So, it is prevalent. It is undertreated for many of these populations.

There is opportunity for improvement because it is so underdiagnosed and it is so undertreated, not just in cancer, but in other life-limiting or serious illnesses.

The prevalence of pain ranges from 40 to 80 percent in seriously-ill patient populations and contributes to other issues, such as psychological stress, psychological harms, and social withdrawal and depression. There are a number of citations on the opportunity for improvement around that.

So, that is kind of the overview of really what this is attempting to do. The idea is to be able to screen for pain during the admission evaluation or the initial encounter for palliative care, and the denominator is patients who are enrolled for

more than seven days in hospice or more than one day in a palliative care setting.

So, that is the overview of the measure.

CO-CHAIR LUNNEY: Does anyone on the panel have questions for Pam before we try to go to voting?

(No response.)

Okay. Then, I think we are ready for our group vote on the impact of this measure.

Oops. Thank you, Doug. I see that better than I saw the other.

(Laughter.)

MEMBER CASARETT: Dave Casarett.

This is partly a question for the panel and partly maybe a question for Laura. But the rationale for the denominator being limited to one day for palliative care and seven days for hospice?

MEMBER KALEN: I actually had the same question. It seemed to me that -- and I

am not sure if I misunderstood the denominator, and I am sure she can answer it better, but I wondered if it meant it excluded people who had been in hospice for less than seven days or less than one day in a palliative care setting. And I didn't know if that was because they left the setting or they died, or if it was because they felt that they needed to wait for them to be there for seven days. I thought seven days seemed long.

DR. HANSON: This is Laura.

I have to tell you that both with TAP discussions and within the project team and the CMS observers there was a lot of discussion about time intervals with respect to these quality measures. In particular, basically, these two time intervals were selected with commentary from both hospice and palliative care providers about the time that it may take to complete an initial evaluation of a patient for enrollment.

In particular, with the hospice

timeframe, there was some sensitivity to hospice organizations that may be working with more geographically-disperse, rural populations and a concern that the admission evaluation, meaning the comprehensive interdisciplinary evaluation, may not be completed within 24 hours.

And so, those timeframes were born out of those concerns, that it be generalizable to the interdisciplinary team process and the acknowledgment that an initial evaluation may take in hospice more than one day and in palliative care certainly a day to occur.

And so, really, in practicality, it does exclude a small subset of the patients served.

CO-CHAIR LUNNEY: I would then ask -- Laura, this is June -- is there no way to circumscribe what constitutes an initial evaluation, so that the denominator could simply say those patients admitted to hospice

or palliative care services whose initial evaluation includes an assessment for pain?

DR. HANSON: From my standpoint, I am fine with that. What I am showing you is how the measure was tested.

CO-CHAIR LUNNEY: Okay.

DR. HANSON: It was built this way and then tested this way. So, the data that you see in the application is based on this definition.

I am personally fine with that more inclusive definition of the denominator. I think the reality is especially the hospice organizations were sensitive to a lot of information surrounding the initial comprehensive assessment and what that means for them from a documentation and regulatory standpoint. And that is where the seven-day timeframe really emerged.

CO-CHAIR LUNNEY: Okay. Any other questions. Oops. Doug?

MEMBER WHITE: I think this is

probably a too simple question, but I am still looking for data that there is a gap in performance here, not across the country and across all settings, but in the hospice and palliative care setting.

It strikes me that pain assessment is such a central bread-and-butter part of the care of patients already enrolled or already being seen by a palliative doctor, that I just would like to see some evidence that there's a gap.

DR. HANSON: This is Laura again.

In the application, you can see that in the testing, this is meant to be included as a paired measure. So, there is a pain screening, meaning asking everybody in the population whether or not they have pain and, if they do, asking about severity.

And, then, there's a pain assessment measure that will be discussed in a moment. For those who are screened positive for pain, do they have a clinical assessment?

But in the pain screening itself, in the hospice pilot only 78 percent were screened for pain. But I agree that there are many settings where pain screening is effectively deployed as a fifth vital sign. And when we did this with the hospital-based population, essentially, 100 percent met this. So, there is a ceiling effect in some settings, but in the hospice organizations that volunteered to sample their records for this, only 78 percent were screened.

MEMBER WHITE: Were documented to have been screened?

DR. HANSON: Right. It is a measure based on documentation.

MEMBER WHITE: Yes. From a face validity standpoint, I am struggling with this one.

CO-CHAIR LUNNEY: I think I would like to ask NQF, then, if we were to endorse a measure that ends up with no variability because of a ceiling effect, what good is

that?

DR. BURSTIN: Well, that is the exact point of having you look at the variation at this point. You should keep in mind all measures are reviewed every three years. So, in three years, this measure will get reviewed again. If there is evidence of gap presented now, and not in three years, like you'll look at some of the other maintenance measures, the measure would no longer be endorsed.

But I think that is why you need to determine now if you believe there is a significant gap here.

CO-CHAIR LUNNEY: Thank you.

David?

MEMBER CASARETT: To respond to that briefly, I am actually much less concerned about the presence of a gap. I think the responses are good, but not great, in this sample. These are early adopters who are very, very interested.

Certainly, what I see clinically in some of the data that Keela Herr has collected from a group of hospices suggests that there is, I think, fundamentally far more variability in hospice quality of care than any of us would like to believe.

So, if this were really a ceiling effect item, I would be delighted, but I just don't think that is the case.

DR. HANSON: And I just want to add onto that, David. In the hospice pilot that was part of the CMS contract, only 78 percent of hospices had evidence that they had screened.

But, right around the same time, a group of the NHPCO Quality Partners Collaborative Hospices, so very much those early adopters, highly motivated in quality initiatives, those hospice organizations collected some data on this metric and met it at 94 percent. I think that shows you perhaps some of the variation across organizations.

Many times I think in our published literature the data is from early adopters.

CO-CHAIR LUNNEY: Thank you, Laura.

Naomi?

MEMBER NAIERMAN: It seems to me the seven days in a hospice setting is a very long time to get assessed for pain. It eliminates about a third of hospice patients, patients that are seen by hospices throughout the country. And if you are in pain for seven days and you haven't been screened -- how about if it is six days, even if it is two days?

The other thing is that pain, there is another measure related to pain among these having to do with 48 hours of becoming comfortable, if you have been assessed for pain. That is a measure that is used by quite a few hospices. So, I would really be a lot more comfortable if the window was a lot more

narrow, although if we are confined to a seven-day length of time, and it is the only thing we can vote on, then I will settle for it. But seven days seems -- and the other point I want to make is it is provider-driven. The provider said, "Give us seven days."

Whereas, from a consumer's perspective, it doesn't tell me very much, that within a week they got around to asking me about my pain.

CO-CHAIR LUNNEY: Thank you, Naomi.

Sean, you had a question?

CO-CHAIR MORRISON: Perhaps a clarifying comment that would help, which is, being more painfully familiar with the NQF process than I think I would like to be, the reality is that what we are being asked to measure is based upon very strong reliability and validity data that the developers have done.

In this setting, and in all the other measures, what was tested and what is

before you was seven days. There are no data as to six days, five days, four days, three days, two days.

So that we would be, as a Committee, making that up. So, I think that we have to in some ways trust the developers because that is what the process says that we need to do.

I think in terms of your other question, Naomi, I think I would also highlight that -- and again, being familiar, having read through these -- the comfortable dying measure that is on the table is a different measure, a very different measure than was pain assessed.

And I think one could argue that they are different populations because one is specifically hospice; the other looks at a different patient population. And it's a different measure.

I do think that thinking through those separately is an important thing because

they are different measures and they are measuring different things. They are both probably really important.

CO-CHAIR LUNNEY: I think, at least in the NIH model, if you continue the discussion for too long, you would redesign everything. So, let's not.

(Laughter.)

We are evaluating the measure as it has been brought to us with the data that has been brought to us. We are talking about our comfort level with that.

Pam, you had one more comment to make?

MEMBER KALEN: Yes, I just wanted to make one clarifying comment because we are using the terms "screening" and "assessment" sort of interchangeably. These are two measures. The first one that we are talking about right now is related to screening at admission, and, then, the second measure, which will come immediately following this, is

related to assessing for those who screen positive.

So, I know the terminology is easy to use interchangeably, but only because I know that the very next one is on assessment, I just want to make sure that we keep in mind that this is just screening positive for pain versus assessing level of pain.

CO-CHAIR LUNNEY: Okay. Then, I think we are ready to go to voting.

What I have heard in the discussion is that there are several modifications we might like to make, but we are not getting to make. We will deal with what is in front of us. Also, we might like to believe that 100 percent of people are screened, but evidence suggests that that is not the case.

So, our first question, then, becomes the importance of this measure and report. With your instruments ready, are you ready to tell us?

MS. TIGHE: I thought we decided to skip that for all of them.

CO-CHAIR LUNNEY: Okay. So, are you ready to determine whether or not the data demonstrated considerable variation and, overall, less-than-optimal performance across providers and/or population groups?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: For those on the phone, that's 12 high, 7 moderate, 1 low, and zero for insufficient evidence.

CO-CHAIR LUNNEY: Our next criteria to vote on is the importance to measure and report, 1c, evidence for outcome. Is the measure a health outcome with relationship to healthcare structure, process, intervention, or service?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Eleven yes, 9 no.

CO-CHAIR LUNNEY: Now we're voting on 1c. What is the quantity of studies that are in the body of evidence to support the

importance of the measure?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Fourteen high, 6 moderate, zero low, zero for insufficient evidence.

CO-CHAIR LUNNEY: 1c, related to the quality of the body of evidence, is it high, moderate, or low?

(Whereupon, a vote was taken.)

MS. TIGHE: If you could all keep trying until we get that 20?

MR. COLCHAMIRO: Sixteen high, 4 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: And 1c, consistency?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seventeen high, 2 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Now we are dealing with the reliability of the measure itself. Are there precise specifications and

testing to demonstrate that we consistently get a similar score for the same situation?

(Whereupon, a vote was taken.)

It looks like you had better press again.

MS. TIGHE: Yes, again, keep trying.

MR. COLCHAMIRO: Sixteen high, 4 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: In terms of the validity?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seventeen high, 3 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: Scientific acceptability of the measurement. If disparities have been identified, will this measure capture them?

(Whereupon, a vote was taken.)

If everybody thinks they've voted,

try again. Now we're good.

MR. COLCHAMIRO: Eleven high, 7 moderate, 2 low, zero insufficient evidence.

CO-CHAIR LUNNEY: In terms of usability, is this measure easy to understand for public reporting and useful for quality improvement?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Sixteen high, 3 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Feasibility, easy to do?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Nineteen high, 1 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: And overall, does it meet suitability for endorsement?

(Whereupon, a vote was taken.)

MS. TIGHE: We still need three. If you guys could keep trying?

CO-CHAIR LUNNEY: Try again.

MR. COLCHAMIRO: Just remember to point at the machine, please.

CO-CHAIR LUNNEY: I think our clickers get tired.

(Laughter.)

MR. COLCHAMIRO: Twenty yes, zero no, zero abstain.

CO-CHAIR LUNNEY: Now our next measure in order would be the assessment. I think that would make logical sense, but I do want to see if Karl is on the phone and if there are any time limitations to his availability.

Carl, are you there?

(No response.)

THE OPERATOR: Mr. Lorenz was dialed, but has since disconnected. I have been watching for him to dial back, but he has not done so yet.

CO-CHAIR LUNNEY: Is he going to be able to return?

CO-CHAIR MORRISON: Sydney, you

have collaborated with him on the RAND measures. Can you speak to some of those, if there are questions?

The bowel one, at least on the preliminary, looked pretty straightforward. So, okay, I think we're fine.

CO-CHAIR LUNNEY: Then we'll stay in order, and we will go to the second measures sort of, if you will, that is connected to the screening measure, the pain assessment measure. And Pam also has this one to tell us about.

MEMBER KALEN: The percentage of hospice or palliative care patients who screened positive for pain and who received a clinical assessment of pain within 24 hours of that screening.

I believe what they are trying to assess in this measure is the level of pain. Let me make sure I've got this right here. Okay, yes. So, they screened positive pain during the initial assessment, and now they

are being assessed as to the level of pain that they have.

And again, it has the same exclusions as the other measure did and looks at -- I feel like I'm missing something here. Sorry, bear with me a second.

Patients who are enrolled in hospice or who are receiving palliative care who report pain when pain screening is done on the admission. And, then, the denominator exclusions, again, are the same. So, it is also patients who were not screened for pain. And it is paired with the pain screening measure.

Uses a very similar summary of the evidence of impact and the opportunity for improvement in terms of the level, the number of people who have high degrees of pain, the underdiagnosis, undertreatment, the prevalence.

So, yes, it is very similar, the way this measure is written is very similar to

the other one, other than at this point we have identified that people have pain and are assessing the level of their pain, which would be really important in terms of being able to identify the appropriate treatment for that pain.

CO-CHAIR LUNNEY: I think we want to point out that the numerator is not just severity, but also etiology and impact.

MEMBER KALEN: Right.

CO-CHAIR LUNNEY: That is a rather broad, sweeping assessment. It is not just a pain thermometer. It is knowing a great deal more about the pain than the pain thermometer or equivalent.

Do you have anything you want to bring up? We are talking about using the same evidence about the variety and screening to discuss whether or not actual practice includes the evaluation of all of these criteria, etiology, severity, impact. Do we have any other evidence? I mean that's a

different question, isn't it?

MEMBER CASARETT: This has been a very interesting eyesight test for Dr. Lunney, and I'm afraid she is not doing well.

CO-CHAIR LUNNEY: Who is due for cataract surgery. So, bear with me.

(Laughter.)

MEMBER CASARETT: I had a question about what is included in documentation for the assessment component.

And Laura is still on the line, right?

Laura, I was wondering if you could say a little bit about how you came up with the five out of seven, and whether there is any background discussion about whether some of those components, which appear to be all weighted equally, might be more important than others.

Because I think the question we will need to struggle with to some degree is, to what degree are each of these components

actually associated with better outcomes if you measure them? Does that make sense?

(No response.)

Laura?

(No response.)

MS. TIGHE: Debbie, is Laura Hanson still on the line?

THE OPERATOR: Yes, she is. I'll reopen her line.

MS. TIGHE: Oh, you can leave it open. Thank you.

THE OPERATOR: Okay. And while we have a break here, Neil Wenger has also requested that I let you know that he is on and his line is now open.

DR. HANSON: Can you hear me now?

(Laughter.)

MS. TIGHE: Yes. Yes.

DR. HANSON: All right. So, the five of seven assessment components needed to be present, and those included the location of the pain, its severity, its character, its

duration, its frequency, what makes it better or worse, and its effect or impact on function or the patient's life experience. And these characteristics were derived from expert basic guidance on how to assess pain from sources like cancer pain guidelines and others that really tell us how to do pain assessment in a patient going beyond the question of severity.

And the characteristics were then not weighted, David. We actually didn't even consider that. I think it is because I and the other people working on this were trying to keep these measures simple in their generation from chart documentation.

We had initial concerns about just the inter-rater reliability potential for this measure because one person's sense that the location that was described we had some concerns might vary to the next rater. But the inter-rater reliability was quite high. The Kappa was .94, and it really was more feasible than any of us expected to get this

data and to be clear whether a clinician had assessed the same characteristics.

CO-CHAIR LUNNEY: Any other questions?

(No response.)

So, Laura, I just have one question. The numerator says etiology, severity, and impact, and the --

DR. HANSON: June, I think that is in the general description. Then, if you go further into the documentation, they ask for the numerator details. It may be my fault or our fault in the way we filled the documentation out for NQF. But I think in the section that gives numerator details, this other description is probably clearer for your purposes and really is the operational definition.

CO-CHAIR LUNNEY: Oh, Eduardo?

MEMBER BRUERA: Thanks very much.

I think it is following up on David's initial comments. I wonder if,

knowing that Laura is there, if she could help us out.

But I think there are two issues that I think are important. The simple zero to 10 JCAHO pain intensity assessment, when it was initially validated, was found very reliable and very valid. When it was then conducted in real-world assessments, the association between the JCAHO assessment a second-party assessment within two hours ended up being like .3 or so, much lower than was initially expected.

Since then, a lot of work has been done, but we are still getting two values in the .6 area for only one question. That is, from zero to 10, how much does it hurt?

So, I would be a little bit worried about doing two things: first, moving into multiple assessments of dimensions. But the second question is I am not sure there is a lot of evidence that what it makes it better, what makes it worse, how does it

affect your function, and so on, really has significant therapeutic or prognostic implications as compared to making sure that you have regular, consistent, obsessive assessment of intensity.

So, that would be one of the main concerns of implementing a multi-pronged, a multidimensional, we might call it, assessment of pain that I don't think the evidence backs up that because of the fact that you say, this or that, I should have done differently.

And I wonder what Laura's position is on that or what they thought.

DR. HANSON: I think that is a really interesting point, Eduardo. I think that when we were developing this quality measure, honestly, we had some of those same questions, but we counterbalanced that question that you are framing so well with the concern that is in the pain literature that we treat not to pain score, but rather treat to maximize function or treat to a level that is

satisfactory to the patient; and that this kind of pain assessment I think is advised both with that concept in mind and with the idea that we want to understand more about the pain, in order to design treatment, than its simple severity. Treatment is driven not just by severity, but also by its impact on function and on other characteristics of the pain, like how frequently it occurs or the information that might guide understanding about etiology like the actual character of the pain that would lead us to conclude it is neuropathic instead of somatic in origin.

So, I think it was really those issues that guide treatment beyond the pain score that resulted both in this kind of information being present in expert guidance about pain assessment, but also really led to the development of this approach to quality measurement going beyond severity.

And I was fully prepared, as I said before, to find that this measure did not

have good inter-rater reliability and not be thrown out or did not have good face validity with clinicians and not be thrown out, but we found differently.

CO-CHAIR LUNNEY: Pam, my question might be for you. Then, if we are evaluating the evidence that this measure, as opposed to pain screening, is supported by evidence that there is a variability in practice that we need to track and improve, is that evidence in the application? Or, Laura, do you have that evidence to add?

DR. HANSON: That is in the application, at least from our data. This measure was met in the hospice pilot testing at a 60 percent level. And in the testing with hospital-based, seriously-ill patients, 42 percent had assessments in the population that did not have specialty palliative care, and 67 percent of those who did have specialty palliative care had this pain assessment measurement.

So, there is certainly some variability.

CO-CHAIR LUNNEY: Then, I guess perhaps what I am really trying to ask is that link to outcomes. Is this better than just screening?

DR. HANSON: Say that again? Oh, the link to outcome, is that what you asked?

CO-CHAIR LUNNEY: Yes.

DR. HANSON: Yes. I think that the link is not direct in the sense that I am not familiar, maybe somebody else is, but I'm not familiar with a study that purposely sets out to test these descriptors of a pain assessment against patient's pain relief. But this is the process of care used by experts in palliative care and pain consultation in the studies that have shown that those interdisciplinary interventions make a difference in pain outcome.

CO-CHAIR LUNNEY: Thanks, Laura.

Any questions before we move to

voting?

Oh, sorry, Russ?

MEMBER ACEVEDO: Hi. This is Russ Acevedo.

In another measure we are going to be looking at this screening, you just have screening by itself, while here you have broken out the screening and the assessment. Is there any reason to do one and not the other or to support one or the other?

DR. HANSON: Oh, that's a great question. Obviously, you noticed that. When we looked for expert guidelines for dyspnea assessments, we could not find them.

Clearly, there are mechanisms for screening. So, for asking patients about dyspnea and in Meg Campbell's work for evaluating the signs of dyspnea in non-verbal patients, and therefore, rating its severity. So, basically equivalent to the description that we used for screening. But we could not find expert guidance the way there is for pain

on dyspnea assessment of etiology, severity, and impact on function.

CO-CHAIR LUNNEY: Thank you, Laura.

Tina?

MEMBER PICCHI: I have a question regarding the denominator detail section where it is a positive screen for a hospice patient if it is greater than zero, and it is a positive screen for a palliative care patient if it is greater than four. Can you just comment on that and the rationale for that?

DR. HANSON: The rationale for that was, in the initial phase of the project, in the phase of the project where we were working with hospices, there was a recommendation that any pain should be assessed. When we moved into the second phase of the project, working with the hospital-based, seriously-ill population, and working with these quality measures with hospital-based clinicians, they did not feel that mild

pain should be included.

So, we do have a different cut point. I am not particularly happy about that because I think it adds a level of complexity. But that was based on input from the clinicians involved.

CO-CHAIR LUNNEY: Thank you.

Eduardo, do you still have a question?

MEMBER BRUERA: Yes. There is no doubt that sometimes when people write would be ideal to do, that doesn't necessarily mean what is useful to do in a clinical setting. And I think, unfortunately, there is not a lot of evidence that these assessments are conducted.

In fact, if I would have to look at the practices that I am aware of, the vast majority of the highly-specialized practices based in tertiary hospitals would have to be modified dramatically to adhere to these guidelines because those assessments are not

really done on a regular basis. That reflects probably the fact that in some specifically problematic situations one would go through these multidimensional assessments, but in the bread-and-butter situation one wouldn't necessarily do that.

So, my concern is regarding the level of evidence that backs up the fact that all these assessments need to be done and documented on a regular basis because they do have an evidence-based difference on the outcome. If it doesn't, I think it would put a certain level of burden on the different clinical teams.

DR. HANSON: Eduardo, this is Laura again.

I just want to make sure that you understand that this is reflecting the initial assessment only. It is not reflecting sequential followup assessments over time. It only applies to the initial encounter with the patients.

CO-CHAIR LUNNEY: All right. Is the group ready to move to voting?

Our first voting is on the performance gap.

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Fourteen high, 5 moderate, zero low, 1 insufficient evidence.

(Whereupon, a vote was taken.)

CO-CHAIR LUNNEY: Try again, folks.

MR. COLCHAMIRO: On 1c, it's 8 yes, 12 no.

CO-CHAIR LUNNEY: The quantity of studies in support of the evidence?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: On quantity, 11 high, 6 moderate, 2 low, 1 insufficient evidence.

CO-CHAIR LUNNEY: The quality of the evidence?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Ten high, 8

moderate, 2 low, zero for insufficient evidence.

CO-CHAIR LUNNEY: The consistency of the results?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Ten high, 6 moderate, 1 low, 3 insufficient evidence.

CO-CHAIR LUNNEY: Reliability?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seven high, 11 moderate, 2 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Validity?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Six high, 11 moderate, 2 low, 1 insufficient evidence.

CO-CHAIR LUNNEY: Scientific acceptability in terms of disparities?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Five high, 9 moderate, 3 low, 3 insufficient evidence.

CO-CHAIR LUNNEY: Usability?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seven high, 7 moderate, 6 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Feasibility?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Three high, 12 moderate, 5 low, zero insufficient evidence.

CO-CHAIR LUNNEY: And the overall question?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Sixteen yes, 4 no, zero abstain.

CO-CHAIR LUNNEY: Okay, our next item, No. 1617, is a RAND document. Is there anyone familiar with the development of it? Treated with an opioid, those patients treated with narcotics who get a bowel regimen.

DR. WENGER: I think you have on the line both Neil Wenger and Carol Roth.

Carol, are you there?

MS. ROTH: Can you hear me?

DR. WENGER: Carol?

MS. ROTH: Can you hear me?

DR. WENGER: Yes.

MS. ROTH: Okay. I am.

DR. WENGER: Great. So, we would be happy to present this. In five minutes, I need to spin off onto a different call.

So, Carol, maybe you could continue.

MS. ROTH: Okay.

DR. WENGER: Do you want to take up the opioid bowel regimen one first?

CO-CHAIR LUNNEY: Yes, that would be good.

DR. WENGER: Okay. So, this is a process measure. Maybe I will spend just a second talking about the mechanism with which these measures are developed.

This uses the RAND UCLA Modified Delphi panel method of measure development. It begins with the literature and experts, and, then, is subjected to a rigorous evaluation using clinical experts and panel Modified Delphi methodology to link processes

and outcome that takes into account both what the literature is able to show along with clinical expertise.

This set of measures has since been administered in a number of different venues in three different ACO studies and two different ASSIST trials.

These measures are evaluated on their reliability from a chart abstraction perspective as well as validity with important outcomes for vulnerable older people, looking at both survival and functional capabilities. But they are looked at as a group rather than as individual measures for the process outcome link, largely because in some cases the "Ns" aren't large enough. For these sets of measures, there really aren't good outcomes with which to link the process in general.

I will get down to the specifics of this measure. So, this is a measure that evaluates for a denominator of vulnerable older patients -- and the definition of that

is included within the measure -- who are treated with a new opiate prescription, whether they are given a bowel regimen.

I would be happy to go through the details of who the vulnerable older patient definition is as well as what a bowel regimen is, but I think it has been presented. Maybe I will just allow you to ask questions concerning it.

The bowel regimen must be prescribed within 24 hours of the new opiate prescription.

The measure has excellent reliability based on numerous evaluations from chart-based extractions and has demonstrated a rather startling performance gap ranging from zero percent of patients receiving a bowel regimen after a new opiate is prescribed to a maximum of 61 percent in four different studies that range in "N" from as low as 46 or I guess as low as 39 up to 460 patients.

The measure is supported by a

number of clinical guidelines. Yet, there are no RCTs underlying this measure. We are unaware of any randomized studies of patients receiving versus not receiving bowel regimens related to either adherence or pain control.

We couldn't find any measures that tread in the same area that are already NQF-endorsed.

CO-CHAIR LUNNEY: I guess, actually, Neil, since your time is limited here, I would be interested if there is anything of the set of measures that you have familiarity that you feel you need to speak to before we lose you. We have Sydney here to speak to some of them, right?

DR. WENGER: Right. I think that Sydney can probably address the pain screening measure, which is the other RAND measure that is currently on the docket.

DR. DY: The other one is the dyspnea. That would be for you, Neil.

DR. WENGER: I don't think I heard

the last statement.

DR. DY: The other one is the dyspnea.

DR. WENGER: Right, but that is actually on the next set at three o'clock your time, right?

CO-CHAIR MORRISON: That's correct, Neil.

CO-CHAIR LUNNEY: Okay. Then, I think we can move to the presentations by the members of the panel who are prepared to present on that. And I have Doug Nee doing 1617.

MEMBER NEE: Since a wonderful job was done of presenting the initial measure description, I guess I really don't need to go back over that.

At least just to mention to the group here some of the details that you can already read. But vulnerable adults, individuals greater than 74 years old, a vulnerable elderly survey scale rating of

greater than two, prognosis of terminally-ill, expectancy of life, less than six months, and stage 4 cancer, just to qualify who the vulnerable adults are.

With the denominator being the vulnerable adults, given a new prescription, as was mentioned, for an opioid, and the numerator are patients from that denominator that are given a bowel regimen or there is documentation as to why this was not needed.

One of the things that we were asked to do as well is to kind of summarize the rationale that was given for a number of points that we are voting on here. So, I am going to go ahead and do just that briefly.

As far as importance to measure and report, those that did respond kind of identified there was a Grade 1A that was assigned to the guideline recommendations by the developer with no contradictory guidelines cited.

Measure demonstrates a high impact

on healthcare for a large number of patients to improve quality of life and reduce negative health outcomes.

Evidence demonstrating performance gap was provided in the form of literature citations. The studies cited, however, had a very small number of patients. Yet, it is suspected other references would have more support.

Though considerable variation in performance has been demonstrated in the studies across population groups, benefits of this measure are expected to improve opioid treatment compliance, quality of life, and reduction of patient discomfort.

You know, it was also identified, too, that though constipation is a common issue, it seems a little minor to consider as a measure. However, in general practice, prevention of constipation was identified as foremost, and if it fails, we continue to treat.

Citing the literature cite from the Canadian study, it kind of questioned the emergent nature of looking at constipation where there was 4 percent of the patients and only 1.7 percent of 194,000-plus total visits by these patients made to the emergency department were actually for constipation. So, it is just something that was brought up as a concern or an issue.

Looking at scientific acceptability measure of properties, the measure is precisely specific providing clear definition, qualifying the denominator patient set with a high level of reliability testing.

The measure is consistent with the evidence, and though validity testing was not tested empirically for this measure alone, the level of validity testing is seen as fair and methods and scope are modest. And this is also feedback as well from the individuals who provided this.

The steward reported the process

outcome link for the set of quality measures, including this measure, has been tested.

Some of the issues cited:

validity is rated low, as the measure is not yet specifically tested or valid. They have been getting most of the data from just the reports of individuals who are prescribed opioids and, in fact, do need to have a bowel regimen.

Additionally, data requires chart abstraction, and that may impede reliability. It is unclear as to why the steward only supported the measure for vulnerable adults, and not actually other adults. No disparities were actually identified.

Just kind of looking at usability, the rationale cited for the votes that were given: the measure information has credible rationale. It is clearly defined relative to the use of bowel preparations with initial opioid therapy. The measure information appears understandable across audiences.

Some of the issues cited: the measure seems intended for internal quality assurance, and public reporting may not necessarily be seen as helpful. Not certain the public wants to know just how constipated people are.

(Laughter.)

Or they may even like the fact that there are others out there, including themselves. Who knows?

(Laughter.)

The measure really just kind of looks at if a prescription was given, and not if the patient ever started the bowel protocol.

Questioning the necessity of time required to abstract this particular bit of information, too, was also put out there, too.

As far as feasibility, relative to the rationale of the input and feedback, dataset elements for this measure are easily found in EMRs or patient charts containing

routine daily care information. Dataset elements for this measure are easily found in EMRs or patient charts containing routine daily care. Recording elements can be easily obtained from the electronic health sources.

Although cited issues, no information is provided on susceptibility to inaccuracies, errors, or unintended consequences or ability to audit. The data collection strategies were not necessarily provided, and no information is provided on susceptibility to inaccuracies, which sometimes do occur due to unintended lack of objective documentation or failing to record care processes, which we know in practice occurs on a certain frequency.

The denominator limited to vulnerable adults limits feasibility, and the inpatient data may be more difficult to collect than outpatient data. I am not exactly sure what inpatient and outpatient is actually specifying other than reference to

hospital.

And capturing contraindications might also be difficult.

In general, as far as summary goes relative to endorsement, though the evidence is low specific to the measure, the measure makes common scientific sense. It is a well-validated measure, as outlined in opioid treatment guidelines. The measure is easily implemented and can have significant impact on healthcare cost and patient distress.

In practice, we know a patient will often become constipated with opioid therapy at some level unless a bowel preparation is initiated. Literature documentation supports a proactive use of bowel regimen with initiated opioid therapy.

And the fact that this measure is being presented and reviewed for endorsement is telling of the national healthcare issue associated with opioid therapy. NQF endorsement in this measure is important to

drive home the attention needed to assess for initiated bowel regimen automatically with opioid therapy to avoid negative healthcare consequences, as cited in this document.

When I first read this and I saw this come up as a measure, my first comment was, "Really, after all these years, we're looking at this?"

And, then, in a meeting a couple of weeks ago, it was also brought up as a concern, that if someone is started on an opioid, that we should start the bowel regimen, and is somebody monitoring that? Because then the quote came out that this is becoming a national problem, and I was actually amazed. Either I was under a rock or I thought that everybody else was doing the right thing, you know, by our patients and giving them a bowel regimen.

Some of the issues that were identified really in the feedback is: while this is an important treatment issue, it is

believed that there may be more important issues to concentrate attention on, and not necessarily certain that this is as significant a problem to measure as maybe some of the others. However, I think like we have identified earlier today, that the measures that are coming to this group are because there are national issues associated with them, and it is something we need to focus on. And that's it.

CO-CHAIR LUNNEY: Thank you, Doug. Are there questions from the panel? Or perhaps I should say, is there a response to anything on the part of the developers?

DR. DY: This is Sydney, Carol, since Neil is off.

We kind of did these together and assisted ACO, and we had between us probably 100 different measures to choose from to put forward. These were the ones that we felt were the biggest problem. As an outpatient

private care provider in a cancer center, this is an issue that probably we are dealing with every day. So, out of all the measures that we could have put forward, this is one that we felt was really a major issue. And the other problem is a lot of these measures are really, really difficult to get, and this was one that we could actually reliably get. So, that is the reason why this one is here.

CO-CHAIR LUNNEY: So, a question from --

MEMBER NEE: Actually, it is not a question. It is just an additional comment.

Probably of the thousands of newly-admitted hospice patients to programs that I review, their medications, I would say just to shoot from the hip, minimally, 20 to 30 percent of those individuals who are on an opioid therapy or other types of constipating therapy, I'll throw in, are not on a bowel regimen, which kind of speaks to the same level.

CO-CHAIR LUNNEY: Okay. Question? I don't know whose tent went up first. We'll let David go first.

MEMBER CASARETT: Yes, this is Dave Casarett.

This is actually quick. I notice that one of the bowel regimens that counts is a bulk agent. And particularly for vulnerable elders on opioids, I was sort of surprised by that. It is not something that we usually encourage. Was there a rationale for that that I was missing?

CO-CHAIR LUNNEY: We'll follow up and ask. Okay.

DR. DY: I think Neil would have to speak to that.

CO-CHAIR LUNNEY: Doug?

MEMBER WHITE: Mine is not actually about the bulking issue, but about why we selected this population. Am I right that we endorse this as a yes/no, including the population to which it is applied? Sean,

is that right?

CO-CHAIR MORRISON: My understanding, and I look to the group, we, as an NQF process, need to endorse these in the populations that were tested.

MEMBER WHITE: Okay.

CO-CHAIR MORRISON: When people, measurement developers, were initially moving forward to think about that, we were given pretty clear instructions that it had to be --

MEMBER WHITE: Okay.

CO-CHAIR MORRISON: -- which I see Rick's tent up. There's no reason that, from my perspective, this shouldn't be the same across all age groups, but it was only tested, this measure was only tested in vulnerable elders.

MEMBER WHITE: Yes. It just becomes relevant because -- we skimmed a little bit over the feasibility parts of this -- but a lot of the things that make you this group, this high-risk group, would be a little

bit hard to abstract from the chart. So, there's some effort that would be expended for this thing because we are keeping it so narrow.

And, then, I do start to wonder about kind of benefit/burden ratios for this particular measure.

CO-CHAIR LUNNEY: Question here, Rick?

MEMBER GOLDSTEIN: Just to clarify, because Sean read my mind, but if the rationale applies in populations beyond what this measure is tested for, could we, then, ask the developers why this shouldn't be applied more broadly? Because, I have to tell you, it seems, from some of the comments, that constipation is, you know, it is the unusual jokes about constipation, but where I stand, I would have to say one of the things that I regret most is when it turns out that the last day of consciousness for a child is spent writhing with belly pain because they are

constipated. It just seems an easy thing to try to prevent and a hugely important quality measure.

CO-CHAIR MORRISON: I think, having talked with the staff beforehand, I think that this Committee, not to the developers, but I think that we could make the recommendation that, as the measurement is moved forward, it could be brought across.

I know we said not personal statements, but I will tell you, you know, my biggest regret was a patient we saw for a palliative care consultation two years ago who we saw for belly pain, and 90 minutes after we hit the scene he was dead from a perforation because he had been on opioids for two weeks without a bowel regimen. Real consequences.

CO-CHAIR LUNNEY: I just have one question of clarification. I didn't hear that there was much evidence in the application about usability and ease of data collection, but we could go wider than that, correct? Is

the general sense of the panel that these data are not that hard to uncover?

MEMBER LIAO: Correct. This is Solomon.

Yes, at least on the hospital side, it is easy to collect electronically. I mean we did a PI project in our institution on this subject, and the data is easy to collect.

But if I can play devil's advocate back to the earlier question about giving feedback to the developers to expand to other populations, I think we, as a Committee, need to be careful about talking out of two sides of our mouths. One side saying they have to have evidence in order for us to endorse, and, then, the other side saying, well, we then really want you to extrapolate to populations in which there is no evidence.

CO-CHAIR LUNNEY: Doug, do you have your tent sideways for a good reason? Okay. Sean?

CO-CHAIR MORRISON: I look to Helen for this clarification. I don't think what you are hearing, Solomon, is us, as the Committee, going back to the developers and saying, "Tell us to expand it." I think what you are hearing is the Committee can make a recommendation, based upon the expertise and their review of the literature and the evidence, that it might make sense to expand this to other populations.

And I am not sure that we are talking out of two sides of our mouth. As Helen said, some evidence can be expert opinion. We don't like to use expert opinion. We would prefer not to. But in some cases we can make the recommendation that just because it has been tested in a narrow population doesn't mean, for example, it couldn't apply to a 45-year-old cancer patient.

DR. HANSON: This is Laura on the phone. I'm not sure if it is appropriate for me to make a comment at this time.

CO-CHAIR LUNNEY: Laura, can you hold that until we make sure we have time for the panel?

DR. HANSON: Yes. Fine.

CO-CHAIR LUNNEY: Thanks.

DR. BURSTIN: I would point out just two points for information. I think there's actually two issues here we are really talking about. One of them is, does the evidence expand to be broader than the vulnerable elders, which I think is question one.

And I think the second question is, is it tested such that you can reliably collect the data in those other populations. I think what I am hearing the Committee say is you would like the developer to explore both of those potentially, but you are not saying to do it unless there is evidence and it is tested.

CO-CHAIR LUNNEY: Eduardo, you had a question?

MEMBER BRUERA: I would just like to echo that it is quite retrievable. It is not difficult, both in the inpatient setting and in the outpatient setting, and we did have experience in setting these in different institutions and places.

And I would also like to echo the comments from the team; that is an extraordinarily-valuable point.

And finally, emphasize what Sean said, that requesting or inviting submissions of a wider population would be a wonderful contribution.

CO-CHAIR LUNNEY: I think you had the next question. Or I don't know. Doug, how long have you been waiting? I missed yours.

MEMBER KARP: Well, mine is quick. So, do we absolutely know for a fact that it has not been tested in any other population?

MS. ROTH: This is Carol Roth. Can you hear me?

Actually, the population is not just vulnerable elders, but we expanded it to vulnerable adults because the ACO populations that we tested were all vulnerable elders. However, the ASSIST were individuals of various ages. But, as mentioned in our definition, those were patients with poor prognosis or stage 4 cancer.

DR. DY: Right. Yes, we don't have reliability testing. We did test this, but we didn't have enough patients for reliability testing for cancer. So, we only have prevalence. We don't have reliability.

CO-CHAIR LUNNEY: Doug? Oh, you're down? Sean, are you still up?

MEMBER NEE: Actually, I did have just two things.

One, if you include hospice and the outpatient setting, the data is easily retrievable as well, as long as they have decent chart information.

The other one, too, is this is a

different language than what I am used to, speaking, discussing reliability and such, and evidence. But, you know, when it comes to opioids, for the most part, people are going to become constipated no matter what age they are.

So, it is interesting to note that, even though we are looking for other populations, the bottom line is more than likely it really won't matter. It is one population is going to be the same as the other for the most part as far as opioid constipation goes.

CO-CHAIR LUNNEY: I'm not seeing any more standing-up tents. So, I think we are ready to go to the voting.

The first one, the performance gap?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Sixteen high, 3 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Next, we are

looking at the evidence.

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Thirteen yes, 7 no.

(Whereupon, a vote was taken.)

CO-CHAIR LUNNEY: Still looking for two more people.

(Pause.)

Try again.

MR. COLCHAMIRO: For evidence related to quantity of studies, we have 10 high, 10 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: So, the quality of the evidence?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Sixteen high, 4 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: So, the consistency?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seventeen high, 3 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: Reliability?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Fifteen high, five moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: So, the validity?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Thirteen high, 6 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Ability to detect disparities?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Eight high, 6 moderate, 3 low, 3 insufficient evidence.

CO-CHAIR LUNNEY: Usability?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Ten high, 9 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Feasibility?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Thirteen high, 7 moderate, zero low, zero insufficient evidence.

CO-CHAIR LUNNEY: And finally, the endorsement?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Nineteen yes, 1 no, zero abstain.

CO-CHAIR LUNNEY: Okay. So, at this point we move to the last of the four measures under the pain section. This one is 1628, developed by RAND, patients with advanced cancer assessed for pain at outpatient visits.

Are there any additions from the developer to the general overview that we heard?

DR. DY: I think we have already discussed this in detail. I just want to say that it is actually extremely difficult to

reliably extract pain information, and we tried this measure a number of different ways. The way that it is written is the way that it could be reliably abstracted from charts.

The other piece that is not in here is we only tested reliability in one setting because in our Cancer Center, despite all our many issues, we can actually get this data electronically as a vital sign. So, we didn't need to do reliability testing.

CO-CHAIR LUNNEY: Okay. Then, Sarah, you present it from the evaluation perspective?

MEMBER HILL: Sure. So, advanced cancer, the definition is stage 4, obviously, and this was promoted as a process measure by the team.

It is very similar to 1634, which was previously presented, in that the number of citations on impact and the performance gap are pretty high.

As far as scientific

acceptability, as mentioned, they utilized a Modified Delphi methodology to test for reliability and validity. And also, the validity of the process itself as an outcome link was evaluated by the ASSIST project. So, we can see that it is pretty reliable and valid.

Concerns: it is unclear to some as to why this was limited to just stage 4 cancers and why limited to those who are alive 30 days post-diagnosis.

And, then, also, in general, for most of these items, it was marked as high or moderate, but there was one person who had marked many of them insufficient. So, perhaps if that person wants to ask further questions of the developers as we move through this?

For feasibility, if data is captured -- a couple of concerns with that -- if data is captured in oncology practice EMRs, then this becomes very feasible. So, if anybody could tell the group whether or not

that is already being done?

And, then, a second concern was that feasibility is limited by the study population, which could complicate measurement and identification of the population targeted.

So, those are two major concerns.

But, in general, the summary was that most of us felt very comfortable with it and said yes, except for the one person who had insufficient. And so, perhaps, again, they might have questions.

We all just basically felt that assessment of pain is very important and that perhaps often it may be missed in outpatient settings. So, just to have a simple track of whether that is being assessed is probably pretty easy to do and quite worth it.

CO-CHAIR LUNNEY: And I am the one person who was coming at it from an NIH model, and the information wasn't in the application. So, I didn't go out to the world to the find it. But I understand that, now that I am

here, either I should have known all that information and used it or I can take your word for it.

(Laughter.)

Do we have any questions from the panel for the developer or for our evaluator?

DR. DY: To respond to why the population was what it was, we had limited budgets for the pilot testing, and this was all end-of-life measures. So, that's why it is advanced cancer.

And for us, we were easily able to identify advanced cancer patients from our cancer registry. So, it is not ideal, but that was the reality of the project.

CO-CHAIR LUNNEY: I know my eyes are getting very tired, but I don't see any standing-up tents. Maybe that is because everyone wants to get on to scoring.

All right. I guess we are ready to go to the data demonstrate the performance gap.

(Whereupon, a vote was taken.)
Might try again?
MR. COLCHAMIRO: Sixteen high, 4 moderate, zero low, zero insufficient evidence.
CO-CHAIR LUNNEY: Is it a health outcome?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Eight yes, 12 no.
CO-CHAIR LUNNEY: What is the quantity of studies and the body of evidence?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Eight high, 8 moderate, 4 low, zero insufficient evidence.
CO-CHAIR LUNNEY: And what's the quality?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Ten high, 10 moderate, zero low, zero insufficient evidence.
CO-CHAIR LUNNEY: What's the consistency?

(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Ten high, 10 moderate, zero low, zero insufficient evidence.
CO-CHAIR LUNNEY: Reliability?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Ten high, 8 moderate, zero low, 2 insufficient evidence.
CO-CHAIR LUNNEY: And validity?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Nine high, 11 moderate, zero low, zero insufficient evidence.
CO-CHAIR LUNNEY: Would we identify disparities?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Five high, 5 moderate, 3 low, 7 insufficient evidence.
CO-CHAIR LUNNEY: Usability?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Nine high, 10 moderate, 1 low, zero insufficient evidence.

CO-CHAIR LUNNEY: Feasibility?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Twelve high, 7 moderate, 1 low, zero insufficient evidence.
CO-CHAIR LUNNEY: And our overall recommendation?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Twenty yes, zero no, zero abstain.
CO-CHAIR LUNNEY: Okay, Laura, if you are still on the line, we ignored your comment earlier. Not to be rude, can we come back and ask for it?
DR. HANSON: Certainly, I did not at all want to interrupt the process. I only wanted to add that the quality measure under discussion, the percent of patients given an opioid who are also given a bowel regimen, was actually one of the quality measures that was included in the PEACE Project, and we have additional data on reliability, variability, and validity coming from the hospice

population and the seriously-ill hospitalized population.

I only wanted to put that forward because that was germane to the discussion that was ongoing about the nature of the population.

CO-CHAIR LUNNEY: My hunch is everyone in the room has experienced the problem at some point in their life, and that influenced their voting.

(Laughter.)

We have an interesting dilemma right now. We have three different measures regarding pain, and Heidi would like to lead a discussion to help us sort out how NQF should work with that.

MS. BOSSLEY: Well, so you all thought you were early, but you're not.

You have two measures that deal with pain assessment. They do address slightly different populations. So, typically, once you get done looking at both

measures -- and right now your preliminary recommendation is to have both measures move forward -- we really need you to go back and look and see, are there areas where there should be harmonization?

And the one that I noticed is how the assessment is defined within each of those measures. It is different.

And so, truly, what would be the goal for us is to have it measured and assessed the same way across both of those measures. So, it may be helpful to just kind of look at both of them right now and talk that through.

It may be that we don't have an answer today. We can ask the developers to kind of work together and come up with a harmonized numerator approach, but I did want to spend a little time talking about that.

CO-CHAIR LUNNEY: As I see it right now, we have a measure that screens for pain, a measure that assesses pain among those

who have been screened for pain, and that assessment measure captures the guidance for pain assessment to see whether they are being met.

And, then, we have a measure that looks at whether or not pain was assessed in the outpatient setting. I think what we are seeing as the evidence used for that measure is essentially whether pain was documented or not.

So, Heidi, are you wanting us to -- I mean I think two of the measures had a very distinctly different conceptual orientation, one being a screening for pain and the other following up on that screening. Are you wanting us, then, to line up the outpatient with the screening question from earlier?

MS. BOSSLEY: So, the way I have looked at the measures -- and again, tell me if you are interpreting it differently -- but the screening one to me is a separate measure.

And that one is -- let me go by numbers because it may be easier -- 1634.

But when you look at 1637 and 1628, they both deal with assessing. They are different populations. There may be some overlap, and we'll have to look into that.

But your numerator, how you define assessing, is different.

So, if I look at 1628, since that is the one I have open, it is define pain assessment with a standardized quantitative tool during the primary care or cancer-related outpatient visit. So, that uses a quantitative tool.

If you look at the other one, as it is currently defined, 1634, patients who are screened for the presence or absence of pain. Then, it says screening may be completed using verbal, numeric, visual, analog rating scales designed for use with -- I think they mean with the non-verbal patients -- or other standardized tools.

And again, it may end up being the same, but I think we need to make sure that they are.

CO-CHAIR LUNNEY: And actually, that is a question I had in the dyspnea one on screening because, you know, is it a yes/no, you have pain or do you have to ask someone on a scale of zero to 10 or 1 to 10, "How much pain do you have?"

And I think what we are seeing is that the numerator, especially in this most recent one, is very broadly interpreted; also, in the other one actually. No, in the most recent one, it is a numeric assessment of pain, correct? And in the first one, it is anything.

MS. BOSSLEY: And it may be helpful to know from the developers if there was a specific way, but also to get your input as experts as well.

DR. HANSON: This is Laura. I can comment.

I think that, from the hospice and palliative care measures, the pain screening measure, not the one called pain assessment, but the one called pain screening, 1634, is comparable to the last quality measure that was discussed, 1628. Even though 1628 uses the term "assessed" for pain, the numerator definition -- and Sydney may be able to comment on this -- is really talking about the same thing that we are addressing in the pain screening quality measure, which is to use one of the standardized approaches to ask about the presence and severity of pain.

And in our definition, the description of those standardized approaches, basically, include verbal descriptor scales and non-verbal observational scales, but I would see that as consistent with the 1628 description of a standard quantitative scale.

CO-CHAIR MORRISON: June, can I jump in for a sec?

CO-CHAIR LUNNEY: All right.

CO-CHAIR MORRISON: Well, no, I was just asking because I think this may help.

CO-CHAIR LUNNEY: I'm going to remind you that you are.

CO-CHAIR MORRISON: Yes, go right ahead.

Because I think there's a couple of clarifying questions, things that we need from you guys, Heidi.

Specifically, one of the things that the National Palliative Care Research Center did was over the past year convene as many developers as we could to try to think about what would the measures be that would be submitted, and to look at harmonization.

And one of the reasons that the bundled package that you got put forward was that the group that got together really tried to get overlapping measures across different populations that looked very similar, recognizing that NQF's process meant that a measure developed within one population with

one specific numerator couldn't be extended beyond that.

And I think what I am hearing from you, Heidi, is that we tried really hard that these two measures from the developers, particularly the screening measure from the PEACE Project that Laura says and what is 1628, had that element of harmonization. The issue was they were developed in different populations that had a small degree of overlap. So that they extended into two very high, at-risk populations, one in palliative care and hospice, the other in cancer.

And I guess the question that I am asking you in terms of clarification is, do you want this Committee to wordsmith the two measures so that they look the same, so that they can be applied across that entire spectrum of population, so that you have one measure that goes across that entire two denominators with some overlap? Or are you asking something different? Because that's

what I am not sure of.

MS. BOSSLEY: Okay. Good question.

So, I think these two measures, if we look at the denominators first, they do measure two different populations. I think that is appropriate, and that is fine, from everything I am hearing.

And I think the question that I have is the screening that is used for the assessments for those measures in the numerator does not appear to be the same, if I am reading this correctly.

I guess what would be helpful is, No. 1, is there a reason why it should be different across the two measures in those populations? Or, if not, is there a way to standardize how that is, indeed, assessed? That is truly it.

CO-CHAIR LUNNEY: Just to build on what Heidi said, when we talk about harmonization and competing measures, we talk

about harmonization specifically for different patient populations, but the same measure focus. So, I think here that is really what we are talking about.

We sometimes talk about competing measures, which is the same measure focus, the same populations. And there, we just want one of them. Pick best in class.

So, the question is, in this instance, I think you're right, there's probably not the testing to combine them and make them a single one. But is there any reason, based on the evidence and the science here, that the assessments in one setting for one population are done differently than the other population or the other setting?

MS. BOSSLEY: Kathleen, you had a question?

MEMBER O'MALLEY: I'm just confused because I thought I heard from Laura her concern was that something that is billed as an assessment sounds more like screening.

And so, I am not quite sure. It sounds very fluid to me.

So, I guess my recommendation would be give it back to the stewards to figure it out. I don't think wordsmithing is really our skill at this point in time on their measures.

But, then, I would like to clarify Laura's comment. Does what is being put forward as an assessment process, is it actually a screening process?

And one of the comments I would make about screening versus assessment is this scope-of-practice issue for the application of some of these measures. Because I know doing quality work in nursing homes, nurses' aides can screen for pain, but they cannot assess. So, it makes the measure more useful, and it is important, then, also, to clarify from Laura's comment which one of these measures is really assessment versus screening.

DR. HANSON: This is Laura.

The reason we have a pair of quality measures, one called screening and one called assessment, is precisely that distinction you just made.

I think the cancer measure, 1628, I can't comment on because I am not the measure's steward, but I can only say, as I read the language of the numerator, it sounds more as though it would be harmonized with our screening measure.

As to the difference in patient populations, the question before, I do think that our description of the way that screening can be done takes into account the more seriously-ill population in hospice and palliative care practice, where there may be a significant proportion of patients who cannot use a 1 to 10 numeric rating scale to express their pain, and other ways of rating pain severity have to be taken into account. That doesn't mean that they are not standardized or they are not able to be

quantified and documented as such, but that is why we have the description that we have in our definition.

MS. BOSSLEY: It's perfectly fine if you want to ask to go back to the developers. In fact, we would prefer that you do. If there is anything that would be helpful to them to know from your perspective, though, I would encourage you to give it to them now, because I would rather not have to do this a couple of times with them. But, other than that, that is perfectly fine.

CO-CHAIR LUNNEY: Dave?

MEMBER CASARETT: Thanks.

Yes, actually, I agree with going back to the developers and not try to wordsmith this now, particularly mid-afternoon, long day.

But I really don't think they are that far apart. I really think that it is not even a matter of wordsmithing so much as it is just specification.

And the question may be to the ACO folks, given the list that Laura's group put together of examples of instruments, would those be appropriate or could those be appropriate in their population? If the answer is yes, then I think you can import that fairly quickly and be done with it.

CO-CHAIR LUNNEY: Richard?

MEMBER GOLDSTEIN: And the only other comment that I would make about this is whether the evidence for intensity ratings and its impact on care is sufficient that it will trump these questions just about the presence of pain or not. Because if that exists, then I don't think it should be too much trouble to harmonize.

CO-CHAIR LUNNEY: Naomi?

MEMBER KARP: I'm not a clinician. So, I guess this is a question. It seems to me, for purposes of 1628, yes, 1628, you have to screen first before you can assess, wouldn't you? So, this one looks to me like

maybe it is a combination of both screening and assessment because, why would you do an assessment on an intensity scale if you didn't know whether there was pain to begin with?

CO-CHAIR LUNNEY: I think that is part of why we need to go back to the developers and find out which side of that line they are on.

DR. BURSTIN: Just one additional thought might be, is there any reason why the outpatient measure can't track the same way the screen, if screen positive, assesses as one other option? Again, the last thing you want is inconsistency in what we are doing in one setting versus another, but there is no science to back up the lack of consistency.

CO-CHAIR LUNNEY: I think, then, we have reached the point that we were meant to be at at 2:45 and not too far off from that, ignoring what we haven't done.

(Laughter.)

So, we get a break, and we return

here at 3:00 and turn our attention to dyspnea.

(Whereupon, the foregoing matter went off the record at 2:52 p.m. and resumed at 3:12 p.m.)

CO-CHAIR MORRISON: All right, on we go.

So, the last part, he said with a smile, of today's meeting is we've got three more measures to discuss in the next 75 minutes or so, and, then, just a review of the day one activities, which is scheduled for five minutes. And, then, we adjourn.

And so, this afternoon has been devoted to breathlessness. We've got two measures from the UNC, Chapel Hill, group, another measure from the RAND group.

I am going to flip the order a little bit, just because it makes sense to talk about dyspnea screening, which is 1639, before it makes sense to talk about dyspnea treatment, which is 1638. Then, we will move

on to the RAND measures.

Laura, do I still have you?

DR. HANSON: Yes, I'm on.

CO-CHAIR MORRISON: Excellent. Could I ask you, before we move to the Steering Committee summary, could I ask you again to give us a brief introduction about the hospice and palliative care dyspnea screening and the hospice and palliative care dyspnea treatment measures that your group has developed and put forward?

DR. HANSON: Certainly.

CO-CHAIR MORRISON: Thank you.

DR. HANSON: So, the methodology for the development and testing of these measures fits with what I described in more detail before, the same stepwise approach developing, again, with initial testing in a hospice population and, then, expansion to a broader, seriously-ill, hospitalized population with palliative care utilization in mind.

And again, these are being submitted as a pair of measures with the conceptual framing that dyspnea screening, which really has not been attended to in the same way that pain screening has been -- there is not as much attention to quality measurement in this area, but dyspnea screening is a necessary first step because we do have evidence that dyspnea is underreported and undertreated in a seriously-ill or palliative care population, and that that dyspnea screening has to take place first, then leading to clinical assessment and subsequent treatment to relieve dyspnea.

We have good evidence that dyspnea can be treated and relieved, and particularly strong for opioids, for oxygen in hypoxic patients, and for non-pharmacologic interpersonal interventions that are primarily reported in the nursing literature.

And as one of the panelists commented before, there was no assessment

screening in these measures. And that was specifically because we could not find any expert guidance to define clinical dyspnea assessment in the way that we could find for pain. And, yet, we could find strong evidence for dyspnea treatment. So, that is the rationale for the way these are put together.

Similarly, we found a gap in the hospice pilot with dyspnea screening occurring for only 78 percent of patients on enrollment with higher rates of screening evidence in the seriously-ill hospital population, approaching 100 percent, not at 100 percent, but approaching that; strong face validity, evidence for construct validity with a gap between palliative care, specialty care, and without specialty care, and good inter-rater reliability on both measures.

CO-CHAIR MORRISON: Fantastic. Thank you very much, Laura.

I think, Russ, I have you up first to talk about 1639, which is the dyspnea

screening measures.

MEMBER ACEVEDO: Hi. It's Russ Acevedo.

I would liked the order before because, if we had approved treatment, then that would have made my job a lot easier.

(Laughter.)

Just a couple of comments because, obviously, most of my work has already been done for me.

As far as the numerator and denominator, the population we are looking at is the same population as the pain screening. So, as far as the same comments that we had as far as who was included, meaning that, for instance, the inclusion would be patients enrolled in hospice seven days or more or patients receiving hospital-based palliative care for one day or more, the same discussion as with the pain measures.

As mentioned, it is a prevalent problem. Between 50 and 70 percent of

patients with advanced lung cancer experience dyspnea at the end of life, and it is often undertreated and underreported.

The weight of evidence, there is not specific evidence that screening for dyspnea gives you better outcomes, but, again, it is a necessary step in order to get dyspnea treatment, which I think we all believe there is some benefit to.

All of the folks who reviewed this measure felt it had high impact and there was an opportunity for improvement. The evidence strength was rated as high, along with usability and feasibility. And all of us initially approved the measure.

CO-CHAIR MORRISON: Terrific.

Open for discussion. Rick, did you have a question or are you just up from before? Sorry. Naomi? No? Sorry. But Stephen does.

MEMBER CASARETT: I have just a common-sense question. As an oncologist and

someone who doesn't do hospice and palliative care per se, CHF, COPD, advanced lung cancer, all make sense that there is a reasonably high risk of dyspnea. Is there a subset of people for whom it would seem silly or ridiculous to have to screen when they are being admitted to hospice? Or it is only question, so what does it matter?

I am just trying to picture of there is anything where someone doing this is saying, no, you know, they're rolling their eyes and saying, "Well, now, they're making us ask about dyspnea" for X, Y, or Z. I don't know what that would be, but since I don't do hospice and palliative medicine, I was just wondering if there is any category where that might seem bizarre to the person that is, quote/unquote, "required" to do that.

CO-CHAIR MORRISON: Laura, can I ask -- I know that you have presented pilot data on this -- do you have data from your work that looks at the difference in

prevalence rates within different populations?

DR. HANSON: No, we haven't done that, but we certainly can do that and break that down. Because this is a screening measure, and because we know the prevalence in the overall population of seriously-ill, hospitalized patients in palliative care and in hospice, the prevalence is so high, even higher than pain, I think you are right, there will be some people who you screen and ask and they say no, but that will clearly a minority, on the order of 20 to 30 percent of the target population.

And it really is a single question. It is, "Do you have shortness of breath?" The answer is no and you move on.

MEMBER ACEVEDO: Thank you. That helps educate me. Thanks.

CO-CHAIR MORRISON: Thoughts or comments before we move forward?

(No response.)

All right, I think we can move to

voting.

I know that Laura had talked a little bit about the evidence base for this, but, actually, I just wanted to acknowledge Eduardo, since he is here, since he did all of the fundamental work on the treatment of dyspnea in cancer patients, and so to thank him for that work, which actually demonstrated that we can do something about this.

Now I go to voting. So, we are going to 1b, performance gap, important to measure and report.

(Whereupon, a vote was taken.)

All right, folks, we've got to do it one more time.

MR. COLCHAMIRO: Twenty high, zero moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: Evidence or outcome, 1c?

(Whereupon, a vote was taken.)

Folks are getting familiar enough

with these, so that I don't have to read them again? Okay. Just checking.

MR. COLCHAMIRO: Nine yes, 11 no.

CO-CHAIR MORRISON: Quantity of studies and the body of evidence?

Did I skip something? I don't think so. No. Because 1a, the importance is always a yes.

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Eleven high, 9 moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: I'm sorry, we did that one already, didn't we?

MS. BOSSLEY: No, this is quality.

CO-CHAIR MORRISON: I'm sorry. It's been a long day.

Evidence, quality of body of evidence?

(Whereupon, a vote was taken.)

The screen is not quite far enough for me to see it. It needs to be halfway

across.

Everybody, one more time.

MR. COLCHAMIRO: Fourteen high, 6 moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: Okay. Consistency of results?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Eighteen high, 2 moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: Scientific acceptability, reliability?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Eighteen high, 2 moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: And validity?

(Whereupon, a vote was taken.)

MR. COLCHAMIRO: Seventeen high, 3 moderate, zero low, zero insufficient evidence.

CO-CHAIR MORRISON: Disparities?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Seven high, 7 moderate, 2 low, 4 insufficient evidence.
CO-CHAIR MORRISON: Usability?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Eighteen high, 2 moderate, zero low, zero insufficient evidence.
CO-CHAIR MORRISON: Feasibility?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Sixteen high, 4 moderate, zero low, zero insufficient evidence.
CO-CHAIR MORRISON: And the overall endorsement?
(Whereupon, a vote was taken.)
MR. COLCHAMIRO: Twenty yes, zero no, zero abstain.
CO-CHAIR MORRISON: Fantastic. Thank you very much, Russ, and thank you, Laura.

Laura, if we could ask you to hang in just for the next one, which June is going to discuss, just in case there are any other questions that come up.

June?

DR. HANSON: No problem.

CO-CHAIR LUNNEY: And I hope you can, Laura.

This measure is on the proportion of patients who screen positive for dyspnea who receive treatment within 24 hours of the screen.

And the range of what constitutes treatment goes from oxygen to opioids to non-pharmacological and beta agonists.

Identifying that data, particularly the non-pharmacological interventions, is a question I had, and the application's reliability and validity section dealt with screening and not the specifics of identifying that treatment information.

So, Laura, can you fill us in on

that?

DR. HANSON: I apologize for that being unclear. We have separate validity and reliability data for these two quality measures, but because they were submitted as paired measures, the sections combine information about the two. And I apologize for that being confusing.

The inter-rater reliability on the dyspnea treatment quality measure was still very strong. It was a Kappa of 0.89. So, there was very good ability for two independent raters to identify the presence of those varied treatments in the chart documentation.

CO-CHAIR LUNNEY: Then, I guess the question I have maybe is more one of feasibility. The chart abstractors, presumably, did not rely on, or did rely on narrative data to catch the non-pharmacological interventions?

DR. HANSON: Yes, they relied on

physician, nursing notes, NARs, and order sections.

CO-CHAIR LUNNEY: I think that is probably the only concern I would raise about the instrument then, is the feasibility of that data being collected as a general rule.

CO-CHAIR MORRISON: Questions? David Casarett?

MEMBER CASARETT: Yes, Laura, a quick question. So, there wasn't any mention of dyspnea severity, or at least if there was, I wasn't seeing it. So, the expectation, then, is that anybody with any level of dyspnea, no matter how severe, would get treatment? Or did I misunderstand?

DR. HANSON: No, you completely understood, David. We really could not find good, consistent, and well-validated severity rating instruments. There is some work going on in this area, but, unlike pain, we really don't have that broad array of severity rating standards. That is the reason that is not

included here.

We talked about including that and including some kind of cut point, but, then, had to ask the question, cut point on what? And we were not confident that we could demand of clinicians that in the documentation they not only identify the presence of dyspnea, but also said it is moderate severity dyspnea or it is severe dyspnea, because of that lack of standardized rating approaches.

I think the way to finesse the question that you are asking, which is, does everybody who says, "Yes, I have shortness of breath" require one of these treatments, I think the answer to that question clinically may be no, but that, then, means that the standard that we are striving for with this quality measure is not 100 percent.

And that really goes to the meaningfulness of the quality measure. At some point, benchmarks get set on quality measures, and for some of them I might argue

for screening for dyspnea the benchmark should be right around 100 percent, but for treatment for dyspnea it may be that the benchmark settles out and it is not 100 percent, for the reason that you have just put forward.

MEMBER CASARETT: So, thanks, Laura. That helps.

This is David again.

So, just a followup comment, I guess. One approach, I guess, would be to accept less than 100 percent level. The other concern, though, is that this might push clinicians to treat dyspnea that they wouldn't otherwise have done. So, a patient with either mild dyspnea that is not bothering them or, potentially, depending on how the screening works, even "I'm fine now, but when I get up to go to the bathroom or transfer, I get short of breath," that clinicians might feel compelled to suggest or initiate treatment for that patient. So, I guess that is the other potential risk, not just not

performance, but an unintended consequence.

DR. HANSON: I think that is fair. I think the quality concern in this area, at least as I read the literature thus far, is on undertreatment rather than overtreatment, but I can see that as a concern perhaps in future iterations.

CO-CHAIR MORRISON: Naomi?

MEMBER KARP: Hi. It's Naomi Karp. Sorry.

I just wondered if you could explain how you chose 24 hours.

DR. HANSON: That is basically comparable to some of the other quality measures in this measure set. Once a problem is identified, as I said before, with our technical expert panel there was a lot of discussion of timeframes, but the consensus seemed to be that, given different settings, like home-based hospice versus an inpatient setting, your response times, the consensus on the response time to treat the symptoms

settled out at 24 hours.

In an inpatient setting, one might consider that to be too long. In a home-based hospice setting, where something has to be brought back into the home for treatment, it might be, I guess some hospice organizations might consider that short. But we tried to get a consensus timeframe.

MEMBER KARP: Thanks.

CO-CHAIR MORRISON: Last comments or other comments?

(No response.)

I don't see anybody. Great.

Laura, thank you so much for your help.

DR. HANSON: Yes.

CO-CHAIR MORRISON: This has been really, really helpful.

Oops, sorry, June.

CO-CHAIR LUNNEY: I guess maybe I need a little clarification from NQF in terms of this feasibility question. Are these

measures meant to be easy?

MS. BOSSLEY: That is an interesting way to put it. No, I think you need to evaluate whether you think that the measures are feasible as they are specified, and that they have demonstrated that it can be done. And you need to weigh that within your final recommendation, but it shouldn't be the one and only reason, but it should be a part of your decision.

Does that help?

DR. HANSON: This is Laura.

I would just like to say that this was done by multiple hospice organizations using different forms of chart documentation. We did do qualitative, sort of post-hoc survey with them asking about difficulty and did not hear particular complaints about this quality measure, or we would not have included it.

The seriously-ill, hospitalized population was done in a single setting with a pretty comprehensive electronic medical

record, and I am certain that a comprehensive electronic medical record makes this more efficient.

CO-CHAIR MORRISON: Russ, before we go?

MEMBER ACEVEDO: This is Russ Acevedo.

You haven't indicated as far as receiving treatment in 24 hours any sort of looking to see if the patient responded to treatment or improved in that time period.

DR. HANSON: That's not part of this quality measure. So, it was not part of the data collection. We contemplated going there, looking at improvement on treatment for dyspnea. But when looking at feasibility for identifying repeated documentation of dyspnea severity or the presence of dyspnea, found that that documentation was missing so often that it did not appear feasible to propose as another quality measure.

CO-CHAIR MORRISON: I think the

other thing I would ask, Russ, if you could just hold that one into your brain in a parking lot, because tomorrow afternoon June is going to facilitate a discussion about measurement gaps, about the issues that weren't put forward. And I think that is a critical one that I would love you to bring up again tomorrow. So, if you could just hold onto that thought?

Not seeing any tent cards up, I think we can go, let's go to voting: 1b, performance gap?

(Whereupon, a vote was taken.)

All right, I am going to ask everybody to do it one more time. There we go.

MS. TIGHE: Fifteen high, 4 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: Evidence or outcome, 1c?

(Whereupon, a vote was taken.)

All right, if everybody could do

it one more time?

What happens when we get to zero?

MS. TIGHE: Seven yes, 12 no.

CO-CHAIR MORRISON: And, then, the evidence, 1c, quantity of studies and the body of evidence presented by the developers?

(Whereupon, a vote was taken.)

MS. TIGHE: Twelve high, 7 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: And, then, we have got the quality of the body of evidence.

(Whereupon, a vote was taken.)

MS. TIGHE: Eight high, 11 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: The consistency?

(Whereupon, a vote was taken.)

MS. TIGHE: Seven high, 12 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: Scientific acceptability, reliability?

(Whereupon, a vote was taken.)

MS. TIGHE: Seven high, 11 moderate, 2 low, zero insufficient.

CO-CHAIR MORRISON: Validity?

(Whereupon, a vote was taken.)

MS. TIGHE: Ten high, 9 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: Disparities?

(Whereupon, a vote was taken.)

MS. TIGHE: Five high, 6 moderate, 4 low, 5 insufficient.

CO-CHAIR MORRISON: This is good. Variability is good sometimes.

(Laughter.)

It shows the process works.

Usability?

(Whereupon, a vote was taken.)

MS. TIGHE: Eight high, 11 moderate, 1 low, zero insufficient.

CO-CHAIR MORRISON: Feasibility?

(Whereupon, a vote was taken.)

MS. TIGHE: Two high, 11 moderate, 6 low, 1 insufficient.

CO-CHAIR MORRISON: And the overall endorsement question?

(Whereupon, a vote was taken.)

MS. TIGHE: Seventeen yes, 3 no, zero abstain.

CO-CHAIR MORRISON: Thanks, folks.

We are now going to move to our last measure of the day, which is the RAND measure, hospitalized patients who die an expected death who have dyspnea addressed.

And do I have any of the RAND folks on the line?

DR. WENGER: I think you have Neil and Carol here.

Carol?

CO-CHAIR MORRISON: Hi.

MS. ROTH: Hi.

CO-CHAIR MORRISON: Welcome back, Neil. Thank you, Carol.

So, could I ask one or both of you to give the Committee a little bit of an introduction as to this measure? And, then,

I will turn things over to Solomon, who will lead the Committee.

DR. WENGER: Carol, what is your preference?

MS. ROTH: I think you should do this one.

(Laughter.)

DR. WENGER: Okay. So, this is a measure aimed at a different sort of denominator population. This is patients who have died, who died an expected death in the hospital after hospitalization of three or more days.

This is a chart-based process measure, and it is looking for evidence that, among expected deaths in the hospitals of patients who have had dyspnea during the last seven days, that there is either attention to dyspnea or followup on a positive dyspnea screen.

So, the denominator is adult hospitalized patients who die after a

hospitalization of three or more days and have dyspnea. And the numerator would be attention to their shortness of breath or followup on the shortness of breath.

This is a measure developed in the RAND process and has the validity associated with that process, but no other process outcome link has been performed. In fact, I would ask the panel to suggest what sort of process outcome link would be appropriate for this measure.

The measure has only been tested in one small population. It is a group of 38 decedents, published last year, and 87 percent passed the dyspnea treatment piece and 70 percent passed the dyspnea followup piece. Again, this is among people who died in the hospital.

It has good reliability, and there appear to be no competing measures.

Concerning importance of the measure, it is difficult to point to any one

bit of evidence to show that it is important. I think that it has face validity, and certainly our panels thought so.

There is a considerable amount of dyspnea among patients who die, as has already discussed today. And this is a particularly important symptom among patients who die within the hospital, where this measure is aimed.

There appear to be no other similar measures with which it need to be harmonized.

CO-CHAIR MORRISON: Fantastic. Thank you very much, Neil.

Solomon, can I turn to you as a Committee Member who led the evaluation of this?

MEMBER LIAO: So, Neil, I am going to start with the reviewer's votes for suitability. So, to let you know that all but one reviewer voted for no in terms of suitability.

The major concern of the reviewers appeared to be related to feasibility. And the second concern appears to be due to its usability. Then, also, some reviewers expressed concern about the small amount of evidence base.

So, one of the reviewers said that they potentially could support this, but they wanted to ask, could this measure be expanded to other settings of care, and wanted to seek additional information from the measure developer.

And, then, there was another question, also, about definition, actually, two questions about definitions, one about unexpected deaths, the definition of what is an unexpected death, and, then, also, the definition of what addressing dyspnea is.

So, would you like to address those issues?

DR. WENGER: Sure. So, to take the definitional definitions first, I think

that the definition of addressing dyspnea is explained in the numerator details, as well as the definition of expected death, which is in the denominator details, both in Sections 2A, 2A3, 2A1.3, and 2A1.7. I am glad to go over them if there is interest.

But we have not had difficulty with reliability of the abstraction of the expected death. And in fact, the reliability for the abstraction of expected death, the Kappa is well above .8, which isn't to say that this is a simple measure. I mean it is a chart abstraction measure, but I don't think that it is too difficult from a reliability perspective, certainly as compared to any of the other chart abstraction measures that would be within an end-of-life set.

It is actually quite easy to abstract from an abstractor's perspective because you are looking only at the sample of decedents from a hospitalization. So, it is an easy sample to identify, and it is a

reliable abstraction.

As far as expanding it to other samples, one, it would have to be a sample of attended death. So, it was be feasible, in fact, we have thought of administering this to a hospice sample and/or other samples of patients, for instance, in skilled facilities. It probably bears testing within skilled facilities.

I would bet, based on some of the data I have already heard here today, as well as other things that I have seen, that it would receive very high satisfaction rates within a hospice. And I don't know whether it may have a ceiling effect.

But we proposed it only for hospital because that is the only place that we have tested it.

CO-CHAIR MORRISON: Neil, I think I heard it -- this is Sean again -- but I think Solomon raised the question, and I think in some of the concerns that I am seeing in

the spreadsheet there were questions about the feasibility about gathering the data. I think you have addressed some of them about the feasibility of identifying expected deaths, but also the questions of feasibility of identifying care and treatment of dyspnea.

Could I ask you to comment a little bit more about that?

DR. WENGER: Right. So, there is no doubt that identifying care and treatment of dyspnea in the hospital record is not nearly as easy as pain, as Laura previously pointed out. But it is, indeed, identifiable, and very specific factors concerning both screening for and treatment of dyspnea can be reliably abstracted from an in-hospital medical record. And this is both from an EHR-based record as well as from a chart-based, written-based record.

I don't know if you are asking about the amount of effort, for instance, time, that would be needed. If that is the

issue, there is no question that a medical record manual abstraction takes time.

CO-CHAIR MORRISON: We have some comments. Naomi, you were up first, and, then, Russell.

MEMBER KARP: First, I actually looked at the study you cited, and I think the sample size actually was 83, not 38. So, it is still small, but it is not quite as tiny.

I also wanted to ask the question of how you choose 24 hours, particularly because this was a hospital setting.

DR. WENGER: I am going to have to go pull Dr. Walding's paper and see whether that was a typo. Thirty-eight did seem small to me. And we will do that immediately.

Twenty-four hours? Carol, help me.

MS. ROTH: Well, I really can't tell you because Annie is the one who operationalized this.

DR. WENGER: Oh, you mean how we

chose to -- so, in other words, within the documentation of the presence of dyspnea, there has to be an intervention within 24 hours.

You know, this is a practical factor. What we have found is that, when symptoms present, one finds interventions in relation to those symptoms in medical records quite proximate. And 24 hours was chosen to make this a more reliable and simpler abstraction.

Once you start looking out two, three, four days for a response to chart documentation of dyspnea, you reduce reliability and you dramatically increase the amount of effort for the same outcome.

So, the answer is that it is a technical reason.

CO-CHAIR MORRISON: Russ?

MEMBER ACEVEDO: Hi. I have two questions.

From the numerator statement, you

have dyspnea treated within 24 hours or documentation that it has improved or reason why it could not be treated, and, then, (b) a reassessment of their dyspnea.

Is that an "and" or an "or" as far as your numerator? That's question one.

DR. WENGER: It is an "or".

MEMBER ACEVEDO: It's an "or"? Okay.

Being in a hospital that still has a paper-based system, and we are struggling with identifying that pain has been adequately treated, as far as documentation that that has been assessed, I am not sure who is doing this documentation in my hospital. Certainly, my residents are not going to do it. True confessions, I am probably not going to do it. And I am not sure as far as the nursing staff.

So, I guess I don't have that comfort level that that data is going to exist in my medical record.

DR. WENGER: So, let me actually

go back to your first question first. I think I misinterpreted it.

It is (a) and (b). So, it is an "and" between the two.

And, then, to address your second question, I guess I would ask, in other words, you are saying that the treatment is undertaken and the followup is undertaken, but not documented? Or is the lack of a documentation a reflection of the fact that dyspnea is not attended to?

MEMBER ACEVEDO: No, I think it would be the lack of documentation.

DR. WENGER: Right. So, I don't doubt that that is true to a certain extent. However, most of the forms of the documentation that we are looking for, use or change in oxygen, respiratory therapy, non-pharmacologic interventions, pharmacologic interventions, and other sorts of followup, are likely to be documented for a whole variety of reasons beyond a notation.

However, there clearly are cases of followup and other reasons that dyspnea need not be attended to that may not be documented. I think that this measure is developed in part in response to that concern, that dyspnea appears to be attended to inadequately. And therefore, the documentation needs to more strongly reflect the actions taken by clinicians.

CO-CHAIR MORRISON: David Casarett?

MEMBER CASARETT: Thanks.

I was intrigued, Neil, by the use in the numerator, or the denominator actually, the clause about expected deaths and using that as a denominator criteria. I am wondering what your experience with that was. Because I could imagine that there are certainly some clinicians who I work with who see death coming, and then there are other clinicians I work with who don't see death even after it has been by.

(Laughter.)

Which would mean that comparing these among clinicians among hospitals, particularly the University of Pennsylvania, where our motto is we see life ahead, presumably, we don't see death ahead, how that would play out in a more broad, real-world setting where I think we recognize impending death to varying degrees.

DR. WENGER: Right. So, I think your comments are very apt. The data that were published came from a hospital where the CEO in The New York Times said that, "No one dies in our facility."

About half of deaths appear to be documented to be expected deaths, and we require the documentation to be three or four days prior to the death because there has to be time to attend to things like dyspnea care, pain management, spiritual care, and the like. Of course, just the dyspnea measure is submitted here.

So, this would under-identify the depth of the problem. I think that you are suggesting that those who would identify expected death later or never are less likely to attend to symptoms associated with it, and those cases would all be missed in a measure like this.

But it is a relatively big tip of the iceberg to pick up at all, which is why we proposed the measure.

CO-CHAIR MORRISON: Any other comments, questions?

(No response.)

Terrific. I think we can move to voting, if everybody is good with that. So, we are going to go to the performance gap.

(Whereupon, a vote was taken.)

MS. TIGHE: Four high, 10 moderate, 5 low, 1 insufficient.

CO-CHAIR MORRISON: Importance to measure and report evidence or outcome?

(Whereupon, a vote was taken.)

All right, worth doing one more time. It's 25 more seconds we're going to be here.

(Laughter.)

Hopefully, it is not a split vote.

MS. TIGHE: Six yes, 13 no.

CO-CHAIR MORRISON: So, does that mean that I don't go forward?

MS. TIGHE: No.

CO-CHAIR LUNNEY: No.

CO-CHAIR MORRISON: Okay. Right. Okay, keep going. Thank you.

This is why they have Co-Chairs, so one of our brains works.

(Laughter.)

Quality of studies and bodies of evidence?

(Whereupon, a vote was taken.)

MS. TIGHE: One high, 5 moderate, 12 low, 2 insufficient.

CO-CHAIR MORRISON: The quality of the body of the evidence?

(Whereupon, a vote was taken.)

MS. TIGHE: Zero high, 7 moderate, 11 low, 2 insufficient.

CO-CHAIR MORRISON: Consistency of results across the body of evidence?

(Whereupon, a vote was taken.)

MS. TIGHE: One high, 5 moderate, 7 low, 7 insufficient.

CO-CHAIR MORRISON: Ignore that slide?

MS. BOSSLEY: So, I think we do have an instance where there is the potential that this measure does not meet all three criterion for importance. And so, one thing that you could do is, if you think there is something in addition that the developer could provide, we can ask them to do that and, then, revisit this again.

But I guess it may be worth doing maybe even a vote to determine whether or not you feel that it meets, has passed the importance criteria itself. I think it might

give us a sense of where you all think, if it meets all three, which we may have to do a hand vote because I don't think we have a slide for that.

But does that make sense to everyone? I think it may be useful to just see where we are.

MEMBER WHITE: This just demonstrated that it didn't pass the criteria.

MS. BOSSLEY: Well, why don't we do this: can you read back the results again for -- 1a, it would have passed because we assumed it meets that.

1b, what were the results for that again? Lindsey, do you have it?

MS. TIGHE: Four, 10, 5, and 1.

MS. BOSSLEY: Okay. So, it would have passed, I would say it would pass that one.

Can we go through it again?

That one, ignore.

That one, is that --

CO-CHAIR MORRISON: Quantity of the body of evidence.

MS. TIGHE: That's quantity.

MS. BOSSLEY: Quantity?

CO-CHAIR MORRISON: Yes.

MS. BOSSLEY: Okay. If you all feel that it doesn't pass importance, we don't need to vote. It's fine.

Is that okay?

So, Neil, just so you know what has occurred, because you are not in the room, all the measures go based on whether they pass the first criteria, which is importance, and, then, we move on. If it doesn't pass importance, we actually stop. And at this point, it hasn't passed, the largest part being the evidence.

DR. WENGER: Thanks for the consideration.

CO-CHAIR MORRISON: So, at this point, first of all, Neil and Carol, thank you so much for being on the call. I think, as

she said, the question is about, when I look through this, the amount of studies supporting it, which I think there were questions about.

It is now time to open it up for both other Member or public comment. So, first, I guess I look around the table. If there is any Member comment?

(No response.)

And, then, to the back of the room, public comment? Yes?

And there should be a microphone, just right there, yes, right by Helene.

MS. TECCA: Hi. I'm Martha Tecca. I am with Deyta, and I am going to be talking about, one, I am here as a steward of one of the measures for tomorrow.

We also are involved with implementing measures, lots of these different kinds of measures, with folks, just as a little background.

I wanted to back up. First of all, I wanted to say that I am incredibly

impressed with how facile and agile, until this very last second, everybody was, both intellectually and physically, trying to get that all done.

(Laughter.)

You held up to the very last minute, which is incredibly impressive. It is a long, long day, and I congratulate you guys.

I wanted to go back to the morning, the morning conversation about the pain measures.

I'm sorry, there was stuff on the chair when I started. So, thank you.

A couple of different issues, and I want to talk about the first assessment measure. And I'm sorry, I don't have the numbers and the materials that I had, but, I'm sorry, the screening measure, the initial screening measure.

And we were talking about a couple of different pieces. One was harmonization, and I wanted to just make a comment about

that.

Obviously, everybody's head is nodding about the importance of harmonization. I want to make sure that we are -- I just didn't hear anybody explicitly talking about harmonization beyond palliative and end-of-life care settings.

What I found so compelling about the screening definition that Laura had described was it was encompassing such a broad range of pain-screening tools, standardized kinds of pain-screening tools, that it really has the ability to be something that would not only be harmonizable internally here, but across all settings. And it feels like that issue about how well we do with pain management in hospice and end-of-life and palliative settings, it would be really nice if we had a measure that was actually comparable across settings.

That may be obvious. It feels the way the processes have come to date with these

NQF, with the evaluations, that they are very setting-specific. And so, to the extent we can be conscious about things going across settings, I think that would be really useful.

Pain is obvious. Dyspnea is reasonably obvious. You brought it up in the bowel setting as well. But that would be neat to hear folks acknowledge it, as we think about harmonizing measures.

Having said that, I am concerned about that screening pain measure because of the seven-day timeframe. The comments were, "Well, that's what it is" and "That's what it has been tested in" and "We may have to live with that."

I actually think the seven-day timeframe makes it not livable with for a couple of reasons. One is the pain measurement and outcomes measures that have been agreed upon and used in the industry have to do with a screening that is done on admission and determination of whether the

person was made comfortable within two days. And that is just inconsistent with the notion of we might give you seven days to do a screening.

The second thing -- and I don't know which is actually more important -- is that the condition of participation requires a screening on admission for the symptoms that matter most, pain being obviously one of them. So, that is on day one, within 24 hours of admission, the conditions of participation require a screening.

Within five days of admission, the conditions of participation require a comprehensive assessment. So, anything that we would do that we, that you, that NQF, any measure that would in any way indicate that seven days is okay to shoot for or a baseline of any kind, I just don't see how that is reasonable to go forward.

Anyway, thank you.

CO-CHAIR MORRISON: Other

comments?

(No response.)

You know, I do want to just clarify one thing because I don't want misconceptions or misperceptions. The item that was discussed was that patients needed to be screened on admission. The denominator statement is patients who are in hospice for seven or more days.

Okay. So that every patient who has been enrolled in hospice for a week must have been screened on admission, so not screened within seven days, but screened on admission, which is an important point.

Okay. So, the denominator statement is people who have been in hospice for a week, but they had to be screened on admission. Okay? Just an important clarification.

Sorry. Yes, Kate?

MEMBER O'MALLEY: I do think a good point was made, though, in terms of

looking to what we recommend as a Subcommittee and looking at what else is out there in the requirements, as in the conditions of participation for Medicare.

And I realize what we are doing today is making decisions based on the evidence that is available to us. And I am totally in concert with that.

But we wouldn't want our recommendations to look flabby, given that there are contractual requirements that other providers need to make. So, then, whatever is brought forward here looks less consequential than what Medicare would require in COP.

So, I don't know the best process to do that, but I do think that that was a useful canary in a coal mine since these were coming out with a new body of evidence for palliative care, that we be mindful of that, and whatever language we put out around the recommendations takes that into account and addresses it. So, it doesn't look like we are

not mindful of the world in which providers, who will be implementing or trying to implement these measures, actually function.

CO-CHAIR MORRISON: I think that is a very good point, Kate. I think a couple of things. One is Carol Spence has been looking at me all meeting long. And I know that if one of the measures was not consistent with the conditions of participation, we would have heard from it in the public comment pretty quickly.

But I agree with you completely. We need to be conscious about that.

I saw a tent card go up. Tracy, I'm sorry.

MEMBER SCHROEPFER: Yes. So, Sean, I want to go back to your comment about the denominator for the patients is length of stay of less than seven days in hospice. And you said it is not that it took them seven days to be screened, but it is just they have been in hospice seven days.

So, then, why one day in palliative care? Why that difference, going back to that?

CO-CHAIR MORRISON: I don't think -- Laura, are you, by any chance, still on the phone.

(No response.)

I think we sent her away.

I am not sure, Tracy, that I am the one or that I am qualified to answer that. I think that is a question we can put back to the developer.

I do think that what I had heard from Laura on one of the other measures was that was based upon their work with the practitioners about what they felt was a feasible and acceptable way of doing the measure, but we can check back with Laura on that specifically.

MEMBER SCHROEPFER: I wonder, because the reason I thought it was still what was raised was because, when Laura was

talking, she said something about, "Well, it's because of some of the rural areas and it takes longer to get to," which sounds like assessment.

So, I am still not certain that it is just that they have been, and I am bothered by that difference, treating those two things so differently.

CO-CHAIR MORRISON: Yes, we will put that as a note to check back with her.

Never mind, I'm not going to trust my memory about it.

I've got June, and, Eduardo, did you go up and go down? Okay.

(Laughter.)

June?

CO-CHAIR LUNNEY: I just wanted to make a comment to the group that I made sort of offline to some others after this morning's discussion on items that seem to have a different approach to measurement than the items we have just dealt with. This morning

we were talking about proportion of people admitted to an ICU in the last 30 days of life.

And the developer presented that in terms of how a particular practice might look with respect to the norm among all practices. In other words, it was a measure where if there isn't an absolute quality that we want no one admitted in the last 30 days of life, but, rather, that we could use this measure as a broad brush stroke, so that a practice could look at itself and say, "Gee, we have such a much higher proportion of people in the ICU in the last 30 days of life" than the other nine practices or 209 practices that are reporting.

And I think that that is a piece we ought to kind of get in our mindset in terms of some of these measures, like the ones we have been doing this afternoon, there is a quality measure here. We want everyone screened for pain. We want everyone screened

for dyspnea. We want everybody treated.

But that is a different, that is a criterion-based measure as opposed to the measures that we have also heard put forward that aren't about we know what absolute quality is, but, rather, we want to watch what we are doing to see if we are straying or moving in a good direction.

And I don't know whether this is something, but I think it could be taken back to the developers. For example, go back to the developers of the 30 days' ICU bit and say that, really, the measure that they are interested in is having greater than or being in the 90th percentile in terms of the proportion of decedents who spent time in the ICU in the last 30 days of life. It is a different question than saying that we can't have anybody in the ICU in the last 30 days of life.

Have I made any sense?

(Laughter.)

CO-CHAIR MORRISON: Helen?

DR. BURSTIN: Just to follow up on June's comment, because she actually made this comment to me earlier, and it is actually, I think, right on.

I think one of the issues, though, is that oftentimes in quality we don't know what the threshold should be. We like measures, it is always optimal when you can say things like, "Everyone with pain should be screened," "Everyone should be screened for dyspnea."

For some of these other measures, it is really difficult to figure out what the right rate is. So, I was giving an example to June earlier, something very out of your comfort zone, but obstetrics, for example, has two measures like this. You know, what is the right rate of C-sections? What is the right rate of episiotomy? We don't know, and, yet, there has been incredible value in having that information out there in the public domain.

Well, with the exception of the report yesterday on C-sections, there is some evidence that it actually does help drive improvement through the consistent reporting and looking at it.

So, I think that, ideally, we would love to have the measures where the threshold is you're absolutely going to always do this, but those other kind of measures really do serve an incredibly useful purpose. The question, I think, on those is, are some of those really quality improvement with benchmarking as opposed to ready for primetime public reporting? And I think that is one of the issues you need to grapple with.

CO-CHAIR MORRISON: I've got Stephen and Eduardo again.

MEMBER LUTZ: I want to agree with June, but I also want, if you will take my alert for cynicism coming, it is hard when there is no hammer or no carrot. I mean we have some measures in oncology that have had

15 prospective randomized trials, all showing the same thing. It is in the public domain. It is measured who does which. But there is no recompense. There is no answer to what happens for those that don't.

So, behavior patterns don't change. So, it is available and so it is difficult. It is difficult to just put a lot of effort into something that may, then, be even measured, but there is no hammer.

And, then, I think it is hard when there are no measures to say, well, people tend to then get frustrated, and say, "Well, let's just say if they don't do this much, even though we don't have data, we're going to get them."

I mean it sounds cynical, but I have seen this happen in the oncology realm. We have had a big problem with this, and it is hard to figure out how do you even write about it anymore, when you know it is going to be there and ignored.

CO-CHAIR MORRISON: Eduardo?

MEMBER BRUERA: Thank you.

I am very grateful that June brought this up because that is what we had addressed. I think, as we know from figure skating, the one that skates first never wins. As time gets by, people get more tolerant. That is why everybody wants to skate last.

(Laughter.)

But I think the treatment of the initial outcome, there is actually a true outcome. That is, the people who died in the ICU is something of great importance.

And the problem is I think it is not linked to the procedures that take place in the ICU. It is what takes place a month before, two months before, three months before, and there is a lot of evidence about that.

So, I think we got somehow drowned in a glass of water because it was, you know, you get to the ICU; what is the problem with

it? Well, there is no problem with it. The problem is everything that happened before the person gets to the ICU that wasn't done. And there is a lot of evidence for the things that could be done to prevent those events from happening.

So, I think it is fair to go back to the developers to bring this up because this was not brought out by the Society of Intensive Care. These were brought out by the Society of Clinical Oncology. This is an ASCO issue because it is what happens before the critical event occurs.

And so, I am sure they can beef it up. But I think, ultimately, it has to be an issue of comfort we have with the fact that in the majority of cases when you are clearly dying of cancer, an ICU death is clearly inappropriate. And there is an enormous amount of evidence on that.

The problem is it is 100 percent of the time inappropriate, the same as the

screening method, and the answer to that we clearly know will be no. But isn't that for every outcome? I don't know that there are many outcomes where what happens to the patient ultimately -- we're going to deal with outcomes of pain tomorrow.

And, really, I have a strong belief that it is quite ridiculous to expect that you are going to control everybody's pain in two days. The only way you can do that is with something that we have a lot in Texas. That is Colt 45.

(Laughter.)

With everything else, you know, except from that, you are not going to get the number.

So, in 48 hours, I know how to render someone painless very well.

(Laughter.)

So, I think outcomes are always requiring some gradation. The question is, can you ask fairly to anybody who promotes

these measures to come up with those numbers? Well, I think you have the answer with C-sections; people don't bring those.

So, can you come up with comparative values? I don't know how you address that in NQF and what procedures you have to address that the core of this is variation, not a specific number.

DR. BURSTIN: And the fact that the steward of this measure is ASCO, who, unfortunately, is not here with us today, is an intriguing idea. If they have built this into their registry, which I believe they have, then that is inherently exactly what you are asking for. It provides them the ability to do the benchmarking across. Then, the question would be, is there some way to structure the measure that would be appropriate for accountability beyond what is already accomplished in benchmarking?

CO-CHAIR MORRISON: Doug? No? Okay. June? Down? Okay.

I am going to get there. I'm sorry. I know that. Thank you, thank you.

Is there anybody on the phone who would like to weigh in?

(No response.)

I'm sorry. Debbie, can you open the phone lines?

THE OPERATOR: The phone lines are open.

CO-CHAIR MORRISON: Is there anybody on the phones who would like to weigh in? America, are you listening?

(Laughter.)

(No response.)

No? All right.

So, do I hear any last comments before I turn things over to Caren and Lindsey for the day?

(No response.)

Seeing none, I want to thank everybody so much for staying with us. It has been a very long day. I know the temperature

control in the room has been fluctuating, and I appreciate everybody's staying with us.

And, Caren and Lindsey, I have you guys as review of day one activities and plan for day two.

DR. GINSBERG: Thanks, everybody.

I just want to wrap up where we have been today. We have considered, or tried to consider, 14 measures, and we actually tabled complete votes on seven of them, pending further conversations with Craig Earle. And we approved or we endorsed six measures, and one did not go forward for endorsement.

On the list of followup activities at this point are further conversations with Craig Earle about his measure submissions. I am inviting you to submit additional questions to us. We will have a conference call with him and the Committee Co-Chairs, we hope in the next week. So, please send any questions you have for us to ask him soon, by Monday or

Tuesday of next week, and we hope to schedule something with him next week.

We will then give him time to respond to your questions by updating his measure submission forms. And you will have a chance to look at those measure submission forms, and then we will reconvene.

I believe we actually have a followup meeting scheduled at this point, one sometime in August. Is that right, Lindsey?

MS. TIGHE: We do, based on the Co-Chairs' availability. We will probably be changing that, though. So, I will be sending you an email.

DR. GINSBERG: And keep those calendars open. We might actually need more than one followup call.

So, you will have a chance to comment on those and think about those when his measure submission forms have been updated. So, that is one area of followup.

Another is that we will talk to

the developers of the pain measures to see if we can get a common numerator statement for the two different denominators from the two different measures. And we will bring that back to you for your comments and thoughts on that as well.

Then, we had another item of followup, and that had to do with the difference in the seven-day hospice, one-day palliative concerns.

So, that's my to-do list. Is there anything else that should be on there?

(No response.)

Okay. So, that is all that I have at this point.

Tomorrow we start again at 8:30 for breakfast, 9:00 for a discussion of the rest of the measures. Then, we will talk about framework and measure gaps after discussion of tomorrow's measures.

Any last comments or thoughts or issues?

(No response.)

MS. TIGHE: And if you all could leave behind your voting remotes, I will be collecting those and I will distribute them again tomorrow.

(Laughter.)

MR. COLCHAMIRO: And if anyone has any logistical questions about transport to the airport or reimbursement, or anything like that, please don't hesitate to contact or talk to NQF staff.

CO-CHAIR LUNNEY: Do you need for us to check out before we show up in the morning?

DR. BURSTIN: You should have an opportunity to do that at break time, if you would like.

CO-CHAIR MORRISON: Thanks again, everybody. We will see you tomorrow.

For those of you who are runners and want to brave the heat, if you run west on K Street, you'll hit the Rock Creek Park. If

you go south on 16th Street, you'll hit the ellipse and the National Mall. So, it is real easy.

MS. TIGHE: And I would recommend the Mall because there are water fountains there.

CO-CHAIR MORRISON: Yes, that's right. And I was going to say the Mall has water fountains; Rock Creek Park does not.

(Whereupon, at 4:25 p.m., the meeting was adjourned, to reconvene the following day, Thursday, July 21, 2011, at 9:00 a.m.)

A

AARP 2:26 25:17
AARP's 25:14
abbreviated 215:53
ability 142:37 181:46 265:28 281:39 318:35 350:37 366:42
able 49:44 81:24 88:14 91:58 119:10 172:51 177:37 181:28 182:19 184:42 185:26 190:37 191:49 202:21 217:51 235:55 238:17 256:12 286:35 295:26 301:58
absence 82:26 293:46
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This is to certify that the foregoing transcript

In the matter of: Palliative Care

Before: NQF

Date: 07-20-11

Place: Washington, DC

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

Neal R. Gross

Court Reporter