NATIONAL QUALITY FORUM

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MEASURE APPLICATIONS PARTNERSHIP
HOSPITAL WORKGROUP

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WEDNESDAY
DECEMBER 10, 2014

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The Hospital Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:33 a.m., Frank Opelka, Chair, presiding.

MEMBERS:

FRANK OPELKA, MD, FACS, Chair
RONALD S. WALTERS, MD, MBA, MHA, MS, Vice-Chair
RICHARD BANKOWITZ, MD, MBA, FACP, Premier, Inc.
ANDREA BENIN, MD, Children's Hospital Association
MISSY DANFORTH, St. Louis Area Business Health Coalition*
WOODY EISENBERG, Pharmacy Quality Alliance
DAVID ENGLER, PhD, America's Essential Hospitals
KAREN FIELDS, MD, Alliance of Dedicated Cancer Centers
NANCY FOSTER, American Hospital Association
SHELLEY FULD NASSO, National Coalition for Cancer Survivorship
MARTIN HATLIE, JD, Project Patient Care
NANCY HANRAHAN, PhD, RN, CS, FAAN, University of Pennsylvania
EMMA KOPLEFF, National Partnership for Women and Families

JAMIE BROOKS ROBERTSON, JD, Service Employees International Union
BROCK SLABACH, MPH, FACHE, National Rural Health Association
DONNA SLOSBURG, BSN, LHRM, CASC, ASC Quality Collaboration
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KELLY TRAUTNER, American Federation of Teachers Healthcare
CRISTIE UPSHAW TRAVIS, MHA, Memphis Business Group on Health
WEI YING, MD, MS, MBA, Blue Cross Blue Shield of Massachusetts

INDIVIDUAL SUBJECT MATTER EXPERTS:
JACK FOWLER, Jr., PhD
MITCHELL LEVY, MD, FCCM, FCCP
DOLORES L. MITCHELL
R. SEAN MORRISON, MD
MICHAEL P. PHELAN, MD, FACEP

FEDERAL GOVERNMENT LIAISONS:
KATE GOODRICH, MD, Centers for Medicare and Medicaid Services
PAMELA OWENS, PhD, Agency for Healthcare Research and Quality
DANIEL POLLOCK, MD, Centers for Disease Control and Prevention
PIERRE YONG, MD, MPH, Centers for Medicare and Medicaid Services

NQF STAFF:
CHRISTINE K. CASSEL, MD, President and CEO
TAROON AMIN, Senior Director
POONAM BAL, Project Manager
LAURA IBRAGIMOVA, Project Analyst
ELISA MUNTHALI, Senior Managing Director
ERIN O'ROURKE, Senior Project Manager

ALSO PRESENT:

SUSANNAH BERNHEIM, MD, Yale CORE

EMILY CRAMER*

MEGAN HAYDEN

STACIE JONES

BARB JAGELS

ERICA MCNAMARA*

MAMATHA PANCHOLI

JENNIFER PAVELKA

AMITA RASTOGI

*** present by teleconference**

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

8:33 a.m.

CHAIR OPELKA: Thank you and good morning. Welcome, everyone.

We have been graciously joined by Sean. Thank you, Sean. We're glad you joined us yesterday by phone, but it's even better in person. And we actually officially have a meeting now because Dolores is here.

(Laughter)

CHAIR OPELKA: But yesterday we had the disclosure, so if you could, Dolores, inform us who you represent and I believe Ann's not here today to give you the guidance, but the guidance we got from Ann yesterday was any significant affiliations, and that was defined as investments that were $10,000 or more you needed to disclose.

MS. MITCHELL: I'm Dolores Mitchell. I'm the Executive Director of something called the Group Insurance Commission, a Commonwealth of Massachusetts agency for health and other benefits. And I wish I could plead guilty to

having those investments, but I don't. So other than moral conflicts, I have none.

CHAIR OPELKA: Thank you. Sean?

DR. MORRISON: Nothing to disclose.

CHAIR OPELKA: Great. Thank you. And also joining us today; I'm sure she'll be in and out because of her busy schedule, is the leadership of the National Quality Forum Chris Cassel.

Chris, would you like to say hello to the group this morning?

MR. AMIN: Frank, I'm sorry to interrupt Chris.

Sean, do you just mind doing the disclosure into the mic just so that it's on the record? I'm sorry.

CHAIR OPELKA: He was yesterday.

DR. MORRISON: I was here yesterday, but on the phone, but yes.

MR. AMIN: Oh, okay. Thank you.

DR. CASSEL: Okay. So thanks, Taroon, for dotting the "I's and crossing the "T"s.

That's something that NQF is really famous for and responsible for.

So first of all, apologies for not being able to join you yesterday; and Frank and Ron are right, I will be in and out again today. But I do just want to mostly acknowledge the importance of this work and thank all of you for the time and effort that you put into this on behalf of the multi-stakeholder process.

And I want to also recognize and thank the staff and everyone here for the innovations that I've just been hearing informally, which are very much appreciated as we try to streamline this process, make it more workable and more effective, particularly as this measurement environment becomes more consequential and more visible in so many different parts of our health care system.

So thanks very much and I'm not going to slow you down anymore. Let us get going.

CHAIR OPELKA: All right. So our job today, lining this up for you, is we've got

several programs to go through. The hospital IQR, which will be our first. And if there's anything left, then we'll go onto the Value-Based Purchasing Program, the Cancer PPS-Exempt Cancer Hospital Program, and finish with the Hospital Readmission Program. And we're hoping to get out on our agenda on time because I know everyone is at that point of getting back home.

So, what we've got, for Dolores, you did not have the opportunity going through the experience yesterday of a new voting system, but to be very brief, what we present are a series of consent calendars which will be voted on up or down, and those consent calendars require a 60 percent pass to be passed as a consent calendar.

What we put forward are a series of consent calendars to start, and the consent calendars have been populated by the staff using the MUC list that we got from CMS. The staff has applied the rules that we have developed over time to the best of their ability in populating the consent calendars.

We then look at them to see if there's anything we want to move from one consent calendar to another. And that's a simple majority vote to move something from one calendar to another.

So that's been our process. It took us a little time to get used to it, but once we did, I think the group did really well all yesterday when we got past our first trial.

MS. MITCHELL: Do I take it that by "consent calendar being populated," you mean that there is a recommendation which unless pulled is assumed to have passed? Is that correct?

CHAIR OPELKA: It's not necessarily assumed to have passed. It will be voted on as a consent calendar and it may not pass.

MS. MITCHELL: Right, but --

CHAIR OPELKA: So we had a consent calendar yesterday that did not pass.

MS. MITCHELL: But the population that you refer to, the populating that you refer to is a set of recommendations --

CHAIR OPELKA: Right. It is.

MS. MITCHELL: -- about what the staff thinks ought to pass?

CHAIR OPELKA: Correct.

MS. MITCHELL: Okay. Got it.

CHAIR OPELKA: That's correct. But all the rest of the consent calendars actually did pass except for one that we'll bring to the Coordinating Committee.

Okay. So we're beginning with IQR. Poonam, are you going to walk us through?

MS. O'ROURKE: I actually just wanted to make a few housekeeping announcements about the voting process before Poonam gets started with the IQR summary.

I just wanted to clarify the role of our federal liaisons for everyone who might have some confusion. Our federal liaisons, while Workgroup members, are non-voting. So just wanted to make sure that was clear for everyone.

And I also wanted to clarify that while yesterday I was casting Sean's votes, today I'll be casting Missy Danforth's, our substitute

from the St. Louis Business Group on Health, who's joining us via phone.

MS. BAL: Okay. So the Inpatient Quality Reporting Program, also known as IQR, is a behavioral reporting and public reporting program. A subset of the measures in the program are publicly reported on the Hospital Compare Web site. If hospitals do not report data on the required measures, they will receive a 10 percent reduction in their annual Medicare payment update.

A main goal is to provide this incentive for hospitals to publicly report quality information about their services so consumers can be informed about health quality and make informed choices. The critical program objectives that we determined in October were to choose high-impact measures that will improve both quality and efficiency of care and are meaningful to consumers, move toward more outcome measures rather than structure or process measures, align reporting requirements with other

clinical programs where appropriate to reduce the burden on providers and support efficient use of measurement resources. Also to engage patients and families as partners in their care.

And some of the goals were to expand the program to include measures that allow rural and other small hospitals to participate and also rapid filling of the following fairly extensive gap list, which is peds, maternal and child care, cancer, behavioral health, affordability and cost, care transitions, patient education, palliative and end-of-life care, medication, cultural safety, pressure ulcer prevention and adverse drug events.

Last year it was also recommended that HHS look at existing measures in the PPS-Exempt Cancer Hospital Quality Reporting Program and the Inpatient Psychiatric Facility Quality Program and Hospice Quality Reporting Programs to fill these gaps.

MS. O'ROURKE: So our first calendar for the IQR Program is five measures that have a

preliminary analysis of support. Four of these are updates to measures that are currently in the program. One of them is a new measure.

The first two measures are measures that you saw yesterday. The NHSN, CLABSI, and CAUTI measures. These are updates to the measure addressing expanding the setting beyond the hospital ICU, as well as addressing adding another risk adjustment model. So we'll have the SIR and the new ARM models.

We received no comments on the CLABSI measure. We did receive one comment on the CAUTI measure. Again, the same comments we heard yesterday strongly encouraging measure developers and CMS to exclude patients with spinal cord injury from this measure.

The next two measures address updates to the 30-day pneumonia readmission and mortality measures. For the 30-day readmission measure we had a preliminary analysis that this is a high-impact, fully-specified, tested and endorsed measure. It's part of the MAP safety family of

measures. It's already in use in several public and private programs including already in use in IQR. MAP is being asked to consider a revised version of this measure that would expand the cohort of patients included to include patients with a primary diagnosis of aspiration pneumonia. CMS believes that this revised measure would decrease biases in coding.

We did receive public comments on this measure. One commenter noted that all readmission measures should report both the numerator and denominator since there is a possibility that a very low or shrinking denominator might make it difficult to detect -- apologies. I lost my place and I don't want to butcher this commenter's word -- might detect the pattern of practice is actually quite good. All readmission metrics should carry a caveat about the potential for social supports and community resources to affect the determination and the readmissions per 1,000 and admissions per 1,000 metrics that have been presented to NQF should be

listed in the list of potentially useful metrics to CMS. And this commenter will refer to these three conditions in future measures.

MR. AMIN: Sorry, Erin. Could I just point out that that was a similar comment that was provided across all of the readmission measures? So we won't necessarily repeat those same notions around readmissions per 1,000, admissions per 1,000 and the importance of social supports and community supports as we're looking at readmissions. But I just wanted to point out that those comments were received across all the readmission measures.

MS. O'ROURKE: So again we have the pneumonia mortality measure. This had a similar update to expand the cohort of included patients to include patients with a diagnosis of aspiration pneumonia.

We received one comment on this measure. The commenter supported this measure and the three conditions noted in prior measures should be considered here as well, just to carry

over what Taroon was saying.

Finally, we have a new measure under consideration for this program: Cardiac rehabilitation patient referral from an inpatient setting. This measure would address a known gap in care transitions and referrals to the next site of care. Cardiac rehabilitation has been found to be under-utilized despite being included in the American Heart Association Get With the Guidelines Program.

We received a comment on this measure. The commenter noted a key window of opportunity, a Class 1 indication and strong evidence of benefits supported this measure.

MR. AMIN: Given that we have seven calendars, Frank, would it be okay to at least initiate some conversation around this particular calendar to see if there are any that need to be pulled before we move on, or would you prefer to keep moving?

CHAIR OPELKA: I think we need to walk through them all because you don't -- the

conversation is going to be framed by the other calendars.

MR. AMIN: Okay. That's fair. Let's move on then.

MS. O'ROURKE: Our next calendar addresses measures that have a preliminary analysis of conditional support pending NQF review of the testing data in a Medicare population and resolution of parsimony concerns with measures currently in the IQR program.

The first measure is proportion of patients hospitalized with AMI that have a potentially avoidable complication during the index day or in the 30-day post discharge period. This measure addresses a number of adverse outcomes that are meaningful to patients and can increase costs across the system. The preliminary analysis resulted in a conditional support pending NQF review of the testing data in a Medicare population and resolution that this measure might be duplicative of measures currently in the program.

We received one comment. This commenter was generally supportive of this measure.

The second measure in this calendar is a similar measure addressing the proportion of patients hospitalized with pneumonia that have a potentially avoidable complication during the index day or in the 30-day post-discharge period. Again, the same preliminary analysis and comments were received.

And then finally we have a third measure addressing proportion of patients hospitalized with a stroke that have a potentially avoidable complication during the index day or 30-day post-discharge period. Again, we had the same preliminary analysis and received the same generally supportive comments.

Calendar 3 is another conditional support calendar with a condition that this measure should be quickly replaced with a measure assessing results of a survey of a culture of patient safety. We received one comment. The

commenter was generally supportive of this measure.

Calendar 4, another conditional support calendar. This was conditional support pending demonstration of applicability at the facility level and resolution of the duplicative nature of this measure with the falls and trauma component of PSI-90. So on this calendar we had two measures, one addressing a patient fall rate. The rationale for our preliminary analysis was that falls are a common adverse event in hospitals with estimates between 2 to 5 falls per 1,000 patient days. About 30 percent of falls result in injury, disability or death.

While falls and trauma are currently addressed in the IQR program and the PSI-90 composite measure, MAP has previously noted that these measures NQF-141 and 202 are based off of clinical data and may provide better data than claims-based measures. We did not receive any comments on the patient fall rate measure.

The next measure is falls with injury.

Again, we had a similar preliminary analysis noting that these are a pair of measures and work together and could provide better data than we are currently getting through the claims-based measure in the program.

We did receive one comment. The commenter was not supportive of this measure noting the definition of injury levels would have to be very specific for standardized reporting across all hospitals.

MR. AMIN: Thanks, Erin. So there are a few more. I just wanted to point out that we received some indication from CMS that four of the measures under development that NQF had considered under our measures under development pathway have completed testing. So we've updated this Discussion Guide and shifted four measures from what we've discussed as IQR Calendar 7: the kidney, urinary tract infection clinical episode payment measure, the spine fusion/refusion clinical episode-based payment measure, the cellulitis cost-of-care measure and the

gastrointestinal hemorrhage measure into our Calendar 5.

So Calendar 5, I'll just point out here, following along with this updated Discussion Guide that Poonam sent out last night. We'll start with the first, which is hospital 30-day all-cause unplanned risk standardized days in acute care following AMI hospitalization. There are three measures that follow very similar constructs, so I'll just read them aloud and then give the preliminary analysis and the comments since they were very similar.

The second is the hospital 30-day all-cause unplanned risk standardized days in acute care following heart failure. And the third is risk standardized days in acute care following pneumonia.

The preliminary analysis was conditional support pending NQF review and endorsement. These measures helped to address the concern noted by the NQF Admissions and Readmissions Endorsement Standing Committee that

observation days and ED visits may be resulting as an increased focus on readmissions.

We had one commenter across all three of these measures that were supportive of the measure pending NQF endorsement noting the potential of these measures to identify an early warning. Additionally, commenters noted the intensity and cost of ED types -- actually, we had one supportive commenter. And then we also had another commenter that was less supportive noting that the intensity and cost of ED visits in Type 1 observation is much less than for admissions. The commenter also noted that there has not been chart review validation of these metrics which would indicate whether these returns to care were not urgent or emergent.

So moving on, we have the hospital-level risk standardized payments associated with an episode of care for primary elective total hip or total knee. Again, joint replacement surgeries are increasingly common with a significant number in the Medicare population

representing a significant cost to the Medicare Program.

The preliminary recommendation here is that MAP would encourage a timely review of these measures by the NQF Cost and Resource Use Standing Committee to resolve potential harmonization issues and encourage the most parsimonious approach to measuring costs for hip and knee replacements to minimize burden and confusion among competing methodologies.

One commenter was not supportive of this measure noting that CMS has not yet had the opportunity to consider the comments that were recently received on the measure.

So these are the additions to this calendar. We have the kidney, urinary tract infection, clinical episode of care payment measure. This measure addresses the cost of care for a common condition. UTIs are mainly treated on an outpatient basis, but the cost of care can be high if hospitalization and follow-up care is needed. We did not receive any comments on this

measure.

Cellulitis. Oh, we have spinal fusion. Give me one second here. Okay. Well, the comments around cellulitis -- all right. So I'll come back to spinal fusion in a moment. Cellulitis. This measure addresses cost of care for a common but potentially serious skin infection. The cost of cellulitis can be significant if hospitalization is required. There's been no comments on this measure from the public.

And the GI hemorrhage clinical episode of care-based measure, GI bleeding is a common and costly condition and is responsible for more hospitalizations than CHF or deep-vein thrombosis. An episode-based approach could help drive improvement for both cost and quality. We didn't receive any comments on this measure.

And there were no comments on spinal fusion. So again, just pointing out that spinal fusion, the preliminary analysis noted that it's an important area and the cost indicated spans a

period -- I'll come back to spinal fusion. I can't seem to find my notes on that. I'll come back to it. But it follows a similar construction as the other episode of care measures. Given that we've moved it around, I seem to have lost my notes on this one.

So I believe that that captures IQR Calendar 5. So just in summary, Calendar 5 has a lot in it. It's mostly the risk standardized days after acute care and then mostly episode of care cost measures.

So moving on to Calendar 6, these are the do not support measures. We have two in this category. The first is the skill mix measure, so the preliminary analysis of this measure notes that the IQR Program currently includes measures that assess outcomes addressed by nurse staffing levels. The MAP previously noted its desire to move toward the most parsimonious measure set as possible. And the outcomes can be used in place of these structural measures when possible. So noting that the outcomes are available and this

is a structural measure that the MAP has discussed in the past.

Second is the nursing hours per patient day. The IQR Program currently includes measures that assess outcomes addressed by nursing hours. The MAP previously noted its desire to move toward a parsimonious measure set and that outcome measures should be used in place of structural measures as possible. In both of these there was one comment received in favor of this measure.

So maybe we can stop there since those are the fully developed measures, and then I'll turn it over to Frank for discussion.

CHAIR OPELKA: Okay. All right. Well, thank you very much. I know this is a hefty group. I think the best approach will be to go back to the first calendar. And now that you see the various calendars that we have and the measures that are in them, we can walk through each calendar and ask if we've got any desire to move anything that's on one calendar to

another.

So we'll start with the first calendar. Mitchell?

DR. LEVY: So just a point of order. I want to ask a question about one of the measures, but not necessarily ask that it be moved off. So I'm just looking for when we would have a discussion about a measure.

CHAIR OPELKA: When that calendar comes up.

DR. LEVY: Okay.

CHAIR OPELKA: So let's take these that are on this calendar. So we've got CLABSI, CAUTI, the hospital 30-day all-cause, risk standardized pneumonia and readmission and then the 30-day risk standardized mortality from pneumonia, and then the cardiac rehab on the support.

Nancy?

MS. FOSTER: So I'd like to pull the 30-day all-cause risk standardized readmission rate for pneumonia and the cardiac rehab for

patient referral. The first I'd like to put in a probably a new one conditional but conditional upon adjustment for SES. The second one I'd like to put in conditional -- gosh, I've lost track of all those different conditional ones, but conditional on some -- the data issues being resolved, which was a category we had yesterday.

CHAIR OPELKA: The NHSN?

MS. FOSTER: I'm sorry. I'm not pulling the NHSN one.

CHAIR OPELKA: That was the -- yesterday's data question was --

MS. FOSTER: Right.

CHAIR OPELKA: -- on the NHSN data --

MS. FOSTER: Right. I'm just saying the cardiac rehab also has some data issues that need to be resolved.

CHAIR OPELKA: Okay. Richard?

DR. BANKOWITZ: Could I ask a clarifying question on the pneumonia mortality? Has NQF looked at that now that it's been

redefined to include aspiration pneumonia and is that measure endorsed by NQF?

CHAIR OPELKA: Everyone's nodding their heads saying that it's coming back, but no. Maybe we can get clarification on that.

Please tell everyone who you are.

DR. BERNHEIM: Hi, I'm Susannah Bernheim from Yale CORE. We're the developers of this measure and now the re-evaluators. So the changes to the pneumonia measures will go back to NQF this year. So they haven't gone back yet.

And just a clarification. It's not just the addition of aspiration pneumonia. It is also adding patients who have pneumonia POA as a secondary diagnosis with either sepsis or respiratory failure as a primary diagnosis.

CHAIR OPELKA: Okay. Richard, did we answer your question?

DR. BANKOWITZ: I would like to pull that measure if this is the appropriate time. I don't know if Nancy made a motion or not, but I would move --

CHAIR OPELKA: So there are two pneumonia measures. There's at the --

DR. BANKOWITZ: I would pull both of them.

CHAIR OPELKA: All right. Mitchell, is yours still up?

DR. LEVY: Actually I have a question about the CLABSI measure that I meant to ask yesterday. Would this be a time to ask that?

CHAIR OPELKA: Yes.

DR. LEVY: I'm not asking for it to be pulled, but I think this question is either for CMS or CDC. So the two revisions were, one, extending the population, and the other was the addition of a new risk model. And we haven't said anything about it and it's now going to a larger population. So I'm just wondering about this new -- its adjusted ranking metric and has it been validated and in what population? And I don't know who I'm asking.

DR. POLLOCK: Well, this is Dan Pollock at CDC, so I'll start off, Mitchell.

Thanks for your question.

The addition of the adjusted ranking metric to the measure spec does not eliminate the unadjusted standardized infection ratio. There are, however, specific use cases or purposes that the adjusted ranking metric serves. It is, in our understanding, a better approach to rank hospitals when you use the adjusted approach that the adjusted ranking metric has built into it.

It is a full Bayesian method of taking into account exposure volume and other risk factors that are not taken into account in the SIR, which itself has some aspects of risk adjustment. But the primary advantage of the adjusted ranking metric is that it deals with differences in exposure volume and in a Bayesian approach it takes into account all of the data that are available for a particular time period.

So to give you a simple explanation, the difference between a baseball player who's hitting .400 in April and one who's hitting .400 in September after a six-month season is

substantial, and most would recognize that the two should not be equated in terms of their achievement because one has had limited exposure volume. A batter who hits who successfully at .400 clip, which is an excellent clip performance, in April, in all likelihood will regress to the mean by the end of the season.

So the adjusted ranking metric performs a statistical adjustment that takes into account the performance of all of the players and factors that in, using a full Bayesian approach. And so there is regression to the mean in terms of the adjustment. That means that in some instances hospitals will see a different end result, but the implications for ranking are very important because we think it's a more equitable approach than treating the April .400 hitter as though that hitter is equivalent to the September .400 hitter.

DR. LEVY: It makes sense. Has it been validated in a population in terms of outcomes?

DR. POLLOCK: Well, when you say "validated," what do you mean?

DR. LEVY: So looking in the same way that if you did this logic in the first baseball season ever you wouldn't really be able to be sure that hitting .400 in April isn't the same thing as hitting .400 in September, so --

DR. POLLOCK: Oh, we know that.

DR. LEVY: Okay.

DR. POLLOCK: Yes, we've looked at that for sure.

DR. LEVY: Okay.

CHAIR OPELKA: Thank you. Pierre, Kate, did you have anything to add?

DR. YONG: The only thing I'd just want to -- but I believe they also both just received NQF -- were approved for re-endorsement.

DR. POLLOCK: And let me just add just to underscore the point that the NQF measure that has been endorsed -- just as Pierre indicated, that has just been endorsed includes both the unadjusted SIR, which we think is a better metric

for quarterly reporting and in some instances a better metric for annual reporting, as well as the use of the ARM, the adjusted ranking metric, which we formerly referred to as the adjusted SIR, but to avoid confusion we gave it a new name altogether. So the adjusted ranking metric in our opinion, in our view is a much better fit with hospital ranking, whereas the unadjusted metric is a better metric to use to gauge performance improvement over time.

CHAIR OPELKA: All right. Thank you very much. Andrea?

DR. BENIN: How does this methodology then address some of the concerns about stratification that were brought up by the commenter around some of the populations that might be a particular high risk or have some nuances to them? I think one equivalent in pediatrics is kids with short gut. So we'll have a unit at any time of kids who are TPM-dependent, so your line days are extensive. So that unit, when you start expanding it out of the ICU, those

kinds of units. So I think that's the equivalent of your spine injuries with the urine, those types of things. Will this methodology help address this problem? Is this still an appropriate way to go then based on those comments?

DR. POLLOCK: So this methodology does not address that problem or those sets of problems that you're describing. Pretty much have to take each of those individually. I don't know how much of a deep dive we want to do on that.

But let me address the spinal cord-injured patient population for a moment, because I didn't have a chance to yesterday. As Matthew Davis indicated, we've had extensive discussions with him and colleagues in the spinal cord injury community of clinical practice and we recognize from their reports the possibility of an unintended consequence of the CAUTI measure leading to selected non-use of in-dwelling urinary catheters in spinal cord-injured patients

particularly when they're treated in non-specialty centers. That's understood.

We think that is a clinical practice problem that needs to be better addressed with education and ongoing support for the correct way to manage urinary tract function in the spinal cord-injured patient population. The implication of removing patient populations selectively such as spinal cord-injured patients from the data collection process for CAUTI is more complicated than simply finding appropriate codes and using them because the measure requires ongoing determination of catheter use prior to patients' diagnoses being coded. And so it becomes a very labor-intensive effort to identify the spinal cord-injured patient population and remove them from the catheter use counts.

As a result we had a trade-off that we're facing of do we invoke an exclusion for spinal cord-injured patients opening up the possibility that the next would be exclusions for sedated patients, for stroke patients? And soon

we're eliminating groups of patients, all of whom remain at risk for catheter-associated urinary tract infections. Or do we look at the fundamental question of how best to manage those patients in clinical practice and support optimal care of them?

So we made a decision not to remove the spinal cord-injured patient population. We have a standing offer to the spinal cord-injured patient community of clinical practice to help get the message out about appropriate catheter use. So that's where we stand in our interactions with Matthew and his colleagues.

We do have -- with a possibility of capturing data about the extent of spinal cord-injured patient census in a given hospital as part of this annual survey that we do -- have an opportunity to control in a risk adjustment process for the presence of spinal cord-injured patients in a facility's patient care locations that are part of the CAUTI reporting. That's a possibility. That type of risk adjustment would

be separate from the adjusted ranking metrics risk adjustment process.

So that's a fairly long explanation, and I apologize for that. There is complexity in all of this. It's not something that can be addressed in shorthand terms very easily.

DR. BENIN: That's very helpful to me. With the bloodstream infections then as they extend outside of the ICU, will there be the stratification that's similar to how -- so currently the expecteds, for example -- I'll use the NICU example, the expecteds are calculated by your birth weight, right? So there are certain -- the expecteds are calculated by whether you're in a PICU or a med-surg ICU or a surgical ICU, etcetera, etcetera. Are there then other types of stratifications that are going to appropriately define these other areas outside the ICU?

DR. POLLOCK: Well, we tend to stratify, as your question rightly recognizes, by patient care location type, and admittedly, that

is a proxy for the type of underlying medical condition that patients have, medical or surgical condition. Ideally we would have patient-specific, patient-level data. But again, here is a trade-off. The more we place a burden on facilities to report patient-level risk factor data that we can take into account in our risk adjustment model, the more we're burdening the collection of data, predominantly still in a manual form.

Hopefully later today when we have our open discussion about how we all want to go forward, we'll reckon with the need to take greater advantage of the enormous investments in health electronic record systems and look at what we can do collectively to foster greater standardization of key clinical variables that could be used electronically in risk adjustment processes.

Right now the reality is despite billions of dollars of investment we just don't have the granular-level data for risk adjustment

in electronic form in anywhere near the type of coverage that would make it sensible for us to tip that balance towards collecting patient-level denominator data that would enable the risk adjustment.

So we are in a position to continue to use patient care location. Burn ICU versus neuro ICU versus medical ICU versus pediatric ward as a proxy for the patient population that is being treated in those locations, their underlying disease conditions.

DR. BENIN: I mean, I'm very supportive of all this, but I would -- and I imagine that there will be some incentives to sort of -- like where am I going to put all the shortcut patients when I report this data? I may want to think about that. And so I just think that as you work through this it requires a little bit of thought about some these high-risk populations.

DR. POLLOCK: Right, and --

DR. BENIN: I don't want to dwell on

it, but I --

DR. POLLOCK: Yes. No, it's a good point, and we are very sensitive and I think responsive to concerns expressed by our clinical communities of practice and individual practitioners who weigh in. And that leads to in some instances changes in our criteria for what constitutes an infection such as changes that we're introducing this coming calendar year for what comprises a catheter-associated urinary tract infection.

We are, for example, removing fungal pathogens as a cause of urinary tract infections for purposes of CAUTI reporting. That's a significant change. And we're doing that in large measure in response to input that we get from the clinical world. That's very important to us.

It's fundamentally imperative that we maintain to the fullest extent that we can credibility with clinical communities of practice because the ultimate goal is of course to

prevent. And unless the clinicians are engaged, we're not going to be preventing. So that's something we take very, very seriously. But every time we make a change, there's disruption in our capacity to look at what's happening over time. And there are educational challenges and training challenges and all sorts of implications. We update in NQF. That's a process.

So on the one hand; and we're not going to deviate from this, we're going to continue to make sure to the fullest extent that we can with the information practices as they exist in 2014 and 2015 capturing the data and defining infections and criteria in accordance with what's available.

But on the other hand, we fully recognize there are imperfections and shortcomings in what we're able to do right now. We want that to change. We want to continue to work in a concerted way to bring those changes about.

CHAIR OPELKA: All right. And I want to thank you, Dan, for that. Those were very insightful remarks that I think we needed to hear, and it's very helpful.

At this point we have the CLABSI and CAUTI on the support list and we have a recommendation to pull the risk standardized readmission. And that was to go to NQF endorsement, I believe. I'm trying to walk through our conditions.

MS. FOSTER: That will be fine. That was not what I originally said, but that's what Richard said and that's what I --

(Simultaneous speaking)

DR. BANKOWITZ: Originally I wouldn't recommend that. I would recommend not support that measure. And I have a rationale for it at the appropriate time.

CHAIR OPELKA: So we have two motions on that one. So we have a conditional condition to be defined.

MS. FOSTER: No, condition would be

NQF endorsement.

CHAIR OPELKA: NQF endorsement. And then a recommendation do not support. Then on the hospital -- on the mortality pneumonia measure, Richard, where did you want to suggest that one?

DR. BANKOWITZ: I suggest we do not support.

CHAIR OPELKA: Okay.

DR. BANKOWITZ: Do you want a rationale or do you want to --

CHAIR OPELKA: In just a moment. If you'll just hang onto that, because we'll go back to it. I just want to make sure we've got the list right. Cardiac rehab was conditional for data. That's NQF endorsed. So we're going to probably need to understand what data is missing if you've already got endorsement.

Okay. Any other thoughts? Is everyone pleased that we can walk then into the detail? Emma?

MS. KOPLEFF: Just sort of a question

about the framing of these motions. Given that we're reviewing in this case, and there will be others, measures that are already in programs and have been in programs, if we were to discuss a measure that's been pulled to either a conditional support calendar and a do not support, are we discussing that those can -- let's say the conditional support route. Are we discussing the pneumonia measure if the condition is not met, does that mean that the currently NQF- endorsed, currently in the program version of the measure stands, or are we discussing the inclusion of the measure, period, in the program? I think that can be --

(Simultaneous speaking)

CHAIR OPELKA: Well, what we're talking about is -- take IQR.

MS. KOPLEFF: Yes.

CHAIR OPELKA: If a measure is in another program, it doesn't matter. We're only looking at it in IQR. In IQR if the condition is NQF endorsement and it does not achieve

endorsement, then the MAP is not supporting that measure.

MS. KOPLEFF: We're not supporting this version of the measure or we're not supporting --

CHAIR OPELKA: We're not supporting that measure that is on this list if it is conditional upon NQF endorsement and it fails.

MS. KOPLEFF: Okay.

MS. KOPLEFF: So what I'm trying to clarify if --

CHAIR OPELKA: So that means we're not supporting it.

MS. KOPLEFF: Understood. But if I may restate, I think we're not supporting this version of the measure for the IQR Program, but we aren't necessarily making a statement it is not within our scope to discuss the finalized version of the measure that is currently in use in the IQR Program.

CHAIR OPELKA: That's correct. We're looking at this measure as it stands here.

MS. KOPLEFF: Okay. Thank you.

CHAIR OPELKA: Any other questions?

(No audible response)

CHAIR OPELKA: Okay. So then we go to the readmission rate, and the motion is to move this to NQF endorsement, conditional support pending NQF endorsement. All right. So any discussion?

MS. FOSTER: That was my motion. Are we only entertaining my motion and not Richard's?

CHAIR OPELKA: Yes, we can't have multiple motions on the same measure.

MS. FOSTER: All right.

CHAIR OPELKA: So if your motion passes, then Richard's motion -- he can make his motion, but we'd have to --

MS. FOSTER: Understood. Okay.

CHAIR OPELKA: Or re-pulling a measure for another motion. But yours is the only one.

MS. FOSTER: So just to be clear for Emma, my motion was intentional of not supporting this new iteration of the measure. And for me

there are two important issues here. One that we understand fully and have NQF endorsement and understand fully the implications of the major changes in this measure and their scientific integrity, and which to me come through NQF endorsement, at least in part.

And secondly, I know you all have heard me on this subject, so I'll just be very brief. Any change to this measure that does not include adjustment for socioeconomic factor or proof that there is no need for adjustment for socioeconomic factor, which is doubtful as far as I'm concerned given the growing body of evidence about the need for socioeconomic adjustment, is not supportable. We just have to get around to making those adjustments and getting these measures into that process.

CHAIR OPELKA: And I want to be clear, because I think the socioeconomic adjustment status is different from socioeconomic risk adjustment. So if it's stratified versus risk-adjusted, that's been the issue that is on the

table within the NQF. It's in a pilot program now. The NQF came to a point of saying it's split on whether we should have risk-adjusted or risk-stratified socioeconomic -- and that pilot is moving forward in testing that.

MS. FOSTER: Could we have an update from NQF staff, because that's not how I understood what the pilot was testing.

MR. AMIN: Okay. So, and I actually had a follow-up question for you, Nancy, as well.

So for those of us that are maybe a little less familiar with insider NQF baseball, NQF is moving forward January 1 on implementing a pilot to a trial period to look at the question of SDS adjustment. Prior to January 1st, 2015 NQF had essentially restricted the use of SDS variables for risk adjustment for the purposes of outcome measures, or any measures in general, any risk-adjusted measures. Starting January 1st, 2015 that restriction is being lifted and we are allowing measures to be submitted to NQF that include SDS adjustment.

In addition, the trial period is asking specific questions around the conceptual and empirical relationship between SDS factors and the outcome being measured, in this case pneumonia readmissions.

So that's the definition of the pilot. We are asking for multiple specifications, meaning specifications for including SDS adjustment in the risk model and not including it in the risk model, which would serve as the foundation for allowing the measure for an SDS-adjusted measure to be stratified for the purposes of internal quality improvement and understanding the differences in performance.

So with that being said, the question I have for Nancy is the way that you framed the motion to begin with was conditional on adjustment for SDS. I would ask the question is it really an adjustment for SDS or are you asking the question that NQF consider whether SDS adjustment is appropriate for these measures, which would fit under the construct of what we're

doing starting January 1, which is we're not requiring SDS adjustments for risk adjustment. We are asking measure developers to work along with NQF and CMS to work along with NQF to evaluate whether SDS adjustment is appropriate conceptually and empirically for each outcome and measure that we're looking at.

MS. FOSTER: Thanks for the clarity, Taroon. I meant the latter. I was trying to be brief --

MR. AMIN: Okay.

MS. FOSTER: -- and in so doing shorthanded it too much. I want SDS considered for these measures, this measure in particular that we're talking about now, and other readmission measure that comes along.

CHAIR OPELKA: But it's in this framework of it's the trial which is both risk adjustment and risk stratification. Arguments were both of sides of that.

MS. FOSTER: Correct.

CHAIR OPELKA: And they were very

strong on both sides.

So I really want to kind of frame this condition once and not 100 times today, because we had a pretty good healthy discussion on it yesterday. So I would really like you to consider on this particular measure, as a good one for us to work on, how do we frame the guiding principles that we can then apply when you wish as a group conditionally so that we're not going to do this -- have this conversation over and over again all day long. It's an important one to have. I would love a proposal.

MR. AMIN: Okay. What I'm hearing as the condition; and maybe we can recycle this condition going forward, is the condition is support with the condition that the measure is considered for SDS adjustment during NQF's upcoming trial period.

MS. FOSTER: And my only addition to that would be an that it becomes NQF endorsed.

CHAIR OPELKA: And I'm going to go down the list here in a minute, so if you're just

hang on for a second, because I want to clarify your action on this measure within this condition. Okay? It's important for our discussion so that all risk standardized readmission for pneumonia would have two conditions. One would be the NQF endorsement and the other one would be within the framework that Taroon just identified regarding socioeconomic status adjustment within the pilot. Okay?

Okay. Everyone understand that? We good?

(No audible response)

CHAIR OPELKA: All right. I'm going to go down the list. Jack?

DR. FOWLER: Since you said you want to talk through this now, I'd like to put in a word for stratification as compared with risk adjustment or in addition to. I mean, as most folks have thought about this, I guess I understand, the problem is that the argument is partly; at least as I hear it, one that people from disadvantaged backgrounds, I'll represent,

have more challenges when you send them home to take care of whatever it is that they've got to deal with when they get back there.

So on the one hand you say, well, if you're a hospital that has a lot of those, then you're at an unfair advantage because you've got more challenges. The alternative argument is, well, you're supposed to take care of the people you've got to take care and we don't give you a break because you've got a set of people that are harder. If you have harder cases, you deal with it. And so to have different standards doesn't make sense.

And I think that's a complicated argument for sure; we've talked about that, but I am just a huge fan of stratifying as in reporting the results for, if you can, the people who are at higher risk and the people who are at lower risk and see what your readmission rates are for both of those.

Now, if you want to combine those in some fashion, you can do that, but at least we

would then have the information both at a hospital level by how well they were doing overall and also how well they were doing with their people who were more challenged. And that from a patient perspective would give me the information that I would me most interested in.

And so, I know that there have been a lot of articles written and there won't be an right answer, but I think stratification is a really strong model for giving patients and users the information they need to understand how well hospitals are dealing with their challenging cases.

CHAIR OPELKA: Richard?

DR. BANKOWITZ: Yes, I have a concern of a question about the whole process of this conditional recommendation on NQF approval. So I would like the NQF staff to correct me if I'm wrong or give me some guidance here, but when NQF looks at a measure for endorsement, they're looking at the scientific validity of the measure and they are looking at utility of the measure.

Is it useful for some purpose? They don't specify what the purpose is. We're asked to decide is this suitable for public reporting?

And I find it very difficult to say, yes, I support this without any data, without looking at any data on sensitivity, sensitivity specificity, how this behaves in the field. And my only condition is NQF will find it scientifically valid, which is important, and suitable for some purpose. But that might not be the purpose that I'm asked to decide here, so this is why I have a bit of a dilemma.

Am I saying this right? I'd like you to help my logic here.

CHAIR OPELKA: You want to comment?

MR. AMIN: Well, I mean, so the NQF endorsement process evaluates whether measures meet scientific properties and also evaluates broadly whether the measures are appropriate for quality improvement and accountability applications. Whether the measure is uniquely appropriate for the use for this program is up

for this group to decide.

Now whether you have enough information to make that decision or not as you're describing, that is your own -- I mean, I can't speak to that element.

DR. BANKOWITZ: Well, I'd feel much more comfortable if we'd say we would reconsider after NQF endorsement, but that's not what we're doing. We're saying we support after NQF endorsement. So that's why I'm a little uncomfortable. And my only other choice is to say do not support. So each of those is not an optimal choice, but are those are the two choices I have, I have to say don't support because I'd like to see more data.

CHAIR OPELKA: Michael?

DR. PHELAN: I think this is a critical issue, and we all know what's been at least out there published particularly -- and I think Jack spoke very eloquently about the stratification, putting hospitals in whatever category that they belong in order for patients

and the end users to do comparative analysis.

And, Frank, I'm trying to understand from you. From the perspective of this risk adjustment/risk stratification, are they both going on right at the same time and all the data is going to be pushed out to show the adjustment and the stratification? I'm just unsure what the process is at NQF right now around the sociodemographic factors.

CHAIR OPELKA: Yes, it's going to be up to the measure developer for a specific measure that they bring forward. And I think most measure developers were pretty well engaged in the white paper that came out from the NQF regarding this and heard the discussion.

And there were two sides, and they were eloquently stated in that discussion. And I think Jack did a great job summarizing the stratification side. And the risk adjustment side were those who were really looking to look at the population as a whole and have a regression model that corrected for socioeconomic

status. And that's also a reliable reasonable request to put forward, but they have different outcomes.

As a safety net system I actually want the risk stratification. I want to know where the problem is so that I can go get funding. I'm under-funded. I need help. And I can't do that if I'm regressed to the mean and I look good. So I need as much of the truth as I can get to get budgeted to solve my problem.

That's different from someone else who's not in that same bucket who's saying we take care of this population in addition to everything else. Please don't punish us for taking care of that population. We want regression and we want a different adjustment. And those are both rational arguments and they're just fit for purpose.

So that's the challenge to the developers when they put something into a measure now, and that's part of this thought process in the pilot. Let's not kill the idea of

socioeconomic status adjustment. It's obviously important, but let's see if we can define it.

It also gives the payer, whoever it is; CMS being the one that we talk about most here, the opportunity to use multiple levers. They don't all have to be black and white levers. They can identify a hospital as a hospital that takes care of socioeconomic challenge and they could look at that hospital using one set of adjustment factors and incentives and rewards, and they can look at another hospital from its socioeconomic profile differently. But that's not MAP function. That's payer use of different levers in the incentive programs.

DR. PHELAN: And I guess that's where the rub is, so to speak. If this gets on the IQR for a year, it can be utilized in any of the value payment programs or any of the payment or punishment programs, however you want to view it. And the concern is where that's going to fall. And I know it's not the Committee's job to do that, but I would hope our comments make some

kind of recommendation or suggestions that that's what we're concerned about. And I think that's what Nancy is probably concerned about from her hospital side, too.

Is that an issue for you, Nancy, like where this is going to go in the end?

MS. FOSTER: Yes, certainly, but quite frankly, it's been issue that's been on the table for a very long time with mounting set of evidence and any adjustment would be better than none. So move. Let's move and then let's figure out how to do it right.

CHAIR OPELKA: So, all these thoughts, Erin and Taroon get to figure out how to put it into common sense, but it's what we want to capture. It's the conversation we want to share with the Government and liaisons. So it's a very important conversation we're having and I want to get it all out as much as we can.

Sean?

DR. MORRISON: Frank, this is a different topic. Do you want me to table it or

--

CHAIR OPELKA: Yes, let's stay on this one --

DR. MORRISON: That's what I thought. Okay.

CHAIR OPELKA: -- that we have. Marty?

MR. HATLIE: I'm afraid that my question might be very naïve, but I just need to ask it because I'm a little bit unclear. When we talk about socioeconomic factors and when we talk about stratification, are we including demographic factors that aren't necessarily socioeconomic like race? It is? It's included.

And the discussion yesterday about mental illness and substance abuse, those kinds vulnerable population issues, would they be included in what we're looking at now in terms of stratifying data?

CHAIR OPELKA: You want to handle that?

MR. AMIN: So, and this also goes back

to Michael's point, the question around which variables and which outcomes is one of the elements that's really in the trial period, which is to say that we don't want to make any a priori statements about which SDS factors are really the ones that are appropriate to be using because it's very difficult to say that. It really depends on the outcome that we're trying to measure and the data that's available to developers as they're developing these measures.

The real question that NQF will be thinking very strategically about as we start this pilot starting January is encouraging developers to start bringing forward what factors were available to them and really asking the question around the empirical and conceptual relationship between those factors and the various different outcomes that are under evaluation. Readmissions is one of them. Cost and resource use is another area. But they may require different types of variables depending on what we're looking at.

So, the answer to the question is sort of it depends. I mean, sociodemographic factors are broadly under consideration. What developers can bring forward to us is still to be determined, but there's obviously a strong interest by those being measured to have this conversation be much more robust and get it started. I think that's what we're hearing from Nancy as well. So that's what this trial represents, but there are no blanket statements that I think we can make about the specific variables or the data, because we haven't even really begun that process yet.

MR. HATLIE: What I'd like to just say then is, just for the minutes, in the partnership for patients really through the patient/family engagements strand of work a lot of issues around disparity surfaced. And groups that I don't know that we were even thinking about having special issues came forward, like transgender people who are really afraid of violence in the hospital. So that was in a way the voice of the American

people coming up to that campaign because we didn't get patients and families in a really robust way. And I'd just like to be included in general in thinking about what's important when we measure outcomes.

I am not a technical measurement person, so that probably wasn't eloquently stated enough, but I hope you get my drift. I think it is a really important issue for us to think about going forward. Thanks for the time, Frank.

CHAIR OPELKA: All right. Thank you.

Cristie?

MS. TRAVIS: So this is a clarification as well. It's my understanding that when the measures go through the trial period that they will present specifications for stratification as well as adjustment. And I assume that there will be data relative to that from a testing standpoint and some issues around that. I mean, that somehow we'll get some information on that.

But as, Taroon, you indicated, it will

be up to the developer, or maybe Frank, how they use the measure moving forward. So is this our time, I guess is my question, that if we want to say to CMS we would like for you to actually publicly report stratified data, if it comes out? If you get approval, NQF endorsement for SDS adjustment, that we also want you to publicly report stratified data as well as any SDS-adjusted data? I'm trying to see if this is the time for us to say that?

CHAIR OPELKA: No, I think that belongs to this entire pilot project until we learn what's coming out of there. We're kind of getting back into the development side of things --

MS. TRAVIS: Okay.

CHAIR OPELKA: -- and the endorsement side. And it's outside of our scope. It's --

MS. TRAVIS: Okay.

CHAIR OPELKA: -- definitely --

MS. TRAVIS: That's fair.

CHAIR OPELKA: -- an NQF scope issue,

and it's with that whole socioeconomic discussion, the white paper and the pilot will help bring to us --

MS. TRAVIS: Right.

CHAIR OPELKA: -- but you're getting ahead of it.

MS. TRAVIS: Okay. Thank you. That's why I wanted to ask.

CHAIR OPELKA: So what we have is really how Taroon framed it saying that Nancy's request on this is a conditional support, NQF endorsement and all these caveats that are built into the pilot. Okay?

MR. AMIN: I guess one of the additional questions that I have for the group, particularly Nancy, since it's your motion, is that these measures on the calendar are updates. I just want to be clear about how does a question around SDS adjustment relate to the issue around updates, or is this a bigger signal that we're trying to send as it relates to the actual endorsed measure that's in the program, which is

a little bit out of scope, but I'm just trying to understand exactly how this relates to the updates that are in front of you.

MS. FOSTER: I know this will come as a surprise to many people around the table, but we've been trying to send that signal on the measure that's in the program. That notwithstanding, it is my understanding, and particularly after a conversation this morning with Susannah, it was that this will indeed sweep a bunch of patients into the measure that previously have not been in the measure. And so, a significant expansion of the patient population without addressing the significant issue I think is just wrong.

CHAIR OPELKA: Okay. So what we have is Nancy's motion as stated. I need a second.

(Off microphone comment.)

CHAIR OPELKA: Thank you. So we can vote on moving this measure at this time as a conditional support as we've so identified. So we've voting on do you agree with the motion to

move it?

MS. IBRAGIMOVA: So the question is hospital 30-day all-cause risk standardized readmission rate following pneumonia hospitalization, do you agree with the motion to move to conditional support? Vote one yes, two no.

(Voting)

MR. AMIN: Just for the record, the two conditions include the consideration for SDS adjustment during NQF's upcoming trial period and that these updates are reviewed by NQF and endorsed.

DR. PHELAN: Should it be adjustment and stratification, or just adjustment?

CHAIR OPELKA: We're saying socioeconomic status adjustment, which allowed for both risk adjustment or risk stratification.

MS. IBRAGIMOVA: Can you try voting again. We're missing five.

So the results are 78 percent yes, and 22 percent no.

CHAIR OPELKA: All right. Thank you very much.

So the next is the hospital 30-day all-cause standardized mortality rate following pneumonia, and this is moved to do not support. Richard?

DR. BANKOWITZ: So my rationale on this is we have expanded the population significantly. I do think that looking at inpatient mortality rates for community-acquired pneumonia is very important. I think it can tell you a lot. You can make a lot of inferences about the hospital. But now we've included aspiration pneumonia, which is basically seen in patients who are debilitated, have had a stroke, who are in a nursing home, maybe have had alcoholic or drug-induced stupor and also septic patients who are arriving at the door in a state of sepsis, and I have no idea what that is going to do to the usefulness of this measure.

I would like to see what it does to this measure and how the status of hospitals

change when we make this pretty broad inclusion before recommending it to be included in public reporting. I think I personally need to see that data.

Now, I know the trend has been we defer; I'll use the word "defer," to NQF for the scientific validity, which is what we should do, but I also think we need to understand what those changes have done for the suitability of public reporting. I know that's a little bit swimming upstream because it's not what we've been doing; we've been kind of deferring to NQF, but I'll still make the motion to do not support.

But the signal I want to send; and you can maybe help me do this with the motion, is it's important to do this. This is an important measure, but we need to understand what the changes have done before we include it in public reporting. How is it best to do that? Is it best to say, we'll condition it on NQF, or is it best to say we don't support and in the hopes it will come back here again?

CHAIR OPELKA: Sean?

DR. MORRISON: And I just had a comment for the last time. This was the comment I wanted to make before, is I do have a little bit of worry about some of the risk-adjusted rates, particularly around mortality and readmissions as more and more communities get better equipped to take care of these people outside of the hospitals. So what happens is the hospitals may actually be penalized because people never get the opportunity to be admitted. So that as hospital-at-home develops and patients with what would typically be hospital-treated pneumonia are treated at home, they actually never enter into the denominator.

And your comment, Richard, about perhaps nursing home residents with end-stage dementia who actually may be treated in the nursing home and never actually be admitted into the hospital will never enter into that denominator. I don't think it's an issue right now, but I do want to put it on the record as

something we need to think about moving forward and to track to see if the denominator changes.

CHAIR OPELKA: Susannah?

DR. BERNHEIM: So again, this is Susannah Bernheim for Yale CORE.

I have some of the information you're asking about, and I'm happy to share it. You just need to help guide me in terms of again when we're sort of crossing a line into things that you'd rather going to the scientific community. But I can give a couple of sort of high-level pieces of information that may just help the Committee understand why this change came about and how significant it is, if that would be helpful.

CHAIR OPELKA: Please.

DR. BERNHEIM: So the first thing to understand was this wasn't thought about by sort of trying to expand the population per se. It actually came about because a couple of important studies were published that suggested that there's been a lot of shifting in the way

pneumonia is coded for a whole variety of reasons. Some of it may be about payment, but it's also been about greater awareness of sepsis and understanding what should be coded as sepsis even if pneumonia was the original cause.

And what we saw in the literature and then saw in our own analyses is a big increase in the percentage of patients who are coming in with pneumonia on admission, so they're POA, but their principle discharge diagnosis because of how sick they are when they come in is coded as either sepsis or respiratory failure. But not only an increase in that, but also a really clinically unlikely difference in the percentage of pneumonia patients at some hospitals that are coded as sepsis and respiratory failure versus other hospitals.

So the concern about the measure was that we were no longer looking at similar populations across the hospitals, that a hospital that has tended to code most of their pneumonia patients as principle discharge pneumonia will

have those sicker patients in their pneumonia cohort, whereas a hospital that's moved towards using respiratory failure and sepsis code as the principle discharge diagnosis will -- their sicker patients will be pulled out of the cohort. And we were worried that it was -- and this been happening over time, that they were starting to distort and potentially bias the measure results.

So the effort behind this was to fix a problem that's been happening with coding shift. And again, this was coming out of our response to some published literature. And what we found indeed, just for you, Richard, is this change is significant. It will increase the population by almost 50 percent, which is why CMS wanted to bring it to this group.

It's not a small change. It doesn't change the overall distribution of hospital results, but it will change who is seen as an outlier. And not surprisingly, those hospitals that have traditionally had few patients coded as pneumonia and a much larger proportion coded as

respiratory failure and sepsis are going to be bringing those patients into their cohort and it will shift outlier status.

And I have some numbers. Again, I don't want to get into too much detail, but I just want the Committee to sort of understand where this came from and why it occurred. We think that it makes the measure fairer, but it's not insubstantial.

CHAIR OPELKA: Karen?

DR. FIELDS: How do you risk address for the patients? For example, bacterial pneumonias versus fungal pneumonias, especially in an immune-compromised patient population. So patients undergoing chemotherapies, bone marrow transplant, etcetera.

DR. BERNHEIM: So the risk adjustment strategy for these measures has remained the same, however, we are re-selecting risk variables to understand whether or not we need to bring new risk variables into the measure now that the population has expanded. That work is happening

right now, basically.

DR. FIELDS: But that would change the measure and the outcomes. Mortality rates would be expected to be higher in patients with more complex pneumonias like fungal, viral pneumonias. So how do we understand how to approve a metric like this without understanding why the risk factors are?

DR. BERNHEIM: So just to be clear, fungal and viral pneumonias have always been a part of -- well, now you're going to ask me to remember all of our ICD-9 codes. I believe they've always been a part of -- somebody on my team is hearing me and I'm trying to remember exactly what we do about viral pneumonias.

But in general the broad range of pneumonias have always been included. The overall rate will change slightly because there are more patients being brought in, but the outcome remains the same. It's 30-day mortality. And the risk standardization and sort of measure methodology is the same, but the risk adjustment

factors will be updated to reflect this population.

DR. FIELDS: And does that include bone marrow transplant?

CHAIR OPELKA: We're getting off our field now.

DR. FIELDS: The only reason I ask is --

CHAIR OPELKA: I understand, but --

DR. FIELDS: -- because the general hospitals that --

CHAIR OPELKA: I understand. We have --

DR. FIELDS: -- have large academic cancer programs --

CHAIR OPELKA: We have --

DR. FIELDS: -- are --

CHAIR OPELKA: Karen, we have a process, and the process is if we want better risk adjustment, we go through the NQF endorsement process. If we want to know the

measure specs, we go through the NQF endorsement process. We cannot do the technical work, the expert panel work or the endorsement work here. We'll never through these measures. So that's not our job. We've gotten afield here and we've got to bring it back in.

If there are concerns about this measure that need NQF endorsement and its processes and its rigor, then our recommendation is to conditionally support or do not support. And that's how we have to voice it. We cannot walk through the specifications of all these measures. There's just not enough time.

(Off microphone comment.)

CHAIR OPELKA: It's really got to be brief because we're off track.

DR. BERNHEIM: So people know, we look back at all ICD-9 codes in the inpatient and outpatient setting for each of these patients over the prior year and see what comes into the model. So everything is on the table for being in the model. It's pretty robust for claims

data.

CHAIR OPELKA: Sean, is yours back up or --

DR. MORRISON: Oh, I'm sorry.

CHAIR OPELKA: Okay. Emma?

MS. KOPLEFF: I understand Richard's dilemma and I know NQF has worked really hard over the last few years to make the endorsement discussions and the MAP discussions flow together. And I think we've come a long way.

If I could offer sort of a reframing, maybe this will help. Again, sort of going back to the question I asked earlier. If we don't support this measure, we will see the continued inclusion of the existing measure. And as we've just heard, there's some new evidence that's been published that speaks to issues with the current measure. So I do think there's sort of a moral/ethical/academic responsibility to respond to new evidence, and I think that's what CMS is doing.

That might not resonate with you, but

I'm offering that as this is the choice we're faced with even if it is somewhat square-peg-round-hole-kind of thing. I'm done.

CHAIR OPELKA: So just going back and forth and trying to catch the spirit of both these conversations, I think what Richard was saying is that he does not support this measure without fully understanding these changes and what they mean and whether or not it would fit within a public program. And he can't make that judgment without that information, so he moved not to support the measure. An alternative would be a conditional support that meets these requirements that Richard set forth. And he mentioned that in his comments, but he elected to go forward with a do not support recommendation. So the motion that we have is do not support.

Michael?

DR. PHELAN: And I guess I would just add to that that all of these measures are going to be very iterative in nature. They're going to be rolled out and then, oh, wow, look, there's

been a whole bunch of change in coding over the last two years. Maybe we need to add some things to it.

And I would be voting for conditional support in this situation and not not support, because this is already a measure that's currently being used. It's out there.

But I think we have to understand that this is not going to be static. And a lot of these measures which you support, they're going to start adding data into it and adding some modifications, that the idea of not supporting them just because we haven't seen the data yet, I don't think it does it fairness to say that we shouldn't support. We should probably conditional support.

So I would be in the category or the group that would probably conditionally support on the idea that all these measures are going to change over time because they're going to get better. There's going to be sociodemographic factors that are going to be put in. Every

single year they're going to be an iterative process. And it goes to the idea of like throwing the baby out with the bath water. It's a good measure. Let's see what some of the data comes in on it and probably recommend conditional support based on what we see from the data.

CHAIR OPELKA: So, I think that's a theme that is carrying over from yesterday as well and Dan's comments earlier this morning; that is, measures are now getting in to use and they're getting updated. We've got to deal with how do we actually go through the MAP process in updating measures? And I think that's kind of the discussion that's circulating around the room right now.

And so, Michael, thank you for highlighting that.

Nancy?

MS. FOSTER: So I really appreciate your motion, Richard, and I'm sort of torn between the do not support or the conditional support because it's clear to me this needs to go

through NQF. This needs to be reviewed and careful thought needs to be given to both what's not in there now that should be coded and included in this population that's being measured and what will get swept in when we add these new codes that may not be intended. Lots of thought going to that. So part of me wants to support your do not support motion because I really would want this to come back to the MAP before moving it into the IQR Program with the new specs so we more fully understand what we're doing here.

And then to the point you just made, Frank, it seems to me that the other theme that comes out here is there are enormous amounts of communication that are going to have to go on around these new measures, not just when they spring on the interested stakeholders, but starting now. I mean, what are the changes? What should practitioners expect? What should the public expect? What should other users like Leapfrog Group and U.S. News and World -- what should they know about it now so that they are

adjusting their thinking in how they use these measures for the changes that are to come?

CHAIR OPELKA: Any other comments? All right. So then, Andrea?

DR. BENIN: Frank, I think to your comment and to what Emma and Mike were speaking to a little bit, I'm just a little bit disturbed, and perhaps it's my own internal inconsistencies, but sort of the inconsistent perception of metrics as they're changing.

So in general, we didn't have a lot of conversation about the NHSN measures, which are undergoing pretty substantial changes, like quite substantial. And I don't think we know how those are going to perform, but in we were I think generally supportive of leaving those. But then this is a different measure and we have a different approach to it.

And so I don't know if we do need some overarching way to think about these things as they evolve and think about them a little bit differently and think about the different

programs a little bit differently. The IQR has one set of risks to it. The VDP and the readmission reduction have different sets of risks to them. So I don't know if we need a sort of overarching mental model that can help us develop some consistency.

CHAIR OPELKA: Thanks, Andrea. The model that's emerging is that you support it and you live with the change, you do not support it and say bring the change back, we'll live with the older measure, or you can conditionally support it and based on those conditions, we will give you our nod. And the measure that we have on the table right now is that we're recognizing this measure in the program. We're recognizing this measure is coming forth with change, and we've heard about the change. And now the question before you is do you support? Do you not support? And we have a do not support motion.

Yes, Nancy?

MS. FOSTER: Just quickly to Andrea's

point, I think for me one of the key ingredients in the difference between a conditional or a do not support is really around NQF endorsement. And I say that recognizing that I said conditional support for the readmission measure, but this measure has not been to NQF, this revamped measure has not been to NQF. The NHS ones have. So we've seen something about those.

DR. BANKOWITZ: Well, I mean, the whole tenor of the conversation is moving towards the fact that we want progress to be made here. And clearly trying to update this measure to take into account the biases you claimed is a good thing. We don't want to send the message that that's a bad thing to do.

So mindful of that, I would rescind my motion and I'll make a motion we move forward with approval with conditional support of NQF.

CHAIR OPELKA: Any further discussion on that?

(No audible response)

CHAIR OPELKA: All right. So that's

the motion we have. It's a conditional support with NQF endorsement. And can we put this motion then forward for a vote?

MS. IBRAGIMOVA: So the question is hospital 30-day all-cause with standard mortality rate following pneumonia hospitalization, do you agree with the motion of conditional support pending NQF endorsement? One yes, two no.

(Voting)

MR. AMIN: Again, just for the record, the motion is conditional support pending NQF review and endorsement of the changes.

MS. BAL: Also just so everybody knows, this new voting software, once the slide is in full screen, you can start voting even if Laura's talking. So you don't have to wait for her to tell you to vote. Just for your information.

MS. IBRAGIMOVA: The results are 100 percent yes, and 0 percent no.

CHAIR OPELKA: You see that, Ron?

CO-CHAIR WALTERS: Yes.

CHAIR OPELKA: You see that?

(Laughter)

CO-CHAIR WALTERS: In your face.

CHAIR OPELKA: Someone get a picture of that on my behalf.

Okay. So then we have -- I'm sorry. Mitchell?

DR. LEVY: It's a little late in the meeting to ask this, but what does the Coordinating Committee do with the conditional support? Do we have a track record of that? So the Coordinating Committee gets the information that we conditionally support this measure pending X. And in general, do we know what's happened at the Coordinating Committee level with that?

CHAIR OPELKA: The Coordinating Committee gets our report and they can accept our report. And they can accept our report as is and it goes to CMS with the conditional support, or they can look at it as a consent calendar and pull off something for discussion at the

Coordinating Committee. They rarely do that.

We have one unsettled issue from yesterday that will go to the Coordinating Committee and for them to discuss. That was our -- I think it was the advanced air plan issue where we split. It was like 39-17, 40 something, maybe 40 percent. But I think that was our split. That issue will then go to the Coordinating Committee and we'll share with them the collective wisdom of our group.

DR. LEVY: Yes, so I guess my question really is for CMS. I mean, being an outcomes person, I'm just wondering are we just making ourselves feel good by doing the conditional versus full support? And so when CMS gets a conditional support measure, has the experience been that they don't incorporate it into IQR until those conditions are addressed or in general, do those still get adopted? Because I think it would be good for us to have some sense of that.

I don't know that you're going to be

able to answer that right now.

CHAIR OPELKA: I think I'm going to let CMS answer too, but I would share with you that the conversation that we have is heard. And I think that is invaluable. It's taken by CMS, by all their teams, very seriously. It's also taken by their measure developers who are working with them who may have missed one of these aspects of all of our concerns. And so they listen to all of that. If we support it, it's a ringing endorsement. If we conditionally support, and it's got NQF endorsement on it, that carries a rigor statement. If it's got other concerns that we want to measure or put up there for them to consider, that carries another set of concerns. So sharing that information from this group actually is extremely important.

Pierre?

DR. YONG: Sure. Thank you for that question. I think it is an important question and we certainly want the MAP's input. It is taken very seriously. We discuss the MAP's input

after we receive it and in the course of our considerations about as we develop measures and as we consider measures for implementation in our programs.

I also just want to reiterate that this is not the only opportunity for public input into what measures get implemented into our programs. Certainly all of these programs go through public rulemaking, through proposed and final rulemaking, so there will be further opportunities for the public, including members of the MAP to make and voice any support or concerns around measures we want to implement into our programs and we certainly need to consider those as we finalize the rules and measures in our programs.

So there will be multiple opportunities ongoing in the future. And in our rules we actually if you read them, we also do reference what the MAP's recommendations are for each of the measures we put into our programs. And so we acknowledge whether they supported it,

whether they said conditional upon NQF endorsement and we acknowledge where it is in the NQF endorsement and process, et cetera.

CHAIR OPELKA: Okay. We're now on the cardiac rehab patient referral. And this one was a conditional support pending data. I'd love more.

MS. FOSTER: Thank you. The referral to cardiac rehab is certainly consistent with best available guidelines. No doubt, this is the right thing to do. Quite frankly, getting a referral seems like a fairly low bar measure. I know there's some variation in performance.

Two things of concern to me, one, I haven't seen the data to know whether there is, in fact, a sort of a rural hospital problem here where there may not be easy access to rehab facilities for rural patients. And I think that ought to be looked at as we think about this going forward.

Secondly, and maybe some of those hospitals excluded or adjusted or something. But

secondly, the data collection methodology here as I understand it, is through the ACC, Get With The Guidelines registry, which not all hospitals participate in and quite frankly, the thought of having yet another place to send data to with yet a different set of registration requirements and changing requirements, our hospitals, particularly the smaller hospitals, are struggling with getting data to NHSN and to CMS through their vendors on time and HCHPS. Having yet another mechanism will complicate things in a way that I think will unintentionally lead to hospitals failing to get information in when they should.

The caveat I'm offering is we either straighten out how to easily make it possible for people to submit these data at no cost, very little cost, and it is totally aligned as a mechanism with the submission to CMS data or we think about a different mechanism for collecting the data. So that's why I offered the data caveat.

CHAIR OPELKA: I'm looking at measure specs and it does exclude if there isn't a rehab center within 60 minutes or miles of the patient's home.

MS. FOSTER: Thank you. I didn't see that in the specs. So I appreciate it. So I'll take my first off, and we'll just stick with the data submission in the caveat.

CHAIR OPELKA: Okay. I understand that one. Is that Michael down there? I've got glare on the card.

DR. PHELAN: But Nancy, I think most of the patients that have these cardiac rehab referral are patients with PCI, CABGs, and valve replacement. I'm not sure what percentage of PCI places, but don't they all submit data to the ACC registry if they're doing PCI? I don't know if it's like the ICD, implantable cardiac defibrillator, where it's a mandatory -- you're required if anybody gets an implantable cardiac defibrillator, there's a registry you have to submit it to -- it may be run by the government.

But for places that are doing PCI and bowel surgery, those are pretty large hospitals. These aren't small hospitals that are doing that. They may be smaller practices that may be doing it, but is there a concern from them for entering into these registries? I'm just not sure I'm hearing -- because I can see small, rural hospitals, but they're not doing PCI, CABGs, and bowel surgery.

MS. FOSTER: CMS may have better data on this, but I think you'd be surprised at what some small, rural hospitals are doing.

CHAIR OPELKA: Emma, is your card up? Mitchell, are you in the queue? Brock?

MR. SLABACH: Yes, just to follow up on Michael's statement. I think that a lot of these patients get referred back to their communities and then the primary care physicians may be the ones referring them to their cardiac rehab and that may not be immediately available. So it does -- this continuum of care is the problem, I think.

DR. PHELAN: But I think it goes to that coordination of care again.

MR. SLABACH: Right.

DR. PHELAN: You know what I mean? Everything that we're trying to do for our patients here -- to me, here's a measure that seems like a very reasonable measure if there's Class 1 evidence and we have all this, to not help promote something like this, at least from the MAP's perspective even though there's some data issues that Nancy measures, there's not too many Class 1 recommendations out there, guys.

I mean, this is one that seems to be a pretty strong reason to get our patients and our patient population to get into cardiac rehab. I don't want to say regardless of the data issues because that's a huge problem which is more and more that we add on to the hospitals, but at the same time there's not many like this that are out there that is pretty clear cut that it makes a difference in patient outcomes. For a process measure, I don't think it's that kind of a

measure.

MR. SLABACH: I think it would be good documentation, too, going forward and if the evidence becomes more readily available. Part of the problem of lack of cardiac rehab in rural communities is the fact that we have such strict physician supervision requirements for those entities. And if that was relaxed somehow through legislation, I think that could expand the availability of cardiac rehab in many of these rural and underserved areas.

CHAIR OPELKA: Cristie, before I call on you, and Nancy, we're trying to sort out the issue of where the data sources are coming from. It's lookings like it's registry or EHR or it's just paper and measure specs. So I don't know what that is. I wondered if it was claim based, but it doesn't say that. It doesn't appear that it's that.

Cristie?

MS. TALLANT: I guess that was going

to be my question kind of to Nancy about the data issue. I mean, what would we -- if we moved forward with that condition, what would resolve the data issue? I think that's where I'm a little unclear about that. I thought you might have some ideas on that.

MS. FOSTER: I think Cristie, the answer for me would be for those organizations already submitting data to the ACC, if CMS can make it easy for ACC to transmit the data to them which they've done with other organizations, so it seems like submit it once, use it multiple times. For those who are not, and I don't know what proportion of hospitals are not, but those who are not, to have an easy way to submit the data directly to CMS would be the way to handle it.

It's the challenge of thinking that we're suddenly going to end up with a requirement that all hospitals have to participate in -- have to pay ACC, have to participate in ACC in order to just submit data required by CMS. That gives

me angst. Thank you.

CHAIR OPELKA: Nancy.

DR. HANRAHAN: Speaking as liaison for the dual eligibles, this measure is really quite complicated from that perspective. I think collecting the data is one problem, but the other problem is that people often have transportation problems. It's a major factor, a barrier for them to access these kinds of services. So they may have a referral, but they may not get there.

So it's really -- the problem is are we tracking whether simply black and white, do they get a referral and that could come from a database in the hospital, but whether they get there or not is -- and whether they accept that referral is a complicating factor, major, that probably, you know, this was a measure that requires some kind of stratification on a socio-economic vein that -- and I just don't have the specifications or the data to really look at how this measure has been developed or thought through to be able to discern anything more.

CHAIR OPELKA: Nancy, it's just the referral. So if they don't accept, you still pass the measure.

DR. HANRAHAN: But even making a referral --

CHAIR OPELKA: You're identifying a gap, but not a measure.

DR. HANRAHAN: People don't necessarily accept the referral. So maybe it would be documented as being made of not made. I'm not sure.

CHAIR OPELKA: When you say people don't, you mean the patient?

DR. HANRAHAN: The patient, yes, I'm sorry.

CHAIR OPELKA: They still pass the measure.

DR. HANRAHAN: So a physician makes the referral and that gets documented in the record. And that's my understanding of what you're saying is that's what this measure will measure.

CHAIR OPELKA: That's correct. But you're pointing out a gap.

DR. HANRAHAN: I think it's a huge gap in the quality of the measure. You know, a physician can make the referral, but whether or not it actually happens is the other process that I think is even more important than making the referral.

CHAIR OPELKA: Right. So we can capture that as a gap.

DR. HANRAHAN: Yes.

CHAIR OPELKA: But the measure still is. We can't re-spec the measure. That is the measure.

DR. HANRAHAN: Got it.

CHAIR OPELKA: And there's a gap, and I think you're pointing out a disparities gap. So we'll capture that in our comments.

DR. HANRAHAN: Excellent.

CHAIR OPELKA: Okay? So any other comments on this? All right, so the motion that we have is to conditionally support this based on

the data requirements, resolution of the data questions.

Michael?

DR. PHELAN: In the -- if we don't support it, it stays in the support column, is that correct?

CHAIR OPELKA: That's correct. Brock?

MR. SLABACH: I guess it raises a question for me. So if a patient goes to a tertiary facility in an urban area and the patient is discharged with a referral, that counts even though there's not a cardiac rehab center within 60 miles of where they're ending up as a patient at home.

CHAIR OPELKA: It would not count. Those patients would be excluded.

MR. SLABACH: That patient. So then the referring hospital, I mean I go to some of Nancy's comments in terms of data. They're going to have to be getting the map out, I guess, and seeing each patient whether or not there's a referral point within 60 miles of where they

live. And you go out West and there's a lot of communities where that could, in fact, be the case. So there's -- it turns down the ability to make this reported correctly.

DR. PHELAN: But isn't that kind of their obligation if they're going to be taking care of the patient? There's Class 1 evidence that happens. I know there's an issue with the available resources, but I would imagine if I fix someone's heart that maybe I should find out where the closest rehab facility is where they can get that kind of care and it again goes to this idea of like, how do we push the idea of better coordinated care for our patients, rather than "Good luck."

MR. SLABACH: But I'm looking at this as a reporting issue, so the physician writes the order for a referral. The social worker, whoever handles that, then translates it to the patient. The patient then is discharged home and the quality assurance director or whoever is doing the data collection two weeks later has to go

through and figure out where this referral source was going and if that patient was within 60 miles of a cardiac center. How do they know -- they may have to have to a map of all the cardiac rehab centers to be able to see if that 60-mile exclusion would be there.

It presents some issues and again, we're not here to talk about the -- I guess it is a matter of efficiency.

CHAIR OPELKA: I think you raise a good point. I also think it's why God created Google Maps. I can tell you my social worker can do this.

All right, so we have the vote. So this to support the motion to move this to conditional given the data requirements.

MS. IBRAGIMOVA: So the question is cardiac rehabilitation patient referral from an in-patient setting, do you agree with the motion for conditional support based on data requirements? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 71 percent yes and 29 percent no.

CHAIR OPELKA: All right. So let's move to Calendar 2. And this was the conditional support for NQF review of testing data the Medicare population and resolution of parsimony concerns within the IQR program. These were the proportion of patients hospitalized with an AMI and a potentially avoidable complication, similarly with pneumonia and similarly with stroke. And it was during the index stay or the 30 day post-discharge period.

So any -- I'm sorry, Pierre, did you have your card up?

DR. YONG: Thank you. I just wanted to provide some background to the committee about why we had put these on the MAP, just to help the committee understand in your discussions.

These measures -- let me back up for a second. We, in our discussions, are interested in patient safety. That's a big priority for us. We saw these measures as more encompassing of

movement towards sort of a measurement of all cause harm than what we currently have in the program. We understand that these measures have not been tested in the Medicare population as of yet and so there are some issues.

We also understand that they do overlap with some insisting measures in the program, but we did want the MAP's input about the direction of these measures as potential areas for the future for implementation in our program.

CHAIR OPELKA: Thank you very much. Michael?

DR. PHELAN: Pierre, do you mind trying to explain a little bit about these measures? And I think you don't have to do it for one of them because they're all kind of similar, these potential avoidable complications during the index stay for each one. I don't think we have to get into each one, but just like the background of what was the thinking behind it and I know in your comments you mentioned towards

all cause harm.

Some of us in the emergency medicine field don't feel that patients presenting to the emergency department represents a harm in and of itself. Sometimes the only available resource for many patients to come to in a 24/7 cycle, but besides that, if you could help with me understand a little bit that would be great.

DR. YONG: Sure. I'll get started and if we have additional questions, you may ask them and staff also will provide additional input.

So essentially, these measures and they're all similar, as you indicated. They're just different conditions, include a variety of safety events that may occur related to that condition. They capture both events that happened during that hospitalization as well as within the 30-day post-discharge, events that may be related to the condition which are cited in the materials include things like hyper- or hypoglycemia, things like coma, things like gastric ulcers which may develop or hemorrhage.

They also capture things including safety events, so things like DVTs which are preventable or PEs which are preventable are also included.

And they also include re-admissions as well as emergency room visits during the post-hospitalization stay. So they are encompassing of different types of safety events as well as readmission type events.

DR. PHELAN: And are they all weighted equally or is there a difference in their weighting?

DR. YONG: We have made a measure development -- do you mind repeating the question?

DR. PHELAN: How are the different events weighted?

DR. RASTOGI: I'm Dr. Amita Rastogi. I work at Francois de Brantes and the Bridges to Excellence. We are the measure developers. And as they were endorsed by the NQF as described by Pierre Yong, exactly right. From the weighting point of view, we just looked at them equally.

So there is no weighting. If you have one of these potentially avoidable compilations, it is a yes. If you don't, it's a no. So you discount all of the potential avoidable complications one by one. And you just look at the proportion of patients that that condition, say the AMI, how many of them had this complication.

DR. PHELAN: Do you weight a hospital readmission the same as a single ED visit with a discharge home?

DR. RASTOGI: That's right. Any of these -- if there's a readmission, it's counted once. If they have a urinary tract infection during the hospitalization, it's counted as a one. Yes.

CHAIR OPELKA: Mitchell?

DR. LEVY: Sorry, I'm just trying to understand. I'm looking for the list of each of the pacts and it says examples. And in particular, on this one for stroke, the idea that an acute MI is an avoidable complication in stroke patients, not necessarily true. And I

realize that's why it's a potentially avoidable complication, but I'm just trying to get a sense of how you could sort that out?

There are some clear EDT, so we'll agree that that's an avoidable complication. An MI is much harder case to make. And how is that not going to be lumped together especially if the hospital has a more elderly population or at-risk population? Does that come out in the wash in the quartiles? I'm not sure I'm articulating this correctly, but I'm nervous about the P of the pact in this.

DR. RASTOGI: That's right. And these questions were debated very extensively during the NQF endorsement process, especially, for example, coma in the setting of stroke. It is listed as a potentially avoidable complication. So the neurosurgeons did not like that. And the question that was raised -- I'm a cardiothoracic surgeon by training myself and I've done heart and lung transplants.

And the question that comes is can you

avoid one single coma? If yes, then it's potentially avoidable. Just like death. Can you avoid death? Some of the deaths are not avoidable, but some are. So we discount them. It's not that you overtly punished for one of them. That's why it's a comprehensive picture. Each one gets weighted and overall if a particular hospital is having more complications than another, then it is a good measure of a comprehensive performance of that hospital.

DR. LEVY: So you're saying it comes out in the ranking of the quartiles in terms of how you perform. If you are performing in the lowest quartile consistently because you have a pact even if seems like not related, the fact that it's coming up a lot raises the question of whether it is avoidable.

DR. RASTOGI: That's right. And we don't really stratify by quartiles. We just do a continuous count.

CHAIR OPELKA: Just so everyone is clear, I mean this category is a little bit

wordy. These are NQF endorsed below 65, so you could say that what we're seeking is that this is a change in the measure specifications that require NQF endorsement as well. That's basically what we're stating in our proposal here.

Nancy?

MS. FOSTER: So, Frank, the second part of the caveat or the conditions for this has to do with alignment with the -- what word did we use here?

CHAIR OPELKA: Parsimony.

MS. FOSTER: Parsimony was the existing measures. And I'm struggling here. On one hand, sort of having an over-arching measure may be a good thing, but the fact that these don't -- they identify something that someone calls potentially avoidable but not necessarily avoidable gives me heartburn because we want to focus attention on those things that we know are really avoidable. And we have a series of measures already in programs built on a framework

of having readmissions sort of separate from value-based purchasing, separate from hospital-required conditions.

So it seems to me it would be really hard to think about how to use these in ways that would add to the dynamic of pushing forward for quality improvement. That in fact, we may be better off with the separate readmission measures, more direct HAC measures and so forth at this stage of our progress, so that we are targeting people's quality improvement efforts on things that we can say with some confidence really need improvement. Is that understandable?

CHAIR OPELKA: Dolores?

MS. MITCHELL: Just very briefly, I will not have the temerity to deal with the technical issues since the developer is here and it's above my pay grade anyhow. So just to say that I think given the amount of people who are involved or who are patients in these categories, it may not be perfect data and I understand that NQF is doing some further testing on -- not NQF -

- CMS is doing further testing, which, on the Medicare data. But if that is, in fact, the case, it seems to me the importance and the widespread nature of the people who are affected by this that we ought to go ahead. I speak as a purchaser because I'm paying for a lot of it.

DR. GOODRICH: Just to clarify, so as specified, this is 18 to 65, hospital programs, IQRs and all payer programs, we can use data from multiple age ranges, but we would, of course, need to also include the Medicare age range. This is a measure that as specified at this point in time is not something we could use immediately in the program, but we learned about this measure. We're very intrigued by it and wanted to get the MAP's input on the direction of this measure which ultimately, if we were to use it, would, of course, need to also include and be tested on the Medicare population.

CHAIR OPELKA: Emma.

MS. KOPLEFF: Thank you, Dolores and Nancy for your comments. I think Nancy offers a

useful framing or something to consider that on the one hand we have patient safety which is a priority area and we have a number of individual measures addressing those issues. And what this measure is offering is again to Pierre's summary, more of an all cause harm kind of measure. And just really -- I'm really trying to channel Helen Haskell and do my due diligence here as her representative. For her and Mothers Against Medical Error and other consumer groups that are really focused on patient safety, there is some sort of culture shift, I think, being supported by the idea of having a measure that really addresses a wide range of all encompassing potential safety issues as this measure tries to do.

I hear the issues about what is avoidable or not avoidable and I think those are relevant issues for the clinicians. And I'm just offering that from -- on the flip side, a lot of these measures, the measures as we've spoken about, aren't useful for consumers today. I

think this one could be. It's getting at that idea that you really have a patient having the ability to ask what are my chances or is X hospital versus Y hospital safer for me and trying to use that information.

CHAIR OPELKA: Marty?

MR. HATLIE: I totally agree with Emma and I just want to say it more strongly than Emma said it. I do think this is very, very important to consumers. I think there is a culture shift going on. I don't think patients or family members of patients want to see their loved one fear in the hospital. It's really good at one or two or three things, but not good at other things. So I wanted to just strongly support and say that this again reflects a terrific amount of feedback we got during the Partnership for Patients, not just from patients and families, but from hospitals that we should be moving to engage leadership and some of our healthcare workers and everyone in these all across our measures.

I know there's a lot of data issues. I'm hopeful that those will be looked at carefully, but I want to support the direction of this very, very strongly.

CHAIR OPELKA: So let me just clarify for the committee. The request of you right now is do you want to move this out of its current consent calendar?

MR. HATLIE: I do not.

CHAIR OPELKA: We're vetting the measures and if we're good with the measures on the consent calendar as they are, that's a different discussion. For now, the question is do you want to keep these in this consent calendar or do you want to move them?

MR. HATLIE: I strongly support with keeping it on this consent calendar.

CHAIR OPELKA: Okay. Wei, was yours up? You're down. Dana.

MS. ALEXANDER: So I would, I guess, support encouraging direction, but I stand with Nancy on this is that while I think it's an

interesting measure, I think it has some relevance where are today in all of our priorities in front of us. But I think that there are other measures that are in place with readmission support and so forth that are in a better position.

CHAIR OPELKA: So am I hearing a request to move?

MS. FOSTER: So I will move that we move this from the current place on the consent calendar to encourage further development.

CHAIR OPELKA: Okay, that's Calendar 7.

MS. FOSTER: That would be Calendar 7.

CHAIR OPELKA: Okay.

MS. FOSTER: And we've already basically covered my rationale, but I think we may find some surprises in the Medicare population which has not yet been tested that makes this measure further refined.

In addition, I note that even when it was submitted to NQF, and endorsed by NQF without

this, surprisingly to me, there has been no reliability testing done on this. So to your point, Emma, I don't know if this actually gives patients a signal they can use, a signal that's accurate about which place is safer or not. So we need to work on that.

CHAIR OPELKA: All right. Is that a second?

DR. ENGLER: I'll second.

CHAIR OPELKA: Okay.

DR. ENGLER: I'll second. And my second is because of what Nancy just managed and I think is important. This is a very important consideration. I'd be very, very interested in moving this ahead, looking at the results of the tests and the field testing in particular to get to Mitchell's point and also to Marty's point on whether or not this is a big P or a little p. I think that's really important.

I also believe, too, that we want to make sure because I've spent a lot of my time on harm reduction activities. And I know we're

growing that field outward to encompass more and more potential harm events. And we're all in favor of doing that. I just really would like some testing being done on this. And moving it to a testing category would help us with that. I'd be more comfortable. Thanks.

CHAIR OPELKA: Pierre?

DR. YONG: Thank you. Can I make two comments? One was we very much appreciate the discussion because I think that's what we wanted to hear was whether this kind of measure was valuable. And going back to, I think, one of the points made earlier about the value of having more targeted measures versus having a more global measure, I would throw out there another idea to consider is that they're mutually exclusive things.

You can have potentially a global measure and then also have additional reporting on more specific conditions as well and that way, for those who find the global measure more helpful, that may be one place where you start

and for those who want more targeted information may be able to then dig deeper. So that's sort of one point.

I think the second point I just wanted to ask a clarification question about this idea, this motion to move to encourage direction because I think my understanding of when we've used that previously it's been used for measures which have not been fully developed. This is a fully developed and endorsed measure has not been tested in the Medicare population.

CHAIR OPELKA: It is not endorsed. It is not endorsed in its population, so the measure fails in the Medicare program. It's been endorsed -- measure specs as is have passed, but not for this program. So this would need to be tested for this population, but it would need to be tested to show reliability and validity in this population. So it's NQF endorsed at this level.

MR. AMIN: Can I add to that, Frank, as well?

CHAIR OPELKA: Yes.

MR. AMIN: I was going to raise that as a point as well. Just so that everybody is following along, including members of the audience, we do have three categories for fully-developed measures, two more measures that are under development. Nancy's motion is a category for measures under development. Now the way that we've characterized that is fully developed measures and fully tested measures.

And in this case, since we're looking at these measures being tested for the Medicare population, it wouldn't go all the way to the second route. While they're obviously fully endorsed, specified, and tested for the under 65, what this committee is looking for is that to be done for the 65 plus crowd. And as I understand Nancy's motion, that's why it's being moved in addition to other concerns that Nancy has raised to be encouraged for continued development category.

Is that clear? I just want to make

sure that that's clear. So this is an order. And it is also consistent with our framework for how we've divided measures into fully developed and specified and then those that are quote, I use that term very loosely which is measures under development, and fully tested. And since this measure hasn't been formally reviewed for the testing under the Medicare population, it still fits within the rubric that we've been operating. Thank you.

CHAIR OPELKA: Richard?

DR. BANKOWITZ: So I want to support this notion that we move it for consideration for further development, particularly because I'm concerned about the reliability testing. This is incredibly important. It's a very important measure. Do we need to understand potentially avoidable compilations? Absolutely. But this is a very difficult thing to measure.

And I want to let CMS know that as they consider this measure, they really look at the sensitivity of this measure and the

predictive value of this measure. I think it's probably, right now as it stands, a great measure for quality improvement because in the case of the coma that we talked about. Yes, if we find one coma out of five, sure, I would like to know about that. But do I want five comas reported where four of them are false positive? No, I don't think that serves anyone's interest. So we really need to consider the false positives that we're going to acquire here.

The other thing that we need to consider is as you look for these complications, and you simply tally them up, a lot of these things proceed in a causal chain. So you may have a pulmonary embolism which may be accompanied be accompanied by atrial fibrillation and there may be a fluid electrolyte disturbance. So you've already gotten three things and probably four if we consider respiratory abnormalities. And we need to tease apart what's real and what's just sort of part of this causal chain that we're going to tally up. So those two

things need to be really looked at carefully.

CHAIR OPELKA: Michael?

DR. RASTOGI: I'd like to add.

CHAIR OPELKA: Michael? I don't want to get into measure specs. This has to be pertinent to the discussion of movement from one program to another.

DR. RASTOGI: Just a clarification on that last point. If the patient had any of the complications, it's just counted as one. Yes. So if they had five complications or one, it's counted as yes, this patient had a complication.

CHAIR OPELKA: Okay. Michael?

DR. PHELAN: First, can we just look at the measure itself on this --

CHAIR OPELKA: There's three of them.

DR. PHELAN: One of them, just in the description at the top of it. I have it on mine. I think a little bit -- right in there. I was looking for -- for some reason I thought there was a weighting scheme. It's 50-50. All right.

But just to the point, I think this is

incredibly useful data, both for patients and for hospitals. I think hospitals would really like to know, especially the comparative data, to see where they fall to be able to identify places so they can actually do improvements. So I just want to add that as -- I think this is the natural progression of looking at big, you know, HACs and things like that.

And then looking at just a much larger data set on disease condition specific. And I'm glad Pierre is talking about even a larger, just all potentially avoidable complications or acute care issues that happen after a 30-day admission. I think this is incredibly important data and I'm hearing at least the patients are going to want this data. And I'm certain the hospitals want to do it so they can try to improve the care they're giving to their patients.

CHAIR OPELKA: Emma?

MS. KOPLEFF: Taroon, thank you for offering some further explanation on the classifications. I'm still just struggling a bit

because I am in thinking about the fact that we will eventually go to a vote on something on this motion, I'm not actually seeing a difference between the motion and what I'm reading in the support guide which says conditional support pending NQF review of testing data in the Medicare population in resolution of parsimony concerns, etcetera, etcetera. You know what it says.

So just before we go to the vote, I hope we can clarify. I think we're sort of mincing some words and a lot of us are saying I think the same thing about --

CHAIR OPELKA: Let me clarify. So where it stands today, the conditional support with review of further testing really translates into it has to go back to the NQF for endorsement. It's not endorsed. And to do that, they would have to test it in this age group and look for reliability and validity testing in the age group. So that would be the first part of that condition.

The second part of that condition is it would then go through a harmonization exercise with current measures in the field. And somebody would fall off. A measure could potentially go away. So it's looking at the current measures that would be looking at these sorts of things and this is to the point that Nancy and Dana were talking about previously. So it effectively would be a harmonization exercise which says would we take a current measure and replace it with this measure once it's had NQF endorsement?

The motion that we have is to encourage further development of this measure, of these three measures which really means taking it into the NQF process, having it go through the NQF endorsement and then future, bringing it back to the MAP. So that's the difference.

MS. KOPLEFF: I'm still getting my head around that, but thank you.

CHAIR OPELKA: Okay. Sean?

DR. MORRISON: I'm still getting my head around that, too. I do want to, I think I

want to support the measure because I'm very concerned about not so much the reliability, but the validity of this measure in a Medicare population with multi-morbidity that intersect rather than a younger population where it's much easier to tease out what is a complication of an event versus what is a result of a comorbidity or multiple comorbidities.

And the fact that this hasn't been tested in the over-65 population, both for reliability and validity, I'd like to see that NQF endorsement, but I think I'd also like to see it come back here.

CHAIR OPELKA: Okay. So you're supporting the motion.

DR. MORRISON: Yes. I've got my head around it. Yes, I'm supporting the motion.

CHAIR OPELKA: Okay. Marty?

MR. HATLIE: Frank, so help me with this, too. The reason that I am not supporting the motion and support the original recommendation is that I'm concerned that by

supporting the motion it would slow the process down. I don't know if that's an accurate perception on my part. Because I do think this is a movement, a direction that I think many of the hospital associations in this room already support. So I want to send a strong signal that this is the direction that I think patients and hospitals are going and that's why I support the current recommendation.

CHAIR OPELKA: You got it right. You're correct. It would add another MAP cycle into it if we just encourage rather than the current proposal which basically states once there's NQF endorsement, it would then go through a parsimonious harmonization process. Let's look at other measures that are similar and decide which one we want in the program.

DR. MORRISON: Thank you.

CHAIR OPELKA: Okay. Wei?

DR. YING: First of all, a clarification question. What is the difference between what we are proposing, no, actually, why

can't we put it into Calendar 5 which is conditional support ending in NQF review and endorsement? Isn't that what we're trying to do? We want NQF to look at the data coming from Medicare population and if it works, we will endorse.

CHAIR OPELKA: That's a separate motion.

DR. YING: Okay. So then to echo some of the comments made earlier, I like this measure because it's at the global level. Just like the readmission measure, ideally we want something at the global level for each individual and each purchaser or hospital to look whether they're having an issue. And if they have an issue, there will be an individual measure downstream for them to figure out where is the most problematic thing that they should be targeting. Without this global view it's very hard for us to know which hospital has an issue as a red flag. We have to look at individual measure which doesn't represent a big picture view from that

point of view.

And then in terms of the controversy around the potentially avoidable, that has always been the issue from Day 1 of these measures. I think the developer has heard the comments during the years, and they have tried to make that somewhat better and to go back to what Mitchell was saying, if you look at the measure specification, again, the developer can correct me if I'm wrong, did you have a weighting scheme in terms of expected pact rates, is that right?

So it's not a straight-forward observed pack. They sort of have an OE ratio type of concept in there. So that may address a little bit in terms of which potentially avoidable complication is outweighing the other, but in terms of the clinical capacity.

CHAIR OPELKA: Mitchell?

DR. LEVY: Having expressed my concerns, I am very strongly in support of the measure. I do --

CHAIR OPELKA: I'm sorry, the motion

or the measure?

DR. LEVY: So the measure as it stood. What I'm a little lost on is the motion looks like what the calendar is and that's where I'm a little --

CHAIR OPELKA: No. The motion --

DR. LEVY: So that's not the motion.

CHAIR OPELKA: I can't -- see, let's see, conditional support, review --

DR. LEVY: That's actually the calendar then.

CHAIR OPELKA: That's the calendar. The motion is to remove it and encourage further development.

DR. LEVY: Right.

CHAIR OPELKA: And it's different from cure NQF endorsement where it currently sits on the calendar, on Calendar 2. The reason it's on Calendar 2 is there are competing measures. So if we promote NQF endorsement, then there's a risk of us adding another measure that's overlapping with other measures in the program

and therefore there should be a parsimony exercise, a harmonization exercise to pick best in breed so that we don't have overlap. It didn't go into Calendar 5 which was simple NQF endorsement and put it in the program. It went into Calendar 2 which is NQF endorsement and then harmonization.

The motion is to remove it from 2 or 5 and put it in 7 which is to encourage this direction, get NQF endorsement and bring it back to the MAP which was Marty's point, "Does that slow it down?".

DR. LEVY: Right.

CHAIR OPELKA: And it does.

DR. LEVY: Yes, great. One more question.

CHAIR OPELKA: Did I get all that right?

DR. LEVY: Yes, that helped, at least for me that clarified what the question is. The last thing I have is this says review of testing in the Medicare population and the measure is for

18 to 65. So is that not a --

CHAIR OPELKA: So we would be respec'ing the measure. This is now the measure is spec'd today. The reason it has to go back to the NQF is that it would be respecified to include a new population which requires additional reliability and

DR. LEVY: Great.

CHAIR OPELKA: Okay? Nancy.

MS. FOSTER: Very quickly, if Kate and Pierre are looking for a signal, I think you've heard it from others, but a very clear signal that we'd like to send is we would like a broad based harm measure. I know you're aware of at least one other that's in the process of being developed. There are others in the process of being developed. They are all worthy of consideration. Not all are worthy of implementation simultaneously. That would be problematic. But getting to a place where we have a broad based harm measure would be a good thing.

The question, of course, for me are the two that I raised earlier. Are they fairly targetting those things that actually are preventable harm? And are they doing so in a broad population? Because that's the sweet spot. And it's hard to judge these three measures alone when I know others are being developed with the same concept, but very different structures and getting to a place where we know what's the right measure for inclusion in this program, that doesn't step all over the readmission measures and do other things that may be confusing rather than helpful in getting people engaged in reducing harm would be my goal.

CHAIR OPELKA: Dolores?

MS. MITCHELL: Two factual questions. First of all, who does the harmonization? Us or NQF?

CHAIR OPELKA: That's unclear to me. I think it goes to the NQF. I don't think it's a function that we perform.

MS. MITCHELL: Secondly, I take it

that there's some concern about some other measure, perhaps falling off that list, the current NQF list. I take it it is also possible that this measure, because it's broader might be, in fact, responsible for that because it covers that other existing measure in which case what's the harm? What you've done is accomplish what you wanted to accomplish both (a) -- and it's not an extra step, it takes place simultaneously, doesn't it? Or immediately after if NQF were to vote affirmatively, it would take place before it got sent back here?

CHAIR OPELKA: No. If Calendar 2 were the calendar, it wouldn't come back here. It would go to the NQF if it's endorsed. If it's respecified and endorsed, it would then go through a harmonization process that the NQF would have to define.

MS. MITCHELL: Endorsed by us or --

CHAIR OPELKA: By NQF.

MS. MITCHELL: By NQF, yes, okay.

CHAIR OPELKA: Not us. So the

endorsement process that the NQF would take a respecified measure, look at the testing and reliability and vote on it. Passes that endorsement process, then the NQF would have to take a harmonization process or CMS would have to take a harmonization process to look at like-minded measures to get to a parsimonious step. Apply that rules logic and that would be the new measures in this space.

MS. MITCHELL: Okay. But I don't see any harm should it result in some other measure apparently being subsumed under this larger measure falling off the list. It could be a good thing.

CHAIR OPELKA: So you're speaking for Calendar 2 against the motion?

MS. MITCHELL: I'm speaking what?

CHAIR OPELKA: For Calendar 2 against the motion?

MS. MITCHELL: Against Nancy's motion, sorry, yes.

CHAIR OPELKA: Right.

MS. MITCHELL: Yes.

CHAIR OPELKA: Okay?

MS. MITCHELL: Yes.

CHAIR OPELKA: All right, Andrea.

DR. BENIN: I think that these types of measures can potentially become very interesting over time and the harm measures are really tricky to try to build and I think that this could be potentially helpful, but it obviously, to me, needs more development.

In particular, I would be interested, and this is sort of a note for the measure developers that the ability of this measure to discriminate because in the binary nature of of the numerator makes me, with the number of things that can give you the binary yes, I wonder if 80 percent of the patients are going to have this as a yes or what does that ultimately look like.

And I don't need to hear that conversation now, but I would just say in your opportunities to develop and improve it, I think that ability to discriminate would be relevant

because that is often one of the challenges when we use harm measures in reality and they are these compilations of things, they're not super helpful for improvement and we end up peeling them apart in a lot of different ways, but we use them ultimately anyway, so there's a lot of dichotomies about these types of measures. But sometimes you really lose the ability to discriminate what's going on because you don't actually know if your problem is a bunch of DVTs in your ICU or a bunch of readmissions.

So I think that they are sort of -- it's a mixed bag, these types of things. So I would put this in the development category for a lot more consideration. I think it's a really interesting concept.

CHAIR OPELKA: Richard?

DR. BANKOWITZ: So I think again the thing to consider about moving this into the consideration for further development is that this aspect of trying to use ICD-9 coded data to come up with complications is an evolving

science. It's work in progress and there is no one acceptable way of doing this. Every time people do it, they come up with numbers of false positives and numbers of false negatives.

And I do think the work that Bridges for Excellence is doing this year is very important and needs to continue. But it's not as if we have the standing NQF endorsement. It's not as if we have a universally acceptable way of looking at harm in a way that is helpful to hospitals without generating all kinds of false-positive work. So that's why this needs more development. I don't think it's ready to be moved into reporting even notwithstanding NQF endorsement.

CHAIR OPELKA: Thank you. Cristie.

MS. TALLANT: Well, my thoughts on this are that I prefer where it sits in Calendar 2 and I think that a lot of the questions that are being asked here are the very questions that would be asked during the NQF endorsement process. And I think that the discussion we're

having here can actually help inform the endorsement process. So once it's respec'd for the 65 and older population, once it's tested, it has to really answer the very questions that we're all asking here. And if the endorsement process says it's not ready for prime time yet because it needs more development, that is certainly an opportunity that can happen during that endorsement process.

So I think that that's really where it sits right now would be what I would support keeping it where it sits.

CHAIR OPELKA: Emma?

MS. KOPLEFF: I know I've said I support where it sits, but thank you all for helping me think through what that means. And just to spell out sort of the time line thing going on in my head to see if that again helps sort of frame where I'm coming from and where others have been coming from.

I am -- by keeping it in Calendar 2, I think we are appropriately putting trust in

both the NQF process and CMS processes to say that the endorsement process looks at the scientific robustness of the measure. And as part of the regular process looks at harmonization issues with similar measures. So that's just sort of an amendment, I guess I would make to how it was framed earlier. I felt as if it sounded like it was some special parsimony exercise for the endorsement process.

The endorsement process looks at competing measures. So correct me if there's something I'm missing there because I am attributing that trust to the endorsement side.

Also, on the CMS side, I'm putting trust in the fact that following endorsement, if there are still concerns or issues about overlap with existing measures which may or may not be appropriate because to Pierre's point there may be specific individual potentially avoidable or avoidable complications where we do want the ability to either drill down within this measure or have existing individual measures.

So I'm trusting that either through the MAP process or public comments and the other opportunities CMS always provides that in keeping it in Calendar 2, we're not sort of condemning this measure to a fast track of support without really thorough consideration of the implications, but we're giving it a shot to potentially lead the way in offering more of the all cause harm kind of concept.

CHAIR OPELKA: So we've had an awful lot of discussion about this measure and if you've got further comments, brevity is important.

Wei, did you have something? Richard?

DR. BANKOWITZ: I just wanted to reiterate NQF endorsement looks at whether the measure is useful for a purpose which may be quality improvement which may involve members of false positive. It does not say is this measure suitable for something we want in public reporting. That's not what NQF endorsement does.

MS. KOPLEFF: But the current criteria

do speak to accountability. So the current NQF criteria actually to my understanding don't look at measures for quality improvement. They are for accountability purposes.

CHAIR OPELKA: Thank you, both.

MR. AMIN: It looks at quality improvement and accountability applications which includes public reporting and payment applications as well.

However, it doesn't look at a particular instance. We're not looking at it for the purposes of IQR. So it doesn't -- that's what it looks at. It's more of a broad question, but it includes both categories.

CHAIR OPELKA: It's almost a question of do you want to put this in the measure library and then we are pulling the books out of the library and taking them out for public use.

All right, Michael?

DR. PHELAN: Yes, I think Cristie and Emma spoke eloquently to the process here. We're

moving it from the IQR calendar and not relying on the typical NQF process that are going to answer all these questions about is it reliable? Is it valid? Does it work in the 65 and older population? I think it just depends on what kind of message we want to send regarding this.

Do we want to say well, we're just going to knock this down the road again for another two years? Are we going to say, you know what, a good measure, patient safety is a big priority. If the NQF committee that's going to review whether this measure that the measure developer is going to propose goes through the process endorsing it to me is really going to be a no brainer because if it gets NQF endorsement, and they say it's pretty reliable, it's valid, it's good for quality reporting, I think it moves right into the category we want it to say when we support it and go forward from there.

CHAIR OPELKA: So we need to move forward on a vote on this. The motion is to move this to the encourage for continued development.

And it's for all three of them.

MS. IBRAGIMOVA: So the question is proportion of patients hospitalized with AMI that have a potentially avoidable complication during the index stay or in the 30-day post-discharge period. The proportion of patients hospitalized with pneumonia that have a potentially avoidable complication during the index stay or in the 30-day post-discharge period hospitalized with pneumonia. The proportion of patients hospitalized with stroke that have a potentially avoidable complication during the index stay or in the 30-day post-discharge period.

Do you agree with the motion to move to encourage for further development? One, yes, Two, no.

(Voting)

MS. IBRAGIMOVA: The results are 33 percent yes, 67 percent no.

CHAIR OPELKA: So it stays on Calendar 2. It's been a rich discussion. I think you need a break. So let's go for ten minutes.

(Whereupon, the above-entitled matter went off the record at 11:10 a.m. and resumed at 11:35 a.m.)

CHAIR OPELKA: Hopefully, you are recovered. Let's grab our seat again.

So, the team up here, we are learning a lot about these consent calendars. And I think what we learned in this round today is that we created too many conditional consent calendars. And what we should do is consider just having one conditional consent calendar, and then, capture your conditions, and rather have a subset list of conditions that we can apply to a conditional consent calendar.

We think that would be more efficient than what we have been doing. Now we don't know that for a fact. So, we thought we would do some testing.

The test is we are now going to collapse the remaining conditional calendars, consent calendars, into one, so that we will have one conditional consent calendar of these

remaining three, which were the measures should be quickly replaced with a measure assessing results of a survey of culture of patient safety. And then, the conditional support for the measures that were applicable at the facility level and resolution of the duplicative nature of the measures with falls and trauma, and the component of PSI-90, and the conditional support pending NQF review and endorsement. So, that is calendar 3, 4, and 5.

So, these three calendars are now the conditional consent calendar, and we will apply the conditions that you wish to these as they remain on here. So, the question before you is if these are the measures that are conditional supported, are there any you wish to move to the support, do not support, or encourage continued development?

Jack?

DR. FOWLER: Well, as we were discussing, we don't have access to all the evaluative stuff that has gone on. But I would

like to move the patient fall rate to do not support, the total fall, not the one with injuries. I find it implausible to think that anybody can get a reliable measure of how often that happens if it doesn't result in a medical event, and I just don't see how people would know that. And at least from a patient perspective, I would find that implausible as a thing of value. So, that is my motion.

CHAIR OPELKA: Okay. Second?

(Seconded.)

A second. Thank you.

Karen?

MEMBER FIELDS: I would like to address the spine fusion measure. I thoroughly support the concept of episode-based payment systems. However, without understanding what the risk stratification is in that patient population, it is an undue burden on cancer patients. Spinal fusions are common procedures in patients with spine mets, but to have a bundled payment around chemotherapy and radiation

therapy is not an appropriate, without being stratified for that, is not an appropriate stratification -- or bundled piece.

CHAIR OPELKA: So, do not support?

MEMBER FIELDS: I would say either conditionally support or do not support, depending on if it is a risk stratification that is in there.

CHAIR OPELKA: It is in conditional now.

MEMBER FIELDS: So, I will say do not support.

CHAIR OPELKA: Do not support. Thank you.

Andrea?

MEMBER BENIN: I have a process question here, Frank, about if we don't like the condition, what do you want us to do, move a different condition or move a removal of the condition or?

CHAIR OPELKA: Well, if you want to keep it in conditional support and you would like

to clarify the condition, we can.

MEMBER BENIN: Okay.

CHAIR OPELKA: If you want to move it from conditional support to one of the other categories, we can do that. What we want to capture in your discussion of these is what are your conditions. You can pull from any one of the condition lists, and we will just keep it in there based on your condition.

MEMBER BENIN: So, this is essentially a structural measure about participation in a Patient Safety Culture Survey, which is essentially, I believe it is still a Joint Commission requirement to do yearly or every 18 months or something, and is routinely done to help move safety culture.

But the condition is not appropriate. It is not appropriate to have the results of that survey publicly reported. There are actually two different -- I mean, do you want me to go into it now?

CHAIR OPELKA: So, you support the

conditional support, but what would be your condition?

MEMBER BENIN: I think I don't have a condition in mind.

(Laughter.)

I am supporting the general idea of it.

CHAIR OPELKA: So, you would want to move it to support?

MEMBER BENIN: Sure. I think so.

CHAIR OPELKA: Okay.

MEMBER BENIN: I've been weighing for the past 24 hours which way to go with this, but I'm fine with this measure, only as a structural measure, though. I mean, the condition for me is that it would remain as a structural measure.

CHAIR OPELKA: Okay.

MEMBER BENIN: Let me put that -- conditional support in that it would be sort of remaining as a structural measure in that way.

CHAIR OPELKA: It is a structural measure as specified. You would support the

structural measure, and you are not in favor of where it stands with the conditional support by opening up the results?

MEMBER BENIN: Right. Right.

CHAIR OPELKA: Yes.

MEMBER BENIN: So, I would -

CHAIR OPELKA: Support the measure as specified?

MEMBER BENIN: Right, without the addition of the results being added.

CHAIR OPELKA: Okay.

MEMBER BENIN: That would be my --

CHAIR OPELKA: So, I need a second on that.

(Seconded.)

Second. So, we have a second. Okay.

Nancy?

MEMBER FOSTER: Thank you, Frank.

I would like to move all three of the hospital 30-day, all-cause, blah, blah, blah, blah, blah measures to do not support.

CHAIR OPELKA: Okay. Second?

MEMBER BANKOWITZ: Second.

CHAIR OPELKA: All right.

Dana?

MEMBER ALEXANDER: Yes, and if you said this, Frank, and I missed it, but are you making a call to move only those calendars on conditional support or any of these such as the do not support and encourage continued development, if we have a change?

CHAIR OPELKA: Just the conditional support ones.

MEMBER ALEXANDER: Okay. Thank you.

CHAIR OPELKA: Jack? Richard?

MEMBER BANKOWITZ: I move that we take the 30-day payment, episode-based kidney and urinary tract infection and move that to do not support, as well as the cellulitis clinical episode payment to do not support, as well as the gastrointestinal hemorrhage clinical-based payment to do not support.

CHAIR OPELKA: So, that means all of those payment measures because spine was also

moved. All four of those are do not support.

MEMBER BANKOWITZ: Okay. Well, those are the three I particularly disagree with. So --

CHAIR OPELKA: And Karen added the other one. So, that is all four of them. Okay? All right. Yes?

MR. AMIN: Okay, let me just make sure that everybody is on the same page and that I'm on the same page.

So, the existing calendar 1, participation in patient safety culture, the motion is to move that measure to support.

Under the existing calendar 4, the patient fall rate, the motion is to move it to a do not support.

On calendar 5, the 30-day, all-cause, unplanned, risk-standardized days for AMI, heart failure, and pneumonia, there is a motion to move to do not support.

The one that remains of that category is the episode of care for primary elective hip

and knee.

For the four that were moved to the fully-developed pathway this morning, all four of those have been moved to do not support, and that includes the kidney/urinary tract infection episode-based payment measure, the spine fusion, refusion, episode-based payment measure, the cellulitis episode-based payment measure, and the gastrointestinal hemorrhage episode-of-care measure.

I just want to make sure that that is correct. Please let me know if I have missed anything.

CHAIR OPELKA: I'm in agreement. Is everyone else? We captured everything?

Okay. So, the first on our list is participation in the Patient Safety Culture Survey, which has a motion to move to support as currently specified.

Any further discussion?

Cristie?

MEMBER TRAVIS: Although I appreciate

this measure coming in this way this year, I really do think that, for consumers, purchasers, and for healthcare facilities, it is important to know what the results of the patient culture, of the safety culture measure is. And therefore, I would like to keep it where it is, with the condition with which it is stated, that we quickly move to an outcome measure for this.

Because, otherwise, just to know whether you are doing it or not, we know it is a requirement that you do it. So, I think we have got to get beyond the fact-finding phase quickly, so that we can actually understand what the safety culture is in organizations.

CHAIR OPELKA: Andrea?

MEMBER BENIN: So, thanks for that comment, Cristie.

I think that publicly reporting the results of these surveys is really antithetical to what we are trying to do in this country around driving a culture of safety. And I think it will be incredibly harmful for driving that

forward. In fact, I think it will be completely counter to anything that we believe in this room to be useful.

There are two different surveys. There is some decent data showing that they cannot be sort of cross-referenced. You can't take the results of one -- and there is no sort of single result of either one of them that you could say crosses necessarily into the other, although there is correlation between the results of the two of them.

And so, it is not as though everybody in the country uses one single survey. People do submit the AHRQ survey to AHRQ for benchmarking, so that you can anonymously submit -- you submit your data. It is not anonymous to AHRQ, but you can, then, see how you rank up against the rest of the country, of the rest of the people who submit to AHRQ. And certainly, the Children's Hospital Association, they also provide some help with the benchmarking on that.

The other survey, I am a little bit

less familiar with the ability to benchmark. But there is benchmarking data that has been published and that kind of thing.

There are no absolute thresholds from these surveys that help you indicate what they mean. So, if you have a 60 percent or something, you know, there's one survey that was particularly well-validated at Hopkins that may have some information based on what the couplings are, but it is very loose. It is very vague, and it is extremely contextual.

So, for example, you change your benefits package, right? And so, you don't have a cycle for your FOIA Opinion Survey, and your survey is very much swayed by your staff have this idea of how they feel about things because your benefits package isn't changed. It may or may not have anything to do with patient safety.

There is some contextuality to the surveys and the timing of them, as well as to the response rates. Who you survey, there are some vagaries to who you survey. You can include your

doctors or not include your doctors, include your staff or not include your staff. Different people will include their non-clinical or their clinical. It is just not there yet.

Because what we want to be doing is encourage people to use these surveys and to use the work internally to drive progress. And I don't think that there is a good way to compare organization to organization super well in a productive fashion across the country right now.

CHAIR OPELKA: All right. So, let me remind everybody, brevity. Brevity.

I was going to say "Ron," but I'll just say "R".

(Laughter.)

CO-CHAIR WALTERS: I think I gave this talk last year at the same point in this meeting.

Yes, I agree, we always want to go to an outcome measure, and when we don't have an outcome measure, we love a process measure. We are so far behind in this one, let's just get a structural measure in place. I support the

motion to move it just to structural.

CHAIR OPELKA: Any other comments?

(No response.)

All right, let's go to a vote.

So, the motion is to move the conditional support to support.

There is no condition. This goes to support.

MS. IBRAGIMOVA: So, the question is participation in a Patient Safety Culture Survey. Do you agree with the motion to move this to support? One, yes; two, no.

(Vote.)

The results are 71 percent, yes; 29 percent, no.

CHAIR OPELKA: So, we'll move it there and we will throw in the caveat of the discussion that we just had, that there is really a need to sort through how to bring this to an outcome measure. So, that is in the gap analysis for this.

Okay. The next is the patient fall

rate has a motion to move to do not support.

Marty?

MEMBER HATLIE: I think these measures are really important to publicly support because I think patients and families don't understand this risk. I don't think most people even understand that they are at risk for a fall when they are hospitalized. So, just in terms of public information and public education, making them aware of that risk is important. And it is also one of, in my opinion, the low-hanging pieces of fruit for patient and family engagements, that once you are aware of that risk, you can partner with your providers to help prevent these events from happening. Plus, it is frequent. So, I think it plays an important function. And I oppose the motion.

CHAIR OPELKA: So, Marty, if I could, and I don't mean to put you in an awkward position, it is in the conditional support. And we have phrased some conditions around this one. So, I am assuming that this conditional support

that we have as stated would be applicable.

MEMBER HATLIE: Yes. No, I support the calendar that it is on.

CHAIR OPELKA: Okay. Thank you.

MEMBER HATLIE: I think you should leave it there.

CHAIR OPELKA: Jack?

DR. FOWLER: Yes, I don't claim to be an expert on this data, except I have worked a lot with things that show up in claims and don't show up in claims. And this seems like one that won't show up in claims reliably. And if the goal is to increase awareness of falls, there are all kinds of ways to do that rather than have this measure that is supposed to be meaningful, which I don't think will be, unless I hear something I haven't heard.

CHAIR OPELKA: Nancy?

MEMBER FOSTER: So, just to add to what Jack said, because I agree with him, there are challenges in deriving this information accurately, particularly from claims data. There

are concerns that have been raised that taking too careful a look at patient falls can inhibit the clinician's desire to get people up out of bed and get them moving because they are more likely to fall. But it is also better for their recovery if they get them going faster.

So, on balancing this, it seems to me that keeping the falls with injury, which Jack has proposed, and doing away with the general fall rate, would help, would both keep us accurately focused on where patient harm has occurred and not inhibit people from getting up out of bed. So, I support the motion.

MS. PANCHOLI: Hi, there. I am Mamatha Pancholi from the Agency for Healthcare Research and Quality.

I just wanted to offer some clarification around this issue around duplicity or duplicativity. The issue around PSI-90, it does contain a falls component. PSI-8, which is the postoperative hip fracture, it is actually a much more narrower definition. It actually

captures major falls with hip fracture after surgeries specifically. And I think the measure that is under consideration under the IQR is actually much broader than that. So, AHRQ does not believe that there is any duplicity from that perspective.

Just to relate very briefly, so AHRQ does not view the falls measure listed under calendar 4 as duplicative of PSI-90. PSI-90 is a composite measure. Within that, there is a measure, PSI-8, which is the postoperative hip fracture. That is a fairly rare event, as it is really defined as major falls with hip fracture after surgery. It is a much more narrower -- it captures much fewer events than I think what measure is actually considered under calendar 4.

CHAIR OPELKA: Dana?

MEMBER ALEXANDER: So, I mean, we have had discussion about this, the fall measure within PSI-90 about what has been stated, that it is more narrowly defined. And these measures here are more broadly defined, capturing falls

and fall risk.

And I would say, in all due respect to Nancy's comments, that the care team delivery members, and particularly nursing, are very in tune to fall prevention and monitoring falls for patients, and that understanding that in parallel, that mobility and getting patients up and walking, and so forth, is equally as important as well for their progress.

So, I do not support the motion. I think that this is a measure that is being captured today, is very top of mind within hospital settings for falls, fall prevention and fall reporting.

CHAIR OPELKA: So, you support its current position?

MEMBER ALEXANDER: Yes.

CHAIR OPELKA: Okay. Kelly?

MEMBER TRAUTNER: Hello.

(Laughter.)

Actually, Dana's comments were exactly what I was going to say. I think that this is a

very important piece of information for consumers of healthcare to have. I think that it places a bit of market pressure on organizations to ensure that they have adequate mobility programming and that they are engaging the clinicians in developing those programs to ensure that the risk of falls actually goes down in those organizations.

CHAIR OPELKA: Thank you.

Richard?

MEMBER BANKOWITZ: Well, this is a self-reported outcome because it can come from the chart or the medical record. And I think if we want to encourage self-reporting, we need to have people feel safe, to come forward and report when a fall has occurred. I think the best way to push that under the table is to publicly report this and try to compare everybody, because a fall will become a slip, and a slip will become that was just a minor problem. So, if we are going to encourage reporting of this type, I don't think it needs -- it should not be publicly

reported because you will just suppress the reporting of it.

The second point is, if consumers are going to judge this, given that this is self-reported, I think there is going to be a hard time. I mean, I personally would have a hard time understanding what I was looking at. I probably would say I would not go to any institution with a fall rate of zero. That much I would probably say because that tells me the lot.

(Laughter.)

Beyond that, I wouldn't know how to interpret it. So, we need to be careful about what we are self-reporting and what we are making publicly reported.

CHAIR OPELKA: Thank you.

Andrea?

MEMBER BENIN: I would like to really strongly agree with what Richard just said about a measure like this having the ability to drive underground reporting.

The most important thing for me when I am a patient is that I go to a hospital that knows how to drive a reporting culture and a transparent culture, and this is exactly the opposite. This will drive the opposite of that.

I know right now every time a child trips in physical therapy, and I want to know that. And that is because I have people reporting that to me. But that kind of thing gets driven underground quickly.

And so, I think that this kind of measure potentially jeopardizes it, and it can be balanced out by the measure with injury, which probably also has some issues, but regardless, I would strongly support the motion.

CHAIR OPELKA: Michael.

DR. PHELAN: I disagree, and I rely on my nursing colleagues in the room to tell me. I think this is, if I am not mistaken, it is an NCDNI metric, is that correct? The Nursing -- what is it? -- NDNQI. And what does that stand for? Because my acronym -- I have reached the

limit of the acronyms that I can keep remembering.

(Laughter.)

What does it stand for? Do you know? National Database of Nursing Quality Indicators. Thank you very much.

And I think -- where did that come from? From above?

(Laughter.)

And I believe it is like one of the magnet quality indicators that they follow. And not every nurse and not every hospital submits that data. But, from a patient perspective and a hospital perspective, again, I think our nurses care a lot about the patients that we're caring for in our hospitals. And I think a measure like this, I think it would be actually the opposite. I think it would drive the culture of safety if these measures were being publicly reported.

And especially from our nursing colleagues who really care deeply about the patients that they're taking care of, to have a

measure on a patient safety metric like this is, I thought, the purpose of what we were trying to do by organizing under an NQF umbrella and MAP.

So, I would support the current calendar location of that and continue from there.

Thanks.

CHAIR OPELKA: Wei?

DR. YING: I would keep it in the current calendar. Just to follow up what Michael was saying, later on, we are going to discuss the nursing hour measure. I imagine it will be a heated discussion at that time.

For this type of measure that actually represents an outcome of the nursing quality, it is actually where we want to get to. So, that is a type of discussion.

Also, at the same time, one comment. I think a couple of colleagues mentioned earlier about the drawback of the claims data. Actually, this is a measure based on the EMR data and all medical records. So, it is actually better than

the one in the PSI-90 composite.

CHAIR OPELKA: Thank you.

Brock?

MEMBER SLABACH: I am speaking in support of the motion because, if I'm understanding this correctly, the internal measures, the acronym which you failed at thinking about -- and I can't repeat it even now -- it would be terrific for internal reporting and for process improvement within my own facility. But I think this is going to public reporting, which is a whole other level of consideration. And I think that that really makes this problematic for me, and that is why I would support the motion and its passage.

CHAIR OPELKA: Cristie?

MEMBER TRAVIS: So, just in response to a comment that was made earlier about driving a transparent culture, if this is only used internally versus publicly reported, you know, the question that I would have is, transparent to whom?

And I do understand that there is a lot of good information that can be used internally, and I think that it should be used internally. I have a continued concern when we say that when people are going to publicly report information, then somehow they don't report it, period, which, quite honestly, comes back to me as unethical.

And I have a problem with that, and I don't know how to resolve that because I understand the implications of reporting it, and if it is publicly reported, then it goes out to consumers and to purchasers, may end up being used in a payment. But what happened to wanting to get to the truth?

And I have a hard time by saying that people will not report it when it is going to be publicly reported or used in payment because, then, that comes down to, you know, the honesty of the people in the reporting system.

So, I am afraid that, if we keep it the way we are talking about it, we never get to

be transparent with the people who are the patients or the purchasers. And I think fall rate is a very important measure, and we should move it forward, because I think that those people are at risk for the ones with the injuries. And I think together they make a whole lot of sense.

CHAIR OPELKA: Dolores?

MS. MITCHELL: Well, Cristie already said it. I would just add one other thing to that, which is I keep hearing about concerns -- I don't just mean today, but, you know, in the whole quality measurement business -- about the dangers of underreporting if anybody finds out what you reported, which always strikes me as appalling.

But, in addition to that, I think the culture of safety, as has been mentioned by a couple of other people, demands it. And I don't know, you know, those two surveys that Andrea told us you all get include -- you know does your Board get every one of these reported to it? And

what actions do they take, and so on?

It points me to the question of, who is responsible for dealing with the question of underreporting? It seems to me it is the leadership of the profession. It is the leader of the hospital. It is the chairman of the board of the hospital. It is the structure of governance. It is the agenda for board meetings.

To say that there is a danger of it happening or to ignore that there is a danger of happening is probably a misunderstanding of the frailty of human beings. But, since we do know that -- and I'm not denying that there is that potential -- it seems to me that the solution is not to say, well, we won't report it to anybody. The solution is to say to the leadership of the industry, "Get moving on this one."

CHAIR OPELKA: Marty?

MEMBER HATLIE: Quickly, I think there is a tension that Nancy acknowledged between mobility and the fall instructions that a lot of patients get. But this is a perfect place to

start a conversation about patients and families partnering and resolving that tension.

I don't think patients and families are going to make a single decision based on this rate. They are going to factor it into a conversation they need to be having about risk in general. So, for that reason, I think it is really important.

Thank you.

CHAIR OPELKA: Sean?

DR. MORRISON: Yes, I hear that people say, "I am clear this is really important measure." I think what I am struggling with is I don't have enough information about other measures that might harmonize with it.

Because if we take fall rate by itself in the absence of, for example, rates around not getting people out of bed, rates around restraint use, both chemical and others, it is hard to interpret a fall rate.

However, if I had percentage of patients who were gotten out of bed, percentage

of patients who were moved, percentage of patients who are harmonized with this in conjunction, that to me would be a much more relevant measure and one that I could interpret.

I completely agree with the falls with injury. This one, isolated by itself without companion measures to evaluate, I have trouble with.

CHAIR OPELKA: Okay. Nancy?

MEMBER HANRAHAN: Again speaking from a dual-eligible perspective, this measure is an important red flag of an environment that may put a patient at risk. And there are measures that are associated with this one, two measures that I know of. One is nursing staffing and nursing skill mix.

So, if you have poor nurse staffing and poor skill mix, meaning the right qualified nurses to take care of the acuity level of patients, you are going to have higher fall rates. And that evidence is really strong in the literature.

So, I would really encourage you to think about this being one of those consumer red flags that inform about the quality of the environment that the person is moving into and the risks that they are going to be taking.

CHAIR OPELKA: Okay. A lot has been said. So, let's be brief. If it is something new that you need to bring up, let's hear it.

Andrea?

MEMBER BENIN: I will just really briefly say I don't think that having this in or out of IQR sort of makes or breaks our national benchmarking in looking at this. I think this data goes to NDNQI for most places, many places. It goes other places. It is part of the HAC. It is part of this other stuff. There's lots of ways that this gets looked at. So, it is not that these things don't get where they need to go. Whether this is the right place for it is a different question.

CHAIR OPELKA: Emma?

MEMBER KOPLEFF: I appreciate Andrea's

comment. Just sort of grounding myself -- and thank you for the opportunity to share with others -- if we harken back to the program goals we agreed upon for this program, we did speak to providing an incentive for hospitals to publicly report quality information about their services.

And so, to me, if we ground ourselves there, then this measure continues to be really important and some of the concerns about transparency don't stand.

CHAIR OPELKA: So, the motion that we have is a motion to do not support, to move this to the do not support calendar.

MS. IBRAGIMOVA: So, the question is patient fall rate, do you agree with the motion to move the measure to do not support? One, yes; two, no.

(Vote.)

The results are 42 percent, yes, and 58 percent, no.

CHAIR OPELKA: So, it stays.

Next, we have three measures that I

am hoping we can discuss together. It is the 30-day, all-cause, unplanned, risk-standardized stays in acute care for AMI, heart failure, and pneumonia, all of which have been moved to the do not support calendar.

MS. O'ROURKE: I just wanted to jump in, Frank. Our CMS colleagues had asked if they could make some comments about these measures before the conversation begins.

CHAIR OPELKA: Great. Thank you.

DR. YONG: Thank you.

We are going to have Susannah Bernheim come back to the table and just provide you with a little bit of explanation as to how the measure's intent is.

DR. BERNHEIM: We had slides. I don't need to work with them, but it looks like you guys are moving to pull them up. Okay.

MS. O'ROURKE: We're getting those up right now.

DR. BERNHEIM: They're very brief here. I will try, in the spirit of time, to just

start talking while those are coming up because I don't think you really need them in front of you.

Let me make sure I'm looking at the right ones. Yes. Okay.

So, high-level -- in fact, I am going to move through these quickly. Who is going to control the --

The concept behind these measures is to complement the current readmission measures by providing additional information that you can't get. It is really meant to be thinking about other things that patients would want to know about the 30 days post-admission for AMI, heart failure, or pneumonia.

I am now seeing if I can control this. Which way am I pointing with this? Oh, okay.

MS. O'ROURKE: We have a PDF of the slides. So, we will scroll down for you.

DR. BERNHEIM: Okay, great. So, go ahead and move to the next one.

So, this slide just talks about the importance of both readmissions, but also the

occurrence of ED visits and observation stays in the 30-day period after index admission.

You can go to the next slide.

So, the purpose of this measure is to broadly evaluate the quality of transitions from hospitalized patients to a non-acute setting and to let consumers and providers understand a more complete picture of post-discharge outcomes.

So, it includes ED visits, observation stays, and readmissions. It is trying to capture all post-discharge care, and therefore, enhance post-discharge acute care reduction efforts.

You can move to the next one. I hope that gets to it.

So, the key thing to know is that we have harmonized the current measure with the same cohort and risk adjustment and approach to the readmissions and the same measurement period.

Next slide.

But the focus of the outcome now is days. So, rather than just "Yes, no, was there a readmission?", which tells you some important

things about your post-discharge period, this measure will tell you more.

We look at the number of days that you're back in a hospital or an ED setting or an observation care setting. They are not formally weighted, but, essentially, informally weighted because the hospitalizations tend to be for longer; the observation stays are billed based on the number of hours you're there divided by 24. So, we get an account day. And the ED visits are considered a half-a-day. That was with input from our TAP.

This just captures more fully the burden of acute care to patients.

I'm going to keep moving.

So, just quickly, the way this will be reported is a little bit different than our other measures. It is risk -- I am going to get this wrong -- risk-standardized acute care, but it is actually a difference in days. So, what we look at is what, given your case mix, will be expected as the post-discharge days and whether you have

greater or fewer than that. And there is quite a wide range among hospitals.

I think I will stop there because I know you are short on time, and I just want people to have a flavor of this measure. I am happy to answer questions and I have some more slides, if people have further questions.

CHAIR OPELKA: Okay. The measure as it is put forward is do not support.

Cristie, is your card up?

MEMBER TRAVIS: Yes.

CHAIR OPELKA: Well, then.

(Laughter.)

MEMBER TRAVIS: I just have a question, a clarifying question. Is this only for patients that are readmitted?

DR. BERNHEIM: Great question. No, not at all. So, any patient who is admitted with AMI or heart failure or pneumonia, we look at all of the post-discharge events.

CHAIR OPELKA: Richard?

MEMBER BANKOWITZ: So, I think it is

a great idea to try to capture all of the events that take place after a hospitalization, and knowing how many observation visits and how many ED visits is extremely important.

Why I think this measure needs to be sent to the do not support category is because it is blending all of the events into one number. And it is difficult to interpret what a seven-day event would be. If a patient stays in the hospital for a seven-day readmission, is that the same as going back to the hospital for four days and, then, coming back to the obs room for three separate occasions?

It seems to me that there is a difference in patient-centered care, and we are just lumping it into one uninterpretable number, in my estimation. So, if we want to understand these, why not just measure and report obs days and ED days in addition to readmission? It seems much more logical to do it that way.

DR. BERNHEIM: So, just a quick answer to that, because it something that our team has

thought a lot about. And the problem is, if I just tell you obs days, I don't know whether that means -- or I'll use ED days. I don't know whether that means a hospital, it has high ED days. Does that mean a hospital is really effectively triaging patients, getting them back out to the care setting sooner? And that might be a hospital that has low readmission rates.

In fact, we see that hospitals that do particularly well on this measure often have much higher readmission rates and higher lengths of stay for the readmissions, and they do really poorly on this measure. Sorry. But the often have lower ED visit days, and vice versa, which is what I was really trying to get at. A lot of the hospitals that -- let me say this clearly this time -- do well on this measure overall, where patients are coming back for fewer total days, actually have slightly higher rates of ED visits. And we suspect, but we don't know, that they are getting patients in sooner, when they are less sick, and the burden on patients of the

days is fewer.

And it is true that seven days can parse out differently. But we are trying to capture the sense of sort of, what is the patient likely to experience in the next 30 days? How many days are they likely to be back in acute care? We think that is valuable.

MEMBER BANKOWITZ: So, thank you for that clarification. And I think, in a way, you're making my point because you actually look and parse out the events, which I think is what you need to do. But, not having all that information, consumers or interested parties will see one number. So, I think you just made my point. It is useful to look at the individual events.

CHAIR OPELKA: Wei?

DR. YING: I actually like this measurement because it actually addresses one of the concerns while we work with hospitals, the readmission measure. What we found is hospitals are trying very hard to keep patients out of

acute settings, so they don't count as readmissions to be reported out. So, we see a jump in the observation stay during the 30-day post-discharge period.

For our internal program, we actually modify the Yale measure or try to except for that, count them as readmission for our hospitals. So, I think this set of measures is trying to address the issue of making sure our hospitals, no matter how they get paid, depending on the program, patients are getting quality of care during the post-discharge period.

CHAIR OPELKA: Thank you.

Mitchell? All right. Nancy?

MEMBER FOSTER: Oh, sorry.

MEMBER HANRAHAN: These measures are designed for age 65 years and older. And one of the issues with dual-eligibles is many of them are under 65. So, this is a real gap in application of these measures.

CHAIR OPELKA: Thank you very much. We'll capture that.

David?

MEMBER ENGLER: Thank you.

I made a similar comment that Richard just made last time we met, talking about all-cause readmission. And my comment related to lumping all cases and all patients coming back into a hospital into an all-cause readmission rate.

At the time -- and I still argue -- I argued this case that condition-specific readmission rates from a quality improvement standpoint are very, very important. And practitioners and folks that work in quality improvement know what to do with those rates. They can make specific recommendations. For instance, cardiac rehab is an important predictor of readmissions in AMI, et cetera.

But, when you lump it all together, I think when I mentioned this last year I said I wasn't quite sure what I could do with it from a quality improvement perspective. I didn't know what I could do with it.

And over the last year, we engaged in the PFP program and had some success on the hospital-acquired conditions, quite a lot. We reduced the events by about 4,000 events in our network. But we weren't really able to move the ball or the needle on all-cause readmissions.

And it turned out to be just that. We weren't able to further drill into the information and the data to really capture and to get really granular as to what our hospitals that wanted to drive the readmission rates down were to do. So, I just once again raise that as a concern from the field regarding all-cause readmissions.

I sort of like what you have done here with the days issue. It sort of reminds me of the days between events on CLAPSI. I think that is a very clever addition to the measure.

But my concern is, when I know it, outside of just knowing it, which is important I suppose -- that's what was argued by CMS last year, that it was important to know -- but, from

a quality improvement standpoint, from really working in the field, what do I do with that?

So, I would just continue to add that, my words of caution about all-cause.

CHAIR OPELKA: All right. Well, let's be brief.

Kate?

DR. GOODRICH: Just a quick response to that. I think one of the things we certainly do here -- and I think you're get at it, at least in part -- is the data lag. So, being able to give feedback on measures such as readmissions and a measure such as this in a more timely fashion than we are able to do now.

Having said that, we do give hospital-specific reports on these measures and would be able to do the same on this measure. That allows you to drill down to every patient that meets this measure, to know whether they were readmitted, came back for obs or came back to the ED. So, that would be something we would be able to provide.

CHAIR OPELKA: Michael?

DR. PHELAN: Again, I think this is like the natural progression of some of these metrics that are being developed. There is some concern that, you know, there is unplanned acute care was like looking at emergency department visits as a negative. I think looking at this, I think patients and hospitals who desperately want to have this data, and in a much shorter timeframe. And I don't think rolling it up into one single number excludes the fact that CMS can provide much more rich detail to that number to the providers who get that number.

So, I think the idea that, oh, it is just going to be a single number and I am not going to know what to do with it, I don't think that exclusively says you can't get all this data like Kate said; that whatever we want that data to format from a hospital, they can give it. But I think it would be very rich data for hospitals to be able to be more focused on where to address the concerns.

Or they are having patients having higher acute unplanned care in one category. They may want to focus their efforts on it.

So, I see this being a plus, and I also see it as patients being able to look at data like this and saying, because it is a negative number, "It looks like they do a little bit better job taking care" of X, Y, and Z. "I think I want to go there for my hip." Some of the acute stuff is difficult to select your hospital, but it would be nice to have that data for them.

CHAIR OPELKA: Nancy?

MEMBER FOSTER: So, I know I'm sounding like a broken record at this point. But I think this is one of those measures that would be exquisitely responsive to socioeconomic factors.

I mean, we know in some communities patients don't have any other place to go other than to the hospital to get care and followup care from a hospitalization. They may choose to

go to the ER. We may try to redirect them to a clinic, but depending on how they come to us and at what time of day they come to us, we may just see aberrations that are completely understandable if you know the context of the care. And without that kind of careful look, I feel like moving this measure forward would be premature, to say the least.

CHAIR OPELKA: So, I just want to be clear.

MEMBER FOSTER: I support the motion.

CHAIR OPELKA: Pardon me?

MEMBER FOSTER: I support the motion.

CHAIR OPELKA: Okay.

Sean?

DR. MORRISON: I really like this measure, I mean it's creativity, because it addresses an acute problem that we have seen with the all-cause hospital readmission measure, which is hospitals rapidly building obs units, essentially to game the system.

And this really addresses that by

lumping it all together. And I, quite honestly, from a patient perspective, it is not much different to me whether I am sitting overnight in an ED, in an obs unit, or in a hospital bed versus the number of days. They are probably the same, and I would argue, you know, I would probably rather be in the hospital bed as a readmit.

So, I actually think this is a very creative measure to begin to address this issue that we have seen. It is not perfect, but I think it is better than what we have.

CHAIR OPELKA: Be brief.

MEMBER FOSTER: To that point, I just want to say --

CHAIR OPELKA: Go ahead, yes.

MEMBER FOSTER: -- the data actually, Sean, don't support the fact that hospital beds, obs beds are being used as the safety valve here. Even CMS's own analysis, which was recently published in MMRR, says they are seeing no bump there.

So, I know it was a concern, but --

DR. PHELAN: The same point, to Wei's point and to Sean's point, I think that CMS has looked at this, and there hasn't been that -- even though I think there is an impression that that is happening, it doesn't seem to bear out.

I don't know if Kate wants to comment on it or any of your team wants to comment on that Geoffrey Gerhardt paper.

DR. GOODRICH: I don't know the report Nancy is referencing. I know I have seen some of our data internally that do show that there is an uptick in observations. It is not an enormous bump, like 10 or 20 percent, but there has been an uptick.

I apologize, I don't know which one Nancy is referencing, but we have seen that.

CHAIR OPELKA: Okay. We are looking for new comments.

Emma? Brief new comments.

MEMBER KOPLEFF: I know we are not in the habit of proposing new motions. So, that is

not what I'm doing.

Just to be clear where I stand, I hear Nancy's concern about risk adjustment. I do think that is separate from the motion that has been made, which is a do not support.

Per the conversation we have already had around SDS, I would value some consideration from this group of a motion that mixes the conditional support of the measure, based on the reasons we have heard and the importance of this measure in filling a gap and telling us something new about what is happening with patients during their care continuum.

CHAIR OPELKA: So, let me just help.

MEMBER KOPLEFF: Yes.

CHAIR OPELKA: The location of this measure is conditional support. If the motion on the table passes, it moves to do not support. If the motion fails, the conditions can be listed, including NQF endorsement and the socioeconomic condition that we previously described.

But the motion that is out there is do

not support. So, we have three measures taken together, which are on the table currently in conditional support, and the motion is to move to do not support.

Can we bring this up for a vote?

MS. IBRAGIMOVA: The question is hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following acute myocardial infarction, AMI hospitalization; hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following heart failure hospitalization, and hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following pneumonia hospitalization.

Do you agree with the motion for do not support? One, yes; two, no.

(Vote.)

The results are 25 percent, yes, and 75 percent, no.

CHAIR OPELKA: Okay.

Next, we have four measures that were also on this same calendar which we will lump

together. These are the four episode-based payment measures. One was kidney/UTI. One was spine fusion/refusion. One was cellulitis, and one was GI hemorrhage. All of these were moved to do not support.

MS. O'ROURKE: We have additional comments from CMS for these measures as well.

MS. PAVELKA: Hi. I'm Jennifer Pavelka, and I'm from Acumen. We are the contractor that supported CMS's development of the clinical episode-based payment measures.

And if we could skip ahead just quickly? Great. Thanks.

Basically, CMS's hospital-based episode measures are designed to assess the efficiency of clinically-related services provided within an episode of care. It is important to note that these measures are payment standardized to allow comparison for Medicare payments across the country, and these measures are risk-adjusted for the clinical presentation of the beneficiaries who are treated.

Their construction is designed to generally parallel the NQF-endorsed Medicare Spending Per Beneficiary measure, or MSPB, and they were developed to be used in conjunction with measures of quality.

As mentioned, there are four. One is lumbar spine fusion/refusion. The second one is kidney/urinary tract infection. The third is cellulitis, and fourth is GI hemorrhage.

A quick note about episodes of care. These include a set of discrete medical services that are typically involved in managing a particular health event or condition. And they allow a single unit for comparison of these services across all providers to measure efficiency-of-practice patterns.

Next slide, please.

A basic model of an episode of care begins with a trigger event. This is something to indicate the presence of the health event or condition that is the focus of interest.

Next, within the episode, clinically-

relevant conditions and procedures are grouped or included in the episode if they represent a sufficiently-high share of cost, occur within the time window, which is the inpatient hospitalization period 30 days after and for some episodes up to a few days before, if we need to capture events that should be associated. And finally, the episode ends when there is a break in service or after a fixed time period after the trigger event.

CMS's goals for episode cost reporting are primarily to encourage efficient practice patterns of care. Inclusions of these measures in hospital inpatient quality reporting enables CMS to consider them for future inclusion in the Hospital Value-Based Purchasing Program, where stakeholders have specifically requested a more robust measure set, especially for clinically-cohesive measures such as these to complement the more global MSPB measure.

Next slide.

The clinical episode-based measures

fulfil in part CMS's quality strategy to improve beneficiary health and quality of care while lowering medical costs. They meet a requirement in the Social Security Act that calls for the VDP Program to include measures of efficiency. And as mentioned, they are designed to align with the endorsed Medicare Spending Per Beneficiary measure.

The four conditions were chosen for development based on data analysis and expert clinical consultation because they can be linked to near-term outcomes, have high variation in post-treatment expenditures, account for a large share of total Medicare spending, and have a large share of expenditures that are attributable to post-acute care.

CMS has vetted the measures by asking for public comment on the measures in both the fiscal year 2015 inpatient prospective payment system and long-term care hospital proposed rule, and the fiscal year 2015 physician fee schedule proposed rule.

And all four of these measures were reported in the 2012 Supplemental Quality and Resource Use Reports, which are confidential feedback reports that are delivered to medical group practices with 100 or more physicians in the practice.

I understand that there might be some questions. So, please let me know if there is anything I can help answer.

CHAIR OPELKA: All right. Karen?

MEMBER FIELDS: So, the main question is -- and I am not certain it is appropriate for today's discussion -- which are, what are the risk stratifications and what are the exclusion criteria in specifically management of spinal fusion in a patient with underlying malignancy that would require chemotherapy and radiation therapy as part of the total management of that?

But it also would apply in cellulitis, renal, any kind of other kind of planned therapy for treatment of an underlying malignancy can't be included in that bundle. That's my question.

CHAIR OPELKA: We are not going into measure specification. There is an NQF process which they haven't gone through. The measure work is completed. And now, they are ready to go into the NQF process. We can review the risk stratification here. That is for the NQF endorsement process.

MEMBER FIELDS: And I understand. The only one that I put on the table was spinal fusion, and I just need to know if I would take it off the table as a do not support based on that question.

CHAIR OPELKA: Right. And it is purely, the question you are asking about, is it adequately risk-stratified, is an NQF endorsement question, which is not yet completed. The measure is developed and I understand moving toward that, but we cannot go through measure specification and endorsement here.

Richard?

MEMBER BANKOWITZ: So, let me speak to the three UTIs, cellulitis, and GI hemorrhage. I

understand the logic of measuring the efficiency of a discrete well-planned, elected episode, like a hip replacement, where you can standardize the care.

I think it is problematic to try to measure the efficiency of acute, unplanned episodes like UTI, cellulitis, and hemorrhage. One important consideration is that, especially I would say for UTI and cellulitis, but probably GI bleed, the most efficient cost is zero. Those patients should not be admitted or most of them should not be.

So, by focusing on a very biased sample of very ill, presumably ill patients, and trying to see if we can somehow judge the efficiency of care just seems misguided to me. I don't understand how that will help us in any way.

We should be looking, if we are very concerned about the efficiency of UTI, looking at all UTIs. The same is true with cellulitis. The same is true of GI bleed. We should take steps

to prevent GI bleeding from ulcers and other preventable conditions.

So, to focus on these special-cause admissions and try to standardize the efficiency seems to be illogical.

CHAIR OPELKA: Currently, the measures are in the conditional group, which would require NQF endorsement, and that is our condition. And the motion is to move them to do not support.

And I would ask a couple of questions that maybe you can help clarify for me. And I am taking my Chair hat off to do this.

There's cellulitis and, then, there's cellulitis. It seems to be a highly-variable measure. And so, I am a little concerned as to variation could be due to the variation in the cellulitis itself and not the treatment or cost.

And likewise with GI bleed, there is upper GI bleed and there's lower GI bleed. Which GI bleed is this? Is it both? And I think there is high variability in those two.

And yet, the UTI, kidney, and the

total joint, to me, are much more narrow in their scope, as is the spinal fusion. So, I can see those, if they have got adequate NQF endorsement. I am struggling with the cellulitis and the GI bleed because those groups are so highly variable clinically.

MS. PAVELKA: The measure development process used clinician input to narrow the services and procedures that are grouped, once the trigger occurs, so that they would be clinically-relevant to the treatment and the hospital's course of treatment for that episode within the time period.

Once the services are grouped, the payments are risk-adjusted for the clinical presentation of the patients who are being treated. And I won't waste your time with the details on the risk adjustment because I understand that is not the purview here.

CHAIR OPELKA: So, a lower GI bleed is not grouped with an upper GI bleed in the measure?

MS. PAVELKA: My colleague, Camille Chicklis, is on the line.

Camille, can you comment on the lower and upper GI bleed?

MS. CHICKLIS: Oh, sure. This is Camille Chicklis from Acumen.

Yes, both lower and upper GI bleeds are part of this measure specification, and the measure does not currently distinguish between the two.

Is that your question?

CHAIR OPELKA: Correct.

Okay. Thank you.

Michael?

DR. PHELAN: You know, from a point of view is the direction we want to move in looking at these episodes of care. I have a feeling that the variability will wash out because, for the very narrow defined ones, then it is very narrow and everyone has got a narrow category. For the very broadly-defined ones, well, everyone is going to be thrown in the same categorization.

So, the really low-cost cellulitis are going to be washed out, and the really high-cost ones will wash out on both ends. But it will be a number in the end that they can actually look at and see.

So, I am not sure -- and I am not a methodological expert -- but I think that may be what you are worried about. But I think it is going to be a washout in the end.

But I am in the category of supporting these measures because, without having these kinds of episode-based care of the direction we want to go in, what measures are we going to start looking at? These are, I think, our first foray into it.

And again, I will say I am going to trust in the NQF process. If they find issues with the methodology or with the specifications, how it is currently developed, I think that the Technical Expert Panels that are kind of given that task to follow with that will give us the answer that we want for that.

So, I would vote for continuing on conditional support, based on NQF endorsement.

CHAIR OPELKA: Nancy?

MEMBER FOSTER: So, probably a question I should have asked about a number of other measures, but these are specified with ICD-9 codes?

MS. PAVELKA: We use a mix of different procedure and diagnosis codes to identify DRGs, HCPCs, and CPTs.

Camille, can you comment whether ICD-9 is in the list of diagnosis and procedure identifiers?

MS. CHICKLIS: Yes, that's ICD-9 codes. I am guessing your question is getting at whether we will be ready to move to ICD-10. And that is something that we are working on to develop for the future.

MEMBER FOSTER: Well, the first payment program or the first public reporting program this could go into will be an era when we are working off of ICD-10. So, yes, that would

be a key question.

CHAIR OPELKA: Andrea?

MEMBER BENIN: I have a similar question to your question, Frank, about the kidney metric. Does that include both pyelonephritis as well as lower tract infections? Are those lumped in that way? Because they are different.

MS. PAVELKA: Camille, can you check through the list and confirm that?

MS. CHICKLIS: I'm sorry, could you repeat the question? I couldn't hear you.

MS. PAVELKA: Does the kidney/urinary tract infection metric include both kidney infections and lower urinary tract infections?

MS. CHICKLIS: Yes, we do include both. So, the measures are specified based on the MSGRG of the hospital admission, and the DRG for kidney and urinary tract infection includes both kidney and urinary tract infection.

MS. PAVELKA: So, then, does it take into account if there are other sort of like

resistant organisms? Because you can code for, in ESBL, you can code for some of the resistant organisms. So, some of those things really impact the -- but that comes into your risk stratification discussions, I think. I think there is a lot of information that will need to be fully ascertained and understood by the panel, when it gets there, around the ability to appropriately risk-adjust using claims data on these kinds of things. Because there are reasons why you might need to be in the hospital for a bad pylo with an ESBL E. coli that is going to be very expensive.

CHAIR OPELKA: Richard?

MEMBER BANKOWITZ: Yes, I think because this is the first foray into this area, we need to be careful and we need to be thoughtful and send the right message.

I just think everyone needs to understand, if I'm an institution that is particularly good at preventing and treating UTIs in the outpatient setting, it is not surprising

if very sick patients are the ones left to be admitted, and those costs may be, indeed, high. But we are missing the spectrum.

So, if we want to look at efficiency of something that is normally treated as an outpatient condition, we need to look at the full spectrum, not just the special-cause patients that get admitted. Otherwise, we are going to possibly let no good deed go unpunished by keeping the less sick people out of the hospital.

The second point is I'm not surprised there is a lot of variability in these conditions because, as we are discussing now, these patients can be all over the map in terms of their severity, and it doesn't necessarily mean we are being inefficient.

CHAIR OPELKA: Karen?

MEMBER FIELDS: One other comment. I think that Value-Based Purchasing is an important step forward to improve coordination of care, quality of care, decreased cost. However, the attribution model needs to be carefully looked

at. If the hospital gets paid starting with the hospital admission, but gets attributed costs for the three days preceding that, that creates some problems with how do you improve the quality of cost and payment. So, the attribution model may not be appropriate in these settings.

CHAIR OPELKA: Mitchell, is that yours?

DR. LEVY: Yes, just briefly, I would just speak again, as Michael did, in support of trusting the NQF process on this measure. So, I am still against the motion.

CHAIR OPELKA: Okay. All right. So, the motion is that these measures move to do not support. There is a group of them. They are all the episode-based payment measures. And they are coming off conditional support, and the condition was really the NQF endorsement process.

MS. IBRAGIMOVA: The question is kidney/urinary tract infection clinical episode-based payment measure; spine fusion/refusion clinical episode-based payment measure;

cellulitis clinical episode-based payment measure, and gastrointestinal hemorrhage clinical episode-based payment measure. Do you agree with the motion to move to do not support? One, yes; two, no.

(Vote.)

The results are 48 percent, yes, and 52 percent, no.

CHAIR OPELKA: So, they stay on conditional.

So, here's where we are: we have walked through all our consent calendars for the IQR. We have a support calendar. We have a conditional support calendar which has an array of conditions to be applied, as per your conversation today. We have a do not support calendar, and we have the encourage for continued development calendar. So, those are our four calendars.

We are going to open up for public comment on those calendars, and then we will vote on those calendars.

THE OPERATOR: At this time to make a public comment, please press 4, then, the number 1.

MS. O'ROURKE: Hello, Operator. Could just hold off on public comment one minute? We are having a procedural question. Thank you.

(Pause.)

CHAIR OPELKA: Cathy?

THE OPERATOR: Yes, sir?

CHAIR OPELKA: Would you seek public comment, please?

THE OPERATOR: Okay. Once again, as a reminder, you may press *1 to make a comment.

(No response.)

Okay. At this time there are no public comments from the phone line.

CHAIR OPELKA: Any in the room?

Please. And introduce yourself.

MS. JONES: Hi. My name is Stacie Jones. I am giving public comments on behalf of the American College of Emergency Physicians in regards to the three measures on 30-day, all-

cause, unplanned, risk-standardized days in acute care following hospitalization for AMI, heart failure, and pneumonia.

I did submit some of these comments earlier, and I just wanted to reiterate that, actually, within acute care there is a continuum of care. There are patients who are admitted for an inpatient stay. There is care that is delivered in the ED, and there are severity indexes within the emergency department patients.

And there are four different types of observation units within acute care settings. There is protocolized clinical decision unit in the outpatient part of the hospital, and there are also different types of observation within the inpatient range in the hospital.

And each one of those is slightly different. And several studies have been done that highlight the savings that can be realized with observations stays. Some studies have cited 950 million per year for some of these stays, and some studies, 5.5 to 8.5 billion per year.

It is also important to acknowledge that emergency department stays are generally about one-tenth of the cost of a hospital admission. So, I think that to count an emergency visit as half a day of an inpatient stay is not necessarily accurate or reflective of the burden to the system. In addition, many people will not necessarily be in the emergency department for 12 hours instead of 24. So, I think all these are important to take into account.

In addition, appreciating the fact that the measures are risk-adjusted, I think that the community resources in the catchment area for these hospitals needs to be taken into account, too. Because many times the reason for the emergency department visit is simply because it is open and that there will be, although 92 percent of all visits are urgent or emergent, now with many Medicare and Medicaid patients having to wait for a number of days to get in to a primary care physician, in some of these

catchment areas there may not really be very many office-based physicians available.

So, I think looking at the number of primary care physicians available per number of beneficiaries in that catchment area would also be helpful and also looking at the urgent cares in that area.

So, I did just want to elucidate that not all acute care is the same.

CHAIR OPELKA: Thank you.

All right. The team has brought to my attention that we have to highlight the do not support consent calendar. So, that has two items on it, the skill mix, which is the first one, and the nursing hours per patient day. And the question is, is there any request to move any of these items on this calendar?

Dana?

MEMBER ALEXANDER: So, yes, I have a request. On the skill mix and nursing hours per patient day, to move that to conditional support pending NQF endorsement.

CHAIR OPELKA: Both of them?

MEMBER ALEXANDER: Yes.

CHAIR OPELKA: The two measures?

Okay. A second?

DR. PHELAN: Second.

CHAIR OPELKA: Second. All right.

So, that is open for discussion.

They are endorsed?

MEMBER ALEXANDER: Yes, not at the facility level, and I will speak to that.

CHAIR OPELKA: Okay. So, we do have a second. So, if you wish to speak to that, go ahead.

MEMBER ALEXANDER: So, just some brief comments here on both of these measures, that they focus on higher levels of nurse staffing, which has been found to be associated with better patient outcomes, things such as shorter length of stay, lower rates of mortality, failure to rescue, hospital-acquired infections, medication errors, and pressure ulcers, to name a few.

It is a structural measure. They are

structural measures that have high impact on quality, safety, and patient outcomes.

These measures have been well researched and they are evidence-based, and they, again, greatly implicate the staffing impacts on quality and safety and outcomes for patients.

These measures are currently being used in over 2,000 hospitals across the country. And while originally reported at the patient care unit level, they have now been tested at the hospital level by NDNQI, who you heard about earlier, and are ready to submit for endorsement during maintenance review with NQF, I believe at the 2015 Safety Subcommittee review.

Also, I believe that these measures do fill a gap, even though it was stated in the preliminary analysis by NQF that that wasn't necessarily viewed. Because it was noted in the 2014 MAP report to Health and Human Services that multiple stakeholders voiced a gap in nurse staffing skills mix, along with some other conditions as well.

I also understand that the MAP dual-eligibles were grouped, and I will leave that to Nancy to speak to, if she chooses, had a rather robust discussion about the importance of nurse staffing and skill mix for safety in vulnerable populations as well.

So, it is also my understanding -- and again, I would turn to my CMS colleagues here -- that these measures that would be reported, then, and incorporated into the CMS five-star rating of the reporting. And that way, then, these results could really be translated into a meaningful information for consumers and purchasers and others outside of the individual hospital using those reporting measures as well.

It is also my understanding, though, that the NQF staff did not have this information regarding how CMS would incorporate that into the five-star rating at the time of review and preparation for this meeting.

So, again, I know that we have NDNQI subject matter experts on the phone, actually in

the audience as well, and those that actually had conversation with CMS about how this could be incorporated.

Lastly, I would suggest that this is a parsimonious measure that impacts outcomes, given the measure is clearly associated with safety, quality, and patient outcomes.

Thank you.

CHAIR OPELKA: Karen, is your card up? All right.

Any other comments from the group?

Pierre?

DR. YONG: Thanks, Dana, and thanks for the opportunity.

I just want to clarify that in terms of what Dana was referencing in terms of a STAR rating for hospitals, that is the current project that we are working on. We have a TEP in process that is currently underway that is reviewing the measures currently in Hospital Compare and making recommendations about which measures would be appropriate to include in a STAR rating.

So, that process is underway, and those comments will be available for public review and for public comment as well. So, those decisions, final decisions, on which specific measures would be included in STAR ratings has not been made.

I just wanted to offer that clarification.

Thank you.

CHAIR OPELKA: Thank you.

Jack?

DR. FOWLER: Yes, actually, I have to say, when I looked at the list, I was surprised that these were not supported.

From a user perspective, first of all, I have to say this is one of the most easy-to-understand measures around; that is to say, what is the ratio of nurses, et cetera. Those seem very transparent and nice.

The notion that it is more used -- I understand outcomes and how you use your staff can affect how things turn out. But, having lots

and lots of outcomes, almost all of which are negative complications, which is all we can do, again, from an evaluation and user perspective, it is not nearly as helpful, it seems to me, as one or two measures that says, what does the nursing staff look like?

So, I think from a user point of view, this is a pretty useful measure and parsimonious in the sense that it can be a lot simpler than a lot of the other ways we have to evaluate material.

So, I am going to vote for this.

CHAIR OPELKA: Nancy?

MEMBER FOSTER: So, I have lots of questions about the measure, the measures, but really more appropriate for the endorsement process. So, I will hold for that when that comes up.

But my only comment is that there is also a data transmission issue that, in fact, is the same issue as before. If the registry that is currently collecting the data can easily

transmit it to CMS, and CMS can accept it in a way, so that we are reporting it once and using it twice or more times, great. If not, we need an easy-to-use mechanism that all hospitals, including those who choose not to report through the nursing database, can report the data if this measure moves forward.

CHAIR OPELKA: Mitchell? Is your microphone on?

DR. LEVY: I want to echo what Jack said. Of all the measures, the recommendations, this is the one that I was surprised at the decision by staff, the recommendation by staff.

So, I guess, for me, it would be helpful to hear again why the recommendation not to support it. I can read, and I understand about that there are measures, but I am still not understanding fully the recommendation not to support. And it is just counterintuitive for me.

CHAIR OPELKA: I asked the same question. I said, why is this here? Yes, that's what the question is to the staff: how did this

land in the do not support?

MR. AMIN: I will just say that the preliminary analysis by the staff is driven by the programmatic guidance, the measure selection criteria that specifically states what types of measures we're looking for.

And staff put it up as a straw person for reaction. We have no skin in the game.

(Laughter.)

So, if you have an interest in changing it --

DR. LEVY: Was this like late at night after a lot of them, and you're saying, "I don't like this one."?

(Laughter.)

MR. AMIN: It is what it is. If you guys want to change it, it is your decision. I mean, we just put together a straw person for you to react to. So, if you would like to change it, feel free.

(Laughter.)

CHAIR OPELKA: There's no defense for

them.

(Laughter.)

MEMBER FOSTER: I think the fact that we had explicitly indicated a preference for outcome measures and a lesser degree to process measures, and really expressed a lack of enthusiasm for structural measures, was probably what drove their decisionmaking here, just out of defense for their decision.

CHAIR OPELKA: Don't give them any cover.

(Laughter.)

DR. LEVY: Yes, exactly.

CHAIR OPELKA: Don't give them any cover.

Andrea?

MEMBER BENIN: Do we have a sense of how the data will be, like the targets, the benchmarks, like how would that be used? Like how would that be reported? Because like what is good, right?

So, every patient has 24 hours. Is it

8? Is it 17? Is it 12?

And I know that the NDNQI report comes out by unit, but what are we aiming for here when we see this data come up on Hospital Compare, or wherever it is going to come up? Like what are we -- that's my question.

CHAIR OPELKA: Dana?

MEMBER ALEXANDER: So, that was a question that I had as well, and that is where we need the measure steward to really speak to that, and in terms of how the mechanics, and, then, what might be the plan for CMS to incorporate that into the five-star rating. So, I don't know if the measure steward is available to speak.

CHAIR OPELKA: Very briefly.

MEMBER ALEXANDER: Okay.

MS. CRAMER: Hi. This is Emily Cramer. I am with NDNQI, as the measure developer. The American Nurses Association is actually the steward, and I think they have got folks in the audience.

Currently, we report this as sort of

quartile percentages of staffing, and it is adjusted for expectations for different staffing levels across different unit types. Of course, you expect higher staffing on acute care than you would on a medical unit, and so forth.

And so, that is how we sort of calculate for the whole hospital, is to adjust for those expectations of different staffing across settings. And so, the adjustment that we are making, proposing to make for the five-star rating is to move pretty easily from the quartile reporting to quintile reporting. So, you would actually be able to see who is in the top versus the lowest levels of nurse staffing across hospitals.

Does that help --

CHAIR OPELKA: Thank you.

MS. CRAMER: -- answer the question?

CHAIR OPELKA: That was brief.

Any other?

(No response.)

All right. So, there are two measures

that are proposed to conditional support pending NQF endorsement, as respecified for a facility. All right, that's the motion.

The motion is to move from do not support to conditional support, and the condition is NQF endorsement. And it is a respecification.

MS. IBRAGIMOVA: So, the question is skill mix, registered nurse, licensed vocational/practical nurse, and unlicensed assistive personnel and contract, and nursing hours per patient day. Do you agree with the motion to move it from do not support to conditional support pending NQF endorsement? One, yes; two, no.

(Vote.)

The results are 71 percent, yes, and 29 percent, no.

CHAIR OPELKA: All right.

So now, we have consent calendars, and we have a support calendar, a conditional support calendar. We do not have a do not support calendar, and we have an encouragement for

continuing development. So, we have three calendars to vote on.

So, first, the support calendar.

Oh dear. Something is happening to me. I need a telescope. It used to be binoculars. I'm angry. I'm getting angry over here.

(Laughter.)

MS. IBRAGIMOVA: IQR Consent Calendar 1. Support National Healthcare Safety Network central-line-associated bloodstream infection outcome; National Healthcare Safety Network catheter-associated urinary tract infection outcome, and participation in a Patient Safety Culture Survey.

CHAIR OPELKA: All right.

MS. IBRAGIMOVA: Do you agree with the support calendar? One, yes; two, no.

(Vote.)

The answers are 100 percent, yes; zero percent, no.

CHAIR OPELKA: We are going to go in a minute to the conditional support group. And

there were lots of different comments about the conditions. Instead of repeating all those conditions, we are just going to list the measures. We captured your conditions in your comments. So, for this next vote, we will go through the list of those that have conditional support.

MS. IBRAGIMOVA: IQR Calendar, Conditional Support. Falls with injury; patient fall rate; hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following acute myocardial infarction hospitalization; hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following heart failure hospitalization; hospital 30-day, all-cause, unplanned, risk-standardized days in acute care following pneumonia hospitalization; hospital-level risk standardized payment associated with an episode of care for primary elective total hip and/or total knee anthroplasty; kidney/urinary tract infection clinical episode-based payment measure; spine

fusion/refusion clinical episode-based payment measure; cellulitis clinical episode-based payment measure; gastrointestinal hemorrhage clinical episode-based payment measure; hospital 30-day, all-cause, risk-standardized readmission rate following pneumonia hospitalization; hospital 30-day, all-cause, risk-standardized mortality rate following pneumonia hospitalization; cardiac rehabilitation patient referral from an inpatient setting; proportion of patients hospitalized with AMI that have a potentially-avoidable complication during the index day or in the 30-day post-discharge period; proportion of patients hospitalized with pneumonia that have a potentially-avoidable complication during the index day or in the 30-day post-discharge period; proportion of patients hospitalized with stroke that have a potentially-avoidable complication during the index day or in the 30-day post-discharge period; skill mix, registered nurse, licensed vocational/practical nurse, unlicensed assistive personnel and

contract, and nursing hours per patient day.

Do you agree with the conditional support calendar? One, yes; two, no.

CHAIR OPELKA: Laura, you need a break.

(Laughter.)

Okay.

(Vote.)

MS. IBRAGIMOVA: The results are 79 percent, yes; 21 percent, no.

CHAIR OPELKA: All right. There is one calendar that remains. There is nothing on the do not support. The calendar that remains is the encourage for continued development. Nothing was pulled from here.

These were the adverse drug events; hospital-wide all-cause, unplanned readmission; the timely evaluation of high-risk in the ED; the perinatal C-section. All of these I believe we had also discussed yesterday as well. So, these are all, as yesterday, they were in the encourage for continuing development. They remain there

today. So, we are voting on these.

MS. IBRAGIMOVA: IQR Consent Calendar 7, Encourage for Continued Development. Adverse drug events; inappropriate renal dosing of anticoagulants; hospital-wide all-cause, unplanned readmission; hybrid eMeasure; timely evaluation of high-risk individuals in the emergency department, and perinatal care; cesarean section; PC O2; nulliparous; women with a turned singleton baby in vertex position delivered by cesarean section.

Do you agree with the encourage for continuing development calendar? One, yes; two, no.

(Vote.)

The results are 96 percent, yes; 4 percent, no.

CHAIR OPELKA: All right. Lunch.

(Laughter.)

So, at 1:30 we are going to reconvene, but please grab your lunch. And then we will start again at 1:30.

(Whereupon, the above-entitled matter went off the record at 1:11 p.m. and resumed at 1:34 p.m.)

CHAIR OPELKA: So, we're going to ease you back in just a little bit, I hope, by shifting gears just a second going to the last program that you have on your agenda called the Hospital Readmission Reduction Program. That has one measure which is currently classified as support, and then we'll loop back to Value-Based Purchasing in the Cancer Program. So, Hospital Readmission Reduction Program. Would you describe the program, please?

MS. BAL: Okay. So, we'll be talking about the Hospital Readmissions Reduction Program, also known as each readmissions. Basically, pay-for-performance and public reporting, payments are based on information publicly reported on the Hospital Compare website.

This is going to --- the incentive program is for the last related group, so DRG

payment rates will be reduced based on a hospital's ratio of actual readmissions. The main critical program objective as determined in October are to reduce the number of admissions to an acute care hospital following discharge from the same or another acute care hospital, engage patients and their families as partners in care, improve patient care and reduce overall health care costs, exclude planned readmissions for the measures in the program, encourage hospitals to take a leadership role in improving care beyond their walls to care coordination across providers since the cause of readmissions are complex and multi-factoral. Also, to improve care transitions by reducing readmission rates to optimizing processes under the hospital's control, and acknowledging that factors affecting readmissions are complex, and they include environmental, community-level, and patient-level factors.

Lastly, just recognizing that multiple entities across the health care system including hospitals, post-acute care facilities, skilled

nursing facilities, and others all have a responsibility to insure high-quality care transitions to reduce unplanned readmissions.

CHAIR OPELKA: And I realize that if everybody is in agreement and the one consent calendar and one agenda item is unanimous we don't need to do this, but Kelly and David spent some looking at this, so, Kelly, would you like to provide any comments?

MS. TRAUTNER: Only that I'm ready to vote.

CHAIR OPELKA: Good. David, would you like to provide any comments?

DR. ENGLER: Well, I've been told to be brief, so I'll be brief. Let's vote for it.

CHAIR OPELKA: Okay. Boy, I tell you. So, there is one measure and does anybody have a motion to move that measure from the support category? Nancy.

MS. FOSTER: So, I assume this is the same measure we discussed this morning that actually is being respecified and needs to come

back through NQF endorsement, so I'm not sure why it ended up in support here, but I would think that this falls in the --- at the very least support with condition of NQF endorsement. And I want to get clarity from staff on that point.

MR. AMIN: That is correct. It is internally consistent. So, this isn't updated to the finalized measure, and in that case it would fall into the conditional support based on NQF endorsement.

MS. FOSTER: So, I would like to propose that we move this into the conditional support pending NQF endorsement. And as I did this morning, I would also like to add the condition that the --- I'm sorry, whatever Taroon's wonderful language was, but essentially there be appropriate consideration of risk adjustment, whether that's stratification or anything else, appropriate considerations.

MR. AMIN: Let me just clarify that for everybody else. It would be --- there would be a re-review by NQF and endorsement, and then also

consideration for SDS adjustment in the upcoming NQF trial period.

CHAIR OPELKA: Motion has been seconded. Richard, did you have your card up?

DR. BANKOWITZ: I think Nancy covered my thoughts on that. Thank you.

CHAIR OPELKA: Is there any other discussion about this motion, and the entire calendar, and all the measures? Okay, is there any --- would we open it up --- oh, I'm sorry, Nancy.

DR. HANRAHAN: This is a gap. Most of these measures are --- have been developed on age 65 and older. And I know that there's a focus on accommodating or including socioeconomic status and disparities, so that's a whole area of gap in relationship to this Hospital Reduction Readmission Program, and I'd really encourage us to put that as a high priority in some ways for NQF to really take a look at that.

CO-CHAIR WALTERS: So noted. Any comments in the room? Okay, Cathy, can we open it

up to public comment?

OPERATOR: Yes, sir. At this time if you would like to make a comment please press star then the number one. There are no public comments at this time.

CO-CHAIR WALTERS: Comments in the room? Would you tee up the vote, please? So, the motion is to move it into conditional support. We heard the conditions earlier. A yes vote will mean you favor that movement.

MS. IBRAGIMOVA: So, the question is hospital 30-day all cause risk standardized readmission rate following pneumonia hospitalization. Do you agree with the motion to move to conditional support pending NQF endorsement? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are in, 96 percent yes and four percent no.

CO-CHAIR WALTERS: Thanks very much. Okay, now we'll go back to the Value-Based Purchasing Program. The Value-Based Purchasing

Program also has one calendar, all five measures are classified as support, so we'll need details of the program.

MS. BAL: Okay, so this is the Hospital Value-Based Purchasing Program, also known as VBP. This is a pay-for-performance program, and the main goals are to improve health care quality by realigning hospital's financial incentives and to provide incentive payments to hospitals that meet or exceed performance standards.

The critical program objectives determined in October were to include measures where there is a need or opportunity for improvement. Focus on areas of critical importance for high performance and quality improvement, and I link clinical quality and cost measures to capture value. NQF endorsed measures are strongly preferred. Keep the program measure set parsimonious to avoid diluting the payment incentives, and some of the gaps that were identified were to include medical error, mental and behavioral health, emergency department

throughput, hospital's culture of safety, and patient and family engagement.

CO-CHAIR WALTERS: Okay, the lead discussants now. Michael. Sorry I caught you off guard there.

MR. AMIN: Maybe we can walk through the preliminary analysis, Ron, while he's getting prepared.

CO-CHAIR WALTERS: Okay, walk through the preliminary analysis first.

MR. AMIN: So, we won't go into detail on the first --- let's give everyone a moment here. We're still looking for it here, as well. So, we have the 30-day risk standardized COPD hospitalization mortality measure. Again, the VBP Program currently includes 30-day readmission rates for AMI, heart failure, and pneumonia. COPD is another leading cause of death and hospitalization. This measure is also currently used in IQR supporting alignment and parsimony.

I would just point out that there were two comments that were generally supportive on

this measure. We have the pneumonia hospitalization risk standardized mortality rate following pneumonia hospitalization measure. This measure addresses critical program objectives that have been identified. It is tested at the appropriate level of analysis, NQF endorsed, and it remains a critical area for measurement.

There was one comment that was generally supportive on this measure. I don't think there's a need, necessarily, to go through the CLABSI measure. I think we've gone through that measure quite a number of times. There were no public comments received on this measure as it relates to this program.

The quality measure, again, this is an update to the finalized measure, and this was --- there were comments on this measure similar to what we've discussed before very much focused on the spinal cord injury patients.

And then, finally, the final measure on the VBP list here is the death among surgical inpatients with serious treatable complications

which is PSI-4. This measure is NQF endorsed, and has been prioritized by the MAP for inclusion in the VBP Program, and addresses many of the important improvable patient safety concerns. There was one comment that was generally supportive on this measure, so there are five measures for consideration. All five are on the support calendar.

CO-CHAIR WALTERS: Okay, Michael.

DR. PHELAN: You know, to me all these just seem to be exactly as Taroon described, and the idea that we support them kind of speaks to where we want to go with quality measures going forward. So, I would actually move to vote on this support column, and do we need a whole lot of discussion around these? Some of these have been mentioned already. Can I move to make a vote?

CO-CHAIR WALTERS: Okay. So, right now there's a motion on the table for all five to move to support. Hold that a second. Mitchell? Mitchell is not here. Okay. Other discussion?

Nancy Foster.

MS. FOSTER: Thanks. Not to be disagreeable, Michael, but there are a couple of things I need to understand about these measures. But, also, I would like to suggest that we pull the death among surgical inpatients measure for further discussion, and the --- and perhaps do not --- I would recommend do not support. And the --- I'm sorry, the mortality measures because they're being retooled, I think we need to think about conditional support there with bringing it back once we've had a year of public reporting. So, that would be my recommendation.

CO-CHAIR WALTERS: Michael? I'm just wondering if you wanted to change your motion or not?

DR. PHELAN: I'll support --- second Nancy's recommendation to move --- to listen to the discussion on these and see where we go with it.

CO-CHAIR WALTERS: Okay. So, we have number one and number two, motion to move to

conditional support, and number five to move to do not support. Now we'll continue the discussion. Richard?

DR. BANKOWITZ: Yes. With regard to the pneumonia mortality my question was are we going to move into Value-Based Purchasing the old measure at a time when we're beginning to explore the newer measure? That doesn't make sense to me, so I agree with Nancy, we need to let this measure move through the process, and then publicly report the newer measure before it goes into Value-Based Purchasing, unless we want a disconnect between what's being measured in various programs, which I think -- which would be incredibly confusing, I think.

MS. FOSTER: Ron, I'd appreciate clarity from CMS about --- to Richard's point, what are we moving here?

CO-CHAIR WALTERS: Okay. Emma, or Pierre.

DR. YONG: What's currently on the MUC list are the measures that are already in the

program in IQR, so these are the current measures that were previously reviewed by the MAAP.

MS. KOPLEFF: I'm sorry. So, we're --- we never reviewed them for this program, though. Correct?

DR. YONG: Correct.

MS. KOPLEFF: Okay, thank you. And just a clarifying question for Nancy regarding the COPD measure. You mentioned a need to publicly report for a year first, but I'm just staying with the --- how this program works. Wouldn't we already have the --- we would have reporting --- we'd have included in IQR for a full year before the Value-Based Purchasing Program, so I'm just clarifying the condition, if you will.

MS. FOSTER: So, I have to admit I was confused. I thought we were trying to move retooled measures, so I'm with Richard. I don't understand why we'd be moving measures that aren't up --- that CMS has declared not up to snuff and has engaged in a process of retooling to a Value-Based Purchasing Program.

CO-CHAIR WALTERS: So, your previous motion was to move it into conditional support.

MS. FOSTER: Correct.

CO-CHAIR WALTERS: Is that motion modified in any way?

MS. FOSTER: Yes, at this point I would think that it --- do not support, I would move that we do not support moving these into Hospital Value-Based Purchasing with the expectation that the appropriate measures would come back after they've been included in IQR.

MR. AMIN: Well, I think Nancy has brought up an important point that I think we need some clarification on, because I think what --- you've gone conditional support if it was the updated version, and you've gone do not support on the prior --- on the old version. So, if CMS can clarify this measure that we're reviewing, is it the original version, or is the one that's going up --- undergoing updates?

DR. YONG: Yes, I apologize. So, the COPD measure is not in the program, so that would

be a new measure for the program. The pneumonia mortality measure is currently in the program. What's up on the MUC list is the same measure we reviewed before with the cohort change, so that was the expanded to include aspiration pneumonia, as well as pneumonia with sepsis. So, that was the same discussion we had earlier.

CO-CHAIR WALTERS: I believe you probably want to modify your motion again. Right?

MS. FOSTER: I need an aspirin. So, let me see if I have this right. The COPD measure is the one that's currently in IQR and is not being retooled? Okay. So, let me modify my motion to say I am no longer including COPD in my motion. I am only focusing on the pneumonia measure, and in my --- and I go back to conditional support on the pneumonia measure conditioned on getting NQF endorsement of that retooled measure having a year's worth of data on it, and then bringing it back here because at that point, you know, things will have moved on. So, bringing it back for potential inclusion in the program.

CO-CHAIR WALTERS: Yes, number one, number three, and number four currently are in the support bucket, and number two now has been moved to conditional support, and number five is still --- the motion is to move to do not support. Is that your motions?

MS. FOSTER: Thank you for streaming it so well, yes, that is my motion.

CO-CHAIR WALTERS: It does require a little accountancy to keep track of these things. Is there any other discussion at all about the pneumonia --- let's take the pneumonia first. Is there any other --- before we vote on that motion, is there any other discussion about moving the pneumonia measure to conditional support for the reasons that Nancy said, and Pierre agreed to? Okay, hearing none, want to do a vote? Yes. Oh, sorry. Vote on the measure?

MR. AMIN: So, the vote is on your --- pneumonia.

CO-CHAIR WALTERS: Measure two.

MR. AMIN: Okay. Nancy, I thought we

were on the same page.

CO-CHAIR WALTERS: This vote is on measure two to move to conditional support.

MR. AMIN: Okay, yes. It's the pneumonia mortality rate, the hospital 30-day all cause risk standardized mortality rate following pneumonia hospitalization moving to conditional support.

CO-CHAIR WALTERS: Correct.

MS. IBRAGIMOVA: So, the question is hospital 30-day all cause risk standardized mortality rate following pneumonia hospitalization. Do you agree with the motion to move to conditional support? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 96 percent yes, and four percent no.

CO-CHAIR WALTERS: Okay, that just created another calendar. And then the second motion was to take measure five, death among surgical inpatients and move it to do not support.

MS. FOSTER: So, let me be clear about. The concept of being able to accurately measure death among surgical inpatients or any other group of inpatients is incredibly important. However, this AHRQ PSI by CMS' own analysis as they contracted with Mathematica to do, has extremely low levels of reliability, and that --- so low that you really can't suggest that this is an accurate and fair measure. And for that reason, I don't think this measure should be used. Personally, I don't think it should be used for public reporting, but certainly not moving it into a pay-for-performance program where we cannot accurately assess performance, either improvement or actual performance.

MS. OWENS: This is Pam Owens from AHRQ. Can I speak?

CO-CHAIR WALTERS: Yes. Go ahead.

MS. OWENS: Okay, sorry. Nancy, I'm not sure which report you're referring to about Mathematica's analysis. Isn't this the one that was brought up several years ago?

MS. FOSTER: To the best of my knowledge, Pam, there hasn't been another one done, so yes.

MS. OWENS: Okay. So, that one actually has a lot of details that don't make this actually appropriate --- well, appropriate not the word. Completely accurate to this discussion. That was trying to make a distinction between six months of data and two years of data. And, in addition, additional analyses both with Mathematica and our other contractors actually show higher reliability, so I could go back and I'd be happy to come back to the Committee with the full details of why that particular memo actually doesn't adequately reflect what was going on, the reliability was calculated differently than the way that we calculate reliability. For instance, it was based on six months of data, AHRQ actually doesn't recommend using six months of data. I mean, there's lots of details here that are not quite consistent, so I don't want to put --- I understand where you're

coming from, Nancy, but I think at some point we've got to come to some conclusion regarding that memo, in particular, because it doesn't --- on the surface it might look like it's representing what you're talking about, but in its detail it actually doesn't give a fair picture.

MS. FOSTER: So, Pam, I appreciate that, but our read was that they were using 24 months worth of data, so there's a lot of information that needs to be clarified here. And until that is clarified, I cannot suggest going forward with this measure.

CO-CHAIR WALTERS: Pierre, or Richard?

DR. BANKOWITZ: Yes. So, Premier uses this measure in its own improvement collaboratives as a measure we report on. There's a lot of concern about this measure, I will say that. Our members are not particularly convinced it's measuring what it's intending to be measuring, and we're in the process of trying to actually validate some of it, so I do think there

is some concern about whether or not this measure accurately captures these surgical patients with treatable conditions, so I have to support Nancy and say this is not yet ready to go to a Value-Based Purchasing model.

CO-CHAIR WALTERS: Sean.

DR. MORRISON: Just another concern that's been brought to my attention by a number of people in the palliative care field where the majority of surgical deaths are not due to complications. This has had a chilling effect on palliative care consultation because the surgeons are worried, very worried about the mortality rates. Not specifically this one, but the 30-day mortality rates, what we're seeing is consultations on day 31, so that this has had a very, very strong affect on people having a comfortable death in the hospital because of worries about the mortality rates.

MS. OWENS: This is Pam Owens again from AHRQ. I just want to speak to this notion of reliability just so that we can deal concretely

with some numbers. When we look at it with the HCAHP databases using version 4.5, our reliability estimate is on the average signal to noise ratio is .704, just so that's --- I didn't have that number when I was talking before.

DR. PHELAN: Can you tell us what that means?

MS. OWENS: Well, that's a good question. Let's see. So, the metric regarding reliability that we use is a signal to noise ratio, which is the ratio between the hospital variance which is a signal to the within hospital variance which is the noise. So, the formula that we're using is signal over signal plus noise. It is --- we use an empirical base variance shrinkage estimator, and what it's saying is that the percent of signal variance that is explained by performance score is around 70 percent.

DR. PHELAN: Meaning that 30 percent of the time you're getting a lot of noise, so a number closer to 100 percent or closer to one is considered a reliable measure. Correct?

MS. OWENS: Well, not necessarily reliable. That would be a perfect measure which is not possible. But, you know --- so, if you think about it above .65, you know, between .65 and .70 is really actually very good reliability.

CO-CHAIR WALTERS: Cristie had her hand up next.

MS. TALLANT: I just wanted to know, is this measure already being reported in IQR? And do we have any information from IQR as to how this measure is performing, and any variation or any information from the IQR reporting that would help us with this discussion?

DR. YONG: We'd have to check into that.

MS. TALLANT: Thank you.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: And, Pam, I appreciate the data you just shared, but the HCAHP database is an all-payer database, and what we're talking about here is calculating it on Medicare-only --- Medicare fee-for-service only patients, which

has a much smaller sample size, which usually decreases the level of reliability of the data, and the published results that I'm referring to suggest that the measure has a .32 level of reliability.

MS. OWENS: Right. Well, so, Nancy, you're absolutely right in terms of reliability as a function of a sample size. So, when you deal with reliability on six --- which is one of the reasons why AHRQ doesn't suggest using it on six months of data. However, you're 100 percent correct in that what Medicare is --- what this --- what Value-Based Purchasing and IQR refer to as the Medicare fee-for-service population, and then there's IPPS Hospitals. And what the HCAHP analysis is, is an all-payer database and it's community non-rehab hospitals, so there's a little bit of distinction between the hospitals included in one versus the hospitals included in the other.

That being said, AHRQ and CMS are actually working very collaboratively to try to

better align so that going in both in terms of when it goes to NQF, and you all know at the MAP in the future what is the reliability as estimated not on six months of Medicare fee-for-service data but actually estimated on the two-year reporting period, and what is the reliability of an all-payer database? So, we understand exactly what that translation is.

CO-CHAIR WALTERS: Michael?

DR. PHELAN: Would it be possible to get some data, some reliability data on just the Medicare database? Would that help move this from a do not support to a conditional support based on what that data shows? And if the reliability is within a reasonable expected range, you can -- - I'm not sure for this type of quality metric what kind of reliability is necessary or wanted. Would that be helpful to you, Nancy, because I'm hearing two distinct differences. I'm hearing oh, we've got a huge database and it says this, and I'm hearing well, you know, it's an all-payers but we have data on the Medicare, the reliability

on the Medicare database, and would that help you move from a do not support to a support, because I think this is an important area that I want to at least see if we can get some data out around it?

CO-CHAIR WALTERS: Richard?

DR. BANKOWITZ: It wouldn't help me because I think the reliability data is interesting as a measure of the precision of the measure. It's not a measure of the accuracy of the measure. What we want to know is how accurately does this classify patients correctly, and for that you need to go to the chart and make a decision as to whether, in fact, this was death from a treatable complication. So, to my knowledge it hasn't been done yet. We're actually starting to look at that because we think this is an important measure to explore, but I think reliability is only secondary to the accuracy of this measure to accurately classify.

CO-CHAIR WALTERS: So, if I can summarize the last 20 minutes or so today there

are concerns about the validity and the statistical application of the data that's available to this program. We're not going to resolve that today. We're not going to --- the statisticians can go on forever about things like that. So, is there any other discussion from anyone? Emma?

MS. KOPLEFF: I'm wondering if NQF staff can comment or the developers on if and when this measure is due for endorsement maintenance, because I think that could reflect on our desire as we've discussed to sort of see some of the updated research specific to the Medicare population.

MR. AMIN: Yes. Unfortunately, I was just looking around to see if my colleague Andrew --- oh, actually, he is. Okay. No, okay. So, yes, it's not clear when this measure would be up. We can find that information out, but we don't have that in front of us. This measure is currently endorsed, and that process does have a sense of looking at reliability.

MS. OWENS: This is Pam Owens from AHRQ. We are planning on submitting AHRQ's perspective for Fiscal Year 2016, so that would be the next year. It is currently --- PSIs are the focus of all refinement, the major refinements for the AHRQ QI program. Every indicator goes through an annual review, and then we do deep dives into particular modules or particular indicators, so that's an ongoing process, as well. We will bring all of that information back to the NQF. My understanding is that it has already been reviewed twice by NQF and endorsed twice by NQF. That's why it's up again. So, I hope that helps.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: In response to your question, Michael, what would --- I don't think this particular panel is constituted in a way to judge the reliability, and validity, and accuracy of the measure, but if the condition were that it go through NQF for consideration of endorsement as used in the Medicare program, I

could live with that. I could live with that. So, if that is something that people feel more comfortable with, I'm happy to change my motion from do not endorse to endorse conditional upon review by NQF as a Medicare fee-for-service measure with particular consideration for reliability, validity, and accuracy given all of the clinical concerns, as well as statistical concerns that have been raised about this measure. I know that technically NQF always looks at those things, but this one needs an eagle eye.

CO-CHAIR WALTERS: Any other discussions? Okay. Any public comments about --- not yet, not yet. So, we have a motion we have not voted on yet. The motion about measure five, death among surgical inpatients, has been modified now to conditional support with the conditions as mentioned by Nancy and discussed around the table. Are we ready to set up a vote for that?

MS. IBRAGIMOVA: So, the question is death among surgical inpatients with serious

treatable complications, PSI 4. Do you agree with the motion to move to conditional support pending NQF review and endorsement? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 91 percent yes, and nine percent no.

CO-CHAIR WALTERS: Okay, that leaves us now with two calendars, calendar one on the Value-Based Purchasing Program which is support, and calendar two which is conditional support. Before voting on the calendars we would like to open up the lines for public comment. Cathy, would you --- or Andrea.

DR. BENIN: Before it didn't seem like it was the moment to bring it up, but I would move that we pull off the NHSN measures off of the Value-Based Purchasing with the rationale that they are in a lot of flux right now. They're going to be in the IQR anyway. Is now the right time to put them in the VBP? Sorry, I didn't get a chance to make that movement before the other discussion.

OPERATOR: I'd like to ask for public comment, press star one on your telephone key pad.

DR. BENIN: I would just stick it in do not support for now, and then it'll get figured out in the next cycle. That's my proposal. Me and HAC and 50 million other things.

CO-CHAIR WALTERS: Yes, are there any public comments?

OPERATOR: There are no public comments on this time.

CO-CHAIR WALTERS: Are there any comments in the room? Okay, there are no comments in the room.

First, let's --- just a second. So, I understand now that you withdrew your previous comment about pulling them off?

DR. BENIN: Specifically put it into do not support. There wasn't a moment before for me to say that.

CHAIR OPELKA: So, just so we're clear, these measures are in the program.

DR. BENIN: But not in the new format. This is the new format version where there are like different ways of reporting it, and the new definitions.

CHAIR OPELKA: So, the vote do not support what you're supporting is keeping the old format in, because those measures ---

DR. BENIN: I would propose ---

CHAIR OPELKA: --- are in. They're in, so now you're voting to supplant those with new ones. If you want a do not support, you're leaving the old ones in.

DR. BENIN: It would be a conditional do not support with CMS to figure out how to make it all right.

CHAIR OPELKA: No, there isn't a conditional do not support. There's a conditional support.

DR. BENIN: I would do --- then I would do not support on both sets of measures.

CHAIR OPELKA: You can't do ---

DR. BENIN: The ones out of there.

CHAIR OPELKA: The other --- the old measures are not up. They're in the program.

DR. BENIN: Okay. Then why don't I express my concerns in form of commentary because I don't --- there's no motion then that I can make, Frank, that will get us there. So, I will say to you that I think that having measures that are currently under flux ---

CHAIR OPELKA: You can make a conditional support.

DR. BENIN: What is the condition?

CHAIR OPELKA: You can't do a conditional do not support.

DR. BENIN: I can't think of what the condition is, though. The condition is that they get appropriate IQR exposure as they normally would, as opposed to --- like it doesn't make sense to me to do it this way. I'll just say that I think that these measures would need to have their usual --- help me out, Nancy.

MS. FOSTER: If I can, I think Andrea is raising a very important question. Right?

Which is the timing of moving these into Hospital Value-Based Purchasing. You've got to have a year's worth of data collected as they are specified in the new way in order to move them into Hospital Value-Based Purchasing, so my assumption, and I guess I should be very clear about that and get confirmation from CMS, is that they are proposing these for Hospital Value-Based Purchasing at this point knowing that they will not move in for a couple of years.

CHAIR OPELKA: That can be the condition.

MS. FOSTER: Until the ---

CHAIR OPELKA: That they meet the statute.

MS. FOSTER: Okay.

DR. BENIN: That they meet the statute and in that pending time take down the measures that conflict with the other reporting mechanisms.

CHAIR OPELKA: No, that's not ---

DR. BENIN: Because we've now ---

CHAIR OPELKA: --- in order. Those measures are in the program. We're not removing --

DR. BENIN: I'm persistent, I'm very persistent.

MS. FOSTER: But I think the ---we're going to be in this funny flux and that --- because these measures are already in Value-Based Purchasing under the old specification.

DR. BENIN: They are? I thought they were not.

MS. FOSTER: Yes. Yes.

CHAIR OPELKA: They are.

MS. FOSTER: They are in the program under the old specification. You can't continue to run them under the old specification and the new specification to judge improvement. You have to have this sort of strange year. I don't know -- or two. So, I'll be very curious as to how CMS handles that.

CO-CHAIR WALTERS: We talked about this yesterday morning, but yes, looking for some sort

of guidance about how you would phase these in and phase the other ones out.

DR. YONG: So, I think this is an important question that's been raised, and we did just talk about this yesterday. And just to repeat what I said yesterday, I think we are aware that there is potential confusion when, you know, we have two different rates up. I don't think we have at this point figured out exactly how to phase it in, and how to minimize --- but the goal would be to minimize confusion. And, certainly, that would be done through rulemaking, as well, so there would be opportunities for transparency and for public comment.

Just related to sort of the concern here, you know, I think what Nancy's motion, which was approved earlier, which was moving the pneumonia measure with the expanded cohort from support into conditional support after one year of public reporting was my understanding of that motion, seems like maybe the idea that would address Andrea's concern would be to move these

measures into that same sort of condition.

CO-CHAIR WALTERS: Would you like to make a motion?

DR. BENIN: Okay. I move that we move the measures --- the two NHSN measures to conditional support on the condition that they go through the appropriate duration of reporting and evaluation through the IQR and other processes.

CO-CHAIR WALTERS: Is there a second?

DR. BANKOWITZ: Second.

CO-CHAIR WALTERS: There's been a recurrent theme for two days now. Take a vote on the motion about the CAUTIs and CLABSIs moving to conditional support.

MS. IBRAGIMOVA: So, the question is National Health Care Safety Network's central line associated blood stream infection outcome and National Health Care Safety Network catheter-associated urinary tract infection outcome. Do you agree with the motion to move from support to conditional support? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 91 percent yes, and nine percent no.

CO-CHAIR WALTERS: Okay, thank you. Assuming that no one has any last minute changes about measure one, we have one measure left in calendar one, the support calendar. We can now subject that to a vote. Support calendar one.

MS. IBRAGIMOVA: The Value-Based Purchasing consent calendar one support hospital 30-day all cause risk standardized mortality rate following chronic obstructive pulmonary disease hospitalization. Do you agree with the support calendar? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 87 percent yes, and 13 percent no.

CO-CHAIR WALTERS: Thank you for that vote. Now we'll proceed to the vote of what would be calendar two, which didn't start out this session as a calendar but has become a calendar with four measures in it. Do you have those lined up?

MS. IBRAGIMOVA: Value-Based Purchasing consent calendar conditional support. Hospital 30-day all cause risk standardized mortality rate following pneumonia hospitalization, death among surgical inpatients with serious treatable complications PSI-4, National Health Care Safety Network central line-associated blood stream infection outcome, and National Health Care Safety Network catheter-associated urinary tract infection outcome. Do you agree with the conditional support calendar? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 96 percent yes, and four percent no.

CO-CHAIR WALTERS: Thank you for your votes. Okay, that's ---

(Off microphone comment)

CO-CHAIR WALTERS: Okay, that concludes Value-Based Purchasing. Now we'll proceed with the PPS-Exempt Cancer Hospital Quality Reporting Program. Would you delineate the details of the program, please?

MS. BAL: So, this is the PPS-Exempt Cancer Hospital Quality Reporting Program. It is a reporting program with information publicly reported beginning in 2014, so this year. There is currently no financial incentive for the 11 hospitals in this program, and CMS plans to create an incentive program in the future.

The main critical program objectives are include measures appropriate to cancer hospitals that reflect the highest priority services delivered by these hospitals, align measures with the Inpatient Quality Reporting Program, and the Outpatient Quality Reporting Program, where appropriate and relevant. And the following gaps should be considered, cancer care --- I'm sorry, in cancer care quality are pain screening and management, patient and family care giver experience, patient reported symptoms and outcomes, survival, shared decision making, cost, care coordination, and psycho social and supportive services.

MR. AMIN: So, we'll start off with at

least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer. This measure, the preliminary analysis summaries of this measure, these are all within the support calendar, so there are eight measures in the support calendar, and one measure in the measure under development pathway where we're encouraging continued development.

The first is at least 12 regional lymph nodes are removed and examined for colon cancer. This measure addresses critical program objectives identified for the PPS-Exempt Cancer Hospitals. It has been tested to the appropriate level of analysis. This is NQF endorsed and promotes alignment across programs.

This measure received two public comments. The Alliance of Dedicated Cancer Hospitals noted that there are very high rates of performance in cancer centers, particularly the performances between 95 and 99 percent with minimal opportunity for quality improvement. And, further, there was concern around the exclusion

criteria that needs to be clarified and evaluated for comprehensiveness for this patient population.

Second is the post-breast conservation surgery irradiation. So, the measure addresses critical program objectives for PPS-Exempt Cancer Hospitals, been tested to the appropriate level of analysis, is NQF endorsed, and supports alignment.

There was commenters that were very supportive but noted the inclusion criteria needs to be both clarified and evaluated for comprehensive before application to this program. Again, the comments are from the Alliance for Dedicated Cancer Centers, noted that this measure is topped out in the 90 percent range with several centers reporting 100 percent.

Third is a needle biopsy to establish diagnosis of cancer, so this measure addresses critical program objectives for PPS-Exempt Cancer Hospitals, also tested for the appropriate level of analysis, NQF endorsed, and supports

alignment.

So, there was one comment on this measure noting that this measure assesses adherence to important standard of care, but does not support this measure due to its exclusions.

Further, there was concern that this metric might be discriminatory toward PPS-Exempt hospitals that have a high rate of volume of external referrals where diagnostic biopsy is not necessarily by core needle biopsy.

Moving on to number four, hospice and palliative care treatment preferences. This measure is also appropriate for the level of analysis, NQF endorsed, and promotes alignment across programs.

There was one comment again by the Alliance of Dedicated Cancer Centers that was not supportive of this measure since only three of the eleven centers have inpatient palliative care units limiting the scope of application of this measure.

So, we have the MRSA outcome measure.

This has been tested to the appropriate level of analysis, this is NQF endorsed, and also supports alignment.

Again, we got another --- we have a similar comment from the ADCC, the Alliance of Dedicated Care Centers, that generally supports this measure, but believes stratification for cohorts of cancer patients should be applied. ADCC also noted that this would be duplicative reporting through lab ID.

Moving on we have the C. diff outcome measure. Again, preliminary analysis stated that it meets the program objectives, is appropriate for the level of analysis, and is NQF endorsed.

So, we received one public comment that was not supportive, noting multiple concerns, primarily noting that ADCC Centers have patient populations that are uniquely at risk for C. diff infections given underlying factors associated with the diagnosis and treatment of cancer.

We have two influenza measures,

influenza immunization, and influenza vaccination among health care personnel. The first one, again, meets the program objectives, is endorsed, and is in alignment.

There were two comments that were generally supportive of this measure. There are concerns that the target population should be clearly identified and additional exclusion criterias --- exclusion categories should be applied to this measure. And there were some specific recommendations around exclusions related to patients receiving anti-B cell antibodies and patients receiving intensive chemotherapy.

For the influenza vaccination coverage among health care personnel, again that was supported for the appropriate level of analysis, NQF endorsed, and supporting alignment across programs.

And there were two comments generally supportive on this measure with the ADCC noting that contraindications and exceptions for this

measure should be clarified to insure reporting compliance.

And then, finally, if it's okay, Ron, I'll just also include the measures under development for the sake of ease. So, this measure is still under development, and yet to be included in the program. Upon submission and recommendation of NQF endorsement, this should be reviewed again by this group. So, it generally was encourage continued development.

We did receive one comment on this measure from the ADCC that was strongly supportive of this measure, and encouraged continued final testing.

So, those are the eight measures that are in consent calendar one for support. And then we have one measure under consent calendar number two, which is encourage continued development.

CO-CHAIR WALTERS: Before we go to the lead discussants, I will ask for any request to pull anything from the calendar? Karen?

DR. FIELDS: So, we would like to

discuss needle biopsy, E0221, palliative care, E1641, MRSA, E1716, C.diff, E1717, influenza immunization, E1659, and influenza vaccination, E0431. And we'd also like to discuss the measure in development.

CO-CHAIR WALTERS: Where did ---where are you planning on pulling those to? Would you run through that?

DR. FIELDS: Do you want to go through them individually?

CO-CHAIR WALTERS: For now where you'd like to pull them to.

DR. FIELDS: So, I'd like to put the --- we would like to discuss hospice in the do not support category. We would like to discuss C.diff in the do not support category, although I need the comments from the Committee to further categorize that. And then the remainder would be into the support under certain conditions, or support with conditions, conditional support. And then I would like to propose changing the hospitalization measure to conditional support

pending NQF endorsement.

MR. AMIN: Can I just clarify that last one? So, that's the unplanned readmissions?

DR. FIELDS: Yes.

MR. AMIN: So, just for clarification, since it's a measure under development there's only two decision categories currently. The encourage continued development, and you could put additional conditions around that which we will capture. The other option there is the do not support continued development.

DR. FIELDS: Although earlier today we took several under development conditions and moved them into conditional support.

MS. O'ROURKE: So, I think you're referring to the episode-based payment measures. We have received additional data that they were further along in the process. Has this gone further in its development process?

DR. FIELDS: Yes, and we'd like to discuss that.

MR. AMIN: It's fully developed and

tested, this measure?

DR. FIELDS: Do you want to discuss that one now, or do you want ---

CO-CHAIR WALTERS: No, not now.

DR. FIELDS: Yes, we've discussed some new information.

CO-CHAIR WALTERS: Nancy, do you have your card up?

MS. FOSTER: No.

CO-CHAIR WALTERS: Okay. So, the first two have not been pulled. Oh, Cristie, yes.

MS. TRAVIS: Well, just to make it complete. You know, I would like to consider these for do not support with the rationale of the fact that they're already topped out, and that there's not a gap.

CO-CHAIR WALTERS: Meaning the first two?

MS. TRAVIS: Yes, I'm sorry. Yes, the first two. It would be 0225, and 0219.

CO-CHAIR WALTERS: Well, I don't think there's any more that can be pulled from the

calendar one. Okay. Lead discussant, Sean.

DR. MORRISON: So, Ron, I completely missed that I was the discussant on this, and I can't believe this. I'm really sorry, just missed it.

CO-CHAIR WALTERS: No problem, wanted to give you a chance to talk. Shelley?

MS. FULD NASSO: So, I actually think it might be more helpful if I --- if we can hear and respond to some of the reasons for taking it off.

CO-CHAIR WALTERS: And off the top of my head I don't remember who's here for Louise. Okay. Let's take the first measure then since everything is going somewhere.

The 12 regional lymph node measure which has been --- Cristie has suggested be pulled to conditional support.

MR. AMIN: Yes, do not support.

CO-CHAIR WALTERS: Do not support, yes. I've got to get that down. Cristie?

MS. TRAVIS: Just reiterate I think

that the information that was provided indicated that this measure is pretty much topped out between 95 and 99 percent, and I'm looking for where the performance gap is that including it in a reporting program would help improve the measure.

CO-CHAIR WALTERS: Karen?

DR. FIELDS: NQF agrees with the fact that it's --- that this is a topped out measure. We shouldn't want to bring every measure for discussion. We feel that this an important quality measure because it's associated --- no dissection is associated with improved outcomes. However, it's a topped out measure and we would encourage the development of outcome measures, so we would feel supportive either way to not report this, or to report this.

CHAIR OPELKA: Karen, where --- we're trying to find where the NQF said it's topped out.

DR. FIELDS: We're talking about the ADCC Centers that all report outcomes of measures

in the range of 95 to up to 100 percent, so that --- or not up to 100 percent in this measure. I apologize, but high compliance, always over 90 percent, so it's probably just the max that one could achieve based on the anatomy of patients at the ADCC Centers. So, that's why we feel that these --- this measure is topped out for the ADCC Centers. Nationally we think this is a very important measure, and we're happy to continue to report this measure, but ---

CHAIR OPELKA: I don't think this is topped out. I mean, my --- I have a question about these first two, and it may be a problem with all of these, that major cancer centers, these are probably topped out, but everywhere else they're not. So, the 12 regional lymph nodes are not topped out across the country. They may be topped out in these 11 hospitals; in fact, I suspect that they are. And we kind of put them into the program to get these measures into a cancer culture anticipating these would be benchmark hospitals that everyone else could

target, so if we're going to take them out of this program that's fine, but we put them in here fully expecting they would be topped out. And then we were going to consider rolling them over into national programs, and using this as part of the benchmark pool.

DR. FIELDS: And we agree with that rationale as a benchmark. I think that there is -- remains a gap nationally, not just at academic centers, but around the country as a gap, so we defer to --- we'll continue to report those. That's why we did not ---

CHAIR OPELKA: So, let me just check. Is the NCDB on the phone?

MS. McNAMARA: Yes, we are.

CHAIR OPELKA: Do you have --- I'm looking at two measures, the 12 regional lymph nodes and the post-breast conservation surgery irradiation. Actually, I guess I'm looking at three, the needle biopsy to establish the diagnosis of cancer precede surgical excision. Do we know from cancer centers reporting to the NCDB

if there's a gap in these measures?

MS. McNAMARA: So, I'll start with the PPS-Exempt Program. For the 12 regional lymph node measure there is -- for 2013 the minimum compliance rate was 89.5 percent all the way up to 100 percent with an average of about 97 percent within those centers. Overall for programs participating in the rapid quality reporting system which is where this measure is drawn from for this project, the compliance rate was at 90 percent.

For the post-breast conserving surgery irradiation measure, the minimum in the ADCC hospitals was 82 percent with a maximum of 100 percent. This is for 2012, which is the last year that we have complete data because 2013 hasn't completed yet until the end of this year. The average for the ADCC hospitals was about 94 percent, and the average overall in reporting facilities was around 87 percent.

In the needle biopsy measure within the ADCC hospitals for 2012, which is the most

recent year that we have complete, data for this measure, it's in --- it's not in our charts. We don't have current data for it. The mean for the ADCC hospitals was 86 percent compliance, the minimum started out at around 60 percent compliance all the way up to a maximum of 97 percent. And the overall for all COC-accredited facilities is at 86 percent. And that was pulled just a couple of weeks ago.

CHAIR OPELKA: Great, thank you. That's very helpful.

MS. McNAMARA: You're welcome.

CHAIR OPELKA: So, that shows you that there's an awful lot of compliance but there are some tails there, and that was just to try and make sure as you're thinking about this where you want it to land.

DR. FIELDS: So, we kept one and two on the list for reporting, but we defer to the rest of the group discussion on those.

Concerning needle biopsies, we have just a few --- we wanted to ---

CO-CHAIR WALTERS: Hold that just a second because I wanted to make sure we stay focused. Right now we're on the first measure which is the 12 regional lymph nodes, one. We'll get that background information you just heard is important as we work our way through this, but we'll never get through them if we don't get through them in some sort of organized fashion. Nancy?

MS. FOSTER: So, especially given the data we've just heard, I'm wondering if Cristie would consider an amendment to her motion to make this a conditional support, and the condition be that CMS consider rolling them into the broad-based IPPS Program for --- the IQR Program either simultaneously or very quickly thereafter.

MS. TRAVIS: I would fully support that, which is what I have actually had a position on prior to this MAAP, and so my only -- - just to give you the rationale, was I was thinking of them only as applicable to the PPS-Exempt Cancer, but I would definitely support

Nancy's revision. I think we've got to move these cancer measures out into the community-based hospitals, as well as with the PPS-Exempt.

MS. TRAVIS: I would like it recorded that I proposed a couple of measures being moved into IQR.

CO-CHAIR WALTERS: No longer Nancy the destroyer, she's Nancy the creator.

MS. TRAVIS: Let it be known this is the second time in two years that Nancy and I have been on the same page.

CO-CHAIR WALTERS: Michael, were you going to say something?

DR. PHELAN: Just supporting that. I mean, it's a great idea and there's a gap. That's where we need to identify where the gap is, and we need to move that and probably more rapidly than the standard fare.

CHAIR OPELKA: So, the only thing that --- and I agree with what was just said. To me, though, the lesson learned is that while these PPS-Exempt cancer hospitals serve as a great

benchmark and incentive, and we still need to find where are the opportunities for gap measurement and improvement in those exempt hospitals. So, we're finding their sweet spot here in cancer, and they're setting a bar that everyone else has to achieve, but we still have to identify a subset, so there's a gap -- because they're performing so well on these areas, there's a gap in their measurement system that we have to figure out and close.

CO-CHAIR WALTERS: Any other discussion about the first measure? Okay, we'll open up for a vote on the motion to move the measure from support to conditional support. You heard the condition.

MS. FOSTER: Just for clarity, I thought Cristie's motion was around both, but maybe I was just misunderstanding.

CO-CHAIR WALTERS: We're going to get to that second one.

MS. FOSTER: You want to take them one at a time? That's fine.

CO-CHAIR WALTERS: I do.

MS. IBRAGIMOVA: So, the question is at least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer. Do you agree with the motion to move from support to conditional support? One, yes; two, no.

MR. AMIN: Just for clarification just for the record, the condition is that the measure be considered to be rolled into a broader community of hospitals, not just PPS-Exempt hospitals.

(Voting)

MS. IBRAGIMOVA: The results are 95 percent yes, and 5 percent no.

CO-CHAIR WALTERS: There's that Frank vote again. Okay, proceed now to measure two, which you have heard two pieces of it so far. The post-breast conservation surgery irradiation, the proposal there was originally to move in do not support, and then it was modified to move it into conditional support. Do I have that right,

Cristie? With the same condition that we just heard. Is there any discussion regarding measure two? Okay, we'll vote on that motion.

MS. IBRAGIMOVA: So, the question is post-breast conservation surgery irradiation. Do you agree with the motion to move from support to conditional support on the basis of moving it to broader community hospitals not just for PPS hospitals. One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 100 percent yes, zero percent no.

CO-CHAIR WALTERS: Okay, thank you for your votes. We'll now move to measure three, which is needle biopsy to establish diagnosis of cancer preceding surgical excision resection. And the motion on the table made by Karen is to move that to conditional support. Is there further discussion about that? Nancy?

MS. FOSTER: If I could get clarity on what the condition is?

CO-CHAIR WALTERS: Before we take the

NCDB, Karen, would you state your condition?

DR. FIELDS: So, we feel that this is a very important measure. All patients should have a needle biopsy, preferably a closed biopsy prior to undergoing surgical interventions; however --- and, also, the ADCC Centers, as you heard, are not yet topped out in this measure.

We wanted --- the two conditions that we wanted to bring to this group's attention were that as freestanding cancer hospitals that see a large number of referrals, many of the --- some patients that come to us have already had excisional biopsies, and that is required to be reported as an excisional biopsy from our center which would detrimentally affect our scores in that measure.

Additionally, there's been over the years not much clarification about needle --- about biopsies that remove all of the tissue. There's finally a clarification around that measure recently updated, and we recommend postponing the adoption of this measure until

further validation by each registry to assure that no false positives exist for that measure. All of these are outlined in our comments.

I would also say that this isn't a measure that we're actively reporting through AHRQ QRS, so it does pose some additional resources to report this measure. In general, though, we support this measure. We think it's a very important quality measure for breast surgery.

CO-CHAIR WALTERS: Okay, thank you. I believe there was a comment on the phone?

MS. McNAMARA: Yes. I thank the ADCC for their comments. We are actually in the annual update for this measure through the NQF, and we are making some changes, one of which we only include patients where the breast cancer was actually diagnosed within that facility, so that should remove the issue of referrals.

We're also including this to be that patients who receive image or palpitation get a biopsy for the diagnosis of breast cancer, so

we're making a couple of changes to include the exclusions that were in the public comments, which are that just areas that cannot be captured within the cancer registry for medically --- clinically relevant reasons why a needle biopsy would not be performed to establish diagnosis of breast cancer. And those will be reported and submitted to the NQF by the end of this month.

CO-CHAIR WALTERS: Would you say that those changes are in line with the conditions of the conditional support that were stated?

MS. McNAMARA: Yes, it includes the only including patients diagnosed within that facility, which we actually have in our measure rules right now, and all of the exclusions that were in the public comments.

CO-CHAIR WALTERS: Discussion? Karen?

DR. FIELDS: Question, but I'd like to modify my motion then. I'd like to --- my conditions would be upon finalization of the updated NQF endorsement.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: And that was exactly my question. I don't know if these changes are significant enough to require a re-review, but whatever the NQF decides, as long as it --- if it does require re-review, then we wait for that.

CO-CHAIR WALTERS: So, the condition on --- you heard the condition on the motion. It's dependent on NQF endorsement of a slightly retooled measure. Ready for a vote on measure three, and the motion is to move it to conditional support?

MS. IBRAGIMOVA: Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection. Do you agree with the motion to move to conditional support pending review and NQF endorsement? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 100 percent yes, and zero percent no.

CO-CHAIR WALTERS: Okay, thank you again. Now we move now to measure four in this set, which is hospice and palliative care. Karen

made a motion to move that to do not support. Karen?

(Off microphone comment)

CO-CHAIR WALTERS: It's close? We get a few more chances to practice voting. Measure four, any other discussion? Karen?

DR. FIELDS: So, we have put this in the do not support category, but I wanted to clarify that we think that advanced directives are some of the most important things that we can do four cancer patients. And only three of the eleven ADCC Centers have a formal inpatient palliative care unit, or an inpatient hospice unit. The remainder, and also the --- all 11 cancer centers have an approach of early discussions about palliative care, quality of life, supportive care, goal setting that's pervasive throughout the time of care and throughout the diagnosis. So, the other centers all have very strong palliative care teams. It's not clear whether being followed by a palliative care team would constitute being in a palliative

care unit.

And the other clarification is that it defines patients as seriously ill, which is not a --- always a good description of who's the appropriate patient for goal setting, quality of life, and palliative care interventions. So, we feel that this is an important measure, and we endorse the concept of advanced care planning; however, we don't think that this measure applies to enough of our cancer centers to make it a valuable measure for reporting.

CO-CHAIR WALTERS: Okay, Sean.

DR. MORRISON: I figured you'd call on me. So, Karen, just a couple of brief comments. First of all, 11 of your sites do have active palliative care teams and 87 percent of NCI-designated cancer centers do, so palliative care units are actually a small segment of palliative care delivery.

Number two is that the measure applies to people followed by palliative care teams or hospices, if you look at the specs. So, this

would apply to patients who have been followed by either palliative care consultation teams or admitted to units.

Number three, it's not about advanced care planning, it's actually about goals of care discussion, which I would suggest are critically important for anybody with cancer. And I would suggest that anybody with cancer get themselves into a comprehensive cancer center probably has a serious illness.

And number four is, if you would ever suggest --- if you ever need a reason for this measure, I refer you to Bwanda's new book when he talks about how his father is cared for at one of our designated cancer centers. I just can't see any reason why we wouldn't endorse this measure. It's like --- it's as American as apple pie. People with serious illness, people followed by palliative care, they need to have their wishes discussed. They need to have it addressed, and we need to know what their goals of care are.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: Sorry. So, here's my ignorance about the COPs for the cancer care hospitals, the 11. Do they fall under the same Conditions of Participation as general acute care hospitals? No? Oh, you don't know either.

So, I'm curious about this measure as a standalone measure because I would have assumed that for inpatient care that the first step was making sure everybody had an opportunity to articulate their advanced care directives, and that question would come up every time. If it's not a COP for cancer hospitals, I would assume that measure might be something you'd consider. And then I join Sean in supporting this as a critically important aspect of care for these patients.

CO-CHAIR WALTERS: Go back to Shelley. Shelley?

MS. FULD NASSO: I also agree with what Sean said, and how important it is to have patient's goals of care documented. I do --- I find the denominator for this a little bit

confusing that you have to enrolled in hospice or receiving palliative care. It just seems to me anybody who's in a cancer hospital should have this, period. It does --- so, I understand the concern about those two conditions, and maybe you can speak better to that, but it seems to me that the denominator should be anybody who's inpatient in a cancer hospital. I mean, if you're there you should have had these discussions about goals of care, so I think it's really important.

I just don't want it to get lost over --- but I do think it's important that we clarify that because I'm confused by that.

DR. MORRISON: Ron, I can clarify that, if you'd like.

CO-CHAIR WALTERS: Okay. First, I'm going to go to Michael.

DR. MORRISON: Just having been here long enough and chaired the NQF Committee that actually reviewed this, the reason --- that was discussed when this came up for NQF endorsement. It had only been tested in a hospice or

palliative care consultation team setting, and couldn't be applied more broadly, although that was discussed by the panel that endorsed it.

CO-CHAIR WALTERS: Okay. Michael?

DR. PHELAN: I think this is one of those critical measures that we're trying to get to, especially surrounding patient engagement. And, you know, for some small little issues surrounding it, I think it's --- we're going to lose the greater picture here of trying to get these kind of measures to the kind of measures that we want to have our hospitals engaged with. It's an EHR retrieved data point, so making it aware, making it a priority for this Committee in supporting something like this, I see as one of our crowning achievements, so I strongly support this measure.

CO-CHAIR WALTERS: You would not support moving it to do not support. Yes. Karen?

DR. FIELDS: So, I would clarify that we support the concept of advance directives in all patients, and most of our hospitals have a

strategy to discuss advanced care measures with every patient that comes through the door.

The way this metric is written, the numerator and denominator don't define the patient population adequately. And many of the cancer centers have moved towards combining supportive care and palliative care into a team so that patients have early supportive care interventions. So, are you going to ask the teams to go back and say no, you have a supportive care consult, and you have a palliative care consult when the most important thing is goals, and setting goals, and discussion, and quality of life for all of our patients that come through. So, I think that this measure doesn't capture the spirit of what we should all be doing, which is defining patient's goals and objectives of their care from the very beginning. And when we're talking about pain control, and symptom relief, and everything else, that's why we support --- that's why we have these early palliative care support team interventions, rather than the way

this measure says seriously ill patients should have discussions of their advance directives.

I think this is --- I think we agree completely that this is the way we should manage and treat all of our patients, and that's the --- and we should be the lead in doing this, rather than trying to look at only the end of life which is implied by this measure, and offer advance care directives.

DR. MORRISON: So, we don't back and forth, but a clarifying, just a clarifying point. Palliative care in 2014 is provided to improve quality of life for any person with a serious illness whatever the diagnosis, as the same time as disease directed or curative treatments. In many cancer centers because of marketing to oncologists it is often called supportive care. Don't argue with me, Karen. And it's been about marketing to oncologists having sort of them doing that research.

Again, if we think about it from the time of diagnosis in concert with others, it's

very, very appropriate, and I think this is the time to start. I would love to say that all goals of care discussions should happen with every cancer patient, but this is, as Michael said, a really good starting point.

CO-CHAIR WALTERS: Is your card still up? Yes. Karen, is your card --- Richard?

DR. BANKOWITZ: So, in an effort not to let the perfect be the enemy of the good, I'll ask Karen if she would consider amending her motion so that we move this to conditional support, that the condition be that CMS be highly encouraged to apply this over the entire spectrum of patients in the cancer care center.

DR. FIELDS: I guess --- can I --- no one called on me yet. And, Frank, this is going to be your favorite question, but you're not --- Ron's leading right now, which is I think that what our issues with --- are the specifics of the inclusion and exclusion criterion, how we appropriately define patients. The words "seriously ill patients" doesn't give us enough

information. We think that this measure doesn't adequately capture that --- the spirit of early interventions, or life setting goals of therapy and outcomes, and early discussions about advanced care. This talks about seriously ill patients.

Now, if you're going to define every single patient with cancer as seriously ill, then we'll have to come up with a measure to address that. So, I think it's difficult for centers that are very sophisticated, have extensive palliative care programs to understand how to meet the spirit of this measure. So, I would entertain --- and I defer also to Ron, who's also a member of an ADCC Center, if there's any other comments. But we could entertain a conditional measure upon further clarification of the metrics that that's --- otherwise, I think it doesn't necessarily get to the spirit of a lifetime of palliative care and supportive care for patients diagnosed with cancer.

CHAIR OPELKA: Yes, this is --- I'm

trying to put the right filter on this conversation because I think everyone agrees the concept of this measure has just got to be. But, Karen, you're raising really valid points about the measure as it's currently constructed, and I don't this is the simple retooling of the measure. I'm getting a sense that it's bigger than that, so I'm a little bothered by conditional, unless we're going to really put some tight conditions on it. And I understand where you're coming from, by do not support the message is this is an important area. We need a better measure than this, go rewrite it. And that's a bigger statement than conditional support, move it into a Medicare age, or fix a -- - tweak a few things in the risk adjustment. That's a little bit different.

It's almost as if we support the direction, but this needs work. And I'm not -- I don't want to put words in your mouth, but I'm hearing a very strong message from everybody, we want this measure, but it's not spec'd in a way

that makes it work. Karen, that's what I'm hearing you say.

CO-CHAIR WALTERS: I don't think there's any more points that can be made about this measure. The motion on the table is to move it to do not support. Let's open up the voting for that motion.

MS. IBRAGIMOVA: Hospice and palliative care treatment preferences. Do you agree with the motion to move from support to do not support? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 41 percent yes, and 59 percent no.

CO-CHAIR WALTERS: So, the motion to move it to do not support did not --- is no, and so it remains in the support.

Let's move on to measure five, which is ---

DR. BANKOWITZ: I don't know if you'd entertain a motion. Is that in order?

CO-CHAIR WALTERS: Probably depends on

what the motion is.

DR. BANKOWITZ: Well, the motion is that we move this measure to support with conditions, we put some conditions on it around the numerator and denominator, and make it known that there are some serious concerns about how it's defined.

CO-CHAIR WALTERS: So, that's very close to measure development that Frank was alluding to. The measure steward from this is CMS. It's North Carolina, University of North Carolina, so that's right. I remember, I looked at this before. I understand what you said. I just don't ---

CHAIR OPELKA: The way to say this, Richard, if I could would be there's one of two ways, and you would have to think about what's in your heart and pick one of those two. One would be to support the direction and continue retooling this measure. The other one would be a conditional support pending updating this measure and resubmitting for NQF endorsement. So, it's --

- they're very similar to each other, but you're --- the second one has a higher bar of rigor because it requires the NQF endorsement to it.

DR. BANKOWITZ: Then let me amend my motion to reflect the second option that Frank just mentioned, which is to encourage th is be -- - condition this upon being updated, resubmitted, and reviewed by NQF.

CO-CHAIR WALTERS: Second?

DR. FIELDS: Second.

CO-CHAIR WALTERS: Is there any further discussion?

MR. AMIN: I think the only question we have is that we just want to make sure that the conditions are really clear, so I have heard the condition around clarifying the denominator statements, but if there could be additional comments around specifics about what the conditions would be, that would be helpful in our handoff to CMS and to the developers, just to make sure that they were clear.

(Off microphone comment)

DR. FIELDS: Yes, I think that many of them are in our comments, but I would also say that we'd want to clarify what a palliative care team is versus supportive care consults, since hospitals blend those two. So, somehow to describe that issue.

DR. MORRISON: I mean, I just respond to Karen, you know, there is a national consensus project definition of what palliative care and palliative care teams are that's been in existence for now 10 years and three revisions. There's a Joint Commission Certification Program that defines what palliative care is. Please let's not redefine palliative care, or ask the NQF to do that given that people in the field have done that, and defined what a palliative care team is in the patient population they see. So, I would really argue strenuously against redefining that once more.

DR. FIELDS: I'll withdraw that, and many of the NQF centers or ADCC Centers are Joint Commission Palliative Care.

CHAIR OPELKA: That's really helpful, but since you were involved in this measure previously, any guidance that you have specific that would help us in terms of the numerator and denominator?

DR. MORRISON: Yes, the Committee really wrestled with this, Frank, and the issue was that everybody wanted to get away from a prognostic-based definition, because in that case, as we know with hospice, nobody knows when people are going to die except right before death. So, that's why the compromise with serious illness.

There was a strong feeling from the Committee that if you were being seen by a palliative care team, and sort of not a symptom management team, or enrolled in hospice then by definition you probably had serious illness. And serious illness was looked at as a combination of functional impairment, multi-morbidity, disease-specific data, or high symptom burden. And that's why the denominator was either being followed by

hospice or palliative care team. Serious illness was to get away from both the disease-specific, or prognostic-based measure.

The Committee really wrestled with this for a number to get a better specific denominator, and this is the best they could come up with. And this was a lot of people who were -- - I would say that the North Carolina group did present some very good data on reliability and validity about capturing this.

CO-CHAIR WALTERS: Karen?

DR. FIELDS: I don't think that serious illness adequately defines the patient population in the cancer patient.

CO-CHAIR WALTERS: Shelley?

MS. FULD NASSO: I don't think anybody with cancer doesn't have a serious illness, especially if they're at a --- I mean, it seems to me this is defined for a broader hospital population, not just cancer hospitals, but it seems to me anybody with cancer has a serious illness.

It's still limited also by who has the hospice or palliative care, so it's --- I mean, if you are seeing any --- a palliative care specialist or in hospice, you have a serious illness.

CO-CHAIR WALTERS: Okay, these are complicated issues. I want to take this to a vote, so the motion that's on the table by Richard is to do a conditional support based on a bunch of magic occurring.

DR. BANKOWITZ: I don't think it's a bunch of magic. I think that we have some concerns about the precision of the definition which can, I'm sure, be addressed, and we have some concerns about if the denominator can be broadened, which I'm sure can be addressed. So, those are, I think two valid conditions we could put upon this.

MS. IBRAGIMOVA: So, hospice and palliative care treatment preferences. Do you agree with the motion to move from support to conditional support pending updates,

resubmission, and NQF endorsement? One, yes; two, no.

(Voting)

MS. FOSTER: Ron, while we're waiting for the results to come up, is it appropriate after we get the results to suggest something for the gap list or hold?

CO-CHAIR WALTERS: Perhaps we can do that after we get all through all the measures that exist, just so we keep things on. So, the motion carries.

MS. IBRAGIMOVA: So, the results are 68 percent yes, 32 percent no.

CO-CHAIR WALTERS: Measure five is meth resistant staph aureus, which the motion on the table by Karen is conditional support. Would you restate what those are?

DR. FIELDS: So, the main condition is that we think that because of the immune compromised nature of the patients in our centers we would like to --- we will see a higher rate of complications, but if we could have this --- we

recommend that this measure be stratified for liquid tumors versus solid tumors and bone marrow transplant patients so that we're reporting in those three different stratifications rather than overall.

CO-CHAIR WALTERS: Is there discussion about that? Shelley, is that your card? Any discussion, going once, going twice?

MS. FULD NASSO: Which one was that, the C. diff or the MRSA one?

CO-CHAIR WALTERS: This is the methicillin resistant. Okay, we'll put the motion up for a vote.

MS. IBRAGIMOVA: National Health Care Safety Network facility-wide inpatient hospital onset MRSA bacteremia outcome measure. Do you agree with the motion to move from support to conditional support?

MR. AMIN: The condition is that the measure be reported based on stratification of the cancer type.

MS. IBRAGIMOVA: One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 72 percent yes, 28 percent no.

CO-CHAIR WALTERS: Okay, thank you. We'll move on to measure six now, which is the C. diff measure. The motion on the table from Karen was do not support. Would you repeat your reasons why?

DR. FIELDS: So, this one I wanted to get feedback from the group on. The ADCC Centers recognize that reporting C. difficile is an important problem. All ADCC Centers are engaged in routinely monitoring for C. difficile infections; however, our patient populations are at unique risk for C. diff infections because of the underlying factors associated with diagnosis and treatment. All of our patients have had prior hospitalizations, prior antibiotics, advanced stage is common. Up to 50 percent of patients admitted to an inpatient facility are carriers of C. diff and many of the infections are --- thus, the patients are predisposed. And the Society for

Health Care Epidemiology of America, and the Infectious Diseases Society don't recommend screening in asymptomatic patients. They also don't recommend treating asymptomatic patients, so there's --- our recommendation is that our patient --- for reporting purposes, reporting C. diff in a patient population that's very high prevalence of C. diff doesn't necessarily meet the goals. We recommend that we develop measures that focus on improved infection control, and decrease the incidence of --- to decrease the incidence of hospital-acquired infections, as well as the development of rigorous antibiotic stewardship programs, which are the key to solving this problem.

We also would like to at least have a condition that PCR measurement is --- varies from institution to institution, some with high degrees of sensitivity and specificity and, therefore, infection rates may vary from center to center. So, we --- I put it in the do not support category, although I think there's some

conditions under which we could support it. And recognizing that it does --- that our patient population is at uniquely high risk of developing this infection.

CO-CHAIR WALTERS: Thank you. Emma?

MS. KOPLEFF: I'm not going to address all those things, but just on the point about the unique risk for infection of these patients. There is something philosophical there where it seems to me that the unique risk makes it even that more important that this is being measured consistently. And I think we need to identify where things stand, and have that measure as a basis for improving. So, if we could address that through the discussion, that would be great.

CO-CHAIR WALTERS: Dan, we thought we'd hear from you.

DR. POLLOCK: Yes. Well, just a point of clarification that the type of testing is taken into account in the risk adjustment process, so we're well aware of differences, differences in sensitivity, and that is factored

into what's reported out.

I mean, I have to agree with the notion that because this is a vulnerable population, and because there's a great deal of antimicrobial use, it makes it that much more incumbent upon is to conduct sound surveillance in that patient population.

CO-CHAIR WALTERS: Richard is next.

DR. BANKOWITZ: Yes. Thank you, Dan, for those comments. And I wanted to add the definition is looking at hospital onset of C. difficile, so looking at carriers and treating carriers doesn't really, I don't think, come into the picture.

CO-CHAIR WALTERS: Andrea?

DR. BENIN: I think for better or for worse we're already reporting on this for all of the other hospitals, and so for the sake of some standards it would be wise to have this be consistent across all of them.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: So, I'm not sure it rises

to the level of a condition, but I think the point that Karen is making is really important as we think about the comparisons people might make coming to Hospital Compare. So, I guess as I --- given the fact that these 11 cancer hospitals have such a different population, a much more vulnerable population for this measure, and perhaps for some others, I would think that we would want them sort of reported separately so that there can be an opportunity to explain to the viewing public that you can't just take the C. diff rate at Sloan Kettering and compare it to the C. diff rate at St. Mary's in Iowa and think you're comparing apples to apples.

CO-CHAIR WALTERS: In favor of the motion or against the motion?

MS. FOSTER: I believe it is against the motion but in favor of intelligent use of the concerns that led to the motion.

CO-CHAIR WALTERS: Thanks. Karen?

DR. FIELDS: So, having feedback from the CDC was helpful since we don't get to see all

the risk stratifications and numerator and denominator. And if that's taking into account that measures --- that addresses one of our issues.

And I also think that to change this from a do not support to support conditionally so that our --- either the results are stratified by our patient population, or reported separately, both of those would be acceptable to at least put our public reporting of this into light, change it to conditional support.

CO-CHAIR WALTERS: Emma? So, the motion has now been changed from do not support to conditional support. Emma?

MS. KOPLEFF: I just would be remiss not to express a little bit of concern that this is a second infection measure we're discussing for this program, and we're putting a lot of conditions on a lot of these measures, which I think has been a really valuable discussion. But I'm not necessarily disagreeing with this direction we're going, but I think there needs to

be a strong message that still says even if we're voting conditionally we absolutely support these outcome measures as priority areas to address in the short term.

CO-CHAIR WALTERS: Any more discussion? Oh, where am I? Frank. Oh, Frank.

CHAIR OPELKA: I guess I'm uncomfortable. I --- Karen, I hear what you're saying. I don't know that I'd buy it. I don't know how different, and if you're statistically different from other hospitals. Everybody is at high risk for C. diff, and that's pretty clear, and we heard it yesterday that that's the number one problem out there. And MRSA is right behind it, and everyone is at high risk for MRSA. And I don't think your subset population is that much different in risk than mine, which may not have cancer, but may have other immuno compromising diseases. So, what do we do with the hospital that's high in AIDS? Do we say well, we're not going --- we're going to stratify MRSA and C. diff?

I actually don't like this. I'm very, very uncomfortable. I think we all need a national agenda to go after MRSA and C. diff. We all need to recognize it. We all need to understand what the measures mean when they come out, but if we don't go after this world of antimicrobials and how we use them and their impact in the right way, the consequences are all these super infections that are actually bringing on a whole new burden to the health care system. So, I wasn't supportive of the last measure, and I'm not supportive of this one. I think everybody needs an agenda on MRSA and C. diff, and I do not buy what you're saying.

CO-CHAIR WALTERS: Shelley?

MS. FULD NASSO: Just a question. If the motion is changed to conditional support, what are the conditions now? I know the one about the different --- the testing was resolved, so what are the outstanding conditions?

DR. FIELDS: I think just --- the condition was addressed about different testing

stratification, so it was just reporting them separately. I don't understand how that would work. Nancy gave us that information.

Additionally, Frank, we completely agree that MRSA or MRSA and C. diff are incredibly important infections in our population, but we bring this --- this is the collective request of the ADCC. So, that's --- I bring it to this group for discussion.

CO-CHAIR WALTERS: Sean?

DR. MORRISON: I would just --- I would expand on Frank's point. You know, our patients need to take a lot of things into account when they make decisions about where they get their care. And if I'm debating between getting cancer care, for example, at Memorial Sloan Kettering, or across the street at New York Hospital, one of the things that I really might like to know is what are the MRSA rates between those two hospitals, or in this case what are the rates of C. diff, because that actually may be my life-threatening event rather than my underlying

disease. And I do have a lot of trouble trying to segment specific hospitals. Do we look at just community hospitals, do we look at academic medical centers?

Certainly, the data suggests that I might get better cancer care in a designated cancer center, for example. On the other hand, if I'm going to die of C. diff, I might prefer to get my cancer care elsewhere.

CO-CHAIR WALTERS: Okay. I think the discussion has been very fruitful. Currently, the measure, the C. diff measure sits on the support list. Let's put the --- the motion is conditional support. If the motion passes, it goes to conditional support, if the motion fails it stays on the support list.

MR. AMIN: And the condition is that the measure be reported separately for this patient population when publicly reported specifically on Hospital Compare.

MS. IBRAGIMOVA: So, National Health Care Safety Network facility-wide inpatient

hospital onset CDI outcome measure. Do you agree with the motion to move from support to conditional support? One, yes; two, no.

(Voting)

MS. IBRAGIMOVA: The results are 18 percent yes, and 82 percent no.

CO-CHAIR WALTERS: The motion stays on the support list.

Measure seven is influenza immunization, which has been proposed as conditionally support. Karen, would you remind us of the conditions?

DR. FIELDS: The two conditions for the sake of discussion and brevity are to include patients, or exclude patient --- add two exclusions to the list, patients receiving anti-B cell antibody therapy, such as rituximab, and patients receiving intensive dose chemotherapy for induction or consolidation of leukemia, as both of these states have been found to be an ineffective time to vaccinate patients. And those are per the recommendations of the Infectious

Diseases Society of America. Otherwise, we fully support influenza vaccinations in those patient populations.

CO-CHAIR WALTERS: Other comments? Yes, Woody?

DR. EISENBERG: It says here, "If indicated," so given what you've told us about what the Infectious Diseases Society is telling us, does that mean that those people are not indicated to get the vaccine? Then perhaps you don't need to further modify this measure.

DR. FIELDS: They gave very specific exclusion criteria, so we wanted to make sure that those were included in the specific exclusion criteria. Excluded solid organ, or organ transplants, BMTs, other kinds of things, so we felt strongly that we wanted to also include another group of patients. I hear your point, and that's an excellent observation.

CO-CHAIR WALTERS: Cristie?

MS. TRAVIS: I guess my thought, though, is that it seems like there would be a

re-specification of this measure, which would then mean that it would change, and that it would need to go through NQF endorsement, which is why I was curious about Woody's comment as to whether or not these could be considered under as indicated. Because it seems to me if we change the exclusions, we would have --- it's a re-specification of the measure.

CO-CHAIR WALTERS: Jack was next.

DR. FOWLER: I'm sure I'm going to be in the minority on this one, but I have a visceral response to having something that -- might offer me a very, very small benefit, or given competing hazards might offer no benefit at all to have it required, and something hospitals feel they have to do. So, I would vote against this totally, just on that basis.

CO-CHAIR WALTERS: Richard is next.

DR. BANKOWITZ: Yes. For all of these evidence-based process of care measures they are always clinical exceptions. You could get a cardiologist and they're argue about aspirin on

arrival, and that there's that one case in a thousand where you shouldn't use it. And for those cases you just don't use it. And if you get, you know, a checkmark in the negative that's, you know, regrettable, but it's always puzzled me as to why people can reach 100 percent, because there should be clinical exceptions. So, no one is arguing with that, and I would suppose this is no different. If there's a clinical exception, go with your clinical standard of care.

CO-CHAIR WALTERS: Nancy?

MS. FOSTER: So, Karen, I don't have any idea how prevalent the population is you're describing that you would like to see excluded, so I'm curious about that. But I agree with Richard for all of these measures, 100 percent is usually not the right answer. On the other hand, Dan is sitting just down the table from you, and if you wanted to encourage CDC to consider whether further exclusion should be made based on what I understood to be, and excuse my lack of

clinical knowledge, specific drug therapies being --- or specific therapies being rendered, that would make the patient inappropriate for the flu vacc, then maybe that's the message we should be passing.

CO-CHAIR WALTERS: Sean.

DR. MORRISON: Quick question, Karen. I think I agree with you, but just a clarifying comment. I'm not an infectious disease doc, but I am a primary care doc, and I do this a lot. It's not dangerous to have the flu vaccine, it just may not be effective in the setting of these treatments. But that may be the case for anybody who's immuno compromised, not just specific therapies. So, I would say with Richard, you know, we're not going to be 100 percent, and there are some clinical indications where it's not useful, but for the vast majority I think the benefits far outweigh the harms, or lack of efficacy here.

CO-CHAIR WALTERS: Okay, Karen?

DR. FIELDS: The percentage of patients

that might be in the hospital with acute leukemia at an ADCC Center getting induction chemotherapy consolidation can be as high as 30 percent depending on the population at the center. And likewise, a large percentage of the patients get these therapies, We're going to see some new immuno therapies coming down the pike, as well, that render these vaccines ineffective.

So, if the issue is if there's a high percentage of patients in your population that aren't affected, it's not just a handful that you would be excluding, it's a large percentage of patients that won't be appropriate for the vaccine.

CO-CHAIR WALTERS: Is there any more discussion anybody needs to vote on this? Okay, the motion on the table is for conditional support. We'll set up the vote now.

MR. AMIN: And the condition is the exclusion of the two patient populations, patients receiving anti-B cell antibodies and patients receiving intensive chemotherapy. Is

there a question?

CO-CHAIR WALTERS: Cristie, you had a question?

MS. TRAVIS: I guess I'm just trying to understand. So, if we vote that way then it doesn't have to come back through NQF for testing, validity, reliability, all the things, or are we saying that it would need to come back through NQF, or just that it could be changed?

MR. AMIN: The way this condition has been written there's no --- it's that these exclusions are added to the measure. That's the condition. I would say that as these measures get continuously updated, and there's an annual update process ---

MS. TRAVIS: Okay.

MR. AMIN: --- minor exclusions in the patient population wouldn't justify a full review of the measure.

MS. TRAVIS: Okay, thank you.

MR. AMIN: I'm not suggesting that this is a minor revision. We would need to look at how

many patients are ---

MS. TRAVIS: But those types of things can ---

(Simultaneous speech)

MS. TRAVIS: --- annual update.

MR. AMIN: Right, and they get updated ---

MS. TRAVIS: Thank you. That helps.

MR. AMIN: --- in relatively real time. That is correct.

MS. SLOSBURG: We're looking at influenza vaccination. Correct? It says "Influenza immunization," which is number eight. No, I'm talking about the screen. I'm sorry. We were voting?

CO-CHAIR WALTERS: That's the name of the measure.

MS. SLOSBURG: So, we're voting on eight, or we're voting on seven?

CO-CHAIR WALTERS: Seven. We'll get to eight here in just a second.

MS. SLOSBURG: Okay. Well, eight is

influenza immunization, and seven is influenza vaccination. Sorry, it's just a technical point. Did you all just look at number ---

MR. AMIN: Let me just make sure I'm following this. There's seven right here on the screen which is the discussion guide, which is influenza immunization, and what we're voting on up here is influenza immunization. It's still seven.

CO-CHAIR WALTERS: And it's still about the patients. The next measure is about the health care workers.

MS. SLOSBURG: I apologize.

MR. AMIN: So, I just want to make sure everybody is on the same page. I know it's getting kind of late. I mean, we've been at this for a while, so I appreciate it. So, seven on the discussion guide here and that's the measure in front of us, and the motion is to move to conditional support on the exclusions that we've discussed from support.

MS. KOPLEFF: I fully expect to get

overruled so we can move forward with the vote, but I'm just sort of noting some inconsistency in our application of conditions. With the other programs, we didn't sort of pick apart measures, we left that to the endorsement process. And personally not feeling quite clear per the point Woody brought up, you know, what are some of these extra considerations around exclusions? It's hard to judge how big are they, how small are they? But I think we need to view the measures as conditional upon NQF review or not.

CHAIR OPELKA: So, I'm just --- I'm not sure I understand this. So, what I am reading from the American Cancer Society is quoting from the CDC which says that cancer patients receiving chemotherapy are recommended to get a flu shot because they're at higher risk, and they should be treated, and there are at higher risk of complications from this disease, and they should receive a flu shot.

CO-CHAIR WALTERS: Wei?

DR. YING: I think I agree with Emma.

It feels to me we're getting into the measure specification if we specifically say what the exclusion should be. We can say there is concern on the cancer patient, whether this measure can be applicable to all of them. But as we discussed earlier, there are other patients who don't have cancer, but they also may not be appropriate --- it may not be appropriate for them to have this vaccination either.

I kind of feel if --- the condition should be just like Emma stated, it should be revisited for the exclusion qualification, but not necessarily we put down what the exclusion should be.

MR. AMIN: If it would be acceptable, Ron, I would suggest something to be consistent from our approach. And I think, Emma, thank you for bringing that up. Potentially, we could re-frame the condition to encourage --- the condition would be encouraging the relevant NQF endorsement committee to review the exclusions specifically these that have been noted by Karen.

DR. FIELDS: I change my motion to that.

CO-CHAIR WALTERS: Okay. Ready to vote?

MS. IBRAGIMOVA: Influenza immunization. Do you agree with the motion to move from support to conditional support? One, yes; two, no.

MS. BAL: Could everyone just vote one more time, just so we can make sure we're getting everyone's votes. Thank you.

MR. AMIN: The motion is to have the relevant NQF standing committee review the exclusions, particularly those two that have been mentioned by Karen. It's a conditional -Karen is suggesting --- the motion is to move it to a conditional support on the condition that the exclusions are reviewed by the relevant standing committee, in particular these two exclusions that have been noted.

(Voting)

MS. IBRAGIMOVA: The results are 50 percent yes, and 50 percent no.

CO-CHAIR WALTERS: We're going to have a re-vote. So, vote the same way you did the last time, if you want.

(Off microphone comment)

CO-CHAIR WALTERS: Okay. We determined that because a majority did not vote for the motion it stays on the calendar as it is as supported.

The next measure is measure eight, which is influenza vaccination coverage. And this is the one with regards to health care personnel. Karen?

DR. FIELDS: NQF -- or, excuse me, ADCC strongly supports this measure. We feel that all health care personnel should have vaccinations. Our discussion with this measure is that it clearly defines who should get the vaccination and why people shouldn't get the vaccination, but it doesn't address how to get up to 100 percent compliance by wearing masks or other measures that decrease transmission in this high-risk population.

So we might think about proposing the same kind of proposal that we had, which is support this measure conditionally, but request that NQF add additional metrics to increase the safety for our patients by including masks ---- or addressing the people that don't get vaccinations, if I stated that so unclearly.

CO-CHAIR WALTERS: Nancy.

MS. FOSTER: So Karen, in that regard, I think it is consistent with the way it is applied across the entire hospital population right now. And I understand your point that some people, either for religious reasons or personal health reasons or what have you, cannot or won't take the vaccination, and therefore it may be more accurate to show protection of the patient population if you included both the vaccination and the masking, et cetera.

But I don't know how you'd measure masking 100 percent of the time, and it really gets very complicated. So I guess in that regard, while I support the sentiment, I think

this measure ought to stand as is.

CO-CHAIR WALTERS: Woody.

DR. EISENBERG: I have a question about the data source. What does it mean that the data source is the NHSN? I mean, given the fact that health care workers can get their vaccine at Walgreens or from their own personal physicians or maybe in the hospital, how do you figure this out?

DR. FIELDS: I think that's a question for NQF --

DR. POLLOCK: So there are various strategies for doing that, including requirements that employees bring documentation of occupational health, but it's -- sorry, sorry, sorry. There are various strategies for accomplishing that, including requiring employees to bring documentation of influenza vaccination elsewhere, or taking the word of employees. But it is -- it's very important for occupational health to have a complete accounting of who has been vaccinated, who has not and reasons why not.

CO-CHAIR WALTERS: Andrea.

DR. BENIN: This is a classic dilemma in vaccine coverage measurement, is this issue of what do you do with these ones that are excluded, and the fact of the matter is, they are not vaccinated. So they count against the percent vaccinated. Like, that's sort of like the way it is in this world.

I will tell you that at our place every year, we fire a few people over this. So it's mandatory that you get vaccinated if you want to walk into our place, and that includes board members. It includes vendors, and we -- so people bring in their paperwork.

CO-CHAIR WALTERS: Frank. Dan, your card is down, right?

CHAIR OPELKA: So I am not sure I am following our logic here. I understand the measure as it's proposed, but I am not sure I understand making conditions upon this measure to a broader population.

I think that if there's others we need

to address, we ought to use another vehicle. That this measure should just stand and then for those who are not immunized, vaccinated for influenza, if there's a need to put some other measure in there, we'll put it in there. But most places I know ---- and I am not sure I can say this 100 percent, are pretty close to what Andrea said: if you don't get immunized, you don't work there. It's a requirement of employment.

DR. FIELDS: I have no problem changing this to support and not voting on it.

CO-CHAIR WALTERS: It's already on support.

DR. FIELDS: Right --

CO-CHAIR WALTERS: You can withdraw your --

DR. FIELDS: Changing --

CO-CHAIR WALTERS: -- motion.

DR. FIELDS: -- it. Withdrawing my motion, but we did want to make a recommendation that is a gap.

CO-CHAIR WALTERS: Okay. The motion has been withdrawn.

So by my count, we'll do the calendar voting next after public input --

MR. AMIN: Ron, can I just ask a quick question --

CO-CHAIR WALTERS: Yes.

MR. AMIN: -- on this? Could you repeat what the gap was, Karen? I just wanted to make sure I have it for the notes.

DR. FIELDS: We need a measure that addresses unvaccinated health care workers and a policy that includes masks for all unvaccinated health care workers.

MR. AMIN: Thank you.

CO-CHAIR WALTERS: Set up the consent calendars. There is at least 6, 7, and 8 on the support calendar, and 1 through 5, I think, on the conditional support. Is there a public comment?

THE OPERATOR: If you want to make a comment, please press star, then the number 1.

CO-CHAIR WALTERS: Any in the room? Hearing none, okay.

Nancy, you wanted to bring up some gaps still?

MS. FOSTER: Thank you. Not particularly for the cancer hospitals, but because of the measure we dealt with. I think I would encourage CMS to think about whether a similar use of hospice/palliative care measure could be developed for the COPD population, for the congestive heart population, any others where the -- where there is a prevalence of palliative care being provided to patients with that condition would be the gap I would note.

CO-CHAIR WALTERS: Okay. Given the time, let's move on to voting for the consent calendars. Calendar 1, which is support?

MS. IBRAGIMOVA: PCHQR Calender 1: Support. National Healthcare Safety Network Facility-wide Inpatient Hospital Onset CDI Outcome Measure, influenza immunization, and influenza vaccination coverage Among healthcare

personnel, HCP.

Do you agree with the support calendar? One, yes. Two, no.

MR. HATLIE: We're wondering if C. Diff. belongs in this calendar?

CO-CHAIR WALTERS: It does.

MR. AMIN: Yes, let's take a step back. Let's go back to the measures, make sure that we're all on the same page. If you don't mind, Laura, can you take a step back?

CO-CHAIR WALTERS: Yes it was -- sorry. Measures 6, 7, and 8 ended up on the support calendar one way or another.

Calendar 1 is the three measures that you see there on the board, and I'll read them to everybody. It's C. Diff., influenza immunization, and influenza vaccination for healthcare.

MS. IBRAGIMOVA: So do you agree with the support calendar? One, yes. Two, no.

The results are 100 percent, yes, and zero percent, no.

CO-CHAIR WALTERS: Okay. Now, just a second before we do Calendar 2, because there is some discussion about the encourage continued development measure that could potentially land it on Calendar 2 -- could. We are going to go to Calendar 2 for a second and talk about the 30 Day Unplanned Readmissions for Cancer Patients.

I am sorry, I meant the conditional support calendar, which would be Calendar 2 except now there's three calendars.

DR. FIELDS: So this measure is an exciting measure because it's the first measure that we have proposed, as the PPS exempt cancer centers, to report a metric specific for our patients.

We strongly endorse this measure. It was placed on the development -- under development measure because indeed, it was under development, but we've continued to move along with some of the requirements for supporting it and in the conditional status.

Our goal is that this -- the PPS

exempt cancer centers are excluded from the hospital-wide reporting readmission metric, and we feel that that's a metric that we should be recording. So we are asking to do extra reporting here today. We feel that readmission is one of the facets of cancer care that can be preventable. In the unplanned patients, it would encourage us to get data concerning places to improve symptom control and other kinds of toxicities, and we feel that it's an important measure to support.

Our goal is 30 Day Unplanned Readmissions for Cancer Patients can help us reduce costs and improve quality for our patients. The few questions that remained were a steward for the metric, and we have a steward, which is preliminarily -- I am looking at Barb because I never heard the final answer. So Seattle is the steward -- no, MD Anderson is now officially the steward of the measure. And we also have aligned it with the CMS measure 1789, which was another request.

We also have been doing all of the final testing and risk adjustment in order to report the data. Reporting will begin in February of this year. So we would request that it meets -- it should be moved from further development to --

MR. AMIN: Conditional support.

DR. FIELDS: Conditional support, depending on -- pending NQF endorsement.

MR. AMIN: Karen, can you just clarify and just state for the record that this measure is -- testing is complete? Reliability and validity testing is complete and ready for submission for NQF.

DR. FIELDS: I have someone in the back, if you don't mind, that can give me that final answer.

MR. AMIN: Can you come up to the microphone and --

CO-CHAIR WALTERS: Identify yourself.

MR. AMIN: -- and identify yourself?

MS. TALLANT: Hi, this is Colleen

Tallant with the Alliance of Dedicated Cancer Centers. So we're currently collecting data, and that will be completed by January 1st. So we have a submission date to CMS and NQF by February 1st.

CO-CHAIR WALTERS: I'd like to call on Hayden for her comments, if you have any.

MS. HAYDEN: Oh, I am sorry, actually I didn't -- did you want me to speak to the measure? I didn't have any comments, thank you.

CO-CHAIR WALTERS: You spent some time writing ---- wanted to give you a chance.

There's one other person in the crowd. Barb, can I call you to -- ? Barb Jagels, yes. Identify yourself?

MS. JAGELS: Hi, I am Barb Jagels. I am from the Seattle Cancer Care Alliance, Fred Hutchinson Cancer Research Center. I chair the Quality Committee for the ADCC. Would you like me to give my short speech, Ron?

CO-CHAIR WALTERS: Yes.

MS. JAGELS: Very good. So on behalf

of the Alliance of Dedicated Cancer Centers, thank you for entertaining our measure. We are very enthusiastically in support, obviously, because we think that cancer readmissions in particular have been characterized and over-counted.

So we agree with you that foreseeable and avoidable readmissions should be measured, characterized, and prioritized for quality improvement. In the cancer realm, we think that's pain, we think it's chemotherapy and nausea and vomiting, and we think it's febrile neutropenia for high-intensity chemo.

So this measure is different because when we readmit patients intentionally for chemotherapy, radiation, or additional intensive therapy, we think it shouldn't be counted against us. Obviously we're planning around those treatment elements, and instead what we'd like to do is prioritize improvement related to things that we should prevent, to give patients a better outcome.

CO-CHAIR WALTERS: I think the recurring question that has come up so far is where is this in the endorsement process? Because the motion on the table is to move it to conditional support based on that condition.

DR. FIELDS: Can I make a comment? Our concern is that if we continue to develop the measure, and the measure will be developed by the end of this month, then we'll have to wait another year to bring it back to this Committee for consideration.

So we propose that it go to NQF for endorsement and then we adopt the measure at that time. We don't want a delay in being able to report this. We think it's a very important measure.

MS. JAGELS: In support, we already have a year's worth of data. We have data from 2011 and 2012. We're already using that data to prioritize improvement among our centers. So our goal is to put this in our measurement framework for 2017, a year delay would take us out to 2018.

MR. AMIN: Just an administrative clarification -- I mean, the only requirement for moving from measures under development to the fully developed pathway is that the testing is complete, and it seems sufficient that the testing is complete as long as the Chairs are fine with that. So I mean the group can move toward conditional support based on NQF endorsement. So that seems reasonable to me, so I think the group needs to discuss that.

CO-CHAIR WALTERS: Open for discussion. Andrea?

DR. BENIN: I'm not sure what holds the group back from doing what they want to do with this measure, with or without the CMS level of involvement, right? I mean, that's the part I'm missing.

DR. FIELDS: Because it will be a reportable outcome, that -- for the PPS-exempt cancer centers. So this group needs to approve that it's an appropriate reportable outcome, as far as I understand the process. So we need this

group to support this as a reportable measure.

DR. BENIN: You're asking us to fast track it, so ---- that we fast track it a little bit. I am just --

DR. FIELDS: We're not necessarily asking to fast track it. We are suggesting that the data is done and that it should be categorized in a different category than it was categorized for this Committee.

CO-CHAIR WALTERS: Nancy.

MS. FOSTER: So some clarity from NQF around if this were -- if this were to be brought in for NQF endorsement in January, do we have any idea when it would have completed that endorsement process?

MR. AMIN: Yes, I am not sure I can answer the question because that would be determined on when we have an upcoming either readmissions or cancer project where this measure would be able to come into.

The requirement that we've used up to this point -- again, I am not sure that I am

answering your question now, is that the Measures Under Consideration List has to indicate that the measure testing is completed --

MS. FOSTER: Right.

MR. AMIN: We don't actually look at the completed testing until the relevant committee is ready to review it. So in this case, I think that the measure steward is making an update to the Measure Under Consideration List in realtime. So it is a little unusual, but in that sense they are ----

MS. FOSTER: I guess, to Karen's point, the idea here is that this will somehow expedite moving this into use, but my guess, is it actually won't have any impact --

MR. AMIN: I can't speak to that. I certainly can't -- I can't speak to when this measure will be even reviewed by the NQF endorsement process.

MS. FOSTER: Right.

MR. AMIN: That is dependent on the review cycle and funding from CMS to do so.

MS. FOSTER: Right.

MR. AMIN: So I can't speak to that.

MS. FOSTER: I mean this is a very different -- as I hear what the measure is, because I have not seen anything about it yet. As I hear what the measure is, it's a very different framework for thinking about readmissions. Maybe one I absolutely love compared to the current framework we currently have, but you know, it's hard for me to say, yes, let's move this. Without understanding fully the implications both here and for further -- for the other readmission measures, if there are any.

So I'm a little bit in the -- and because I don't actually think that saying we fully support this notion. Let's continue to develop it, continue to use it in the cancer care hospitals. I don't think that actually delays anything because you are going to take probably near to a year, if not more, to get the NQF endorsement. So it gives us a little bit of time to come back next year when more of us have an

understanding of what's in the box that we're trying to vote on.

CO-CHAIR WALTERS: Emma.

MS. KOPLEFF: But as I understand it, we need a motion to vote on something and that voting on it under continued development doesn't really make sense, since it's fully developed. So my question for the group and to Nancy, to your comments, is if you have a motion that's different than conditional support recognizing the measure will go through the NQF process, then we should discuss that but otherwise we could probably vote on it.

CO-CHAIR WALTERS: So again, the motion on the table is to move it to conditional support. If that passes, it goes to conditional support and the condition is NQF endorsement. If it does not pass, then it is on the in-process type plan.

MS. KOPLEFF: Well what I'm saying though is, again, just to be consistent. Earlier today -- and Andrea made this point. Earlier

today, when we had measures that were previously noted as under development, upon receiving an update about the status of those measures, we moved it to the conditional support category, and that wasn't a motion, it was just there.

So I am suggesting we should follow suit and the same process should apply. So a motion needs to be made to something other than the true state of the measures which appears to be fully developed.

MS. FOSTER: Well -- and to your point, Emma, I have to say I was a little uncomfortable with moving the measures previously. I mean, it just seems odd that things can change while you're being expected to review them. There should be sort of a stop process. Let's go for the MAP review deadline, and it seems to me that's December 1 by law.

MR. AMIN: So that is fair, Nancy, and we will take that under consideration as we go forward.

Our approach has been to try to be as

responsive to CMS and any of the measure developers that have submitted measures into the Measures Under Consideration List, recognizing the time it takes to go through the clearance process and that things may change by the time it gets to this Committee.

Obviously between day one and day two of the Committee meeting, may be a little bit too responsive and not recognizing -- or at the meeting itself, may be a little too responsive. So we will take that into account as we go forward into the future.

And I would suggest, Ron, that Emma does make a valid point in terms of how the measure developers -- the testing was updated overnight yesterday as it relates to the two measures, and that's pretty similar to what we're seeing here. So -- .

CO-CHAIR WALTERS: First, let's vote, then -- you've heard the considerations. Let's vote on whether or not to -- again, the measure, the proposed measure right now is in encourage

continued development. The motion is to move it to conditional support, and we'll take that vote first.

MS. IBRAGIMOVA: 30 Day Unplanned Readmissions for Cancer Patients. Do you agree with the motion to move from encourage for further development to conditional support pending NQF review and endorsement? One, yes. Two, no.

The results are 63 percent, yes, and 38 percent, no.

CO-CHAIR WALTERS: Okay, so the motion passed to move it to conditional support.

MR. AMIN: Conditional support pending --

CO-CHAIR WALTERS: Pending NQF endorsement. Which is why -- now to go back about 20 minutes, which is why I wanted to see how this turned out before we then put for vote the conditional support calendar.

MS. IBRAGIMOVA: PCHQR calendar, conditional support. At least 12 regional lymph

nodes are removed and pathologically examined for resected colon cancer, post breast conservation surgery irradiation, needle biopsy to establish diagnosis of cancer precedes surgical excision/resection, Hospice and Palliative Care: Treatment Preferences, National Healthcare Safety Network Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure, and 30 Day Unplanned Readmissions for Cancer Patients.

Do you agree with the conditional support calendar? One, yes. Two, no.

The results are 82 percent, yes, and 18 percent, no.

CO-CHAIR WALTERS: Again, I'd like to thank everybody for their participation and tolerance of a new process. I'll turn this over to Frank right now.

CHAIR OPELKA: Well, first of all, I want to thank all of you for your time. You've stayed past the hour, so -- and all as volunteers. I really appreciate that, and I'm sure CMS and the NQF does. It has been a really

great two days.

Putting out a new process is always a challenge, and you were the guinea pigs, and you vetted it and you moved it. So I want to thank all of you for doing that. I think we've learned a lot. There's another one of these in a week, and I think the team is going to take a lot of lessons learned into that process from all of you today, so I can't thank you enough for that.

I also want to thank the staff who did, I think, an incredible job teeing this up for us.

CO-CHAIR WALTERS: And except for the nursing ones, did a good job at reclassifying --

CHAIR OPELKA: So we have, you know, we're -- we tried to catch more of your gaps today than we did yesterday, so I don't think we have time, and we're after the hour, to go around again and catch any more gaps. But if you have gaps in any one of these areas, if you'd mail those thoughts into staff, I think that's probably the most prudent way to do it at this

point in time.

And this will then go into a report that we'll put together and have to bring forward to the Coordinating Committee. So will that report come back out to this group en route to the Coordinating Committee?

MS. O'ROURKE: We won't have time to get it to you before public comment opens, but we would welcome any public comments members of this group would like to make on the draft report and the draft table that will have all of the workgroup's initial recommendations to the Coordinating Committee.

CHAIR OPELKA: So that's not our normal process at the NQF, but the timelines are so tight that it all gets compressed. So please accept apologies on that, but you're just going to have to help us work with that tight timeline in getting your comments in.

So once again, I want to thank all of you. I hope you have safe travels home and a very happy holiday season.

MS. O'ROURKE: And I just wanted to add a note to thank -- also, thank all of you for attending, and to thank Frank for his three years of service as our Chair and leader.

And to Ron, for surviving his first effort as our Vice-Chair.

CO-CHAIR WALTERS: The Chair is only as good as the Committee members are, and the Committee is fabulous.

MS. IBRAGIMOVA: For those of you who signed the cab share to go to the airport, you could all just huddle outside and figure out who is going with whom.

(Whereupon, the meeting went off the record at 4:13 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Measure Application Partnership

Before: NQF

Date: 12-10-14

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