NATIONAL QUALITY FORUM

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INFECTIOUS DISEASE STANDING COMMITTEE

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TUESDAY
MARCH 14, 2017

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:03 a.m., Woody Eisenberg and Adam Thompson, Co-Chairs, presiding.

PRESENT:

WOODY EISENBERG, MD, Co-Chair; Senior Vice President of Performance Measurement, PQA
ADAM THOMPSON, BA, Co-Chair; Regional Partner Director, Northeast Caribbean AIDS Education and Training Centers
EMILY AARONSON, MD, Fellow, Patient Safety and Quality Improvement, Massachusetts General Hospital *
AMESH ADALJA, MD, Senior Associate, University of Pittsburgh Medical Center for Health Security
ESTHER BABADY, PhD, D (ABMM), Director of Microbiology Service Clinical Operations, Memorial Sloan Kettering Cancer Center *
NANETTE BENBOW, MA, Research Assistant Professor, Northwestern University *
KATHLEEN BRADY, MD, MSCE, Medical Director and Medical Epidemiologist, Philadelphia Department of Public Health
LAURA EVANS, MD, MSc, Medical Director of Critical Care, Bellevue Hospital Center, New York University School of Medicine *

PIERO GARZARO, MD, Chair of Chiefs of Infectious Diseases, Kaiser Permanente
DONALD GOLDMANN, MD, Chief Medical and Scientific Officer, Clinical Professor of Pediatrics, Institute for Healthcare Improvement
JEFFREY HART, MS, Kaiser Permanente *
MICHAEL LANE, MD, MSc, MPHS, CPPS, Assistant Professor of Medicine, Washington University School of Medicine
JEFFREY LEWIS, BA, Medical Case Manager, El Rio Community Health Center *
ROCCO ORLANDO, MD, FACS, Senior Vice President and Chief Medical Officer, Hartford Healthcare*
JAMIE RONEY, DNP, RN-BC, BSHCM, CCRN-K, Registered Nurse
PRANAVI SREERAMOJU, MD, MPH, CMQ, FSHEA, FIDSA, Chief of Infection Prevention, Parkland Health & Hospital System *

NQF STAFF:

SHANTANU AGRAWAL, MD, President and CEO

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

ANN HAMMERSMITH, JD, General Counsel

MELISSA MARINELARENA, RN, MPA, Senior Director

MAURICIO MENENDEZ, Project Analyst

ELISA MUNTHALI, MPH, Vice President, Quality Measurement

CHRISTY SKIPPER, Project Manager

MARCIA WILSON, PhD, MBA, Senior Vice President, Quality Measurement

ALSO PRESENT:

MEREDITH BRANTLEY, PhD, MPH, Health Resources and Services Administration (HRSA) *
LAURA CHEEVER, MD, ScM, Health Resources and Services Administration (HRSA) *
ROBERT DICKERSON, RRT, MHSA, Telligen
FOSTER GESTEN, MD, New York State Department of Health *

STANLEY LEMESHOW, PhD, The Ohio State University *

MITCHELL LEVY, MD, MCCM, FCCP, Brown University *

RUTE MARTINS, The MITRE Corporation *

MARLENE MATOSKY, MPH, RN, Health Resources and Services Administration (HRSA)

LAURA MUNRO, RN, MHSA, PMP, The MITRE Corporation *

EMANUEL RIVERS, MD, Henry Ford Health System *

LEMENEH TEFERA, MD, Centers for Medicare and Medicaid Services

KATHY TERRY, PhD, MA, IPRO *

SEAN TOWNSEND, MD, California Pacific Medical Center Research Institute *

*** present by teleconference**

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

9:03 a.m.

MS. SKIPPER: Good morning, everyone, and welcome to the Infectious Disease Standing Committee Meeting, and we just want to thank you for your patience as we get started this morning. I just want to start off by turning it over to our CEO, Shantanu, to give some welcoming remarks.

DR. AGRAWAL: Thank you. So, thank you, everybody, for coming in, and for being on the phone. I don't normally, since we do so many of these things, I don't normally make it a point to thank the team, the internal team, but this was above and beyond. I really appreciate that.

Not only did you get here, you got food, which we had some consternation about yesterday since our caterer canceled, so really thank you very much. Marcia was talking to me yesterday evening and said, you know, "We are going to have this thing no matter what happens tomorrow," and I thought, "Wow, that's awesome,"

so fantastic.

I actually, we've lived in the area now for eight years, and I realized this morning I finally became a true Washingtonian because my reaction to the snow was, "If I leave now, there will be no traffic," so.

This is great. You know, I've looked over the agenda today. This is, I think, just a really important set of measures that are coming before us. I'm sure there will be some really active conversation.

I want to thank our two co-chairs, Woody and Adam, and I'm told that this is the first time you're convening since 2012, so, you know, spectacular. Thank you again for coming together. Thank you for braving the weather, and I really look forward to a great session today.

MS. MARINELARENA: Hi, everyone, this is Melissa Marinelarena. I'm the Senior Director. Thank you for those of you who are here in person and those of you that are on the phone, especially if you're on the west coast -

it's really early over there - and to the measure developers on the phone, and to Marlene from HRSA who braved the train and made it in. Thank you very much. Welcome.

Like Shantanu and Christy said to the Infectious Disease Project, we've been working really hard to get to this meeting, so we have some important topics to talk about, and we're really excited to work with all of you and get to know you all better, and again, thank you. I'm going to turn it over to Woody and Adam, our co-chairs, to say a few words.

CO-CHAIR EISENBERG: Good morning. My name is Woody Eisenberg. I'm a Senior Vice President at Pharmacy Quality Alliance, and I'm very pleased to be leading what for me is my first meeting of the Infectious Diseases Project, and we'll do full introductions afterwards, or should I do that?

MS. MARINELARENA: Afterwards.

CO-CHAIR EISENBERG: Okay, so let me just at this point hand it over to my co-chair,

Adam.

CO-CHAIR THOMPSON: Good morning, everyone. My name is Adam Thompson. I'm the Regional Partner Director for the South Jersey AIDS Education and Training Center where. We're the Part F Ryan White HIV/AIDS Program.

I'm also a person living with HIV, so I'm very excited to be here. I think it's grateful to NQF for their commitment to engaging patients and having us not only at the table, but now leading the table, so I think that's a really great thing, so thank you very much, and I look forward to the conversations today.

MS. MARINELARENA: Thank you both, and now I'd like to introduce the rest of the team. You've heard a lot from Christy and Mauricio, so if you could just introduce yourselves?

MS. SKIPPER: Good morning, everyone. My name is Christy Skipper, Project Manager. And as Melissa had said, thank you all for joining us both in person and for dialing in today on the west coast or wherever you are, and we look

forward to this meeting.

MR. MENENDEZ: Hi, everyone. I'm Mauricio Menendez. I'm the Project Analyst. And as Christy said, thank you for joining us today, so we hope to have a great discussion.

MS. MUNTHALI: Good morning. I'm Elisa Munthali, Vice President for Quality Measurement. Thank you so much for being here today, and welcome.

DR. BURSTIN: Good morning, everybody, Helen Burstin, Chief Scientific Officer at NQF. Thank you for braving it in person as well as the phone.

DR. WILSON: Marcia Wilson, Senior Vice President Quality Manager, and welcome.

MS. SKIPPER: Now we'll turn it over to Ann Hammersmith to walk us through the disclosures of interest and introductions.

MS. HAMMERSMITH: Thanks, Christy. I'm Ann Hammersmith. I'm NQF's General Counsel. What we'll do this morning is go through oral disclosures of interest. If you recall, you

filled out a several page form that we sent to you where we asked you very detailed questions about your professional activities.

So what we do at the first meeting of a committee, or annually if it's a multi-year committee, is go around the table and have you introduce yourselves, tell us who you're with, and if you have anything you want to disclose. Before we do that, I just want to remind you of a few things.

Just because you disclose something does not mean that you have a conflict of interest. Part of the reason we do this is to be open and transparent, and so the people will know where you're coming from and a little bit about your background, but just because you disclose doesn't mean that you have a conflict.

I also want to remind you that you sit as an individual. You don't represent your employer. You don't represent anybody who may have nominated you for service on the committee.

Our conflict of interest routine is a

little bit different from other organizations. Many other organizations are only interested in financial conflicts or financial disclosures. Because of the nature of the work we do, we're interested in more than that.

So in addition to any financial disclosures you want to make, we're also interested in things that you've done as a volunteer, so you may have sat on some advisory committee for your professional society or something like that as a volunteer. You weren't compensated.

If it's relevant to what's before the committee, we'd be interested in your disclosure of that, and that goes for all of the disclosures. We only want you to disclose things that are relevant to the subject matter of this committee.

We're especially interested in any consulting, research, or grant activity, but of course if you have disclosures that fall into other categories that you believe are relevant,

we'd like to hear about that.

So for the people in the room, we'll just go around the table starting with the co-chairs. If you're on the phone, I'll call on you at the end of the in-person disclosures, so we'll start with the co-chairs.

CO-CHAIR EISENBERG: Hi, this is Woody Eisenberg. I work for the Pharmacy Quality Alliance which does develop quality measures, including HIV and sepsis, but none of the measures that are under discussion today are related to my organization, so I have no disclosures.

CO-CHAIR THOMPSON: And this is Adam. I work for the HRSA HIV/AIDS Bureau funded AIDS Education and Training Centers, and I've worked as a consultant with the Bureau who developed some of the measures we'll talk about today.

MS. HAMMERSMITH: We'll go around the table this way. Can you turn on your mic?

MEMBER ADALJA: Hi, Amesh Adalja, University of Pittsburgh Medical Center. I'm an

infectious disease and critical care physician. I have no relevant disclosures.

MEMBER RONEY: Hi, I'm Jamie Roney, and I work for Providence St. Joseph Health as Sepsis Coordinator. I am a national volunteer for the Society of Clinical Care Medicine and the American Association of Critical Care Nurses where I review a lot of the sepsis stuff that comes out the ACN, but I have no tie to these measures.

MEMBER GARZARO: Hi, Piero Garzaro. I'm the Chair of the Chiefs of Infectious Diseases for Kaiser Permanente Northern California. No disclosures.

MEMBER BRADY: I'm Dr. Kathleen Brady. I'm the Medical Director and Medical Epidemiologist for the AIDS Office of the Philadelphia Department of Public Health, and I'm an infectious disease physician, and I have no disclosures.

MEMBER LANE: My name is Mike Lane. I'm an infectious disease physician at Washington

University in St. Louis. I'm also an outcomes and quality physician at BJC Healthcare, and I have no disclosures.

MEMBER GOLDMANN: I'm Don Goldmann, Institute for Healthcare Improvement, and I also work at Boston Children's Hospital, Harvard Medical School, and the Harvard T.H. Chan School of Public Health.

Full disclosure, although I don't think it will affect what we're doing, I do collaborate with doctors to develop measures for hospital-acquired infections, ventilator bundles, things like that, some of which are published in the literature, but other than that, nothing to disclosure.

MS. HAMMERSMITH: Okay, thank you. I'll call the people who are on the phone. Emily Aaronson?

MEMBER AARONSON: Yes, this is Emily here. I clinically attend in the emergency department at Mass General Hospital, and I'm just finishing up a fellowship at Harvard Medical

School in Patient Safety and Quality Improvement, and I have no disclosures.

MS. HAMMERSMITH: Okay, thank you. Esther Otete?

MEMBER BABADY: This is Esther Babady. I am a clinical microbiologist and I'm the Director of the Clinical Micro Lab at Memorial Sloan Kettering Cancer Center in New York City, and I have no disclosure.

MS. HAMMERSMITH: Thank you. Nanette Benbow?

MEMBER BENBOW: Hi, this is Nanette Benbow. I work at Northwestern University. I'm a research assistant professor, and I have no disclosures.

MS. HAMMERSMITH: Thank you. Laura Evans?

MEMBER EVANS: Yes, hi, good morning. I'm Laura Evans. I'm a pulmonary critical care intensivist at NYU and Bellevue Hospital. One of my volunteer activities is I am the Co-Chair of the Surviving Sepsis Campaign guidelines,

including the recent revised guidelines that just were published.

How this impacts Sepsis 0500, as you know, the original 0500 was based on the Surviving Sepsis Campaign bundles, and so I did collaborate on the development of the Surviving Sepsis Campaign bundles that were sort of behind the original 0500 measure.

I have also served on the New York State Sepsis Advisory Committee which is a group that helps New York State's Department of Health sort of design the sepsis regulations for New York State and implements them, but I had no direct role in the risk-adjusted mortality model or the development of the model or measure for this purpose.

MS. HAMMERSMITH: Okay, thank you. Jeffrey Hart?

MEMBER HART: Hello, Jeffrey Hart from Kaiser Permanente. I work there as a principal consultant in the area of quality reporting and, well, I guess reporting. I'm also a person

living with HIV, and I have no disclosures.

MS. HAMMERSMITH: Okay, thank you. Rocco Orlando?

MEMBER ORLANDO: Rocco Orlando, I'm the Senior Vice President and Chief Medical Officer at Hartford Healthcare. I'm a practicing surgical intensivist and I have no relevant disclosures.

MS. HAMMERSMITH: Thank you. Pranavi Sreeramoju? Are you on the phone? Okay, anyone else on the phone who I missed, any committee member?

MEMBER LEWIS: Jeff Lewis here at El Rio Community Health Center in Tucson, and we - I work in the HIV clinic, and we do use some of these measuring tools. I don't know if that's a conflict or not, but -

MS. HAMMERSMITH: Thanks for disclosing that. Use of measure tools is not a conflict. Use of measures is not a conflict.

MEMBER LEWIS: Okay.

MS. HAMMERSMITH: But thanks for

disclosing that.

MEMBER LEWIS: Okay.

MS. HAMMERSMITH: Anyone else? Okay, thank you for those disclosures. Before I leave you today, one more reminder. If during the course of the meeting, you think you have a conflict, if you think somebody else has a conflict, if you think that someone is going beyond stating their opinion into bias, please speak up.

We appreciate your speaking up in real time. We don't want to get down the road on the measures and then have a committee member say, "You know, I think I had a conflict," or, "So and so had a conflict."

So if you would like, you are always welcome to speak up in the meeting. If you prefer not to do that, you can go to your co-chairs or you can go to NQF staff and we'll work to resolve the conflict. Any questions? Okay, thank you.

MS. SKIPPER: And Ann, I'd just like

to say that Pranavi is online, but for some reason, we're not able to hear her, but she's written in that she has no disclosures for the record.

MS. MARINELARENA: Okay, we're going to go ahead and get started. I'm going to do a quick introduction to the project and we'll do an overview of the evaluation process, and you've had this in steps, and so now we'll put it all together and put it to work. Next slide.

So in our infectious disease portfolio right now, the only two topics that we're looking are at the HIV/AIDS measures from HRSA and sepsis and septic shock, which is the 0500, the bundle that has been endorsed, and then we've got a new measure which is the mortality outcomes measure.

Like we said, right now we have nine endorsed measures. There were a little bit more, but some of them were withdrawn by the developers, so that's why we're at nine now. And of those, they are going under endorsed maintenance because they were previously endorsed

in 2012, I believe, was the last time they were looked at.

So these are the measures that we're going to be reviewing today, the 0500, which is the Severe Sepsis and Septic Shock Management Bundle from Henry Ford Hospital, 2079, the HIV Medical Visit Frequency, 2080, Gaps in HIV Medical Visits, 2082, HIV Viral Load Suppression, and 2083, the Prescription of HIV Antiretroviral Therapy, and all four of those are from HRSA.

These are the new measures that were submitted, so the first three that we have titled as eMeasures, those are the legacy measures. I believe we talked about those on some of our calls, and we'll have a presentation on, I guess, legacy measures, because they're evaluated a little bit different. The testing that we allow for legacy measures is a little bit different.

So these are eCQMs that are based on existing paper-based, claims-based measures that are in federal programs. So the original measures are in federal programs, and then these

are the eMeasures, part of them, and they're in the process of testing them.

So we allow for synthetic testing, and we talked a little bit about that during the work group calls, but for those of you that weren't on those work group calls, my colleague, Jason, will be here to talk about that, and then again, the risk adjusted sepsis mortality measure out of the New York State Department of Health, which is new as well.

These measures are still in our portfolio, but the developers asked that they be deferred. They weren't ready to be looked at for maintenance. The first two, 0058 and 0069, it was our understanding that they are trying to expand the population for both.

And then the other two HIV measures, they may be transferring stewards, so they needed some more time to be able to do some maintenance on those, so those have been deferred. Yes?

Deferred means that they asked, because maintenance - we ask that we do

maintenance on them every three years. They weren't ready for them to be looked at, so they just asked for us to defer the maintenance period, and so we agreed to it. They had a good reason for it, and so we agreed to it. So they remain endorsed. They all remain endorsed. They don't lose endorsement.

If we go to the next slide, the difference here is these were withdrawn. So this was a request by the measure developers to withdraw the measures because they're no longer going to maintain them, so these have lost endorsement, so that's the difference between the two.

So all of these Hepatitis C measures, and then the CD4 cell count and the HIV/AIDS TB screening measures, so all of those have been withdrawn and are no longer in our portfolio and no longer NQF endorsed.

This is just a quick snapshot of our portfolio by data source, by care studying, by level of analysis, by measure type, and by topic

area. And in your handouts here, we probably won't talk about gaps today, but we did put together, as you have requested I think on one of our first phone calls, is we put together all of our measures in our portfolio and then as many other - it's in this handout - as many other measures from other portfolios that were infectious disease related so that you could see, and I tried to group them kind of by topic so that you could see if there were gaps or not.

Because previously, there were some gaps that were identified that we can share with you later, but that maybe have been filled by measures that are in other projects that aren't necessarily in ours, but just so you see what other type of infectious disease related measures were.

So there's a lot of antibiotic related measures. A lot of them are in periop, but there's a lot of the vaccination measures. There's a couple of STI measures, but, you know, keep this and look at it, and then we'll use this

to identify gaps in infectious disease.

So the evaluation process, we have the measure worksheets which you have become familiar with, I'm sure. That includes the preliminary analysis which is something that was provided by staff, and it has in the bottom, the pre-evaluation comments that was provided by you, any pre-meeting public or member comments.

We do put the measures out for comment for about two weeks before our meetings so that we like to get feedback from the public, and we include those, and then they also include the evidence and testing attachments from the measure developers.

As it's noted down here, we'd like to stress that the preliminary analysis from staff, you do not have to stick to that rating. It's just a place for you to start. And if you have any questions about why we rated something a certain way, we try to be very clear in our rationale.

We may not always be as clear as we

think we are, so throughout the day, if you have any questions as to how we got there, you know, we always refer to the algorithms which you have in front of you.

We can go through that or we could help you with the discussion as to how to get to a certain discussion or part of the algorithm, which that is why we're here. But again, that's not something that you have to stick to, but it's just a place to start.

So for our criteria, criteria number one, importance to measure and report, about a year or so, our process changed a little bit between new measures and maintenance measures, and really the criteria didn't change, but it was just the emphasis on different criteria.

So for maintenance measures, we have a decreased emphasis on evidence, and that just meant that if there was no new evidence between maintenance periods, the developers could just attest that there was no new evidence instead of provided the same evidence to us over and over

again.

But if there is new evidence, they can provide it to us. You've seen in the HIV measures, the evidence was just the updated guidelines, and in the substance measure, there was pretty substantial new evidence. So then you see the difference and we tried to provide you with that guidance there.

For gap, there is an increased emphasis for maintenance measures. So once a measure has been endorsed, when it comes back for maintenance, we want to know how it's doing, how it's performing, so we ask for data on performance. That is required.

A new measure may not have it because it could be just testing data, or it could be data from the literature, but once there is maintenance - once it's been endorsed, then we ask for some data on performance on it.

For scientific acceptability, there is no difference for new measures or maintenance measures. If the specs have not changed for the

maintenance measures, then we don't ask for them to be retested. As long as the testing, reliability or validity testing was sufficient the first time around, then they don't have to do additional testing.

Now, we also look for, in the previous report, if there were problems, maybe the committees had recommended that they do some additional testing, we'll pull that information out and then ask whether it was done or not, but it's not required as long as the previous testing was sufficient and it meets our current criteria, and then it's sufficient.

For feasibility and use and usability, for feasibility, there's no difference in the emphasis between new measures and maintenance measures. There is an increased emphasis on usability and use on maintenance measures, again because the understanding is that these measures are endorsed and that they are being used, so we want more information about how they're being used.

And so we're really looking at - we really want - I don't know. Are we still calling it a feedback loop? Feedback, we want feedback on them. How are they working for people who are actually using them? So we do look at that even though this is not a must, what we call "must pass" criteria, but this is an increased emphasis.

Okay, I'll pass it over. First, I'll stop and see are there any questions? No, okay.

MS. SKIPPER: Thank you, Melissa. Now before I get started, I just want to note to the individuals on the phone, if you are having trouble viewing the slides, press "refresh" on your screen and that should reset so that you all can see them as we advance.

So I just want to go over some of the roles of the standing committee. So you all act as a proxy for NQF stakeholder membership. Although you are from your individual organizations, you sit on the committee as individuals and not representatives of your

organization.

You also will serve two or three-year terms, and at our lunch break today, each committee member will have a chance to select their term limit which will either be two or three years.

And then your goal is also to work with the NQF staff to achieve goals of the project, review all of the measures within the project, and let us know today the extent to which each measure meets our criteria, and also make recommendations to the NQF membership for endorsement.

We ask that you also respond to comments submitted during the review period. So following this meeting, our - we will write a report, and that will be summarized and posted to our project page, and will go for a public commenting period. When we reconvene you all following that commenting period, your job will be to respond to any comments received on your recommendations.

We also ask that you respond to any directions from the CSAC, the Consensus Standards Approval Committee, and then also overall just to oversee the portfolio of measures. Next slide.

So a couple of ground rules for today's meeting, I just want to note for those of you in the room that we need to speak directly into the mic as I'm doing now. Only three microphones can be on at one time, so once you've finished speaking, press the red button off.

For individuals on the phone, committee members, you may use the raise your hand function to be acknowledged and we'll have the co-chairs call on you.

And just in general, we ask, and we know that you all are prepared having reviewed the measures in advance, and we ask you to stay on task and remain engaged without distraction, and keep comments concise and focused, and Adam and Woody will help you all stay on task.

And also, just avoid dominating a discussion and allow other individuals to

comment, and you don't need to repeat something that has already been said. And I've already noted that for those of you on the phone, please use the raise your hand function.

And then also, we have all of the meeting materials under the links section on the webinar platform. So to the left of your screen, you'll see links, and beneath that is our agenda for this morning, our measure worksheets, and all of the algorithms, and any other documents that we may reference throughout our meeting today.

Also when you are acknowledged on the phone, if you could just say your name so that we can record who is speaking.

So our process for the measure discussion today is we'll have the measure come to the table, our measure developer come to the table or speak from the phone and give a brief introduction to the measure.

Then we'll turn it over to the lead discussants to provide a summary of the pre-meeting comments or any of your initial thoughts

about the measure, and emphasize any areas of concern or areas of differences of opinions.

Developers will also have a chance to respond to any questions that committee members may have, and we - and we are experiencing a bit of an echo, and it sounds like it's gone away. Okay, so we'll discuss each measure criteria by criteria, so we'll start out with evidence.

You all will vote on evidence and performance gap, and then we'll move onto the next criteria, discuss that, and vote in that order. So we're going to try to, you know, keep your comments about evidence in the evidence discussion, reliability and validity in those sections, and so on.

Okay, so I've kind of alluded to this already, so the first criteria you're going to vote on is importance to measure and report, and there are two votes we'll take on that, the evidence and the gap, and these are both "must pass" criteria. If the measure does not pass either of these criteria, we stop voting and

discussion of the measure and we go onto the very next measure for discussion.

If the measure passes both of these criteria, we then go onto scientific acceptability, so talking about whether or not the measure is reliable and valid. These are also "must pass." If the measure - if you all do not pass the measure on reliability or validity, again we stop the discussion of the measure and move to the next measure.

Feasibility, that's one vote, so you're going to be talking about whether the measurement burden, and then usability and use, whether or not the measure is useful, and that's one vote as well, and those two are not "must pass."

So just talking a little bit more about voting, in order for a measure to pass or be recommended, greater than 60 percent of your votes must be, "yes," and that is the sum of the high and the moderate votes. If we fall between 40 and 60 percent on the "yes" votes, then that

is consensus not reached.

If we do not reach consensus on any criteria, we will not take an overall recommendation for endorsement vote. The measure is not passed and it's not recommended with less than 40 percent of the "yes" votes.

And I want to note that our quorum for today is 66 percent, so we need at least 11 votes at all times during our meeting. For those of you on the phone, you will be able to chat in your vote to the co-leaders, and we will be voting in the room for you. Next slide.

Okay, so I know I've said a lot. Are there any questions in the room or on the phone about voting, discussion of the measures?

MEMBER RONEY: I have one question. Do we have to make a comment to every comment that's made during, or just if we have a valid or valuable insight? Do we provide feedback to all of the other comments that come in on the measures that we spoke about?

MS. MARINELARENA: So yes, we would

like for the lead discussant to present, the lead discussant or discussants, to present the measure criteria by criteria, but then we really want you to have a discussion rather than just going straight to vote because for our purposes for the report, we need to be able to capture your rationale whether you voted for it or against it, so we really want you to have that discussion. So yes, if you have comments, please share them.

MS. SKIPPER: All right, well, we'll move right into the consideration of candidate measures, and I'll turn it to our co-chairs.

CO-CHAIR THOMPSON: Great, thank you. So I think the first step is to hear from the measure developers, correct?

MS. MATOSKY: Good morning, I'm Marlene Matosky. I'm from the Health Resources and Services Administration's HIV/AIDS Bureau. I'm joined on the line with the rest of the team who unfortunately, could not be here because of the weather.

We have Dr. Laura Cheever. She is a

board certified practicing infectious disease physician, but she is also our Associate Administrator for the HIV/AIDS Bureau. I'm also joined by Tracy Matthews. She is the Deputy Director of the Division of Policy and Data, Antigone Dempsey, the Director of the Division of Policy and Data.

And I also have three members of our team that specifically worked on our eCQMs component. In that team, we have Rute Martins Baptista, Laura Munro, and Renee Workwood, and then finally I have two of our statisticians with us who work in the HIV/AIDS Bureau along with me. I have Meredith Brantley and Allison Mariner.

So we're really pleased to be here today. And first and foremost, I wanted to say we believe in these measures because we believe in improving health outcomes, quality of life for people living with HIV, and we're only going to achieve that through quality improvement, and thus we need measures in order to do that.

We've worked very hard to develop a

suite of HIV measures, many of which you are reviewing here today. And though these measures have been developed and tested by the HIV/AIDS Bureau and HRSA, we expect these measures are applicable as well as in use by many providers across this country outside of the Ryan White program.

To that end, we've worked with our partners over at the Centers for Medicare and Medicaid to adopt these measures into many of their programs, which we'll get to individually.

More specifically about our measures here today that we have in front of us is the viral suppression measure. We're looking at the proportion of patients who had a viral load less than 200 at the last test during a 12-month measurement year.

We have both in front of you a paper copy, or a paper measure, or a chart-abstracted measure, as well as the eCQM. It had come up earlier in discussion in that the measures, we had questions around field testing and what have

you.

As I've mentioned on previous discussions, we've sort of pivoted more towards the development and testing of the measures as eCQMs, and that's why we have two versions that are here in front of you today. And then finally, I just want to talk a little bit about performance gaps and areas for improvement with these measures.

As many of you know, we have the HIV Care Continuum which is a framework in HIV care and treatment that really tracks folks across the multiple phases of care and treatment from diagnosis all the way to viral suppression.

When you look at national CDC data that is inclusive of every person in this country living with HIV, you'll notice that there are persistent gaps in care when you move across that care continuum, and it's estimated that right around 30 percent of folks living in this country with HIV are virally suppressed, so there is a significant area for improvement.

And you will notice not only from previously published CDC data as well as in our testing data here, there are inequities or disparities as well when we look especially by age and race and ethnicity. Dr. Cheever, is there anything else you would like to add?

DR. CHEEVER: I don't know if we want to get into the discussion of why we used the less than 200 cutoff, if that's now, or appropriate for later on in terms of technical considerations?

MS. MATOSKY: We can do that later. Folks are saying perhaps later that would be better.

DR. CHEEVER: Yeah, I don't really have anything to add other than that there is a great deal of evidence about viral suppression being a very good surrogate marker in terms of morbidity and mortality for HIV.

MS. MATOSKY: So I think that is all we have at this time, and I guess we'll turn it back over to you, Christy or to Adam.

CO-CHAIR THOMPSON: Well, thank you very much, and now we will pass it over to our lead discussants. So we have in the room with us Piero and Michael, and Laura on the phone, so which - who's going to be the brave one?

MEMBER LANE: I'll take over and Piero can chime in. I'm recovering from the flu, so my voice is still not quite there all that well. So as the developer indicated, this is an outcomes measure up for maintenance review.

In terms of evidence, they've provided a significant amount of evidence indicating that there is linkage between control of viral replication and outcomes with regards to disease progression, OIs, and decreased risk of transmitting HIV to those that do not.

In terms of the evidence provided, they have updated, as indicated earlier, largely updated guidelines to support the measure. I don't have anything else to add as far as evidence.

Part of the discussion that's already

been alluded to is why the cutoff of 200 was chosen, and that was part of the discussion during the pre-conference call and in the comments here. Some of the discussion and the comments was related to it.

There is evidence saying that lower viral loads may be better, and with improvements in medications and assessment assays, that undetectable viral loads is now less than 200, which is the measurement level for this metric. I want to get comments back.

MS. MATOSKY: Sorry, so as outlined in the HIV guidelines, the HHS guidelines, it notes that although there are laboratory tests that can quantify a viral load down to individual copies of the virus, it's generally accepted that 200 is the marker at which folks would draw the line for either viral suppression or on suppression. Dr. Cheever, is there something else you would add?

DR. CHEEVER: Yes, I think that it's expected that over the course of a disease, people do have what are called blips which is

less than 200 where there is breakthrough of virus often from a cell that has died and the virus is released into the blood, and you know, that these intermittent blips are really not associated with disease progression. If people have recurrently detectable virus, then it is a cause for concern, but having one viral load of 150 or 50 is not of concern in and of itself.

MEMBER LANE: I think even with the, in terms of the performance gap data that you present, that even with a more permissive metric, there is still a significant gap in opportunities for improvement, so you know, from my standpoint, again, even using that more permissive, you know, cutoff measure, there's lots of opportunity to improve.

CO-CHAIR THOMPSON: Thank you. I've got a question and I think this kind of applies to a lot of the HRSA measures. We saw in the measure information, you say, "comprehensive HIV care," and we had a question as far as how is that defined, primarily to make the distinction

between a specialist environment and a primary care environment, so if individuals are hitting both of those systems, how do they count in the denominator?

MS. MATOSKY: So I'll kind of back up to the first component of your question. So within the United States, HIV care and treatment can be offered to patients in a variety of different models.

You can have the models as Adam has suggested where you have an internist or a primary care physician who is providing both the management of someone's HIV disease, as well as the routine primary and preventive health care.

Then you can have a strategy whereby you can have a board certified infectious disease physician providing both accommodation of the HIV disease management as well as the primary as well, and then you can have another model where folks, they're seeing an infectious disease physician, but they're getting just the management of their HIV care and treatment. So I

just kind of wanted to make that distinction.

In general, all of those are acceptable models of care, and we have to develop measures that are applicable to all of those models of care. Dr. Cheever, is there anything else you would add?

DR. CHEEVER: No, I think that's exactly right. I think why we use that term is that people can sometimes be seeing a - be seen frequently through the emergency room or seen by a primary care physician that is not addressing their HIV.

And so we're saying they have to be seeing someone who is addressing their HIV care and there are markers of that, that they're on antiretrovirals or their viral load has been checked, as a measure that their HIV is actually being attended to.

CO-CHAIR THOMPSON: Thank you. Any other questions or comments about evidence or gap?

MEMBER GOLDMANN: I'm not sure if this

falls under that category exactly, but, so I'm sure it's here somewhere, but the unit of analysis for this measure is at what level?

Because the background talks about states and federal, and yet obviously this depends on the practice environment, and so what is the level of reporting and analysis? How granular does it get?

MS. MATOSKY: For this measure, we went to the provider or clinic level. We do recognize that as more and more especially health records, electronic health records are doing analysis at the individual clinician level, we would think that is acceptable as well.

MEMBER GOLDMANN: So one of the conundrums here, I'm kind of appalled by the statistics, and part of the statistics is the number of people who are undiagnosed, and then a number of people are diagnosed who are not in care and therefore won't have a once a year visit, and therefore would be excluded from this.

What if a provider systematically

fails to see patients who - or creates an unfavorable environment to see patients, so they ace the measure, but they're not acting responsibly? Is that another measure or how does that get looked at?

DR. CHEEVER: This is Laura. So I think that that is why we in fact do work very much at a sort of public health level, either with cities or states, to look jurisdictionally at what the levels are in the community, but it's really hard to capture that from an individual provider because the way healthcare is provided here, the individual provider often doesn't have a lot of say of which patients they see. That will be determined by insurance and other issues.

But I do agree the, you know, making sure they have a welcoming environment. We actually have a longer term, a two-year measure to look at some of that, whether or not patients are coming back to a particular clinic. But to really capture what's happening in the community,

we need to look at the jurisdictional level.

MEMBER GOLDMANN: So I guess the rationale for my question is that the reason to have a measure, as you said, is to drive improvement efforts, and I'm not exactly sure that I understand how looking at this measure - or who it will drive to undertake the improvements.

So I'm getting the impression that it's public health, state, community, but I'm not sure, and without that link, I don't know how much progress we'll make just by having a measure.

DR. CHEEVER: Yes, so I can give you an example. So we've been using this measure for many years, and between 2010 and 2015 in the clinics that we have been monitoring and working on quality improvement, we've worked from a 69 percent viral suppression rate for people that actually had walked in the door at least once in that year, to an 83 percent viral suppression rate.

So we've made great progress at the individual clinic level, but I do agree that overall if we're going to end this epidemic in this country, we need to look at the jurisdictional level, and we're actually doing quite a bit of work in that area, but we still need a measure by which - we still need a measure we can use.

The other thing is when you actually break down this measure and we're looking at health disparities, we can see with individual clinics a significant amount of health disparities.

I think the average viral suppression rate across our programs for people that are, you know, between 13 and 24, is something like 55 percent compared to the overall rate of 83 percent. Fifty-five is, I'm remembering, but it's something around that.

So we still, amongst some populations, see a significant amount of disparity that needs to get addressed at the clinic level.

CO-CHAIR EISENBERG: I have a question that I think, Don, is a follow-up to what you were saying.

When we're looking at missing data, apparently, if no viral load count data were present for a given patient, the patient was considered to have had no viral load test during the measurement year. But that, as far as I can tell, isn't counted against that provider. Is that correct?

MS. MATOSKY: That is correct.

CO-CHAIR EISENBERG: Okay. So, did you consider counting those situations where there is a patient known to have HIV infection, but with no viral load, against the provider rather than simply not including them in the counts?

MS. MATOSKY: So, as the measure is written --- well, let me back up. So, in the testing data that we presented, we did stratify by --- and I think it's here on the screen --- those patients who had at least one medical

visit. Sorry, I misspoke. We do include folks who had a visit but did not have a viral load in the measure. I apologize.

When we had looked at this deeper, we suspect to some degree that it may be a data completeness issue. By the way that we're collecting our data, it's not coming --- it's coming through a rather complicated system.

But going back to Dr. Cheever's point, we take a public health approach with this, because it is a communicable disease. So if the client came in for at least one visit, they're counted in that patient population regardless if they had that viral load test or not.

CO-CHAIR EISENBERG: And counted how? They're in the denominator --

MS. MATOSKY: The denominator, yes. Yes.

CO-CHAIR EISENBERG: But they wouldn't hit the numerator, because they either have a higher than 200 count or because they have no count?

MS. MATOSKY: Exactly.

CO-CHAIR EISENBERG: So then I'm not --- I didn't --- I'm misinterpreting the measure. So patients who have HIV infection but who have no viral load would be counted against the provider in this case because they wouldn't --

MS. MATOSKY: As long as they had one visit.

CO-CHAIR EISENBERG: As long as they had one visit.

MS. MATOSKY: Yes.

CO-CHAIR EISENBERG: Thank you.

MEMBER GARZARO: So, we're talking about visits. How would you define -- or how are we defining "medical visits"? Now, in the 21st century, we can have a medical visit in my iPhone or a video or a telephone appointment.

CO-CHAIR EISENBERG: Piero?

MEMBER GARZARO: Yes.

CO-CHAIR EISENBERG: I'm sorry, could I just interrupt? We'd like to just stay on the evidence for now and then --- you and I are

ranging, I think, a little bit too far away. So, I'm going to try and ---

MS. MARINELARENA: Yes. So, if there's any more discussion on evidence, we'll have a discussion on evidence. If not, I would recommend voting on evidence or not.

MEMBER BRADY: I have one comment on evidence. And it's just some new data that became available from CDC at CROI looking at viral suppression and that looking at the last measure of a given calendar year of less than 200 may actually overestimate viral suppression rates by 20 percent.

They did an analysis looking at durable viral suppression over an entire year. Most people did improve, but that there were lots of people who met the measure at the end of the year that didn't necessarily meet it throughout the year. So, that might be something, I think, to look at.

MS. MATOSKY: Can I respond?

CO-CHAIR EISENBERG: Yes.

MS. MATOSKY: So, to be clear, our --- I appreciate your comments, Dr. Brady. To be clear, we don't intend this measure to be a durable suppression measure. We're looking at it at, you know, during the year, at the end of the year, you know, thinking that perhaps there's that cumulative effect, what have you, of the interactions with the care team.

And in general, I think, with all measures, and I think we can all agree, that we have to give up some level of specificity to gain broader applicability and also not create overly complex measures so that we spend more time talking about the numerator and denominator than actually implementing it and moving on to quality improvement.

So, I do appreciate the comments about durable suppression. I mean, it is rather important and there's a lot of research in that area, but that's not the focus of this measure. Thank you.

CO-CHAIR THOMPSON: Any other comments

on evidence?

(No audible response.)

CO-CHAIR THOMPSON: Do we have any comments from our phone?

(No audible response.)

CO-CHAIR THOMPSON: Okay. With that, I think we pass it over to Mauricio for voting.

MR. MENENDEZ: Okay. So, for the voting instructions, as Christy mentioned, we'll have the different categories. I will state the name of the category and open the poll up to voting. Once we have enough votes in, I will close the poll and we will tally up the final votes.

So, just to restate, I'll state the name of the category and open up the polling. And once we have enough votes, I'll close up the polling and we'll tally up the votes for the final consensus. And please point over here to this monitor by me to put in your votes.

And for those of you on the phone, again, as Christy said, you can vote in through

the chat.

MEMBER HART: Excuse me. This is Jeff Hart. I've lost connectivity. I live here in the D.C. area and my network has gone down. So, I won't be able to see the WebEx and would like to vote. So, can I just speak up yea or nay?

MS. SKIPPER: Yes. Say your name and your vote.

MEMBER HART: Thank you.

(Pause.)

MS. SKIPPER: And just give us one moment.

MR. MENENDEZ: Okay. For the first category, importance to measure and report, the voting is now open.

Click 1 for yes, and 2 for no. Oh, I'm sorry. So, yeah, each category will have a number for you to vote. So, 1 for yes, and 2 for now. And the category, again, is importance to measure and report for evidence.

(Voting.)

MEMBER HART: This is Jeff Hart. Yes,

please. Thank you.

(Pause.)

MS. SKIPPER: And just a reminder for those of you committee members online, please chat in your votes to either Christy or to Elisa Munthali.

MS. MARINELARENA: So, let's just do a hand vote. We're going to do a hand vote in the room for evidence for Measure 2082, Viral Load Suppression. And this is importance to measure and report. And you're asking rationale supports the relationship of the health outcome to at least one healthcare structure, process, intervention or service.

For all of those who want to say "yes," raise your hand.

(Voting.)

MS. MARINELARENA: So, we have eight in the room, yes.

No? Zero nos. And what do you have online?

MEMBER HART: This is Jeff. I vote

yes.

MS. MARINELARENA: Okay.

MS. SKIPPER: And all votes online came through as "yes."

MS. MARINELARENA: How many votes are those, Christy? Is it seven?

MS. SKIPPER: Eight.

MS. MARINELARENA: Eight? Okay. So, that's a total of 16 yes. A hundred percent yes. This measure passes on evidence.

So now we'll move on to gap. Does anybody else want to have further discussion on performance gap?

(No audible response.)

MS. MARINELARENA: If there's no further discussion, we can go ahead and vote.

Anybody on the phone, do you want to have more discussion?

(No audible response.)

MS. MARINELARENA: Okay. Hearing none, we will go ahead and vote.

Do we need to do this by hand?

MR. MENENDEZ: Sorry. We're having some technical difficulties. We're losing connection.

MS. MARINELARENA: Okay. We'll wait before we hand vote. Is that okay? Okay.

(Pause.)

MR. MENENDEZ: Okay. So, for the second category, importance to measure and report, performance gap: data demonstrated considerable variation or overall less than optimal performance across providers and/or population groups, disparities and care.

Vote 1 for high, 2 for moderate, 3 for low and 4 for insufficient. Voting is now open.

(Voting.)

MR. MENENDEZ: And please point your clickers over in my direction. Thanks.

MEMBER ORLANDO: This is Rocco. Can you repeat the categories of the vote?

MR. MENENDEZ: Sure. This is for performance gap. Data demonstrated considerable variation or overall less than optimal

performance across providers and/or population groups.

Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

(Voting.)

(Off microphone comments.)

MR. MENENDEZ: Sure. For performance gap, the four categories were 1 for high, 2 for moderate, 3 for low and 4 for insufficient.

MEMBER HART: This is Jeff Hart. I would vote high. I don't have the evidence in front of me, but I think, from memory, that's appropriate.

MR. MENENDEZ: So if there is a large gap, then it would be high.

MEMBER HART: Correct.

(Pause.)

MS. SKIPPER: Okay. And we're waiting for a vote on gap from Emily and Jeffrey Hart. We're voting on performance gap. 1 high, 2 moderate, 3 low, 4 insufficient.

Emily, I see that you have a comment.

Would you like to say it on the record?

MEMBER AARONSON: No, that was my vote. I concur that I think the evidence is strong.

MS. SKIPPER: Okay. And so, what you typed in here is your vote for gap?

MEMBER AARONSON: Yes.

MS. SKIPPER: So, is that a 3 for gap?

MEMBER AARONSON: Well, I guess -- sorry. I think I'm also sharing some of the confusion around the gap. So, a high number is a low gap between the evidence? Can you just summarize the numerical scoring again, please?

MS. MARINELARENA: Sure. Emily, this is Melissa. So, when you vote high for gap, you are agreeing that there is a high gap in performance, meaning there's still room for performance or that there's a high variation between performers. Moderate means that there's a moderate gap in performance.

MEMBER AARONSON: Okay.

MS. MARINELARENA: Low would be, say,

a measure that is topped out. Everybody is performing the same. And then insufficient ---

MEMBER AARONSON: So, that would be a 1, not a 3, for my vote.

MS. MARINELARENA: So, just to be sure on your vote, if you believe that there is a high gap in performance, there's lots of room for improvement, that's a 1.

MEMBER AARONSON: Yes.

MS. MARINELARENA: Moderate room, 2. No room, 3. And if there's insufficient information, it's a 4.

MEMBER AARONSON: That's very helpful. Thank you. I would vote a 1, then.

CO-CHAIR THOMPSON: I just want to make sure I see -- some people would like to switch their votes with that explanation?

(Off microphone comments.)

DR. WILSON: No, this is not like Chicago where you vote early and vote often. The clicker will take ---- if you want to change your ---- the voting is open. You can change your

vote. It takes your last click.

MS. MUNTHALI: We're having internet connection issues. So we're going to have to re-vote again overall. So we're going to do a hand vote for this. Sorry about that.

MS. SKIPPER: Okay. So, for performance gap for Measure 2082, 1 high, how many are voting 1 high?

(Voting.)

MS. SKIPPER: All hands for 1 high on performance gap. Could you keep your hands raised high? We're voting on performance gap for 2082. Please keep your hand raised high for 1, high. Seven. Okay.

And for those on the phone, if your vote has changed, please resubmit it.

MEMBER HART: Jeff Hart. I'm still high.

(Laughter.)

MS. SKIPPER: Okay. For those in the room that are voting moderate, one moderate. Low, zero low. Insufficient, zero insufficient

in the room.

(Pause.)

MR. MENENDEZ: So, the final counts were 12 for high, four for moderate, zero for low and zero for insufficient. So, overall pass.

Should we try the voting system again?

MS. MARINELARENA: Let's move on to discuss the next criterion, which is specifications under reliability, while you see if that works.

I'm going to turn it over to Mike.

MEMBER LANE: Alright. With regards to the measure specifications, as we discussed already, this is level of analysis is at the facility level. The numerator is defined by number of patients with a viral load of less than 200 at the last viral load testing during the measurement year.

The denominator includes all patients, regardless of age, diagnosed with one medical visit in the measurement year. And they have to meet the following requirements. A, of any age,

diagnosed within the first three months of the measurement year, or prior to the measurement year, and at least one visit.

There are no exclusions outside of those conditions and there are no ICD-9, ICD-10 or CPT codes. The calculation algorithm is a simple ratio.

And with that, Piero or Laura, any questions from the group?

MEMBER GARZARO: As I said before, the question that I have is how are we defining "medical visit" in the measurement year? And would that -- if we're only including an in-person medical visit, wouldn't that bring an error into the measurement? Because we're not measuring either video visits or telephone appointment visits that the patient may have.

MS. MATOSKY: Can I go ahead? Okay. So, for the paper measure, the chart-abstracted measure, we're defining a measure --- or a "medical visit" as a visit with a provider with prescribing privileges.

So, that would include anyone in a jurisdiction who is licensed to prescribe, including physicians, nurse practitioners, physician's assistants, advanced practice nurses, et cetera.

We're not including --- or by that definition we wouldn't include if a client showed up at a clinic just to get labs drawn or pick up paperwork or meet with another ancillary member of the care team.

MEMBER GARZARO: I'm thinking more ---

DR. CHEEVER: We do not exclude, though, if it was a video visit or other type of visit that's documented as a visit by the prescriber. They're not excluded.

MEMBER GARZARO: Oh, so they are included also in the medical visit. It's not only an in-person visit with a provider, but it could be a visit with their attending provider.

MS. MATOSKY: Yes. Sorry, Dr. Cheever.

MEMBER BRADY: Would that mean a

billable visit?

MS. MATOSKY: We've just defined it as a visit between the patient and a provider prescribing privileges. We haven't added on any additional criterion. It can be face-to-face, or it could be non-face-to-face if they're using telehealth, what have you.

DR. CHEEVER: But we don't address issues of billability.

CO-CHAIR THOMPSON: Any questions or comments on reliability?

(No audible response.)

CO-CHAIR THOMPSON: If not, I will pass it over for voting. Oh, we're going to go through the testing.

MEMBER LANE: Yeah. With regards to reliability testing, they updated the testing from previous years.

They used the Ryan White RSR database to do beta-binomial modal testing to assess signal-to-noise ratio. They have found medium reliability ranged over the years from 0.95 to

0.98, indicating pretty good reliability for the measure.

They also looked at provider distribution reliability scores and showed a variation at different provider levels with some differences related to sample size from low reliability areas.

Any comments, Piero or Laura?

MEMBER GARZARO: No, no comments. Very reliable measure.

CO-CHAIR THOMPSON: Okay. So, I think --- are there any other final questions about either of those two elements under reliability?

(No audible response.)

CO-CHAIR THOMPSON: Okay. We'll pass it to Mauricio.

MR. MENENDEZ: Okay. We're going to try the voting one more time. I think we figured out the technical difficulties, I hope.

So, for scientific acceptability -- oh, I'm sorry.

MEMBER GOLDMANN: I'm not a big expert

on reliability, but could you just talk a little bit about the distribution of provider level reliability scores, which seems a large variation. What is --- can you explain that a little bit? What actually happens there? Who was examined? I'm not sure I understand exactly what was done.

MS. MATOSKY: Sure. I'm also going to ask our statistician, Meredith Brantley, to chime in as well.

So, as you can see from our data, we had a significant number of providers. In this dataset, we have over 800 individual clinics or providers that were included. And from my very basic understanding of the signal-to-noise testing, is that, generally speaking, the higher the score, the closer to 1, the greater the reliability of the testing.

And so what we did was we stratified it. We gave an overall, you know, median, the min, the max. And then we gave, as well, the breakdown by greater than 0.7, providers that

scored greater than 0.8 and then a number and percentage of that greater than 0.9.

I'm just checking --- Meredith is asking me --- is there anything in specific or ---

MEMBER GOLDMANN: Well, if you look at 2014, I'm just trying to -- because this will come up with all the measures. I'm new to the committee, so I want to be sure that I don't have to just raise my hand.

So, in 2014, there are 813 providers. And what this table says is equal or greater than 0.9, equal or greater than 0.8, equal or greater than 0.7. And then there are numbers below and I'm just trying to make the numbers add up and I can't do that. So, what is --- I don't understand the columns.

MS. MATOSKY: So, when you perform the signal-to-noise analysis, you end up with a fraction of a fraction. And so --- and, as I said, with the signal-to-noise ratio testing you're aiming to get your signal-to-noise greater

or as close to 1 as possible.

MEMBER GOLDMANN: Right.

MS. MATOSKY: And, generally speaking, a signal-to-noise ratio greater than, you know, approximately, you know, 0.8 or so is considered good signal-to-noise.

And so what we did was we just stratified just to show the variance of the signal-to-noise at the individual provider level. We stratified it by those who had their signal-to-noise ended up being a 0.7 or greater than those who ended up being a 0.8 or greater or 0.9 or greater.

And the folks who had a lower score, it tended to be because they had a smaller patient population size. So, for instance, in 2014, 95 percent of the providers had a reliability of 0.9 or greater.

And, like I said, anything over generally a 0.8 or higher is considered good signal-to-noise. And that's what you're ultimately trying to do with this when you're

testing reliability.

MEMBER GOLDMANN: So this is --- so you --- basically you're saying, in 2014, this was terrific.

MS. MATOSKY: Yes.

MEMBER GOLDMANN: Okay. I still don't see why it's terrific, but ---

MEMBER RONEY: What I see is a large degree of variability. If you have a minimum reliability of 0.29 and a median of 0.98, that, to me, would signify there are some that just aren't doing very well. Is that your minimal reliability?

MS. MATOSKY: So, we've generally found the sites where we weren't getting good signal-to-noise it's because they had an incredibly low patient population. I mean, some of our sites, you know, see fewer than 25 patients. So it's really hard to distinguish signal-to-noise when you have such a small population.

And just, you know, for being, you

know, up-front, you know, with our data, we included all of our sites regardless of the number of patients that they had.

Earlier on in the measure, I think we talk about --- I know we talk about the characteristics of all of our sites. We, you know, included everyone and not excluding any of our sites. And the majority of our sites have more patients, though.

CO-CHAIR THOMPSON: Alright. Any further questions?

(No audible response.)

MR. MENENDEZ: Okay. We're now voting on Measure 2082, reliability. 1 high, 2 moderate, 3 low, 4 insufficient.

(Voting.)

MEMBER HART: This is Jeff Hart. 1, please --- I'm sorry --- yeah, 1.

MR. MENENDEZ: Thank you, Jeff.

(Pause.)

MR. MENENDEZ: So, voting is now closed. The final tallies were 75 percent for

high, 25 percent for moderate, zero percent for low, zero percent for insufficient. The measure passes on reliability.

And the final counts were 12 for high, four for moderate, zero for low and zero for insufficient.

So, now, we move on to validity.

MEMBER LANE: Alright. With regards to validity, face validity was tested for this measure. The developer describes a process where a technical group and Ryan White recipients were allowed the opportunity to provide feedback.

During that process, no feedback was garnered that indicated the measure did not have face validity or did not accurately reflect quality.

However, there was no systematic process in place to evaluate the ability of the measure to distinguish good and poor quality.

Any other comments?

CO-CHAIR THOMPSON: Woody.

CO-CHAIR EISENBERG: I have a

question. Was the technical group that was established for the development of the measure the same as the technical group that decided on face validity, or were these two different groups?

MS. MATOSKY: It was the same group.

CO-CHAIR THOMPSON: Don.

MEMBER GOLDMANN: Yeah, I tend to be fairly humble about what I don't know, and I really don't know a lot about your terminology. This is my first meeting.

So it would be really useful when we come to something like validity, which has a lot of meanings that are, you know, from criterion validity on down, and I see that it's either face validity or some other validity.

Can someone just quickly review how you view validity, and is face validity good enough, and what other specific categories of validity do you consider?

MS. MARINELARENA: Sure. This is Melissa.

So, face validity is the minimum threshold of validity that we accept. And we don't consider it empiric validity testing, but we also have a very specific definition for "face validity." And I wrote it in here.

"NQF guidance states that face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process by identified experts and explicitly addresses whether performance scores resulting from the measure, as specified, can be used to distinguish good from poor quality."

So that's what we consider face validity. We want to see that specifically, because it is such a low bar, because, really, it's not empiric testing.

If we want empiric testing, we could either have validity testing at the measure score, which you will see in some of the other measures. We also have data element validity testing, which you will also see in some of the

other measures. And that is empiric testing. And that moves us, when we go through the algorithm, moves us down the algorithm.

They did describe the type of testing that they did and here is a little summary of it. Marie may be able to describe it in a little bit more depth, but, you know, here they use a technical group for the development of the measure. And the group voted on importance, ability to assess quality care, feasibility to implement the measure and use in quality improvement activities.

MEMBER GOLDMANN: So, as an example, if we were looking at the IHI Global Trigger Tool and we came to you and said, "The face validity, a lot of people are using it, they think it's great, we had an expert meeting," it would sort of meet your definition for "face validity"?

MS. MARINELARENA: Sort of not.

MEMBER GOLDMANN: Well, I just want to know.

MS. MARINELARENA: I mean, ideally we

want to see the list of experts who you use to determine that it had face validity. This is the ideal face validity. And a lot of people do like a Likert score and we like to see, you know, 19 out of 20 of these experts believe that, yes, this can be used or something like that.

MEMBER GOLDMANN: Yeah, yeah. I mean, if we did a typical consensus or Delphi or whatever, that would be good enough.

DR. BURSTIN: Bare bones.

MEMBER GOLDMANN: Yeah. And if we came to you and said, "We tested this measure with some people in the field" -- I'm trying to figure out, since it's for improvement, apparently, then it gets squirrelly to get to a higher level of validity. You have to show that people actually used it and improved, or that they used it and tried to improve? I'm kind of lost in the empiric piece.

MS. MARINELARENA: Well, the empiric piece is when you actually test it. That doesn't have to do with face validity.

MEMBER GOLDMANN: No, no, I understand.

MS. MARINELARENA: Face validity is just getting, you know, some experts to agree that this does distinguish good from poor quality.

MEMBER GOLDMANN: Right.

MS. MARINELARENA: And like Helen said, that's bare bones. The empiric testing is when you actually use the measure as specified.

So, you take the different data elements, and whether it's the patient level data elements and you're testing those, say, against the gold standard, or you're taking the measure score and testing the validity, so testing the measure against another measure to see how it performs.

MEMBER GOLDMANN: Okay. So, that's -- I'll be done in a minute, I swear, but, so, that's a standard way to look at validity, but it has nothing to do with improvement. Whereas face validity sounds like people have to have

consensus that this is relevant to improvement.

So, I could take the Global Trigger Tool, which we did, and have three really superb people independently and blindly review what people had done in the hospitals using it, and they came back and they said, they gave me, you know, a statistical test, the Cronbach alpha or whatever it was, and said, "This looks really --- it's 0.8, looks great," but that doesn't tell me anything about whether the measure has something to do with improvement.

DR. BURSTIN: And I think that's an important point, Don. This is Helen, for those on the phone. We have typically had a harder time getting at data from implementation, particularly for newer measures.

So, most of it does tend to be either face validity or, you know, construct validity or something, for example, where you say you have the Global Trigger Tool and it's supposed to be an overall safety measure, how does that then correlate with other known measures of safety

that people have high confidence in with some truth of measurement?

But you're right, we don't have as much. We'd love to have more from the field that gives us the sense "we use this measure and we were able to see improvements in this. If this was an outcome, we saw improvements in the outcome." Very little data on that is available.

MEMBER GOLDMANN: Okay. Sorry.

DR. BURSTIN: No, it's a good point.

(Pause.)

CO-CHAIR THOMPSON: Any comments on validity?

(No audible response.)

CO-CHAIR THOMPSON: So, I have a question, and guide me if this is the wrong time to ask. But when looking at this, and I know on our pre-work call when we talked about the risk adjustment, the argument that was made was that the majority of individuals living with HIV are already a marginalized population. So, there's sort of like this "people are already kind of on

the disparity end."

And the thing that I'm concerned about is it says here that this measure is not used for pay-for-performance. And yet later on it does say that they want to move to use it in a program like MIPS. And from my understanding of the MIPS program, that is pay-for-performance.

And my concern is, as we look at healthcare environments that specialize around certain populations, that there might be lower viral suppression rates. For instance, homeless health centers. If they're going to be treating a population of homeless individuals who, I've seen in the data, are really challenged sometimes in viral suppression, that if they're compared on that scale, they could end up being quite penalized for actually providing care to people who other centers, you know, as you were saying, Don, sometimes push you out, right? Kind of keep you out of their care.

So, I wonder what thoughts there are around that and how to account for that,

especially when you look at behavioral health now. It seems like there's a lot of folks who might end up in a behavioral health home where they may be active substance users, which also creates challenges around adherence.

So, is this the appropriate time to ask that question?

MS. MATOSKY: So, thank you for the question. So, I'm going to address it in two parts.

So, first, you are correct in that we have not approached this measure with any risk adjustment criteria. This is something that we're at the very beginning stages of working on.

As you had appropriately stated, HIV disproportionately affects most people who are risk adjusted in other measures, and that's the preponderance of the people living with HIV. So, existing methodologies for risk adjustment don't necessarily apply.

So we're going to, you know, be doing what we feel like is de novo work in this area.

So it's going to take more time. So, that's number one.

Number two, on to your point about inclusion in the Centers for Medicare and Medicaid programs. It is our understanding that we will be able to work with CMS around setting any sort of thresholds, what have you.

At this point, the MIPS program is not setting any thresholds for performance at all for any of their measures, but it is our intent that we would continue to work with them as we develop our own methodologies around risk adjustment and have a better understanding of how that would play out with people living with HIV.

CO-CHAIR THOMPSON: Yeah, I know they're not setting thresholds. But from my understanding -- and, again, correct me if I'm wrong -- they're just going to spread the providers over their performance, right? And if you're on this side, you end up with a bonus. If you're on this side, you end up with a penalty.

So, I actually think the lack of a

threshold is the problem, like not having set that, because otherwise how do I then look at my population and make an argument where we stand? Because otherwise I'm just going to be sort of thrown across that curve. And if I'm in a challenged population, I'm always going to fall potentially on the penalty side.

MS. MATOSKY: I'm going to ask someone from our team. Laura, are you able to comment on this?

DR. CHEEVER: Yeah, I don't think I can comment on exactly what CMS is planning to do. And in terms of even when we're looking at our disparities and how we're going to be doing some of those analyses around risk adjustment, it's complicated because there are actually good indicators in charts, often, if someone who's actively using substances, for example, or has an untreated psychiatric disorder.

So, it is going to be a complicated piece of work in front of us, but I think the issue really at hand is how CMS is using it, and

I can't comment on that.

DR. BURSTIN: This is Helen. I could add, certainly. And I think Adam's interpretation of the MIPS program is accurate, that it will potentially be used again.

For now, at least, it is physician self-selection of measures. So you're not required to pick this measure, for example. If you did pick this measure, it would potentially be playing into your payment.

Important to note, though, NQF does have two processes: the endorser process, which looks at the quality and the scientific evidence acceptability of the measure. We then have the Measure Application Partnership where we advise CMS where we can then look at the program, the way it's being used. And I think those are the issues you'd want to make sure float from this discussion to the MAP as those measures come up for consideration in the programs.

(Off microphone comments.)

DR. BURSTIN: I don't believe this

issue was addressed by the MAP.

MS. MARINELARENA: No, the MAP --- they discussed them, but then the MAP deferred the conversation to this group.

CO-CHAIR THOMPSON: Can we defer it back to them?

(Laughter.)

MS. MARINELARENA: But that was for the eMeasures only. Those were the ones that went before the MAP, not the existing paper-based measures. But it's the same concept.

DR. BURSTIN: It's the issue regardless of whether it's on paper or on charts. I think it's something we can certainly put in our report as something that was raised as a concern and something we could promise to share directly with CMS. I think it's a fair point.

CO-CHAIR THOMPSON: Thank you very much. I mean, I do think it is important to note that. I mean, there is concerns amongst people with HIV that as more and more of our care is measured, that people will push out individuals

or make it an unfavorable environment for them. So, thank you for already having brought it up and continuing the discussion.

DR. BURSTIN: And actually, I mean, you raise another interesting point about people getting pushed out. And I think as we move towards more outcome measures, or intermediate outcome measures in this case, there's often consideration, as well, of whether you need balancing measures.

And I don't know, this might be sort of a topic for conversation in the future for HRSA of whether there might be measures you would look at to see, for center patients who leave particular centers, as a balancing measure to make sure that part of the reason you're not doing better is you're actually excluding out some of the patients who might be performing poorly on the measure. It's a really good thought, Adam. Yeah.

MS. MATOSKY: I just wanted to ask one other member of our team, Laura Munro, did you

have a comment that you wanted to make?

MS. MUNRO: Just a general comment. And this is Laura Munro from the MITRE Corporation supporting HRSA.

General comments in regards to the MIPS program is that CMS has been very intentional in how they apply the MIPS program and they explore categories that they take into consideration. Quality, which is 60 percent. And for the 2017 performance year, cost is zero percent. So they are not taking that into account. And then improvement activities is 15 percent. And advancing care information is 25 percent.

So, they are looking to providers to actually be more actionable with the data that is provided to them. They will be providing preview reports so you can look into it. So, it's not necessarily that if you don't perform well with a quality measure, you're automatically going to be penalized.

They also go through a rulemaking

process where there's opportunity for public comments, where you'll be able to provide your input in terms of how you feel the measure is impacting the care that you're providing or the burden or, you know, other issues.

So I would strongly encourage folks to go to their website, which is www.qpp.cms.gov, to get more information about the MIPS program. They have webinars and recordings specifically for small, rural and underserved practices. That was recorded February 1st. And if you have any specific questions, you can email CMS at qpp@cms.hhs.gov.

CO-CHAIR THOMPSON: Thank you. Any other comments about validity? Any comments on the phone?

MEMBER GARZARO: I just had a comment related to the other comments that have been made before.

So, this measure, eventually it's going to be used for pay-for-performance, from what I'm getting at. Eventually that probably

will happen. But I'm seeing this measure as something that the patient is very dependent on. And like my husband, who's a psychologist, always says, "patients are entitled to make poor medical choices." And I see that in my practice every day.

I can tell them, let's go, let's have a medical, let's have a viral load done today. We haven't done it for two years. Then they tell me, "Oh, yeah, sure." And then they go throughout the door and I don't see them for two, three years.

So, how does this measure measure the availability of the patient to actually have the care, but them simply not getting to that care?

I mean, I practice in Northern California, the Bay Area, it's definitely not private insurance. We don't see most patients that are homeless, but they're actually upper/middle class and many of them actually simply don't care about their HIV, don't even want to know. But the opportunities are there,

so they decide that they don't want to have either a doctor visit or they don't want to have even a viral load or even be on treatment.

So, how does the measure actually get to that part?

MS. MATOSKY: Dr. Cheever, do you want to respond first?

DR. CHEEVER: Why don't you start, Marlene?

MS. MATOSKY: Okay. Thank you. So, a couple of things come to mind in response to your question. I think, with all of our measures, we've never taken the stance that anything is ever going to be zero percent or a hundred percent. There's going to be something in the middle.

Even when you look at something like WHO has set out, the World Health Organization, WHO has set out some targets for HIV care and treatment. They're saying 90, 90, 90. So, they're maxing out at 90 percent.

And based on mathematical models, they

feel like if folks are meeting those 90 percent targets, then we're going to have a rather, you know, substantial reduction in the HIV epidemic if not, you know, bend that curve down towards zero. So, that's the first thing I would say.

The second thing I was going to bring up is that these measures are intended --- they're not --- I would say the --- there's probably a technical term for this. I'm looking to our measure friends over here. This is not a measure of a patient's compliance or a patient's ability to participate in care. Rather, this is a measure of a clinic's ability to support a client in achieving this particular outcome.

So I think the intent of the measure is different than, you know, focusing on measuring patient compliance.

Dr. Cheever, is there anything else you would add?

DR. CHEEVER: No, I think that that captures it. It really --- there are always patients that refuse to be on treatment. And I

think that that gets documented in the chart. So, in terms of internal quality review, there is a reason for that. But I think in the past, we've definitely seen there were clinics where 40 percent of patients were refusing treatment.

And there, I'd say you probably have an issue around the way care is delivered. So, it's worth investigating that. But the issue is not to coerce patients, it's to make sure they're well-educated in making their decisions and that they're documented.

CO-CHAIR THOMPSON: Yeah. I think that harkens back to a big piece of the conversation we had at this committee meeting last time around medical visit frequency and whether or not you could hold a physician accountable for patients coming to their medical visits. So, I mean, what you're raising is something that I think drove a lot of the conversation last time.

As a patient, I kind of look at it as, you know, in a partnership, there's going to be

cost on either side. On the physician side, it might translate out to their payment. And on the patient side, it translates out to our viral load.

So, I think there's a -- you know, both sides kind of have some skin in the game, but a little bit different. But I think, from my viewpoint, I do think that how practices, not just physicians, but the care team, sort of interact with people, can overcome fear of treatment, at least in my view.

DR. CHEEVER: Yeah. This is Laura. I should also add that I think that, as we've already discussed, that we're really dealing with a very disenfranchised patient population in HIV. That the main reasons people aren't on medications is because they can't access it, they can't negotiate the system, they can't figure out where they can get assistance with their co-pay. I think those are the main barriers.

And the barrier around not wanting to be on treatment, or that decision, is maybe a

part of it, but it's a relatively small part of it compared to all those other issues for the patient population where a majority of them are living below the federal poverty line.

CO-CHAIR THOMPSON: Any other comments around validity?

(No audible response.)

CO-CHAIR THOMPSON: Alright.

MR. MENENDEZ: For Measure 2082, validity, the options are 1 for moderate, 2 for low, 3 for insufficient. Also note that, because of face validity, that the highest possible rating is moderate.

MEMBER ADALJA: I have a question just on the algorithm. When you look at this, the guidance for evaluating validity, it says in box 4, it says, "Answer no if focused on data element accuracy, availability, feasibility or other topics."

Is that --- is this --- is it =-- this is focused on a data element, right? Or because it's --- the other option is, was it --- "the

computed performance measure score for measure as specified."

Is there any difference between --- is it a computed performance measure score, or was it data element accuracy? That's ---

MS. MARINELARENA: It was just face validity. So that's how we ended up in box 4.

MEMBER ADALJA: In box 4 it says, "Answer no if focused on data element accuracy, availability, feasibility."

So, is it --- I get it was face validity systematically ---

(Simultaneous speaking.)

MS. MARINELARENA: Right.

MEMBER ADALJA: But this computed performance measure score, is that --- is that what it is, or is it just focused on data element accuracy?

MS. MARINELARENA: So, staff rated it as insufficient, because that was the interpretation that the face validity was focused on getting the element accuracy, availability,

feasibility or other topics, based on the information that I have.

Now, we're asking you, as experts in the field and using this measure, do you believe that the measure, as specified, does, in fact, distinguish good from poor quality based on what we have here and your experience.

If you believe it does, then you could go over and either rate it moderate or low. If you agree with what the staff analysis came up with, then you rate it as insufficient.

MS. MATOSKY: So, before we go to voting, my understanding, and please correct me if I'm wrong, is that the committee does not need to vote on validity. Is that accurate? I thought you had said earlier, because this is a maintenance measure, this does not --- the committee does not need to vote on validity.

DR. BURSTIN: There's no new testing. That's why.

MS. MARINELARENA: Right.

DR. BURSTIN: Yes.

MS. MUNTHALI: So, Melissa, what you may want to do is ask the committee, do you accept the prior evaluation of this measure on validity? If not, then you go ahead and vote. If you do, then you accept, you know, what was done previously.

MS. MARINELARENA: So, it passed before. And if you accept that, like Elisa said, usually what we do is say --- we'll have somebody say, okay, if somebody wants to vote, then we take a vote. If nobody wants to vote ---

MS. SKIPPER: Alright. So, does anybody in the room want to re-vote on validity? I'm seeing nos.

Does anyone on the phone want to vote on validity?

MEMBER HART: No.

MS. MARINELARENA: Okay. So, we will not re-vote on validity. If we take the previous vote, we had previously passed on validity.

CO-CHAIR THOMPSON: Great. So, our next element, feasibility.

MEMBER LANE: Alright. So, with regards to feasibility, all data elements for this measure were generated during routine provision of care in defined fields in electronic health records. Although, you know, which records or systems were not indicated. And, you know, data is easily accessible in EMRs.

Any other comments, Piero or Laura?

CO-CHAIR THOMPSON: Any other questions or comments on feasibility?

(No audible response.)

CO-CHAIR THOMPSON: Alright. Can we move to vote?

MR. MENENDEZ: Okay. For Measure 2082, feasibility, the options are 1 high, 2 moderate, 3 low and 4 insufficient.

(Voting.)

MEMBER HART: Jeff Hart votes high.

MEMBER LEWIS: And I've lost my --- this is Jeff Lewis. I've lost my connection, web connection. So, I'm going to vote over the phone for now, and I would vote high as well.

MS. SKIPPER: Pranavi, if you're on the line, if you'd like to submit a vote for feasibility 2082; 1 high, 2 moderate, 3 low, 4 insufficient.

(Pause.)

MR. MENENDEZ: Okay. Voting is now closed. 14 for high, one for moderate, zero for low, zero for insufficient. 93 percent for high, so the final vote is high. Passed.

CO-CHAIR THOMPSON: And our final element, usability and use.

MEMBER LANE: Aright. So, the measure is currently publicly reported and is used by accountability programs, as we previously discussed, including MIPS, PQRS.

The use of the measure has shown improvement in viral load suppression during the time, and there have been no potential harms identified during implementation of this measure.

CO-CHAIR THOMPSON: Any comments on usability?

(No audible response.)

CO-CHAIR THOMPSON: Any comments from the phone?

(No audible response.)

CO-CHAIR THOMPSON: Alright. We can move to vote.

MR. MENENDEZ: Okay. Voting on usability for measure 2082 is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

(Voting.)

MEMBER LEWIS: This is Jeff Lewis again. I'm still working on my computer, but I'm going to vote over the phone as high, 1.

MEMBER HART: The other Jeff, Jeff Hart, 1.

(Pause.)

MR. MENENDEZ: Okay. Voting is now closed. The final count was 15 for high, zero for moderate, zero for low, zero for insufficient. A hundred percent pass for usability for Measure 2082.

CO-CHAIR THOMPSON: And now we will do

our overall vote for endorsement.

MR. MENENDEZ: So, vote 1 for yes, and 2 for no, for overall suitability for endorsement.

(Voting.)

MEMBER HART: Jess Hart, yes, 1.

MEMBER SREERAMOJU: Pranavi Sreeramoju, 1, yes.

MEMBER LEWIS: Jeff Lewis, 1 as well.

MEMBER SREERAMOJU: Hi, this is Pranavi Sreeramoju. My vote is a yes as well. I'm not --- I can't hear the audio on the webinar.

CO-CHAIR THOMPSON: That's okay. We got you. Thank you.

MEMBER SREERAMOJU: Okay. Great. Thanks.

(Pause.)

MR. MENENDEZ: Alright. So, we have a hundred percent pass for overall suitability for endorsement.

CO-CHAIR THOMPSON: So, we'll take a

break at this point, correct, for how long?

MS. MARINELARENA: How about ten minutes? A real quick ten-minute bathroom break. When we come back, our colleague Jason Goldwater will go over the eMeasures and then we'll review the accompanying eMeasure to this one. It should go a lot faster because it's basically the same thing. We're just going to review some of the synthetic testing.

So, five after 11:00 we'll come back. So, those of you on the phone, five after 11:00 Eastern Time.

(Whereupon, the above-entitled matter went off the record at 10:56 a.m. and resumed at 11:11 a.m.)

CO-CHAIR THOMPSON: So I think we're going to go ahead and try and come back together. Okay, so I think we're going to begin, and we're going to turn it over to Jason to do us a walk-through of the eMeasure overviews.

DR. BURSTIN: Jason, are you with us?

OPERATOR: Jason has not joined on the

phone lines yet.

DR. BURSTIN: Okay, I could -- just to keep us moving, I'll just do it, if you could pull them up, that's fine. I want to just flip ahead I think to like slide, just keep going, kind of want to -- skip, skip, skip.

We're just going to go to the highlights here. Skip, skip, very pretty, skip, skip. You guys don't need an orientation to why HIT is important, etc. Stop.

Okay, so we just want to briefly give you a little bit of a context for how you're looking at one measure that's the existing legacy measure, as we call them, measures that have already been around for a while, in use in the federal programs, now becoming an eMeasure.

We have different standards for those today, it's going to change in the future, than we do for new, de novo, as we would call them, eMeasures generated to start with for an EHR.

So I want to run through a couple of the key sort of techie elements of what we call

and what ONC and CMS call an eCQM, an electronic clinical quality measure. And they require these different elements, so I'll walk through them each. Next.

I cannot see them, can anybody else? Okay, I can see it on my screen. All right, so, essentially what this says is -- it's probably way too little to see. Let me just pull it up on my screen so I can at least. Right, yup, yeah.

So basically what this is is it's just a way of describing what's called the clinical, the quality data model, the QDM. It's just a way to kind of think about the parts of a measure, the clinical concepts within a measure, in a standardized format.

So, for example, some things you can't see there is, you know, a QDM element would be something like active diagnosis HIV, active diagnosis asthma. So that it's described in the same way in each measure. It's kind of building blocks of measures.

You could also look at things like is

-- the question you raised earlier, what's an office visit, what's a medical visit, would also be, for example, a standardized element within the quality data model. Next slide.

The other big part of this is something called the -- these are all approved standards. This is the health quality measure format, which is the thing on the left, which is a standard way in XML, so lots of coding words there, to document both the content and the structure of a measure. That's the input, the actual data that comes from the EHR in a standardized format.

The output is called the QRDA, which is the Quality Reporting Document Architecture. And that's just a way of standardizing what comes out at the other end in terms of reporting the quality measure.

Again, as we move to eMeasures, we just want to make sure that as we're moving to something we hope is more standardized, we're actually getting some standardization out of the

deal. So this essentially allows us to do that. Next slide.

And this, for example, is a list of what's called the value sets. The other building block of an eMeasure that we hope helps with both standardization, as well as harmonization across measures, is the ability to identify using a code set system, let's, for example, it's listed here as SNOMED CT, a way of always describing the same group of patients in the same way.

So this is listed out here, this is specifically around birth outcomes. But, for example, there is a value set that is for a live birth, so that it is always what's the codes, what's the standard within the architecture of an EHR that you can always describe a live birth or HIV in the same way.

One of the complicating factors is, on the next slide, the reality is that, and I didn't, I like the Stephen Colbert graphic there. It's not -- it's still pretty difficult to do, particularly when you're starting from scratch.

These are a little easier since they're re-specified from an existing measure, or re-specified, as I mentioned, from a legacy measure.

But we also have another option of a brand new measure can also come to us which may not yet be tested as an eMeasure, but we'll bring it in just to get it out to market quickly, so people can use it as an eMeasure for trial use, meaning they will pass all criteria but they haven't yet been tested.

In this instance, the measures you're going to see today, just to keep it simple for today's discussion, are what we call legacy measures, existing measures, already endorsed on paper, you just re-approved it moments ago.

And the question's going to be, as you look at the eMeasure format, is it meeting some of these key standard elements that we would require as part of a legacy eMeasure. Next slide. No more pretty pictures, okay.

So how do we evaluate them? Some of

these you've already gone through. There's not going to be an expectation that the eMeasure version of the HIV measure you just looked at is going to have a different evidence base.

Reliability, it's still well designed, specification's consistent. Essentially, these are all the criteria we would already use to look at a measure. That would really be if it was a de novo measure. Next slide.

Particularly for an eCQM, we do require that it be tested, particularly if it's a new eMeasure, tested in more than one electronic health record. And part of the idea is for any of us who practice clinically, you've seen one EHR, you've seen one EHR.

The expectation that they're going to work across more than one platform is difficult. I mean, even within the same vendor applications sometimes, you know, one epic installation, for example, could still be wildly different than another one.

So we do require at least more than

one EHR. Again, for new measures, we do want to require that if there are value sets associated with this, for example, patients who have HIV would be a, hopefully, a coded set that everybody would be plug and play into their measures.

The National Library of Medicine maintains something called the Value Set Authority Center, where they maintain the lists of all these value sets.

The next frontier that hasn't yet happened, and we did some work with the Office of the National Coordinator last year on this, is how do we begin harmonizing them. There could, for example, be ten different value sets for HIV, and that's ongoing work that's going to have to happen in the future.

We do require that the eCQM is formatted with that measure format I mentioned earlier, the HQMF. And we want to, as much as possible, see there's some alignment between the existing measure and the new measure. Next please.

So Bonnie is, interestingly, it is actually not an acronym, it's just a word, I'm told. It is a tool developed by the MITRE Corporation, who I believe helped as part of this effort with HRSA to respecify these measures. And it allows you to take the eCQM and test and verify the measure logic.

I often think about it as basically if you put the measure in a simulation test, it works perfectly in this idealized environment. It's not necessarily saying it's going to work in these two EHRs. But in this idealized environment, you can in fact get the data you need to calculate the measure.

So you want to be able to make sure there are no defects in the way the eMeasure's been structured. And ultimately it helps you then convert the measure into the appropriate electronic data specification that allows you to calculate the measure directly from the measure logic. Please.

MEMBER BRADY: I just noticed an

inadvertent disclosure. I have a family member who works for the MITRE Corporation but is not involved in this project. That's not an issue.

DR. BURSTIN: Okay, don't think so. That should be fine, but thank you for letting us know.

Now, it was a brand new eMeasure, which is not the case for today, Bonnie testing would not be sufficient. We would require the full assessment of testing in more than one EHR.

In this instance, because it is a legacy measure, for now at least, and this is probably the last round, by the way, for our friends at HRSA and others, that we'll allow legacy measures. In the future, we will require that they in fact go through the same full testing as any other eMeasures. Next slide.

So this just gives you an example of an evolution, for example, of a blood pressure measure, what the eMeasure looks like. Next, don't think we need this, goes through it, for example, just a couple of elements of this.

So, for example, in this blood pressure measure, the data elements correspond to what's in the quality data model. So you get, for example, things are characterized in the right kind of way around, the way birthdate should be characterized, the way diagnosis should be done. So, for example, let's take this in the HIV context.

You'd want to make sure that it's an active diagnosis of HIV that's part of an active value set. Next, please.

The numerator obviously, next, to be important. We want to look for numerator, we're going to look for denominator. Next slide, please.

And exclusions if there are any, and it didn't sound like there were very many before in this instance. Next slide.

How a quality measure is calculated. That looks very complicated. I'm sure Jason had a good joke associated with this. I don't know what it is, we're just going to move on. Next.

And this is the HQMF, which I mentioned is the input. This is essentially taking the measure logic, putting it in XML format to go in to the system, and then what comes out the other end. Next slide, please.

And then on to the QRDA. Again, nothing you need to look at specifically, and Jason says thank you.

So, you know, in summary, very briefly, for today's exercise, the measures you will look at are legacy measures, they are already existing measures endorsed by NQF, in use in the federal programs.

The only requirement we would have is you want to see that there is still precision of the specifications for an eMeasure, and we want to see that the body testing demonstrates that the measure logic plays out in an idealized sort of simulation environment. It does need to be in the HQMF format, unless there's an exception to it. I don't remember if there's an exception in this instance.

And otherwise, I think these will be relatively straightforward. Hopefully, we'll get some new eMeasures for you guys to look at in the future, and we'll have a slightly different discussion.

Any questions? All right, and I'm sure the HRSA folks or MITRE will help you as we walk through this as well. Okay, thanks.

CO-CHAIR THOMPSON: Great, thank you. So I believe HRSA has already gone over the explanation of this measure. Yup. So I think at this time, we'll go ahead and pass it to our lead discussants, to begin with the evidence.

MEMBER GARZARO: So this is more or less a mirror of the previous one. So the evidence was, if I understand correctly, the evidence is the same that was presented before. There's no performance data available. And we're going to the gaps. But the evidence is the one that was presented before.

We go into the gap, there's no performance data available from eCQM, but the

developer did provide the nationwide data from 2014, from the CDC that estimated that although 86% of people living with HIV have been diagnosed, only 30% have achieved viral suppression. And we can see the data there in the tables.

But it would be the same kind of gaps that we saw before. Any questions with that?

MS. MARINELARENA: So because this is, the evidence is the same, and because it's a legacy measure, there is no gap performance on the eMeasure. As a committee, you can choose, we'll carry the votes over from the chart-based measure for evidence and for gap.

So everybody agrees to carry the votes over from the chart-based measure. On the phone, does anybody disagree? I hear no disagreement. Jamie, would you like to say something? Okay, okay, great.

See, we'll get this moving faster. So then we can move on to reliability, and we can start talking with these specifications, because

we do have to vote on reliability and validity.

MEMBER GARZARO: So for specifications, the data source was electronic medical record, because this is an eMeasure. The numerator were the number of patients and the denominator with an HIV viral load less than 200, and at least one viral load during the measurement year.

And the denominator, the same as before, includes the number of patient regardless of age with the diagnosis of HIV and at least one medical visit in the measurement year.

As far as reliability testing, 34 synthetic patients were created using the Bonnie testing, and to evaluate the logic. And the result, the testing results for the Bonnie tool reached 100% coverage and confirmed that there was a test case where it's pathway logic.

The measure had a 100% passing rate. We've confirmed that all the test cases performed as expected.

CO-CHAIR THOMPSON: Any questions or

comments about reliability?

MS. MARINELARENA: Does anybody have any questions for MITRE about the Bonnie testing or the method?

MEMBER GARZARO: Right now, all, according to the health care law, all, this data should be available to everybody in the electronic medical record. All physicians should have an electronic medical record. So it should be able to be extracted from any clinic, right?

CO-CHAIR THOMPSON: There are definitely, at least I know within the Ryan White System, there are clinics that still operate on paper charts, yeah. However woeful that may be.

MEMBER RONEY: A lot of small, rural Texas frontier hospitals that do not have EHR.

MS. MARINELARENA: In the Bonnie testing, just as a reminder, what Helen said, the Bonnie testing shows, demonstrates that the measure logic worked. So the way they constructed the measure electronically, that works.

So they actually did a very good job of coming up with their, with the synthetic patients, and they simulated their Ryan White patients. So they're very, they have different races and genders and age to be able to test the measure, and came up with different situations to be able to calculate this measure.

What you would see in real life, but they did it with the synthetic patients, and showed that the measure logic as constructed does work. So that's what Bonnie testing does.

CO-CHAIR THOMPSON: So any other questions? Any questions from the phone? Questions or comments? No? Should we go ahead and move to voting on this element, correct?

MR. MENENDEZ: For measure 3210, reliability, voting is now open. Vote one for moderate, two for low, three for insufficient. Moderate is the highest possible option.

(Voting.)

MEMBER HART: Jeff Hart votes for moderate, number two. Is that correct? Number

one, whatever it was.

MR. MENENDEZ: Yeah, one is moderate, two is low, three is insufficient.

MEMBER HART: One.

MEMBER LEWIS: I thought you said two was moderate, the highest.

MR. MENENDEZ: Right, for this one, one is the highest, due to it only having patient level data elements associated with it.

MEMBER LEWIS: Oh, okay. So I'm going to change my vote online.

CO-CHAIR EISENBERG: Okay, so does everyone have that straight, the highest you can vote? One is moderate, two is low, three is insufficient.

MS. SKIPPER: And to the individual who stated that they were changing their vote, will you say your name again?

MEMBER LEWIS: I'm sorry, this is Jeff Lewis. I'm online as well, so I just changed it online to one instead of -- thank you.

MR. MENENDEZ: The final tally is 15

for moderate, one for low, zero for insufficient, 94% pass.

CO-CHAIR THOMPSON: And now on to validity. Do we have anything from our lead discussants around validity?

MEMBER GARZARO: For validity, I would mention that this measure is not used for pay for performance or penalties, missing data. All the synthetic patients with missing data perform accordingly to the HQMF standard, and as expected. So nothing else to add.

CO-CHAIR THOMPSON: Any other comments or questions? All right, we can move to voting.

MR. MENENDEZ: Voting for 3210, validity, is now open. One for moderate, two for low, three for insufficient. Again, moderate -- oh, I'm sorry.

(Voting.)

MEMBER GOLDMANN: Can somebody, this to me is -- the Bonnie testing environment with 34 synthetic, can somebody just explain that? It sounds great, I know MITRE's a great company, but

to me, I'm voting on something that basically I have no idea what it is.

MS. MATOSKY: I'm going to ask Rute from our team to discuss this. Rute.

MS. MARTINS: Yes, sure, can everyone hear me?

MS. MATOSKY: Yes.

MS. MARTINS: All right, so my name is Rute Martins, and I am with the MITRE Corporation, and we've been working with HRSA on these electronic clinical quality measures.

And so the way the Bonnie tool works is you can create your own patient. So you actually enter the data scenarios on whether a patient has a HIV diagnosis, age, race, and other demographics, as well as potentially a sequence of encounters, lab test results, all of that information.

And you create this set of patients, and you import the XML specifications for the measure. So essentially the measure is imported automatically and run against the data that you

enter manually in the tool.

And it gives you a result. So it tells you whether that patient fell in the numerator, denominator, etc. And so the way the testing actually works, so, one is the measure can be used and automatically consumed, right, and run against patient data. So that's one piece.

The other piece is we actually define expectations for how we think that patient with that clinical scenario, where they should fall in the measure population. So we tag a particular patient as a numerator patient if they had a viral load that is 200 or more anytime during the measurement period.

And so the second output of the Bonnie tool is really that report that tells you whether the actual result of calculating the measure against the patient data that you put in matches what your expectation was.

And the expectation could be that the patient wasn't included in the denominator

population at all, or was in the numerator population. So you can generate as many scenarios as you'd like.

And then what we did is we created this group of patients where we're testing each one of the individual lines of logic. So, for instance, if we're looking for a patient that is within a particular age range, we would test for a patient that is within that age range, and then we would also test some edges, right.

So if the threshold is 18, we would test for a patient that's 17 and a patient who's 19, and that sort of thing.

We also test for patients who have missing data or that don't meet a particular timing for an encounter. So for instance, for this measure, a patient could have two encounters, but they happened two years ago instead of the year of measurement.

And so that patient would not qualify for the denominator for the measure. So we actually create these comprehensive scenarios

where we're making sure that we're testing each individual logic line and making sure that we're hitting 100% coverage with that.

And then also we create positive test cases to test positively, obviously, against those criteria, and negative test cases, such as those with timings that are out of range, etc., and some additional ones with missing data. So that's how you get to that number of patients.

And I believe for this measure, we actually came to 64 patients, if I'm not mistaken. But that's essentially how Bonnie works. No, it's 34 for this measure, I apologize. Any questions on the process or how we actually did the testing?

There was nothing unexpected for this measure in terms of the scenarios that we had, so all of our expected behavior for classifying the patients in the measure for the synthetic patients matched how the measure actually calculated.

CO-CHAIR THOMPSON: Thank you. So

just to make sure I'm understanding this correct, I'll use my little clinical teach-back tool. So essentially you're looking at if people code visits in ten different ways, you want to make sure that this picks up on all those ten ways a person could code a visit?

MS. MARTINS: It's more focused on the actual calculation of the measure, rather than the mapping of the data.

CO-CHAIR THOMPSON: Okay, okay.

MS. MARTINS: So, yeah, yeah.

CO-CHAIR THOMPSON: Excellent, thanks.

MS. MARTINS: But it's all about the algorithm of the calculation.

CO-CHAIR THOMPSON: Any other questions around validity? Okay.

MR. MENENDEZ: Please resume voting again for measure 3210, validity. The highest possible score is moderate. Vote one for moderate, two for low, three for insufficient.

(Voting.)

MEMBER HART: This is Jeff Hart,

number two for moderate, please.

CO-CHAIR EISENBERG: Jeff, sorry, one is moderate, two is low, three is insufficient.

MEMBER HART: Sorry. Number one, moderate. I'm high.

(Laughter.)

MR. MENENDEZ: Voting is now closed. Total count is 16 for moderate, 100% pass, zero for low, zero for insufficient.

CO-CHAIR THOMPSON: Now move on to feasibility.

MEMBER GARZARO: Okay, so here it gets a bit complicated for me. So they've illustrated that a feasibility assessment conducted by consents of the panel of metric clinical informatics measure development and eCQM experts.

And on a scale from one to three, three being the highest score, all the data element received a score of three except the encounter performed, face-to-face interaction, and two, the patient characteristic payer.

For the encounter performed face-to-

face interaction data element, the developer stated that the Health IT Standards Committee recommends SNOMED CT as a standard terminology for encounters. However, SNOMED CT isn't currently widely used for this purpose. The eQCM allows for capture of encountered SNOMED CT as well as CPT, a more widely used terminology.

Overall, the measure is currently 98.89 feasible and 99.44 feasible in one to two years, according to the score card.

See we had questions there for -- they said that it's very feasible, but they have problems with the encounter performed, face-to-face interaction. I think that goes to what I was asking before, about the type of encounter that the patient made -- had.

And then the patient characteristic payer, that one I simply didn't understand very well what they were meaning by that. It seems to me, and overall I think it's very feasible to do. It should be easily accessible to the electronic medical record if the insurer or the clinic has

an EMR. If they don't, that is going to be definitely harder to obtain electronically. But I think that shows that it is very feasible to do.

CO-CHAIR EISENBERG: I have a question.

MS. MARTINS: This is Rute Martins.

MS. MATOSKY: Go ahead, Rute.

MS. MARTINS: I was just going to speak to the two data elements that were rated as not a three. So the reason why we rated the face-to-face interaction data element at a lower rate, it is because that specific value set is defined in SNOMED, whereas all the other encounter value sets that are used in the measure are defined in CPT.

And we know that SNOMED is not widely adopted yet, especially to denote and represent encounters. And we don't think that in the next one to two years, that's going to change immensely, so that's why that's a two.

But the measure does provide for all,

I think one, two, three, four, five, six -- there's another six value sets that represent medical visits, and those are in CPT. And so we would expect those would be available. So it's just one of the options that we're providing in the measure that we don't think is very feasible now, but that's definitely where health IT seems to be going.

And finally, the patient characteristic payer is actually not used in the measure logic itself. It's a supplemental data element that is usually required to be submitted for all the measures that are part of federal programs. So it's kind of, there's a group of demographic data elements that are included.

And right now, there's a standard developed by the Public Health Data Standards Consortium for a taxonomy, for payer data. And that is increasingly being adopted, and in fact, the 2015 edition Health IT Certification Criteria, which is issued by ONC basically to certify EHR systems, does require the use of the

source payment topology standard defined by this Public Health Data Consortium.

So we think that in the next couple of years, we're going to see an uptick in the use of this standard to represent payer. So I just wanted to provide that background there.

CO-CHAIR EISENBERG: And could you explain, please, where the numbers come from and why you expect it to improve from 98.89 to 99.44 percent?

MS. MARTINS: Sure. So this is a standardized score card that is provided by NQF and that is required to be submitted with every measure. And our feasibility assessment and the way it was filled out was by a group of MITRE team experts.

And so we had three clinical informaticists, and three eCQM standards experts and one measure development expert who weighed in on the rating. So it's basically the MITRE experts' consensus on where these elements fall.

Now, they are ratings, so we have to

decide whether, for instance, in the data availability category, a score of three means that the data element exists in a structured format in an EHR. And a one means that the data element is not available, and two does not exist for this particular criterion.

For data accuracy, we're rating for whether the information could come from the most authoritative data source and the likelihood of it being correct.

And then for data standards, we're really talking about which, how the elements are coded. So is it coded in nationally accepted terminology or not. And for workloads essentially, if the data can be obtained as a routine part of care.

And in addition to the ratings that we included, just based on the team consensus, we did go back and looked at meaningful use, stage one and stage two data, as it related to the data elements for these measures. So, for instance, for laboratory test results, and this is the

latest data available for stage two meaningful use provider, about 54,000 providers reported in 2014.

And about 90% of those providers, 91% of those providers reported on the ability to capture lab test results in a structured fashion. And about 93% reported that they were actually able to do that 80% of the time or more.

CO-CHAIR EISENBERG: Very good, thank you. I think that's good, thank you. Kathleen.

MEMBER BRADY: Yeah, I just wanted to reiterate that the measure is currently nearly 99% feasible. And that's based on the CPT coding.

And with the addition of these SNOMED codes in some places over the next few years where the current rating was two will only increase the feasibility to 99.44%, correct?

MS. MATOSKY: Are you there, Rute?

MS. MARTINS: Yes, yes. So the reason why it doesn't get to 100% is because for the SNOMED code, we didn't actually change the rating

for the future. We don't think that the extended use of SNOMED will be significant enough to say that that data element is going to be routinely coded in SNOMED.

So that encounters are going to be routinely coded in SNOMED, but we can fall back to the CPT.

MEMBER BRADY: Yeah, no, I understand. I just, I don't think 100% feasibility is probably ever a reality. So I think 99.44% is very high, obviously.

CO-CHAIR THOMPSON: Any other questions about feasibility? Okay, we can move to the vote.

MR. MENENDEZ: Vote one for high, two for moderate, three for low, four for insufficient.

(Voting.)

MEMBER HART: This is Jeff Hart. Two for moderate.

MR. MENENDEZ: Okay, voting is now closed. The final tally is twelve for high, four

for moderate, zero for low, and zero for insufficient. Seventy-five percent for high, pass. Again, 3210 feasibility.

CO-CHAIR THOMPSON: And the last section on usability.

MEMBER GARZARO: For usability, mentioned that it's currently not in an accountability program. However, it was reviewed by NQF MAP for consideration of CMS merit-based incentive payment in the future.

Unexpected findings, there were not any unexpected findings, and the MAP recommended support of this eCQM for rulemaking, with the condition that it completes successful testing and the NQF Behavioral Health Standing Committee reviews the performance data to ensure a gap in care continues to exist.

So one of the things that I see here, it's currently not being used for accountability program, but it's planned to be used in an accountability program. And I think that ties in to what we were talking before, the use in the

clinics rather than at provider-level accountability. Is that correct?

MS. MATOSKY: So the intent is that it would be used at a facility or clinic level at this point, yes.

MEMBER GARZARO: So the final usability and use is a moderate for this measure, rather than high, as in the paper version.

CO-CHAIR THOMPSON: Any questions or comments on usability? Okay, we can move to the vote.

MR. MENENDEZ: For 3210, usability and use, voting is now open. Vote one for high, two for moderate, three for low, four for insufficient.

(Voting.)

MEMBER HART: Jeff, hi, two for moderate.

MR. MENENDEZ: Voting is now closed. The final tally is eight for high, eight for moderate, zero for low, zero for insufficient. So again, 50% for high and 50% for moderate, with

a final vote of pass.

And so now do we move on to the overall vote? And now for the overall vote of this measure, for overall suitability for endorsement, vote one for yes and two for no.

(Voting.)

MEMBER HART: Jeff Hart, yes.

MR. MENENDEZ: Voting is now closed. One hundred percent pass for 3210.

MS. SKIPPER: And I just want to note for the record, one committee member changed their vote to moderate. It doesn't change the overall, the measure still passed on usability. I just wanted to note it for the record, seven votes high, nine votes moderate.

CO-CHAIR THOMPSON: And I will pass it off to Woody.

CO-CHAIR EISENBERG: And we'd like to just move along now. The next two measures, one of which is simply a maintenance of endorsement measure, and the next one will be the new electronic version of that measure, will be first

presented by Marlene, and then we'll have some discussion.

And Marlene, since the developer rationale is much the same for these measures as for the previous one, if you could just emphasize the things that are unique about this measure. It's 179.

MS. MATOSKY: All right, so this measure is the medical visit frequency --

CO-CHAIR EISENBERG: For those of you on the phone, this is measure 2079. Okay, thank you, Marlene.

MS. MATOSKY: No problem. So this is the medical visit frequency measure. This measure concept is focused on retention in medical care. It's a little different than many retention measures you may think about, and many other measures in general, because this is aiming to look at longer-term retention.

The denominator is clients who had at least one visit in the first six months of a 24-month measurement period. So to emphasize, the

measurement period overall for this measure is two years or 24 months.

The numerator is clients who had a visit in the subsequent, each of the six month periods within that 24-month period. So clients had to have a total of at least four visits, one in each six month period over 24 months. Once folks generally wrap their head around this measure, they find it's pretty easy to use.

And why we've, you know, looked more towards a longer retention measure or a longer-term retention measure is that data indicates that a degree of clients, a fairly high degree of clients, engage in medical care early on, and then they fall out, and then they become unvirally suppressed. And that could lead to more HIV transmissions.

CDC data that came out a few years ago, I think it came out in 2015 actually, reported that nine out of ten HIV infections are related to people who are not in HIV care, whether they know that they are positive or not.

So for that reason, in addition to others which I'll talk about, we've really focused on a longer-term retention measure.

Another point I wanted to bring up about this measure is that, and I think it goes back to something that Adam had brought up earlier about models of care, in HIV care and treatment, we see a significant portion of patients getting both their HIV as well as their routine primary and preventative care at one care location by one provider.

So, for instance, somebody's HIV may be well managed, but they have other co-morbidities, and we do know that people living with HIV, one, are pre-disposed to other co-morbidities, as well as it's an aging population. So just because of age, they're seeing other co-morbidities as well.

One other item I wanted to bring up about this measure, and it relates to the subsequent measures as well, we like to think about having more than one measure in HIV care

and treatment, because for some organizations, as you've seen by our data, achieving the outcome of viral suppression might not be the first goal that they could adequately achieve with their patient population. So we need to include other measures as well that lead into viral suppression, such as the retention.

I'm going to pause there and ask Dr. Laura Cheever if she has anything else she would like to add about this measure.

DR. CHEEVER: No, I think you actually captured it well. I think this does get back to earlier conversations we've had about cherry-picking clients and clients not coming back. By measuring over two years, we are able to capture some of that type of behavior of people that had started care and then simply fall out.

MEMBER LEWIS: Hi, this is Jeff Lewis, I have a question as it relates to that data in terms of patients who get their care at one place, and those who get their care at a primary care and then see an infectious disease

specialist. Was that looked at as well, or like separately, in terms of viral load suppression?

MS. MATOSKY: That's a really interesting question. So the data that we presented in this submission did not stratify clients in terms of the model of care they were receiving.

In fact, when we look at our data in the Ryan White Program, we don't capture whether a client is seeing one individual, one provider for both their HIV and their routine primary care, or just seeing one provider for primary care, another provider for their HIV care.

We do have a project that's going on now that's going to look at some of these factors, but we don't have that project in data collection at this point.

DR. CHEEVER: I'll add the fact that we are doing that more comprehensive special evaluation because it is so hard to actually know that. Many people are in a system where they need to have a primary care provider that does

referrals. In fact, they never see that person.

And so it's really actually hard to distinguish even in the medical chart how that care's being delivered, which is why we're doing the special study.

CO-CHAIR EISENBERG: Okay, thank you for that. Does anybody else have questions for the measure developer before I hand it over to our discussants? If not, Nanette and Kathleen, please take it away.

MEMBER BRADY: I think Nanette was going to start on this one, is that correct?

CO-CHAIR EISENBERG: Nanette, are you on the phone? If so, we can't hear you.

MEMBER BENBOW: I am, can you hear me?

CO-CHAIR EISENBERG: We hear you know, thank you.

MEMBER BENBOW: Okay, great. So, yes, Kathleen and I were the discussants. I'm taking the lead. So this is a process measure, and we're looking at a maintenance of endorsement. So I'll start with evidence, and since it is a

maintenance measure, there's less emphasis on evidence.

The developer provided updated evidence for this measure. They provided a diagram outlining the sequential steps of medical care.

CO-CHAIR EISENBERG: Yeah, we're getting a little feedback, but Nanette, we can hear you just fine. Please continue.

MS. MARINELARENA: For those of you that are not speaking, can you please put yourself on mute.

MEMBER BENBOW: Hi, sorry, can you hear me now?

CO-CHAIR EISENBERG: We do.

MEMBER BENBOW: Okay, I'm trying to get rid of the feedback. So, let's see, okay.

MS. SKIPPER: If you are listening online, you need to also mute your computer. And that'll eliminate the feedback.

MEMBER BENBOW: Yeah, I think when I muted my computer you couldn't hear me. Let me

try it again. Can you hear me?

MS. SKIPPER: Yes.

MEMBER BENBOW: Oh, perfect, okay. Sorry about that. So there was updated information provided by the developer. They looked at the evidence that supports this measure and states the systematic monitoring of retention in care, which may include surveillance of visit adherence, gaps in care, and the number of visits during a specified time period.

That was based on a panel from Anti-Retroviral Guidelines. And also from the IAPAC guideline for Optimizing Care Continuum. Another recommendation that they identified was the systematic monitoring of retention in care that is recommended for people living with HIV. And that had a level of 82, so strong and a high quality of evidence.

Let's see, what else? Just kind of addressing some of the questions.

Based on the algorithm, the committee agrees that retention in care is a major

predictor of viral suppression, and that there is, we agree that it is acceptable to hold providers accountable for medical frequency visits, based on DHHS guidelines on HIV care and treatment, and that there is evidence of systematic assessment of expert opinion beyond those involved in developing the measure. Again, based on guidelines from review panel recommendations.

I think that's it, I'm trying to keep it short. Kathleen, is there anything you'd like to add?

MEMBER BRADY: Nope.

CO-CHAIR EISENBERG: I have a question.

MEMBER BENBOW: Okay.

CO-CHAIR EISENBERG: Either, probably, Marlene, for you. Is there evidence to suggest that the six-month blocks are meaningful in some way? And then, within that question, the minimum of 60 days between medical visits, where does that come from?

MS. MATOSKY: Sorry, I was just taking some notes here. So I'm going to take a bite at that first question and then I'm going to pass that off to Dr. Cheever.

So as outlined in the Department of Health and Human Services guidelines, it outlines how frequently a patient should be getting different labs performed and visits, depending on their length of diagnosis, as well as their achievement of viral suppression, sustained viral suppression.

And we chose sort of a middle of the road based on what the guidelines are suggesting in terms of how frequently people should be seen. You know, for instance, if a client has their prescription changed, they should be followed up shortly thereafter. You know, less than a month, about six weeks.

And then if folks are sustained, have a sustained viral suppression for two years or more, they can be seen at least twice a year. So we've sort of kind of split the difference on

this across all the cases.

CO-CHAIR EISENBERG: The reason I ask is because, as you said, you were taking a middle of the road sort of path here, and we did receive comments from the public that there were some, in some cases, there were some patients that were stable enough that they might be seen less frequently and that that could be considered perfectly reasonable care.

MS. MATOSKY: Exactly. One other thing I would want to mention about the number of visits, and I had mentioned this, I made reference to this when we were on the phone about two weeks ago.

So we did some very preliminary analysis or data to look at visit frequency, and we're only looking within a year because we're not able to link our data at this point across years. We're on the verge of doing that. And it turns out that 37% of our clients are getting five or more visits a year.

So it's actually a relatively small

proportion of people living with HIV in the Ryan White Program who are getting very few visits in a year. And it turns out that about 12% of patients are only getting one visit. And 18% or so are getting two visits in a year.

Additionally, and this would kind of be a comment that I would make in that, in the gap measure as well, in this preliminary analysis, we did see a rather sizable bump in viral suppression between clients who'd had one visit in a year and clients who had two visits in a year.

Clients who had one visit in a year experienced viral suppression at a rate of 73.7%, and we saw a 7.3% point increase for folks who had two visits in a year, at 81%.

Finally, your question about how we came up with the 60 days between visits. This went back to when we were doing our face validity and really kind of workshopping this measure with our panel of experts, and we wanted to capture a time so that a client who'd had a visit on

January 1 and January 2, per se, wouldn't be counted in the measure.

We wanted some time between the visits, and based on experience from the providers that participated in that panel, we settled on 60 days between visits. I know Adam --

DR. CHEEVER: Yeah, and that -- sorry.

MS. MATOSKY: No, Doctor, I was going to turn it over to you, Dr. Cheever.

DR. CHEEVER: Okay, yeah, so I think, and part of that initial consultation around scheduling visits, there was a pattern that many of the providers had seen where a patient would be acutely ill in the hospital and be discharged and be seen several times as they got better.

And as soon as they got well enough that they didn't need sort of semi-urgent medical care, they stopped coming in. So we were really trying to make sure we weren't having that counted as, you know, sufficient visits in the year. And that's why we put the 60-day gap.

CO-CHAIR EISENBERG: Very good, thank you. Adam.

CO-CHAIR THOMPSON: Yes, I just have a question. Are you able to distinguish, when making the correlation between two visits and a bump in suppression? Can you distinguish, because I know you said you can't look at people over time, whether that bump is artificial in the sense that you're looking at individuals who may have become newly engaged in care?

So their two visits are going to be more meaningful in that measurement year than an individual who's been sustained in care over time. And I think, I mean, I'm a huge fan of retention, absolutely. And the last time we did this measure, as I'm sure you remember, I presented it in full faith.

And I think the concern I have is that over time, people have gotten better, right, as a result of this care. And as we look particularly at costs, I think especially when we're discretionary funding, I get very, you know,

hyper about whether or not we're requiring not only a patient's additional co-pays, but also the system time that it takes for individuals to be seen and the follow-up that it takes.

I know in the clinics I'm seeing, people are just willing to take a hit on the measure. And we don't expect 100% performance. But I see a lot of evidence around, like poor retention in the first year, right, newly diagnosed. Or poor retention in individuals that are non-suppressed.

And I just wonder, as you've seen your viral suppression jump almost 20% in some cases, is that going to affect whether or not this measure of, you know, two years over one, two visits in each six months, which you rightly say is the middle of the road, because it's one if you're thoroughly suppressed, four if you're unsuppressed, I believe. Can you pull those apart?

MS. MATOSKY: Did you want to respond first, Dr. Cheever?

DR. CHEEVER: Yeah, so I think that -- so I completely agree with what you're saying, and it's one of those things that in terms of trying to make a measure that's going to work well and be robust and measure for most patients, and the variability of the types of people we see, I think you're completely, that's completely true, everything you said.

I think it's been our experience, and I think that our data shows it, that still most people with HIV have numerous issues around access and barriers to care, that more frequent visits mean that they are able to better connect with a comprehensive system to make sure that those multiple barriers are being addressed throughout the year.

So I think that's part of the reason why we did see that increase. Our number of new patients is relatively modest, so I don't think that that could account for the increase we've seen, and I think it really has to do more with keeping people engaged over time when they've got

multiple competing life priorities.

CO-CHAIR THOMPSON: Thank you. Kathleen.

MS. MATOSKY: Can I just make one additional comment before we go to Dr. Brady? One other piece and, again, this is very preliminary analysis, but to your point, Adam, if somebody was new back in 2010 versus 2015, we still saw that increase in viral suppression between one visit and two visits.

MEMBER BRADY: So I feel a little schizophrenic or bipolar about this measure. You know, we look at retention all the time. I think it is incredibly important, you know. I mean, based on the guidelines, I'm wondering whether it should be more about frequency of viral load testing.

But, you know, with that said, I will actually tell you some data that we have. I presented some of this on the call. And that is, we did an analysis of individuals in Philadelphia of all people who were living with HIV in

Philadelphia between 2010 and 2015.

So to be entered into our cohort, folks basically had to have had care in 2010. And we looked at retention in care actually over a five-year period using this measure that people had to have care in each six-month period, with 60 days in between the visits, and looked at annual retention as well as durable viral suppression -- I'm sorry, annual viral suppression.

So last viral load less than 200, and then durable, all viral loads being suppressed during that time period. And individuals who met the annual retention measure were four times as likely to achieve annual viral suppression, and nearly three times as likely to achieve durable viral suppression over that five-year time period.

So I think that's an even longer time period, and this is including everyone who was alive in Philadelphia. So I think the data actually supports that we really should be

measuring retention, because it is associated with improved long-term outcomes.

CO-CHAIR EISENBERG: Good. Thank you. Are there other comments or questions about the evidence?

MEMBER GARZARO: Yeah, I agree with Kathleen. I mean, at what point we're putting so much weight on medical visits rather -- if the patient needs getting his labs, or his or her labs, every three months, but they don't go see the doctor every three or six months because they simply don't have anything to say. They're taking their medications. They're feeling fine. I tell my patients, oh, you want to see my pretty face every three months, by all means, come. But you will have to pay a co-pay.

And they say, why am I going to pay a co-pay just for you tell me everything is okay? And they know it's okay because they can see their labs in the computer.

So, I would put the weight more on testing rather than the patient having seen their

provider. Because I've had patients that have been infected for 20 years. They know their pills. They take their pills. They come see me maybe every two years, right before they go to Hawaii and make me jealous. But they get their labs every three months and without fail and they're there and they're fine, undetectable, T-cell count in the 800, 900.

So what am I going to do with a medical visit for that type of established patient?

CO-CHAIR EISENBERG: Are there any questions from people on the phone?

MR. MENENDEZ: I have --

CO-CHAIR EISENBERG: Oh, I'm sorry. Well, you know, it's always -- as long as I ask. Any questions on the phone? If not --

MEMBER LEWIS: Yeah, I don't -- this is Jeff Lewis. I'm sorry. I don't have a question. I just had a comment in regards to the cost. When you started talking about having the labs versus the visits, the cost differential,

the visit maybe cheaper and covered, where the labs sometimes aren't. And the cost could be a little bit -- because it's done so frequently, they only cover so many per year.

So, depending on the insurance, the demographic of your patient population, things of that nature, cost could be a factor in the frequency of visits.

CO-CHAIR EISENBERG: Amesh?

MEMBER ADALJA: This is already in existence? This is already on the books? And has it always been at six months? Or has it ever -- because I think there was guidance and change from three month visits to six month visits, I guess in the HHS guidelines.

But is there, you know, as you see HIV care become more less intense in terms of the visits because of the durability of suppression with good antiretrovirals, do you anticipate this that the HHS guidelines might say for some of these durably suppressed, maybe they have one -- they have -- just like what he said, have labs

checked and not necessarily physically come in?

And how would that -- you know, how would you account for not penalizing providers who have a patient who is durably suppressed and just knows, you know, is very sophisticated and looks this all up?

And that part of it is hard for me to come up with a full recommendation for it because of that. Those types of patients that exist in everybody's clinic.

MS. MATOSKY: Dr. Cheever, do you want to go first and speak about the guidelines?

DR. CHEEVER: Yes. So, I do hear what you're saying. And I think that's a valid point there in the sense that some patients are able to keep up with their -- keep up with their labs or checking on their labs, or, you know, seeing things online that are coming back.

And so you're right. So, I don't think we, once again, expect 100 percent, that people would have 100 percent in terms of who's achieving this. But I think for a majority of

patients seen, we do know that coming into care will improve their outcomes, as has already been stated. So, that's really the essence behind this.

I don't have much more. I'll turn it over back to you, Marlene.

MS. MATOSKY: Sure. I wanted to make two points. One is that whenever HRSA is developing any performance measures for HIV care and treatment, we have to root them in the HIV guidelines, the Department of Health and Human Services guidelines. Because that's really sort of our launching point, or, you know, the guidelines that exist for HIV care and treatment. So that's the first thing.

The second thing I just wanted to clarify, and I have the guidelines up in front of me. And it says, after two years of antiretroviral therapy, viral load consistently suppressed, CD4 consistently 300 to 500 cells per millimeter cubed. It says, can extend viral -- it can extend for viral load monitoring to every

six months for a patient with consistent R-load for greater than two years.

So the guidelines are still saying that if you have somebody who's virally suppressed for two years or more, they should still be getting a viral load every six months.

And, again, this is really where we have to root our measures in the guidelines at this point.

MEMBER ADALJA: Great. So that's saying viral load measurement, not a physical visit.

MS. MATOSKY: Mm-hmm.

MEMBER ADALJA: So I think those are two different things. And one doesn't necessarily have to go with the other.

MS. MATOSKY: And then --

MEMBER BRADY: But --

MS. MATOSKY: Go ahead.

MEMBER BRADY: But towards that point, the vast majority of people living with HIV in the United States are not virally suppressed

based on that two-year measure. It is the minority that are actually -- meet that.

And from our data, just even when one year only, I mean, it's about 20 percent of people who are virally suppressed don't meet the retention measure. So it's actually a fairly small group of individuals.

MEMBER GARZARO: I think it depends where you practice. I mean, at least in Northern California, Permanente, I would say 95 percent of them are suppressed. Because we make it a goal to be suppressed. But, again, you can consider that a very special population.

MEMBER BRADY: Yeah, I'm talking about people who -- so I'm working in public health. You're looking at it from people who are actually engaged in care.

MEMBER GARZARO: Yeah. Yeah.

MEMBER BRADY: And so I'm looking at it from everybody who is living with HIV in my jurisdiction. And the vast majority of individuals do not meet the retention measure.

And they are not virally suppressed.

MS. MATOSKY: So to kind of dovetail with what both of you are talking about, again, I'd just like to emphasize, when we look at the HIV care continuum -- and that's looking at everybody in this country living with HIV. Regardless of where they're getting care or not getting care, we are definitely seeing rather significant gaps when we're going from diagnosed all the way to viral suppression. So that's the first point.

And then, you know, the other point is that we're here to develop measures that are applicable broadly across all care providers in this country who are serving people living with HIV, those who have a client panel that are achieving high rates of viral suppression and those who are not.

So, you know again, I think I had said this earlier, you know, I think that's one of the elegance of measure development, is creating a measure that has a slightly less specificity so

you can gain that better applicability of the measures, as well as making them simple in their logic.

CO-CHAIR THOMPSON: Yeah, I just want to say what you two just pointed out, I think, for me, is the discussion point around this measure. I think people do find it incredibly useful at a systems level to look at how retention is happening in a city or a jurisdiction.

But I think at the clinical level, I think that's where this measure is very challenged. Not only because of the way the denominator is defined, and how lost-to-care is defined in most clinics. Like, when they're no longer a patient going out after a year versus two years, as well as the evidence lining up for retention for newly diagnosed or newly engaged. Right?

I mean, I think there's some questions here about it. And I think even though there are small numbers of individuals who are suppressed,

I don't think that we should have to bear an additional cost burden so that the measure falls in the middle.

And we have a comment from Rocco on line.

MEMBER ORLANDO: Yeah, this is Rocco Orlando. So, my comment is, I think this discussion is really focusing on the difference between, is this a public health measure or is this a quality measure?

And so I think clearly a measure can support both objectives. But I think we're seeing that divide here, you know, that based upon different practices and different patient populations, this maybe a better population health, public health measure, but perhaps not a quality measure applicable to all practice settings.

CO-CHAIR EISENBERG: Thank you. Are there other comments, either from the room or from people on the phone? Yes?

MEMBER RONEY: I'd like to thank Rocco

for that comment. I feel very schizophrenic as well over this, because the evidence is clear that six months works. But then I hear the other arguments that also make sense.

And so it just seems like the evidence that came out of Philadelphia, and that it's a practice guideline, that we are questioning stuff that's already been vetted through evidence and, I guess, experts. So, I'm not an HIV expert. But I feel very much torn on your discussion, both directions.

MS. MARINELARENA: This is Melissa. So, let me drive it back to NQF criteria and the requirements for NQF. Okay?

So, for a process measure, we ask that the measure focus, which is medical visit frequencies, that the evidence provided shows that there is a direct -- that there's a relationship between the measure focus and an outcome. In this case, the outcome is viral load suppression. Right? So that's what we're looking for.

Now, it's great that we have that evidence, but that's not what was presented here. If there's additional evidence that you can provide to us, we would love to take that in.

What we have in front of us are guidelines. And it's multiple guidelines for HIV care. And they were all the same ones that were submitted for all the different measures.

What we could find -- and Marlene, you can correct us if we were wrong. There was one piece of the guideline that supports measure visit frequency. That part of the guideline is unrated.

So, when we go through our algorithm, which they have pulled up here, we require a systematic review, which is box three.

If you have the systematic review, then we ask for a QQC, which is a quantity, quality, and consistency of the body of the evidence. And that can come from a guideline. We didn't get that. But the one guideline is unrated.

But instead of going through and

rating this as low, we went down to box seven, because we did get empirical evidence. But there was no systematic review and no grading of the evidence. So, that takes us to number four --

CO-CHAIR EISENBERG: And I'm sorry, the empirical evidence that you evaluated showed what?

MS. MARINELARENA: Well, we got a guideline, right? But it's not rated. We don't know anything about it. We don't decide that it is. This is a standing guideline.

So we go to box ten. The important question here is, are there, or could there be, performance measures of a related health outcome or evidence-based intermediate clinical outcome or process?

So that's the question based on -- unless there's a different part of the guideline that we missed that is graded, then we can take you through a different part of the algorithm.

But the question we're posing to you, if there is, we can go through -- if the evidence

isn't sufficient without any grading, no systematic review, no QQC. But as experts you can determine the evidence is sufficient, but we'll pass it with exception.

But we've got to get past box ten first. So the question here is, are there, or could there be, performance measures of a related health outcome or evidence-based intermediate clinical outcome or process. That was viral suppression, which was the measure that we just looked at before.

Unless there is other evidence, and graded evidence, that supports medical visit frequency and ties that to viral suppression. Does that make sense?

CO-CHAIR EISENBERG: Jamie?

MEMBER RONEY: Did we look at the guideline development and the rigor behind it? Because I know there's various degrees of rigor in different guidelines.

MEMBER ADALJA: Isn't it true that the guideline doesn't say visit, though? The

guideline says viral load measurement. It doesn't say visit.

MS. MATOSKY: The guidelines do talk about laboratories and performing -- you know, drawing blood for labs. You know, I don't know if there's been any evidence, and, you know, I'll ask Dr. Cheever if there's been any evidence to say, you know, what proportion of visits -- what kind of -- what proportion of labs are occurring outside of visits. I don't think there's been great correlation of that data or even the undertaking of that assessment.

I think most of us would say -- oh, sorry. Dr. Cheever?

DR. CHEEVER: Yeah, I agree. I don't think we have those data around, you know, what proportion of patients get labs when they're not having a medical visit.

CO-CHAIR EISENBERG: Don?

MEMBER GOLDMANN: Yeah, I don't know where my intrinsic bias comes in here. But, in general, measures of frequency of visit are the

earliest thing you do. If we can't see them, we can't treat them. And, you know, especially in pediatrics, because there aren't many dissent measures.

We always default, well, did you get your adolescent medicine checkup? Did you have your well-child visit? And none of that is based on really solid evidence. It's just there because it seems reasonable that people should be seen.

So, the question I have is, in current PEPFAR work, in working around the world, is a measure like this felt to be important or credible? Or is it just, are they or are they not on drugs? And are they or are they not suppressed? Because the bottom line, that's all I really care about. I don't care if they do it with a cell phone and electronic bottle caps. It doesn't matter to me.

CO-CHAIR EISENBERG: Okay.

DR. CHEEVER: Yes, so --

CO-CHAIR EISENBERG: Oh, I'm sorry, do

you want to respond? Please, go ahead.

DR. CHEEVER: Yeah, this is Laura Cheever. So, in PEPFAR in general, their rates of lost to follow-up are incredibly high.

So, I don't know that they've looked specifically at whether someone just had a laboratory done or, you know, whether they actually came in for a medical visit. Because their overall rates of lost to follow-up are pretty high in almost every country.

CO-CHAIR EISENBERG: Very good. Pranavi, did you have a comment?

MEMBER SREERAMOJU: Yes. I just wanted to add that it's a very interesting discussion. As an ID physician, the visit frequency is definitely related to the outcome, which is viral suppression and other clinical outcomes for the patient.

But the measured visit frequency is less under the control of the individual physician or the provider, and more controlled by the health system and the ability to address

socioeconomic factors.

For example, if the patient doesn't show up, does the health system have a way to reach the patient and maybe give Uber vouchers to make them show up? Things like that.

So, that's the reservation. But I think the measure, as is, is a good measure. The ability to control is something else.

CO-CHAIR EISENBERG: Very good. Thank you. Are there other comments or questions about evidence?

(No audible response.)

CO-CHAIR EISENBERG: If not, Mauricio, I think we're ready to move on.

MS. MARINELARENA: If the committee wants to go with the past in -- you know, you voted on this before and it passed on evidence. You can agree not to pass. If there's one person who wants to vote, then we'll go with that.

So, how about if we start with the negative. Is there anybody who does not agree with just moving on?

CO-CHAIR EISENBERG: Yeah, I don't. I'd like the committee to vote.

MS. MARINELARENA: Okay.

CO-CHAIR EISENBERG: I've heard enough discussion that I think we ought to think it through again.

MS. MARINELARENA: Well, there is an option for -- if it were to be voted insufficient because we don't have grading of evidence, that's how we get to a moderate or a high, you want the option to vote it insufficient with exception. Then it --

CO-CHAIR EISENBERG: What does that mean, with exception?

MS. MARINELARENA: With the exception that you say, okay, there is no empiric evidence. There probably won't be. But, as experts, we think that this is important. And it should be passed. Does that make sense?

DR. BURSTIN: Yes. So maybe to give an example. So, for example, in the palliative care committee, there is a measure that was put

forward using this evidence exception that spiritual counseling should be provided to patients at end of life.

You're not going to gather new evidence to demonstrate that spiritual counseling should or should not be provided. It just clinically makes sense.

And specifically, the thought is that that would logically -- the expert opinion of those of you in the room is that the benefit there would certain exceed any potential downsides of using that measure.

So, again, in this instance I guess one question for the group collected here and on the phone is, will there be evidence at any point on the benefit of an office visit? Or is some of that simply expected as part of care?

So, again, just something for you to consider.

MEMBER LEWIS: This is Jeff Lewis again. I think there will be. And I think we should vote on it.

CO-CHAIR EISENBERG: Okay. So, we will. So, Mauricio, please.

MS. MARINELARENA: So the process is, you would vote it insufficient if you want to pass it that way. It has to go past -- you have to vote insufficient. And then we vote to pass it with exception.

MR. MENENDEZ: Okay. Voting for Measure 2079. Evidence is now open. Vote 1 for moderate, 2 for low, 3 for insufficient. Moderate is the highest possible rating.

(Voting.)

MS. SKIPPER: Just waiting for a vote from Jeffrey Hart, if you're there.

CO-CHAIR EISENBERG: Jeffrey Hart, are you still with us?

MEMBER HART: Yes. Sorry. I'm here.

CO-CHAIR EISENBERG: Are you voting?

MEMBER HART: This conversation got me a little lost. But --

CO-CHAIR EISENBERG: Okay. Well, what we -- the committee decided that they did want to

vote on evidence even though some thought it was not necessary.

And we're voting now that the evidence to support this is moderate, it's low, or it's insufficient. Now, if you vote for insufficient that means we go on to further examine evidence to move forward. If you vote for moderate or low, then --

MEMBER HART: I would say low at this point. Thank you.

(Pause.)

MR. MENENDEZ: Okay. The final count is 23 percent for moderate, 44 percent for low, 44 percent for insufficient.

MS. MUNTHALI: So, a low vote means that the measure fails and we would stop voting here. If you did vote insufficient, you'd have the option, as we've been saying, to evoke the exception, insufficient with exception.

So, right now we're discussing how to go forward, because it is a split vote. Essentially, consensus is not reached. But it's

not reached between what would pass it as a moderate, but also low -- in between low and insufficient.

So we just want to make sure that you understood what your low vote would be. And if there is a motion to maybe revote if you were unclear.

MS. MATOSKY: To clarify. If it's rated -- if the preponderance of the votes are either low or insufficient, does this mean that this measure is dead in the water and we would not proceed to discuss this measure further? As well as we would not discuss the ECQM for this measure?

MS. MUNTHALI: So, if more than 60 percent of votes were low, the measure would be dead. We would not continue voting.

If 60 -- I mean, more than 60 percent were insufficient, there is the option to continue. You would recognize that there may not be evidence that's been presented in this submission. But, as we talked, there may be

evidence we can evoke the exception to that.

DR. BURSTIN: And since this was insufficient plus a couple of people who voted moderate. So, that's the question. It wouldn't have to be 60 percent insufficient. It just would have to not be 60 percent low.

MS. MUNTHALI: Right.

DR. BURSTIN: So, we're still sort of gray zone at this point. Right?

MS. MUNTHALI: We're very gray zoned.

CO-CHAIR EISENBERG: Does anyone have any other questions on the voting?

MEMBER HART: This is Jeff Hart. I can't revote, but I would be -- I would be willing to move from low too insufficient. I think the measure has merit. And I think there's enough evidence to support or -- I can't say that if I'm saying it's insufficient.

Yeah, I'll move it to insufficient I don't know if that makes a difference. But, yes.

MS. MUNTHALI: It may. So what we're going to do is just revote. So, again, low, more

than 60 percent low, the measure fails. And that's it.

Oh, your microphone.

MEMBER GOLDMANN: Yeah. You know, by stating it that way, you kind of force us, it's such a heavy pressure not to say low. I mean, that's how it feels.

MS. MUNTHALI: Yeah, not to force you.

MEMBER GOLDMANN: Because if I do this, I'm screwing things.

(Simultaneous speaking.)

MEMBER GOLDMANN: Tell me again, what is insufficient mean exactly? Which is worse? To have low evidence or insufficient?

MS. MUNTHALI: Low is worse.

DR. BURSTIN: Low is worse. So low means that the rated evidence would suggest that, for example, this process is not evidence-based. Right?

MEMBER GOLDMANN: Right.

DR. BURSTIN: Insufficient means, we can't say it's low, but we also can't say it's

moderate or high. There just isn't sufficient evidence, in this case, on what's the evidence for HIV visit frequency on outcomes.

MEMBER GOLDMANN: Okay.

MS. MUNTHALI: Right. And not to pressure you.

DR. BURSTIN: And we're not pressuring you. I think particularly with --

MEMBER GOLDMANN: No, I just got this feeling like --

(Simultaneous speaking.)

DR. BURSTIN: No, no, no. People should vote however they want.

MS. MUNTHALI: People confuse, they conflate the two often. And so we want to make sure that you're clear, that there's a clear distinction between the two choices.

DR. BURSTIN: Especially with so many people being on the phone. It's just a weird environment.

MEMBER BENBOW: This is Nanette. Can I ask a question? What do we do with the fact

that because it's a maintenance measure there's supposed to be less emphasis on evidence? So, if there is less evidence, then how could we kind of kill this measure?

MS. MARINELARENA: Well, because a measure has been endorsed before that does not mean that it's automatically re-endorsed. And because there was sufficient conversation around the table today, there was a motion for there to be a vote on evidence.

MEMBER BENBOW: I see. Okay.

MS. MARINELARENA: And our criteria has not changed over the year but -- over the years, but it is a little more, we've tightened it a little bit. So we give a little more guidance and we try to be a little clearer. It sounds a little funny after the conversation we just had. So we're trying to be a little clearer today then we were in 2012. So sometimes the votes maybe a little difference because of that. Or because the science has changed or not.

MEMBER BENBOW: And then just one

other question. With insufficient, does one then say -- would there -- so, if the majority were to fall under insufficient, would we then vote whether it's with exception or no exception?

MS. MARINELARENA: That's correct.

MEMBER BENBOW: Okay. Okay. And with exception it would mean that there's enough empirical evidence from all of our experiences that this is a measure that is worthwhile continuing?

MS. MARINELARENA: Yes. So with exception we would ask -- if it's insufficient then we ask, does the standing committee agree that it is okay or beneficial to hold providers accountable for performance in the absence of empirical evidence of benefits to patients?

So the most extreme question would be, like Helen had said, you know, there will probably never be RCTs for patients with medical frequency visits and those that have not had them. Right? And then see what the outcome is.

So the questions is, is it appropriate

to hold providers accountable for that without that kind of evidence? Which may never happen.

MEMBER GARZARO: So, insufficient means we're entering evidence-free zone.

DR. BURSTIN: It's a place where expert -- I want to qualify that ever so slightly. It's where expert opinion is taking the place of not having a clear empiric evidence base on which to base the decision. And you're the experts.

MEMBER GOLDMANN: No, I get it. Actually hand hygiene is insufficient evidence. This is a question, you've probably already dealt with this, but it seems important to me in just thinking about this globally.

So, if I'm a primary care physician or an HIV doc and my patient wants to communicate with me totally by cell phone as needed, is that -- those encounters are lost to this. Right? So I could be giving superb every other day care and that would not get counted.

MS. MATOSKY: So, we do include the

options for tele-visits, whether that be using, you know, phones, or any other more advanced tele-help methods.

MEMBER GOLDMANN: Okay. And there's a mechanism to record that?

MS. MATOSKY: Yes.

MEMBER GOLDMANN: Because it's not paid for, right?

MS. MATOSKY: Because we don't -- as we had stated before, when we're looking at the chart-abstracted or the paper-based measures, the definition of a medical visit is a visit with a provider with prescribing privileges.

And we don't add on any additional criteria to say it has to be face-to-face or it has to be a billable visit. I mean, because we have a number of patients who are uninsured. And so, you know, what is a billable visit?

MEMBER GOLDMANN: That's very helpful. Thank you.

CO-CHAIR THOMPSON: Yes. And just to clarify, alternative visits like that are a

requirement in most of the new recognition programs. So that's a completely acceptable way to provide care now.

MEMBER LEWIS: I have a question. This is Jeff Lewis on the phone. How is that communication charted if they -- if they talk to you via the phone or email, like that? How do you get that in the medical records in terms of that it happened?

MEMBER GARZARO: I mean, I can explain. We have telephone appointments and they're entered into the medical record as a telephone appointment or as a video visit. So, it does get into the medical record or clinical documentation. So, we do enter it.

MEMBER LEWIS: But it's not billable? Or is it?

MEMBER GARZARO: Well, we don't bill it. It's an HMO so we don't bill directly. I'm not sure how other people do it.

CO-CHAIR EISENBERG: Keep in mind that billing is not part of this measure. It's

visits.

MEMBER LEWIS: I understand that. I was just curious of how it was charted in the grand scheme of things. Sorry.

CO-CHAIR EISENBERG: Are there other comments or questions about the evidence at this point?

MEMBER ORLANDO: This is Rocco with a comment. It really has to do with the data collection. And my concern about the measure has been that one doesn't want the force of this kind of measure to constrain innovations in care.

This really has to do with tele-health. And sadly, the billing and the documentation are related. Again, I think I'm comforted that there are ways to document electronically without generating a bill, which is a very troubled area right now.

But, again, our electronic health records are structured so that those are commingled. But I think, in a world where you can create an electronic document that the client

hasn't touched, that's what's important here.

CO-CHAIR EISENBERG: Yeah. Keep in mind everyone, this is a paper measure. We'll be dealing with the electronic measure, maybe, soon. Okay? So, good comments. But it may not relate directly to this measure.

MEMBER BRADY: Right. So it means there has to be some sort of a note. Whether it's electronic or whether it's on a piece of paper. But that's what you'd be looking for. Evidence in whether that visit happened face-to-face or over the phone does not matter.

CO-CHAIR EISENBERG: So, Melissa, now what's our next step?

MS. MARINELARENA: How about we revote for evidence? Remember, low is bad, insufficient is not bad. And so we'll revote for medical visit frequency on evidence. Number 1 moderate, number 2 low, number 3 insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

MR. MENENDEZ: So the revote totals

are 13 percent for moderate, 6 percent for low, 81 percent for insufficient. The final verdict is insufficient.

We'll move onto whether or not it's with exception or not.

CO-CHAIR EISENBERG: Very good. Okay. So how do we do that?

MS. MARINELARENA: Well, there's another slide.

CO-CHAIR EISENBERG: Alright.

MR. MENENDEZ: Okay. Now, for 2079, vote 1 for insufficient evidence with exception or 2 with no exception.

CO-CHAIR EISENBERG: And Mauricio, could you define for us what it means to rate as insufficient evidence with exception? What will then happen?

MS. MUNTHALI: We would go forward and continue with performance gap. If you go no exception, we stop and it dies.

MR. MENENDEZ: Okay. So, voting for evidence, vote for 1 for insufficient evidence

with exception, or 2 for no exception.

MEMBER HART: Sorry. Could you repeat that?

MR. MENENDEZ: Vote 1 for insufficient evidence with exception, or 2 with no exception.

(Voting.)

MEMBER HART: This is Jeff. One, please.

MR. MENENDEZ: Jeff Hart?

CO-CHAIR EISENBERG: Jeff Hart or Jeff Lewis?

MEMBER HART: Jeff Hart.

(Pause.)

MR. MENENDEZ: The final count is 88 percent for insufficient evidence with exception, 13 percent no exception.

CO-CHAIR EISENBERG: Okay. Thank you. So at this point we're going to move on with our evaluation of the measure.

And Nanette or Kathleen, if you could now take us through the next section.

MEMBER BENBOW: Hi. It's Nanette.

I'll continue. Hopefully I'll really try to speed it up.

So, gap in care, the developer presented data from the HIV Research Network, which is a consortium of community and academic HIV providers that are representative -- there are 11 sites total. They represent four major geographic divisions and insurance status and coverage types typical of the population in care.

They present data for a number of different years. 2011 and '13 were not presented due to resource constraints. But of the data presented, the mean performance was nearly 67 percent for 2007 to 2008. And that increased to nearly 73 percent in 2014 to 2015.

So, the measure does indeed allow and assess improvement over time. And for any given time period you can also observe variation across sites. So it is also helpful in distinguishing where different clinics and providers might be.

If we look at disparities, we observe improvement in some of these and not in other

categories. For 2014 and 2015 we're able to distinguish disparities in this measure across race, ethnicity, gender and age.

So, it is adequate in being able to assess where people are now. And that there is indeed room for improvement.

CO-CHAIR EISENBERG: Does anybody have any --

MEMBER BENBOW: Kathleen, anything you'd like to add?

CO-CHAIR EISENBERG: Kathleen, do you have your mic on? Thank you.

MEMBER BRADY: I did not have my mic on. I apologize.

The only other thing that I wanted to really add was that the disparities that are actually seen in terms of race and ethnicity are actually also very similar to what we see in terms of viral suppression, for the most part. Except for those under the age of 18 where there's often lower rates of viral suppression. But definitely in terms of race and ethnicity.

CO-CHAIR EISENBERG: Great. Thank you. Does anyone have any questions or comments for Nanette and Kathleen or the developer regarding gaps in care and opportunity for improvement?

(No audible response.)

CO-CHAIR EISENBERG: No? Hearing none, let's proceed.

MR. MENENDEZ: For Measure 2079 performance gap, voting is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

(Voting.)

MEMBER SREERAMOJU: Hi, this is Pranavi. I vote two, moderate.

MR. MENENDEZ: Say that again, please Pranavi.

MEMBER SREERAMOJU: Two, moderate. Did you get that?

CO-CHAIR EISENBERG: We got that. Thank you.

MEMBER SREERAMOJU: Thank you.

MEMBER HART: Jeff Hart, I vote 2 for moderate as well.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: The final count is 81 percent high, 19 percent moderate, zero percent low, zero percent insufficient. The final vote is passed.

CO-CHAIR EISENBERG: Very good. Thank you. So, we will be proceeding with the rest of the areas for voting for this measure. But we're at a point now where we need to take a break. And two things, before we grab some lunch, we need to have time for public comment.

So, at this point, Christy, do we direct now our operators, please?

MS. SKIPPER: Yes. Operator, could you please open our lines to hear if there are any public comments?

OPERATOR: Yes, ma'am. If you would like to make a public comment, press star-1 on your telephone keypad.

(No audible response.)

OPERATOR: And currently no public comments.

CO-CHAIR EISENBERG: Okay. Thank you. So, in that case, we are going to take a little break here just to pick up our lunch.

So, for those of you who are on the phone, it's now ten minutes to 1:00 almost. We're planning to pick up our lunch and come back and start talking again at 1 o'clock.

So, we're hoping that you all will be able to join us to continue the session in ten minutes. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:52 p.m. and resumed at 1:03 p.m.)

MS. MARINELARENA: Okay. Hi, this is Melissa. To those of you on the phone, I hope you had enough time to grab your lunch. While everybody here has their mouth full, I'm going to go ahead and speak for Woody. A verbal order from Woody.

We are going to continue voting on the

measure that we were on. Which is, for the record, 2079. We were on reliability. We're going to finish discussing this measure, voting on this measure. Then we're going to continue on the accompanying eMeasure.

Then we're going to move on to sepsis. We're going to finish the discussion on the additional two HIV measures on post-meeting call next week, on the 24th, I believe. The 23rd. I'm sorry.

And in the meantime, Eileen is also going to get us some additional data to support that process, the measure process and the outcomes.

So, we'll have some more information for you so that we have something in addition to the guidelines that they provided for us. So that we don't do this, you know, going around and around. So, she's going to get us some stronger evidence for that.

So, who was leading the discussion on reliability?

CO-CHAIR EISENBERG: Kathleen and Nanette are going to kick us off again. No lunch, Kathleen, sorry. Okay, Nanette, please, take it upwards.

MEMBER BENBOW: Okay. Can you hear me?

CO-CHAIR EISENBERG: We hear you. And we're on the reliability. Go for it.

MEMBER BENBOW: Okay. Reliability. Quickly, specifications of the measure. The measure is specified at the facility level and the clinician office clinic. I won't go through the definitions of numerator and denominator. I think we've covered that.

Since this is a maintenance measure, in previous review of this measure, the developer conducted signal-to-noise testing to assess reliability. Testing was not updated.

Summary of testing, the reliability testing level, it was a measured score. And reliability testing performed with a data source and level of analysis indicated for this measure.

The dataset included to review the section was, again, the HIV Research Network data that I described earlier of 11 different sites with over 17,000 patients and were representative of geography and other indicators representing people in care.

Results show a median reliability of .97. As discussed, 1 is good, is the highest possible. So, high median reliability.

Based on guidance from the reliability algorithm, the preliminary rating for reliability is high.

CO-CHAIR EISENBERG: Thank you. Are there any comments or questions from the committee members for Nanette, Kathleen, or our measure developer?

(No audible response.)

CO-CHAIR EISENBERG: Anyone on the phone have a comment?

(No audible response.)

CO-CHAIR EISENBERG: If not, Mauricio, would you take us on?

MR. MENENDEZ: So, voting will now begin on Measure 2079, reliability. Option 1 is high, 2 moderate, 3 low, 4 insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR EISENBERG: Okay, Jeff. Thank you.

(Pause.)

MR. MENENDEZ: Can Nanette, Esther, and Laura please cast their votes?

MEMBER AARONSON: Oh, I thought I had. I just did it again.

MS. SKIPPER: Yeah, we got it. Thanks.

MEMBER EVANS: This is Laura. Likewise.

MS. SKIPPER: Thank you. We got it.

(Pause.)

MS. SKIPPER: Emily, are you still on the line?

(No audible response.)

MR. MENENDEZ: Voting is now closed

with the final count at 87 percent high, 13 percent moderate, and zero percent low and zero percent insufficient.

The final vote is high. It passed.

CO-CHAIR EISENBERG: Very good. Thank you. So let's move onto reliability testing.

MEMBER BENBOW: Okay. For validity, validity specifications. The specifications are consistent with the evidence.

Validity testing, the results demonstrate sufficient validity so that conclusions about quality can be made.

I'm looking at the committee pre-evaluation comments. One of the comments says, though guidelines agree, I do not see evidence of the score for this measure as specified as an indicator of quality. Only in terms of method of validity testing for measure score, it was face validity only.

And do the results demonstrate sufficient validity so that conclusions about quality can be made? Again, face validity only.

And it's unclear why the developer has not tested validity for its approval in 2013.

Marlene, I don't know if that's something you can comment on.

MS. MATOSKY: Sure. As I had mentioned last week, or two weeks ago on the panel work group conference call, one, if it had passed last time with face validity, we weren't required to redo validity.

So, rather than devoting resources to working on the validity of the paper measure or the chart-abstracted measure, we decided to put our resources into the development and testing of the ECQMs. Because as you probably have gathered just through today's conversation, doing additional work on measures, you know, more specifically around the testing, it requires a significant amount of resource.

So, we wanted to pivot those resources elsewhere. Thank you.

MEMBER BENBOW: Okay. Thank you. And data presented from 2014 and '15, the mean

performance of HIV medical frequency was 72.6 percent. Which was up from 66.7 in 2007/2008.

And providers in the 75th percentile had medical visit rates between almost 80 percent in the most recent year, compared to the 68 percent for providers in the 25th percentile.

Analyses of data provided indicate that the measure identified meaningful differences by year and by provider.

The guidance from the validity algorithm, preliminary rating for validity was indicated as insufficient, I think primarily due to the fact that it was face validity. But, this was indicated as -- was approved by a panel of experts.

CO-CHAIR EISENBERG: Very good. Thank you. Does anybody have any comments or questions for Nanette or Kathleen?

(No audible response.)

CO-CHAIR EISENBERG: Well, if not, we do not necessarily have to vote on this. But, if any of the Committee members would like to, we

will.

So, anyone in the room that wants to vote on validity? Anyone on the phone who would like us to vote on validity?

(No audible response.)

CO-CHAIR EISENBERG: Hearing nothing, we will then move on. Please, Kathleen?

MEMBER BENBOW: I'll continue. Nanette. In terms of feasibility, the developer states that all data elements are collected, generated, and used as part of routine delivery of care.

And preliminary rating for feasibility was high.

CO-CHAIR EISENBERG: Thank you. Any Committee members with comments or questions?

(No audible response.)

CO-CHAIR EISENBERG: And was this something we need to vote on or not? No? So, again, we don't -- no? So we can continue.

MS. BENBOW: Okay. So, the last --

CO-CHAIR EISENBERG: Oh, I'm sorry.

I'm sorry. Now I'm being -- my mistake, please.

So we do have to vote on feasibility?

MS. MUNTHALI: Yes.

CO-CHAIR EISENBERG: Oh, okay. Fine. Are there any other questions on feasibility before we bring this to a vote?

(No audible response.)

CO-CHAIR EISENBERG: If not, Mauricio?

MR. MENENDEZ: Okay. Voting for 2079, feasibility is now open. One for high, two for moderate, three for low, four for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, high.

CO-CHAIR EISENBERG: Thank you, Jeff.

MR. MENENDEZ: Voting is now closed. The final count is 13 for -- sorry, 93 percent for high, seven percent for moderate, zero for low, zero for insufficient.

The final count is passed.

CO-CHAIR EISENBERG: Very good. Thank you. Let's proceed. Use and usability.

MEMBER BENBOW: Okay. The measure is

currently being used by the Physician Quality Reporting System and Value-Based modifier, the Merit-Based Payment System, and the HRSA Ryan White HIV/AIDs Program.

The developers received feedback during the initial development of the measure. And reports that Ryan White grant recipients have provided positive and supportive feedback.

Ryan White recipients also suggested that the measure elements be aligned across related performance measures.

Do the benefits of the measure outweigh any potential unintended consequences? No potential unintended consequences were identified.

And has the measure been vetted in real-world settings by those being measured or others? And there is local data that supports this.

There were other questions regarding sort of how this was calculated. And whether it was -- if it was presented nationally. And as

Marlene mentioned earlier, they're in the process of calculating this measure across years. And will soon be in their Ryan White Services report data.

CO-CHAIR EISENBERG: Thank you. Any comments or questions?

(No audible response.)

CO-CHAIR EISENBERG: If not, we now vote on use and usability.

MR. MENENDEZ: Measure 2079, voting for use and usability is now open. One for high, two for moderate, three for low, four for insufficient.

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MEMBER HART: Jeff Hart, high.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Hi Laura, could you please cast your vote?

Okay, voting is now closed. The final count is 73 percent high, 27 percent moderate, zero percent low, zero percent insufficient.

The final verdict is passed.

CO-CHAIR EISENBERG: Very good. Thank you. So at this point we're ready for our final vote on whether to recommend this measure for endorsement. Correct? Okay, Mauricio?

MR. MENENDEZ: Okay. Voting is now open. Vote one for yes, overall suitability for endorsement, or two for no.

(Voting.)

MEMBER HART: Jeff Hart, yes.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: The final count is 100 percent yes.

CO-CHAIR EISENBERG: Very good. So this measure continues to move forward for endorsement. Thank you.

And now we're going to consider the electronic version of this same measure, which is 3209. And Marlene, is there -- would you like to fill us in just on the things that are different about the electronic measure, please?

MS. MATOSKY: Rute, are you on the line?

MS. MARTINS: Yes.

MS. MATOSKY: Is there anything that you would add?

MS. MARTINS: No. I think that the measure was designed to be consistent with the chart abstracted measure.

The only elements that I would point out are that in terms of the timing calculations representing a visit every six months, we had a bit of a challenge in making sure that the periods were represented absolutely accurately.

So there was one day in the entire period of two years that maybe a little bit counter-intuitive. So, I think it's the las -- the first day in April that counts as being part of the first semester. So, that's very, very minor.

And then the other elements that I would like to point out is that for the eCQMs, we -- and this is true for all of the, we reused the values that Sarah used for other eCQMs out there.

So, there's a lot of feedback from the

provider community and the vendor community in that measures need to be harmonized in order to reduce the barriers and the effort to implement them.

And so we made sure we were using the value sets that already existed.

CO-CHAIR EISENBERG: Very good. Thank you. Does anybody have any questions for the developers before I had it over to our facilitators here?

(No audible response.)

CO-CHAIR EISENBERG: If not, Kathleen?

MEMBER BRADY: Yes. I'm doing this one. So, actually my first question is, we do not have to do the evidence, correct? Okay. Or the gaps? Okay.

So, we will move directly to validity. Or reliability, excuse me. Okay. All right.

So, the data source for this is it's an eMeasure. So, -- and they did provide the specifications for this eMeasure.

The level of analysis is at the

facility level. The numerator and the denominator are the same for the previous measure. And same exclusions that we saw before.

And basically in terms of the reliability testing that was done, it was at the data element level, a measure score. And reliability testing was performed with the data source and level of analysis indicated for this measure.

Basically, the data set used for testing included 64 synthetic patients created in the Bonnie testing system, simulating the year 2012. They developer tested data elements including name, date of birth, race, ethnicity, gender, pair diagnosis, among others.

And basically they actually provided reliability results from the paper version of the measure. And stated currently, there are no performance data available to test the eCQM.

And so, based upon that, the preliminary algorithm gave it a rating of moderate.

CO-CHAIR EISENBERG: Thank you. Any comments or questions from Committee members?

(No audible response.)

CO-CHAIR EISENBERG: If not, we can move to a vote.

MR. MENENDEZ: Okay. Voting for 3209, reliability, is now open. Moderate is the highest possible score. Vote one for moderate, two for low, three for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Voting is now closed. The final count is 67 percent moderate, 33 percent low, and zero percent insufficient.

The final vote is passed.

CO-CHAIR EISENBERG: Very good. Thank you. Okay, Kathleen, validity, please.

MEMBER BRADY: Sure. Okay. So, for validity testing, once again, the testing level was data element testing against a gold standard. They used the Bonnie testing tool and the 64

synthetic patient records.

We've heard about the Bonnie tool already. The testing results from the Bonnie tool reached 100 percent coverage. And confirmed there was a test case for each pathway of logic, both negative and positive test cases.

And the measure had 100 percent passing rate, which confirmed that all test cases performed as expected. Oops, sorry, I just popped ahead.

In terms of assessment for threats to validity, excuse me, so there's one exclusion. And that is that the patient died during the measurement period.

And the developer reports that the exclusion was tested similarly to other criteria using synthetic patients in Bonnie. And when the exclusion element was present, the patients were correctly excluded from the measure.

And in the absence of the exclusion element cases were not excluded from the measure. So, it performed well. There's no risk

adjustment method.

And in terms of additional results, in 2014 to '15, the mean performance for HIV medical visit frequency was 72.6 percent. Actually it's the same data actually, correct? From -- that was presented with 2079. So we don't have to repeat that.

CO-CHAIR EISENBERG: Thank you. Are there any questions or comments from Committee members? Yes?

CO-CHAIR THOMPSON: Just a question that has to do with, when looking at populations living with HIV again, as we know, the marginalized of the marginalized, when looking at folks who have been incarcerated, how is that going to be handled here?

Will that -- because I know there was a denominator exclusion for that at one point a long time ago. And I was an advocate to get rid of it. Because I think we should be considering individuals who are swinging in and out of jails.

But when you look at over two years,

I think it could be, for some providers, again, who provide services to specific populations that this could be a measure they could get really dinged on for folks who are kind of swinging in and out of incarceration.

MEMBER EVANS: Yes. This is Laura. I think this difficulty is trying to capture that electronically anywhere, or even in a chart. That you are saying this person is incarcerated.

Often you don't know what happened to the person until they come back, you know, a year and a half, or two years later. Just from a practical perspective.

MS. MATOSKY: And this is Marlene. I just want to remind us that this is the eCQM measure. So, any time we're going to put a variable into the eCQM, there has to be a standardized variable that already exists.

And there isn't a standardized variable for incarceration that exists in EHRs.

CO-CHAIR THOMPSON: Okay. Excellent. Thank you for pointing that out.

CO-CHAIR EISENBERG: Other comments or questions?

(No audible response.)

CO-CHAIR EISENBERG: Hearing none, let's move to a vote.

MR. MENENDEZ: For measure 3209, voting is now open for validity. Moderate is the highest possible score. Vote one for moderate, two for low, three for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Voting is now closed. Ninety-three percent moderate, seven percent low, zero percent insufficient.

The final verdict is passed.

CO-CHAIR EISENBERG: Thank you. Kathleen, if you could take us through feasibility, please?

MEMBER BRADY: Sorry. The developer provided information on feasibility testing in the eMeasure, a feasibility scorecard. And so,

this was -- the assessment -- a feasibility assessment was conducted by consensus of a panel of minor clinical informatics measure development in e-CQM standard export -- experts, excuse me.

On a scale from one to three, where three is the highest score, all but three of the data elements received a score of three. Both encounter performed face to face, and patient characteristic care, scored a two on data standards.

And basically that sounds like it's an issue between SNOMED codes, as we saw in the first measure. And basically they indicated that on a scale of zero to 100 percent, the measure is currently 98.21 percent feasible. And in one to two years will be 98.81 percent feasible.

So, very high on that rating scale.

CO-CHAIR EISENBERG: Thank you. Any comments or questions for Kathleen from the Committee members?

(No audible response.)

CO-CHAIR EISENBERG: Hearing none,

let's move on to a vote. Mauricio?

MR. MENENDEZ: Measure 3209, feasibility, voting is now open. Vote one for high, two for moderate, three for low, four for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Voting is now closed. The final tally is 60 percent high, 40 percent moderate, zero percent low, zero percent insufficient.

The final verdict is passed.

CO-CHAIR EISENBERG: Thank you. Kathleen, move us onto use and usability, please.

MEMBER BRADY: Great. So, currently the measure is not publically reported. And is not in use in an accountability program.

But it is planned to be used in an accountability program. Specifically in CMS' Merit-Based Incentive Payment Program, or MIPS.

And the developer reports that the

paper-based version of the measure has -- that has been adopted by CMS. And the developer reported no harms in using the measure.

It's been vetted the same way as the other measures. And has been used in national quality improvement campaigns. And they received feedback from Ryan White grant recipients, and who have provided positive feedback.

CO-CHAIR EISENBERG: Thank you. Any comments or questions for Kathleen?

(No audible response.)

CO-CHAIR EISENBERG: Hearing none, let's move onto a vote, please.

MR. MENENDEZ: Measure 3209, usability and use, voting is now open. Vote one for high, two for moderate, three for low, four for insufficient.

(Voting.)

CO-CHAIR EISENBERG: Jeff Hart, are you voting?

MEMBER HART: Yes, sorry. Moderate.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Voting is now closed. The final count is 44 percent high, 50 percent moderate, zero percent low, six percent insufficient.

The final verdict is passed.

CO-CHAIR EISENBERG: Very good. Thank you. Okay, so at this time we're at a point where we can do the overall -- yes. We're ready to vote to recommend that this measure move forward for endorsement.

So, unless there are any other comments or questions?

(No audible response.)

CO-CHAIR EISENBERG: Hearing none, Mauricio, please move us forward.

MR. MENENDEZ: So, for the overall suitability for endorsement for 3209, vote one for yes, two for no.

(Voting.)

MEMBER HART: Jeff Hart, yes.

CO-CHAIR EISENBERG: Thank you.

MR. MENENDEZ: Voting is now closed.

The final count is 100 percent yes. So the measure moves on for endorsement.

CO-CHAIR EISENBERG: Very good. Thank you. Okay. Now at this point there still are some HIV measures that we must consider.

But we've made a decision not to do that right now. Because we have some other areas that require our full attention.

So Marlene and team, thank you so much for joining us. Your presence on the call has been very helpful in helping this to move forward. And we'll want to engage you again by teleconference at a date to be announced by Melissa. Okay?

So but at this point, I'm going to hand it over to Adam so that we can move into the sepsis measures.

CO-CHAIR THOMPSON: Right. So, our next measure up is 3215, Adult Inpatient Risk Adjusted Sepsis Mortality. The measure's steward is New York State Department of Health, Office of Quality and Patient Safety.

Are they in the room or on the phone?

MS. MARINELARENA: They're on the phone.

CO-CHAIR THOMPSON: On the phone. If you want to go ahead and give us the measure overview.

DR. GESTEN: Hi. This is Foster Gesten from the Office of Quality and Patient Safety. Can folks hear me okay?

CO-CHAIR THOMPSON: Yes, sir.

DR. GESTEN: Great. Well, thanks for the opportunity to be part of the discussion and to submit the measure.

This measure of risk adjusted sepsis mortality for adults was developed as part of an overall initiative in New York State that began a few years ago. That included regulatory requirements for hospitals to develop evidence and form protocols to identify and treat patients with severe sepsis and septic shock, as well as report information to the Department of Health to evaluate the degree to which those protocols were

in use.

And also the outcome of those -- implementations of those protocols, including the data that would enable the department in consultation with clinical experts to develop a risk-adjusted mortality model. All of which to be used both for feedback and quality improvement at the hospital level.

But also eventually for public reporting. Public reporting will be started in this year.

We built the model using both clinical expertise and also made use of the existing model that had been in the literature from the Surviving Sepsis campaign. But made some adaptations and changes based on data that we had available and in a different context for an application of risk adjusted model.

We -- I think all the members or most of the members of the team that helped us in the development of this, both within the New York State Department of Health, and also externally

at Brown and Ohio State, excuse me, are on the phone and able to answer questions.

And they were all instrumental in the development, in the iterations of the model. Including input from our clinical advisory panel, which included clinicians from a number of different hospitals across New York State.

I think I'll stop there and let you move on. And if there are questions, I or other folks on the phone can try to answer them.

CO-CHAIR THOMPSON: Great. Thank you so much. We'll pass it off now to our lead discussants. Who will be taking the lead on this one? I see.

MEMBER RONEY: This is Jamie Roney. Thank you for joining us on this call, and to the rest of the Committee.

They're looking at standardizing the way we measure sepsis mortality in a way that's generalizable across the United States. Some of the questions that came up in our discussion on the phone call was the idea of comparing -- or

differentiating between what kind of healthcare facilities they were in, whether it be teaching hospitals.

But the authors of this kind of really wanted to keep it generalizable. And then further break down and analysis could be done for comparison.

So, it has been used in the State of New York already. And for reporting purposes and standardizing across the United States, I think it would offer some benefit to us as clinicians on how each of our facilities does with sepsis and sepsis mortality.

And I don't know if anybody else from the groups on the call.

CO-CHAIR THOMPSON: Yes. I believe we have Pranavi, who has a comment. And also, I just want to make sure we focus right now beginning on the evidence piece of it.

So that we can kind of keep it driving forward. And I believe we have a comment from Pranavi?

MEMBER SREERAMOJU: Yes. So in addition to what Jamie said, we did have a limited discussion on comparability between organizations.

The measure as it stands, the evidence is strongest for within institution comparison. Risk adjusted sepsis mortality is definitely an important measure that's needed to track the efficacy of interventions to improve sepsis mortality.

So, it's a -- the evidence is strong for -- within organization tracking and trending.

MS. MARINELARENA: Hi. This is Melissa. So, this is an outcome measure. Again, I want to remind you that the criteria for an outcome measure is different from a process measure.

So, for an outcome measure we just ask the measure developer to provide a rationale that links the provider to the outcome measure. Is there something that a provider or a hospital system can do to impact the outcome?

And then the committee decides, yes, they provided a rationale. Or no, they did not provide a rationale.

So it almost seems like for a process measure we require the evidence to be -- we're more stringent. This is just a yes or no, did they provide a rationale.

And we, you know, did a couple of bullet points here summarizing what they have provided.

CO-CHAIR THOMPSON: And I believe we have a comment from Laura on the phone.

MEMBER EVANS: Yes. Hi everyone, this is Laura Evans. Just to echo Melissa's comment then. I think that there is clearly a rationale for how healthcare facilities and healthcare providers can change processes to impact sepsis mortality.

I don't see specific references listed here. But at last time I checked, there's at least 50 publications in the literature of implementation of sepsis bundles and looking at

how that impacts inpatient mortality.

So I think there's a very robust evidence base to suggest that what we do locally can impact sepsis mortality.

CO-CHAIR THOMPSON: Thank you. Any other comments about the rationale presented for evidence?

(No audible response.)

CO-CHAIR THOMPSON: I think we can move to voting. Hold on one second. Don?

MEMBER GOLDMANN: Yes. Not a comment about the rationale. I think there's a strong rationale.

I just take exception to the statement that there are scores of papers in the literature or tens of papers in the literature showing that sepsis bundles reduce mortality. Which I think is not an evidence-based statement.

CO-CHAIR THOMPSON: Thanks. All right. Let's go ahead and with our vote.

MR. MENENDEZ: Okay. For measure 3215, evidence, vote one for yes, two for now.

(Voting.)

MEMBER HART: Jeff Hart, yes.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: The final count is 100 percent yes.

CO-CHAIR THOMPSON: Making the next step: performance gap.

MEMBER RONEY: There's definitely a performance gap in how mortality is measured and reported across the United States. Which again, leads to the need for standardizing mortality reporting.

CO-CHAIR THOMPSON: Any comments or questions?

(No audible response.)

CO-CHAIR THOMPSON: Any comments from the phone?

(No audible response.)

CO-CHAIR THOMPSON: Okay. We can go ahead and move to voting. Don?

MEMBER GOLDMANN: I'm probably going to say these things over -- the same thing over

and over again.

But, while I'm sure there is variability in risk adjusted or even through mortality rates of sepsis across the country, which is real, the current state of coding for the diagnosis of sepsis has been clearly shown to alter the denominator that's included, and the risk adjustment.

So, therefore, I don't know that the variability that's being displayed here is the actual variability. Or it's distorted by coding.

MEMBER RONEY: I'll just add to that. He's absolutely correct. There is a large variability in coding by practitioners out there.

And so, it's very hard to know what our denominators truly are based on coding. But it's the best we have.

MEMBER SREERAMOJU: Yes. I will just comment as well. This is Pranavi.

MEMBER AARONSON: Yes. This is Emily. I would also echo that. Particularly we've run into the issue of sepsis being sort of the final

common pathway for many of our sick patients in hospitals will come in with many different diseases.

So coding becomes a fairly large problem if it's a disease that's only present at the very end of life.

CO-CHAIR THOMPSON: Oh, Kathleen?

MEMBER BRADY: So how can we measure something, or how well we're doing with something if we can't measure it well? Because that will come up under validity and reliability, but.

MEMBER SREERAMOJU: Hello, this is Pranavi. We have to start somewhere. So, and this is the best we have at the moment.

And that's the best I can come up with. We start here and fine tune it as we go. This is by no means a perfect measure overall. Not specific to what we're discussing.

But, at the same time, we don't have anything else to go with. And sepsis is so important. And this intervention has the potential to save lives.

So, we can't wait before we can get a perfect measure. And the way to reach a more perfect measure is to go through this process of iteration. Those are my thoughts.

MEMBER BRADY: Wouldn't it -- well, I may be wrong. But wouldn't the first step be actually developing standards on how to code for sepsis?

MEMBER RONEY: This is Jamie again. We have had definitions for sepsis that were published in 1992. And the first practice guidelines came out in 2002 for Manny Rivers' randomized control trial. And then in 2003 our early goal directed treatment.

But, the best description I've ever heard of sepsis is it's like trying to hug the fog. It's not like we have a test that says you have this.

So it's very difficult. And there's so many variables in the diagnostic process that I don't know how best to describe sepsis to somebody that's not familiar with the diagnostic.

MEMBER BRADY: Well, I'm quite. I'm an infectious disease physician. I'm quite familiar with it.

But, I've seen people, you know, called sepsis and they're sitting on -- in a floor bed with a normal heart rate and a normal blood pressure. So, -- but that's, you know, documented that they're septic in the medical record.

So, and I'm sure that ended up in a billing code, so.

MEMBER BRADY: And right, we understand that.

DR. LEVY: So, this is Mitchell Levy from the New York State Department of Health. Can I add something?

MEMBER BRADY: Absolutely.

CO-CHAIR THOMPSON: Yes. Please do.

DR. LEVY: So, I totally understand the concern about the accuracy of the diagnosis. And as an author on the recent definitions paper and -- that was published in JAMA last year, I

definitely feel partly responsible for the confusion.

But I think we're talking about two different things here. In many ways you could say that this risk adjusted mortality model is the answer to the inadequacies of coding.

In that what this model does, is actually address, if you have a mortality reported, whether it's called sepsis, septic shock, a severe sepsis, how do you compare that mortality with a different institution that may have more or less severe patients with different comorbidities, different other kinds of admitting diagnosis?

And there is to this point, no single sepsis specific risk model that's been developed. And that's why I think this is so important. Especially now with more and more States moving to mandate reporting of sepsis.

This allows almost like a leveling of the playing field. That if you report a patient and you report a mortality, we can now allow

hospitals to compare each other's mortality regardless of how they code it in many ways.

MEMBER SREERAMOJU: This is Pranavi. I have two comments to add. One is, I believe there is a separate group that's developing a definition for sepsis mortality that there's not depend on coding. And that's something we all need to watch out for, look out for.

And the second comment is, the coder rule book, I believe it's pretty clear. I'm not a coder, but I've worked with coders quite a bit. So, their rule book is clear.

But, what goes through the coding is also there are these clinical opportunities and documentation opportunities. So no two providers will call the same thing sepsis.

And similarly, some providers have a tendency to over-document sepsis, whereas some don't. So, that contributes to the coding problem as well.

That's what makes this imperfect. But that's what we have right now.

CO-CHAIR THOMPSON: I believe we also have a comment from Rocco on the phone.

MEMBER ORLANDO: Yes. Rocco Orlando. The -- I think that this really highlights what really is an inter-rater reliability challenge.

And having said that, I think that having this measure really will enhance institutions across the country to begin grappling with coding and inter-rater reliability. It is a chicken and an egg problem.

And in a perfect world we would define all of the definitions up front. The world isn't perfect. And I think this really is a way to advance the ball.

MEMBER GARZARO: I had a comment. I mean, this is going to become a, again, pay for performance. But if you have a crappy measure, how can you interpret it in a pay for performance when you know it's really not good.

And you're going to say, well that's the best we have. I mean, like Kathleen was saying, I've diagnosed patients after 48 hours

with sepsis in the hospital.

That the first thing that he tells me that I feel like I have a dog sitting in my chest. The patient was having an acute MI. Or a patient that is sitting in the chair in the floor and like, oh, you're septic. No, he's not septic.

And then we say our mortality so has increased so much simply because we have increased the denominator of healthy -- more or less healthy patients that we coded as septic. And oh my God, they're not dying. Well, they're not going to die no matter what.

So, seeing this measure and knowing what it's going to be used for, that's what scares me. That it's really not -- and we are admitting that well, this is the best we can.

I don't think we should allow that to happen, say that is the best we can. But yes, it's going to be pay for performance and there's going to be money attached to this.

CO-CHAIR THOMPSON: So I -- just a

question to NQF about this. Much like the other measure when we had started talking about its applicability and the performance programs, are we to include that in our discussion?

Or are we to consider it regardless of that later use?

DR. BURSTIN: Yes. We've got to disconnect it from that in this instance. It's not clear how this measure, this particular measure in particular will be used.

At this point it's a New York State measure that they're bringing to us for their consideration. And again, I don't know if the developer wanted to add anything specifically about what, if anything they've, you know, learned.

And this really will come up, I think, under validity. I want to hold the comments on this specifically around the definitions. Because I know they've done a fair amount of validation work on this.

CO-CHAIR THOMPSON: I believe we also

have a comment from Laura Evans on the phone.

MEMBER EVANS: Yes, hi. I was going to, I think, sort of say some of the same things around a question for the developer.

But maybe it's best served in the validity about how specifically patients are included in the data base. Or how sites, you know, was it all coding. Or were they also using, you know, clinical definitions, you know, the 2001 consensus conference definitions and so forth to include patients in this data base?

But, I also just wanted to maybe try to get us refocused a little bit on the -- I think we're in the performance gap section still.

And I do think that the data that's presented by the New York State Department of Health here does illustrate a significant decrease -- a significant variation in mortality by -- particularly by age group. Also somewhat by race and ethnicity, and by payer status.

So I do think, at least in the New York State cohort that there is evidence of

variability of performance. And I would say that there is a performance gap here.

CO-CHAIR THOMPSON: Don?

MEMBER GOLDMANN: So, just a question. Because this is going to come up on the other measure as well. About the coding issue.

I'm really happy about anything that standardizes or encourages people to code properly. But in the case of sepsis, the evidence seems very clear that much of, at least some of the increase in survival is attributable to coding.

I think that Clompus and others clearly showed that. I didn't see that cited in the literature. I probably missed it. Felt strongly enough to write a New England Journal perspective on it, cautioning the use of a measure that's subject to up-coding.

So, that's the observation. The question would be, in New York State, and again, I wasn't the primary reviewer on this, I may have missed it. But, was there an audit performed, a

random audit of these hospitals to see the extent to which coding was accurate?

MS. MARINELARENA: Hi, this is Melissa. So that's under validity. It did do some data element validity --

MEMBER GOLDMANN: Okay. We can wait for that.

MS. MARINELARENA: And some inter-rater reliability that they can talk about if we can talk about gap right now.

If there's any more discussion, I would vote on what is in front of us. This is what they used. It was a years' worth of data based on this measure.

And if you determine that on their test data that there is a gap, we'll vote on that.

MEMBER GOLDMANN: Yes. One other question, which I think probably does relate to this. It's -- statements have been made about saving lives. And the only lives that can be saved of course are those -- well no, take that

back.

But most of the lives that can be saved are those who have been treated with antibiotics. It's one of the core elements of early treatment for sepsis.

And all the cases of sepsis that are due to influenza or inflammatory storm or whatever, can be saved with antibiotics.

In New York State have you tried to advise the community that while there are in fact preventable deaths or highly preventable deaths that not all deaths are due to "sepsis" as coded are preventable?

And therefore the public shouldn't just do a simple extrapolation. Which I've seen in multiple papers. Including from Surviving Sepsis and the lives saved.

MS. MARINELARENA: Is that for the developer?

MEMBER GOLDMANN: If New York State, when they used the data and look at the evidence for the mortality and so forth, that they make it

clear that there are different etiologies of sepsis, only some of which are addressed by the bundles that were cited by them earlier.

MS. MARINELARENA: Oscar?

DR. LEVY: This is Mitchell Levy. I'm a little lost since I don't think we're -- maybe I'm on the wrong measure.

I thought we were talking about the risk adjusted mortality measure that the New York State Department of Health had submitted. Which has nothing to do with the bundles.

This has to do with just --

MEMBER GOLDMANN: I raised it only because the bundles were raised in the rationale. And then there was a comment about saving -- about lives saved based on this measure.

And the rationale and the evidence for the measure depends on how it's interpreted. And --

DR. LEVY: Of course. But the whole point it seems is to try to be able to evaluate what the word mortality means.

So, since obviously there are so many different patients who die from sepsis, just as you say, I think what our attempt to do in this database was to be able to risk adjust so that we could compare mortalities across institutions independently of any bundles.

MS. MARINELARENA: That's why --

DR. GESTEN: Yes, this is Foster. Let me just jump in.

The addition of the risk adjusted mortality, and they're adding the risk adjusted mortality to -- and data to be able to evaluate that initiative, we thought of as an additive and important ingredient to really being able to evaluate the degree to which various interventions, whether they're bundles or other interventions, are effective.

But, in order to be able to really evaluate that, as well as evaluate the initiative, we felt strongly that having a risk adjusted mortality outcome measure was important.

So, if the question is, do we believe

somehow that magically that all sepsis mortality is preventable, the answer to that, you know, both in terms of my experience with the initiative as a clinician, would be the answer is no.

Did we communicate and somehow falsely communicate that we think that if people just did all these things there would be no mortality, I think the answer to that is also no.

Do we believe that there are different patient populations with different characteristics that may have an increased or decreased risk, or maybe more or less advantage by certain interventions, the answer to that is yes.

And I think we're in the process of using the data to try to better understand and link the data that we have on the interventions and patient characteristics and facility characteristics with this outcome.

So, I guess we've never -- we haven't viewed this as being the -- well we've always

viewed this as being part of the overall initiative. And never sought to advertise or say that we knew or thought that if only you did X, Y or Z, there would be no deaths from severe sepsis or septic shock.

But we are, I think, we're motivated by the amount of variation that was displayed, as well as the comparator of the mortality rate that we see, at least in our population, non-research population, and some of the mortality rates that we've seen reported, whether it's in the process trial of 18 percent, or in other institutions across the country that have been re -- have reported, you know, much lower mortality rates.

Does that help answer the question? I mean, we can get into some of the validity later. But, I just wanted to be responsive to the question.

MEMBER GOLDMANN: Yes. That's fine. We'll come back to it. I don't want to be persnickety and yapping at your heels.

It's just when talking about it so

far, these terms get introduced. The prime stakeholder for this, I think, is the patient population, the customers. And real clarity about what this risk adjusted measure means in terms of risk is just so important.

And it's been -- so far there have been some statements that just perked up my ears. Because they went to things like lives saved, bundles.

So, let's not use those terms in looking at this measure. Let's just look at whether the measure is a valid measure or not. And I think we'll -- I'll keep much more quiet.

MS. MARINELARENA: Hey Don, this is Melissa. I think that was one of the Committee members who used those terms and not the measure developers. That used the terms bundles and lives saved.

CO-CHAIR THOMPSON: So, any comments on gap and performance in disparities?

(No audible response.)

CO-CHAIR THOMPSON: All right. Were

there any online?

(No audible response.)

CO-CHAIR THOMPSON: Okay. We can move to vote.

MR. MENENDEZ: For Measure 3215, performance gap, voting is now open. Vote one for high, two for moderate, three for low, four for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, high.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: The final count is 75 percent high, 19 percent moderate, zero percent low, six percent insufficient.

The final verdict is passed.

CO-CHAIR THOMPSON: All right, moving on to reliability.

MEMBER RONEY: So as I looked at reliability of their measure in New York, it has been in place in New York for I want to say, on the call the developers are here, too, for over a year and they have been able to kind of compare

their responses and chart instructions.

And so, again, it was at the facility level that it is being reported and then reliability was compared in between facilities in the State of New York.

CO-CHAIR THOMPSON: Do we have any questions or comments about reliability?

MEMBER RONEY: Add to reliability they did exclude the patients that came in from outside of the facility to match that of the CMS sepsis core measure.

It has the same exclusion criteria so it only measures those who were diagnosed, developed, presented, or developed severe sepsis, sepsis, septic shock, whichever definition we are using, during their hospital stay.

MEMBER GARZARO: I have a question on the denominator. So the patients admitted with this diagnosis of septic shock then is changed to acute MI, that's counted in the denominator so that that patient will be counted?

(Simultaneous speaking.)

DR. GESTERN: Yes, this is Foster. Let me, why don't we just get into the denominator issue that was raised earlier.

So in terms of the data that we collected from the hospitals, we asked hospitals to identify using any and all means, both, you know, retrospective means, administrative data, clinical data, registry, individuals that met the existing clinical definition of severe sepsis or septic shock.

And we were asked repeatedly about, you know, which codes to use and, you know, people were aware that there were ICU 9 at the time codes, but we were clear repeatedly, and still are clear, in our instructions that those codes and, you know, almost any way of identifying has various kinds of frailties and issues.

And so essentially the data dictionary and the information to the hospitals was to if anyone is to be included who met that clinical definition.

What that would mean is that if somebody was incorrectly, you know, had an administrative code that said sever sepsis or septic shock but on review of the case the hospital found that they did not, in fact, meet the clinical definition they were allowed to exclude that case.

But it also meant, and we can get into some of this with some of our validity and liability testing, that if we wanted them to also make use of cases in which they might have billed for, identified somebody as severe sepsis and septic shock, and see whether or not, in fact, that was accurate.

In fact, whether those individuals met the definition, including even if they did not initially send them to us in a clinical dataset.

So we did some work with the hospitals and with our own dataset comparing the clinical dataset to the administrative one, identifying cases that might have been identified administratively that were not in the clinical

set and fed that information back to the hospitals with instructions of if these are individuals that met the clinical definition then they should be included in the clinical dataset and you can resubmit them and if they aren't then, you know, in some cases you should look at your billing and administrative processes as well, because we have, you know, also have concerns not only about the accuracy of the coding for this project but also accurate billing as well.

So in the case and scenario that you mentioned, if somebody was incorrectly identified on, you know, a presumed initial diagnosis of sepsis that turned out to be something else, then they would not be included, and they should not have been included in the denominator.

DR. TERRY: One of the things that I want to -- This is Kathy Terry also representing the DOH from IPRO. One of the things that I want to add to what Foster was saying is that we did audit the cases to determine whether or not there

was severe sepsis/septic shock and that performance was over 98 percent accuracy.

So the cases that we did receive in our database did accurately reflect severe sepsis and septic shock.

CO-CHAIR THOMPSON: Any other questions or comments?

MEMBER GOLDMANN: Do you all report or look at crude mortality, crude sepsis rates? The reason I ask is that I think this includes sepsis occurring in the hospital, right, so if it includes sepsis occurring in the hospital do you look at trends and comparisons among just the number of cases with sepsis?

DR. GESTERN: Yes. So we have looked at trend back, both in an aggregate way and also at the individual institution level, quarter-by-quarter at the number of cases that are being reported, looked at that over time, and, also, you know, I have done comparisons to looking at the phenomena of what we see in the coding.

So, you know, we are familiar with,

and the article that was referenced earlier about coding issues and some of the challenges of using administrative data, the challenges of denominator creep, if you will, that may explain some changes in mortality that have been seen, and concern about it.

And as Mitch was saying earlier, you view the risk adjustment as one way to potentially try to address that in addition to trying to be as precise and clear as we could be about a definition that is after a clinical definition, which is on I guess its third lap of international definitions.

There is some discussion about the application of the most recent definition. So we do think that there is value in tracking both, you know, crude denominator numbers, you know, as well as crude mortality as well as risk-adjusted mortality, and hospitals have access to both of those, and I presume that they look at their own rates and can obviously trend internally what they are seeing over time.

MEMBER GOLDMANN: Yes, I was not getting into so much coding with that is that you could have a lot of sepsis and do a very good job of treating it in your ICU and that wouldn't be a good thing, so I'm just always cognizant if you look at, for example, you can have a low catheter infection rate and be using seven times too many catheters.

So it's just a kind of a balancing measure, if you will, that might be --

(Simultaneous speaking.)

DR. GESTERN: So you are talking about hospital-acquired sepsis and looking at that as sort of a --

MEMBER GOLDMANN: Yes.

DR. GESTERN: Yes.

MEMBER GOLDMANN: Yes, I would separate them frankly.

DR. GESTERN: Yes.

MEMBER GOLDMANN: I would have de novo admitted in the ED and I would look separately at inpatient because I think their pathway to

infection and how they might even have different outcomes is probably pretty important, but that's a nuance.

DR. GESTERN: Yes, it's a really good point and we certainly have looked at, and intend to continue to look at, differences in both population and outcomes for people that acquire, you know, sepsis in the hospital versus people that present with it, and the notion of, which is really kind of a separate of idea, of, you know, does hospital-acquired sepsis, would that be potentially a good quality measure is an interesting question.

It's not what we are posing here, but it's something that, you know, is worth looking at.

CO-CHAIR THOMPSON: All right. Anyone, comments on reliability testing, I'm not sure if we walked through that one at least, from folks at our table? Jamie, do you guys have anything about the reliability testing?

(No audible response.)

CO-CHAIR THOMPSON: No.

MR. MENENDEZ: So voting for Measure 3215, Reliability, is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: Final count is 13 percent for high, 50 percent for moderate, 0 percent for low, 38 percent for insufficient. The final verdict is pass.

CO-CHAIR THOMPSON: Next section, validity and validity testing.

MEMBER RONEY: I feel like we have already touched on most of this validity testing as we heard that they went back and re-abstracted and audited charts as well as they used logistic regression data analysis on the data that they got from, I think it was almost 200 hospitals that submitted data in the State of New York.

CO-CHAIR THOMPSON: Any comments on validity?

MS. MARINELARENA: So this also includes --

(Off microphone comment.)

MS. MARINELARENA: I'm sorry. This is Melissa.

DR. GESTERN: I'm sorry.

MS. MARINELARENA: This was a risk adjustment model, threats to validity, any missing data, so if you want to have a discussion on that as well.

So we look at the, consider the risk adjustment model. They did the measure score validity testing, so they looked to see how the model would perform on two different samples, so I don't know if you want to have a further discussion on that.

If you would also want to discuss the different variables, we do ask measure developers to consider SDS risk adjustment for outcome measures.

They did not provide a rationale as to why they would or wouldn't use a certain

variable, but they did demonstrate how they used certain variables when they started testing the model and then talked about which variable ended up in the model.

I don't know if you want to have more discussion about that. I know on the work group call there was a lot of discussion about the different types of hospitals, but we're talking about patient-specific variables to include in the model.

MEMBER RONEY: And when that came up they mentioned they wanted to keep the model as simple as possible because there were so many variables that could impact mortality.

And so they tried to, based on, and correct me if I am wrong, you guys on the development team, but tried to come up with the variables to limit the number but come up with ones that they thought impacted or would have an impact on mortality the most, but they couldn't include everything or it got really complicated and muddy.

And there is a 60-page addendum to this measure just on how they calculated mortality. So there was a lot to read through as far as their development and how they tested it.

But I don't know if you guys want to talk to the specific measures that you included in your model?

DR. GESTERN: Sure. Let me just start. This is Foster, let me start, and then I want to hand it over to Stan and Gary and others on the group as well.

But just in a general way in terms of the model, we obviously, or maybe not obviously, it is important to say that we deliberately did not want to make adjustments for characteristics of the institution, deliberately did not want to make, include in the model characteristics of the interventions, but do the best we could with the data that we were collecting, the data variables, to make adjustments for co-morbidities and "severity" were I believe those variables that we thought, or from the literature or from our

clinical advisors, were critical and important relative to predicting outcomes of survival or mortality.

But maybe for a more detailed or a more statistical way of describing, Gary or Stan, can you jump in and want to just say a words maybe starting at a high level about decision making around variables in the model?

DR. LEMESHOW: Sure. This is Stan Lemeshow. As with any model building exercise we started with many potential predictors of the outcome, which was hospital mortality.

We go through a model building exercise where we select from among the many variables available the ones that are significant in the light of the other variables in the model.

That is, a variable by itself in a crude sense might be significantly associated with mortality but together with the other predictors is no longer important.

So our objective is to develop the simplest possible model and provide to the best

estimate of the probability of mortality, and I want to really make it clear that we are not predicting outcome, we are estimating the probability of outcome.

And by estimating the probability then we can turn those estimates of probability into an expected number of events for each hospital. So to be in our model a variable has to be clinically significant as well as statistically significant.

MEMBER SREERAMOJU: This is Pranavi. I think there is no disagreement there about estimating the probability and not predicting, but we run into issues at an organization level as to whether it is reflective of the organization's characteristics and I think it's best at this stage because the measure development team deliberately did not include organizational variables.

It's best to -- I mean I would take the approach of accepting the measure as proposed and not -- and then work on our -- and accept

that it is a limitation that it doesn't include organizational variables, because many of us in the field know and appreciate that organizational variables do modify the probability of mortality for patients.

It's not just the patient characteristics and that is why there is no way to simplify a prediction model for something like this -- or something like this because there are way too many factors.

CO-CHAIR THOMPSON: Any other -- Don, do you have something?

MEMBER GOLDMANN: Yes. So I just appreciate the rigor of the statistical model and I am sorry I didn't read the 50-page addendum and now I will because it seems -- It's so important, obviously, to do that.

But it looks as if your calibration was really superb but your discrimination, although it's good, I am never totally thrilled by something that's in the 0.7 or 0.7 plus range because it indicates there is something missing

that you wish you had and I wondered if you'd talk about.

It looks like you used not a split half, but a split 10 percent model to satisfy, to validate, the model, and that's how you got some of the data.

But can you just comment on that C statistic and what you think you wish you had?

DR. LEMESHOW: It's a great question, what we think we, what we wish we had. Certainly having an area under the ROC curve with a C statistic as high is possible is desirable.

And for those who may not be aware the C statistic is a measure of whether the model tends to produce higher probabilities for the people who actually die and our C statistic was in the high 70s, I believe, and so we didn't quite make it to 80 percent, which everybody would have been very happy with.

But we were very -- Actually, our C statistic is high enough in the high 70s that we are satisfied with that. I mean certainly if our

C statistic was below 70 percent we wouldn't have a model that we could bring forward.

So being in the high 70s I think is adequate and the fact that our model performed well, not only in the dataset we developed it on but also in the dataset that was set aside that was not part of the estimation of the coefficients, I think that is reassuring that the model does, in fact, perform well.

DR. LEVY: Yes. The other point, remember, is we intentionally left out treatment variables and since there are no treatment variables in the model our expectation for the C statistic was not that great.

Yes, you know, had we added those variables, some of those treatment variables in, then the C statistic does get up into the 0.8, but we did not want to intentionally include those variables in the model.

MEMBER GOLDMANN: Yes, that just reminded me --

DR. LEVY: Foster, I think the other

--

(Simultaneous speaking.)

MEMBER GOLDMANN: -- of the C statistic I am looking for here. I think it was in the high 70s.

DR. LEVY: 0.77.

(Off microphone comments.)

DR. LEVY: It's 0.77.

MEMBER GOLDMANN: What was it?

DR. LEVY: 0.77.

MEMBER GOLDMANN: Okay, all right.

DR. BURSTIN: And this is Helen, I'll just point out --

(Simultaneous speaking.)

DR. LEVY: Right. And 0.773 for the validation dataset.

DR. BURSTIN: This is Helen. I'll just point out that is actually quite a good C statistic for many of the outcome measures we tend to see.

DR. LEVY: But I would love to know what it was --

MEMBER GOLDMANN: Actually, you stumbled on an area where I have done a considerable amount of work and when we, using physiologic variables for predicting neonatal mortality hit a C statistic of 0.92 I thought we were into something really important and we would have been -- I understand that a lot of these models end up with C statistics in the 0.7s, which is acceptable, and I am not dissing it.

I am just saying it would be great to know what you think might have sharpened it. For example, organ dysfunction, was that included at all? It's in general now thought to be a really important predictor of mortality in general in sick patients.

DR. GESTERN: We had a number of organ failures in the model.

(Simultaneous speaking.)

MEMBER GOLDMANN: Is it a -- It's not a formal scorch, probably you didn't have the data for that, right?

DR. GESTERN: No.

DR. LEVY: Correct. And I mean I think in a general way we would love to know what the variables are that we think could be reasonably and feasibly collected across the State across 190 hospitals. That would improve the model.

So we did, not in the submission, we did take a look at, in a cohort that we had that we had charts and had further data, to look and see if there was some of the physiologic variables that were part of the new definition that might, you know, contribute to the model in some way.

And I think maybe Stan and Gary, or Mitchell, you may recall, you know, that it did not contribute in any significant way to the model, and these were more physiologic, you know, variables related to respiratory rate, and heart rate I believe as well, on admission or on initial diagnosis.

But, you know, whether there are other "severity" variables or refinement of co-

morbidity that might improve the model, unclear, but, you know, we, like you, would love to see even a higher number.

CO-CHAIR THOMPSON: Real quick, just --

(Simultaneous speaking.)

DR. GESTERN: Yes, and I would just reiterate what Helen just said --

CO-CHAIR THOMPSON: One second.

DR. GESTERN: -- which is that given the measures that are often looked at by NQF this is a very good C statistic.

CO-CHAIR THOMPSON: So I just want to remind the folks who are joining us on the phone to be sure to say your name before your comment. We would like to attribute your astute comment to you and have you not show up as participant on the line. Don?

MEMBER GOLDMANN: And just a final question, this is kind of true/true and unrelated, but I didn't see, and maybe again I missed it, kind of a histogram or some other

display showing the range of hospital performance and how many were actually true statistical outliers versus within the error?

DR. LEMESHOW: So while we didn't include it in this proposal, what we have produced is we have calculated for each hospital, all 190 hospitals, we computed the observed, well we counted the observed number of deaths and we compared the observed number of deaths to the number of deaths that would have been estimated based on the model.

Taking the ratio of the observed to the expected number we have what is called the standardized mortality ratio and we have actually produced plots that look at the standardized mortality ratios and the confidence intervals without the standardized mortality ratios for all 190 hospitals.

Obviously, if that ratio is above one then the hospital is exhibiting more deaths than the model would have predicted and if the confidence interval doesn't include one then that

confidence interval is significantly above one and the hospital is doing significantly worse than would be expected overall.

On the same token, a hospital that has a standardized mortality ratio of less than one is demonstrating fewer deaths than the model predicts and if you look at the confidence interval, if that confidence interval doesn't include one, that's a hospital that can be kind of pointed at as best practices because whatever they are doing it's working and I think it really helps us understand what works and what doesn't work.

You can do that, by the way, for the different kinds of hospitals, whether it's community hospitals, university-based hospitals, rural hospitals, this kind of thing can be very revealing as to which hospitals are most successful.

MEMBER GOLDMANN: Yes. So the committee can tell me to shut up anytime, but you are getting into exactly the point of this

debate, and that is I would have like to have seen a funnel plot.

I would like to see how many hospitals of what size are outliers and what your statistical threshold is, because if you use a 95 percent confidence interval that's way too liberal and you are going to get all kinds of outliers that won't repeat when you come back a year later or that if you use somebody else's model will not -- That's basically what Sharon-Lise Normand and others found with looking at HSMR against other mortality measures.

And so in order to really understand where this measure is going to be useful it would be really nice to know what your threshold for being an outlier is and what your funnel plot looks like.

And that would be really helpful to me personally because it would tell me whether you are going to see real variation or noise and put people through a lot of work.

Just because they are an outlier

doesn't mean that they have a problem in most of these kinds of models.

CO-CHAIR THOMPSON: Kathleen?

MEMBER BRADY: Yes --

MEMBER GOLDMANN: Do you have funnel plot?

MEMBER BRADY: Oh.

DR. LEMESHOW: No.

MEMBER GOLDMANN: Do you -- I assume you know what it is, people are looking at me puzzled.

DR. LEMESHOW: We don't have a --

MEMBER GOLDMANN: A funnel plot is simply a very elegant way to show both size of the sample in a hospital, the statistical threshold that is used, and whether anybody comes out of the cone of probability that you create and it's -- It's not really different than a fancy histogram with confidence intervals around it and so forth, but it includes the thing you are talking about which is the smaller, more typical hospitals, not just the huge medical

centers and it is pretty standard in the NHS now after the various problems they have had in the staff inquiry to use funnel plots and it would be really, really helpful to see it.

CO-CHAIR THOMPSON: Thanks. Kathleen?

MEMBER BRADY: Yes. So my comment is related to the fact that sepsis is reportable to the New York State Department of Health and as a result of that, I'm not sure when that was implemented, but do you think that since these results only come from New York State is there any kind of possibility that the reliability and validity of your model would be different in other areas where maybe that is not the case?

DR. GESTERN: This is Foster and I will take the first whack at that. I mean it's clear since we didn't test this in other States it's hard to be able to answer that precisely and it's accurate that the data upon which this is, you know, this is based is a submission, you know, a unique submission, of not administrative data but clinical data from hospitals.

On the other hand I don't know, you know, the data dictionary is, you know, explicit and, you know, across the State 190 or so hospitals were able to use that to submit data to us that we think is reliable.

I don't have any reason to think that the ability to identify cases or to identify the variables that are in there are in some way unique or special to patients in New York or in New York hospitals.

But I think the direct answer to your question is, you know, it's hard to know for sure that if somehow this wouldn't be different and clearly one of the questions for the group to think about is is this generalizable to other places that may have a different way of either identifying patients and/or of collecting that information.

So the model is built on a specific way in which, you know, we described the identification of patients, were described as well as a specific way of collecting a specific

time period and a specific way of reporting those cases to us using a discreet data dictionary, but I don't know.

Does Mitchell or anybody else have a thought about generalizability?

DR. LEMESHOW: Yes, this is Stan Lemeshow. I just want to say one quick thing on this. I was involved with developing models based on an international sample of general medical surgical ICU patients.

Once our model was published and became very well-known there were many, many papers published so people would explore the performance of our model in the Netherlands or they would explore the performance of our model in Italian ICUs.

And we learned that it's very -- Once the model is out there, the basic variables are out there, it is very simple to adjust the coefficients in the model to customize it to a particular country.

And I would say that, you know, you

can make the same argument. None of us can guarantee that our model will work extremely well in any hospital in any State, that is impossible to say right now.

What we can say is that we could look at the performance in different States and we can actually customize easily these coefficients so that it does perform well wherever it is tried, at least that was our experience in this international study.

MS. MARINELARENA: And the question that we posed to NQF, and it's a standard question, was is a test sample adequate to generalize for widespread implementation, so take into consideration the size of the sample.

A lot of the times we see testing and it might be, you know, 30 providers and a few thousand patients, where in this case, you know, we have a 179 hospitals over a year in 30,000, what was it, 40,000-some patients, so take that into consideration.

CO-CHAIR THOMPSON: Any other comments

on validity? Any comments from on the line?

All right, I think we can move to voting.

MR. MENENDEZ: Voting for 3215, Validity, is now open. Vote 1 for high, 2 for moderate, 3 for low, and 4 for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: Voting is now closed. The final count is 25 percent high, 50 percent moderate, 6 percent low, 19 percent insufficient. Final verdict is pass.

CO-CHAIR THOMPSON: Feasibility.

MEMBER RONEY: Feasibility leads to more challenges because of the number of co-variants that are required to be input into this risk-adjusted model.

A lot of the stuff that came up on our phone call discussion was the amount of chart abstraction that would be required, and so feasibility wise it's a little more difficult but

not impossible.

CO-CHAIR THOMPSON: Questions or comments on feasibility?

(No audible response.)

CO-CHAIR THOMPSON: All right, I think we can move to vote.

MR. MENENDEZ: Voting for 3215, Feasibility, is now open. One of high, 2 for moderate, 3 for low, 4 for insufficient.

(Voting.)

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: Voting is now closed. The final count is 6 percent high, 69 percent moderate, 19 percent low, 6 percent insufficient. The final result is pass.

CO-CHAIR THOMPSON: And, lastly, usability.

MEMBER RONEY: I guess there has been a lot of discussion around this as well, but is it generalizable data that will be produced with this risk-adjusted mortality and will we be able

to improve the care that we deliver and/or measure of the care that we deliver.

Those are all questions that have been raised, but usability of the measure in itself, maybe even just at the institutional level, may be seen as promising, but I think most of us are looking at mortality already but as far as generalizability across the nation.

Again, I don't know what other comments may want to be added to usability.

CO-CHAIR THOMPSON: Woody?

CO-CHAIR EISENBERG: Yes. The comment that I would add is one that's been made already and that is that in New York State it's required to report sepsis so the hospitals sort of bite the bullet and do it.

But I am wondering about other States that may not have that as a requirement and whether the burden for them would prove all but insurmountable.

CO-CHAIR THOMPSON: Do we have a sense of how many States require reporting?

MEMBER RONEY: I have it as required reporting but it is because it is my 1115 waiver project.

MEMBER SREERAMOJU: This is Pranavi Sreeramoju. I would like to add that our hospital reports sepsis mortality as 1115 waiver project, but it's not that it requires reporting in the State of Texas.

To me the usefulness of this metric is something that is available for organizations to use if they are looking for risk-adjusted sepsis mortality but it's not yet primetime for inter-institutional compatibility as it stands, but it's definitely useful in the organization.

DR. BURSTIN: And I'll just add that NQF has inexperience of bringing in some innovative State measures just to kind of get that, some of these measures in use even if they haven't been introduced in federal programs.

That is often a good way to get a good sense of its performance.

MEMBER RONEY: To tag onto what Helen

just send, this is Jamie for you guys on the phone, we did have to develop our own risk-adjusted sepsis mortality model at our institution and so it may just be that it could be a resource for others to have a risk-adjusted mortality measurement for sepsis without having to develop it and look at the co-variants and go through the statistical analysis process within, at the national level to be NQF endorsed.

CO-CHAIR THOMPSON: Any other comments or questions about usability?

(No audible response.)

CO-CHAIR THOMPSON: All right, we can move to vote.

MR. MENENDEZ: Measure 3215, Usability and Use, voting is now open. Vote 1 for high, 2 for moderate, 3 for low, 4 for insufficient.

MEMBER HART: Jeff Hart, moderate.

CO-CHAIR THOMPSON: Thank you.

MR. MENENDEZ: Voting is now closed. The results are 13 percent high, 63 percent moderate, 6 percent low, 19 percent insufficient.

Final verdict is pass.

CO-CHAIR THOMPSON: Okay, now we can move onto the final endorsement vote. Yes, Don?

MEMBER GOLDMANN: Some comments before we vote on the final. So here is some concerns I have kind of been hinting at, and it comes from a really deep experience with mortality, risk-adjusted mortality measures, and aside from whether you think that HSMR or the UHC or the MMM or any of those are perfect models and whether mortalities are all preventable, aside from that I am really chasing by the study by Sharon-Lise Normand and others on risk-adjusted mortality where it basically took the hospitals in Massachusetts, with arguably the best, most well refined, over and over again iterated risk-adjusted models, and showed that the four measures they tested gave different results.

Not only did they give different results, but hospitals that were outliers in one were inliers in another and the rankings changed considerably from year to year, which the

conclusion of the paper, and there are a lot of critics of the paper, but it was pretty well done and it argued that any one risk-adjusted model, particularly one that hasn't been, as best as I can tell, published and scrutinized in terms of statistical methods by independent people, is probably, it may be premature.

And Brian Jarmin would often say that my model was not developed to create a lead table where Mount Sinai could look at Montefiore and say well where, we have lower mortality than you do, there is a sort of self-fulfilling prophecy in using your own data to validate your own data, and he would say what it is really good for is for people to say, well, we can do better and how are we going to track it and to look for real outliers.

And real outliers were outliers that had a confident, sort of 0.99, a real, you know, and repeatedly, and preferably with multiple, different ways of looking at it.

And in England, therefore, rather than

just publishing it and whatever they notify confidentially the hospital that you are an outlier and then they have a 60-day I think it is response period to, you know, explain why the data doesn't apply to them.

So I am just a little worried that -- I haven't seen a peer review paper, I haven't seen -- Is there any independent statistical evaluation of this, I don't know.

It's done in New York State data, which may be special. I haven't seen a final plot, I haven't seen how many true outliers there are, and I just have an opinion, and I'm just expressing it, nobody has to listen to me, but that some further development research and the validation would be a good idea.

DR. BURSTIN: Do the developers want to respond to -- I know there are several papers submitted that they couldn't share with us yet because they are under embargo. Foster, any comments?

DR. LEMESHOW: This is Stan Lemeshow.

It's an interesting argument, but I think that none of us believe that this is the somehow best, God given, correct model.

I mean what we know is that we have a model that has gone through a lot of trial and tribulation. We know that the model does perform well in the data that we developed it on.

We know that it does perform well in data that was set aside. We also know that it would be possible to develop a completely different system for the same, using different data, and we know that those two systems probably would not agree with each other 100 percent of the time.

But I am completely convinced that there is a need for models that can --

(Telephonic interference.)

DR. LEMESHOW: -- probabilities of an outcome that can be applied in institutions and that can be validated in institutions over time, because I think it adds a lot of information that we don't currently have.

And I think this model that we developed has potential for being useful going forward and none of us are arguing that it is the best one that will ever be made, but I think it's a good one for the time right now and I think that we have an opportunity to use it for important purposes.

So, you know, I understand and can well appreciate the comments made previously, but I do think that this is something that we can latch onto and actually demonstrate the usefulness of this particular model over time and in different institutions.

DR. LEVY: This is Mitchell Levy. And that was, by the way, Stan Lemeshow, I just want to make it clear. And, Stan, you have worked on what other risk models before?

DR. LEMESHOW: I worked on the SAPS model, the Simplified Acute Physiology Score model, that involves something like 15 different countries, and I worked on the Mortality Probability Model that was exclusively in the

United States.

DR. LEVY: Yes, and I just wanted to -- I think that's important. I think the comments about risk modeling altogether are well taken. I also want to, hopefully everyone is clear is that there are a lot of risk models out there that are currently used to risk adjust people, especially in critical care.

And I think the advantage of this model, which is as imperfect as any other risk model out there, is that this is the first sepsis-specific risk model and given the increasing attention nationally and internationally to sepsis to have a sepsis-specific risk model, we think when one that, as you just heard Stan describe, can be as helpful as we think it is, I think it's an important contribution to the field.

MEMBER GOLDMANN: Yes. I just want to state I am not impugning that the talents and the abilities of the modelers here at all. I mean I think it looks very sophisticated and appropriate

methods were used.

DR. LEVY: Yes.

MEMBER GOLDMANN: But a question for NQF since I am new this panel, if we were to vote yes on this measure are we sending a signal that this is suitable for national adoption or is it more like what they are saying, well, people will use it and will learn more and it's better than, it's nice to have something out there?

So to what extent are we endorsing this that, for example, it might be picked up in, since sepsis a national HHS priority, that it could end up as a national pay-for-performance measure?

DR. BURSTIN: Right. So, again, I want to try to separate out this is the measure, the quality of the measure is what you are doing today.

There is another group that will then evaluate it in the context of, if, for example, it got brought up to say this measure is potentially being considered for the Inpatient

Quality Reporting, or IQR, at some point, they will then look at the measure, your evaluation, the context of how it will be used, and some of that assessment will be made.

I think what you are saying is based on NQF's criteria does this measure meet those criteria, it has met the threshold, and that it is suitable for use.

We are not saying, we are not prescribing which use, but that it is out there and people could have some confidence that it is evidence based, valid, reliable, et cetera, and begin using the measure.

CO-CHAIR THOMPSON: Okay. All right, I think we are ready to vote.

MR. MENENDEZ: Okay. For the overall suitability for endorsement of 3215 vote 1 for yes, 2 for no.

(Voting.)

MEMBER HART: Jeff Hart, yes.

MR. MENENDEZ: The final count is 69 percent yes, 31 percent no. Final verdict is

pass.

CO-CHAIR THOMPSON: Great. Thank you to those of us, you, from the New York State Department of Health who joined us from the phone. We appreciate you answering all of our questions. And I believe Christy has an announcement.

MS. SKIPPER: Yes, thank you. So before we all go to break I just want to let you know that as a standing committee you all will randomly be assigned to two or three year terms.

So before you go to your break please see me to draw your term slip from this cup and when we return we'll have you call out your number for the record so we know which term you have been assigned, either two or three.

And then for the committee members on the phone we will draw a slip for you and I just want to let you know that committee members may serve up to two consecutive terms.

The second term will automatically be a 3-year term, but you don't have to accept that

second term. Yes?

(Off microphone comment.)

(Laughter.)

MS. SKIPPER: Mike, I'm sorry?

(Off microphone comments.)

MS. MARINELARENA: This is starting fresh. Those were steering committees. This is a standing committee so we can bring you together any time.

(Off microphone comments.)

MS. MARINELARENA: You didn't realize what you got yourself into, right. So this is going forward, yes.

(Off microphone comments.)

CO-CHAIR THOMPSON: So we will -- Folks, remember to draw your term, and we will take a 10-minute break and be back just before 3 o'clock.

(Whereupon, the above-entitled matter went off the record at 2:49 p.m. and resumed at 3:03 p.m.)

CO-CHAIR EISENBERG: Okay, let us get

back underway. We are about to discuss our last measure of the day, I believe, which is 0500, and for this measure Laura Evans will be recused because she has been involved in the construction of the measure.

We have with us the measure developers, yes, and --

(Off microphone comment.)

CO-CHAIR EISENBERG: Oh, hold on, we're taking a little interruption here. We have to -- Oh, is that a formal part of the --

MS. SKIPPER: Yes.

CO-CHAIR EISENBERG: Oh, okay. So at this point before we actually get to the measure we need to report in on whether we are getting a two or a 3-year standing committee appointment and apparently that has got to be part of our recorded proceeding, so, Christy, let me hand it over to you.

MS. SKIPPER: Yes. So I guess we will start with Amesh here. If you will just call out the number, your name, and your term limit, and

we'll go around the room.

MEMBER ADALJA: Amesh Adalja, three.

MEMBER RONEY: Jamie Roney, two.

MEMBER GOLDMANN: Don Goldmann, two.

MEMBER GARZARO: Piero Garzaro, three.

MEMBER BRADY: Kathleen Brady, three.

MEMBER LANE: Mike Lane, three.

CO-CHAIR EISENBERG: Woody Eisenberg, two.

CO-CHAIR THOMPSON: Adam Thompson, three.

MS. SKIPPER: Okay. And I will call out numbers for individuals on the phone, I am drawing from a cup. Nanette Benbow, three. Esther Babady, two. Emily Aaronson, three. Laura Evans, two. Rocco Orlando, two. Pranavi Sreeramoju, three. Jeff Hart, three. And Jeffrey Lewis, two. Thank you.

CO-CHAIR EISENBERG: Okay, now we are going to address a new measure, 0500, which is Severe Sepsis and Septic Shock, which is the management bundle.

This is a composite measure. It is a maintenance of a previously-approved endorsed measure and at this point let me hand it over to the measure developers to describe the measure to us, please.

DR. RIVERS: Can you hear me okay?

CO-CHAIR EISENBERG: No. Try that again, please.

DR. RIVERS: Emanuel Rivers, can you hear me okay?

CO-CHAIR EISENBERG: Just barely.

DR. RIVERS: Okay. How about that?

CO-CHAIR EISENBERG: Oh, that's better. That's better.

DR. RIVERS: Okay. Sorry about that.

CO-CHAIR EISENBERG: That's okay. Go ahead.

DR. RIVERS: Good afternoon, everyone, and thanks to the National Quality Forum Infectious Disease Committee and everyone on this call for their dedication to quality improvement.

As the measure stewards Dr. Townsend

and I apologize for not being able to attend physically but we definitely are there in spirit.

This is the tenth year after the first submission of NQF Measure 0500 and represents the third submission for re-endorsement.

The concept of a sepsis measure began almost 20 years ago after observing the mortality at Henry Ford Hospital approaching 50 percent. So as a result a quality initiative began in 1997 which gave way to the concept of early interventions in sepsis.

Interestingly, the sepsis mortality of 46.5 has been validated within the last year by an expert panel, recently published in JAMA. So, clearly, sepsis continues to be a condition where there is a gap in the quality of care.

The following are some noteworthy statistics from CMS. The incidences of over a million cases a year, over 250,000 of these are septic shock.

The mortality is responsible for the largest number of inpatient deaths in the United

States, and if you look at the number of deaths it outstrips prostate cancer, breast cancer, and AIDS combined.

Sepsis patients are eight times more likely to die in a hospital than other diagnosees and an average death rate of about 258,000 patients per year.

From a resource consumption perspective it is the fifth largest consumer of hospital days. It is also the largest increase in emergency department visits from 2006 to 2011, which is about a 74 percent increase.

And from a cost perspective it is the most expensive reason for hospitalization. It actually represents 5 percent of all U.S. inpatient hospital costs.

So as a committee I am sure you are aware about the concept of goal-directed therapy, which was a combination of many studies that created the components of composite NQF 0500.

One must remember that in the year 2001 there were no standards for early

identification and care for sepsis, so protocols-based care was not a standard of care.

The landscape changed after adoption of this methodology by the Surviving Sepsis Campaign in 2004 and after a decade of the Surviving Sepsis Campaign and after publication of multiple protocol-based care trials there has been much discussion about the elements of the measure.

The protocol-based studies all revealed that when core treatments of early detection, risk ratification, fluid challenge, cultures, antibiotics, and profusion exam, if done within six hours, sepsis mortality has dropped to an all-time low below 20 percent according to these trials.

It is important to note that these trials do not question protocol-based care, which is the foundation to NQF 0500, but only the component related to the profusion exam.

We made these modifications in the measure to accommodate this research in the last

NQF submission.

More importantly, the most recent trials, the most recent data, is CMS data. The adoption of the measure by CMS in 2015 and inpatient quality reporting has provided further insight to sepsis care nationally.

This report reflects three quarters from 2015 to 2016 and represents over 159,000 cases of eligible patients, and this is out of over 300,000 patients submitted.

The sobering news is that the mortality of septic shock is still 38 to 42 percent and severe sepsis 28 to 32 percent, which is twice as high as the mortality reported in these previous trials.

Needless to say, we have a lot of work to do to improve sepsis care and NQF 0500 is leading the charge to improve sepsis mortality nationally.

The good news is that when the Sep 1 measure is adhered to, now this is a CMS measure, mortality decreases by an absolute value of 8

percent and a relative mortality reduction of over 25 percent.

We would like to also note that 100 percent of hospitals successfully reported the measure and that the hospital performance have been increasing each quarter.

After two NQF measure approvals and in response to thoughtful stakeholder feedback regarding the specification manual we have made multiple changes to minimize clinician documentation and decrease hospital extraction burdens.

Most notable is the simplification of the profusion exam which minimizes extraction, but provide also guidance to the clinician.

So in keeping with the mission of NQF, IHI, and the Institute of Medicine, we have identified a disease of high mortality and a performance gap.

We have also shown that improved outcomes are associated with improving measure performance. We believe that NQF 0500 will

continue to be a vital component of the national sepsis quality improvement efforts.

So on behalf of the measure stewards, Dr. Sean Townsend, Henry Ford Hospital, and I, we would like to thank NQF and CMS for its past support of this measure.

After 20 years of development we feel we have made significant strides and taken the best available science and converting it into improving sepsis outcomes. Thank you.

CO-CHAIR EISENBERG: Thank you. Are there any other comments that the representatives here would like to make?

(No audible response.)

CO-CHAIR EISENBERG: No. Are there any questions or comments from the committee members for the developer before we hand it over to our facilitators?

(No audible response.)

CO-CHAIR EISENBERG: No. If not, we have Emily Aaronson, Amesh Adalja, Esther Babady, and Donald Goldman. Take it away.

MEMBER GOLDMANN: I was asked by my colleagues to lead it off. I should have recognized the potential, I guess something to disclose, which is Sean Townsend has been in the past a, well once a faculty member always a faculty member, and the same for Mitch Levy, actually, so the degree to which my personal affection for those people leads me to be civil has yet to be determined.

(Laughter.)

MEMBER GOLDMANN: So basically there are two distinct aspects to this bundle, one of them to be completed within three hours and the rest to be completed with six hours.

And the three hours include measuring the initial lactate, drawing a blood culture prior to antibiotics, and administering broad spectrum or other antibiotics.

The rest of the three hours is to administer a crystalloid bolus for hypotension or lactate greater than four and then at six hours there are other things to be done, repeat the

lactate level, which I presume is for guidance.

It, in and of itself, of course, doesn't cure anything, but it's for guidance in the future I imagine, and then, also, to apply vasopressors, reassume volume status, and so forth.

And there is a point made that you can really assess volume status however you think is appropriate and all you have to do is do a test to it.

So that is the nature of the bundle. I do have one question. Can I ask a question about that now or should I -- So to the developers, I didn't understand the three hour for antibiotics.

I think a lot of literature says as soon as possible or within two hours and I wonder where the three hours came from and whether that is evidence-based, and then I also wanted to ask as to whether there are any balancing measures about inappropriate use of antibiotics?

DR. TOWNSEND: Hi, Don, it's Sean

Townsend. I am not worried about your affections for me overwhelming your comments regarding the measure.

My experience over time has been that you are very direct and very capable of telling me your concerns where they may come up.

That much being said let me address your question regarding antibiotics. Yes, there is actually very good literature that every hour counts and potentially every half hour if you look at some of the published literature, which was initially spearheaded by Anand Kumar, and we are quite aware of that and cognizant of that.

The three hour requirement is actually a property of the measure. We determined that given the nature of hospital operations the likelihood that hospitals can achieve the one hour mark is quite low.

I mean you have to imagine the patient arrives, they are seen at the triage desk, they are triaged, vitals are taken. If they are not brought back right away they wait for a bit in

the emergency department, then they are taken back by the bedside nurse who then has to do their own checkup on the patient, their own exam, and then the physician comes in, meanwhile the patient is getting into a gown, and then they go to x-ray.

These types of logistics in the hospital create a circumstance where even if we could do the ideal thing, getting antibiotics in within the first hour, the likelihood of success is awfully low.

So we agreed and tested this three hour measure, but the guidelines clearly state that the sooner the better with regard to the administration of antibiotics and we stand by that, it's just that we hold hospitals to a three hour measurement standard.

Your other question regarding balancing measures, as you know to submit a measure to NQF and to have it accepted for national adoption later on you have to have data in order to make your case.

And so things like antibiotic stewardship, well, highly, are very important, and, you know, mentioned in the 2016 guidelines repeatedly, and a foundational aspect of the work CMS is promoting along with the CDC are important things to exist alongside this measure.

The measure had no data internally to submit a measure such as antibiotic stewardship to go along with it.

MEMBER GOLDMANN: Great. And the developers offer a considerable amount of backup support for the effectiveness of the bundle in improving mortality and outcomes in general. And it led to a question that I had that I would like some elucidation. I'm going to turn to you guys a lot because if it wasn't clear to me in the submission, I think I should probably ask you so we can be clear.

The actual level of evidence in the table that's in this report varies from element to element, and for some of it the evidence is low or weak or doesn't have as a high a level.

So if you look at all of these elements which occur over time, is the level of evidence robust for all of them, and can we say every one of these is necessary for the bundle to be effective, or is the evidence -- I know the evidence is really good for early blood culture, I know it's really good for drawing the lactate to gut therapy, and I know you got to give fluid if somebody's going into shock, but what about some of these later elements, the reassessment, the vasopressors, the repeating lactate level? Is the level of evidence for that of the same type?

DR. TOWNSEND: It's Sean again. I think there's variation, as you point out. If you were to scroll down further on the page, there's an evidence rating where the preliminary assessment shows -- compared to the 2016 guidelines, the expert panel's rating there using the grade methodology for the evidence. And as you point out, they measure not only the quality of the evidence using the grade criteria, but

they also measure the recommendation of the panel is an aspect of the reporting under grade.

So in each case and I think right there you've got it, or just up a little bit. In each case, you see that the NQF staff have taken from the guidelines what the recommendations were on these aspects. Where there are low quality of evidence, especially around things like lactate or repeating lactate, that's the lowest -- ranked the lowest evidence and the lowest quality recommendation as a weak recommendation. Everything else gets a strong recommendation or it's a best practice statement, which is also a strong recommendation.

So I would say there's variation. It's been adjudicated independently by this expert panel and it's pretty much as listed here.

Manny, I don't know, you may have a different thought to say.

DR. RIVERS: No, I think we should point out that things like antibiotic administration, which is given a strong

recommendation, actually has a moderate level of evidence simply because you can't do a randomized prospective trial with plus or minus antibiotics. So I think a lot of it's limited by just basically best practice.

And if you look at the remainder, such as the profusion exam, there are multiple studies that show that they do add outcome benefit. Now there's not randomized prospective trials, but large case series, observational studies have shown that if you itemize each measure element, there is additive mortality reduction.

DR. TOWNSEND: And this is Sean again. I should disclose I was an author on these guidelines as well.

MEMBER GOLDMANN: So the developers present a review, the various studies have been done to show association between the application of one bundle or another. One thing you'll clarify for me, I hope, or for us is that not all those studies use exactly this bundle, I think, because it's evolved. But a number of studies

are quoted. The great majority of them are one form or another of a observational or prospective study. There's very little with a true counterfactual.

Do you think that it -- what is the application of this bundle that's before us today to those multiple studies and do you think they all can be recruited as evidence that this is the bundle we should adopt because it's -- works?

DR. TOWNSEND: This is Sean.

(Simultaneous speaking.)

DR. RIVERS: -- Rivers.

DR. TOWNSEND: Oh, go ahead, Manny.

DR. RIVERS: No, please go ahead.

DR. TOWNSEND: You go ahead, Manny.

DR. RIVERS: Oh, no, I think in principle all studies take the three-hour bundle almost exactly as it is. What the issue becomes is how to assess volume and profusion. And because of two -- the three recent trials: process, promise and arise, they all agreed with the three-hour measure was essentially the same,

the reassessment of volume and profusion status. Because multiple methodologies were done; i.e., usual care, we consolidated this aspect into multiple options for the clinician to use, but in general they all showed that a re-profusion assessment was additive in improving mortality. So essentially the bundles are all the same except that re-profusion aspect.

DR. TOWNSEND: And I would add onto that, if you don't mind. So it's -- I think it's really very important to recognize that, as regards septic shock at least, there are only four randomized control trials in literature which sort of govern the application of these principles to the care of sepsis patients, first Dr. Rivers' trial back in 2001. Then there were three trials that came out in 2014 and '15: process first, then promise and arise.

And what's very important I'd like to draw everybody's attention to is there's a condition of randomization in those three trials I mentioned. Patients received -- the first four

of these elements they had their -- they had a lactate checked, they received blood cultures before antibiotics were given, they got broad-spectrum antibiotics, and on average, if you look at the supplemental tables for those trials, they received 30 mLs per kilogram of fluid. That's before enrollment. So 100 percent compliance is what those patients had with those elements every time, which is pretty remarkable.

When it comes to these other questions later about applying vasopressors or how volume status was reassessed, we know that there was a high degree of reassessment of these patients because they were in a clinical trial. Bedside nurse, study nurse, ER physician, ICU physician monitoring those patients the entire time.

So we feel and we tried very hard in 2015 to -- when this measure was last up to make it perfectly compatible with those three new trials. And Don Yealy, the author of the process trial, worked with us at that time. And we came up with a solution, as Manny mentioned, which

included all these strategies to measure human dynamics. And we went forward with that. And I think when we reevaluated that strategy, we said, you know what, we should be more consistent with usual care and allow people to determine their own ways to reassess volume status and not require that measurement.

MEMBER AARONSON: So this is Emily Aaronson here. I just had a clarifying question based on what you just said. So just to clarify, when you say that patients received all those things prior to enrollment -- so does that mean that that's for folks that did not receive the fluids, for example, they then could not be enrolled or could not be enrolled in the intervention arm?

DR. TOWNSEND: That's right. I should have said prior to a randomization. I apologize. Yes, there was a requirement of entry to the process trial. Patients were initially required to have two liters of fluid -- was the number that they mentioned in the protocol. That was

later changed in subsequent years to simply one liter. But on average, if you look at what those patients received, it's close to 30 mL per kilogram.

MEMBER AARONSON: Okay. And does that raise any concern about sort of confounding by indication that the clinicians were making choices about who could handle that amount of fluid, and so not really true randomization? Just when we think about the level of evidence to support applying this to all comers, which is really what we're talking about with this measure.

DR. RIVERS: This is Manny Rivers. Number one, I want to make sure that people understand that in the process trial there were three different groups. There was a goal-directed, there was a usual care and then there was a modified goal-directed group. Even with the original bundle as it stands, it was compared against the other two groups and it was equal in terms of efficacy and mortality. So at minimum

the original measure as submitted showed to be as efficacious as any other delivery of care in that study.

So one thing, it was a confirmatory study that if you just did the original measure, you would have equal mortality reduction. However, they provided other methodology that would allow us to extend our profusion exam. So in essence it was a confirmatory trial of the original measure, meaning that sepsis mortality was less than 20 percent for all groups.

Now there may have been some other confounders such as patients were admitted to ICUs within two to three hours of hospital arrival, which is not the norm, but it's important to understand that that mortality reduction was the same in all the groups.

DR. TOWNSEND: And to your question, Emily; this is Sean again, I guess there could -- I think my clarification that I should have used the word "randomization" makes a difference, because the -- if the patients were enrolled in

the trial, they would only be excluded for whatever exclusions the trial accepted. And the -- and when I said prior to randomization patients received this amount of fluid, then that should get rid of that possible confounding by indication. In other words, you would -- unless you hypothesize that people looked at patients and said I'm not going to enroll you in the trial. And then -- but I can't tell you about the set of patients who didn't enroll. I just don't have any information.

CO-CHAIR EISENBERG: Okay. Are there other questions before Don continues? Yes, Jamie?

MEMBER RONEY: Hi, this is Jamie Roney from Texas, Dr. Townsend, and our paths cross again. I have a couple of questions for you guys.

One, Dr. Rivers, was your meta-analysis of the resuscitation bundle alone that included like 20,000 almost patients included to support this measure, because we can only discuss

evidence that was presented to us for consideration. But that meta-analysis, was it included?

DR. RIVERS: It was more of a -- you mean the evidence placed in the measure?

MEMBER RONEY: Yes, that you published on looking at resuscitation bundle a decade later.

DR. RIVERS: The analysis basically included all the literature, so personal studies that I may have done was not the essence of the meta-analysis, but it was an all-inclusive look at all studies, both observational, quasi-observational, randomized studies. So if there was included a meta-analysis that I did, this was not a reproduction of that. It was basically a comprehensive assessment of the literature as it stands.

MEMBER RONEY: Okay. I just wanted to be able to consider that since it was a higher level than even a randomized control trial because of the number of studies that you

included in that meta-analysis and the patient sample size.

My other question is regarding the six-hour piece of this new three-hour and six-hour bundle. Why do vasopressors and a second fluid bolus wait until a six-hour bundle? Is there really a need for a six-hour bundle, or could it all be lumped into a three-hour window?

DR. TOWNSEND: This is Sean. We've never studied requiring vasopressors at three hours. All the data we have is based upon the notion of within six hours of the time of presentation the patient, if they qualify for vasopressors, receive them. So it's difficult for me to say, Jamie, what the right thing to do there would be.

The evidence on vasopressors in general hasn't been based on the timing of giving those agents at six-hour or three-hour increments. So I don't see a lot of evidence in the literature to support it. And in terms of data to support the measure, I -- we wouldn't

have the data to advance a three-hour time frame.

DR. RIVERS: But there is data to show that the longer the duration of hypotension, the worse the mortality. So that cause and effect is definitely established in the literature.

MEMBER RONEY: Thank you.

MEMBER GOLDMANN: So we can probably move on. Just a couple of other clarifying things. As I looked at your review of evidence, a lot of what you use as experience to back up the effectiveness of the bundle -- and we'll get back to this when we talk about validity in some of the other studies you present. It has to do with trends in mortality due to sepsis over time. And I had some trouble; and I hope you can clarify this, really dis-aggregating the effect of the bundle from secular trends.

So what particularly puzzled me was on page 4 -- oh, it's a different page number that they'll have, isn't it?

These are figure 1 where you draw a line through a bunch of data points over -- from

a number of countries and over quite a period of time. And you say, look, there's been a decline in mortality over two decades. And to me you've drawn kind of a regression line through a bunch of plots. You've drawn a regression line through a bunch of data points without any reference to whether or not bundles are involved. I mean, it looks like mortality due to sepsis for one reason or another has gone down.

And that prompted me to look at the Keystone Project's work on sepsis where they couldn't distinguish better outcomes in those who participated in bundle implementation in arguably the best collaborative in the United States for getting results from the people who didn't participate in the exercise.

So how convinced are you that there's really an impact of this bundle or modifications thereof per se? I think you point out that most of the data is observational and that there isn't a counterfactual, that there are at least a half dozen potential biases involved including

confounding by indication. So what's your level of confidence?

DR. TOWNSEND: I think the question is well stated, Don. And the real question is what is the underlying secular trend and what -- why would that just be happening without any actual interventions in the real world influencing a decline in mortality due to the disease process of sepsis?

The Surviving Sepsis Campaign is a global phenomenon in each of the countries that are listed here: Australia, New Zealand, the U.K., the United States. There are robust arms of the Surviving Sepsis Campaign which has been promoting in one form or another all of the strategies listed in the current elements of this measure, plus others over time.

And so, it gets very difficult to tell you, well, absent the efforts of the Surviving Sepsis Campaign promoting these efforts throughout all of medicine in these industrialized countries, what would have

happened? That is a question that is nice to think about intellectually and impossible to answer in reality.

So instead we're forced into looking at, well, what happens when we apply sepsis bundles to patients? And I'll just point out I heard a comment earlier in the New York State call. There are over 40 observational trials that suggest sepsis bundles reduce mortality. There is not a single trial that says that they don't exist, that that doesn't happen. And so I was surprised by the comment that those studies don't exist or that they were counterfactual studies where they don't exist.

So it gets to be very difficult to answer your question because I can't speculate about what we don't know, which is what would have happened absent the Surviving Sepsis Campaign.

DR. RIVERS: And also I refer to you an article published in JAMA just last year. It was about new sepsis definitions. And

accompanying those articles was one about the sepsis mortality. And they actually did a meta-analysis in that study. And these were over 50 publications where they examined just as you see in the slide where you see the change in sepsis mortality, they found that the mortality 15 years ago was projected to be 46.5 percent, which is exactly the mortality in the original goal-directed study in 2001. And this was 15 years later. So with the same analysis they performed, that I performed submitted to you in this measure, they came up with the same mortality.

MEMBER GOLDMANN: Okay. So let's -- yes, I'm aware there are lots and lots of observational studies and none have been published with, as you say, different results. But I still think that you might want to -- I'm sure you have considered the effect of coding as shown in the Clompus study, the effect of just a general improvement in the understanding you're supposed to give people fluids and antibiotics.

And I just wonder if only fluids and

antibiotics had been given whether we'd still be -- there's kind of a -- this disconnect here between the miserable performance you talk about and the gap we're all trying to address and the rationale for this and the dramatic improvement monotonically over time --

CO-CHAIR EISENBERG: All right. So --

MEMBER GOLDMANN: -- in sepsis mortality. So --

(Simultaneous speaking.)

CO-CHAIR EISENBERG: Don --

MEMBER GOLDMANN: -- but let's move on.

CO-CHAIR EISENBERG: -- and others, could we move on from that point?

MEMBER GOLDMANN: Yes, that's it. I'm done.

CO-CHAIR EISENBERG: You're done? All right. What about other members of your facilitation team? Anything further for them to say?

MEMBER BABADY: Hi, this is Esther

Babady. I think for me the main -- not so much concern, but question I have for the measure is the fact that with the new guideline, to me there seemed to be some disconnect. And I know some of the presenter are also part of that guideline. And mainly in terms of the definition of sepsis and severe sepsis as it relate to this measure and what's in the new guideline, as well as the timing. I know we talked about the three-hour versus one-hour, but -- versus six-hour, but one-hour is also included in those guidelines. So when hospital tried to reconcile all of this, wouldn't that create some confusion?

DR. RIVERS: Can I chime in? This is Manny Rivers. One reason why you have a one and three-hour is simply because inpatient efficiency is much better than emergency department. So when you look at emergency department measures, they actually get a three-hour window simply because of the processing time of patients is -- are much different. An inpatient is usually a one-hour time frame because the care is more

expedient and obviously the patient familiarity is there. So that's one reason why you have the two different time points because it becomes very difficult for emergency department to actually process a patient and get antibiotics within less than three hours.

MEMBER BABADY: Is there some time of presentation or recognition or sepsis, because that's where -- where is sort of the -- when does the clock start?

DR. RIVERS: Recognition. We actually over time adopted it because the time of triaging can be anywhere from hours --

MEMBER BABADY: Hm-mm.

(Simultaneous speaking.)

DR. RIVERS: -- patient may not be processed quickly.

MEMBER BABADY: Okay. Because in the document I think I was reading it as presentation and I was worried about that. But that just needed clarification.

How about the definitions? Are we

changing those at all?

DR. RIVERS: Definition-wise, again a work in progress. If you go and look at perhaps the video that accompanied that article, they deemed it as a work in progress. There's what they call prospective validation of that sepsis definition. Just for instance, if you look at the definition for septic shock, they wanted to eliminate severe sepsis, so either you're septic or septic shock.

But what they didn't realize also is that patients with lactates greater than two would be considered septic shock, but 30 percent of patients in florid septic shock on vasopressors would never make a lactate of two. So in essence you will exclude 30 percent of patients with those new definitions. So they have to be re-calibrated once again and prospectively validated before they become standard.

DR. TOWNSEND: Yes, and this is Sean Townsend. I would just say as regard to the

definitions there are a number of difficulties applying the Sepsis III definitions, but the two largest hurdles that -- is put out there are: (1) ITD-9 -- rather 1TD-10 doesn't recognize that classification. So no hospital in the country could bill using Sepsis III definitions until such time that ITD-10 converts to those definitions. And that would be disastrous financially for hospitals.

Secondly, the purpose of using the existing definitions in Sep I or in NQF-0500 is that there is a long history of applying those definitions to patients, and it helps with early detection. So a number of trials suggested that if you use SIRS criteria, you're much more likely to detect a patient at an early stage, whereas the Sepsis III definitions favor much later detection. They are more specific. And so you detect people later in the disease process.

CO-CHAIR EISENBERG: Are there other comments or questions at this point from any of the Committee members?

(No audible response.)

CO-CHAIR EISENBERG: No? Okay. If not, Don, is there anything else that you or others would like to present regarding the evidence, or should we --

MEMBER GOLDMANN: I think we're all set. I did have -- just prompted to ask a minor question. Antibiotics are -- what are antibiotics in your definition?

DR. TOWNSEND: I think you're asking the question do we apply antifungals or antivirals as well to that category. Is that what you're asking, Don?

MEMBER GOLDMANN: Yes, I mean, if somebody came in with influenza and sepsis and didn't get antivirals, would that be adjudicated as not getting proper treatment within three hours?

DR. TOWNSEND: No, the measure looks at bacterial sepsis.

MEMBER GOLDMANN: But there is a mention of candidemia in some of the background

data and how important that is, so would amphotericin be required or acyclovir for herpes sepsis?

DR. TOWNSEND: The measure wouldn't measure -- if sepsis -- if the cause is determined to be fungal, then that would not be a part of the measure data set.

MEMBER GOLDMANN: Okay.

DR. TOWNSEND: If it's viral, it's not as well.

MEMBER GOLDMANN: Thanks.

MR. DICKERSON: Yes, and, Sean, if I could; this is Bob Dickerson from Telligen, that's one of the things -- when you're looking at infection criteria is patients with fungal or viral infections, those are disregarded. So if that's --

DR. TOWNSEND: And that should have been --

(Simultaneous speaking.)

MR. DICKERSON: -- infection, you would be excluded from the measure. I didn't see

that --

(Simultaneous speaking.)

DR. TOWNSEND: And if I may, I apologize; it's Sean, I should have introduced the -- because Manny and I aren't in the room, a couple of our colleagues who work closely with us on the measure are. Bob Dickerson is one and Dr. Tefera from CMS is there as well. And from time to time they may help us since we don't have feet on the ground.

MEMBER GOLDMANN: Yes, I must have missed the exclusion. Is it in the --

MR. DICKERSON: So it's not listed as an individual exclusion. Within the data element that identifies whether or not patients have severe sepsis, if the infection is identified as viral or fungal, you disregard that infection.

MEMBER GOLDMANN: Yes, so this is actually important. So very often, at least in my ICU, a patient without a positive culture, somebody will say it's viral sepsis. That's how it will be coded. So all those patients are out,

correct?

DR. TOWNSEND: That's right.

MEMBER GOLDMANN: Okay. Is that good or bad? I'm not sure.

DR. TOWNSEND: Well, yes, that's a good question, Don. And I think what I hope is that there's a bleed-over effect, that the -- at the level at the ground the provider doesn't have the capacity to measure in their head all the three-hour and six-hour elements, but they know they're treating sepsis. And for the most part, I suspect, that if they followed this algorithm even for viral sepsis, as long as they provided acyclovir for herpes, for example, in the place of using ceftriaxone or something, the other pieces of the algorithm are still very important. And I hope that just by osmosis essentially they're used to this strategy.

DR. TEFERA: Yes, this is Lemeneh Tefera from CMS. Since we're talking about antibiotic selection, I also wanted to call out that we recently changed the specification manual

to allow for more directed antibiotic choice. In the initial measure it was a broad-spectrum choice that allowed the case to proceed, but in our recent update if a clinician can document both a culture and sensitivities, then the clinician can choose an antibiotic that they have evidence works for the cause of the sepsis, and that will pass the case.

And it is important for the broader question I think that was raised earlier about antibiotic stewardship and not having the unintentional impact of promoting too aggressive use of broad-spectrum antibiotics. And we're pleased with that, with our recent change.

DR. RIVERS: And also I just wanted to add that --

MEMBER GOLDMANN: We'll come back to this later under another section, but let's -- before we forget. So if a chart abstractor is looking at a chart and it says sepsis, no organism specified, is that in or out?

DR. RIVERS: This is Manny Rivers.

You have to look at the nature of our diagnostics. Number one, 30 percent of all septic shock patients will have negative cultures. So many times your therapy is empiric simply because -- whether you get sputum, blood, urine, etcetera, just the fact that patients will be culture-negative -- and they have the same mortality actually as a patient who's culture-positive.

Over the last year there's been two developments: There is procalcitonin that's become FDA-approved, which has been shown to have a decrease in antibiotic use of about four percent in a recent article in JAMA. That will aid in terms of antibiotic stewardship. And there's also some PCR-based technologies that will actually tell us whether you're bacteremic within one-and-a-half hours of presentation.

So I think as we evolve and accommodate more developments, that will aid our diagnostics as well as therapeutic interventions. I think that's just the fluidity of how sepsis

is, but I think we're in some --

(Simultaneous speaking.)

MEMBER GOLDMANN: Yes, and that's fine. I'm just trying to settle on what the denominator and numerator are, but that --

DR. RIVERS: Yes.

MEMBER GOLDMANN: We can probably move on.

DR. TOWNSEND: No, but, Don, let me answer your question. I can be very specific.

So, yes, sepsis not otherwise specified would be caught as -- initially as one of the coded diagnoses that could qualify for the measure. Very important for the Committee to understand. Sep I does not base its whole denominator on coded data. There's a review for whether severe sepsis or septic shock is present based upon criteria specific for the measure that determines the denominator. It's not simply the coded population.

MEMBER GOLDMANN: Okay. Great.

CO-CHAIR EISENBERG: Are there other

questions for the developers? If not, this is a maintenance measure. It's been endorsed already, which means that we don't necessarily have to vote on evidence, but we can if any Committee members want us to.

Are there any Committee members that would like us to vote on the evidence? Okay. We've got one.

MEMBER AARONSON: This is Emily. I'm just wondering if we don't vote on the evidence, does that preclude us from continuing on to look at validity and reliability?

CO-CHAIR EISENBERG: No. No, it's simply on the evidence.

MEMBER AARONSON: That's helpful. Thank you.

CO-CHAIR EISENBERG: Okay? And we will go -- we will be voting on the evidence, because there is one Committee member that wants to. Okay?

So, Mauricio, are we ready to move ahead with that?

MR. MENENDEZ: Ready to go. For Measure 0500 for evidence, please vote now. One for high; two for moderate; three for low; four for insufficient.

(Voting.)

MR. MENENDEZ: Okay. Voting is now closed. The final count is 27 percent for high; 60 percent for moderate; 0 percent for low; 13 percent for insufficient. Final verdict of pass.

CO-CHAIR EISENBERG: Very good. Thank you, Mauricio.

Okay. Let's move forward then and talk about gaps in care and opportunities for improvement, please.

MEMBER GOLDMANN: Yes, so I think there's a lot of evidence presented here that there's a gap. I don't know that we need to spend a whole lot of time on this. Abundant data based on experience so far shows that not only is there a general gap in the country, but there's a lot of variation including some variation in stratified data by race, ethnicity and so forth.

So I don't know that we -- I don't have any particular problems with that. Anybody else have questions?

MEMBER RONEY: I would just like to have a comment on the record that we definitely see gaps in clinical practice of use of these measures for whatever reason. It's been decades that these guys have worked to get these implemented in our hospitals and yet we still see lack of implementation.

CO-CHAIR EISENBERG: Any other comments or questions?

(No audible response.)

CO-CHAIR EISENBERG: If not --

MR. MENENDEZ: Voting is now open for Measure 0500 for performance gap. Vote one for high; two for moderate; three for low; four for insufficient.

(Voting.)

MR. MENENDEZ: Voting is now closed. The final verdict is -- or sorry, the final count is 93 percent high; 0 percent moderate; 7 percent

low; 0 percent insufficient. Final verdict is pass.

CO-CHAIR EISENBERG: Thank you.

Now the next section is something that we haven't done yet, at least at this Committee meeting, and that is to evaluate the composite quality construct and rationale. Let me read to you what that means.

"The quality construct and rationale should be explicitly articulated and logical. A description of how the aggregation and weighting of the components is consistent with the quality construct and rationale also should be explicitly articulated and logical."

So let me ask our facilitators to tell us what they can about that.

MEMBER GOLDMANN: Well, I'd like to either let my colleagues weigh in or ask the developers to comment on why -- specifically why we need to have all these elements in two different time periods in a single put-together measure. It wasn't clear. I have the sense that

they're weighted actually quite differently in terms of evidence versus people saying it's a good idea and in terms of the time in which they're administered. So I'd love to hear a little bit more about that, because it -- I couldn't get my arms really around it, to be honest.

DR. TOWNSEND: So this Sean. I'll take a stab at that.

Our -- the reason we chose an all-or-nothing measure for sepsis care was it actually emerged out of the Institute for Healthcare Improvement, circa 2004, where all-or-nothing measurement became all the rage, to say the least. And this -- the IHI and the Surviving Sepsis Campaign banded together and developed sepsis bundles as an all-or-nothing measure with equal weight at that time.

There's a sense and logic to it beyond just being the same time and place as when this was a popular idea. Here in the case of this diagnosis it spans two degrees -- two different

diagnoses, really. Severe sepsis and septic shock are elements that qualify for -- or both diagnoses qualify for this measure. And the measure is constructed so that they are -- there are dependencies both in time and then qualifying for one component based upon them qualifying for a prior component.

And so the best example here would be the fluid requirements. Patients are required to receive fluids only if two things are -- two criterion are met: that they're hypotensive or the lactate that was required in number one, the first part of the numerator statement, came back greater than four. Otherwise, patients don't qualify for that part of Sep I or NQF-0500, and they can pass through without receiving fluids.

Likewise, for vasopressors patients are required to get vasopressors if they remain hypotensive after getting that fluid challenge. So there's another dependency there. So there's an internal dependency of each piece of the next, and it really reflects in many ways the severity

of the illness that the patient has.

CO-CHAIR EISENBERG: Good. Thank --

DR. TOWNSEND: They don't all apply. So the right answer I guess to say is this: If a patient doesn't qualify for vasopressors or doesn't qualify for fluids, they still pass Sep I --

CO-CHAIR EISENBERG: Thank you very much.

DR. TOWNSEND: -- without -- yes.

CO-CHAIR EISENBERG: Piero?

MEMBER GARZARO: Yes, I have a question. At any point did you mention having read the whole documents, let's start out with that-- but at any point do you mention or comment on all the conditions that could cause an elevated lactate that are not related at all to sepsis? Because I see, at least in my hospital, the lactate level has become equivalent of the gold standard. If the lactate level accelerated, the patient must be septic, therefore they may need to get vancomycin irrespective of what they

had. Either they are crushing chest pains or have liver failure. So do you account for those elements?

DR. RIVERS: This is Manny Rivers. One thing that lactate is is it's a risk stratifier. It does not diagnose sepsis. So it is an adjunct to help the clinician look at how -- or decide illness severity. So a stand-up lactate alone, you can have asthma, metformin use, vitamin deficiency. These are all things that can cause lactic acidosis. However, in the presence of suspected infection along with lactate, that is the risk stratification piece of why we use lactate. So a stand-alone. It is not a diagnostic criteria for sepsis.

DR. TOWNSEND: And to further help you with that, we permit the provider to say this is not sepsis if they don't believe this is sepsis, and the abstraction of the chart stops at that point. So there is a mechanism by which a provider can just simply say, yes, lactate 7, but this is not sepsis.

MR. DICKERSON: And if could add -- this is Bob, if I could add one more thing. There are -- there is guidance within the specifications that if a sign of organ dysfunction is identified as being due to something -- say for example a chronic condition or something other than infection, then you would disregard that value. So an example may be an elevated creatinine and they've documented the patient he has chronic kidney disease.

MEMBER AARONSON: This is Emily here. So that question I know has come up just in our work group offline, and so just wanted to raise it here. And perhaps this is better discussed in validity. But that piece exactly around the determination of if organ dysfunction is new or not, I'm concerned that that requires abstractors, many of whom are not clinical -- clinicians themselves, to make a clinical determination. How do you all sort of navigate that piece around having abstractors determining what the delta is for new organ dysfunction which

may be superimposed on a chronic condition?

DR. TOWNSEND: So a good example here; this is Sean Townsend, would be chronic kidney disease again. There are criteria that the measure lays out that there needs to be an increase in creatinine above the baseline of a certain amount to qualify in chronic kidney disease for an organ dysfunction. And so, one answer to your question is that there are criteria available.

The other answer is that the onus should not be on the abstractor. The onus is on the provider to declare whether there is an acute and chronic condition that's occurring. And if there -- if they say it's a chronic condition and not acute, again that -- the patient will not be considered part of the measure.

CO-CHAIR EISENBERG: Any other comments or questions regarding the rating for composite quality construct and rationale?

(No audible response.)

CO-CHAIR EISENBERG: If not, I think

it's time to vote.

MR. MENENDEZ: Voting for 0500 composite is now open. Vote one for high; two for moderate; three for low; four for insufficient.

(Voting.)

MR. MENENDEZ: Rocco, can you please place your vote?

CO-CHAIR EISENBERG: Jeff, are you voting on this one?

(No audible response.)

MR. MENENDEZ: Okay. Voting is now closed. The final count is 33 percent high; 47 percent moderate; 7 percent low; 13 percent insufficient. Final verdict of pass.

CO-CHAIR EISENBERG: Thank you. Let's move onto reliability.

MEMBER GOLDMANN: So this was done back in 2012, if I understand correctly. And we've already talked before about the statistics of signaling the noise ratio, which very few of us in the room truly understand, but it looks

good. It's in the 90s and it seemed pretty clear. So, but others on this group may have comments.

CO-CHAIR EISENBERG: Are there any other comments or questions about reliability?

(No audible response.)

CO-CHAIR EISENBERG: All right. Are we -- let's move onto a vote.

MR. MENENDEZ: Voting for 0500 reliability is now open. Vote one for high; two for moderate; three for low; four for insufficient.

(Voting.)

MR. MENENDEZ: Voting is now closed. Final result is 47 percent high; 47 percent moderate; 0 percent low; 7 percent insufficient. Final verdict of pass.

CO-CHAIR EISENBERG: Thank you. Let's move onto validity testing.

MEMBER GOLDMANN: So there was an analysis done on some enormous number of records. I think it was done by CMS. Was it done by CMS?

(No audible response.)

MEMBER GOLDMANN: And certain associations and conclusions were drawn about the fact that those patients who had successful completion of the bundle had a lower mortality, substantially lower mortality actually than those who failed the bundle. I think those were the words, in quotes, "failed the bundle."

So to be honest, without access to the primary data and the model and the methods used I can't evaluate this. It's -- I -- what I appreciate is, I think we'd all appreciate is a discussion of the forms of biases you think may be involved, the explicit way in which variables were entered into the model, confounding was adjusted for. Was there any thought of indication bias? Just as it stands it's just another observational study like the women's health study that --

DR. TOWNSEND: Could you articulate your problems with the women's health study? That was a joke.

MEMBER GOLDMANN: I'm just thinking about --

(Laughter.)

(Simultaneous speaking.)

MEMBER GOLDMANN: -- at risk for significant myocardial and cerebrovascular events for years. There was an observational study that apparently was not backed up by a clinical trial. So, and here I think the risk is potentially higher in some ways in terms of the nature of the data. So I'd like to hear defense of this --

DR. TOWNSEND: Sure.

MEMBER GOLDMANN: -- particular approach.

DR. TOWNSEND: Sure. Well, I don't want to defend it. I'd rather describe it.

Did I hear Emily? Did somebody have a question?

MEMBER AARONSON: Yes, sorry. I guess just to add to our sort of initial -- We're going to ask you questions and have you reply. I just want to be sure that you have sort of all of our

questions available.

I think from the validity perspective, just to share with those in the group that are not in our work group and maybe haven't gone through all of the materials in detail, I think the piece that was really helpful that we received in Section 2B.2.2 of the data sheet that described the measure was the 303 cases which were selected randomly to be validated.

And I guess the concern around validity that I have that I'd be interested in hearing more about is that from that analysis 73, or 72.7 percent of those data elements did not reach sufficient levels to be deemed sort of acceptable. They were below that 90 percent threshold.

And I know that there's a hypothesis which is presented in this document, which is that -- acknowledging that it's fairly low agreement -- but that since the time that this data has been collected there's been lots of clarification provided to abstractors, and the

hypothesis is that since that clarification has been provided to the abstractors and since the measure itself has been streamlined, that the validity -- we would expect to be much higher at this point. But I guess it's just a little concerning in my mind that we don't have that data available and that the data we do have available suggests that actually the validity is quite low in looking at the cases that were reviewed in detail.

DR. TOWNSEND: So --

MS. MARINELARENA: Sean --

DR. TOWNSEND: It's Sean. Go ahead.

MS. MARINELARENA: Hey, Sean, this is Melissa. Do you mind if I just quickly describe what is required from NQF and then I'll let you talk about the data that is provided? Is that okay?

DR. TOWNSEND: Sure.

MS. MARINELARENA: Okay. So what the updated data that we got from the measure developers; and I'm going to talk about what --

this is a composite. So for a composite we require different testing. And for this at maintenance we require measure score validity testing.

Now CMS does do the data element validity testing, but that's at the patient level. We want it at the measure score at the facility level. So it's interesting to look at the data elements, but that's not what we require for a composite measure. And I quote it here. And this link will actually take you -- if you look on page 11, the link that says "NQF Composite Performance Measure Evaluation Guidance 2013" will take you to our report.

That states that, "Validity testing is directed toward the inferences that can be made about accountable entities on the basis of their performance measure scores. For the purposes of endorsing composite performance measures, validity testing of the constructed composite performance measure score is more important than validity testing of the component measures. Even

if the individual component measures are valid, the aggregation and weighting rules for constructing a composite could result in a score that is not actually a reflection of quality."

So I just want to let you know that that -- it's a different requirement for a composite measure for validity. So we're looking at the measure score.

DR. TOWNSEND: So this is Sean Townsend. So with Melissa's remarks we were aware when we submitted the measure. And there were two different questions. I heard a question about the data element information that was presented and a separate question about the mortality analysis. And I'll try to handle those in turn starting with the last question first regarding the data elements pieces.

So we're aware that the appropriate testing was at the performance measure score, not the data element score. At the same time, we wanted to provide some insight into the performance that we had assessed on the data

element level for purposes of full disclosure. And we do advance the position that the measure has gone through a stabilization phase.

And the first four revisions of the measure; they happened in each quarter performance, had substantial changes to the data elements as they were written. And this would by nature lead to some degree of confusion among the abstractors who had to abstract those data elements. And we believe that the differences that you're seeing at the data element level are attributable to the changes we were making as the measure unrolled.

As you may be very well aware, this is the most complicated measure that has been in the IQR to date. And so the specifications were quite broad as they were taken from its initial conception into its application nationally. And in some ways the hospitals drive that themselves because they pose questions to quality and say what happens in this circumstance and what happens in that circumstance? And then the

answers are aggregated and then we update the specifications in response to that type of questioning.

So you do see some variation at the data element level, which has caused us to suppress the measure for benchmarking purposes. So there is no benchmarking data available to hospitals with regard to Sep I until such time we're convinced that there's stability at that level.

That said, at the performance measure score level, which as Melissa pointed out, is appropriate for assessing the validity of a composite measure, the roll-up of all those elements suggests that there is tight correlation with the observed mortality of the patients in the data set.

And so, at that level of testing we show a couple different ways we demonstrate reduction in mortality. The first method is just a straight comparison of those who passed the measure versus those who failed the measure,

looking at mortality of those patients up to 30 days post-discharge. And there it's a 1.36 to 1.41 difference overall risk ratio in mortality if you pass the elements versus if you were to fail them.

But then we thought, well, at the performance measure score, which is the appropriate testing, we ought to also break down, well, what happens at percentiles of performance? Can we show that there's correlation at each level of change? So if you perform at 20 percent, what's your mortality? If you perform at 30 percent, what's your mortality? If you perform at 70 percent, what's your mortality?

And we provide that information as well, demonstrating that in the majority of changes between deciles of performance and compliance there are statistically significant correlations and drop in mortality.

So ask me questions about that, but that's the general overview.

MEMBER AARONSON: That's very helpful.

Thank you.

DR. TOWNSEND: In the absence of further questions I just would say that the mortality analysis that -- there was a specific question about that, and if I didn't answer it in full, please ask me further questions.

MEMBER GOLDMANN: It's a question about the statistical analysis and how it dealt with bias and confounding that often makes these kinds of things problematic.

DR. TOWNSEND: Well, which biases would you be thinking of, Don?

MEMBER GOLDMANN: That's for you to tell me. I'm not going to coach you on bias and confounding. If you guys don't know what biases are in play, then I'm really worried.

CO-CHAIR EISENBERG: So I think can we move forward at this time or are there still unanswered questions that we'd like to address?

MEMBER GOLDMANN: I think that the developers who did a statistical analysis that claims robust association mortality should be

able to tell us how they controlled -- what they did what they thought were biases and what they did was confounding, and whether there's residual confounding and bias that could account for these results, which are pivotal results. I mean, if they are, quote/unquote, "real," then this is a terrific thing.

DR. TOWNSEND: So I'll be glad to answer this, Don. It's very -- the analysis is an analysis that you're very familiar with, the type of work that we've both done at the Institute for Healthcare Improvement together.

We simply took all-or-nothing compliance and we said for all comers that applied to -- this measure applied to them, if you pass Sep 1, what was the mortality in that group? And if you failed it, what was mortality in that group? And then you see the results here. So it's raw mortality and there's no risk adjustment involved in this.

The measure in some ways self-stratifies in terms of risk of illness. And I've

alluded to this previously. You don't qualify for certain elements if you're less ill and you qualify for more complex elements if you're in shock, for example, versus severe sepsis. So you get vasopressors or repeat profusion assessment, or the fluid bolus for that matter. Each of those things are -- they're clinical data upon which you qualify. So severity of illness is dealt with by the nature of the dependencies themselves.

MEMBER GOLDMANN: Yes, I -- well, first of all, the Institute of Healthcare Improvement has never done a multi-variable analysis on anything, but -- so I actually -- so basically did not make an effort to control for confounding or for confounding by indication or by why some people were prone to get the bundle, some weren't. So basically this is a crude bivariate analysis of association, right?

DR. TOWNSEND: That's essentially right. And my recollection of the measurement that we incurred at hospitals was very similar to

this.

MEMBER GOLDMANN: Okay. I just want to for the record be clear, because it influences the weight in which I put on this study.

DR. RIVERS: This is Manny Rivers.

CO-CHAIR EISENBERG: Are there -- oh, go ahead.

DR. RIVERS: Yes, if you look at --

(Simultaneous speaking.)

CO-CHAIR EISENBERG: I'm sorry, we can barely hear you.

DR. RIVERS: Oh, I'm sorry. If you look at figure 2 -- we supplied this on page 40. If you look at all the trials; and this is combination of experimental, randomized, et cetera, the mortality reduction of 25 percent is almost identical to the literature. So there is not a great deviation from what we've seen from an historical examination of the literature. And this is almost identical.

DR. TOWNSEND: This is Sean again. And I would just add here that it's very easy to

say, well, hypothetically maybe this could have happened, didn't it? But in fact, there is just nothing but a dearth of evidence to suggest that acting on the measure and complying with it does not reduce mortality. There's simply no evidence to that effect.

And so while we could speculate about things were uncontrolled or perhaps confounded the analysis, we see no evidence that that's what's happening.

(Pause.)

CO-CHAIR EISENBERG: There seems to be a break in the action. Does that mean our questions have been answered to whatever degree of satisfaction --

(Simultaneous speaking.)

MEMBER GOLDMANN: All I'm doing is I'm talking about the data that's sitting right in front of us, not about the vast number of studies and all the weight of evidence. Obviously all that stuff influences your degree of confidence in whether or not there's a true association.

And I don't think we need to do some sort of a publication bias analysis and all that kind of stuff. I mean, there's a lot of stuff out there. But I'm just pointing out this is a rigorous committee, and what you presented here is not a rigorous study. So that's the only point.

CO-CHAIR EISENBERG: Okay. So noted. Thank you. But I think at this point we've gotten as much information from the developers as we're going to get on that particular question.

DR. TOWNSEND: I do have one more remark, actually. Enrolling this many patients in the type of simple analysis that I've described and compliance versus non-compliance associated with mortality is unheard of in the course of three quarters of data. And so, the likelihood that the difference in the two statistics being described by some confounding element is extraordinarily low at this degree of enrollment.

MEMBER GOLDMANN: Can we cut this debate off? I think the last thing you want to

do is challenge me on this. So let's just cut it and do a vote.

CO-CHAIR EISENBERG: Okay, so this is Woody Eisenberg and I think that it's a good idea for us to cut off the debate on that particular issue but I do have to ask the committee members if there is any other comments or questions that they would like to raise.

Any on the phone?

MEMBER LEWIS: No, I don't have any.

CO-CHAIR EISENBERG: Okay, if not, Mauricio, can we move ahead?

MR. MENENDEZ: So for 0500, validity, voting is now open. Vote 1 for high; 2 for moderate; 3 for low; 4 for insufficient.

Voting is now closed. The final count is zero percent high; 73 percent moderate; 7 percent low; 20 percent insufficient. Final verdict is pass.

CO-CHAIR EISENBERG: Very good. Thank you.

So, at this point, we are going to

move on to feasibility, which again, is a little bit different because we've got a composite measure. So, I -- I'm sorry, what was that? Oh, I'm sorry. I've skipped a spot -- a portion of our responsibilities here.

So we're moving on to analysis to support composite construction. Thank you.

Does the facilitating team have any comments on it?

MEMBER GOLDMANN: Any one of my colleagues can lead; kind of lay it out here. Yes, why don't you take a crack at it?

MEMBER ADALJA: So for 2(d) for the composite, the empirical analysis should demonstrate that the component measures add value to the composite and the aggregation of weighting rules are consistent with the quality.

And then they have an analysis showing a demonstration of each component to the composite score, the three-hour and six-hour measures. And they have, they breakdown repeat volume and profusion into a focused exam in

hemodynamic elements that are no longer -- that's no longer required and they don't have any data on the new attestation strategy, where you just have to say that you have done this.

And then there is a little chart below there that I think is kind of helpful to show you what the three-hour and six-hour elements are to catalogue -- to catalogue what goes on in the bundle itself.

So I think then the question is whether or not these components add value to the composite measure. And I think there's a lot of discussion in general about unbundling the bundle and which are the most important and which ones aren't. And clearly, some of them are linked to each other and dependent upon each other and fit the criteria for a component but there is some debate that goes on regarding unbundling the bundle.

But I don't have anything else specific to say.

CO-CHAIR EISENBERG: Thank you. Any

other comments or questions?

Okay, if not I think we're moving ahead.

MEMBER GOLDMANN: I just have one question. I note there was a note that there's no -- that this is not yet suitable for an electronic measure. And does that come here or do we do that under usability?

MS. MARINELARENA: That's under feasibility. This is just the composite construct. So you're looking how each of the data elements -- how each of the elements contribute to the overall composite.

MEMBER GOLDMANN: Okay.

MS. MARINELARENA: Usually, we're looking to make sure that none of the elements are top-tottered or covering up anything. That's what we're looking for.

MEMBER GOLDMANN: All right.

MR. MENENDEZ: Okay, voting for 0500, 2(d) composite is now open. Vote 1 for high; 2 for moderate; 3 for low; 4 for insufficient.

Voting is now closed. The final count is 7 percent high; 67 percent moderate; 13 percent low; 13 percent insufficient. Final verdict of that is pass.

(Simultaneous speaking.)

CO-CHAIR EISENBERG: Very good. Thank you.

Could I ask those of you on the phone who aren't speaking as part of the meeting to put yourselves on mute, please?

And now --

MEMBER GOLDMANN: Could I ask a procedural question?

CO-CHAIR EISENBERG: Yes.

MEMBER GOLDMANN: When this goes forward for whatever use, others may consider, do they know the vote or do they just say it passed? Because that's an unusually divided vote.

MS. MARINELARENA: Well, we will, when we summarize it, we do, we list out the number of votes. And it's actually we look at the high -- the combination of high and moderate. We had 7

percent for high and 67 percent for moderate. So we take -- we are actually looking at the combination of the two. So that's well above our threshold for passing. It was split between low and insufficient at 13 percent.

So, it's not --

MEMBER GOLDMANN: So nobody -- so they'll just say it passed and then --

MS. MARINELARENA: No, no, no, we write it out in the report.

MEMBER GOLDMANN: Oh, okay.

MS. MARINELARENA: We list it by individual vote.

MEMBER GOLDMANN: Because I think it's important that people know when there's division of opinion.

MS. MARINELARENA: If it was closer, we were -- if it goes into the gray zone, the consensus not reached, then we definitely say that. For a criteria that is must-pass, we say that and then we continue voting. This is not even close. So we say we pass it; now we can

move on.

But when we write out the report and we give a summary to CMS, we list out number and percentages.

MEMBER GOLDMANN: That's great. Thank you.

CO-CHAIR EISENBERG: Okay, are we ready to move on?

So now we're going to be looking at the -- I'm sorry. Further comments? No, okay.

Then let's move on to look at feasibility of the measure.

MEMBER ADALJA: So next is feasibility, the extent to which specifications include measure logic or prior data that are readily available that could be captured without unique burden.

Here, this is -- they talk about data elements are abstracted from a record and you think -- if you look at some of our committee pre-evaluation comments, a lot of them I think have already been addressed because the fact that

the attestation doesn't have to -- it's not something that is a date. It comes really from the burden on the abstract. The burden is on the provider for this. So I think most of that has been already talked about and addressed with regard to the feasibility of this measure.

CO-CHAIR EISENBERG: Now, it's been talked about and the conversation was what? I'm sorry I don't remember.

MEMBER ADALJA: And so we talked about the fact that the burden on the abstract is in -- the developers had talked about the fact that this is -- the burden is actually on the care provider to do this. It's not the abstractor that has to go rooting around looking for the diagnosis of sepsis or new organ dysfunction, that type of stuff. It should all be acute versus chronic and that it should all be already available in what they're doing. It's not -- the burden isn't on the abstractor to extract that -- to make that diagnosis.

And the other point is that some of

the stuff, there is some comments that came out earlier in the call we talked about the fact that extensive documentation of parameters that do not currently exist in discrete fields, such as bedside, cardiovascular ultrasound, passive leg raise and I think that's been addressed, as we've emphasized earlier, that this requires an attestation, rather than actual enumeration of which measure is being used for reassessment.

CO-CHAIR EISENBERG: Jamie.

MEMBER RONEY: I would like to say that from somebody that does these chart abstractions, that it is not very easily done, even for somebody at the doctoral level clinician. And to find the fluid resuscitation and determine appropriate antibiotic, especially based on Biograms and I'm well aware of our Biograms in my area and I'm still determining whether they got the appropriate antibiotic.

So, it's important but difficult for us to do and it's been almost impossible to capture fluid resuscitation electronically in the

EHR.

MEMBER GOLDMANN: I actually have a question. Maybe the developer can help with this.

Do we have any idea, based on all the work that's been done, the tens of thousands of records, what a 600-bed teaching hospital would have to put in in terms of FTEs to collect the data?

DR. TOWNSEND: This is Sean Townsend. I don't actually -- I can't directly answer your question. I don't know how much effort -- well, actually, since I am a 600-bed teaching hospital in San Francisco and I run the abstraction at this hospital, I can tell you how many people we have dedicated. I have 12 FTE abstractors in my department and four of them work on this measure but they don't exclusively work on this measure.

So for an n of 1 and an anecdote from one of the measure developers' hospitals, that's the best answer I can give but I --

MEMBER GOLDMANN: Well -- go ahead.

Sorry.

DR. TOWNSEND: What I like to remind people of is we talk about the burden of collection. You have to compare that to the burden of the disease that we're working with.

And here, as Dr. Rivers points out in the beginning with the largest number of inpatient deaths in the country was disease process or people are eight times more likely to die from this disease than other diseases in the hospital, or the fifth largest number of hospital days are attributed to sepsis, the dedication of resources to this disease, this is sort of a minimum of what we ought to be doing.

MEMBER GOLDMANN: You know, so have there been actual, even with your own staff, interviews with people who do this work to ask them how this fits into their flow, what it's like to -- I didn't find any qualitative inquiry or ethnographic inquiry about the burden of data collection on the institutions, the opportunity costs. I mean this is very important. Everybody

thinks this is very important. I, above all people, know that but everybody thinks their measure is important.

And I'm just trying to understand what it means to put this -- and there are some judgments here which I think makes it a little bit more difficult about antibiotics, about attestation, and somebody's got to attest, and is that really an attestation. So people are making judgments. They've got to be trained. And I'm kind of -- I don't understand what the national burden would be if every hospital had to do this, even compared to the impact that a little bit better compliance from the quality improvement activities that would result would be.

(Simultaneous speaking.)

DR. RIVERS: Yes, I'm at Henry Ford. We have almost a thousand -- well, 850-bed hospital. We average about 60 sepsis cases a month. We have pretty much a 1 FTE and we've been maintaining our database for over eight to nine years.

But electronic health records, we were able to basically create an abstraction segment that basically collects the data from medical record into one chart and that chart is actually read by our data collectors.

So with electronic health records, it's easy to program -- not easy but that is to say that you can program these healthcare records to abstract this data from certain fields, which actually aids abstraction. So, we're able to accomplish 50 to 60 cases a month with one FTE.

DR. TOWNSEND: This is Sean. I would just -- what I would say here is that the information we've provided is that of the 3,000 hospitals to whom this measure applies, each of them in three quarters have been able to report cases, 99 percent of those hospitals in each of three quarters has been able to do this work.

So as an empiric matter, it is feasible and there's little question about that.

The burden of it, it may be substantial but the burden of this disease is

justifying that degree of effort.

DR. TEFERA: And this is Lemeneh Tefera from CMS.

So we do get regular feedback from hospitals and hospital abstractors. And it's certainly a true statement that when the measure initially debuted in the Inpatient Quality Reporting Program, there were a lot of challenges for abstractors. Those challenges were communicated to us and part of the issues related to the validity of the measure is always this ongoing reassessment refinement of the measure from quarter to quarter. We think that the current version, Version 5.2, will be a stable and plateau version. In the last three specifications, there were significant changes and with direct feedback from hospitals to decrease the challenges for their abstractors. And we received the feedback that subsequent to those changes, that abstraction has been more fluid. And our results show that performance has been increasing for the various data elements and

the various bundles and we hope that trend continues.

MEMBER GOLDMANN: And in your opinion or the opinion of others, if the -- and I know we can't do this ad hoc here but if the elements that require adjudication by a chart abstractor as to whether or not something was appropriate or truly whatever, as opposed to was lactate drawn, was antibiotics given, was fluid given, which is probably extractable by other means, do you think that would eviscerate the bundle and, therefore, we would not make any dent in the problem?

DR. TEFERA: This is Lemeneh Tefera. The specification, as written, doesn't really provide the abstractor the opportunity to adjudicate. It's sufficiently precise, where we think the abstractor will be able to determine the clinician's actions and appropriately categorize the case.

I think the most recent changes have focused on decreasing clinician charting requirements. So today, clinicians don't feel

overly burdened to have to be hypervigilant about what they're writing.

So the current specification in the next version we think will continue to drive the improvement we seek without being overly challenging.

MEMBER GOLDMANN: Just -- go ahead.

MS. MARINELARENA: If it's helpful, CMS offers a free tool. Every hospital uses different software. I worked at Cedars-Sinai and we used Midas.

But I went and pulled the free tool that CMS offers off of qualitynet.org, which is the cart tool, and pulled the questions off for this measure. And it's literally you know -- and it asks did the patient receive this. If so, at what date. If it's helpful, I can send that to the committee, if you want to see how this is actually -- how CMS implements the measure.

MEMBER GOLDMANN: I've actually been through some of those algorithms and the aids that you get to do it. So I do get that.

This is just a quick narrative because narratives are powerful. In our hospital we have certain highly structured and very much supported by the CEO clinical pathways, some of which are required for reporting, although in pediatrics there is less of that. And I can tell you that residents are hounded that they did not check the box of whatever it was when they're on their 18th hour and the patient is sick with status epileptic. It's right in front of them and somebody's hounding them because they didn't put that down, the attestation and, therefore, the hospital is going to get penalized.

And so all of this, all we hear, all I hear is people at every level of hospital saying not on us. It's too much. I just can't take anymore.

So this may be the most important measure ever but in terms of its impact, I just think we need to really hitch up our pants and say this has real impact; we'd better be darn sure about this one.

MEMBER ORLANDO: This is Rocco Orlando and I emphasize that point about the burden on documentation. I think certainly the measure developers have commented on how the provider needs to provide appropriate documentation that that is a very significant burden because of the complexity of the measure and the number of items that need to be documented.

I think the task is getting easier for the abstractors, as Dr. Tefera has pointed out but there is -- you know the amount of documentation, the burden on documentation, I actually think may be a distraction from our performance improvement process.

And we're, you know our health system is making major investments. I agree with the order of magnitude in terms of nurse performance improvement and abstractors. It's large. We're making that but are we deploying them on documentation and coding or are we deploying them on process improvement.

DR. TOWNSEND: I'd like to be a little

bit helpful here, if I can. It's Sean Townsend again.

You know the only element that's of the type I just heard you folks describe regarding box-checking applies to the attestation in the measure. And every other piece is just routine clinical care and doesn't require the doctor to document anything extraordinary.

So let's take the fluids example. In order to determine whether a patient received 30 mLs per kilogram of fluid, we look for a few things. We look for a physician order. We look for a volume of infusion, and we look for a rate. Those are all things that anybody writing an order for fluid has to do. It doesn't require special documentation or anything unique for providers.

So the abstractors have clear guidance on looking for those elements. If they find them, the measure -- they pass the measure. If they're not there, they fail the measure. But nobody would order fluids without specifying

those elements. Likewise for antibiotics, we tell you we need a date and time, when did they begin, and what the drug is.

So we're actually just observing care, with the exception of the attestation, where yes, there is an onus to provide that documentation.

MEMBER GOLDMANN: Yes, why do you need that? I'm puzzled as to what -- if there was no attestation, everything else were in place, what would change? I mean you really think that somebody is given the fluid bolus, given the antibiotics, drawn the lactate, and all that has to attest that they did an assessment?

DR. TOWNSEND: Well, I'll tell you why it's there, Don. You know we forget when we think of our academic facilities where we work that they are not the norm across the country for care. In fact, what, there are 250 or so academic facilities versus more than 2,500 nonacademic facilities in the country. And in most of those hospitals, where you have beds of less than 300, you have a single hospitalist on

overnight, covering the entire house.

And so if you stop and think for a second, I want to be sure that hospitalist gets back and checks on the person they put in the ICU, while they're off discharging somebody else, and admitting somebody from the ER, and taking care of that asthma exacerbation that shows up. It's to make sure that in the staffing situations we see in typical hospitals, that they get back to the bedside and they actually say they did it.

We believe doctors won't say they did it if they didn't do it.

CO-CHAIR EISENBERG: Let me just interrupt this conversation. We have somebody on the phone that has a question, too.

Rocco, please.

MEMBER ORLANDO: I asked my question.

CO-CHAIR EISENBERG: Oh.

MEMBER AARONSON: Yes, this is actually Emily here.

CO-CHAIR EISENBERG: Okay.

MEMBER AARONSON: I guess I just

wanted to clarify around the physician documentation piece. I think that what I'm hearing is that the attestation is the only piece that really alters routine documentation.

But I guess I would ask about some of the other elements which were mentioned earlier in the call around, for example, being very explicit about underlying chronic conditions as what's contributing to current lab abnormalities, as well as we talked about abnormalities and vital signs that may look very similar, even in the setting of infection to things like sepsis. However, as long as you document that there's no sepsis suspected and I think those are some things that we have begun to get some coaching on that are a little bit different than what we would always 100 percent of the time routinely document.

DR. TOWNSEND: That's right, Emily. I think a good example is metformin use and elevated lactate. I see a lot of charts and a lot of the time I see providers indicate, just as

a matter of routine habit now, that the lactate elevation is attributable to metformin, as opposed to infection. And we do that in our differential diagnosis a lot of the time when we write a note or in medical decisionmaking elements of our urgency department notes.

So I see doctors trying to describe their actions, mainly, as a part of the work that they do. It's also, like the examples I've given to you are a safeguard. If people are cognizant that SEP-1 is out there and they're being monitored and they want to make sure that they say this is not sepsis, then that is an option but it's not a requirement.

CO-CHAIR EISENBERG: Yes, Jamie.

MEMBER RONEY: I just wanted to quickly move back to feasibility.

I abstract about 1,700 charts from four hospitals a month. And we have four full-time quality people assigned to sepsis. I'm a full-time sepsis coordinator for the region. We have another full-time quality person and we have

seven abstractors.

And so it's a burden but I'm with you, Dr. Townsend, it's worth it. But it is a burden. And so I think as we look at feasibility, it's not -- this doesn't impact whether we have endorsed the measure but we do need to realistically look at feasibility.

MEMBER GARZARO: I have a comment here. And I think the main problem that we're seeing is that the definition of sepsis is more of a syndrome. It is not a disease but a syndrome. So it is a constellation of symptoms. We're trying to treat sepsis like we treat stroke -- stroke alert, sepsis alert, MI alert.

But with sepsis, it has a little bit more nuances on it. And what I'm seeing, at least in the hospitals that I work with is the hospitalist or the ED is saying the patient is sick. I have a three-hour window. I am going to start antibiotics. I'm going to start fluids. I'm going to get a lactate. Lactate is 0.1. All right, I'm calling it sepsis. You enter it into

that flow sheet and you don't have to think anymore. The patient is septic; that's it and they can push it to the next physician.

But is this lack of clear definition of what sepsis actually is, which is severe inflammation and presence of an infection but many times we cannot find the infection, yet we still call it sepsis, which again, goes a little bit against my reality. How could that be?

But at some point you have to say well, how much harm are we doing by these very well-intended measures that in the end are just creating people getting antibiotics, vanco and Zosyn; vanco and Primaxin; vanco, Primaxin and Levaquin just because they are very sick. They may be hypotensive for multiple other reasons but we are creating more C. diff. We are creating more work and we say well, our mortality is decreasing. Like yay, you classify somebody that has acute appendicitis as septic, of course they are going to improve with antibiotics but they were going to improve no matter what we did.

But in these windows of time, that somebody in the ED really doesn't or the hospitalist doesn't have time to think or get the studies back, they are just going to throw antibiotics, the same way that they did for pneumonia when we had the pneumonia four-hour window that later, fortunately, was eliminated.

But in my colleagues here that practice probably have the same experience. Whenever we see a patient admitted with sepsis, we think well, 50-50 chance that this patient actually has sepsis and we need to start investigating well what did the patient actually have, diagnose sarcoidosis, diagnose acute MI, all have diagnosis of sepsis because they fit the definition but really, that's not what they have.

So, I'll set down my shoebox now.

DR. TOWNSEND: This is Sean. What I think is good news is that we would look for evidence or studies that suggest that that's occurring indiscriminately, that we are inappropriately treating patients in order to

make a decision about whether that's actually happening. And you know to date, I haven't seen data or information in peer review journals to that effect that we bring to the table today to make a decision.

MEMBER GARZARO: I think that the reason is because we don't publish those. So we are not in a -- if you go to big hospitals that are not research hospitals, it happens. I mean that is the reality. That is real-world medicine. It is not academic medicine. We are not there trying to publish in a journal a study of how badly do we treat our patients.

So but that's what happens.

DR. TOWNSEND: I appreciate your comment.

CO-CHAIR EISENBERG: So let me just remind us all that we sort of strayed from the feasibility issue into the use and usability and burden issues.

Pardon me?

DR. BURSTIN: Burden is feasibility.

CO-CHAIR EISENBERG: Okay. So we're okay.

MS. MARINELARENA: If anybody has anything else --

MEMBER AARONSON: Yes, is there anything new? Are there any other new ideas that we should be hearing?

DR. RIVERS: Well, I just wanted to add that if you look at a parallel disease like stroke and you look at the actual diagnosis of stroke and treatment, only ten percent of patients who get diagnosed with stroke actually go on to get TTA. Ten percent of stroke patients actually are mimics. They are not stroke patients. They have hypoglycemia. They have other issues but it's a highly-documented disease that, obviously, is looked at at various high levels of government, as well as clinical practice. So I think that disease perfectly parallels sepsis and the actual reality is that that's another problem with stroke.

CO-CHAIR EISENBERG: Very good. Thank

you. Okay, does the --

MEMBER GOLDMANN: I have a question for NQF.

CO-CHAIR EISENBERG: Yes.

MEMBER GOLDMANN: I have a question for NQF. So does NQF ever, as part of endorsing a measure, specify the need for a balancing measure, so I'm thinking of the pneumonia core measure? And that's what everybody around the table is reacting to. We all know that imipenem is thrown at every patient that walks in and doesn't look good.

So can you do that?

DR. BURSTIN: There have been a couple of examples of measures endorsed with balancing measures but not very many.

I guess one question would be what would be a balancing measure for something like this.

MEMBER GOLDMANN: I think the two and that they make more burden but one would be overuse of broad spectrum antibiotics, the other

would be heart failure and patients getting over-hydrated who had an MI.

MEMBER GARZARO: Incidence of C. diff, hospital-acquired C. diff, secondary to overuse of antibiotics. A patient that was just given antibiotics because they were sick when they came in.

DR. BURSTIN: It's actually in existence because we do have endorsed measures of C. diff. We do have endorsed measures. We don't have the measure of fluid overload and CHF. We do have a measure of -- CDC put in a measure last year that is now endorsed that looks at overall use of antibiotics in hospitals. So, again, it may be interesting to begin thinking about how those should get looked at.

MEMBER GOLDMANN: Yes, it would be good. We don't have to do it now but with antibiotic stewardship now becoming an HHS thing and there is going to be penalties, you just can see it coming. There is going to be this tension between the two camps. Right? ID is going to

want to beat down the antibiotics and sepsis is going to want to make sure everybody gets them.

CO-CHAIR EISENBERG: Other comments or questions regarding feasibility?

DR. RIVERS: Well I have to say we'll have point-of-care testing hopefully within the next five years or so --

CO-CHAIR EISENBERG: I'm sorry we can't hear you.

DR. RIVERS: We'll have point-of-care testing that's been FDA approved in the last year that hopefully will help both antibiotic administration, as well as stewardship.

CO-CHAIR EISENBERG: Thank you.

So, Mauricio, I think we're ready to move on to our vote.

MR. MENENDEZ: Sure. So voting for feasibility for 0500 is now open. Vote 1 for high; 2 for moderate; 3 for low; 4 for insufficient.

Voting is now closed. The final count is 7 percent high; 60 percent moderate; 33

percent low; zero percent insufficient, with a final verdict of pass.

CO-CHAIR EISENBERG: Very good. Thank you.

So we're on the usability, right?

MEMBER GOLDMANN: I think we've conflated reliability and usability. I think we've already discussed usability.

CO-CHAIR EISENBERG: I think we mostly did. But nonetheless, there may be some comments or questions.

So, there is nothing further that the facilitators would like to address on use and usability. Yes, I agree, I think we covered both topics with that last discussion.

Are there any comments or questions on the line? No.

So it sounds like we are ready to move on to -- oh, yes. Let's just hold. One of our committee members just stepped out. I'm sure she couldn't conceive of the fact that we could move to a vote so quickly. So let's --

MS. MARINELARENA: We have quorum.

CO-CHAIR EISENBERG: We have quorum.

MS. MARINELARENA: We can vote without her. We have quorum.

CO-CHAIR EISENBERG: Oh.

MS. MARINELARENA: We have quorum because we just need a minimum of 11 votes. Without her, we have 14. As long as we still have 14 votes. We want to move forward so we can get you out of here. Yes?

CO-CHAIR EISENBERG: Let's do that.

MEMBER LEWIS: That's fine. That works for me.

CO-CHAIR EISENBERG: Okay. Okay, Mauricio, it's yours.

MR. MENENDEZ: Okay, so voting for 0500 use and usability is now open. Vote 1 for high; 2 for moderate; 3 for low; 4 for insufficient.

Voting is still open.

MS. MARINELARENA: Jamie, voting is still open for use and usability, if you want to

vote. If not, were going to --

MR. MENENDEZ: The final count is 14 percent high; 43 percent moderate; 43 percent low; zero percent insufficient. Final count is --

MEMBER AARONSON: So it's consensus not reached. It's not a must-pass criterion but we will gather input from our public and member comment period.

CO-CHAIR EISENBERG: So at this point, we can move on to the vote. Is that right?

All right, are there any other comments?

MEMBER LEWIS: I didn't hear the question. This is Jeff Lewis on the line. I didn't hear that question.

CO-CHAIR EISENBERG: Elisa, could you please say -- repeat your comments on that last vote?

MEMBER AARONSON: Yes. So this is not a must-pass criterion but we do want to hear what our members and the public think about use and

usability. So, we will gather that information during the 30-day member and public comment period.

CO-CHAIR EISENBERG: Very good, thank you.

MEMBER LEWIS: Oh, okay, thank you.

CO-CHAIR EISENBERG: Yes. And so now what we're going to do is move on to a final vote on recommendation for measure endorsement, unless there are any other comments or questions that the committee members have before that vote.

MEMBER LEWIS: This is Jeff Lewis again. I have a question.

This is an ongoing measure, right?

CO-CHAIR EISENBERG: It is a maintenance -- yes, this is for maintenance of a measure that's been in existence for quite some time and has had many revisions. That's right.

MEMBER LEWIS: Okay. All right, thank you.

CO-CHAIR EISENBERG: Any other questions or comments?

If not, Mauricio.

MR. MENENDEZ: Overall suitability for endorsement for Measure 0500. Voting is now open. Vote 1 for yes; 2 for no.

(Simultaneous speaking.)

MR. MENENDEZ: Rocco, would you like to place a vote for overall suitability for endorsement?

The final count is 71 percent yes; 29 percent no.

CO-CHAIR EISENBERG: So the measure moves ahead. The measure will move ahead with our recommendation for endorsement plus there will be some further information collected from public comment, which I am actually going to start right now, right, because we have some time for public comment.

So are there any people in the room that would like to add comments? No.

Are there any on the phone that would like to add either member or public comments?

OPERATOR: If you would like to make a

public comment, please press star 1.

MEMBER LEWIS: This is Jeff, I don't -- Jeff Lewis. I don't have any comment.

OPERATOR: And there are no public comments.

CO-CHAIR EISENBERG: Thank you. Okay, hearing none, let me now turn the meeting back over to Melissa so that she can give us some parting words of wisdom and tell us our next steps.

MS. MARINELARENA: First of all, thank you all very much for hanging in there, those of you here in the room and especially those on the phone. I know it is a very long day being on the phone.

Thank you to our measure developers, also on the phone, who were able to make it and those of you who braved the weather and made it here today.

Next steps, very quickly I am going to talk about, and then Christy will actually give you the specifics. But we are going to have a

post-meeting call, which is next week, and Christy will verify the date, where we are going to finish discussing the two HIV measures that we deferred today with some additional evidence that they are going to give us so we don't have that discussion that we had today about insufficient evidence.

And then we are going to discuss gaps. We have a copy here. You don't have to take it. I'll email it to you. I did sort of a framework where I took all of the measures within our portfolio and additional infectious disease-related measures, I think like some of you had requested, and sort of categorized them into screening, diagnosis, treatment, and outcome. And if there's a lot of antibiotic-related ones, a lot of the C. diff, MRSA, typical ones. So, we'll email it to you so you don't have to take the hard copy. Take a look at that, as you think about gaps within the portfolio.

Again, as a standing committee, you are responsible for the management of this

portfolio.

We'll send you a list of previously identified gaps. There's not a whole lot. A lot of them have already been filled with other measures in different portfolios. So just so you know, just because it's not before this committee, they do exist within our portfolios in different projects.

And so we'll talk about that and then we talk about related or competing measures that once all the recommendations have gone through, the measure has to be recommended on its own merit and then we'll look at either related or competing measures. And we'll pull that information for you as well and we'll have all of that.

After the post-meeting call, we draft the report. We'll put it out for comment for 30 days and then we bring you all together again and we will have a post-comment call.

Okay? I'll turn this over to Christy.

MS. SKIPPER: Thank you, Melissa.

MEMBER GOLDMANN: To clarify, on that vote where there was almost even -- I didn't quite get what happens with that.

MS. MARINELARENA: So that is consensus not reached because it did not pass the threshold of greater than 60 percent but it is on a criterion that is not must-pass.

So, we will draft -- when we draft the report, we also draft a memo accompanying it, asking for specific comments around usability and use of our members and the public. We want to get that feedback.

We'll give that feedback to the measure developers. We'll give it to you. We have the committee also respond to the public. Then you come together and you know depending on what kind of comments we get, do you decide if you want to revote. But it is not a must-pass criterion. It does not kill the measure. The must-pass criteria was scientific acceptability, importance to measure and report.

MEMBER GOLDMANN: Because I think you

heard a lot of angst in the room about usability. So I just wanted to make sure it got transmitted.

MS. MARINELARENA: Absolutely. And we want feedback from users. So we encourage you to -- you know when we put the report out, we'll send it out to you as well. Please encourage your organizations to provide feedback as well, which I think is really helpful to CMS. We have CMS right here and measure developers on the phone. So that feedback is really important.

MEMBER GOLDMANN: Great, thank you.

MS. SKIPPER: Thank you, Melissa. You've covered pretty much what we will be doing on the post-meeting and the post-draft report call but you can see there on the slide our next webinar is March 23rd from 1:00 to 3:00. Following that, we will have drafted the report of the deliberations and post it for a 30-day member and commenting period and we will bring you back together for that post-comment call on June first.

Then your measure recommendations go

out to the committee for member voting for 15 days. And then member voting, as well as the committee's recommendations go to CSAC review on June 29th. And then this project will be discussed at this -- I'm sorry? The CSAC review -- the measure recommendations and the votes go out for CSAC review on June 29th. And then at the in-person CSAC meeting on July 11th, this project will be discussed, where the CSAC will make the final endorsement decision on the measures.

Following that point, all measures are moving to the 30-day appeals period.

Are there any questions about next steps or about anything?

CO-CHAIR EISENBERG: Not a question, just a clarification. So at our meeting on the 23rd, we'll be expecting those committee members that were identified for the HIV measures that haven't been covered yet to be prepared to present.

MS. SKIPPER: Yes, that's right.

All right, so if there are no other questions in the room or on the phone, we can adjourn for the day.

And again, just echoing Melissa, thank you all for making it out here and for hanging on the phone all day. And we'll talk to you next week.

Thank you.

(Whereupon, the above-entitled matter went off the record at 5:05 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: Infectious Disease
Standing Committee

Before: NQF

Date: 03-14-17

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.

Court Reporter