NATIONAL QUALITY FORUM

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NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY-COMPLICATIONS ENDORSEMENT MAINTENANCE STEERING COMMITTEE

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FRIDAY,

DECEMBER 16, 2011

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The Steering Committee met at 9:00 a.m., at the National Quality Forum Conference Center, 1030 15th Street, N.W., 9th Floor, Washington, D.C., Pamela Cipriano and William Conway, Co-Chairs, presiding.

PRESENT:

PAMELA CIPRIANO, Ph.D., RNA, NEA-BC, FAA, Co-Chair

WILLIAM CONWAY, M.D., Co-Chair

JASON ADELMAN, M.D., M.S., Montefiore Medical Center

CHARLOTTE ALEXANDER, M.D., Memorial Hermann Healthcare System

JOHN CLARKE, M.D., FACS, Drexel University College of Medicine

JEAN de LEON, M.D., Baylor Specialty Hospital

VALLIRE HOOPER, Ph.D., R.N, CPAN, FAAN, Mission Hospital

CAROL KEMPER, Ph.D., R.N., CPHQ, Children's Mercy Hospital

STEPHEN LAWLESS, M.D., MBA, Nemours Foundation

LISA McGIFFERT, Consumers Union

CHRISTINA MICHALEK, PharmD, RPh, BSc, FASHP, Institute for Safe Medication Practices

PRESENT(Cont'd):
SUSAN MOFFATT-BRUCE, M.D., Ph.D., The Ohio State University
JANET NAGAMINE, M.D., BSN, Permanente Medical Group (via phone)
LOUISE PROBST, MBA, BSN, St. Louis Area Business Health Coalition
GINA PUGLIESE, MS, R.N., Premier Healthcare Alliance (via phone)
PATRICIA QUIGLEY, Ph.D., MPH, ARNP, FAAN, Department of Veterans Affairs
MARY SIEGGREEN, MSN, APRN, Detroit Medical Center
JIM SMITH, PT, DPT, Utica College
IONA THRAEN, MSW, Utah Department of Health
TRACY WANG, MPH, Wellpoint, Inc.
RICHARD WHITE, M.D., University of California Davis

STAFF PRESENT:
HEIDI BOSSLEY, MSN, MBA, Vice President, Performance Measures
AKINLUWA DEMEHIN
KAREN JOHNSON
JESSE PINES, MD, MBA, MSCE
ANDREW LYZENGA
JESSICA WEBER

ALSO PRESENT:
NONI BODKIN, Centers for Medicare & Medicaid Services
JOHN BOTT, Agency for Healthcare Research & Quality (via phone)
DALE BRATZLER, The Joint Commission

KYLE CAMPBELL, FMQAI
MAUREEN DAILEY, American Nurses Association
DEBORAH DEITZ, Centers for Medicare & Medicaid Services (via phone)
JEFFREY GEPPERT, Agency for Healthcare Research & Quality (via phone)

ALSO PRESENT(Cont'd):

DAN GREEN, Centers for Medicare & Medicaid Services

SHARON HIBAY, Quality Insights of Pennsylvania

DAVID HITTLE, Centers for Medicare & Medicaid Services (via phone)

PATRICIA HOLTZ, Centers for Medicare & Medicaid Services

RABIA KHAN, Centers for Medicare & Medicaid Services

DENISE KRUSENOSKI, The Joint Commission

SOEREN MATTKE, RAND Corporation

EUGENE NUCCIO, Centers for Medicare & Medicaid Services (via phone)

MICHAEL PHELAN, Cleveland Clinic (via phone)

GARY REZEK, Quality Insights of Pennsylvania

PATRICK ROMANO, Agency for Healthcare Research & Quality

KIM SCHWARTZ, Centers for Medicare & Medicaid Services

DAVID SHAPIRO, ASC Quality Collaboration

DONNA SLOSBURG, ASC Quality Collaboration

ANN WATT, The Joint Commission

DON WILSON, Quality Insights of Pennsylvania

ALMUT WINTERSTEIN, University of Florida

C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S (Cont'd)

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

(9:02 a.m.)

WELCOME AND RECAP OF DAY 1

CO-CHAIR CONWAY: We're going to open the day, instead of a recap of yesterday, which Pam did yesterday -- we don't need to repeat that, but in the room next door, the Measures Application Partnership was deliberating on some general rules about the hospital measures that they help our work. And Heidi can give us an update on what happens.

MS. BOSSLEY: Sure. So I don't know if all of you are aware of some of the other activities that NQF does, but one is we serve as a neutral convener.

So we have the National Priorities Partnership, who helps advise on the national quality strategy priorities. And then we have a new group that has been in existence for just about a year. That is the Measures Application Partnership.

And that is the group that is advising HHS on what measures should be used in payment programs, public reporting, everything you see out there: The inpatient quality report, all of those.

They have been sending the last, I would say, nine months, providing overall conceptual guidance and developing criteria on how they would evaluate these measure sets that come forward out of HHS. And in the last week, it has been a marathon run for four workgroups.

There's one more meeting today: clinician workgroup, the post-acute care, long-term care, and then the hospital workgroup that met yesterday. And then there is the dual eligible workgroup that is meeting today.

All of them are looking at the lists, the finalized rules that came out, and providing final recommendations to HHS on whether they think those measures are

parsimonious across the programs, if appropriate.

Measures that are used in one program perhaps should be used in another program. They're putting those recommendations forward, so basically have gone -- some groups have gone -- and the MAP Hospital Workgroup did it yesterday -- measure by measure, saying they support, they do not support, or they support the general direction, but they don't think the measure is quite there yet.

And so a lot of the work that you have done today was being discussed yesterday because a lot of these measures have been included in a lot of the federal programs.

So what will happen next with that group is it will go to the over-arching Coordinating Committee, which is many organizations and subject matter experts that sit around the table. And they will come up with some final recommendations to HHS.

But all of the decisions you make today you may not see as a result because, again, you haven't finished your process. It hasn't gone out for comment, all of that. But the recommendations that you do put forward will eventually go to the Measures Application Partnership and be used as a guidance of whether or not that measure should continue to be used in a federal program.

So it was a marathon run for them. They had seven programs they needed to look at yesterday. They got through all of them in nine hours. So it was very fascinating to kind of get the emails and find out what was going on.

Lisa, I think you have a question.

MEMBER McGIFFERT: So I'm always trying to figure out how things work. So the things we were discussing yesterday, which are already on tap to be in the IPPS system in 2003, they were discussing -- so like they were making another set of recommendations for

after 2013. I think I said 2003. After 2013?

MS. BOSSLEY: Yes. Rabia is from CMS. She could probably provide even more information on that for you because it does vary by program as well.

MS. KHAN: Right. So this is related to ACA section 3014. And it's a pre-rulemaking process that involves a multi-stakeholder group, which is the MAP. And they are convened to provide their input on our selection of measures for the federal rulemaking, the next federal rulemaking process.

So it's a pre-rulemaking input that we would receive when considering new measures for our reporting programs. And that specifies or wheedles down to our programs that go through the federal rulemaking process that are publicly reported that fall under the Social Security Act. And then within the statute, there are some programs specifically listed.

So the input that they were providing or for new measures that were not finalized in the past rulemaking process but for the upcoming year.

MEMBER McGIFFERT: So after 2013?

MS. KHAN: Well, right. Well, it would be the federal rulemaking process for the calendar year 2012. So that could relate to programs in future years depending on each rule. So if --

MEMBER McGIFFERT: The rule will come out in 2012?

MS. KHAN: Right. The rule comes out in 2012.

MEMBER McGIFFERT: Okay. I was just trying to get the timing straight.

So if they were discussing, like if this group chose not to endorse certain measures, that would go to them and they would not recommend them or what would that --

MS. BOSSLEY: Again --

MEMBER McGIFFERT: Would they take

another bite at the apple?

MS. BOSSLEY: Right. So they developed criteria that they are using. And the first criterion is that it is NQF-endorsed or at least eligible to be submitted to NQF if it hasn't been prior. So anything that has not been endorsed -- and literally that is why Helen Burstin was not able to be here with us today. She was over there advising.

As we know, recommendations are coming out. And they're being ratified by the Board. We're providing it directly to the MAP. So they may very well decide that they would propose that measures be removed off the list because they're no longer endorsed.

We typically don't make that final recommendation until the Board ratifies the decision just because anything can change at any point in time up until then. So this is where it is truly an almost day-by-day update that we are providing to that staff as well as CMS and HHS.

CO-CHAIR CONWAY: Clear, right?

MEMBER THRAEN: Food in mouth. It is more likely that the ones that we have vetted and moved forward may not be approved versus the ones that we haven't moved forward, someone would advocate to bring it forward, correct, the probability is?

MS. BOSSLEY: I think so. I think we need to see how this plays out a couple of more times to know for sure, but I think that is a good assumption.

CO-CHAIR CONWAY: In a way, it is a series of hurdles. The first ones have got to get by a group like this to even be an NQF measure. And then CMS may or may not select.

MS. BOSSLEY: Exactly.

CO-CHAIR CONWAY: Okay. Any other questions on that background?

(No response.)

CO-CHAIR CONWAY: All right. Thanks, Heidi.

Can the operator let us know if

panel members are on the phone today?

OPERATOR: We do have a few. We have Gina, Janet, and John.

CO-CHAIR CIPRIANO: John, could you identify yourself?

MR. BOTT: Yes. This is John Bott with AHRQ. I'm not a Steering Committee member, but I am here to respond to questions that the Steering Committee may have, along with Patrick and Jeff Geppert.

CO-CHAIR CIPRIANO: Great. Thank you.

CO-CHAIR CONWAY: Great. So can we open up Gina and Janet?

OPERATOR: Their lines are open.

CO-CHAIR CONWAY: Okay.

MEMBER NAGAMINE: Good morning, everyone.

CO-CHAIR CONWAY: Good morning. So we have Janet. And, Gina, are you on the line, Pugliese? Operator, is Gina Pugliese opened up?

OPERATOR: Yes, her line is open.

CO-CHAIR CONWAY: Okay. She must be on mute. All right.

Other preliminaries? I think that's that.

MEMBER PUGLIESE: I'm sorry. I think I was on mute.

CO-CHAIR CONWAY: Okay.

MEMBER PUGLIESE: This is Gina Pugliese. I'm sorry.

CO-CHAIR CONWAY: Good morning.

MEMBER PUGLIESE: Good morning. How are you?

CO-CHAIR CONWAY: Wonderful. Okay.

STEERING COMMITTEE REVIEW

0349: TRANSFUSION REACTION (PSI 16).

0350: TRANSFUSION REACTION (PDI 13).

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

CO-CHAIR CONWAY: We're going to start working on 0349 and 0350. They are transfusion reaction measures from AHRQ. And

Patrick would like to say some opening over-arching comments on this. And then we will turn to our reviewers. And we welcome Patrick back. We had a lot of fun yesterday.

(Laughter.)

DR. ROMANO: Okay. Good morning. Well rested hopefully everyone is.

Yes. So I just wanted to say a little bit in preparatory comments regarding these two indicators of transfusion reaction because these are both extremely rare events. So we are literally talking about four events reported across the entire country in 2008 for the pediatric indicator, 64 events for the adult indicator.

There were some complaints that we received from users several years ago that these codes were capturing some other types of transfusion reactions related to minor blood group antigens that were not AB/O or Rh.

And so we actually petitioned the IC-9 CM, Coordination Maintenance, Committee

to revise the codes and to add additional codes for non-other types of transfusion reactions.

So these codes are now limited to AB/O and Rh. And, hence, they're extremely, extremely rare. So it does bend the concept of importance. And I put that out to you just initially as the overriding policy question for the consideration of these indicators.

Also, of course, related to the extreme rarity is the fact that we can't organize any kind of a conventional validation study to assess the accuracy of these codes. Instead, we have to rely on feedback from users to let us know if they find an event that is false positive and to explain that.

And so that, in fact, resulted in our petition for the new codes. We haven't heard any complaints since then. But that doesn't necessarily mean that the new codes are working, despite the observed decrease in the incidence.

So I will just put out that policy question related to the extreme rarity of these events and what that means and put it forward to you for comments and discussion.

CO-CHAIR CONWAY: Okay. Questions? John and then Richard?

MEMBER CLARKE: Just as a point of clarification, one of the reason that these reactions are rare is that the transfusion community takes these things very seriously and has been in the forefront of quality in this area. And I assume they have had for my whole career, in fact, their own system for monitoring and correcting this.

And so I wonder to what extent you feel that NQF guidelines are complementary or are redundant to the standards within the industry.

DR. ROMANO: While I certainly agree that this has been an area of focus for the industry for many years, you would probably be better off addressing that

question to people in the industry.

There probably is some potential for redundancy there. Hopefully there is complementarity. This is obviously based on a different data stream, again, public use data, as opposed to confidential data that would be reported to blood banks.

But aside from that, I welcome comments and input from others or if anyone on the phone has comments.

MEMBER WHITE: I missed what year the new codes came into effect and what the number of AB/O incompatibility there was after the new codes. You said 64-something before, but how many do we have of the new codes?

DR. ROMANO: I'll look that up while the discussion continues.

CO-CHAIR CONWAY: Okay. Charlotte, could you describe the -- summarize the workgroup?

MEMBER ALEXANDER: That was not my one.

CO-CHAIR CONWAY: Oh, sorry. Steve?

MEMBER LAWLESS: I am Charlotte today.

(Laughter.)

CO-CHAIR CONWAY: Yes.

MEMBER LAWLESS: Anyway, the transfusion reaction, the measure we talk about, obviously just for pediatrics, this was mentioned. And the new readers are, as we were discussing, AB/O and Rh compatibility.

With the numbers this low, with the user group I come up with -- I missed that meeting, but came up with, which was, again, a discussion we had yesterday, which is counts versus rates. And this is a way of looking at rates here because literally if you look at rates on this, this is near a six sigma level or maybe even be better than a six sigma level.

So it is unbelievably rare, but, as mentioned by John, it's systems that have

got in place that are very rigid, actually, with this. So that was a major discussion in that regard from the user group.

From the measure itself, as mentioned, there are 11 measures of these incidents reported. Seven of them were present on admission. So they probably happened the year prior, obviously if it were a year or two prior. And then, four, it happened in the year 2008, when the data was reported.

The data, the numerator is limited to AB/O and Rh. And I would argue that from a pediatric perspective, those are not the errors that we are seeing.

In terms of -- and I'll elucidate that. From the different organizations that are actually following this and are rigid, if you have an error at all with this, if the American Red Cross, the FDA, it's never events. So the payers and the states are actually wanting to reporting this. This is

qualifying as a never event in some areas. It is the sentinel event. And it is a national patient safety goal. So besides that, nobody is paying attention to it.

So it actually is a hugely regulated, very dynamic, very, very, very tight-knit, people are different from everyone else.

The errors that we're seeing in pediatrics, which are probably a little more prominent, are things like where CMB negative or positive; irradiated, "Yes" or "No"; and minor grouping compatibilities and risk of hepatitis C. Did you give blood that was hepatitis C-positive but didn't know about it or didn't follow up?

So in terms of scale -- and you include it in the measures -- the exclusions actually make -- those exclusions can actually make this so unbelievably rare, it's almost like why are we even -- this is redundancy more than anything else versus those things

which are more the process-oriented, we tell you how well the system is communicated. They may not pop up into codes per se. But, again, irradiation "Yes" or "No"; CMB, "Yes" or "No"; and things like platelets, single donor versus multi-factor donor. These are the things that are the communication items.

So that's it. I think one thing in exclusion which was a little bit bothersome, actually -- I'll just look at this for a second. No. That's the summary.

CO-CHAIR CONWAY: So, Steve, is that a summary of both of these: the adult and the pedes?

MEMBER LAWLESS: I can't. I am just speaking for the pediatric one right now in terms of that. The incidence, as was mentioned, is a little bit higher. The same regulatory bodies are following the adults as in pediatrics. So it's not much of a difference.

I don't know if CMB -- I think CMB

and irradiated, those issues are only real issues for, you know, compromised patients and straightforward patients.

I would tell you just from a personal note the trauma patients we are seeing and the people who get blood in the OR on type of -- just give it to them, that we have only had four reported with even a trauma getting them urgently. That even tells you how tight the system is that even within minutes, you could actually get -- this is not an issue.

And so I cannot speak to the adult part of it otherwise.

CO-CHAIR CONWAY: All right. Questions or comments from the panel members? Jason?

MEMBER ADELMAN: So forgive me. I'm just going to do what I did yesterday. I pulled one of the articles again. And I am just going to read. There's a very, very brief paragraph on transfusion reactions.

Sorry. This is the article that was given to us, "Pediatrics: Evaluation of the AHRQ Pediatric Quality Indicators." I think it's three sentences. Give me a second.

So in this study, I will remind you that it was 70-some odd hospitals over 3 years. It was almost two million discharges. They picked up 15 transfusion reactions.

The denominator was all medical and surgical patients aged 0 to 17 years excluding neonates. The numerator is any patient with a code for AB/O incompatibility reaction, Rh incompatibility reaction or mismatched blood. Twenty-nine percent were present on admission. This is extremely rare: 15 cases in 3 years in 76 hospitals.

And none of the seven cases reviewed were considered preventable. There were reactions to correctly typed blood known to occur, even with the best typing available, because of untypable antigens or antibodies. The reactions were usually transient fevers or

rashes. So they have it.

In this study that was given, they found 15 cases. Half were present on admission. And the rest were, you know, nothing, not nothing but they were not -- this is a quality indicator. And they, you know, weren't a quality issue, minor adverse events without any errors. So I just thought that is something to consider.

CO-CHAIR CONWAY: Sure. John?

MEMBER CLARKE: I'm struggling with this because I know it is extremely important. I know it is also extremely well-done. And, yet, so are we being redundant if we have one of these standards or is it valuable for public reporting since maybe this is the only way it gets reported out publicly?

And Steve's implication was perhaps we should expand on that and that, in fact, we should look at some of these minor things since we seem, the industry seems, to

have solved the problem with the major things.

And so I raise those issues. Should we not do it at all because everybody else is doing it and doing it well or should we do it because it constitutes public reporting or should we recommend that more of it be done because then more valuable improvement would be done?

And I would actually not be swayed by the fact that most of the problems right now seem to be problems that are unavoidable because yesterday's unavoidable problems are tomorrow's avoidable problems.

CO-CHAIR CONWAY: John, since you are active in the State of Pennsylvania reporting, what measures --

MEMBER CLARKE: This is our least common problem in Pennsylvania.

CO-CHAIR CONWAY: But what definition are the states using for the reporting? Is this --

MEMBER CLARKE: We get everything.

We get everything from people drinking back rub solution, X-rays going out of the helicopter, two cases, two different institutions, by the way. And so we get every minor mishap. But the major mishaps in transfusion. Our transfusion category is the smallest category we have.

CO-CHAIR CONWAY: Let me restate my question. What definition does the State of Pennsylvania use for transfusion reaction reporting?

MEMBER CLARKE: Everything. That's what I'm saying: everything from mislabeled specimen -- see, we have near-miss reporting. So if you just mislabel the specimen and catch it, we get the report. So we get every possible thing that might potentially have affected the patient in the way of the chain of blood custody.

CO-CHAIR CONWAY: Let me just continue with this line of reporting. Patrick, do you know if this measure was not

out there, what would happen? What is the down-side risk of not having this available for public reporting?

DR. ROMANO: I can't. My crystal ball is weak on that. But probably again, you know, the systems that are in place that have been described I think have already established a six-signal level of performance in this area. So it would be hard for me to predict a clear negative consequence, to be frank.

There are some interesting proposals on the table here. I would say that it was Scanlon's work that has been cited as well as other feedback that led us precisely to petition for the separation of these codes. So that was done.

The effective date of that was October 2010. So, unfortunately, the data that we have cited regarding the prevalence of these events in hospitalizations predates the change in the codes. So we would expect a

further dramatic decrease, even below the 4 and 64 events that are reported for the pediatric and adult indicators, respectively.

CO-CHAIR CONWAY: Okay. Why don't we do Charlotte, Lisa, Jason, and Iona?

MEMBER ALEXANDER: As I understand it, one of the requirements is that there has to be an opportunity for improvement. And I don't see that here. I think we have done what we need to do unless we change the criteria to pick up some of these more difficult-to-detect minor antigens.

CO-CHAIR CONWAY: Jason?

MEMBER ADELMAN: To me it is the same as yesterday with the retained foreign bodies. It's a mixture of somebody accidentally giving blood to the wrong patient versus much more commonly a minor antigen causing something relatively insignificant. And so it's hard to -- you can put in bar-coding to try to prevent wrong patient errors, at the same time be doing more blood

transfusions. And what is reported will be a mix of the two.

And, despite the fact that transfusion reaction does not say, "I gave the patient the wrong blood," I am afraid that too many people think that that is what this is a measure of.

You had asked a question of John of what information he collects. And they collect everything. But they don't publicly report everything and mix it all together. And I think there is a distinction there.

And, again, even though it's not anybody's fault that the term "patient safety indicator transfusion reaction" because it's a patient safety indicator is believed to be, I think far too often, the wrong patient got the wrong blood. It's just I'm afraid too confusing. It's one of the goals of usability, like, "Well, people understand what this indicator means." And I think they will think it is one thing, but it is actually

something else.

CO-CHAIR CONWAY: Iona?

MEMBER THRAEN: A couple of observations. First of all, we wouldn't know that we are at six sigma unless we have collected this data. So that is the first observation.

And we are always in patient safety looking at what people do wrong. This is an opportunity to celebrate, folks. I think that if, in fact, we are at six sigma at a population level on this particular issue, that this is something that needs to be communicated to the industry because when an event like this occurs at a local hospital, it is a big deal. And it is usually that kind of event is not the reaction. It is the wrong blood to the wrong patient kind of event. And the hospitals and the staff suffer deeply when an event like this occurs.

So, you know, I don't know that that is within the scope of this Committee,

but if we are going to retire this indicator or maybe reframe it based on the conversation that you're talking about, at least rename it possibly, that we need to also say to the world out there that we have made some improvement, significant improvement, in a particular area that we can celebrate.

The other thing I want to say is that I think this is an SRE. So separating out the sentinel event issue, wrong patient, wrong blood, from transfusion reaction rates I think is worth exploring since we do have an SRE already in place for the other side.

CO-CHAIR CONWAY: Steve?

MEMBER LAWLESS: I actually agree in terms of the celebration of success. And I think if you were retiring in terms of the measure itself, this measure is saying, guys, this is an example, just of something that really worked. And now it is going to go maybe to the next level or something else. But that I think would give people hope out

there in terms of wow, it's not just lingering, but it's actually something very, very positive.

But, again, I think the bigger issue, actually, people are grappling with is things like how to handle blood transfusion. It's the decision-making process about blood transfusions. This is kind of an assumed "I am going to get the right blood. Now what do I do with it?" is where the bigger, major issue is.

CO-CHAIR CONWAY: Louise?

MEMBER PROBST: If there's an interest in having one place to go for measures -- and so I know there is a lot of discussion in our community among our hospitals and others about trying to use NQF-endorsed measures and having one place to go. So I don't know if you start taking some out, whether that means that it is just multiple places folks have to go to find the measures that they are using internally.

So I don't know if there is any opportunity there for harmonization or streamlining. That could be lost if we took the measure out.

CO-CHAIR CONWAY: Okay. Other comments? Patrick?

DR. ROMANO: John Bott might be able to address this, but I would say that AHRQ may decide to continue the indicator as part of the PSI set, even if NQF endorsement is withdrawn. So those two aren't necessarily linked.

I might also ask Heidi to comment on the link between the serious reportable event program and this program because, yes, this is a serious reportable event. It's being defined through the SRE program. But one of the interesting features of that program is that it doesn't exactly have fully operational specifications.

And so states then have to try to implement those specifications. Some states

have mandatory reporting programs. Some don't. There is a lot of variability there in the extent to which they even follow the NQF definitions.

So Heidi might be able to illuminate the group on that question.

MS. BOSSLEY: Right. So one of the things I think we have tried to continue to work on the definitions for the SREs over time, but they still remain somewhat open to translation I think when you start looking at some of the coding, et cetera. And there is work underway to start putting a little more meat on the bones, I would say, around the SREs and everything.

It just occurred to me I never thought this would come up in this Committee, but there is an option for all of you, which is putting the measure in reserve status. This is a new status that we developed. Patrick is a little surprised, but I am throwing it out there. It is an option.

We have done it. And we just had cardiovascular and surgery committees take a look at this. This has been the first time that we have really looked at measures undergoing maintenance. And there have been some measures where there has been clear improvement to the point where the measures meet all of the other criteria with the exception of 1B, which is the opportunity for improvement.

So there is actually little variation. There is a small gap, if anything. I think you would want to look and see the disparities piece, if there continues to be variation in that. And I'm not sure if we have that data or not. I haven't looked to see.

But you do have the opportunity to say the measure remains endorsed, but it is in reserve status. It is not the first one we think that everybody should uptake and look at, but it should be looked at periodically.

It would be reviewed again in three years. AHRQ would continue to maintain it and provide the updates to us.

And then in three years' time, we would revisit and see if there's any new data that would then make us realize maybe we need to either say the measure is now gone, you are doing great, or we need to actually move it back into full maintenance again or endorsement again and people need to actively start reporting it.

It's an option. I am throwing it out there because I can hear everybody kind of struggling. That is an option or you can just continue to move through and vote and either vote the measure not to be endorsed or endorsed.

CO-CHAIR CONWAY: So how would we proceed? We would see if this hits the threshold or importance? And if it fails there, we could entertain a motion for reserve status?

MS. BOSSLEY: So what we have done -- and this is still a work in progress because we have only done it a few times. So we typically have you vote everything. So we have you vote the importance.

You may vote the importance down because, again, it needs to meet all three and then go through and vote everything else: scientific acceptability, usability, and feasibility. And then we stop and say, "Okay. Would you want to revisit the importance piece because it is actually meeting everything but 1B, the opportunity for improvement?"

So we can run through that process if that is something you all would like to do. I don't want to cut off discussion, but I do want you to know that is an option for all of you to use if you'd like.

CO-CHAIR CONWAY: Thank you.

Let's just go around the table. I've lost track. Jason?

MEMBER ADELMAN: I just want to

respond to one thing Patrick said. I think that if it does not get endorsed, that AHRQ should continue it. I see it has a great role for widening the net, as John talked about before.

If we get five cases and four of them are nonsense but one of them is a real bad medical error that slipped through the cracks, we might pick it up.

I am just personally afraid the public won't understand what exactly this is. Many of these measures need an asterisk and a paragraph below it explaining exactly what this means.

CO-CHAIR CONWAY: Lisa?

MEMBER McGIFFERT: The way this is collected is not particularly labor-intensive, right, because it's coming out of the administrative data, right?

And the other thing that I was wondering is I know there is a composite score and I know that there is a lot of interest in

composites recently because of the multitude of measures we have.

And I am wondering what benefit it would have in a composite score looking at it with a bunch of other rare events because we have, you know, 15 rare events that might happen or measures.

And then you have a cumulative number. Is that valuable to look at whether a hospital is taking these serious events as seriously as they need to or whether they need to improve?

And I think that taken collectively -- I know we have trouble communicating this, these kinds of measures to the public because they are so rare, but I think the public understands when things aren't supposed to happen. And I think if there was some way to move towards a more composite look, that that might be beneficial.

CO-CHAIR CONWAY: John?

MEMBER CLARKE: First of all, I

have been curious, Lisa, the whole time. How do you feel about the public reporting aspect of this, the fact that this would allow public reporting, rather than just within-industry reporting? Is that important to you or do you think the public has enough confidence in the blood supply at the moment to not worry about that?

MEMBER McGIFFERT: Well, I would say there probably aren't a lot of people in the public that say every day, "Gee, I am worried about the blood supply. Let me go look at this measure." But I do think when these issues are presented, it is pretty obvious to anybody that they are rare events and that the public really understands there are never events.

I mean, I am intrigued by what you said about maybe there are some other things that we should be measuring in safety with a blood supply and that this is a never event or a serious event but maybe there are some other

things we should be measuring.

But I do think people understand that these things are things that shouldn't be happening. And I think there is some comfort in knowing that they are rare.

I think sometimes there is some skepticism, but when you are pulling it from codes and things like that, there is probably -- you know, I don't know what to say. I do think that there is a real need for us to get to a point where we can have some good composites that say overall this hospital is safer or safe.

MEMBER CLARKE: Yes.

MEMBER McGIFFERT: And I think we are all looking for that and there is no magic --

MEMBER CLARKE: Right. And that is the other thing I wanted to comment on. We looked at three never events in the -- are you allowed to use the word "never" event in an NQF building?

(Laughter.)

MS. BOSSLEY: You can. I can't.

MEMBER CLARKE: "You can. I can't"? Okay.

We looked at three never events in the operating room: wrong site surgery, retain foreign objects, and surgical fires. And we looked at institutions that had these events. And the correlation between having one of these three events and having another one of these three events -- and for those of you who know linear correlation statistics, the r2 on that is zero. That is, there is no relationship between the facility for operating on the wrong patient, setting the patient on fire, or leaving something behind. Those are totally unrelated aptitudes. And so --

MEMBER McGIFFERT: There was a study that looked at all of the PSIs. And they found that number 7, which was the infection measure, was the canary measure.

MEMBER CLARKE: Yes. I would think that would be true.

MEMBER McGIFFERT: Yes.

MEMBER CLARKE: So what happens is that the rare events may, in fact, be idiosyncratic. And they may not be a good indicator of the overall quality of the institution. I think that some of the things like infections and readmissions, recovery from complications, those things, particularly recovery from complications, are very good parameters of quality. But these rare events probably aren't.

MEMBER McGIFFERT: My understanding of the study was they looked at how well it correlated with all of the other PSIs so that, you know, it might be interesting for you to look at that with yours to see if that was a good indicator of some correlate

CO-CHAIR CONWAY: Well, let's pick up Iona. She has been waiting a while. And

then we will go to Patrick.

MEMBER THRAEN: I just wanted to make sure that we are clear on the SRE versus this type of event. So the SRE related to this is defined as patient death, serious disability associated with the wrong transfusion.

So I think that, again, the SRE definition is truly a definition of a sentinel event, a very rare, rare event. This is a transfusion reaction measure, which we have already talked about is a broader capture of information related, not necessarily related, to death.

So the SREs are being reported, mostly manually because the requirements for reporting are in the moment where when you get to ICD-9 code use, we're talking two-year delays in terms of being able to capture data.

And that may not be true for CMS in the future. But at the state level, by the time we get the data, we have cleaned the

data, we validate the data, et cetera, et cetera, we are two years behind. So it's a look-back approach and used for different reasons. So I think we just need to be clear on the differences.

CO-CHAIR CONWAY: Sure. Patrick?

DR. ROMANO: No disagreements with anything that has been said, just a couple of clarifications. So we do have, AHRQ does have, a PSI composite. And the composite measure does not include this indicator. And the reason for that is because it is a reliability-weighted composite that is based on a weighted average of rates for each of the PSIs.

But this PSI, as has been discussed, is not really estimable as a rate. It is really idiosyncratic. And, therefore, it wouldn't add any information value to a composite, which is why it is not included in the composite.

As far as disparities, again, we

are limited by the fact that we have a legal requirement that we cannot report cell sizes less than ten or anything that would imply a cell size less than ten.

So, therefore, we can't estimate disparities across different sociodemographic groups using the HCUP data. And we apologize for that limitation, but it is a legal requirement.

And if John has any policy issues related to this that he wants to address, he is welcome to jump in.

MR. BOTT: Yes. In regard to the question Patrick asked before about AHRQ's continuance of a measure, so in 2012, we are going to be taking a hard look at what we call the measurement life cycle process. We have in the past primarily focused on measure development and measure maintenance and measure enhancements.

But we need to do more to acknowledge that there comes a time for

measures, to retire measures. And we want to do more to develop solid criteria around that.

Although this is work yet to come, I imagine the loss of NQF endorsement of a measure will bear weight. And the question will be how much weight, informing whether a measure would be retired or not.

CO-CHAIR CONWAY: Jason?

MEMBER ADELMAN: I just want to respond to what John said and what I said earlier. Again, I just see sometimes I wish we can endorse these measures with qualifications, like this will be good for public reporting and this is good for value-based purchasing and this is good just as a net to capture because I still think it is good for the purpose of finding cases that we might have otherwise missed. That's all.

CO-CHAIR CONWAY: Lisa won't let us. Lisa?

MEMBER McGIFFERT: I would disagree with that. I mean, I think I was

arguing for that with some of the process measures yesterday, that they may not be that useful for the public but they're useful internally for the hospital to use.

CO-CHAIR CONWAY: Louise?

MEMBER PROBST: So in our community, we look at these measures and talk about them with our providers. And our message to the public, whether we are in the press or to our own constituents, is that these are not measures by which you would choose a hospital. But there is comfort to the public to know that there are measures out there and that someone is looking at them.

And so what happens is because we don't have any public reporting and our organization's position is that there should be public reporting of never events by region but doesn't have to be hospital-specific but there ought to be something that says to the public, "Health care is risky. And sometimes bad things happen. And, you know, you should

be careful when you go into the hospital, but they don't happen that often." And so what happens is we don't have anything like that.

And then suddenly something does happen. The press finds out about it. They interview the patients. They put it in the paper. And then all of the hospitals look really bad. But if there was just something that was out there once a year that, "Oh, here is the rate. And, look, it isn't very many," then people take comfort in knowing that their state or some other entity is providing this oversight and they don't really have to look at them.

And so I think there is value in some of that public reporting. I agree it is not valuable to say this is a good or bad hospital. But there is a consequence of not having the public reporting.

CO-CHAIR CONWAY: Just as a reminder, there are multiple users of NQF measures. And it is the user that has to

evaluate whether it is a reasonable public reporting measure or not. Maybe NQF should clarify that, but they don't, in their proceedings.

Okay. John, are you up or down, your card?

MEMBER CLARKE: No.

CO-CHAIR CONWAY: Okay. Any other comments? Anything new about these measures that could add to people's thinking about this? Okay. Anyone on the phone? Yes? Go ahead.

MEMBER NAGAMINE: For Heidi. In your experience, the few measures that have gone to reserve status, do you -- what has been the experience when they go into that status? Are they still used or do people just kind of ignore them once they are in that status? What tends to happen?

MS. BOSSLEY: It's a good question. Unfortunately, we don't know. The Board is actually acting on the first set. It

is one or two measures in the next month. So it will be interesting to see how others continue to use it, but honestly we are not sure. So this is something we are going to monitor over time to see if it is at all helpful to put something in this type of status.

MEMBER NAGAMINE: Thank you.

CO-CHAIR CONWAY: Okay. Should we move on to a vote? Jessica?

MEMBER CLARKE: Before we vote, could we reiterate what the strategy would be if we want to put it in reserve status?

MS. BOSSLEY: Okay. So you vote based on whether the measure meets the criteria. So in this instance, again, this is your call on whether you want to do this or not.

If you believe that this measure doesn't meet a performance gap, 1B, then you would actually vote down importance because it doesn't meet all three criteria.

But then we would stop if that happened and ask you if you want to continue on to see if the measure continues to meet the other three criteria because it needs to meet the other three in order to be able to go discuss reserve status. If that is the case, then we would continue on. And then we would bring you back and have you re-vote on whether you think the measure applies for reserve status. Does that make sense to everyone?

MEMBER LAWLESS: And then the last question about should it be endorsed, the very last question, then we say reserve, do we say "Yes" or "No" to that?

MS. BOSSLEY: Yes. So what we will do is if you take a look at this slide here -- and for those on the phone, what it says is "If a measure is under endorsement, maintenance review, and did not pass importance only due to lack of a performance gap does it meet criteria to consider for potential reserve status," oh, I guess the way

we have it written they changed it and then "further evaluation and reliability and validity."

Okay. Is it importance and then this? Did we change it? Okay. So we'll do it what makes more sense to that I just said. So we will --

MEMBER LAWLESS: Can I suggest that maybe before every vote, you kind of give us a guide?

MS. BOSSLEY: I will do that. Let's do that. We'll guide. I am happy to guide because this is confusing. We keep changing the slides. And clearly I can't keep up with them.

CO-CHAIR CONWAY: But, Heidi, if it doesn't pass importance, we ordinarily wouldn't vote on keeping the measure.

MS. BOSSLEY: Right.

CO-CHAIR CONWAY: So, therefore, we wouldn't --

MS. BOSSLEY: Right.

CO-CHAIR CONWAY: -- have to do that. We could flip to the reserve status vote, instead of that.

MS. BOSSLEY: Right.

CO-CHAIR CONWAY: Does that make sense?

MS. BOSSLEY: So the reason why you still need to demonstrate that the measure continues to meet the other three criteria, which is why I would like you to do importance.

If it doesn't pass, then we'll stop and say, "Do you want to continue?" Then we will go to scientific acceptability, usability, feasibility, but then I'm not going to have you vote "Yes"/"No" until you discuss the reserve status. And then we'll do an overall "Yes"/"No."

Does that make sense to everyone?

MEMBER CLARKE: Heidi?

MS. BOSSLEY: Yes?

MEMBER CLARKE: Just as a kind of

a Robert's Rule, --

MS. BOSSLEY: Yes.

MEMBER CLARKE: -- may I suggest in the future that what you do is you make the known motion the reserve motion and then you make the amended motion the pass motion. And then once it passes the amended motion of being accepted, then you could go to the main motion, which is to be accepted in reserve. And I think Robert's Rules would solve some of your convolutions.

MS. BOSSLEY: Yes. We keep trying to follow Robert's Rules but, for some reason, keep changing it. But it is a very good idea. Thank you. Yes.

CO-CHAIR CONWAY: Okay. Jessica, take it away.

MS. WEBER: All right. Importance to measure and report high impact, performance gap and evidence? It is a "Yes"/"No" question. There should be 19 responses. Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Gina? Gina, would you like to cast your vote for importance?

MEMBER PUGLIESE: Yes. I vote yes.

MS. WEBER: Six yes, 15 no.

CO-CHAIR CONWAY: Okay. So shall we keep --

MS. BOSSLEY: So now did everyone agree you want to continue on to scientific acceptability?

CO-CHAIR CONWAY: Yes.

MS. BOSSLEY: All right. So scientific acceptability, then.

MS. WEBER: Scientific acceptability, reliability and validity. It is a "Yes"/"No" question. Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: Nineteen yes, two no.

Usability: high, moderate, low,

or insufficient? Janet?

MEMBER NAGAMINE: Moderate.

MS. WEBER: Gina?

MEMBER PUGLIESE: Moderate.

MS. WEBER: Five high, ten moderate, six low.

Feasibility: high, moderate, low, or insufficient? Janet?

MEMBER NAGAMINE: Moderate.

MS. WEBER: Gina? Gina, would you like to cast your vote?

MEMBER PUGLIESE: Moderate.

MS. WEBER: Fourteen high, five moderate, two low.

CO-CHAIR CONWAY: Okay. Now, a rules ruling.

MS. BOSSLEY: Right. So now I think we need to go back. Can you go back to the slide where it is reserve status? So, again, what you are saying here is that you know it didn't pass importance but you still want to consider it for reserve status.

So I think for the purposes of this, if everyone agrees, let's just use this as you're recommending this measure for endorsement as a reserve status measure. Does that make sense to everyone? And then you are done. We will go back and fix this. "Yes" or "No"?

Patrick, yes?

DR. ROMANO: Question. Can you just clarify what the implications are of reserve status, what it means for the world of --

MS. BOSSLEY: Right. So the measure remains endorsed. So we don't really categorize endorsement other than we do have now two statuses. We don't know what to call them other than that. Time-limited is where measure meets everything but the reliability and the validity. They haven't yet provided that. And this one would be it's endorsed, and it has a kind of asterisk. And it says "reserve status." And then we explain what

that means.

Beyond that, we make no judgments of how it is used or not, but our recommendation is that shouldn't be the first thing you are going to do. But you should continue to monitor it and report that occasionally. Does that make sense?

CO-CHAIR CONWAY: Well, based on the voting, it would be valid and reliable but not important to use regularly.

MS. BOSSLEY: Yes, exactly.

CO-CHAIR CONWAY: All right. Jessica?

MS. WEBER: Endorsement for reserve status, "Yes"/"No" question. We need one more response. Go ahead and cast your votes again.

MEMBER PUGLIESE: Jessica, a question. How are people voting, electronic?

MS. WEBER: Yes. They are voting electronically.

MEMBER PUGLIESE: I wondered how

that --

MS. WEBER: Sorry? Could you repeat that?

MEMBER PUGLIESE: Do you see on the screen how the votes are going? Does everybody get a sense of how the group is voting?

MS. WEBER: Not until it is cast.

MEMBER PUGLIESE: Okay.

MS. WEBER: And then I am reading them off for the record. Janet, would you like to cast your vote?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: This is going on reserve status?

MS. WEBER: Yes, whether you would like it to go in reserve status.

MEMBER NAGAMINE: Yes.

MS. WEBER: Nineteen yes, one no.

CO-CHAIR CONWAY: Okay. And that should do it.

MS. BOSSLEY: Right. So now we did this for measure 0349.

CO-CHAIR CONWAY: That is the adult measure.

MS. BOSSLEY: Right.

CO-CHAIR CONWAY: Is there any sense? Would anybody like to debate the pediatric one or would your votes be the same?

MEMBER QUIGLEY: Sorry. This was the pediatric one, wasn't it?

CO-CHAIR CONWAY: No. Three forty-nine is adult. Yes.

MEMBER McGIFFERT: Yes. Are there any particular issues that are different in the pediatric measure that the group identified?

DR. ROMANO: No.

CO-CHAIR CONWAY: The only thing I heard is even more rare in pediatrics.

DR. ROMANO: Correct.

CO-CHAIR CONWAY: So I am not seeing anybody wanting to separately vote in

additional transfusion reactions. So we'll consider the votes the same and the reserve status decision the same.

MS. WEBER: Yes.

CO-CHAIR CONWAY: Wonderful. Do you need a break or can we forge on? Yes. So we'll forge on. All right. We'll next take on 0419, "Documentation of Current Medications in the Medical Record."

This comes from CMS. And Christina is the spokesperson for the workgroup or Tracy. Okay. Tracy. Sorry.

MEMBER WANG: Sure. Great.

0419: DOCUMENTATION OF CURRENT MEDICATIONS IN THE MEDICAL RECORD.

CENTERS FOR MEDICARE & MEDICAID SERVICES.

MEMBER WANG: So this is a CMS measure. We are looking at the proportion of patients that are 18 years or older and have a list of current medications. And that includes prescription, over-the-counter, herbals, vitamins, minerals, dietary

supplements, et cetera. And it is documented by the provider.

And the documentation needs to include four components: drug name, dosage, frequency, and route. The exclusions are when the patients refuse to participate or they come into through emergency situations and need immediate treatment or they are cognitively impaired. So those are taken out.

This is a process measure. The data is captured using administrative claims and registries. And there is concern in our discussion that G codes may not be used consistently to reflect what is being captured.

So in terms of importance, this measure addresses medication safety. And that is in outpatient settings. And the tie-in is that if there is increased knowledge of the patient's medication history, it will help physicians make appropriate clinical decisions. And it will lead to desired

outcomes in reducing adverse events.

In terms of the body of evidence, the workgroup felt that it was kind of light. So perhaps the developer if they are present can expound on that a little bit.

In terms of the scientific acceptability, this measure was previously endorsed with the time limit to endorsement. And so the developer did follow with a field test done in two different ways. And there is documentation alone which resulted in a moderate reliability rating, and then there is documentation, perhaps the verification component, which they found was somewhat low reliability.

So the quick question is, how accurate is the documentation and coding interpretation? And the developer did solicit input from a technical expert panel. And it concluded that the certain type of testing, which involves documentation plus verification, was very difficult to document.

And so the expert panel concluded that there is faith in content validity. So we wanted to make sure that is acceptable.

In terms of usability, the measure is currently being used for public reporting programs and quality improvement efforts.

And in terms of feasibility, data is captured via claims. And the expert panel also recommended changing the numerator to documentation only since the documentation plus verification, we had a low reliability score.

I think that is pretty much it. I didn't know if the other team members had any additional inputs.

CO-CHAIR CONWAY: Others on the workgroup?

MEMBER WANG: Chris?

MEMBER MICHALEK: I just want to say just the whole medication reconciliation process is there are so many errors related to incomplete reconciliation. So I think we all

felt that this was really an important measure.

We certainly see a lot of errors, certainly more so on the inpatient side because they are the errors that we see through ISMP and through the PACERS Program. So I think we kind of collectively all agreed on the importance of it.

Personally I did have some question about the quality of the reconciliation, you know, coming from claims data, that whole validity piece of are they really doing the reconciliation the way we would like them to do it in order to be effective to prevent those errors that occur. And when we make recommendations at ISMP, we go well beyond what is even in here.

We ask our scripted questions. We ask about drug-eluting implantable devices. And we like to see that whole piece together to avoid any of those events.

CO-CHAIR CONWAY: Before we get

too deep into this, why don't we just hear from the measure developer? Don, do you -- there were some questions the workgroup had posed to you all. Maybe you can answer those.

DR. WILSON: Sure. This is Don Wilson with the Quality Insights team.

I think one of the issues that I know people talked about was the impact of this measure. And I think we provided some literature. I think the Nazarel article that I think we supplied to you really talks about the effect of how actually medication reconciliation in the outpatient environment actually causes more deaths than it does even in the inpatient world.

And I think it has been an area, like you said, where the TEP has always been emphasized on the inpatient arena but not necessarily on the outpatient side.

I think the real gap in this measure is the fact that in order to pass the measure, you have to really not just document

the medication list and say that it's current, but it is a matter of having the frequency route accepted, having all four of those elements present, which is really where I think a lot of the gap occurs.

If you look at some of the literature, the actual -- some of the articles that we supplied have rates of something like 20 percent being documented when you really look at all 4 of those factors being present. And lots of times it is really the route and the frequency that fall down. So I think again it was a matter of really trying to get that across that you really need all four of those elements.

I think another area that -- and I know we had a discussion about this in the workgroup last week, but I think another element that our TEP really felt important -- and when you look at the literature, I think it really bears it out -- is that the over-the-counters and the herbals are really

important to be included. And they are frequently left out. But I think most of the literature really supports the concept that they really need to be included as well.

So I think that is another area that we really need to raise the awareness that that needs to happen and where there is a significant gap.

Other questions?

CO-CHAIR CONWAY: Tracy, did that answer the workgroup's set of questions? Thank you.

Let's go around the table. Jason, you can start.

MEMBER ADELMAN: Yes. I have a couple of questions for Don. I don't understand this measure multiple ways. So, first of all, just simply the English language of the numerator/denominator.

The numerator is current medications, including name, dosage, frequency, route, and route documented by the

provider. So for patient with seven meds, from what the English says, that would be seven medications.

And then the denominator is all patients aged 18 years and older on date of patient encounter. And so as they encounter ER visits, hospital visits, outpatient visits, so is it all the meds documented at every encounter over every hospitalization? Is that what it is?

DR. WILSON: This measure was written actually for the PQRS program. So it is really taking place in the ambulatory site. So if you look at the -- it also talks about the fact that the denominator is defined by the codes. If you just look at the denominator coding set and they are essentially the outpatient kind of code. So it really doesn't include inpatient or even ER, as I recall. So, you know, it really would be an outpatient visit.

MEMBER ADELMAN: You know, the

codes are a list of numbers. I don't know enough to know what those numbers are. But maybe so in the denominator statement, you could just make it clear that this is for outpatients.

And even that I don't understand the validity of what's the difference if somebody has two meds or seven meds. If this is a quality measure and a patient comes in, the provider writes nothing or writes down the patient meds and this patient happens to be on five meds, so that doctor gets credit five times because the patient happened to be on five meds?

DR. WILSON: The way that coding is written is basically that in order to pass, the physician has to write that these are the current meds that the patient is on. And at each visit, they have to document that these are the current medications that the patient is on.

MEMBER ADELMAN: Right.

DR. WILSON: That is per patient or per visit.

MEMBER ADELMAN: The language can be clarified to make it more like, you know, documentation that a medical history was taken and completed would be much more accurate than the numerator being the current meds because that is what it says. I mean, you can read it.

And then the denominator I guess you are saying is every encounter. It's not the patients.

DR. WILSON: It's all the outpatient encounters, right, for every encounter for that patient, right, that that patient is seen during the reporting period, which is --

MEMBER ADELMAN: And then --

DR. WILSON: The current medications are documented. I guess I am still not quite understanding your point about documenting versus the current medications.

MEMBER ADELMAN: I read the numerator, Don. If you read it again -- and I don't want to keep going over it, but I just think it's -- I find it to be confusing. I don't know if others agree, the way it is written and what you are describing.

CO-CHAIR CONWAY: Thank you.

MEMBER ADELMAN: Sure.

CO-CHAIR CONWAY: Lisa?

MEMBER McGIFFERT: So I was looking at the exceptions. And it looked like -- oh, where is it -- one of the exceptions was people who are cognitively impaired and no representative. And I understand that that is hard to document, but the target population are elderly people who may be in that situation. Does that create some kind of an issue for the measure when you are eliminating maybe a bunch of the population that you are trying to target.

MEMBER QUIGLEY: Excuse me. The target population is the entire adult

population, 18 and older.

MEMBER McGIFFERT: Well, I know, but the target population is elderly. And I read it somewhere --

DR. WILSON: I mean, I think the measure --

MEMBER McGIFFERT: -- in your testing, that you don't find that there are a bunch of them that are not documented because they are accepted because they some kind of senility or dementia or something like that?

DR. WILSON: But, I mean, that is actually an exclusion. If the patient is cognitively impaired --

MEMBER McGIFFERT: Right.

DR. WILSON: -- and they can't obviously give the history, then the provider can --

MEMBER McGIFFERT: Right.

DR. WILSON: -- actually list that as an exclusion if they aren't able to obtain the --

MEMBER McGIFFERT: Yes. Yes. This concerns me that that is the population that probably needs this the most. That is my point.

DR. WILSON: Right. And I guess the question is, how do you get at it, then? You know, it's a matter of if the patient is cognitively impaired, it can't actually give the information, you know, I think it's a dilemma for the provider for sure.

But at least we have documented that whenever they can, they do get that information from the patient or their caregiver.

MEMBER McGIFFERT: And my question was, in the studies, did you find that that excluded a significant number of people?

DR. HIBAY: My name's Sharon Hibay. I am from Quality Insights.

Our finding is so the exclusions reported just slightly over one percent of all the population.

CO-CHAIR CONWAY: Jean?

MEMBER de LEON: I would ask that you also put something in on the timing of the medications. Some of them are very self-limited. And to not know when a medication was started, an antibiotic, for two weeks and they're on it, they stop taking it because they forgot to take it or they felt better, then they started up again, if something is time-limited, that it is documented as well, so not just the name of the medication and the dosage but it's for two weeks or it's for a month and it started on a particular date.

CO-CHAIR CONWAY: And, John, we'll come up this side of the table.

MEMBER CLARKE: I'm a surgeon. So excuse me for being stupid about pushing, but it seems like what we are doing here is verifying medication reconciliation by looking at a list of medicines that the doctor says that the patient has had and the doctor's

signature that this is the medicines that the patient is on.

And we're concerned. We're going to ding you if he doesn't capture the medicines, all the medicines, that the patient has. So I wonder how you find out what medicines the doctor missed by looking at the medication list.

CO-CHAIR CONWAY: Don, can you answer that?

DR. WILSON: Again, I would think it's a matter that the point of this measure is to assure that on every single visit, the provider actually does at least take the time to document all of the current medications that the patient is on, including dose, frequency, route.

MEMBER CLARKE: Right. But this happens to me every day in practice. I have a patient comes into my office. And I say, "Are you on any medications?"

"No," to which I say, "Do you have

any medical problems?"

She says, "No."

I examine her. She has pitting edema of the ankles, three plus. I say, "You have big, swollen ankles."

She says, "Yes. I have high blood pressure."

And I said, "Do you take any medicines?"

And she says, "Yes. I take a blood pressure medicine."

So if I didn't go back and I had just written down what she said, "No medications," you would never know. I would never know that she was on a high blood pressure pill without examining her, which is an ancient Druid custom that I still practice. And you would never know because you are using my documentation to evaluate whether or not I am picking up the medications.

DR. GREEN: So hi. Sorry. I am Dan Green. I am a medical officer at CMS. I

worked with Don in Pennsylvania in developing the measure.

As you know, we use this in a pay-for-reporting program currently, which will be transitioned to a pay-for-performance program. I am sure as a practicing physician you can imagine myself -- I am an ob/gyn by training. There are numerous times that we get notes from people where the medications are not fully documented.

And you are correct in that we won't be going back behind every single physician or other provider to see whether or not the medications were documented in an accurate fashion.

However, we feel this is an important concept. And the idea here is to encourage all professionals who are in contact with a patient each time to document the medication. So if they are prescribing some treatment, they at least have an idea that there may be some contraindication, some drug

interaction, or some other thing that they might consider when they are recommending a particular treatment for a given patient.

I am sure those on the CSAC here that are clinicians can certainly appreciate and have seen personally where patients have not had their medications documented. It sounds like a simple thing.

And I am not into low bar measures in general, but, unfortunately, the gap for this process, as simple as it is, exists. And this is one thing we are trying to encourage physicians and other eligible --

MEMBER CLARKE: There's no doubt it exists, but how do you capture the fact that the doctor didn't get the medication, didn't get all of the medications?

DR. GREEN: So that's a great question, but I would suggest -- and I am not saying that this is a great answer to your question. I would suggest that that is true basically of any of the measures that are

self-reported and that are not either coming directly from an electronic health record. And even then there could be errors in the system because it is only as good as the person inputting the information.

But, you know, all the measures that we had, did you give an antibiotic before you operated on a patient, that is a self-reported thing. How do we know that the antibiotic, in fact, was given? We only know by the doctor --

MEMBER CLARKE: Yes, but at least in that case, the doctor wasn't -- maybe I'm being more pay care, but you went to ding me if I didn't put on my record that the patient was on an antihypertensive.

You look at my record. My record does not show that the patient is on antihypertensive. How do you ding me?

DR. GREEN: We would "ding you," basically how you report the measure, same way we would ding you in the penicillin thing. If

you told us you reported penicillin, we can't possibly nor I don't think any quality program, be it CMS, be it any program, go behind and say, "You know what? Did Dr. Clarke really prescribe the antibiotic for this particular patient?" If a doctor says that he or she document the medications in the record to the best of his or her ability -- and, again, it's --

MEMBER CLARKE: Let me try to rephrase this. How do you know that i.e., I asked the question "Are you on an antihypertensive?" and the patient said, "No" or that I never asked the question?

DR. GREEN: What we would know by you telling us that you documented the medications in the record is that you asked the patient for all the medications he or she was on. That's what we would know.

CO-CHAIR CONWAY: Yes. John, let me try and help. And I want to go back to Jason's question and get this clarified. Don,

could you? Maybe people here aren't familiar with G codes. Could we just go through the mechanics here? Is this a single G code checkbox where the doctor said, "I created a medication list" or is it more complicated than that?

DR. WILSON: If you look at the -- I don't know if you guys have the measure specs or not, but there are three G codes for this measure as it is currently configured. So basically -- and the way it is done through the claims reporting for PQRS is the physician actually has to append one of these G codes to their claim submission.

CO-CHAIR CONWAY: Which page are you on?

MS. BOSSLEY: It's on page 6 of the form.

CO-CHAIR CONWAY: Okay.

MS. BOSSLEY: And in the .pdf, it's page 49 if you look at the workgroup.

DR. WILSON: So if the physician

did indeed create a list of current medications for that visit, then they would report G-8427. And the definition of that G code says, "List of current medications, including prescription, over-the-counter, herbals, vitamins supplements, or documented by the provider, including drug name, dosage, frequency, and route."

So, again, it's a matter of the measure itself -- and I understand where you are going with this. It's like how do you really know that that is the accurate list or that -- but I think the point of the measure is, you know, right now doctors when you look at -- and other providers, like I said, in the couple of studies we have, only like 20 percent of the time did they even ask or document that they had checked the current list. So we have to get them to start trying to verify that they at least asked and tried to document this is the current list, as I understand it, you know, for this visit.

I think that is a whole different set of issues, you know, around the current. And, really, what can you really hold the provider to at that moment in the world once hopefully we get the electronic medical records and have health information exchange, et cetera. That is obviously the big benefit that that is going to provide, you know, the provider can get that information, but right now, that is one of the major problems with our current fragmented health care system. Lots of times the patient is your only source of information. So yeah, exactly.

So, I mean, I think that that is case in point for why we need better health information technology. But for at least for now, I think if we can at least just consistently get providers to say that every time they see a patient they are document, as I understand it, this is the current meds, including over-the-counters, et cetera, that the patient is on. And I am taking that into

account as I am creating my treatment plan.

CO-CHAIR CONWAY: Okay. Let's continue on up the table. Is Patrician next?

MEMBER QUIGLEY: Thank you, Dr. Conway. Was that Janet or --

CO-CHAIR CONWAY: Janet, we'll get to the phone in a minute.

MEMBER QUIGLEY: Thank you, Dr. Conway.

I would just like to share that I was one of the members of this workgroup. And my scores aren't up there, but I did enter them into the database. But I was one of the people that had multiple difficulties with this quality indicator.

And part of my difficulty is that it did include everything in terms of medications. It was even the over-the-counter meds and the herbals and the vitamins. And we had this discussion on our workgroup. And I talked about it with a couple of the physicians that I work with. And I am a

prescribing provider. To be able to include all of this as medications was one of the issues that we had. And was it really realistic?

But what I learned in the workgroup discussion and having our measure stewards on our call is that for this to pass, it has to be the current list of meds. And you have to make sure that you have addressed the name, the dose, the frequency, and the route. And, even if you can't get that, every time you see a patient when they come into your clinic or in the ambulatory area is you have to write that the patient doesn't know.

So, for example, they're on a dietary supplement and they don't even remember the frequency that they are taking it. You have to be able to write that to be able to pass. This is what I understood on the conference call.

So I have issues with this as, you know, if this is really valid and reliable and

this could truly be an indicator to be able to indicate medication safety in that regard.

CO-CHAIR CONWAY: Okay. Thank you.

And Vallire?

MEMBER HOOPER: I think I am getting more confused as the questions go around. I am confused as to if this is self-reported by the provider, "Yes, I did the reconciliation" or "No, I did not."

CO-CHAIR CONWAY: Yes, it is.

MEMBER HOOPER: Okay. And in that case, what is the current compliance level because this is a maintenance set? And do you do any checks where we go back and see? This seems right now to be a very easy checklist, "Yes, I did it" or "No, I did not." It's kind of like the education measure yesterday, "Yes, I did it" or "No, I did not."

When you talk about pre-op antibiotics in a hospital, there are electronic components that you can pull from

the chart to document that it was prescribed and it was given.

So I am just a little bit confused as to how we actually know this was truly done and all of the elements were truly accounted for.

MEMBER QUIGLEY: Dr. Conway, my understanding is that for this to pass, all of the elements of the medication have to have been reviewed. For this to pass and the numerator, it had to include the dose of frequent --

MEMBER HOOPER: So how do the --

MEMBER QUIGLEY: Right. It's not just a simple "Yes" or "No" for medication --

DR. WILSON: I can maybe provide some clarity with that. Again, it is a matter of, as it is currently being operationalized in the PQRS system, it is a self-reported measure.

But, as with all measures in the PQRS program, physicians are always aware that

they could be audited. And when we do our testing -- and we can talk about the testing -- that is literally what we do when we pull the charts is we want to see documentation.

If the provider reported that G code that they indeed did it, then we requested a series of records randomly pulled across the country and assess how often there is documentation in the medical record that supports that they indeed did do it if they reported that code.

MEMBER QUIGLEY: What are the findings?

DR. WILSON: What was that?

MEMBER QUIGLEY: What are the findings?

DR. WILSON: The findings were the reliability. If we just looked at at documentation alone, the statistics -- it was about 78 percent of the time where we really felt that there was documentation to support it that they had done it.

So it was felt to be reliable and that providers were reliably reporting, you know, accurately whether they -- in other words, there was documentation in the medical record to support the fact that they had done it if they reported that they had.

MEMBER THRAEN: The ones --

MS. BOSSLEY: Iona?

MEMBER THRAEN: The ones that were reported --

MS. BOSSLEY: Iona?

MEMBER PUGLIESE: Can I make a comment?

CO-CHAIR CONWAY: Yes. We're going to do Carol, Charlotte, and Janet.

MEMBER PUGLIESE: And Gina.

CO-CHAIR CONWAY: Okay. And Gina.

MEMBER THRAEN: The ones that they're reporting that they did not do it, what was the finding for that?

DR. WILSON: The ones who reported they did not do it? First off, that was a

fairly small number because, again, I think the thing that you have to understand is the way this program is currently set up is voluntary reporting.

So it is unlikely in all honesty that a provider is going to report this measure if they didn't really do it, you know, what I mean, if they are not complying because it is voluntary reporting.

But the intent, though, is eventually it won't be that way, you know, that these measures will evolve into this point where this will be into a pay-for-performance kind of an initiative, where it won't matter and it may become mandatory.

But for right now the data you have -- and I think you always have to remember that in all the data that when we get down into the testing data are looking at some of the prevalence kinds of how it was reported that this is really sort of a -- it's a biased

sample because you are really only looking at physicians who elected to voluntarily report this measure. So I don't know if I answered your question.

MEMBER THRAEN: Okay. So just so I understand, of those that agreed to report, 78 percent compliance with the documentation, agreement between "I did this" and there is documentation in the record to support it.

You don't have a sense of who chose not to report. So you don't know how big it is. You know, is this like representing one percent, 2 percent, 30 percent, 100 percent of your physicians? So you don't have any sense of that, right?

DR. WILSON: I don't think we have a number as far as who chose not to report the measure because, again, in the PQRS Program, if you understand the way it works, physician can pick three measures out of the total cadre of 200 measures that they want to report on. And they can get a performance incentive or an

incentive just based on actually reporting because, again, the whole impact right now for the PQRS Program is just to get physicians in the mode of starting to report data, you know, with the idea that it is going to transition further down the road.

CO-CHAIR CONWAY: Okay. Now, I know there is a lot of enthusiasm over it, but let's proceed in order. We'll go up the left side of the table, to the phone, and then down the right side. So Carol is next.

MEMBER KEMPER: Okay. Thank you.

Just to preface, I would say I think this is a really important process. And it's one that we have struggled with. And I think someone mentioned thereabout that it is deceptively simple. And I would agree with that. I mean, we have struggled with this process on an inpatient and ambulatory side within our organization.

But I think that what is really important to kind of echo what Jason said. I

still am not completely clear on the measure. And so I think that needs to be refined.

I'm still unclear if the code is each visit. So each visit do I assign that code or do I assign that code for each medication because it looks here almost as if you would assign it for each medication so I could see that all of those components were completed.

So that I think just needs to be more clearly written because I think you are going to get varying results if you keep it this way.

CO-CHAIR CONWAY: It's each visit. Physicians here probably are familiar with G codes. It's each visit you need to check certain boxes.

Charlotte?

MEMBER ALEXANDER: In just response to that, maybe even adding something like "a list" at the preface would clarify it.

I have been using this measure for

a while. And I have got several observations. Lisa, when you were concerned about the elderly and that that was the one that is the most important, it takes a huge amount of time in my office, but if we can find the pharmacy that they used, we can call the pharmacy. Their list of meds doesn't pick up everything if they have used more than one pharmacy.

It is an effort. And I have to say that this reporting mechanism has given validity to my office staff more than my just asking them to do that. Now that we have to report it, I get more buy-in. It helps me a great deal because I tend to pick up a little bit better when people are on an anticoagulant therapy, which for me as a therapist or a surgeon is an important thing.

I fall into the same problems that John does in that people don't tell me what medicine they are on. If they are a diabetic, they just assume I know they are on insulin. They won't tell me they are on insulin. And

so you do have to do some querying to fill it out.

The challenge in my mind is how we pick up whether we are really reconciling. If I have someone come in that is on two anti-inflammatories, I am very comfortable saying you can't take these two at the same time and trying to reconcile that. I am not comfortable when they are coming in in on three or four blood pressure medicines or heart medicines saying, "You are on too much medicine."

And I think the goal in the long run is that we are giving safer care and that we are really reconciling the meds. And so I don't know how we start progressing to go to that point. It may be the list is the start, that we are actually just looking at it, and that we can hopefully move forward toward better care.

CO-CHAIR CONWAY: Okay. Thank you.

Janet?

MEMBER NAGAMINE: Thank you. So I just want to echo what was just said about the list being the start. There is nothing that says that this list is going to be accurate. And there are different levels of effort.

So, that said, I completely agree that we should set the expectation that we should have an accurate meds list on the outpatient side.

I also, though, wanted clarification about the measure specifications. Does this apply to the primary care physician or any physician? So if you get referred to GI or a subspecialist, is it the same expectation for the subspecialist that views it maybe once or twice or does this apply only to the primary care physician?

CO-CHAIR CONWAY: Don?

DR. WILSON: It applies to any physician. So, again, if you would look at

the codes in the back -- and I understand if most of you are like me, you don't really have these things memorized like some people do that are coders, but it would be anybody that bills those codes.

And so the E&M codes that are listed are the same E&M codes that a primary care physician bills as specialists also bills those codes as well because, again, when you really look at the literature, I think it is very much emphasized that every provider that sees a patient really should have a current list of medications.

MEMBER NAGAMINE: In theory, I completely agree with you. I am an internist. And this is one of my pet peeves. I deal with this every day. It is either an incomplete list or the wrong dose or someone is admitted to the hospital because one guy gave him Metoprolol, another gave Atenolol and, gee, they're bradycardic now --

DR. WILSON: Right.

MEMBER NAGAMINE: -- or they have Lasix and hydrochlorothiazide and they're now in renal failure.

So I just don't know how to operationalize this measure in a way that is realistic, but, for example, if someone comes into their primary care physician for a rash and you have given hydrocortisone or some cream, do you really need to spend the time to go over their ten meds, you know, because I know how long that takes.

I do think it is important in certain situations to, critically important to, have that list, but I don't know that in everyday outpatient practice that this would be realistic for an internist whose patients are very old and on -- that's just my hesitation there.

CO-CHAIR CONWAY: Okay. Anything else?

DR. GREEN: Hi, Janet. May I, Dr. Conway, make a comment?

CO-CHAIR CONWAY: Sure.

DR. GREEN: Hi, Janet. This is Dan Green. I think you bring up a great point. I mean, obviously, you know, with internists, their time is being squeezed more and more. I would suggest, though, that as e-prescribing is further adopted, you know, one of the components, even, in the measure that you all have endorsed is the ability for the eRx program to actually query the pharmacy benefit manager, which would, in turn -- the payer basically, which would, in turn, be able to help provide a list of medications that the person is on.

I would suggest, I mean, hydrocortisone, probably not that big a deal, but for many other medications that internists would prescribe, you know, after a short visit, like somebody perhaps on an antibiotic or whatever coming in for an upper respiratory infection, obviously the medications would be important because of the potential drug

interactions that could be associated with that.

So I think this will work itself out in terms of being able to get a more accurate list, like Charlotte was talking about and Dr. Clarke was also mentioning, but I also think that as the eRx is further adopted. So I can appreciate your comment, though

CO-CHAIR CONWAY: On that point, let me just try to clarify something. This doesn't ensure med reconciliation. This just states that you maintained a list, correct, Don?

DR. WILSON: That's correct. Can I just say one other quick thing before we move ahead? We just realized it. I think one of the reasons why there may be some confusion is there is a set of instructions that are listed in the measure specs that are out on the PQRS side that providers see when they report this measure. And apparently that's

not on the NQF form.

If I can just quickly read, basically it says, "This measure is to be reported at each visit occurring during the reporting period for patients seen during the reporting period." And it is intended to determine whether or not documentation of current medication lists occurred for all patients age 18 years and older.

And it goes on to say, "This measure may be reported by eligible professionals, who perform the quality actions described in the measure based on the services provided in the denominator coding."

So I think, again, maybe that was why there was some confusion about the fact that it's reported every time.

And, again, to go back to your question about whether you report the G code for every medication, again, if you would look at the -- and maybe we need to -- because if was confusing to you, then perhaps it is

confusing to others.

But if you would look at the G code, it basically says you report the G code on each visit if a list of current medications were documented by the provider. So the assumption is in order to be able to report the measure, the G code, you have to have the complete list there and all the four elements for each drug or over the counter is actually listed as well.

So you have to be compliant with all of that in order to report, and you just report one code. But, again, if you feel that there is some confusion --

CO-CHAIR CONWAY: Okay. Gina?

MEMBER PUGLIESE: Oh, yes. I don't really have anything to add. I think it is an important measure as one of the important safety measures, even though we justify and make sure that it's accurate and whatnot, that they're using to collect it, I think that it's important to keep. And I

think that the -- I think that we can at least find out what some of the issues are.

CO-CHAIR CONWAY: Okay. Thank you.

Turn to the right.

MEMBER LAWLESS: Okay. A couple of things. The emotionality created by this measure is just short of the emotionality that's going to be created when you have a handoff measure.

(Laughter.)

MEMBER LAWLESS: So I am just preparing you ahead of time. Is there a category called "Strategic Measure. Don't worry about it. Please work on progress. Don't worry about perfection" category that you can put in place?

This has been an area of my research interest. We just published a lot of the pediatric results on this. So I can tell you that from a system standpoint, we have it in a fully electronic system. We compensate

for our providers for doing medication reconciliation.

We have ER, outpatient, inpatient, the whole nine, the whole system that way, any prescribing rates up in the 79 percent range. Okay? So we report 95 percent.

The accuracy I'm telling you, that when we go back and look, somebody does med rec. They try. When you then go back and you make calls to families and say, "Bring your medicines in now," 50 percent of the time the families get it right. So we ask them to bring their medicines in because we don't trust you. So we now tell the providers, "Just list your medicines. Don't worry about dose, dosage, and everything else unless you actually have the medicines in place.

So now if you take that, so take your 90 percent rate, cut it in half because the families don't get it right, and then you take that and you look at the sig statements, which is the written part of the statement,

which is not granular, there is about a 12 percent inherent error in that.

So now I am about 37 percent accurate in terms of a medication list. And that's even with the electronic systems. But it is an unbelievably important issue.

So I would say you have got to start somewhere with it and do it. And that is why I say strategic measure, what do you really want to accomplish at first? Maybe it is getting duplicative medicines, which you can get from claims data. You are on the thiazide, and you are on the this. You know, do you really want to be on both these medicines because they interact with each other?

It almost I guess strategic focus, if we are going to start this first and then this one and this one and/or put out a call for proposals to people and say, "Who has got it right? Where in this country are they doing this correctly?" because otherwise what

you are doing, you are throwing darts at a problem which is crucial, but you are contributing to it.

You are saying to people, "You do" this, this, this, this. Nobody is comfortable with it. But is there any place you can point to in the country that is actually doing it right?"

Right now this is a measure that is unbelievably important, and it is really the heart. But it is just not telling you a story.

MS. BOSSLEY: Just hit the mute. It's a mute button there. Dr. Green?

DR. GREEN: Sorry. I'm only an ob/gyn. If I were like ID or something, I would have figured it out right away.

I think your points are very well-taken. To my knowledge, I don't know of any place in the country that has got it perfect. I would think that Kaiser is probably as close to perfect as you can get

because it's a closed system, but even Kaiser has patients that are taking botanicals.

And I can tell you, especially as an ob/gyn, you know, with some of their herbal supplements and things like that or the compounded pharmacies where people go, you know, because of the preeminent gynecologist, Dr. Suzanne Somers, who advocates these bioidentical hormones -- excuse me. I'm sorry. Did that actually come out on the mike? But, putting that aside --

PARTICIPANT: But she looks good.

DR. GREEN: She does look very good. She looks great. But, in any case, you have patients that are taking these kinds of things -- and you are not going to capture that, obviously, even from a system such as Kaiser's.

But I think your initial point was probably the most important point. And that is we have got to start somewhere. You have too many health care providers that are not

even making an attempt to document the patients' medications. And until that is done, you know, even if -- let's say you're using your numbers. Let's say it's even 20 percent, less than the 37 percent you said.

If there's one out of five medications that the patient is on, that's still better than zero out of five because if that particular medication is going to interact with the other medication that I am going to prescribe, okay. I happen to have gotten lucky, but I've gotten somewhere. But if I haven't even asked, you know, the horse is out of the barn. And if the patient has a drug interaction, then, you know, we can be discussing the untoward effects for the patient in the population.

MEMBER LAWLESS: See, that's why I'm saying maybe the suggestion would be to have someone outline the whole process. You know, the idealized process is this, the whole soup to nuts through it. And then you say

component pieces of it, and you say, "We're working on this piece, this piece that fits into the organized hole" because what it looked like is we have thrown out med rec out there as a -- which is good. And then people are interpreting it or people are finding now the holes, but we just have to --

DR. GREEN: You know, I think we would all, especially you guys here, agree that quality reporting and measures are important, obviously, like with PQRS. And I'm not saying that that is the be all and the end all because we know that it is not. But it was a start and to get doctors in the habit of reporting quality measures.

Is it perfect? No. Do we pay them on performance at this point? No. We pay them simply for reporting. So it was a start to get doctors to change behavior in terms of, hey, now I've got to send some information in.

It seems like some of these

measures are easy, but, again, it's a start and the same thing I would argue with the medication reconciliation. Can there be improvements to the measure? I hope that there are improvements.

Again, even if we get to the PBM thing, the pharmacy benefit manager I was talking about with the e-prescribing, that is still not going to give us 100 percent because, as you know, patients use these herbals and botanicals and, you know, the health food store and all this kind of stuff. And some of them are embarrassed to tell their traditional medical person that they are actually using them.

So we may never get to 100 percent. But by virtue of not being able to get to 100 percent doesn't mean we shouldn't start somewhere and make an effort.

So thank you for that opportunity to speak.

CO-CHAIR CONWAY: Jason?

MEMBER ADELMAN: Just I'm an inpatient provider. I don't see outpatients. I haven't used G codes. I just want to make sure I understand this.

You are saying that when a provider sees a patient as a outpatient, they fill out a code to generate a bill. And there is a G code, where they are attesting to the fact that they took a current list of medications and that is what this is capturing.

So if Dr. Clarke sees a patient in his office, as part of generating a bill, even though he might not have gotten the exact -- because the patient will attest to the fact that he got a current list.

DR. WILSON: Yes.

MEMBER ADELMAN: And, you know, the Joint Commission had a med rec rule. And then it disappeared for two years, went on hold. And then it came back. And they added language like, you know, "We made a reasonable

effort because we realize it is impossible."

But I guess that language isn't in the code itself. It doesn't say, "We made a reasonable effort to get a complete list." It just says I've got a -- so you have no choice to either say you did it or you didn't do it, even though the truth is you made a reasonable effort. You didn't call the patient's pharmacy and check or the patient's daughter and check. But I have that right. Okay.

And so because of that, then, this is those attestations because I was going to say yesterday we looked at a DVT prophylaxis measure. And it just said DVT prophylaxis was done or documentation why it wasn't, but it didn't say the accurate DVT prophylaxis, just that it was done. And the way you described it was that we captured some med list. We are not so concerned about the accuracy. That's a first step in a process.

And so I would say change the language to -- we just captured a list, not

the actual list, but because you are relying on that the physician attested to the fact in their bill that it was an accurate list, that is why we are going with this.

I understand I think more than I did before.

DR. WILSON: I think understand what you are saying. And I wasn't here yesterday for the DVT prophylaxis piece, but I am sure you have probably looked at all of the DVT measures. And, as you know, that is the first measure sort of in a set.

The first thing is, did you do it or not? But then there are subsequent measures in the hospital reporting program, for instance, that looks at, did you do the right one, and did you do it in a timely way, and that sort of thing. So it is kind of like a group of measures.

And I would anticipate that eventually, especially as we get more into electronic health records, et cetera, we will

be able to have more sophisticated measures in the outpatient world. And I am sure it will come out through meaningful use. You know, there is going to be better med rec done through the EMRs.

MEMBER ADELMAN: I have a better understanding of what the intention is. I still think the language can be cleaned up a little bit to make it more understandable.

DR. WILSON: Okay.

CO-CHAIR CONWAY: Mary?

MEMBER SIEGGREEN: I just wanted to comment on how important I think this is. I work in an academic medical center. And before we had med reconciliation, we had residents who would discharge the patients on all the meds that we put them on in our hospital. And our hospital formulary carries different medications from what they were on before. And they also put at the bottom, "Resume all home meds."

So when the patient got to us in

the office, it was like you would look at the medications. If you did look at the medication list, you would get chest pain right there.

I think, even if we can begin something like this so you're looking at this duplication, it is a huge safety effort and a change. And I think it is really critical for those patients, whether or not you are the prescriber of these medications. But in our practice, we prescribe things like pain medication and antibiotics a lot.

So it is really important to know what all the patient is on and also anticoagulants but also all those other things that you might have in combination with it.

CO-CHAIR CONWAY: Jean?

MEMBER de LEON: I just wanted to point out there is a very big indirect benefit just by having asked to make a list, whether I have got the list right or not. I see a lot of geriatric. I probably don't have it

exactly right.

But in some ways, I am probably more correct than the pharmacy because I have asked the patient. So now they are going to tell me, "Well, yeah. But I don't really take it like that" or "I don't take this one at all" or "I only take this once a week" or "I only take this one when I notice I have swelling." So I get a much more accurate picture of what the patient is doing.

And because I asked, now they are actually being a little more forthright about what they are taking or how they are taking it because they feel that it is going to impact my evaluation that day.

So there is a huge indirect benefit to just asking for the list, whether it is correct or not.

CO-CHAIR CONWAY: For the next loop around, maybe we could focus some of those new questions or clarifications that I will cover.

John?

MEMBER CLARKE: Thank you.

I agree that I think this is an important concept, particularly the herbals, but I have concerns because it seems to be a crude measure of a poorly done process.

And so the point of the National Quality Forum is to come up with quality measures. And I think that quality measures could be interpreted two ways: measures of quality and quality measures of quality. And I wonder if we are not just premature in tackling this problem with a crude measure of a poorly done process.

And it might be better to defer this kind of reconciliation until we can, in fact, correctly measure true reconciliation with deferring this until after we have the kind of prescribing that would allow us to do this properly, rather than the way it is being proposed right now.

CO-CHAIR CONWAY: Okay. Thanks.

Tracy?

MEMBER WANG: I have a question regarding that mode or criteria. So if I understand this correctly, it is a way of looking -- the numerator the way it is written, it is looking for both documentation plus verification. But your field testing results show that the reliability is only about 22 percent. Am I interpreting correctly?

And so it also seems like when you consulted the technical expert panel, the recommendation seems to be moving to a different numerator code. So when we are voting and dosing this metric, are we voting with the previous for the way it is written currently or are we moving into the new recommendation made by the Committee?

CO-CHAIR CONWAY: Don?

DR. WILSON: The original measure did say documentation and verification, that the meds have been actually verified by the

provider, not just the fact that he had documented a current list.

As you correctly point out, when we did our testing on the measure and actually requested 500 or so charts and got them in and looked at it, it was the providers who reported that they were compliant with the measure.

The consistency, as we have talked about already with the documentation piece that they had that indeed the current medications were documented was high. The part that was not reliable was that the abstracters who went and tried to verify this couldn't really meet the criteria of saying that the provider had gone an extra step in saying these were verified or with the patient.

And when we went back to the TEP panel, they really felt that that was inherent in the measure, that if you actually obtained a list from the patient or their caregiver

during their visit, that that verification piece was really an inherent part of that. And, therefore, we didn't need to actually have that be sort of a separate piece that needed to be documented.

So with our last iteration of the measure, we actually took the verification statement out and just basically say now that the current medications have to be documented at the time of the visit.

Does that answer your question, Tracy?

CO-CHAIR CONWAY: Okay. Any other questions that people need to clarify this measure? I'm sorry? What? Yes?

DR. HIBAY: Again Sharon Hibay. I would just like to make a couple of comments on some information that was shared.

There was a question about potentially deferring this measure this time. And I just would like to put out my thoughts on that that when you look at this, we have

talked about this medication reconciliation process. And Dr. Wilson and Dr. Green have also spoken about the magnitude of the work that is done in medication reconciliation. Again, medication documentation is just one step in that whole process.

One of the articles that we provided for impact, et cetera, talks about the different possible breakdowns or failure points in the entire medication reconciliation process: physician/provider-related health system, practice/process-related, pharmacy-related, patient-related. So this one has the opportunity to kind of go after that patient/provider link and do some positive work there.

But to defer this measure until another time provides an opportunity for missed patient safety, missed improvement, missed communication between patient and provider to be able to take a look at recognizing the safety issue and trying to

move these initiatives forward.

CO-CHAIR CONWAY: Thank you.

Gina or Janet, do you have any final questions?

MEMBER PUGLIESE: No.

CO-CHAIR CONWAY: Then, Jason, one --

MEMBER ADELMAN: You know, if we are about to vote, if the numerator and denominator stand as is and that is what we are voting on, I still think it is very confusing. However, if the numerator said something like, you know, it is the attestations by the providers that a current med list was on, I might vote differently because the numerator is not current medications. That is what it says. But what was described was an attestation. And even the denominator, it's not all patients, you know, blah blah blah. It is encounters.

And so before we vote, if the developers agreed that the language would be

changed to reflect what it actually said, it would affect the way I voted.

CO-CHAIR CONWAY: Don, is that something --

DR. GREEN: I'm green. I'm good. There's a little pun there, actually.

So, look, no. The intent of the measure is for these services, did you query your patient about what medications is he or she on? That is it, nothing more, nothing less.

We are not looking for the doctors to sign, you know, their chart in blood or whatever. We realize that you are only as good as the information you get, which is true of anything that you do in your office.

Forget medications. You know, you can only rely on what the patient is telling you. You know, we all know and understand that. I don't mean just we as CMS. You guys all understand that as well. So that is the intent.

And I can speak from a CMS perspective. We have no problem changing the instructions, the way the measure is written to capture that intent if there is confusion on your part. So we would be happy to work with whoever the content person was at NQF that helped to steward this through.

I'm sorry. I'm coming through a little bit -- coming in a little bit late. But to come up with a language that captures exactly what I just said. And if you are comfortable voting on that concept, then I would hope that you would vote for it.

So does that answer your question, sir?

CO-CHAIR CONWAY: Iona?

MEMBER THRAEN: I'm just going to speak in favor of what Jason just said because this is used for public reporting. So it's attestation is what this code is. It is an attestation code is what you are actually capturing.

And so I think it is important that the language reflect the reality of what you are doing.

CO-CHAIR CONWAY: Okay. Any additional questions?

DR. WILSON: If I could just make one comment? I think that is fine. I am sure we can work out the wording for that. But we just have to be careful that we don't get it such that the physician has to in his -- because this is kind of where we ran into the issue with the verification piece is, you know, the physician may document these to the current medications, but if we are going to actually require them in order to be able to verify that I attest that these are the -- as long as it is inherent that if they report to code, they literally are testing. That is kind of how this evolved because of the fact that you can't find that in a medical record.

And the other thing that our TEPs pointed out, for instance, when we go from

electronic into EMRs, you know, there is not going to be a checkbox that says, "I attest that these are the current records." You are going to assume if they do the meds, that that is implying that they are the current medications.

MEMBER THRAEN: So, then, given what you just said, does that mean, then, the definitions for the numerators and all the pieces that are in this proposal in the document today changes as soon as electronic medical records get in this.

DR. WILSON: I think it doesn't the way it is currently written. That is one of the reasons why we took that verification piece out because the TEP was concerned that as you go to EMRs, there won't be an easy way to document that in an EMR. It would require actually another structured element of a checkbox. They would have to click and without an additional step in the workflow or provider to document that.

And, again, we felt that it was inherent, that it was understood that if a provider actually collects that information during the visit, that they are attesting that that is the current list.

But I think that we can say that if it makes you feel more comfortable in the documentation of the G code, we can say that a provider is attesting by submitting the G code that that is the current list.

DR. GREEN: Or something like "documents to the best of his or her ability" or something like that.

MEMBER ADELMAN: I'm sorry. Perhaps instead of voting now, we are going to meet again. You have the opportunity to change the language to reflect more what you mean because I don't think what is written matches what you have said. And so you are given the opportunity to tweak it. And then we'll vote on it next time. I don't know if that is an option.

MS. BOSSLEY: Well, if you keep pushing things to phase two, we are going to have to make your meeting in phase two like three-four days.

(Laughter.)

MS. BOSSLEY: So one thing we can do is I think you should vote now, even on the -- it's up to you all, but you could vote now on how the measure is. We could give them an opportunity to come back with some revised language.

We have the one measure that you deferred yesterday that we are hoping to be able to bring back to you in the next few weeks. We can have that, any changes, reconsidered by you at that point if you would like to do it that way.

And so you can either vote today or not. But I would prefer not to defer all the way to phase two, but we can defer for a couple of weeks if you would like.

CO-CHAIR CONWAY: Steve?

MEMBER LAWLESS: Actually, for you guys, if you go down the hallway to the people taking care of meaningful use, they actually word meaningful use with the electronic format exactly as Jason is mentioning it.

So in year one when you are getting your reimbursements for meaningful use or you are qualifying, you actually attest that you are doing meaningful use. And there is an electronic format just a check. It's not by G code.

So I think you can very easily reconcile by using this language what they are using for meaningful use. So when people transition to the EMRs, it's not a big deal. And they do the same thing.

CO-CHAIR CONWAY: Okay.

DR. GREEN: I'm familiar with what you are saying. There are processes set up currently as an attestation. They will most likely be migrating eventually from a strictly attestation.

We are trying to make this as painless on the docs as possible. I get that the G codes are hardly anything but painless, but the idea in the future is to try to move away from that so it is a seamless process.

I mean, all of you are clinicians in here. I mean, I can honestly say in my 17 years of practice I never once documented a medical record and only put one medication or the one that I cared about.

You know, if we are taking the medications, we are taking all of the medications as best we can that the patient will give us or the family gives us of a little list that they bring in.

So, you know, no one is looking from a CMS perspective. And I realize you don't just endorse measures for CMS. I get that. But no one is looking to come back and check behind the provider "Oh, you missed one. You know, you lied to us. We are fining you $10,000 and sending you to jail for 6 months."

I mean, obviously that is crazy and that is silly. We are looking for the providers' best effort.

Jason, I'm sorry. I don't know your last name. So I will have to call you by Jason.

MEMBER ADELMAN: Call me Jason.

DR. GREEN: Okay. Thank you. You can call me Dan.

(Laughter.)

DR. GREEN: We will, you know, change the language so that it is more reflective of the concerns that we heard because you understand, I hope, what our intention is.

We want people to try to document the medications as accurately as we can. And that is what we are trying to encourage.

CO-CHAIR CONWAY: Go ahead.

MEMBER THRAEN: I'm sorry. But I understand the intent today. And I absolutely agree with it, but the intent today changes

tomorrow. CMS has just issued a set of provider preventable conditions and which they are not paying facilities on.

So this moves from an intent to change behavior to a financial remuneration or lack of payment in the future. So I think that we have to stay true to making sure that the definitions reflect the reality, labeling reflects the reality, and that if we are going to support the measure today, that when it is used differently in three or four years down the road, that we are comfortable with what we did today.

CO-CHAIR CONWAY: Okay. Maybe I will take a Chair prerogative. I would suggest we go ahead and vote on this. It is not clear to me that it will even reach the threshold of importance. Therefore, language becomes a moot point. If we get beyond importance and we begin to fail on scientific grounds, we could debate whether CMS could recover that.

So if that sounds okay, we will move on to voting. Jessica?

MS. WEBER: All right. Importance to measure and report. Are all three subcriteria met: high-impact, performance gap, evidence? It is a "Yes"/"No" question. We need one more vote. Oh, there.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

CO-CHAIR CONWAY: Okay.

MS. WEBER: Nineteen yes, two no.

CO-CHAIR CONWAY: Good.

MS. WEBER: Scientific acceptability of measure properties: reliability and validity. It is a "Yes"/"No" question.

DR. PHELAN: Excuse me. Janet?

MEMBER NAGAMINE: Yes?

DR. PHELAN: It's Dr. Phelan. You know, I don't have the agenda in front of me.

When is the endotracheal tube confirmation metric going to be evaluated?

MS. BOSSLEY: Michael, it's Heidi. You are next. Just give us a couple of more minutes.

DR. PHELAN: Okay. I'm sorry.

MS. BOSSLEY: That's fine.

DR. PHELAN: I am getting paged. So I am going to have to walk away from the phone a little bit. Then I am going to come back. So I'm going to have you on mute for a moment.

CO-CHAIR CONWAY: That will be okay. We are going to have a break after this. So it will be a little bit.

MS. BOSSLEY: You will be good.

DR. PHELAN: Oh, it will be a little bit? Should I call back in?

CO-CHAIR CONWAY: Fifteen minutes.

DR. PHELAN: I will call back in in 15 minutes. Thanks

CO-CHAIR CONWAY: Okay.

MS. WEBER: All right. Janet, would you like to cast your vote for scientific acceptability?

MEMBER NAGAMINE: Well, this one, reliability and validity, it's different for me. I am not sure in this.

CO-CHAIR CONWAY: It has to pass both.

MEMBER NAGAMINE: Okay. Then it would be a no.

MS. WEBER: Okay. Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: All right. Eleven yes, ten no.

CO-CHAIR CONWAY: So should we ask if we --

MS. BOSSLEY: I think I am even possibly confused on whether everyone voted based on the measure as it is currently before you or what was discussed as potential changes. And it sounds like everybody did it differently.

MEMBER THRAEN: I voted on what is in front of us because, even though there are lots of promises to changed language, they have to take it through a process. No?

DR. GREEN: We are going to change it. You have my word. We will change it.

MEMBER THRAEN: I want to see it in writing. I'm sorry. I want it in writing.

DR. GREEN: We will change the language based on capturing the intent of the -- obviously it was including all of you, but the one that --

MEMBER McGIFFERT: Can we vote and then rescind our vote if it doesn't get changed in a way that we feel is acceptable?

CO-CHAIR CONWAY: We're very, very tight here on scientific credibility. So, you know, we can table this. Heidi won't be happy, but we can table this.

The problem with the changes, I heard a whole lot of requests. And it's not clear to me how that is going to shake out.

So it may be best if we table this and bring it back at our next meeting.

MS. BOSSLEY: So what we can do is even not wait until the next meeting. I think they can make the changes fairly quickly, it sounds like.

Again, you have got the other measure that you deferred that I think we are going to be able to bring back to you on a conference call within the next month it sounds like.

Let's see if we can bring this measure back and then have you vote on it after you see the changes that they have made. Is that acceptable to everyone?

CO-CHAIR CONWAY: Anyone disagree with that?

(No response.)

CO-CHAIR CONWAY: Okay. Let's do it that way.

Okay. Let's take a break. I think you just earned it.

(Whereupon, the foregoing matter went off the record at 11:01 a.m. and resumed at 11:18 a.m.)

0501: CONFIRMATION OF ENDOTRACHEAL TUBE PLACEMENT. CLEVELAND CLINIC.

CO-CHAIR CONWAY: Well, why don't we start with measure 501, confirming endotracheal tube placement. The measure developer from Cleveland Clinic is not on the phone yet, but Louise could begin by giving us a summary of the workgroup's assessment.

MEMBER PROBST: So I'm happy to walk through the measure. It was not available at the time of our workgroup. So our workgroup has not actually discussed it and I don't believe measured it.

But, with that, I think you all have a copy of it. And it is a maintenance measure. Its measure owner is the Cleveland Clinic, as was mentioned. And we are really measuring here confirmation of ET to placement following emergency room or pre-hospital

placement of an ET tube.

And let's see. So the numerator is the number of emergency department patients with an ET tube placed or assessed with an endotracheal tube already in place who had their ET tube confirmed, position confirmed.

The denominator is the total number of endotracheal tubes evaluated, including those patients who had ET tubes placed in ER and those that arrived with them, so the total number of patients. The denominator is the total number of the patients who are in the ET with an ET tube because they got it there or got it previously. And the numerator is those that have documentation placement of the ET tube was assessed.

In terms of importance, there is quite a bit of documentation about the need to have a properly placed ET tube in terms of oxygenation. And I think there was a study that suggested that about 5.5 percent of

patients with an ET tube have it inadvertently placed.

And there have been some studies that look at how often there is documentation of proper placement. I think one study showed that 18 percent of the time there was no documentation at all, 26 percent of the time it was just documented that placement was checked by auscultation or listening to the lungs, which was not deemed to be adequate.

There seemed to be a lot of discussion about gaps in terms of registries to really track patients and ET tubes, but probably the registry that would be the most useful is the one that looks at in-hospital cardiac arrest. And in that situation, there is information about ET tube placement.

But the biggest concern about the gap seems to be that people aren't familiar with the best practices and the most sensitive measures for assessing ET tubes. And so they're really looking to see that not only

that it's documented but the way in which it is documented.

Let's see where we're at.

DR. PHELAN: I'm back on the phone.

CO-CHAIR CONWAY: Okay. Michael, just hang on a minute. We're beginning your measure.

DR. PHELAN: Sure.

MEMBER PROBST: Okay. Let's see. And so the best practice is to use a tool that looks at CO2 coming out of the tube or test that. I've actually never seen that. I actually left nursing when they still did chest X-rays. So I'd love to come see it. And, of course, with bedside oxygenation and things.

So, but, what most impressed me about the literature was the huge opportunity here just if you're measuring to educate people about what the proper techniques are.

There was some question in terms

of its validity and reliability that just documenting the two -- that you have done an assessment doesn't necessarily mean that it is in the right place or that it doesn't move from time to time.

And so, you know, it wasn't a correlation there, but there are strong correlations that when the tube is in the wrong place, morbidity and mortality are higher. And so it seems like an important measure.

With that, I'll turn it over to the measure developer.

CO-CHAIR CONWAY: Okay. Michael? Michael?

DR. PHELAN: Yes, sir? Yes, sir?

CO-CHAIR CONWAY: We just heard a summary from our lead panel assessor. Do you have anything to add about this measure?

DR. PHELAN: I believe there was some concern about the validity --

CO-CHAIR CONWAY: Okay.

DR. PHELAN: -- and reliability.

CO-CHAIR CONWAY: And how has that been tested?

DR. PHELAN: It really hasn't. And one of the things that -- I mean, it's like any chart-reviewed abstracted measure. The National Registry of CPR, now called the -- you know, get with the guidelines resuscitation -- does reliability and validity testing of the whole abstracted chart on someone who has an in-hospital cardiac arrest.

And the way that they do their study is you become a participating member through a fee. They teach you how to do the abstraction. And then they do intermittent, periodic reabstractions. They will just randomly select charts to review and make sure that they are capturing what they are supposed to be capturing.

And one of the things I said, this is kind of like the validity and reliability testing that you would do for -- I think I

sent someone this article on parachutes for gravitational challenges.

CO-CHAIR CONWAY: All right. Okay. Are there questions from the panel members? Steve?

MEMBER LAWLESS: Yes. It seems to me this is a measure of what is a best practice. I'm not sure about translating it into a reportable quality measure per se. I mean, I just absolutely agree this is the best practice. You should be doing this. It happened.

As a reportable measure, though, I'm not really sure where it fits in as a reportable measure.

CO-CHAIR CONWAY: And Vallire?

MEMBER HOOPER: I agree it is an important measure in that we still get many incidents where the placement of the ET tube is not confirmed and we have subsequently very poor outcomes.

This measure, although the

evidence in the discussion sections, talks about the appropriate method for confirming ET tube placement, which is end tidal CO2. But, yet, in the numerator, it just states placement confirmed.

And there are still a lot of people in this world that think bilateral breath sounds or what they perceive as bilateral breath sounds are placement-confirmed or that, heaven forbid, they should wait for the chest X-ray, you know.

So to retain this measure, I would like to see that we are actually ascertaining that best practice is being done. So I would like the measure to reflect confirmation with end tidal CO2.

Additionally, I am curious as to if there are other measures that evaluate this process in-house, as opposed to just the ED, because we have the same episodes and poor outcomes in emergency intubations in-house as

well as in the ED.

So I am curious as to if there are other measures that also look at that. And if not, I would recommend expanding this measure to outside of the ER.

CO-CHAIR CONWAY: Okay. Heidi, do we have other measures?

MS. BOSSLEY: No. This is the only measure we have endorsed looking at this.

CO-CHAIR CONWAY: Carol and then John.

MEMBER KEMPER: I agree with Vallire. One of the things that I think is needed is just to confirm, have a more clear definition of what secondary confirmation includes because it looked like that was pretty open.

The other thing is there was a lot of discussion about the physicians' documentation and looking at physician documentation that this had occurred. I wondered if that was the only documentation

that would be looked at in the measure because I know, for example, in my institution, it is usually the respiratory therapist who is documenting this.

And, of course, it is documented in a variety of places. So it can be challenging as it always is, I think when you are trying to do a chart review, but I think to get at the data, the measure would have to include that it would have more documentation forces than just the physician.

DR. PHELAN: May I speak?

CO-CHAIR CONWAY: Sure, Mike.

DR. PHELAN: The reason it was left intentionally vague is there will be situations where end tidal CO2 won't be present in cardiac arrest situations, prolonged cardiac arrests. And yes, as a matter of fact, I think it just says confirmation. And it doesn't label which specific practitioner is required to do that.

We deliberately left that vague

because in an arrest situation, oftentimes the nurse will be contemporaneously documenting. The physician and maybe respiratory therapy will do their documentation at some later point. So we left that answer vague that it wasn't physician documentation, just any documentation in the medical record.

CO-CHAIR CONWAY: Thank you.

And John?

MEMBER CLARKE: I think a point that shouldn't be lost here is the potential for using this to document and report E tube placement from the field.

My guess is that this is actually the only place you are going to be able to capture how well the EMTs are doing when they put in tubes in the field because you need that in-house confirmation for that. So I think it shouldn't be lost that this is a way of monitoring a pre-hospital performance.

CO-CHAIR CONWAY: Vallire?

MEMBER HOOPER: And I understand

that since a prolonged cardiorespiratory arrest, that the end tidal CO2 may not be exactly appropriate but if we're not going to recommend best practice, then why have the --

DR. PHELAN: You know, American College of Emergency Physicians has come out with a practice guideline. And I think I have provided the link for you. It goes over some of the situations and issues involved, which is saying every single time you have to have this because there are situations where it may not -- not many but some.

And if you just say, "If you don't have an end tidal CO2, you fail to measure," it might not be appropriate because if you use something called an esophageal detector device or a relaryngoscopy, where you re-look and you see the tube actually going through the cords, that is considered satisfactory, especially in situations where you may not be able to get an end tidal CO2 because there's no CO2 getting to the lungs.

Massive pulmonary emboli is one situation. Your tube will be in place, but you won't get a positive end tidal CO2 in that situation. In prolonged cardiac arrest, where there is no movement of blood through the system anymore, either it's all clotted off or it's not moving, you won't get an end tidal CO2 there. And, of course, there are situations where end tidal CO2 will be positive, but it could actually mean you are still in the stomach.

So there are best practice recommendations, but there are tiny caveats to each of them. So if you said, "We want 100 percent confirmation of end tidal CO2," it may be problematic from that perspective.

MEMBER HOOPER: Could you include, then, some exclusionary criteria related to those situations? I mean, it just seems to me leaving it wide open is really opening it up to measuring, to getting a high score for non-evidence-based practice and for --

DR. PHELAN: Correct. And I think it may have to go through different editions of it. You know, first give us documentation. And I think Joint Commission has worked on an in-hospital cardiac arrest package of metrics that they are looking at. And one of them is documentation of endotracheal tube placement for cardiac arrest patients.

So I think they're working on it and waiting for the appropriate time to release it, but they haven't released it. But they had asked me to participate in some phone conversations and sending them some literature regarding it.

So I think it is one of these things that it may take a little bit of a process, you know, baby steps. "Oh, look, everyone is 100 percent." Well, when have we asked for appropriate documentation, which would be the three, you know, either end tidal CO2; EDD, which is the esophageal detector device, or re-look as an adequate means of

confirming endotracheal tube placement.

And some of them involve a cost. The end tidal CO2 monitor, which watches, you know, end tidal CO2 over time, is very expensive or the quick easy cap is a $15 piece of equipment that is on most code carts in the hospital and in the emergency department.

MEMBER HOOPER: So why not --

DR. PHELAN: But getting at -- go ahead.

MEMBER HOOPER: I was going to say, so why not expand the measure to include those three steps now?

DR. PHELAN: We could. I would be fine with that.

MEMBER HOOPER: I would recommend that. Thank you.

DR. PHELAN: Okay.

CO-CHAIR CONWAY: Susan?

MEMBER MOFFATT-BRUCE: Yes. Thank you.

I think that looking at what the

numerator is, looking at the number of ED patients, as a thoracic surgeon, we are often asked to fix the situation when those endotracheal tubes don't end up in the right place. Actually, the biggest opportunity out there is in code patients.

DR. PHELAN: You're right.

MEMBER MOFFATT-BRUCE: So to be exclusive of your Code Blues, where we have practitioners placing endotracheal tubes that often don't do it, I think would be much more of an opportunity for improvement. And so I would ask that.

And then I would echo using al algorithm approach that in the event that you can't detect the end CO2 because of cardiopulmonary arrest that's prolonged, then going to the appropriate next steps, which are well-established in the literature around emergency medicine and Code Blue resuscitation I think is most appropriate. So I thank you for that.

CO-CHAIR CONWAY: Steve?

MEMBER LAWLESS: Yes. I second what Val was saying, also in terms of it's the process. It's the endotracheal tube. It's the intubation. So it's confirmation of wherever the intubation is, not just the ER. It could be in the field or wherever else. It's the confirmatory steps.

So as long as you take a confirmatory, rather than just listening to the breath sounds, there is something you are documenting. We did this yesterday.

There is a logarithm or something that you are using to document beyond just one facet that is there. It is a big problem. But it is a big problem also in inpatient movements.

So, actually, when you are moving a patient from the ICU to the OR or whatever else --

DR. PHELAN: Correct.

MEMBER LAWLESS: -- they do this.

And so I think it is with patient movement or initial any intubation, there is a primary and a secondary confirmation of some sort. So I think it is a good start, but it could be expanded.

CO-CHAIR CONWAY: Okay. Michael?

DR. PHELAN: Yes, sir?

CO-CHAIR CONWAY: There is some enthusiasm for perfecting this measure. It sounds like it's a couple of different ways. One is to include three steps that Vallire has pointed out.

The other is looking at the sites of care. NQF is trying to take its measures across the continuum of care. I guess this could stand as an ER measure, but if you're interested, you may want to expand this to other locations in the hospital and even potentially pre-hospital care.

DR. PHELAN: You know, the only concern --

CO-CHAIR CONWAY: Do you have

interest and ability to do this?

DR. PHELAN: I don't have ability. The only concern about expanding it to outside the hospital is, all of a sudden, you have to say, "Well, does the OR get included? Does the PACU get included?"; although they confirm 100 percent of their tube placement.

That is something that was in my mind. And I'm like "How far do we want to go with this? And do we want to go with baby steps first, see if we can get the EDs on board on it.

And then by the time the Joint Commission's cardiac arrest metrics get that put out there, then, all of a sudden, we have an opportunity to -- what do they call that? -- marry the two.

CO-CHAIR CONWAY: Harmonize.

DR. PHELAN: Harmonize. Yes. So right now there is no opportunity to harmonize.

Sorry. My mind is working on a

couple of different things here.

So I am thinking from my perspective stick to the ED. And adding the caveat to the measure that it must be done by according to the American College of Emergency Physicians, practice guidelines would not be difficult. The question is, how would you turn that over to a hospital and say, "Review all of your records and make sure any intubated patient or any patient who arrived intubated met these three guidelines. And if they don't, it's a fail"?

CO-CHAIR CONWAY: Very good. So the scope remains focused on the ED. That answers that question.

And then, Vallire, you want to have a follow-up?

MEMBER HOOPER: I was just going to say I would not be opposed to starting with the ED as long as we consider expanding to other areas as soon as possible.

CO-CHAIR CONWAY: Okay. Susan,

are you still up? All right. So the measure is as written is the answer, I think.

Any other questions or discussion on this? Sorry.

MEMBER HOOPER: Are we voting on the measure as written or are we going to vote on the measure with the added algorithm as we discussed, where if it's not confirmed by the end tidal CO2 cap, then you do -- if not confirmed by A, then you go to B and then you go to C?

CO-CHAIR CONWAY: Michael, can you recast this in that manner?

DR. PHELAN: Yes. And I will send you something. How soon do you need it?

CO-CHAIR CONWAY: And then, Heidi, how do we handle that?

MS. BOSSLEY: We can work with Michael over the next couple of weeks and see if we can do anything. But I still have a question I guess to the Committee of whether the measure now or even with the changes will

continue to meet the scientific acceptability criteria and especially if we make the changes and add in the algorithm. I'm not sure that we have any testing information on that.

Michael, I guess one of the questions I have is, you have stated that there is a group out there that is abstracting data now. And one question would be, can you get that data from them so that we can bring this back to the Committee with some reliability and validity testing?

DR. PHELAN: Let me call, get with the Guideline Committee, and see about specific to that element alone, I am not sure. But specific to the overall get with the guideline criteria, I can see.

MS. BOSSLEY: Okay. Well, and so maybe it makes sense to table/defer the measure and we'll see whether it's defer it for the next month or so or if it's something that we would bring -- we'll work with Michael and figure out because I think the other --

DR. PHELAN: Can I give you another option?

MS. BOSSLEY: Sure.

DR. PHELAN: Approve the measure going forward with the caveat if it's satisfactory to the group, then it can continue on.

MS. BOSSLEY: Again, that is for the Committee to ultimately decide, --

DR. PHELAN: Sure.

MS. BOSSLEY: -- although we essentially indicated before it needs to pass the criteria. And I am not sure that you have provided enough information for them to say that it passes the criteria. And I am seeing some nodding in the room.

MEMBER LAWLESS: Yes. I would just say I would rather not -- I mean, we vote on it and whatever else. If it doesn't pass, you know, it needs more work if it's the criteria the reliability is not there yet. It doesn't mean that it is not going to continue

to go on without it.

DR. PHELAN: Okay.

MEMBER LAWLESS: It's not ready for prime time.

DR. PHELAN: Okay. The only problem is I don't think that they have -- what was the heading of this measure? It got put in the category of approved but --

MS. BOSSLEY: So yes. I think I did mention this to the Committee.

DR. PHELAN: Right.

MS. BOSSLEY: This measure was one of the time-limited measures that we brought into maintenance --

DR. PHELAN: Right.

MS. BOSSLEY: -- that had met all of the criteria on its first review but had not provided reliability and validity testing yet. And so, as you can tell, Michael is still identifying that data to be able to bring it to you.

So we're in that unusual spot of

can he be able to bring that to you quickly enough so that you can evaluate it or the question will be, is this a measure that you all think he needs to continue to move forward and bring back at another point?

MEMBER THRAEN: What's the time limit?

MS. BOSSLEY: So the time limit there, we're lucky. We have two options. So we can work with Michael and see if he can bring something back in the next I would say month. We need to consider it because you do have a few remaining things you need to do on a conference call. If not, if he can get it to us by the time of your next meeting for phase two, we can move the measures back.

If he cannot -- and Michael will have more conversations about this offline. If he can't, then I think your choice will be to vote on the measure as it stands before you and then move forward. And that could be I would assume removing endorsement.

CO-CHAIR CONWAY: Which of those would you like to pursue, Michael?

DR. PHELAN: I would like to continue the metric as an approved metric pending the revision to the definition, adding that it should be according to ACEP practice guideline recommendations and then b) pending some validity and reliability testing from the abstraction process in the national or get with the guidelines resuscitation, if that is sufficient, approve the measure.

And the question I have is, how do I pose the question to the people that get with the guideline resuscitation to make it sufficient for you to be satisfied with their answer to get to the --

MS. BOSSLEY: So, Michael, yes. This is Heidi. We will work with you offline --

DR. PHELAN: Perfect.

MS. BOSSLEY: -- and make sure you have everything that you need to be able to go

to them. We're happy to be on the call as well. So we'll --

DR. PHELAN: That would be nice. Yes.

MS. BOSSLEY: Yes. We'll figure that out. That is not a problem. I guess the question to the Committee is, would you prefer to vote on this now or would you like to wait and have us come back to you with more information? Defer?

DR. PHELAN: It sounds like if we vote on it now, it would get turned down.

MS. BOSSLEY: Right. So they are all agreeing to defer.

DR. PHELAN: So option B is if it's got another month of life into it, let's give it another month of life. Let's reconfirm that endotracheal tube placement. I think I am seeing a positive end tidal CO2 here.

(Laughter.)

MS. BOSSLEY: You're deferred.

We'll touch base with you next week.

DR. PHELAN: Awesome, Heidi. Thank you. Everyone have a nice holiday and a good New Year.

CO-CHAIR CONWAY: Thank you.

DR. PHELAN: Bye bye. You bet.

MEMBER THRAEN: Okay. So I inadvertently went to NQF's website to look at measures. There is a -- this relates back to the last conversation and NCQA 0019 medication, documentation of medication lists in outpatient records, measure that was approved in 2009.

So when we revisit the CMS measure, could someone look to see about harmonization related to that one?

MS. BOSSLEY: I had mentioned that to Pam and to Bill as well. What we will do is when we bring back the revised measure from quality insight from CMS, we will also give you kind of the list of all the other measures that are related to medication reconciliation

and documentation of medication, et cetera, so you know what is endorsed, what that covers, and everything else. And then we can address the harmonization as well, yes.

CO-CHAIR CONWAY: For people on the phone, we are going to take a lunch break. But it is going to be a working lunch. So we will be back to work here in about 15 or 20 minutes. Okay, Janet and Gina?

MEMBER NAGAMINE: Sounds good. Thanks.

MEMBER PUGLIESE: Also thank you.

CO-CHAIR CONWAY: Okay.

(Whereupon, the foregoing matter went off the record at 11:44 a.m. and resumed at 12:08 p.m.)

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

(12:08 p.m.)

CO-CHAIR CIPRIANO: Lisa, are you ready for measure 0346, iatrogenic pneumothorax rate? That is you, right?

MEMBER McGIFFERT: Do you want to get started or do you want to wait a few minutes for people to come back?

CO-CHAIR CIPRIANO: I think we have got our Committee members on the phone.

MEMBER McGIFFERT: Okay.

CO-CHAIR CIPRIANO: So I think I would like to get started.

MEMBER McGIFFERT: Okay.

0346: IATROGENIC PNEUMOTHORAX RATE (PSI 6).

0348: IATROGENIC PNEUMOTHORAX RATE (PDI 5).

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MEMBER McGIFFERT: And Carol and I are going to do this in tandem because she's got the pediatric measure also. And I am going to have to get it up. Just a second.

CO-CHAIR CIPRIANO: All right. So

you are suggesting that our conversation will cover 346 and 348?

MEMBER McGIFFERT: Yes.

CO-CHAIR CIPRIANO: So if you would just tag team and let us know what specific --

MEMBER McGIFFERT: Yes.

CO-CHAIR CIPRIANO: That would be great.

MEMBER McGIFFERT: Do you want me to kind of start or do you want to --

CO-CHAIR CIPRIANO: Hang on one second. I think Patrick would like to make introductory comments.

MEMBER McGIFFERT: Okay. Did you say hang on?

DR. ROMANO: Sorry.

CO-CHAIR CIPRIANO: Can we defer to Patrick first?

MEMBER McGIFFERT: Yes.

DR. ROMANO: A couple of preparatory comments. So we are back in the

realm now of events that are mishaps related to, we hope mishaps related to, procedures, but they're not extremely rare. In this case, they are more common events. However, they are not always preventable events. And so we are now back in the realm where we have a risk-adjusted rate that is based on a numerator and a denominator. And it is based on patient characteristics in the risk adjustment mode.

A lot of the action with these measures and a lot of the concern focuses on the exclusion criteria because the intent is to exclude large groups of patients for whom the event could be an expected consequence of the procedure and less preventable. In some cases, the exclusions may be drawn overly wide. In other cases, they may be too narrow.

We do have some additional information and analyses that we have done based on the workgroup discussion as well as some additional validation information. We

are happy to put that into the forms. It is up to the Committee, of course.

We can discuss that in this context and I can present that information verbally or we can defer discussion until everybody has a chance to review it on paper. But we have done some additional analyses to address the comments that were raised in the workgroups.

CO-CHAIR CIPRIANO: Okay. Maybe as the leads come to those areas, they will ask for additional input. Okay. Did you say Carol was going to go first or are you?

MEMBER McGIFFERT: Well, I was just going to say that was the biggest concern in the workgroup, which I vocalized and a lot of people countered. There are pages and pages and pages of exceptions.

And I understand that this is an expected outcome in many procedures. And so there was a lot of discussion about that.

So I think we may want to hear

about the exceptions ahead of time. What do you think, Carol?

MEMBER KEMPER: Well, I think kind of, as Patrick has said, the exceptions, the exclusions that are in the pediatric measure -- and this is iatrogenic pneumothorax. So it's the percentage of discharges among cases that meet those inclusion and exclusion criteria, where iatrogenic pneumothorax is in the secondary diagnosis field.

The exclusion criteria are primarily related to patients that have had chest trauma, so again could have a pneumothorax associated with that, also thoracic surgery or cardiac surgery, so some of those kinds of surgeries where there would be some disruption and potentially expected to have a pneumothorax.

MEMBER McGIFFERT: I was thinking exceptions were exclusions. Are exceptions something else?

MEMBER KEMPER: I was speaking of

exclusions.

MEMBER McGIFFERT: Yes, exclusions. That's what I was. I wonder if Patrick was talking about exclusions. Okay. Okay. Good.

I guess the other -- and I understand that that is the situation. And the question that I asked is, is there a measure or should we try to solicit a measure that would measure all of those exclusions where it is expected to happen? And does the right response happen when it is expected to happen?

And I don't know. Maybe some of you know of other measures, but to me when you have so many that are, so many situations where this is "expected to happen," a quality measure, a good quality measure, would be so how does the surgeon respond or how does the team respond when it does happen as an assessment of quality?

So I think, Patrick, if you can

talk to us about those exclusions or the analysis, further analysis, that you did or do you want to wait until after everybody discusses it?

CO-CHAIR CIPRIANO: No. We can go ahead. The only thing I would say in response to what you just presented is that that seems to me almost like a different measure.

MEMBER McGIFFERT: It is, but it just came up because this is staring us in the face. That's it.

CO-CHAIR CIPRIANO: Right. And I think as we work through these measures, it is very -- again, we are always tempted to say we need more, we want more, we want to see the actual management.

And, you know, obviously I want Patrick to speak to the exceptions, but it may be that for now we will need to address this measure with the limited scope that it has.

Carol?

MEMBER KEMPER: I wonder if we

could just -- we could even just like provide the summary and then come back to some of those kinds of questions, I think.

So, you know, we have talked a little bit about what the exceptions are. Again, just like all the other AHRQ PDIs and PSIs, it's pulled from administrative data. So certainly pulling it seems to be reliable and have some consistency there.

From the pediatric side, the rate seems to be about .2 I'm going to say from what I'm seeing in the literature per 1,000 discharges. And the study that a lot of us have been talking about as we have discussed the PDIs, which is that Scanlon article, mentions for this particular measure that over that 2003 to 2005 data pull from 72 hospitals, I think it was, they had 646 cases. And of those, 11 percent were present on admission. Now, again, the present on admission code wasn't in place at that time and is now.

Sixty percent were not considered

preventable because they were expected during procedures that the software had not flagged for exclusions. And they were things like tracheal reconstruction, although -- and Patrick can talk about this more, but there have been refinements to the algorithm I think since this article was written so that some of those may not be an issue currently.

And then 30 percent were associated with central line placement and were considered preventable. So, I mean, those are the ones that I think we are really trying to capture and are concerned about.

The positive predictive value -- again, this is data that is a bit dated because changes have been made since that time -- was a high of 64 percent positive predictive value. And the low was reported as 29. The reason they had that spread there on the positive predictive value is they included and excluded those that were considered uncertain preventability.

So the low included the uncertain and the high -- or I'm sorry. I switched that. The low excluded them and the high included them, I believe.

So I think there have been additional changes to the measure since even that data were evaluated. Again, I think, like we have talked about before, there is a lot of value in case finding. I think with this measure, the question on comparison still comes up. And some of that is related to the discussion that we had yesterday about low volumes.

And it is really hard to detect a difference, a hospital that is really worse because of the low volumes but can be a valuable measure, certainly for these situations where we're finding that it is related to a central line placement.

MEMBER McGIFFERT: And on the adult side, two studies were cited that estimated the positive predictive value of

79.6 and 83.9. So that seemed pretty high to me.

MEMBER THRAEN: Why the difference between pediatric and adult? Do you know?

MEMBER KEMPER: As far as?

MEMBER McGIFFERT: The predictive value?

MEMBER KEMPER: Positive predictive value?

MEMBER McGIFFERT: I don't know.

MEMBER KEMPER: Well, and, again, remember that I don't what all the codes are that are included in the adult measure, but, you know, as was cited in this particular article, there were some that those values that I gave you did not include some codes that I think have now been added. So I am not sure if maybe they would be closer now. I don't know. Patrick might be able to speak to that.

MEMBER McGIFFERT: And this measure has been out for a while and has been

used pretty extensively, it looks like, you know, in various settings. And I am trying to --

MEMBER NAGAMINE: Iona?

MEMBER McGIFFERT: It allows users to risk-adjust the rates. And let's see.

MEMBER NAGAMINE: Iona, I was on the TAP when this was discussed. And I believe in the pediatric population, it is very different, particularly with preemies. So it was very weight-dependent how often this happened and to whom.

MEMBER KEMPER: And this particular measure that we're looking at, PDI 5, excludes neonates.

MEMBER NAGAMINE: Oh, okay. Okay.

MEMBER KEMPER: There's a separate measure for neonates.

MEMBER NAGAMINE: Got it.

CO-CHAIR CIPRIANO: Okay. Are we ready to hear from Patrick again, then? Okay. Please go ahead.

DR. ROMANO: Okay. So yes. It's correct that we have gotten some information from the authors of these studies, both the adult and pediatric studies, that has allowed us to augment the list of exclusionary procedures. Unfortunately, I can't tell you right off the top of my head exactly which procedure was added in which year and which version.

But the current list of procedures does reflect some incremental changes with each annual update. So I am going to read some numbers to you, which you may not be able to follow, but we will certainly give them to you in writing. But it will give you a sense of the impact of these different exclusions.

So this is for the adult indicator. Based on one year of national data from the nationwide inpatient sample, 5,139 events were flagged by PSI 6, 5,139.

Three hundred and twenty-six -- now I am going to talk about the exclusions,

but these exclusions are potentially overlapping. So I am going to give you numbers for each exclusion independently, not marginally. Okay? So the marginal impact of any one exclusion would be less than what I am describing.

But the chest trauma exclusion basically eliminates 326 cases. So those are patients who came in with some form of chest trauma. And for those patients, we have some concern that the pneumothorax was actually present on admission and was not reported accurately as being present on admission.

Some of those patients may not have a pneumothorax apparent on their initial chest X-ray and then after some period of observation in the hospital, they develop a pneumothorax but it's really related to the chest trauma that brought them into the hospital in the first place. So that's 326.

We have 4,945 events excluded related to pleural effusions. And the reason

for that is because pleural effusions are, of course, often treated with chest tubes or with a diagnostic thoracentesis. And particularly the chest tube usually involves some air getting into the pleural space. It may be a small amount of air depending on how sharply the radiologist reviews the X-ray. It may or may not be documented. But we anticipate that this would be a natural consequence of chest tube placement for drainage of pleural effusion.

Nineteen cases excluded because of pregnancy or childbirth. That's a universal exclusion because there is a separate set of codes and it's complex coding issues.

Thoracic surgery, 7,535 events excluded. Those are patients where there is some opening of the pleural space in the course of the procedure. And so it is expected there that air will get into the pleural space and may be apparent on a postoperative X-ray.

Two thousand, ninety-two cases excluded in the course of lung or pleural biopsies. Now, in those cases, the pneumothorax may be preventable, but these are patients who often have large lesions. They're often getting percutaneous biopsies, often by interventional radiologists, sometimes by surgeons.

But these procedures, depending on the placement, there is a known risk of pneumothorax. And it is part of the embedded risk of the procedure; in other words, that the physicians decide to pursue this route to achieving a diagnosis because it is better and safer than an alternative route, recognizing that it involves a risk of pneumothorax.

Then there are 3,379 exclusions related to cardiac surgery. Again, that usually involves entry through the mediastinum or through the pleural space or both, where there is a known risk of pneumothorax.

And, finally, 124 cases due to

diaphragmatic surgery, where, again, there may be diaphragmatic surgery, where air may enter the pleural space as a direct consequence of the procedure.

So that gives you a spectrum. Certainly the number of cases captured is much smaller than the number of cases excluded, but we think that there is a rational basis for these exclusions.

But it has been an incremental process over the years. The exclusion list has evolved. And it will continue to evolve. So we are certainly open to suggestions about how to narrow it or expand it.

MEMBER McGIFFERT: I think on page 25 is where there is a reference to based on analysis, that you have made recommendations to revise the exclusions. And it looks like only one, exclusion 1, is recommended to be dropped or were you referring to something after this paper was written or am I looking at the wrong place?

DR. ROMANO: Well, let me make sure I am looking at the right place. You are only page 25 --

MEMBER McGIFFERT: At the bottom. And it says --

DR. ROMANO: -- of the PSI 6 document?

MEMBER McGIFFERT: -- "Results." And it says, "Based on the analysis."

DR. ROMANO: Oh, yes. So this is what I have given you verbally. I am sorry about reading numbers aloud, but that is an oral representation of the numbers behind this analysis that is described here.

The specific recommendations here are draft recommendations from the analytic team. And so they haven't really gone through the internal process of review by a clinical panel. But yes, the essential argument here is that almost all of these exclusions would be retained except possibly for the first one, which is the chest trauma exclusion.

And the reason for that basically was in the analysis, when we actually drilled in and looked at when patients got chest tubes and so forth, it appeared that in most of the cases, the chest tubes were placed late in the hospital stay, suggesting that these were patients who actually didn't have pneumothorax at admission and had a central venous catheter placement and then may have had the complication as a result of that.

CO-CHAIR CIPRIANO: Okay. Open it up to discussion. John, is your card up?

MEMBER CLARKE: I think my card is up. I want to talk, but I think it would be more appropriate if Susan talked first since she's a thoracic surgeon.

MEMBER MOFFATT-BRUCE: So I think that on page 1, we did a service to understanding what the exclusions are when you simply summarize it by including the exclusion of chest drama; surgery, whether or not it's cardiac or thoracic; and then having

underlying thoracic pathologies.

And then when we open it up to page 8, that is basically a reflection of how difficult it is, our coding is, currently around -- this is basically a list of every thoracic or cardiac procedure that we do. And that's unfortunate. We have 12 ribs because it lists out by number of rib fractures. It lists whether or not I go in thoroscopically or through a thoracotomy. And God forbid I do it robotically. And so that really is what that is a reflection of within our specialty. So you can imagine what --

(Off mic comment.)

MEMBER MOFFATT-BRUCE: Yes, absolutely. Yes, you know, in the STS database right now is just expanded from four pages to seven-page collection tool because of this complexity. So I apologize for that on behalf of our society.

You did a very good job, Patrick, of summarizing that, awesome, very nice.

CO-CHAIR CIPRIANO: Okay. John and then Jason?

MEMBER CLARKE: I concur with Susan. I think the list of exclusions, although extensive, is imminently reasonable because when you cut into the pleuralist cavity or cut into the lung or the tracheal tree --

CO-CHAIR CIPRIANO: Gently dissect.

MEMBER CLARKE: Well, yes. Cardiac surgeons say, "Gently dissect." I'm a trauma surgeon. We just cut.

(Laughter.)

MEMBER CLARKE: And I think it is a perfectly reasonable list because those things will produce air leaks inevitably or at least you assume they would produce air leaks.

With regard to the pneumothorax, I don't object to some nuances on the delayed presentation of pneumothorax. People who come in without an apparent pneumothorax except on

CT sometimes do show up with a pneumothorax, although it is unusual.

And in terms of putting central lines in those patients, we actually put the central line in on the side of the trauma, rather than run the risk of giving them the pneumothorax on both sides: one from the trauma and one from the central line. We only provide the risk on the area that is at risk anyway.

I do want to make sure -- and I hope that's evident -- that when you talk about a thoracic procedure, that you are not talking about a subclavian line and no one is misinterpreting that as a thoracic procedure because that is obviously -- thyroid trauma from respirators and central lines would really be things that we are trying to capture. I think this does a reasonable job doing that.

CO-CHAIR CIPRIANO: Thank you.

Jason?

MEMBER ADELMAN: Just, Patrick, forgive me. I am going to make a general statement about all of these measures. Right now we are talking about the positive predictive values are a little bit better. I just have a problem with all of the -- I think that this work is great and it is important and it has its role.

And we discussed earlier that it is just great for helping to find cases where we can learn a ton. But once you get into moving into publicly reported data as some way that it is a measure that either a provider can judge us or it can be a value-based purchasing measure, where, actually, our compensation could be judged by it, then like the statistical rigor should really be there.

And so, for example, like we don't know the sensitivity specificity. I don't know that we could because it is so hard to find false negatives, but I am thinking back to the blood transfusion discussions.

Like I know of wrong patients getting blood. I have a feeling that there is a huge number that is being missed. And we could even get some idea of what the sensitivity specificity is, maybe by comparing the data from the PSI with the data from some of the other reporting systems that John mentioned are really very good.

But the point is I am a huge fan of the PSIs for the purpose of learning about errors and making it better. Just I feel like, you know, even if the positive predictive value is 80 percent, what is the sensitivity specificity and negative predictive value? You can't even answer it.

And it surprises me sometimes. I feel like AHRQ hasn't put enough into funding research around this. A lot of the studies that we talked about have n's of like 120 charts were reviewed, like they couldn't -- you know, they're the ones that are begging for money. They control the money. It's

their PSIs. More studies can be done. Better studies could be done. And I am just nervous about making a blanket statement, all of these as publicly reported data for those reasons.

Thank you. Sorry.

CO-CHAIR CIPRIANO: Okay. Rich?

MEMBER WHITE: Do you tell us why the positive predictive value is so much higher in adults than kids?

DR. ROMANO: I think that the major reason for that is because there are different procedures that are sometimes done in children, which contribute to the risk. And some of those procedures were not in the original exclusion list. And so they were added subsequently.

And one of the examples that is specifically cited I believe in Scanlon's paper is some tracheal procedures, tracheal reconstructive procedures, which are procedures related to congenital anomalies of the trachea in general.

To address your question, I'll defer to John. I think that certainly we are happy to do additional validation work. And I think AHRQ is currently reassessing its priorities for validation work going forward. So I ask John to make some comment on that.

MR. BOTT: Yes. So I apologize if I missed the very front end of this conversation. I got back about 12:10. And it sounds like we were already en route in discussing these measures.

Actually, Patrick and company just provided a paper, which I think is at the very beginning of this, of validation methods used up to this time. And so we're reviewing that at the time, some statisticians at AHRQ and et cetera, as one of the steps.

But I had mentioned before that one of our big priorities in 2012 will be reassessing what we're calling here at AHRQ the measure life cycle process.

And as a part of that, we're going

to be looking at criteria by which we'll be used to evaluate measures for retirement.

But another part of that will be revisiting the measure validation process. We think some good work has been done to date from that validation pilot that we have been doing for several years but want to stress that that was a pilot phase.

And we have learned a lot from that phase, but we do need to go back and systematically think about how do we with a high degree of rigor go about periodically the validation process, repeating it periodically and developing criteria by which even when we do establish a process, when would measures come out of the sequence to be for validation outside of that, say, when codes change substantially or when our methodology changes substantially, it needs to be done even more frequently than planned.

So it is a high priority to develop that, a validation process going

forward for all RQIs. And so that is the first step in moving this from pilot to what we perceive will be a more rigorous process going forward.

DR. ROMANO: What John alluded to at the beginning of his comments was that we have proposed and pilot-tested a methodology for assessing sensitivity of these relatively uncommon events, basically using a sampling method that would oversample cases where we had reasons to suspect that the event happened, but it wasn't reported.

For example, we can sample cases that had a chest tube inserted after 24 hours into the hospital stay and see whether some of those chest tube insertions were related to a pneumothorax. And that potentially gives us the power to estimate sensitivity; whereas, we couldn't if we were just doing a random sample of all hospitalizations. It would be hopelessly inefficient.

So we pilot-tested that method.

It actually seems to have worked reasonably well. We did find some false negatives for this indicator. And we hope to extend that now to a larger sample, a larger group of hospitals. And obviously I defer to the Committee about the fact that we obviously don't have those data yet.

CO-CHAIR CIPRIANO: Okay. We have Bill and Charlotte and then Pat.

CO-CHAIR CONWAY: Patrick, that was a nice rundown of the frequency of those exclusions. Do you have information? What are we measuring with this now? What's left?

DR. ROMANO: Right. So what we're measuring, I think, is best described -- and I'm sorry that the references weren't included in the submission, but there's a paper by Sadeghi and colleagues, including me, from the non-VA hospitals and then a paper by Kafirani and colleagues from the VA hospitals. And those are the two sources of the positive predictive values that Lisa mentioned and so

what those two studies show.

So from the Sadeghi study, basically 200 cases that were reviewed. And of those 200 cases, basically 69 of them had a central venous catheter as the cause of the event. Nine had a trans-thoracic needle aspiration or biopsy. Fifty-six had other invasive procedures, most commonly pacemaker lead placements or defibrillator placements. And then five were barotrauma related to mechanical ventilation. One was related to cardiopulmonary resuscitation. And 16, we couldn't figure it out. That was based on chart review.

CO-CHAIR CONWAY: The nine that were tarns-thoracic biopsies, I thought that was on the exclusion list.

DR. ROMANO: Right. Well --

CO-CHAIR CONWAY: Did they just --

DR. ROMANO: -- unfortunately, our concern is that that type of procedure is often done at the bedside, especially when it

is an aspiration, rather than a biopsy, which means that it is under-reported.

So, therefore, we don't rely on that procedure code as the basis for the exclusion. Instead, we rely on the diagnoses, like pleural effusion, that would trigger that procedure.

So it is possible that we could revisit. So that if those procedures are, in fact, coded, then we could add that to the exclusion list. But currently they are not.

CO-CHAIR CIPRIANO: Thank you.

Charlotte?

MEMBER ALEXANDER: My question sort of tails in on what Bill was saying. If what we are really looking at is iatrogenic pneumothorax after a central line insertion, for example, why don't we title the measure that, instead of having a blanket measure with so very many exclusions?

CO-CHAIR CIPRIANO: Bill, did you want to give an opinion on that? I'm sorry.

Patrick?

DR. ROMANO: I can tell you that the reason that we haven't done that is because previous -- and this is older literature now. So this is literature that goes back 15 to 20 years -- showed that bedside central venous catheter placements are under-coded substantially. Only about 50 percent of them were actually coded.

So, for that reason, we were concerned that if we limited the denominator to those cases, we would be missing a lot of the patients who are actually at risk.

Now, that may have changed. And that is quite possibly something that we should reevaluate because to the extent that those procedures are now being done under more controlled situation with concurrent nursing involvement -- when I was in training, you know, we used to do this without a nurse anywhere in sight. But now, of course, it is a very different -- surprise, surprise. So

now it is a very different situation. And the nurses make sure that we document things correctly. And so this may need to be reevaluated.

CO-CHAIR CIPRIANO: Okay. I think we have Pat next.

MEMBER QUIGLEY: Thank you, Dr. Cipriano.

My question was related to in reviewing both of them, the evidence was very clear and presented I thought clearly for the adult one and graded, but the evidence and the literature to support the pediatric one was not and actually wasn't included, but, yet, it was entered by AHRQ as being moderate.

So I just wanted to just make sure that there was evidence to support the pediatric one. If someone maybe could speak to that?

DR. ROMANO: There was a little bit of a rush when we submitted the forms. And I apologize for that. But some of the

material that should have gotten into both forms did not. So I apologize.

CO-CHAIR CIPRIANO: Okay. Iona and then John?

MEMBER THRAEN: I can't find it now, but back to the same kind of question. In the pediatric version, there is a statement that between 2000 and 2007, there has been an actual decrease in the incidence of the condition that we are talking about. So that then raises the question similar to what we were talking about before about the performance gap in the room for improvement.

CO-CHAIR CIPRIANO: John?

MEMBER CLARKE: Like Charlotte, I struggled with whether this should be an inclusive or exclusive set of criteria, but the thought occurred to me that there are so many new technologies, particularly minimum invasive technologies, coming down the pike that I think to make it just an inclusive criteria might be to miss potential future

problems. And so I would actually support Patrick's concept of exclusion criteria.

I think the exclusion criteria, unfortunately, will be a long list. But you know what? When you are trying to have a really accurate measurement, this kind of fine-tuning always occurs.

CO-CHAIR CIPRIANO: Okay. So if you guys will put your tents down over here if you're not asking a question? Having a little post-lunch fatigue.

(Laughter.)

CO-CHAIR CIPRIANO: Okay. So we heard a lot of discussion and explanation about the inclusive measure with very specific exclusion criteria with data. We have heard a little bit more background in terms of additional studies that speak to the evidence and validity of the information.

Are there any other questions or comments, either for Patrick or from Patrick or anyone else on your team, at this point?

DR. ROMANO: Just to respond to one question. So the reduction in the prevalence was from 2.134 to 1.329, so roughly a one-third reduction. So I think we would argue that we certainly made progress, but we're not at the six sigma level.

CO-CHAIR CIPRIANO: Okay. And then I think this probably is a good example that as we are seeing additional technology, we are seeing improvements that at the next measure maintenance assuming it is approved now, that we may, in fact, be seeing a very, very small gap, which would be great.

Question was, was it true for both pediatric and adult?

DR. ROMANO: Yes, but the numbers on the adult side are more consistent, more reliable.

CO-CHAIR CIPRIANO: Okay. Are there any comments or questions from those on the phone?

OPERATOR: Just a reminder it is

*1 if you have a question today.

(No response.)

OPERATOR: No.

CO-CHAIR CIPRIANO: Okay. Are we ready to vote?

(No response.)

CO-CHAIR CIPRIANO: All right. And what I would suggest is that we are voting on both measures consistently unless someone would like to deal with them separately. Is there consensus that our votes will count for both measures? I see lots of heads nodding. Okay. All right.

Jessica, if you will lead us through that, please?

MS. WEBER: All right. Importance to measure and report. Are all three subcriteria met: high-impact, performance gap, evidence, "Yes"/"No" question? And if you could just cast your vote again? I think we need one. Oh, there it is.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: Eighteen yes, one no.

Scientific acceptability of measure properties: reliability and validity. It is a "Yes"/"No" question. Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: Seventeen yes, two no.

Usability: high, moderate, low, insufficient? Janet?

MEMBER NAGAMINE: Mod.

MS. WEBER: Gina?

MEMBER PUGLIESE: Moderate.

MS. WEBER: Six high, 12 moderate, 1 low.

Feasibility: High, moderate, low, insufficient? Janet?

MEMBER NAGAMINE: Moderate.

MS. WEBER: Gina?

MEMBER PUGLIESE: High.

MS. WEBER: Nine high, nine moderate, one low.

Overall suitability for endorsement. Does the measure meet all the NQF criteria for endorsement? Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: Eighteen yes, one no.

CO-CHAIR CIPRIANO: Okay. Thank you very much. And, again, thank you, Patrick and colleagues, for that discussion.

DR. ROMANO: And if I could just ask if NQF staff would be willing to reopen the forms, we would be happy to enter some more full information in response to the questions.

CO-CHAIR CIPRIANO: Great. Thank you very much.

Okay. We are ready to move to the next two measures on pain assessment. And,

Operator, if you would make sure that we have open phone lines for Deborah Deitz, Eugene Nuccio, and David Hittle?

OPERATOR: Yes, I can do that.

CO-CHAIR CIPRIANO: Okay. Thank you very much.

And Jim? Where did Jim go? Oh, he's left. Sorry. All right.

0523: PAIN ASSESSMENT CONDUCTED.

0524: PAIN INTERVENTIONS IMPLEMENTED DURING SHORT TERM EPISODES OF CARE.

CENTERS FOR MEDICARE & MEDICAID SERVICES.

CO-CHAIR CIPRIANO: So 0523 is pain assessment, and it is specific for home health. Is there anyone else in the group that would like to describe this measure? This is a process measure.

MEMBER de LEON: If you would like, I can just at least summarize because --

CO-CHAIR CIPRIANO: Sure, Jean. That would be great.

MEMBER de LEON: -- it kind of

goes into the next one.

CO-CHAIR CIPRIANO: Okay. Great.

MEMBER de LEON: It is a process measure. It is looking at strictly the home health setting and the assessment of pain on the initiation of a home health episode of care, not each visit but the episode of care. And the numerator is those patients who were accepted into the home health agency. The denominator is all of the patients basically.

Our discussion on this had to do with trying to pair this with the following indicator or the following measure and what else was out there in the home health.

There is very little literature that is targeted at home health patients. And the majority of the evidence is on education, but there is no evidence -- and this will follow in the measure after this, the intervention. There is no evidence that says that doing an assessment changed the quality of care for the patient. But we all would

reason that if you didn't asses, how were you going to start to initiate an appropriate treatment?

But the evidence doesn't link an assessment to an actual outcome. This is a process measure, same thing for the treatment.

Is it okay if I discuss the next one a little bit as I go?

CO-CHAIR CIPRIANO: I think it might be beneficial for the group, especially if we want to have some discussion about pairing the measures. Thank you.

MEMBER de LEON: The same thing was very true of the intervention, the fact that you make unintervention, didn't talk about the quality of the intervention, that it had anything to do with your pain but that you did something and it was in the orders, is not linked with the outcome. And there is no evidence to support that.

But common sense tells us that pain is affecting a lot of our patients in a

home health setting. It is not being addressed well from the literature, but we don't have the evidence that tells us exactly what we need to do to effect that outcome.

But reason tells us you need to assess it. Then you need to come up with a treatment plan. And then you need to initiate the treatment plan.

But what we would come to in the discussion group is -- and then you need to measure whether that treatment plan was appropriate. And that is what the measure is missing.

So we have a couple of pieces but not the actual piece that most of us felt would make the difference, which is measuring what the intervention was and whether that was appropriate and whether the pain scores go down or the patient's perception of their function improved or something like that. These measures don't cover that. Simply did you assess it? And did you do anything?

CO-CHAIR CIPRIANO: Okay. Thank you.

Is it okay with the Committee members if we asked the measure developer to speak to these next -- okay. Deborah, Eugene, or David, whoever is going to take the lead, if you would like to describe the measure and give us any additional background, please?

MS. DEITZ: This is Deborah. These two measures are part of our pain suite for home health measurement, which consists of four measures. One is, did you do an assessment? Was it addressed in the care plan? And then was that care plan implemented?

There is also the fourth outcome measure. Did the patient experience a reduction in the amount of pain that would interfere with their movement?

So we do have all four of those measures. We presented those four measures to NQF several years ago. And these, the outcome

measure is endorsed. And the pain assessment and the pain implementation were endorsed.

Some of the issues around adequately assessing whether or not the patient received the care that they need for their pain are influenced by their bio how we collect information in for these home health measures, which is strictly through the OASIS data assessment. So we are a bit limited in what we can measure based on what the OASIS collects.

If you have any other questions, I will be happy to respond to them.

MEMBER de LEON: Okay. So if I understand you correctly, you are saying there are some outcome measures that NQF has already endorsed that get at --

MS. DEITZ: There is an outcome measure for a patient, yes.

MEMBER de LEON: -- that get at the concerns of whether a home health visit where they ask about pain actually resulted in

addressing that pain?

MS. DEITZ: Yes.

CO-CHAIR CIPRIANO: Or is it the actual treatment intervention, not looking at the upstream activities, but once there was an intervention, was it effective?

MS. DEITZ: The measure, the outcome measure, does not tie the was the intervention effective. It doesn't tie the intervention and the outcome. It merely asks whether there was an improvement between when the patient began home care and when the quality episode ended at the end of care.

CO-CHAIR CIPRIANO: Okay. Let's go ahead and take other questions from the group. Vallire?

MEMBER HOOPER: I have several questions. My first question, just for point of clarification, because home health is not my area, is my understanding was an episode of care was not each visit.

MEMBER de LEON: The

certification. It's a certification period. So it's depending on assessment that --

MEMBER HOOPER: So we are not evaluating pain assessment with each visit, nor are we evaluating pain intervention with each visit. So an episode of care could be weeks, months.

MEMBER de LEON: But you would be excluded if you said you didn't have pain on the first assessment.

MEMBER HOOPER: And then there wouldn't be a reassessment.

MEMBER de LEON: Because if you have pain on the next assessment or the next visit, we're not counting that.

MEMBER HOOPER: Okay. Secondly, I am very concerned with 0524. And, again, I am going to preface this statement with I am not a home health care nurse. But I am concerned with the terminology of physician plan of care and that from a nursing perspective, someone implies a medical model to pain management,

which may not be the case, but even though there may not be a lot of data about assessment and management of pain in the home health care setting, there is a huge amount of data assessment and management of acute pain and chronic pain. And all of that data points to a multimodal approach to pain management.

So I am a little bit concerned about what the implications of physician plan of care or --

MEMBER de LEON: The physician signs a plan of care for each of the home health patients. And it can be -- when I signed a plan of care, 9 times out of 10, 80 percent of what is there has nothing to do with me because I am a wound care specialist. And I started them on home care for their wound.

But the internist has 12 meds going on. They may have infectious disease that has added a couple of things going on. And then it's compiled by the home health

agency. It's printed up as a physician plan of care. Some physician has to sign that plan of care.

MEMBER HOOPER: Okay. That is helpful.

MEMBER de LEON: So it is not as though somebody is over there just going, "Well, let me think about this carefully." It doesn't happen that way.

MEMBER HOOPER: And a third area of concern is -- and I would be curious to see the outcome measure, the measure related to outcomes because I am not seeing anywhere the recommendation for the establishment of a comfort function goal, which is very strongly supported in the evidence, whether it is acute pain or chronic pain, that we need to be assessing the patient's pain, working with the patient using a patient-centered approach to establish a comfort function goal, and then working with the patient and their significant others to create a treatment plan to meet that

comfort function goal.

And I am curious as to if the comfort function goal is addressed in any of these measures because I am not seeing it in these two.

CO-CHAIR CIPRIANO: Deborah, would you like to comment?

MS. DEITZ: No. I mean, yes, I will comment that, no, we have not developed, nor are we currently collecting any information about the establishment of a comfort function goal. That would be something that we would be interested in looking at for future development. But that has not been something that has been done today.

CO-CHAIR CIPRIANO: So I think, to summarize, Vallire, there is no comfort measure here. It does say electronic clinical data are the source for this.

But it does tie back to only interventions included in the signed plan of

care. So there may be additional measures that are provided by the home health nurse, with or without a formal comfort measure plan, that they would not be picked up.

MEMBER HOOPER: And am I also understanding that this is not exploring assessment and intervention with each individual visit? It is --

MEMBER de LEON: That is correct.

MEMBER HOOPER: -- exploring it just -- there is no dictation about how many times this is addressed over the episode of care, which is quite different from what the performance measures around acute care -- this is very, very short of the mark if you look at the requirements for the management of pain in the assessment and reassessment of pain in the acute care setting. This is very, very short of the mark.

CO-CHAIR CIPRIANO: Right. And, again, is very different.

Okay. We have Carol, Lisa, and

Iona.

MEMBER KEMPER: Some of my comments are similar. Just I am concerned if we are only picking up those physician orders and just there are a lot of interventions that I think home health nurses are doing that I just think I want you to be able to capture those. And so I think limiting it to the physician order is concerning.

The other thing is -- and Vallire sort of alluded to this -- that there are measures out there. And I know home care is very different. I have practiced in a home care setting. And I know there are unique issues there.

However, you know, some of the measures, like the NDNQI measure associated with pain, which has an assessment intervention, reassessment, if there was a way to tailor that and have all of those components into one measure, I just think that would add a lot more valuable information.

CO-CHAIR CIPRIANO: Lisa?

MEMBER McGIFFERT: I would just say this is a process measure and that we should move away from process measures and especially one that has as many flaws as this one seems to have. And I would be very interested in seeing the details of the outcome measures that are out there before we vote or --

MS. BOSSLEY: I can point the one outcome measure that they have been referencing. I can tell you what that is. So the title is "Improvement in Pain Interfering With Activity." And the description is "Percentage of patients who have less pain when moving around and the way it is captured." Just a second.

So let me start with the denominator first. This is the same developer. It's home health. It's using the same data source and everything. It's all home health episodes. And, Deborah, tell me

if it has been updated. I think it is an update now.

But all home health episodes except where either of the following conditions applies. And that's where at the start or resumption of care, assessment is zero, indicating there is no pain. They are excluded. And then the patient did not have a discharge assessment.

So this is looking at from the time of when they are admitted to when they are discharged within that home health episode.

And the numerator is the number of home health episodes where the value recorded in OASIS is numerically less than the value recorded at the start. So, again, I am looking at the difference in the scale.

MEMBER McGIFFERT: Can I ask, so the pain is less than when it started?

MS. BOSSLEY: Yes.

MEMBER McGIFFERT: Okay.

MS. BOSSLEY: Yes. That's it.

MEMBER HOOPER: No comfort function goal in that measure.

MS. BOSSLEY: No unless -- Deborah, I am assuming it has not been updated to include that. Right?

MEMBER HOOPER: Thank you.

MS. DEITZ: No, it has not.

MEMBER HOOPER: Okay.

MS. DEITZ: I would like to just comment on this issue about the physician-ordered plan of care. I just want people to understand that this is not restricted to a typical -- I mean, it includes non-pharmacological and other interventions.

The reason that we stated that it had to be included in the physician plan of care is because that is the plan of care that the clinician uses when they are treating the patient. And if it is not in that plan of care, there is no assurance that it will be consistently understood that that is the plan

of care.

In other words, it is not like there is a physician plan of care. And then there is also the other plan of care. That is the plan of care that is documented for what the agency is going to be doing for that patient. So that's why. But it frequently includes all kinds of other measures beyond pharmacological.

MEMBER THRAEN: Excuse me. I think the challenge with these two is that they are using the OASIS tool. The OASIS for CMS is the primary assessment tool. It is a quasi billing, quasi clinical tool, kind of falls in between those two ends of the continuum. And they are using the data from OASIS in order to capture some measure of this issue.

So it is really a problem of the OASIS assessment tool and the kind of data that it is capturing. So in order to make changes to do a better job at getting at the

answer that you are asking for, the OASIS assessment tool in and of itself would have to be changed in order to capture different kinds of data.

Currently OASIS is probably the only thing that is available in the home health world in any kind of standardized fashion to capture what is going on at all.

I have not heard much conversation about the clinical information systems in home health. There probably are some. But I know that its meaningful use is starting at the hospital level. And in about probably 10-15 years, it will eventually probably get into the home health world. But as it stands right now, OASIS is it.

So if you want any kind of surveillance in that world, you have to use the OASIS tool as the mechanism.

CO-CHAIR CIPRIANO: Pat and then Carol.

MEMBER QUIGLEY: Thank you, Dr.

Cipriano.

My comments and my concerns are related to the assessment indicator. And that is because the literature review to support this indicator to me did not even reflect the standard of practice. And it is really quite dated.

I would look for a synthesized literature review in relationship to pain management. The article that was reviewed to indicate that nurses had issues with knowledge and a knowledge gap and pain assessment is over ten years old, and it is one study. And the nursing profession for two decades has been really building science related to nurses' role and leadership in pain assessment and management.

And I know in the Department of Veteran's Affairs, pain assessment is our fifth vital sign, as it is in many places. And it is across the entire continuum of care, be it in hospice or home care or ambulatory

care or even in assessing our homeless veterans. You know, we still ask patients about pain upon every encounter. It's not just upon admission.

So I was really very concerned that, you know, a quality indicator should not just be based on the state of the science but should be able to help us advance our practice to a higher level and move that gap, move the standard of practice forward. So I was very concerned about this indicator.

And, Madam Chair, those are my comments.

CO-CHAIR CIPRIANO: And, Pat, did you have any similar concerns about the evidence in the second measure: the intervention measure?

MEMBER QUIGLEY: Yes, I did. Thank you.

CO-CHAIR CIPRIANO: Carol?

MEMBER NAGAMINE: This is Janet. My hand is up when you are ready.

CO-CHAIR CIPRIANO: Okay. Janet, go ahead.

MEMBER NAGAMINE: Just to tag onto the question of evidence and impact, it seems like the gap or the problem is focused on nursing assessment in home health of pain, rather than a patient-centered gap of what is the incidence of lack of pain management in this population?

I'm looking for evidence that there is a gap from the patient perspective. And I didn't see that. And so I just throw that out there that I am not seeing that impact.

CO-CHAIR CIPRIANO: Okay. Carol?

MEMBER KEMPER: Just a comment again about the OASIS data. And I think, you know, if OASIS is limited in what it is providing, I would hope that there is some other mechanism to get that information. I know it is easier to get it out of OASIS because, you know, I have electronic data

pull.

But it would be more meaningful to look at some other data source if OASIS isn't providing us the detail that we need.

CO-CHAIR CIPRIANO: Iona, is your card up again?

MEMBER THRAEN: Oh, I'm sorry.

CO-CHAIR CIPRIANO: Okay. That's all right. Vallire?

MEMBER HOOPER: I guess my question would be -- and this may be a little bit early, but given the concerns that we have around the quality of these quality measures and what they are actually getting at, I feel very strongly that there should be quality measures in the home health setting regarding pain, as there should be across all settings.

But it's like Patricia said. Pain should be the fifth vital sign. It should be assessed at every visit.

We need quality measures, but these are of poor quality. And I don't know

that they're telling us anything that would be helpful to improve patient outcome.

CO-CHAIR CIPRIANO: Deborah, would you like to respond to that? And then also in general terms, if you would speak to us about the fact that if this measure were not continued for endorsement, I mean, these are reported activities that you are going to look at as part of the home health evaluation system. So what would be the impact of having the measure not endorsed?

MS. DEITZ: Well, I just want to say that, you know, in the first paragraph of the document that we provided to you, that we say that pain, both acute and chronic, has been identified as areas requiring frequent assessment and follow-up. So we are aware that these have been identified as pain assessments requiring standards of care, you know, as applicable in all the health care settings.

We are, as has been stated,

restricted by what OASIS collects. And in my experience, which -- I have recently been going out to home health agencies. We have received a lot of feedback that this has really changed the way that they are dealing with pain assessment because it requires them to use a standardized, validated pain assessment and to use it consistently. And agencies have changed their behavior to address that.

So I think it has been very useful. And our concern is that if we take away a measure like this that agencies really are paying attention to, that they will be backsliding. There will be kind of the message that, actually, we are not really considering this important anymore because agencies do very much pay attention to "Oh, this is what is important because this is what CMS is measuring. And this is what is being reported on us."

So that is our concern about re

moving a measure before we have a better -- I mean, we are very interested in improving the measures, particularly if we can access some kind of data that we could use for those measures, but we would be concerned about removing the measures without a new and improved measure to replace them.

CO-CHAIR CIPRIANO: Okay. Thank you.

Bill?

CO-CHAIR CONWAY: I have a question and a statement for the record. The question is, Deb, do you have home care CAHPS? And if so, aren't there questions related to pain on that?

MS. DEITZ: No. I was thinking about that when you were talking about other sources of data. And I have to say I am sorry I am not particularly familiar with CAHPS.

But perhaps I don't know, David, if you would want to, David Hittle, if you would want to comment on CAHPS if you have

more familiarity with what is being collected in a CAHPS?

DR. HITTLE: Am I on?

CO-CHAIR CIPRIANO: Yes.

DR. HITTLE: Yes. Okay.

CO-CHAIR CIPRIANO: Yes.

DR. HITTLE: Actually, I'm not that familiar with the specifics of all the different items in the scoring of the home care CAHPS. I can certainly probably find that out in a few minutes.

DR. NUCCIO: This is Gene Nuccio.

We do have CAHPS, a CAHPS instrument. It is new. The home health provider group of HHS began being required to have that instrument in October of this year. So the data are rather limited. Regarding the specific items, I can't recall if pain is one of the items on there and how it would be assessed, but we can certainly find that out.

CO-CHAIR CONWAY: Okay. Thanks.

The statement for the record --

Heidi has already heard this, but now she can formally record it. When panels are asked to look at questions like this that appear fragmented, it is helpful if we see this in the context of what is going on.

Most people here aren't home care providers. And we don't see the whole picture. OASIS has a whole array of process measures home care nurses have to report. And I would just learn we have an outcome measure in the CAHPS instrument that tells us what the patient thinks of the adequacy of their comfort care.

So, rather than viewing each of these things in isolation, it helps if we see them in a broader context.

CO-CHAIR CIPRIANO: And I guess do we happen to know, Heidi, when the outcome measure that was described that you pulled up is due for maintenance?

MS. BOSSLEY: I looked at the endorsement date. That was endorsed in 2009,

which is why it wasn't pulled over because it had not yet reached the 3-year mark, same with the home health CAHPS. That's also endorsed.

So those should be looked at in the next safety cycle or, actually, no. I take that back. The home health CAHPS will be looked at next year because we have a patient experience and engagement project underway then. And then the next one will actually come back to the next safety group. So that would be 2013.

DR. NUCCIO: This is Gene Nuccio.

Sorry. Actually, the assessment of pain interfering with activity outcome measure has been around since 1999. And it was approved later on by NQF in its work. So the process measure is actually a very recent set of items for OASIS.

CO-CHAIR CIPRIANO: Okay. I'm going to suggest we go back and specifically look at these two items in order.

Vallire, is your tent up or down?

Okay. Well, why don't you go ahead?

MEMBER HOOPER: Well, and this is actually a comment related to the first measure. I appreciate that the fact that these two measures are currently NQF-endorsed likely have improved the process of pain assessment and management or at least increase the awareness in the home health care setting. And I would hate to see that backslide.

I certainly would be supportive of -- the pain assessment measure does not cause me so much concern. I would like to see, if possible, that that would be required for every visit, as opposed to an episode of care. So I would be in support of that.

The pain intervention measure, I am not so sure that that is really telling us anything, but I do appreciate the need to have something out there.

CO-CHAIR CIPRIANO: Okay. Bill?

CO-CHAIR CONWAY: When we have the opportunity to measure an outcome if there is

a CAHPS instrument -- and Heidi can read the question in a minute. I mean, we do have an instrument. I just hate to see providers having to go through mindless checkboxes that I did something if we have the ability to measure the outcome.

So why doesn't CMS clean up the CAHPS question, hear what the patient has to say about pain management, and let the poor home care provider not go through these extra checkboxes?

You might want to read the question, which isn't exactly adequate today, but that could be fixed.

MS. BOSSLEY: Right. So I just pulled up the most current version of the home health CAHPS. And the only question that I could identify that dealt with pain is in the last two months of care, did you and a home health provider from this agency talk about pain? And it's "Yes"/"No."

CO-CHAIR CIPRIANO: Gene, is that

the measure that you were referring to?

DR. NUCCIO: That's the item on the CAHPS. Referring to the item on the instrument is more detailed regarding the frequency of pain interfering with their activity. So it asks if the patient has had pain that does not -- has pain, but it does not interfere with activity or movement, pain on a daily basis or less often than daily, daily basis but not constant or all the time.

MS. DEITZ: You're talking about the OASIS measure?

DR. NUCCIO: Right. That's the OASIS measure, yes. Yes. The item on the CAHPS instrument is fairly minimal.

CO-CHAIR CIPRIANO: Okay. Let's take another comment. Pat?

MEMBER QUIGLEY: Thank you, Madam Chair. And I appreciate being able to provide one more comment.

My comment was I am concerned that still both of the indicators to me really are

standards of practice. You know, this is what was expected of a nurse in home care or any practice setting as well as interventions that should be interdisciplinary.

So I don't know how in 2009 something that is considered a standard of practice became a patient safety indicator when it should be a standard of practice. So I had a little disconnect with that.

I would certainly understand if it was false, but for something that is really considered to be a standard of practice, you know, in every arena, you know, this is what should be expected in patient care.

And the Agency for Health Care Research and Quality has had guidelines for pain management since the 1980s. They were expert opinion. There's standards of practice and care for home health nurses from the American Nurses Association, I am sure, that addresses that this is a standard of practice. So to me this is just not congruent with our

workgroup.

CO-CHAIR CIPRIANO: Thank you.

Jean?

MEMBER de LEON: And I would echo that it is confusing when you look at these because pain is such a major problem. And it is probably under-treated. It doesn't mean that it is not important, the measure or what it is looking to to push the provider to do an assessment, do an intervention is important.

But it is not necessarily a measure of quality care. It should be standard or best practice. And if you have the detail of the OASIS in the outcomes, then the measure should all be based upon those questions, not about just checking to see if we asked.

CO-CHAIR CIPRIANO: Okay. Gina or Janet, do either of you have any comments or questions at this point?

MEMBER PUGLIESE: No.

CO-CHAIR CIPRIANO: Deborah or

Gene, do you have anything else that you would like to add?

DR. NUCCIO: No.

MS. DEITZ: No.

CO-CHAIR CIPRIANO: Okay. What I would like to do, then, is go back to 0523, which is the measure of pain assessment being conducted at a single episode, not per visit. But, actually, let me ask a question of Deborah, then.

Is it feasible that this could be revised to be an assessment at every visit? And what would the issues be with that kind of change? I mean, is that something --

MS. DEITZ: Yes. That is a good question. I would ask the Committee to think about what that would entail in terms of burden for the agency. And I think that is why it was not originally designed that way because what we would do is we would say the way that the OASIS collects information, it would say at the end, was this patient

assessed for pain at each visit?

And then in order to be able to adequately answer that, the person who was doing the discharge assessments would have to go back and look at every patient visit that occurred during an episode of care, which could be longer than a year under the visits. So that is why it is not collected that way.

CO-CHAIR CIPRIANO: Iona?

MEMBER THRAEN: I know in the MDS, there is a schedule of how often the assessment process has to take place. Is there a similar schedule for the OASIS?

DR. NUCCIO: Yes, there is.

MS. DEITZ: Yes.

MEMBER THRAEN: Could you articulate that schedule?

MS. DEITZ: The OASIS assessment information is collected at least every 60 days. There is no requirement for --

DR. NUCCIO: Actually, which is actually more often than the MDS.

MEMBER THRAEN: Okay. So going back to the question of episode versus visit, if a patient is under home health care for more than 60 days, you would have 2 or 3 time intervals where this data would be available, correct?

And I don't know what the average length of stay is for home health. So I don't even know if that is even feasible, but my point is if you are making assessment every 60 days and the patient is with home health for 120 days, you have 2 assessment time periods, getting --

DR. NUCCIO: The average length of stay is actually less than six days. So for most of the episodes, we have a start of care and a discharge or a transfer to inpatient care. And that is all we have.

MS. DEITZ: For the majority of home health.

DR. NUCCIO: For the majority. There's a substantial tail. You know, there

is a long tail.

MS. DEITZ: When the measure was initially proposed, we did, in fact, have -- we looked at the last episode of -- for burden purposes, we said, "Okay. We'll go back and look at the last episode and tell us, you know, since the last OASIS, did you assess the pain?"

Oh, I'm sorry. This is the pain assessment. I am misspeaking. I am thinking about the implementation. So that is different. I'm sorry.

So yes. There could be for patients who are in longer than 60 days. We could assess it every 60 -- we could ask about was it assessed every 60 days --

MEMBER THRAEN: But that's going to --

MS. DEITZ: -- resistance to that because of burden issues.

MEMBER THRAEN: But that has got to be rare, right? That is a rare event.

Those are the rare cases.

DR. NUCCIO: Well, they're a minority. I wouldn't say they're so rare, you know, a small enough number as to be considered really rare, but they are a minority.

CO-CHAIR CIPRIANO: Okay. Well, I think we are ready to vote on measure 0523, which is that the pain assessment was conducted at the start of home health episode. Any additional comments or questions before we vote?

(No response.)

CO-CHAIR CIPRIANO: Okay. And I think we need to vote based on what we have here, not any proposed revisions. Okay. Jessica?

MS. WEBER: All right. Are all three subcriteria met for importance to measure and report: high impact, performance gap, evidence? It's a "Yes"/"No" question. I think we should have one more vote. Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Gina?

MEMBER PUGLIESE: Yes.

MS. WEBER: Eight yes, 11 no.

CO-CHAIR CIPRIANO: Okay. So that renders this measure rejected. Okay. So it will not be recommended for endorsement again, for maintenance.

Okay. So let's go to measure 0524, which is pain interventions implemented during short-term episodes of care. So this is episodes during which pain interventions were included in the plan of care and implemented.

Any additional questions or comments?

(No response.)

CO-CHAIR CIPRIANO: All right. So are you ready for voting? Okay. Jessica?

MS. WEBER: Importance to measure and report. Are all three subcriteria met: High impact, performance gap, evidence? It is

a "Yes"/"No" question. There should be one more vote. Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Gina?

MEMBER PUGLIESE: No.

MS. WEBER: Seven yes, 12 no.

CO-CHAIR CIPRIANO: All right. So this measure will also not be recommended for measure maintenance.

Okay. Well, we thank Deborah, Gene, and David on the telephone, appreciate your participation. I suspect there is some disappointment, but I hope you can appreciate the concern. I think probably one of the key aspects is, does this really fall into a patient safety measure versus is it in synch with current practice as well as the advances in the evidence over the last decade? Okay.

MS. DEITZ: We appreciate your consideration.

CO-CHAIR CIPRIANO: Thank you very much.

1729: POLYTHERAPY WITH ORAL ANTIPSYCHOTICS.

CENTERS FOR MEDICARE & MEDICAID SERVICES.

CO-CHAIR CIPRIANO: Okay. So I think we are at 1729, our last measure for the day. Is that right? Christina?

MEMBER MICHALEK: This measure is polytherapy with oral antipsychotics. It is actually a new measure. What we know about polytherapy is that monotherapy with oral antipsychotics has demonstrated efficacy, but 20 to 35 percent of the patients will fail or have an incomplete response to monotherapy. And polytherapy has not been consistently proven to be either safe or effective in those people that fail monotherapy, but, despite that fact, there are a lot of patients out there that are on more than one oral antipsychotic.

In those patients that fail monotherapy, there is really only one proven alternative. And that is clozapine. And those studies were done in patients who have

resistant schizophrenia, although these drugs are used across other diagnoses as well.

And we do know that with clozapine, it does have side effects. It requires frequent white blood cell and ANC monitoring every two weeks. There are some patients who have been on it longer. That can be extended out.

And some physicians will try polytherapy for incomplete responses, although there's really not a lot of data out there to support that.

There are two other measures, approved NQF measures, out there from Joint Commission, related to this. One is about decreasing polytherapy to monotherapy at discharge from a health care facility. And the other one relates to documenting justification of polytherapy for one of three reasons: either a history of three or four failed monotherapy trials, cross-titration with a goal of eventually getting to

monotherapy or that the patient is on polytherapy and one of the agents is clozapine.

MEMBER THRAEN: Are those antipsychotic-related measures or polytherapy in general?

MEMBER MICHALEK: Yes, antipsychotics.

MEMBER THRAEN: Thank you.

MEMBER MICHALEK: As far as the impact, this does affect a large number of patients. And it utilizes a large amount of resources, dollars. Overuse of medications is an NPP priority under safety. Then, like I said, there are those other NQF measures as well.

The staff that reviewed this measure did note that it really seemed to be more of a resource one. And I'll comment on that a little bit further into my discussion.

As far as a performance gap, it appears from the stats that we were given that

overuse is evident. It looks like of the patients that are on more than one, only a small percentage were on clozapine. And there are a lot of patients on more than one.

Unfortunately, really, the information that we have really just addresses the resources and not necessarily the quality. Although there is a lot of data out there to talk about poor quality when you use more than one, the measure really seemed to focus more on resources.

There are not a lot of randomized clinical trials that have examined efficacy of switching from polytherapy to monotherapy. There was one that showed that when you have polytherapy, it was associated with more weight gain than monotherapy. I mean, that is a minor adverse effect, I guess, depending.

There is really no empiric support for having more than one. There was a meta analysis done. It showed that polytherapy was slightly more effective than monotherapy when

clozapine was used, again pushing back to the second agents: clozapine. It also showed that polytherapy was associated with a higher risk of non-serious side effects.

I mean, if you look through a lot of the guidelines that are out there, I mean, they really do suggest taking one agent, pushing that dose to the maximum allowable for that patient before switching to another. There is really nothing out there that says outside of clozapine to combine two.

And although it seems that the goal is really to avoid polytherapy, there is really just not a lot of evidence to support it.

In our discussion -- I'm sorry. I should also say they did have an expert panel. And 83 percent of them strongly agreed or agreed that this data as collected based on the measure would be interpretable so as far as looking at the usability of the data.

The things that came up in our

discussion were, should we be looking at polytherapy as compared to looking at finding the lowest dose that is effective for the patient with the least amount of adverse effects? And we also had discussion around the fact that this seemed to be very dollars and cents-driven as not necessarily quality-driven. I guess you could make maybe perhaps the leap that it could be quality.

Also, the age groups are 18 and above. A lot of the data that is here to support not using polytherapy is in the elderly.

And I think that summarizes everything. If any of my other team mates want to add anything that I might have missed, please do so.

CO-CHAIR CIPRIANO: Okay. Well, I don't see any tents up. So if our measure developers would like to comment? And if you would tell us your names first, please? Thanks.

DR. CAMPBELL: Okay. My name is Kyle Campbell. I am a pharmacist and project director at FMQAI. I have with me Dr. Soeren Mattke from RAND, who is a physician; and Dr. Almut Winterstein from the University of Florida.

Just a few things to respond to the comments. One is that the point of it being a resource use versus a quality issue, I apologize the way the form indicated we did tend to emphasize more of the resource utilization aspect of that, but there are a number of observational studies that have quantified both metabolic syndrome and adverse cardiovascular events associated with polytherapy as well as greater rate of non-serious side effects, like you pointed out.

And one of the things that I think is important to consider in this particular patient population is that adherence to this particular class of drugs is essential. And

any of these side effects that occur, although there are no studies to support this inference, are likely to reduce adherence to the regimen in this population if they had a side effect profile.

The other thing is with regard to the evidence and the age criteria, the meta analysis actually was for patients that were -- just one second -- 16 to 65. And that included 19 RCTs.

The existing NQF-endorsed measure is inclusive of all ages and has submeasures for pediatrics as well as those 18 and over. Our particular measure is, as you said, 18 and over and is inclusive of all ages above 18.

DR. MATTKE: I also wanted to clarify. So if the clinical decision-making -- and I have to paraphrase my psychiatrist colleague Machana Horowitz here, who explained that to me because I'm just a lowly cardiologist, so more an electrician and a plumber than somebody who actually understands

this.

The antipsychotics all have a fairly similar way of affecting the brain, but they all have a slightly different side effect profile. So what she says is if you combine more than one drug, you actually do not gain effectiveness of treatment but you gain the possibility of adding a second side effect profile to the profile that you already have. And this has been borne out in several studies, 19 randomized trials, that adding a second antipsychotic with the exception of clozapine to an existing regimen that doesn't work, is clinically not effective.

And so, therefore, the guidelines do not support that practice but recommend that if the current regimen is maxed out, you switch to a different drug, rather than trying to add a second drug to the existing drug.

And we think this is a key quality issue in a vulnerable population and, therefore, a safety issue. We take the cost

reduction of avoiding adding a relatively ineffective or a proven ineffective treatment to an existing treatment, sort of as a side effect of implementing such a measure, but insist that this is really a key safety measure, not a resource use measure.

CO-CHAIR CIPRIANO: Okay. Bill and then Iona and Pat.

CO-CHAIR CONWAY: Could the measure developers or somebody on the workgroup help out by elaborating on what those side effects are?

The write-up here is very vague in general. So it is hard to assess the safety issue here. The utilization issue and the cost issue I completely understand, but this is a safety panel. So give us a little more detail.

DR. CAMPBELL: Okay. So the observational studies that are out there suggested an increased risk for metabolic syndrome and diabetes and higher

cardiovascular mortality in this population. And the increased risk of non-serious side effects were extrapyramidal symptoms, sexual dysfunction, and sedation.

CO-CHAIR CONWAY: I understand. I can read that, but, I mean, does that happen a half a percent of the time, 20 percent of the time, what?

DR. CAMPBELL: I don't have -- I would have to get back to you on the relative percentages of those particular side effects. I don't have that with me.

CO-CHAIR CIPRIANO: Iona?

MEMBER THRAEN: First, a point of clarification. In the conversation a moment ago, you referenced another NQF-endorsed measure. Is that different than this CMS measure that is before us?

DR. CAMPBELL: Yes. The existing endorsed measure is for inpatient care. And this measure would be for ambulatory care using Part D data.

MEMBER THRAEN: All right. That's the clarification. Thank you.

CO-CHAIR CIPRIANO: Pat?

MEMBER QUIGLEY: Thank you, Madam Chair. Madam Chair, I was actually asked by people that I work with because we run falls clinics and we see patients for falling. And our geriatricians oftentimes will make recommendations to modify psychiatric medications to reduce fall risks. But the question that they had asked is, you know, the geriatrician would not make those modifications but would ask the psychiatrist, make those recommendations to the psychiatrist.

So is this population really the patients who have a known mental health disorder and are being treated by psychiatry. I mean, is it a very specific patient population that we are targeting here? And I did not know the answer to that.

Who would be the one prescribing

this that we would be really targeting for their safe medication prescribing practices?

DR. CAMPBELL: So the answer to that question is it would be all patients who receive antipsychotics. It wouldn't just be patients that were prescribed antipsychotics by psychiatry. So the entire --

MEMBER NAGAMINE: And that would be in and outpatient?

DR. CAMPBELL: That would be in an outpatient setting. That's correct.

MEMBER NAGAMINE: Outpatient only?

DR. CAMPBELL: Outpatient only.

MEMBER QUIGLEY: So these were patients that have a mental health disorder?

DR. CAMPBELL: Yes or potentially off-label use of antipsychotics as well would be included in this patient population.

CO-CHAIR CIPRIANO: Okay. Iona?

MEMBER THRAEN: I'm a little bit familiar with this, not specific to the adult population but specific to foster care

children, same kinds of issues. But the problem has been in the Medicaid population that the patient may start out initially with a psychiatry consult of some sort but that the management of the patient usually falls into the hands of a family medicine physician or advanced practitioner and that oftentimes the psychiatry because of the reimbursement issues remains only in a consultant role and that the management of the patient really takes place at the primary care level.

And so you often see primary care practitioners not fully understanding the use, utilization of these kinds of drugs and may be incrementally adding drugs over the course of time. So it is a problem because of the reimbursement problem associated with specialty care.

CO-CHAIR CIPRIANO: Susan?

MEMBER MOFFATT-BRUCE: Just for a point of clarification. So this would include the patients that are coming to the ED as

well? It would be captured in the ambulatory cohort?

DR. CAMPBELL: Yes. So patients in ambulatory care that were filling their prescriptions through Medicare Part D would be included in this population, so measures calculation on the Part D claims data.

MEMBER MOFFATT-BRUCE: If they go to the emergency room, this would be captured?

DR. CAMPBELL: If they were a Medicare Part D patient, yes.

MEMBER MOFFATT-BRUCE: Okay. Because I do think that this is a very important measure in that we just don't have enough psychiatrists for all of these psychiatric patients. I mean, we are turning them away after being in the emergency room for 72 hours because we just can't get them into our institution.

So I would be in favor of really encouraging you to meet the expectations of the group because I do think that we need to

have metrics out there around how we treat this very under-served patient population. And so I congratulate you on facilitating this. And I would encourage the meeting of our expectations.

DR. CAMPBELL: Thank you.

CO-CHAIR CIPRIANO: Thanks. Jason?

MEMBER ADELMAN: There was a mention from one of the developers -- I'm sorry. I didn't catch your name. I think it was the cardiologist -- that there was I think you said 17 randomized controlled trials that showed that polypharmacy does not work. Is that right? Because I didn't see.

I guess I have seen a lot of measures where a profound evidence-based practice like giving aspirin to somebody with a heart attack becomes a measure. But taking away a physician's right to maybe do something a little bit outside of label is like a step beyond what I typically see.

A patient that is really resistant and somebody wants to try an extra -- even though there has been -- but 17 randomized controlled trials would be pretty strong evidence. I just didn't see that. I saw a place that mentioned two and another one that mentioned three, but I didn't see it. So I would think the evidence would have to be really overwhelming before you could tell a provider that you can't try to add an extra drug.

And I understand that there was the risk-benefits and the side effects were sexual dysfunction. It wasn't like major mortality or life-threatening kinds of side effects are mentioned, more morbidity kind of stuff.

So I just wanted to scrutinize the evidence a little bit more. And I didn't really see 17.

MEMBER NAGAMINE: Bill, my hand is up.

DR. MATTKE: It's a meta analysis of 19 trials that have compared the effectiveness of combination therapy. And that meta analysis showed that already the combination with clozapine has superior effectiveness to any monotherapy. That is the meta analysis by Correll.

So it is possible that in exotic cases where everything else fails, the polytherapy may be justified. I can't speak to that. I think it is more likely that what our colleague just mentioned, that this is done in primary care and primary care approaches this like hypertension treatment. If the ACE inhibitor doesn't do it, let's add a beta blocker. Let's add the diuretic.

This is not effective, at least from what we know today. And the guidelines are very clear about this not being an effective practice.

It is also not the case that there are only known serious side effects. I mean,

there is weight gain, but there is also increased risk of metabolic syndrome and evidence for increased cardiovascular mortality under polytherapy. So it's not like a dramatic short-term effect, but you will see longer, higher long-term mortality out of combination therapy, again with no positive evidence of this practice being effective.

CO-CHAIR CIPRIANO: I have one clarifying question. Then we'll go to Chris.

Where is the language that says this is specific for outpatient? And is that on further explanation somewhere in terms of a numerator/denominator.

I don't see that, but I may just be missing it. I see others are saying they don't see it either.

DR. CAMPBELL: I'm not sure where it is in the form, but by nature, the Part D data are outpatient claims data. And in this particular case, we're attributing the care to the unit of analysis of a Part D plan or a

physician group. Obviously physician group would be outpatient care.

There are, I will say, just to clarify, patients that would be in long-term care facilities that would be included into this population when their Part D benefit would be covering their medication use in an LTC. So I do want to clarify that.

CO-CHAIR CIPRIANO: And I guess just general clarification, though. The measure would not be limited to Medicare beneficiaries. So if others wanted to use the measure, it would seem that we would need to --

DR. CAMPBELL: Absolutely.

CO-CHAIR CIPRIANO: -- make clear that it was for outpatient?

DR. CAMPBELL: Correct.

CO-CHAIR CIPRIANO: Okay. Chris? And then, Janet, you will be next.

MEMBER MICHALEK: The other point that we had some question about in your -- you

had said in here about having difficulty to determine at the physician level -- now I lost -- here it is -- by physician group that the data wasn't I guess in your testing, that data wasn't reliable at the physician group level. And if you could just speak to that at all?

And what are you going to use? Are you going to just hold the data that way? And how are you going to -- it talked about maybe at least using 30 patients. Is that going to make a reliable result?

DR. CAMPBELL: Sure. Let me speak to that. What we said in the submission form, that we had the ability to make limited statistical inferences for those physician groups with at least 30 patients because when we compared quintiles, we weren't able to see -- we had an overlap of our confidence intervals in order to achieve the denominator threshold in which 90 percent of the physician groups had a reality score greater than or equal to .7 was 137.

So when we operationalize this, we would do so with the larger physician groups and should it go to the physician quality reporting system.

CO-CHAIR CIPRIANO: Janet next.

MEMBER NAGAMINE: The difficulty I have with this measure is it's unclear to me exactly what entity and the population we are dealing with because antipsychotics could be applied to so many different situations.

And I am inpatient-based as a hospitalist, but I could certainly see at a long-term care facility the range of things that you would be seeing in especially the elderly population.

Is it delirium? Is it hallucinations? Is it psychotic depression or bipolar episode, in which case sometimes you do have synergies in combinations of drugs? So I was wondering if you could speak to that.

DR. MATTKE: Again, it's very commonly practiced, but there does not seem to

be any clear evidence that, regardless of the indication, the effectiveness of the antipsychotic is greater in combination therapy. So if you have psychotic episodes in a depressed patient, I think combination with an antidepressant that is being recommended but not combination of more than one antipsychotic drug.

MEMBER NAGAMINE: What about delirium specifically?

DR. MATTKE: I am beginning to be way out of my --

MEMBER NAGAMINE: Okay. Because that is the common thing that we see --

DR. MATTKE: Right.

MEMBER NAGAMINE: -- in this population.

DR. MATTKE: But do keep in mind this isn't by -- virtue of the data source, this is for patients that are mostly in outpatient care. If you have delirium in a hospitalized patient, I think that's a very

different situation where you use intravenous drugs in all kinds of strange combinations.

But we really require a lengthy overlap of more than one antipsychotic to label a patient to be on polytherapy. So these very acute situations would not fall under our measure.

CO-CHAIR CIPRIANO: Jean and then Lisa.

MEMBER de LEON: I have two questions. One, the 19 studies in the meta analysis, were all 19 randomized controlled trials?

DR. CAMPBELL: Yes.

MEMBER de LEON: Yes, they were? And then this is just that I don't prescribe a lot of antipsychotics. What happens if the drug companies are working on something that works synergistically?

We have now decided that the people that are the Medicare beneficiaries are no longer able to access this newer drug that

may be synergistic with what is out there according to this measure.

DR. CAMPBELL: Right. So if a new drug were introduced to the market, we maintain these measures annually. And the universe of drugs that is included in there right now is the drugs that are currently on the market.

So when the measure came up for an annual update, if there was some change in regard to the evidence with regard to this measure, we would capture that in our surveillance and potentially come back to NQF.

MEMBER de LEON: If you deemed that the manufacturer had adequate evidence?

DR. CAMPBELL: Correct, yes.

MEMBER de LEON: Then you would change it?

DR. CAMPBELL: Right.

MEMBER de LEON: And the patients would not have access to it until you deemed that their randomized controlled studies were

adequate. And I do this with devices, not really with medications, but even though there is a lot of research behind a new product, it doesn't ever seem to meet CMS' bar to change. So it's not any study. It's your level of evidence before you deem that you will change that.

DR. CAMPBELL: Well, under part D -- and I don't want to get too far afield in the policy area because that is not my area necessarily of expertise, but under Part D, antipsychotics are in a protected class. And so if there were concerns of that nature where a new drug came to market and synergistic effects -- that would be part of, like I said, the measure review and something that we would take into consideration.

DR. MATTKE: Also it's not that we are taking away coverage. This is a quantity indicator, not sort of strictly prescriptive.

MEMBER de LEON: But you're affecting the prescriber.

DR. MATTKE: Yes.

MEMBER de LEON: Yes.

DR. MATTKE: Yes, but not sort of as strictly as taking it away. You could still prescribe it, but --

MEMBER de LEON: But you are affecting the prescriber, who is not going to prescribe it because you are going to mark against them that they are doing this.

DR. MATTKE: And I think --

MEMBER de LEON: So they won't.

DR. MATTKE: At the current rate of prescribing, I think we do a lot more good by making it harder than by sort of being neutral on that issue.

MEMBER McGIFFERT: Can I just get in on a follow-up with this conversation?

CO-CHAIR CIPRIANO: Yes. You were next anyway, Lisa.

MEMBER McGIFFERT: Since we are kind of walking into policy, I mean, I think it is probably a really good idea for CMS to

be cautious about adding new drugs before they have been on the market for a while because there is quite a bit of evidence that it takes a while to really get the feedback from a broad use of a drug before you know it is effective and safe.

CO-CHAIR CIPRIANO: Pat, is your tent up? Yes?

MEMBER QUIGLEY: Thank you, Madam Chair.

My comment, I would just like to reemphasize some of the discussion that we had in our workgroup. And that is that one versus two doses does not necessarily indicate quality.

And we did emphasize the importance of the correct prescribing the best possible dose and combination of medications to manage such difficult patients.

And, realizing that that is oftentimes the approach that geriatric psychiatrists will use or psychiatrists in

dealing with head injury patients, traumatic brain injury patients, PTSD patients, we really wanted to emphasize our focus on the best possible combination of medications with the safest dose.

And this indicator did look at persistent use of these medications over time. So it was a 12-month period of time. So, you know, they would have to be able to track that someone was on two of these meds over a period of time.

But, even when you look at the randomized controlled trials and the medications that are there, this is a tough population to be able to do these kinds of studies on, be able to follow the patients prospectively over time to see if there is really indeed a change in behavior.

So there are even limitations with these kinds of studies. And we know that there are always methodological issues with randomized controlled trials.

So for behavior management, I would just like to say that in talking with the prescribing practitioners in this area, psychiatry, geriatric psychiatrists, their focus still was on the best possible medications to go give with a single patient at the best possible dose.

Thank you.

CO-CHAIR CIPRIANO: Okay. Jason?

MEMBER ADELMAN: I really did want to just eyeball that article. And I really can't find -- I mean, you said it was the Nancy Correll article? But I don't think that's right.

DR. CAMPBELL: Correll.

MEMBER ADELMAN: How do you spell Correll?

CO-CHAIR CIPRIANO: Go to page 17.

MEMBER ADELMAN: Thank you.

CO-CHAIR CIPRIANO: It says, "Correll and others."

MEMBER ADELMAN: Okay. Thank you.

CO-CHAIR CIPRIANO: Okay. Well, while Jason is doing some speed reading here, Chris, I think you are back up.

MEMBER MICHALEK: I just had a comment. And it is related to that. We get this list of articles. You can't tell if they are trials or not based on the title. We expect we see an expert panel has reviewed them.

But, you know, a lot of us want to try and validate some of that ourselves. So you have to understand our difficulty in that you're telling me that there are 19 randomized controlled trials in that meta analysis that includes patients from 18. You know, I've got to trust you on that, but I don't know that.

So, you know, when you are developing these measures, I think it would be helpful for those of us that really want to validate that a little bit more. And, unfortunately, there has been some negative reinforcement in that some of these measures

include trials that aren't related to the measure topic. So then it makes us question more, just a point of note to you who are developing the measures.

MEMBER THRAEN: Maybe a couple of seminal articles ought to be included when we do this if there are some, like a meta analysis-type thing.

MS. BOSSLEY: We can work with developers. What we do is overload you with paper already. It's a balance. We'll keep working on it.

CO-CHAIR CIPRIANO: Lisa and Jean, are your tents still up again? Sorry. Okay. Jason?

MEMBER ADELMAN: I'm done reading the article.

(Laughter.)

CO-CHAIR CIPRIANO: We have one more comment if you want time. That was fast.

MEMBER ADELMAN: No.

CO-CHAIR CIPRIANO: Go ahead.

MEMBER ADELMAN: Either way.

CO-CHAIR CIPRIANO: Rich, would you like to go ahead?

MEMBER WHITE: I may have found it. I was looking for persistent, and in 2a.1.1, it does specify 12 months. So they have to get scripts for 2 agents for 12 months. And we are finding it in ten percent of the population that you are interested in, Medicare, who have a diagnosis of a psychosis or who are taking at least one.

Of the five percent that are taking one, ten percent are on two. Is that correct?

DR. CAMPBELL: Okay. Let me just clarify the definitions for you so we're all on the same page. So the denominator is individuals 18 years of age and older who are prescribed at least one routinely scheduled oral antipsychotic. "Routinely" in this case means they have 2 fills of at least 25 day supply each with no more -- a

medication/possession ratio of .8. So what we are trying to avoid is someone that has just had just a single prescription for an antipsychotic?

And then in terms of the numerator, what we are requiring is that the overlap of therapy between 2 antipsychotics during the 12-month measurement period is 90 days or greater. And we did that.

Specifically we looked at a sensitivity analysis with our TEP to ensure that we weren't capturing patients that were cross-titrating. So that is the rationale.

MEMBER WHITE: You found eight percent incidence of dual therapy?

DR. CAMPBELL: Yes, across the 8 states 8.9 percent, excluding those beneficiaries that had clozapine, which in the RCT or in the meta analysis was shown to be more effective, the polytherapy that is more effective.

MEMBER WHITE: Just a comment. So

that won't affect our delirious patients. They won't be delirious for 12 months.

CO-CHAIR CIPRIANO: At least we hope not.

Jason, are you ready?

MEMBER ADELMAN: We have a psychiatrist at Montefiore that sometimes uses Neurontin for a psychothymia. It is not indicated, but he believes it works. And he says that many providers do.

You know, unfortunately, we don't have evidence-based medicine for everything. So sometimes doctors use things outside. So I think you need really compelling evidence.

And so I looked at some of the articles in the initial section that defends the evidence behind the requests for the measure where this article wasn't listed, and I didn't see it.

This particular article, just reading from the abstract because I feel like it should be close to giving aspirin to a

heart attack if you are going to make an NQF measure.

So all I had to do is read the abstract and the conclusion of the article. In certain clinical situations, antipsychotic code treatment may be superior to monotherapy. However, the database is subject to possible publication bias and too heterogeneous to derive from firm clinical recommendations, underscoring the need for further research.

So it just doesn't have the strength to start publicly reporting that doctors are bad, even though I understand the evidence is leaning towards that way and I see the point, to start saying, you know, that doctors are really bad for adding extra-site antipsychotic for a child who is really resistant and is delusional seems like a stretch or adults. I just use that as an example.

MEMBER THRAEN: But this is specific to seniors.

MEMBER ADELMAN: For anyone, really.

MEMBER THRAEN: Well, but if you are talking about Medicare Part D, does Medicare Part D cover non-seniors?

DR. CAMPBELL: Yes, yes. We do have some.

MEMBER THRAEN: So you're talking about your disabled population?

DR. CAMPBELL: Correct.

MEMBER THRAEN: Okay.

MEMBER QUIGLEY: Madam Chair, I just would like to say that, Jason, I think you confirmed my comments as well.

CO-CHAIR CIPRIANO: Okay. Richard again?

MEMBER WHITE: So there are societies and guidelines that go along with this exact measure where they say this is a no, no?

DR. CAMPBELL: So the most recent publication, the PORT Guidelines for

Schizophrenia, do not support the practice of polytherapy. There isn't an evidence-based statement to say specifically not to do it but the guidelines do not confirm that polytherapy should be used.

MEMBER WHITE: So why would that be that you don't have a guideline that says this is something that shouldn't be done and, yet, we're doing this measure?

CO-CHAIR CIPRIANO: Jason?

MEMBER ADELMAN: I left it up before, but I just was -- you know, schizophrenia is one of 12 diseases where you can use antipsychotics.

CO-CHAIR CIPRIANO: Okay. Are there any other questions for the measure developer or comments from the panel or the measure developer? Iona?

MEMBER THRAEN: I'm confused.

CO-CHAIR CIPRIANO: What would you like clarification on?

MEMBER WHITE: You need two

antipsychotics.

(Laughter.)

DR. CAMPBELL: I just wanted to mention that this measure did go through an extensive public comment period. And the comments that we received during the public comment were favorable towards the measure.

MEMBER ADELMAN: Sorry. I think it's probably right. And I don't want two antipsychotics used on my family members. It's just that the evidence isn't strong enough to start publicly penalizing providers if they do it.

They may have reasons that they are justified in trying and we don't have strong enough evidence to say that they are wrong. That is my feeling.

DR. WINTERSTEIN: I think just to put this in the analogy of drug approval because you used this argument that there needs to be a clinical trial that proves that aspirin should be used after MI -- and this is

the exact analogy that I think we should apply here -- there is no clinical trial that proves that dual therapy is efficacious.

So what that means is that you are essentially using anecdotal evidence to establish the benefit of a treatment where there is proven harm. And if you wanted to go to to the FDA with this and ask for approval of dual therapy, it would not make approval.

So I think that given there is a safety focus, I think it is important to look at what kind of evidence is there that supports that dual therapy should be used in a patient. And the reality is there isn't.

And I do understand. I do work a lot in psychiatry but not in this particular area. There are a lot of empirical treatment approaches. I understand that psychiatry in itself is a lot of trial and error, but we also realize that, in particular, atypical antipsychotics have grown tremendously. Their market share is unbelievable. They have grown

tremendously over the last decade for a variety of indications.

And I think when we are looking at ten percent of patients here, we are not looking at schizophrenic patients and patients who have delirium, who make a very, very small population. We are looking at patients who are managed for a variety of different diseases or disorders that we have not started to look at.

So in terms of weighing efficacy and safety, I think we should take this in mind, keep this in mind when we are looking at this measure here.

MEMBER ADELMAN: It's just that, you know, we can make a bucket measure that says any time a provider uses a drug that is not for its indication, it will hold them accountable. But I just don't think we're there yet.

Most of the measures that I am familiar with are about a very well

evidence-based practice, not the lack thereof and especially if you have, as I said, a patient that is resistant psychotic and people are desperate and a doctor wants to try something. It happens all the time.

I am not sure if anybody else knows of another measure that is like this where it is judging a provider for doing something, you know, like this. Sorry.

MEMBER NAGAMINE: That may be indicated.

DR. CAMPBELL: Just to respond, I mean, there is an existing NQF-endorsed measure in inpatient setting for this same concept. You know, we can't operationalize all of the exclusions in that particular measure, but we have operationalized what I feel like is one of the most important exclusions, which is the therapy of clozapine, the dual therapy, which does have evidence for support. We exclude those patients from measurement.

CO-CHAIR CIPRIANO: I just have one question before we go to other speakers. Are there any efforts that have been put forward by the professional societies in this area that have not been successful to reinforce the safety issue so that it has come forward to say if there is a more rigorous enforcement of something like a quality or safety measure, that that will change practice or is it just that you are looking at the evidence coming from the field or, again, is there anything else that you can add to that?

DR. CAMPBELL: I'm sorry. No. I don't have anything specifically to add to that question.

CO-CHAIR CIPRIANO: All right. Thanks.

So we have Bill and then Richard.

CO-CHAIR CONWAY: I may be just echoing that point. The debate has been around whether this is effective. This is not an effectiveness panel. We're a safety panel.

And we're looking at safety measures. So I'm still struggling to find this evidence of toxicity.

And even in your own way, you say, "The evidence on the medium and long-term safety of antipsychotic polytherapy comes primarily from observational studies."

I don't know that we have got compelling data that says we have got a safety situation here. I'll grant you you have got an efficiency question. Again, I am asking from the measure developers, where is the compelling safety problem?

DR. CAMPBELL: Yes. I mean, we acknowledge, just as what is written in the write-up, that the evidence to support the safety concerns are observational. And the only RTC that I am aware of that we cited in the documentation was related to weight gain.

So it was a relatively mild side effect that we saw in an RTC. But the rest of the data that we have are all observational in

nature.

CO-CHAIR CONWAY: And I am not a psychiatrist. My understanding, weight gain is associated with almost all antipsychotics. So that could happen with monotherapy, too.

CO-CHAIR CIPRIANO: Richard?

MEMBER WHITE: So I'm a little hard-pressed to understand who is going to be treating someone for 12 months with dual therapy not seeing some kind of benefit. You know, it really strikes me that what you are saying is some really dumb docs out there who are just really drugging their patients.

Why in the world would you keep someone on both of those for 12 months at least without some beneficial effect that might be going on or you need to go get the data to drill down on those and show these people are unquestionably being mismanaged?

You know, this is travesty. This is tantamount to, you know, tying him up with the drug. I mean, do you have that kind of

data? Otherwise I am really hard-pressed to see how the primary care providers want to give them dual therapy.

So I guess I just need more evidence that this is really a bad thing that they are doing. I just don't hear that. I just can't imagine anyone doing that, but it might be the case.

CO-CHAIR CIPRIANO: Any other comments or questions? Chris?

MEMBER MICHALEK: It's not 12 months of concomitant therapy, right? It's less than that, isn't it?

CO-CHAIR CIPRIANO: Is there anything over 90 days?

MEMBER MICHALEK: Ninety days of concomitant therapy. And so the question, there is information out there from psychiatrists as to why they would put patients -- some have argued against the whole polytherapy. You know, this is just something I found on my own. But, you know, this is one

person's feeling.

You know, rather than conclude that polytherapy is unwanted, we might want to speculate that many treatment-resistant patients need to be given more than one antipsychotic to reach the same therapeutic level as less treatment-resistant patients.

And they acknowledge there are no trials for it. Sometimes I think reading what other psychiatrists are saying is that you may be able to avoid some adverse effects. You know, maybe your patient is having an incomplete response but not a partial response and maybe you want to add something in there.

I am not saying it is right or wrong. I am just saying that is the thought. That is some of their thought process, you know, for perhaps using polytherapy.

CO-CHAIR CIPRIANO: Any other comments or questions?

(No response.)

CO-CHAIR CIPRIANO: Okay. Then I

believe we are ready to vote on this measure. Jessica?

MS. WEBER: Importance to measure and report. Are all three subcriteria met: high impact, performance gap, evidence? It is a "Yes"/"No" question. Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Gina?

MEMBER PUGLIESE: No.

MS. WEBER: Two yes, 16 no.

CO-CHAIR CIPRIANO: Thank you. So this measure is not approved to go forward.

And, again, we appreciate all of the efforts and the background and the hard work to bring it forward and hope that we have been able to express the concerns and the issues, which are somewhat controversial, I think, again in terms of trying to meet the bar of identifying the safety issues. And that is really the evidence we have to weigh in order to take positive action on it. So thank you very much.

DR. CAMPBELL: Thank you for the opportunity. Appreciate it.

CO-CHAIR CIPRIANO: Thank you.

NQF MEMBER/PUBLIC COMMENT

CO-CHAIR CIPRIANO: Okay. Operator, would you please open the lines for any public comment?

OPERATOR: Just a reminder it is *1 if you have a question or comment today.

(No response.)

OPERATOR: And there is no one in my queue at this time.

CO-CHAIR CIPRIANO: Okay. Thank you very much.

Is there anyone in the room who would like to make any public comment on any of the items discussed?

(No response.)

CO-CHAIR CIPRIANO: Seeing none, okay. I believe this concludes our agenda for today. And maybe we can just spend one minute to hear from Heidi about what we can expect in

the communications coming forward.

As you know, we have deferred a number of items. So we have been talking about scheduling a conference call. And, again, I will turn it over to Heidi to give us a little more direction.

MS. BOSSLEY: Okay.

WRAP-UP/NEXT STEPS

MS. BOSSLEY: I first want to thank everyone. You all have done a phenomenal job in the last two days. And there is still a little bit more to come.

You deferred, I think, it looks like, if my memory is correct -- we will go back through our notes. But you deferred two that we're hoping to get considered on a conference call. We'll work to schedule something in January. Give us a few days to figure out the developers, where they are and everything. And then we'll get back to you and schedule it.

Then you have one measure that you

have deferred to phase two where we are hoping that they can come back with some testing. So you will see that measure again.

What we will be doing as staff over the next I would say few weeks -- again, it's a holiday. So it will take a little bit longer than normal maybe. We're going to take all of the information, your discussion, and try to synthesize and provide the rationales of how you came to those decisions you came to. We will circulate that with everyone so that you can have a chance to comment and make any additional edits, any other information you would like provided in that report.

It will then go out for comment for 30 days to the membership as well as the public. And we will work to schedule a call after that where you will go through all of the comments and make your final recommendations that go to the Consensus Standards Approval Committee.

So I estimate roughly February I

think this will go out for comment if we can again wrap up the couple of things that we have left. And then stay tuned for phase two as well. We will send you more information because that will be starting up after the new year, too.

PARTICIPANT: When will that start?

MS. BOSSLEY: We went through that yesterday. I think it's we'll have you meet sometime in the summer, May or June. So by the time you finish this first phase, you will be moving right into the second phase.

PARTICIPANT: And those meeting dates, can you please take college and high school graduation times in to consideration please.

MS. BOSSLEY: Yes. Actually, because we have the committee set, what we will probably do is just poll all of you to see availability. And we will try to do that as much in advance as we can. Yes. It is a

very good point.

CO-CHAIR CONWAY: And I would like to thank the whole panel. This has been a very engaged panel. Thank you for all your work. And we are looking forward to seeing you again. Have a great holiday.

CO-CHAIR CIPRIANO: I would add my thanks as well and want to thank our troopers on the phone, particularly Janet for two days and Gina for joining us today. I heard you might be under the weather. And we certainly want to thank our staff for their support and all of the measure developers who have come in to help us. So thank you, everybody. Safe travel.

MEMBER PUGLIESE: Happy holidays.

(Whereupon, the foregoing matter was concluded at 2:16 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Patient Safety Complications

Before: NQF

Date: 12-16-11

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter