THE NATIONAL QUALITY FORUM

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NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR AMBULATORY CARE-OUTPATIENT MEASURES 2010

MEETING

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TUESDAY

APRIL 6, 2010

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The Steering Committee met in Suite 600 North of the Homer Building, 601 13th Street, NW, Washington, D.C., at 10:00 a.m., John Moorhead and Suzanne Stone-Griffith, Co-Chairs, presiding.

PRESENT:
JOHN MOORHEAD, MD, CO-CHAIR
SUZANNE STONE-GRIFFITH, RN, CNAA, MSN, CO-CHAIR
JAMES ADAMS, MD
EVALINE A. ALESSANDRINI, MD, MSCE
TANYA ALTERAS, MPP
ARA CHALIAN, MD, FACS
VICTOR COHEN, BS, PHARMD, BCPS, CGP
BEVERLY COLLINS, MD
JEFFREY COLLINS, MD, MA
ANDREW C. EISENBERG, MD, MHA, FAAFP
WANDA GOVAN-JENKINS, RN
EDWARD JAUCH, MD, MS
LEIGH ANN MCCARTNEY, RN, MBA
NATHAN NEWMAN, MD, FAAFP
ROBERT O'CONNOR, MD, MPH
CATHERINE ROBERTS, MD
RICHARD M. ROSENFELD, MD, MPH
JOHN SALTZMAN, MD
HEIDI BOSSLEY, NQF STAFF

PRESENT:

HELEN BURSTIN, MD, MPH, NQF STAFF

DELL CONYERS, NQF STAFF

ANN HAMMERSMITH, ESQ., NQF STAFF

ELISA MUNTHALI, NQF STAFF

EMMA NOCHOMOVITZ, NQF STAFF

JESSICA WEBER, NQF STAFF

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

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

10:02 a.m.

CO-CHAIR MOORHEAD: Good morning, I am John Moorhead and I am co-chair of the steering committee and I think we have one member who we think will wander in here in a few minutes. I am very much looking forward to this process. I think, with the amount of material we got in the last few days it is going to be challenging but this is a good group and I know we will get through all these measures.

I am an emergency physician from Oregon Health & Science University in Portland, Oregon. I have had the pleasure of co-chairing the previous two emergency medicine steering committees. I am looking forward to working with you all on this project. Suzanne?

CO-CHAIR STONE-GRIFFITH: Thank you and good morning everyone. I am Suzanne Stone-Griffith and I am delighted to be here, a

little overwhelmed by the material as well. A lot of good plain reading, though. I think I killed a printer, though. Not very green.

I participated in the last steering committee and I think we have a very full and busy agenda and I am delighted to be here.

CO-CHAIR MOORHEAD: I think what we would like to do is just go around the table and everyone introduce themselves. That way you get to know each other a little bit. Why not start here, Eddy?

DR. JAUCH: Good morning. My name is Ed Jauch. I am from the Medical University of South Carolina. I too am an emergency physician and spend half my time in the Department of Neurosciences and I was bemoaning the point I spent way too much time with the American Heart Association. It's kind of like quicksand.

DR. ALTERAS: Hi. I'm Tanya Alteras from the National Partnership for Women &

Families. We are a consumer advocacy organization that works very strongly in health quality issues and I also am the associate director of the Consumer Purchaser Disclosure Project, which focuses on quality measurement, public reporting and using those public reporting data for changing the way consumers and purchasers make their healthcare decisions and look at payment reform issues.

DR. ADAMS: I am Jim Adams. I am Chair of the Department of Emergency Medicine at Northwestern University in Chicago.

DR. JEFFREY COLLINS: I am Jeff Collins. I am an internal medicine and pediatric physician and I run the urgent care center at Mass. General Hospital. It's located out in Chelsea.

DR. NEWMAN: I am Nathan Newman. I am the Chief Medical Officer of Solantic. Solantic is 30 urgent care centers across the State of Florida. We have 160 physicians and I am a boarded family physician and

geriatrician.

DR. BEVERLEY COLLINS: Good morning. I am Beverly Collins. My speciality is preventive medicine. I am the medical director for CareFirst BlueCross BlueShield in the medical informatics department. CareFirst is also in this region too, if you want some good insurance.

DR. CHALIAN: My name is Ara Chalian. I am an otolaryngologist at the University of Pennsylvania in Philadelphia. I am a patient safety officer in our organization and, in our academy, I served on our patient safety and quality committee and also on our geriatrics committee.

DR. ALESSANDRINI: My name is Evy Alessandrini. I am a pediatric emergency physician at Cincinnati Children's, although I was at CHOP for 17 years and just left nine months ago, so we haven't even met yet. That's not hard to believe, right? And I direct the Quality Scholars Program in Healthcare

Transformation at Cincinnati Children's, which is a training program for fellows and junior faculty who are learning improvement signs.

DR. COHEN: My name is Victor Cohen, clinical pharmacy manager at the Department of Emergency Medicine. I am also director of the pharmacy practice residency program there, specializing in emergency medicine as well as an assistant professor at Long Island University and I have written a book on Safe and Effective Medication Use in the Emergency Department, which American Study Health System Pharmacists has edited and published.

MS. BOSSLEY: Heidi Bossley, Senior Director in Performance Measures here at NQF.

DR. BURSTIN: Good morning, I am Helen Burstin, Senior Vice President for Perfomance Measures here at NQF and I want to add my welcome to all of you.

MS. MUNTHALI: Elisa Munthali, Project Manager for Performance Measures at

NQF and welcome and thank you so much for your participation.

MS. MCCARTNEY: I am Leigh Ann McCartney. I am the Operations Manager for the Neurological Institute at University Hospitals Case Medical Center in Cleveland and prior to that I worked for six years in our quality center, working a lot with our emergency department in quality measures and compliance with them as well as we are currently standardizing stroke care across our community hospitals and developing measurement tools to measure the compliance with the national stroke standards.

DR. SALTZMAN: Good morning. I am John Saltzman. I am a gastroenterologist and Director of Endoscopy at the Brigham and Women's Hospital in Boston, associate professor of medicine at Harvard Medical School.

DR. EISENBERG: Good morning, Andy Eisenberg. I am a family physician with most

of my experience in rural communities, although I sold my practice a few years ago and do mostly emergency medicine work now. I am representing the American Academy of Family Physicians and with them I am active on their Commission on Quality and Practice.

DR. ROBERTS: Hi and I am Catherine Roberts. I am your only radiologist and I am from Mayo Clinic in Arizona. A pleasure to be here.

MS. RIEHLE: My name is Jessica Riehle. I'm a nurse with Madison. I work on software which is measure development.

MS. WEBER: I am Jessica Weber.

MS. NOCHOMOVITZ: Hello. I'm Emma Nochomovitz. I am also a research analyst in the performance measures.

DR. COOPER: I am John Cooper, I am a medical officer at CMS.

MS. TIERNEY: I am the sole person over here. I am Sam Tierney I am with the American Medical Association.

DR. O'CONNOR: Sorry I am late, I'm Bob O'Connor from the University of Virginia. Good morning.

CO-CHAIR MOORHEAD: Well, I hope everyone had uneventful travel. I am told some of you guys sat on the runway in Chicago last night for four hours while we got lightning and some thunder and then the captain came on and said, "Well, one of our indicators says we have enough gas to get to Washington. Unfortunately the other one says we are going down in the Great Lakes. We all thought it would be a good idea if we just checked that out before we took off," so we pulled in about 2:30 this morning so, if I fade, Suzanne is going to prop me up over here I know. He was a very active captain, he went out and shut the door and he was doing all these things himself. I was pretty impressed actually. Nice man.

All right. So we're going into project overview. I will say that I know many

of you have worked on previous measure development and sometimes we see our measures get developed and they go off through NQF and they get picked up by various other parties and some are passed as time-dependent measures and we frequently lose track of where they are in the process.

We thought it would be helpful as part of this over view and I've asked Elisa to, Elisa, I'm sorry --

MS. MUNTHALI: That's okay.

CO-CHAIR MOORHEAD: To include that as part of the overview this morning because I think that will help us as we go through these measures -- there are some similar measures that are already out there -- and for us to understand where they are at in terms of the time-dependent process and are they coming out for re-review or whatever, and how will that impact our review of several of the measures that we are going to look at today and tomorrow. So we will include that as part

of overview of the project and help us get going.

MS. MUNTHALI: Great. Thank you. Before we go into the slide presentation there are a couple of housekeeping items that I wanted to bring to your attention. First, the restrooms. I know that is very important. We have the keys at the back of the room. The female bathrooms are to the right of the elevators and the male bathrooms are to the left.

Also just to let you know this is an open meeting. This is open to the public and at certain points in this meeting, the public will have the opportunity to give comment. Members of the measures development teams are here and they are also participating through the tele-conference portion of the meeting and so you can ask any questions of clarity on their measures.

And finally, this meeting is being taped and transcribed by Eric, our court

reporter. Eric is in the corner over there and so we ask that everybody please speak into the microphones, the transcript and audio recording of which will be posted to the NQF website in a few weeks following this meeting.

We are also going to prepare a meeting summary, our staff, and that will also be posted to the NQF website.

We just included this slide here to let you know of all of the other participants, my colleagues that are working on the ambulatory care project. And for many of you who attended the orientation call last week, you received some of this information but we thought it was important to reiterate today.

NQF is a private, non-profit, voluntary, consensus standard setting organization with a membership of over 400 groups. Our members are organized into eight very distinct stakeholder councils, and they include consumers, purchasers, health plans,

health professionals and suppliers. Our board mirrors the diversity of our stakeholders with a deliberate but slight over-representation of consumers and purchasers.

Our board established three standing committees to help guide their work and those include the Consensus Standards Approval Committee, which is also known as CSAC, and they consider all of the candidates' standard and make recommendations like the ones that you bring forth to them after this meeting for NQF endorsement to the board.

The National Priorities Partnership is a 32-member organization collaborative that assesses high-impact priorities and goals and takes collection action to address them and the leadership network, they provide guidance on our education, research and recognition programs.

I would like to talk a little bit about developing consensus and we apply a very specific process to that and we call it the

Consensus Development Process, also known as the CDP. We do this to gain consensus about which measures or practices should be national voluntary standards. And as I previously mentioned, we are an open organization with a diverse representation of healthcare stakeholders and they include private and public entities.

This is a visual schematic of the CDP and it shows the important steps in the entire process, including the current step that we are taking right now. You, as the steering committee, are going to review the candidate measures, after which you will draft recommendations and those recommendations are subject to member and public comment. You also draft consensus standards. Members will vote on those and CSAC will review them and following endorsement, there's a 30-day appeal process.

Now let's shift to the ambulatory project in particular. This project is funded

by CMS, the Centers for Medicare and Medicaid, and through our CDP process, we are tasked with identifying, evaluating and endorsing additional measures that are suitable for public reporting and quality improvement that speak to emergency department and urgent care and ambulatory surgery.

In addition to that, we are identifying gaps in existing ambulatory care measures and to recommend potential measures to fill those gaps.

We initially intended to convene two steering committees, one to evaluate emergency department and/or urgent care measures and another to evaluate ambulatory surgery measures but we didn't receive the interest that we had hoped for the ambulatory surgery measures so we just have one steering committee to evaluate emergency department and urgent care measures.

As you can tell, we have a very aggressive timeline and we have put some of

the important milestones for our project up here. And I just wanted you to keep in mind that these dates are not inclusive of all of the project activity. Depending on what we are able to accomplish today, we may have some follow-up conference calls to discuss issues that haven't been resolved in the next two days so you can refer to this list later on when you have some time.

We also wanted to reiterate your roles as a steering committee and, as members, you represent the multi-stake holders that are reflected in our membership and, in general, you work with us as NQF staff to achieve the project goals. But most importantly you evaluate the candidate measures and recommend them for endorsement.

After recommending, after making your evaluations you make these recommendations to the NQF membership for endorsement and you may be asked to respond to your recommendations. Your co-chairs, Dr.

Moorhead and Ms. Stone-Griffith will serve as your representatives at the CSAC meeting and you in turn may be asked to respond to directives from CSAC.

As individual members of the steering committee you were assigned reviewer responsibilities and you used our measure evaluation to do your evaluation, to summarize your findings for the steering committee. You were asked to evaluate the criteria and associated sub-criteria for accuracy and completeness and to indicate the extent to which each of those was met.

We included the evaluation criteria in your meeting materials and I think we have some copies here today if you don't have those.

And now I will turn it over to Helen who will talk about our endorsement policy.

DR. BURSTIN: I just want to briefly go over our endorsement criteria and

I think you had a little bit of this on the call earlier. A fair number of you have been on our committees before. We have done an update of our measure evaluation criteria in August of 2008 and actually made them tougher. And part of the idea was to try to say there's a lot of measures now, what's the next set of measures that would really, we think, drive improvement and help improve quality.

So those measure went through in two-thousand-and, just about a year ago, actually almost two years ago, and specifically we wanted to try to establish a stronger link to the national priorities and goals that the national priorities partnership, which NQF convened about a year-and-a-half ago promulgated. We wanted to, again, push towards higher level performance. It seemed like many of the ones that we were getting sort of seemed like standard of care as opposed to necessarily quality so we tried to raise the bar a bit there, trying very hard

to harmonize measures.

I was glad that Dr. Moorhead mentioned what we have endorsed before versus what is in here now because I think there's some really important issues for us to think about. Is what's on the table now really value added? Do we already have what we need? Are there opportunities for us to really enhance the portfolio by bringing things in?

We are trying to move as much as possible towards outcomes. I think, you know, we have many, many process measures. We now currently have about 600 endorsed measures so there's a whole lot of measures, about a hundred of which are outcomes. So we are trying to move in that direction. There's a lot of work this year on outcomes. There's going to be a very large project beginning this summer focused on resource use. So there's a lot of new areas of measurement that we are really trying to push towards, and increasingly trying to make the case that if

a process measure comes through, it's fine, there are obviously very important roles for process measures. They direct you to where you improve.

But there's got to be a pretty tight link to outcomes. So if something is pretty, speaking clinically, if something is fairly proximal to the actual outcome, then that would be very logical and you would want to drive that process measure because you think it will improve outcomes.

We tend to sometimes get measures that are pretty distal from where the outcome action is really so the question is, is that really an internal QI activity as opposed to something that you would actually want to publicly report since the ultimate goal of NQF endorsed measures, is you would need to feel comfortable, these are appropriate for public reporting.

Next. So the major changes are several. The first is that -- they have this,

but not in the, we'll get you the pretty color ones later in the day, this is our updated measure evaluation criteria and we give this now to every committee because we really want to as much as possible standardize the process, make it very clear which sub-criterion you are voting on so we can make sure we are being appropriately cognizant of all the issues involved.

So the first major change is that importance to measure and report is now a must-pass criterion. If it doesn't pass the importance test, there is no reason to evaluate it further. So essentially it's really, is the juice worth the squeeze? If it's really not going to get us to improvement, allowing consumers or purchasers to make better decisions based on having that information, or if it's really not heavily linked to the evidence-based, we really just don't need to consider whether it's scientifically acceptable, feasible or usable,

we are going to stop there. So you should feel free today if there's a measure clearly that it's stopping at that point, we don't need to evaluate it further.

Now there's three parts to importance. The first, as I mentioned earlier, is a link to our national priorities and goals so the six national priorities, trying to really ground in and what we are hoping everybody really focuses on and many of these really do, because that's care coordination, safety, patient and family engagement, palliative care, overuse, and it's inevitable that when you list six things, the last one escapes you so I'll come back to that in a moment. I think it's just to be psychological. Five out of six you can get, but that sixth just never -- care coordination. There you go.

So that's the first sub-criterion. The second sub-criterion is even if it's not one of those national priorities, there's still areas of care that are high-impact in

terms of the impact on the patient, the mortality, the morbidity, even if it's a small population with a significant impact or the volume of patients even for something that perhaps is not as high-impact, that would still be appropriate.

And part of that sub-criterion is also saying, is there really a gap in care? So if something is at 90 percent already, the question is, is it worth collecting the data to push it forward if in fact we're not going to make a whole lot of progress based on it.

And the last one is very important, which is really, is the evidence for the measure focus sound, is it based on high-quality guidelines, is it based on high-quality evidence. So those are the three sub-criteria I'll have you look at before we even move on to scientific acceptability.

I'm sorry. Go back one more second. Scientific acceptability is really as we all focus on it today, all about

reliability and validity for the most part, unintended consequences as well. You have measures coming before you today, as was also mentioned earlier, that have not yet been tested and so those can only go forward in our current work as time-limited endorsed measures. We are actually tightening that funnel.

We are really finding that is important to say which measures really could come in as time-limited. We are now not allowing complex measures, outcome measures, composite measures, things like that, to come in as time-limited. They are complex enough without knowing whether they perform when tested. So we have narrowed that funnel. We have also tried to tighten the time to time-limited. From the time you guys led this last time they had two years. Some of them are still working on it and that's a pretty long time if you tried to shorten that to a year, and also it's got to be an area where we

already have measures, where there's a need and we don't have measures.

So if those three criteria are met, we'll go ahead and potentially bring in a time-limited measure. I think over time, though, that will constrict and contract even further.

And we have two important task forces going on now, one focused on the evidence for the measure focus and a second one actually on testing and we are trying to establish what is an acceptable but low level of testing that we would accept, de minimis, what is moderate and what is high, just to really standardize again across committees. That work's ongoing.

Usability, much greater emphasis on harmonization as the biggest issue here and the last one, feasibility, not surprising with ARRA and a push towards EHRs, thinking about could you do this using electronic data sources. Next.

So there are conditions for consideration that actually staff go through up front. There has got to be an intellectual property agreement signed with the measure steward. They have to agree that they're the steward and they're going to maintain the measure. I mean, the evidence-based changes for measures as reflected by the changing guidelines, they have to agree, yes we'll take on that responsibility, they have to agree that the intended use is really not just for internal QI but it would be appropriate for public reporting as well and then we make sure obviously that it's complete when it gets to us. Next.

I think I've probably, I just went through all of this. And I'll turn it back to you for going over what is in our hand -- and just one last thing. John is with us from CMS and the question that was asked earlier, a fair number of the measures that you endorsed in one of the first two cycles, I was just

looking at the notes, are up for hospital compare this June so we can maybe talk to John and see if we can actually talk about that a little bit later. So some of those have come full circle, I was just looking at it earlier including things like time to -- where did it go -- we'll come back to it. I'll find it for you and we'll come back to it.

But it is nice to see that the work you did is actually progressing for the outpatient rule on EDs. So with that I'll turn it back to Elisa.

MS. MUNTHALI: Great. I just wanted to talk a little about the measures that we received. The steering committee will evaluate 27 candidate measures related to emergency department and general urgent care, pediatric ENT, urgent care, and procedures especially, specifically endoscopy. Nearly 75 percent of those measures are untested and may be eligible for time-limited endorsement.

We handed out an attachment with

similar measures and Dr. Moorhead alluded to this earlier, so if you'd like to turn to that now we can discuss that a little bit before we get to the disclosure of interest segment of the meeting.

And it looks like this. I think there are about six pages. So the first page and the second one list two measures that we received during this call for measures for this project. They are similar measures. They both deal with acute otitis externa, antimicrobial therapy and one is an American Medical Association measure and the other is an Ingenix Incorporation measure.

The reviewers for both measures, we assigned reviewers, the same reviewers for both measures, so they are reviewing them on head-to-head and they and you will decide which is best in class.

What follows are measures that have been submitted and so the first, what you will see at the top of the page is the

proposed measure, and at the bottom is the measure that is endorsed. For the most part all of these endorsed measures are time-limited.

The first one is patient left before being seen and the endorsed measure is left without being seen. We have tried to include some of the specifications here on this table and I think Jessica was able to pull some for us that we will have on a laptop so when we get into that discussion you can refer to those.

The next measure is the syncopy and ECG measure and this proposed measure is from Ingenix again and the endorsed measure that is similar to it is a measure from the American Medical Association and similar to the other measures that I mentioned, we have included the specs, and we have detailed, additional detailed specs on the laptop.

Following that is the proposed measure non-traumatic chest pain and ECG. It's

also an Ingenix measure. And the endorsed measure is from the American Medical Association. It's also time-limited and it's the ECG for non-traumatic chest pain.

So those are the similar measures, similar measures that are competing head-to-head, measures that we received during this project and similar measures, measures that we received that are competing with currently endorsed NQF measures.

As I mentioned earlier, the steering committee received assignments as primary and secondary reviewers for each measure based on your experience and expertise and you received the evaluation forms in advance of this meeting to prepare for your presentation today.

Each primary reviewer has been instructed to evaluate both the criteria and sub-criteria and present your findings during this meeting. We will not get started because we have to do the disclosure of interest

portion first and we are waiting for our legal counsel, Anne Hammersmith too. I'm sorry?

DR. BURSTIN: We just sent her a note.

MS. MUNTHALI: Okay. But we will start. I just wanted to go over the agenda briefly with you. We will start with the nine pediatric ENT urgent care measures as they are listed in the agenda. And we have asked the measure stewards to provide a five to 10-minute introduction before each session in which their measures will be reviewed.

For the pediatric urgent care ENT measures we will start with the American Medical Association and then Ingenix.

CO-CHAIR STONE-GRIFFITH: Elisa?

MS. MUNTHALI: Yes.

CO-CHAIR STONE-GRIFFITH: Will you speak a little bit on the time limited measures? We spoke earlier but as you look through this hand-out some of the time limited measures come up for a schedule in this year.

Others have already passed, they came up in 2009. What became of them? Were they re-endorsed for another time limited? How would we know that?

DR. BURSTIN: Yes, we can go through that and clarify with you. Some of the -- it's been an interesting couple of years, certainly. I think part of what we've seen is that a lot of the measure developers have become rapidly focusing on conversion to EHR specs and so we got into this very strange place of people trying to test the old specs while developing the new specs.

So this past, probably about six or nine months ago, the board of directors approved a new policy that allowed those who had time limited measures to take a pathway that would give them time until their scheduled maintenance, which would be an additional year. At that point they are to return with both the original specifications plus EHR specifications with testing on both

data platforms.

So we sort of thought that was win-win, to get the EHR specs we know we want and need and yet to give them a bit more breathing room to finish some of the testing. I know some of them for example -- I was actually just looking at the LSU developers for example. I know we are in the midst of testing and those are due in the fall.

So I think we are kind of right at the middle point. I don't know that we have any completed testing results on that ED set to share with you.

CO-CHAIR STONE-GRIFFITH: Not yet.

DR. BURSTIN: Right.

CO-CHAIR MOORHEAD: There are a couple coming up for maintenance next month. How does that in general impact our discussions about similar measures today? How would you see that?

DR. BURSTIN: Yes, I think the simplest way to do it would be way to -- and

of course we are redoing our maintenance proposal as well so there's a lot of activities ongoing -- part of I think would be the most sense is evaluate the measure before you fully. Go through all four criteria. At the end of that we'll do the comparison to the existing measures and we'll go through any of the issues we know about, measure by measure.

CO-CHAIR MOORHEAD: Okay.

DR. BURSTIN: But let's at least look at what's on the table fully, go through the criteria and then we'll give you whatever information we have. The other thing we try to do is move our maintenance process from one that is always a bit out of synch with when we're looking at new measures, like exactly what we're facing today, that you've got measures currently endorsed that don't quite fit the timing of you to say today, well this measure is better, let's not maintain that other measure and just use this one.

So we can't actually reduce the

size of portfolio of measures we don't think are actually best in class. So there's actually something out currently for public comment that we will bring to the board in May that will move us towards a scheduled new project and maintenance schedule every three years by topic area.

So for example I think emergency medicine is probably in cycle A, which means that we are going to do it now and then probably in three years, you know we are going to do emergency medicine again and at that point all new measures and all maintained measures will get looked at at the same time. So essentially the maintained measures will go through the exact same process of re-endorsement so it's not just this still looks good, move it on, but actually saying, okay, now -- and then it also allows emergency medicine and other specialties and others to say, we know when the next cycle is going to be for NQF so you could really prep and say

what are the measure gaps, let's plan and bring those forward, so apologies for being once again in the midst of a transition but it's a lot of growing pains over the last couple of years.

CO-CHAIR MOORHEAD: Okay. So we are waiting for Ann? Is there anything else that we can --

MS. MUNTHALI: Well, perhaps we could talk about the talking points just in preparation for everyone's presentation to the steering committee. Let's do that. In your meeting materials I included talking points. I hope they were helpful. I thought it would be good to reiterate those today.

So when presenting your measure as a primary reviewer make sure you identify the measure by the ID and the measure description and an example of that is here. Make sure that you are explicitly stating the importance, how the measure addresses importance to measure and report, the first criteria that Helen

mentioned.

Also be sure to state the scientific acceptability, the extent to which the measure produces consistent and reliable results about the quality of care when implemented and also usability. Would the results of the measure be understood to the intended audience and likely to be useful for decision-making? And finally, feasibility. Are the data readily available and retrievable without undue burden and can the measure be implemented?

And include any minor revisions or clarifications that you feel the measure needs, that you'd like to recommend to the steering committee. Are there any other questions? I know we are waiting a little bit. Perhaps about the agenda?

DR. COHEN: How much time do we have per measure?

DR. BURSTIN: In terms of discussion? I'll tell you that our experience

is usually that the first one takes twice as long as everything else so you should expect 90 minutes for the first one. I've been doing this for about three years now. It's pretty consistent and then it drops by about half at that point. Again, we can do this some of this work virtually. We'd like to get through as much of it as we can again today. There's a lot of similar measures so that usually makes it move more rapidly as well.

DR. SALTZMAN: Can I ask about the testing? You say once a measure is adopted it's tested or you could test it. What are the criteria to know that it's been adequately tested and it can move on to the next phase?

DR. BURSTIN: Yes, and that's actually what we're working on clarifying as well through this latest test course that we're doing. It's that they need to be able to demonstrate the reliability and validity of the measure. So I think in a lot of the rush to try to get measures out there, measures

came together, work groups put them together, a lot of thoughtful work doing that and yet then there was not necessarily the time to do a formal testing, for example pulling charts, looking at EHRs, whatever the case would be to say, yes, you can reliably find this data point in this chart at this point. So that's what we're waiting on that, some of that. We'd actually, some of the, for example some of the ESRD measures recently were fully tested and the time limited stamp was removed and they're fully endorsed. But again it's definitely this transition period.

I will also just mention, since we talked about it earlier, what's happened with the measures from last time. So I was just looking and anybody from CMS had more information but certainly from what I've seen, for hospital compare for the June 2010 release, several of the out-patient ED measures are on the list including the median time to fibridolysis, fibrinolytic therapy

received within 30 minutes of ED arrival, median time to transfer for another facility -- if you remember those from phase one, I think John -- for acute coronary intervention, aspirin at arrival and median time to ECG.

The outpatient rule recently also included several of the outpatient measures including median time from -- remember all those median time measures we struggled over, certainly Jim and several people remember this -- median time from ED arrival to ED departure, patients who were discharged, who were admitted went through this past year and then the same indicator for those who were discharged was approved by the Hospital Quality Alliance this year.

So there's several moving forward and there was great interest in left without being seen but concern that it wasn't yet tested so I'm trying to get some more information on what they learned from the developer who's actively testing it when you

get to that measure today. But, some of them are actually being used.

CO-CHAIR MOORHEAD: Any other general comments or questions as you look through the materials?

DR. BURSTIN: I believe, we're just learning, you guys did disclosures on your conference call. So probably we can, I don't think we need to, we'll just let Ann come in and sort of read you the process when she comes but I think we can proceed unless anybody has any new disclosures since the conference call they'd like to -- it's been a whole week.

DR. CHALIAN: Since I wasn't on the call I have a lifetime of disclosures but.

CO-CHAIR MOORHEAD: Well we will settle in and listen.

DR. CHALIAN: Actually I have no disclosures.

DR. BURSTIN: John, I guess you weren't on the call either.

DR. SALTZMAN: No. So what is the disclosure --

DR. BURSTIN: -- and I believe we are starting with measures you're not on anyway, the pediatric ones, so maybe we should just proceed with the pediatric ones for now and we'll get Ann to jump in when she gets here.

MS. MUNTHALI: Okay so do we have AMA here, a representative from AMA? Okay. So would you like to present your measures, the set of measures that you have submitted for the pediatric ENT urgent care?

MS. TIERNEY: Yes, I will defer to the chair of the group, Dr. Rosenfeld.

DR. BURSTIN: Why don't you come to the head so you can have a mic?

DR. ROSENFELD: Are you always ahead of schedule like this? This is rather staggering for any group with the first word national in the title.

CO-CHAIR MOORHEAD: You haven't

worked with Suzanne I guess.

DR. ROSENFELD: Where's the mic? I'm from Brooklyn so I've never been accused of being understated and soft so that's all right. Well thank you for the opportunity to present on behalf of the AMA PCPI the measures that were submitted for otitis externa and otitis media with effusion.

And my name is Rich Rosenfeld, I am a pediatric otolaryngologist who has been involved with a lot of guideline work and performance measure work and I have really enjoyed working with the AMA PCPI and I am delighted that you are considering these measures.

So I was told I have to be brief, five minutes, 10 minutes at most, so we will do that. So the measures that are up today reflect two very common, fairly ubiquitous conditions in kids. One is acute otitis externa, or swimmer's ear, and the other is otitis media with effusion, OME, or fluid in

the ear, both of which have relevance as far as ability to promote appropriate care and more importantly to reduce inappropriate care, overuse and potentially harmful care and in that regard I believe that this measure is the first endorsed by the PCPI that actually deals with inappropriate care and limiting inappropriate and overuse so I understand that's very relevant to this committee now as far as one of your core objectives.

So let me start with swimmer's ear or acute otitis externa, and if any of you have had this, it affects about one in 10 people in your lifetime. You had it, you are smiling, you weren't smiling when you had it, though. It's extremely painful and it's fairly common. It's one of the most common things, infections, that would be seen in an emergency setting or urgent care setting and if you get it, it really, really, really hurts. And unfortunately a lot of times it is mismanaged in urgent settings as well as non-urgent

settings.

The goals here that we see for quality improvement relate to promoting appropriate care and that involves more widespread use of the most effective treatment which are topical preparations and these involved antimicrobials as well as antiseptic preparations like acetic acid and corticosteroid preparations all of which are topical.

There's really very little evidence to say that one is better than the other but all of these preparations are generally highly effective in providing rapid relief. The second opportunity is recognizing how painful this can be and really documenting the pain and providing appropriate analgesics to relieve the pain.

Both of these, we see from some survey data, that roughly about 35 to 40 percent of the time these things are done, so about 60 to 65 percent of the time they are

not done or at least not documented well in typical encounters.

The big opportunity to avoid inappropriate care here is with the systemic antimicrobials. It's almost a reflex action in many, certainly primary care offices and I suspect in certain emergency departments and urgent care settings as well that you show up with otitis externa and you are given amoxicillin or some other oral antibiotic, often in combination with a topical product just to cover all the bases, the problem here being that number one, the oral antibiotics are completely ineffective for the overwhelming majority of otitis externa, which is caused mostly by pseudomononas aerugunosa and to a lesser extent staph aureus, both of which, particularly pseudomonas, escapes the overwhelming number of oral antimicrobials that are given and more importantly the adverse events and adverse effects of systemic antibiotics, both in terms of common things --

rashes, reactions, gastrointestinal effects -- and the societal impact on reduced antimicrobial resistance.

The current data suggest that anywhere between 20 and 40 percent of encounters for swimmer's ear result in an oral antibiotic, sometimes in combination with a topical.

I was going to move on to otitis media with effusion unless there's an opportunity for questions or anything requires clarification about swimmer's ear? Anything unclear on that, or? Okay.

Otitis media with effusion is the second one, which is a little more difficult to get your arms wrapped around than swimmer's ear, which is fairly obvious and easy to diagnose. So otitis media with effusion is basically a build-up of fluid or mucus behind your eardrum. It's somewhat of an occupational hazard of early childhood for those of you who have young kids, especially preschoolers, on

any given day, roughly 10 to 15 percent of them are going to have fluid in their ears, sometimes just from them their lousy eustachian tube that's too short, too floppy, too horizontal and don't work, and sometimes just as a sequela of a common cold or as a hangover after an ear infection.

So it's very common. It's not typically something that gets you to an emergency department in itself, or an urgent care center. But what happens is when you do go to one of these settings for a cold or for a sore throat or for a sinus infection you will often have, particularly children, middle ear effusion or otitis media with effusion accompanying that and this presents an opportunity for inappropriate management of the condition even though the individual is not going there with a chief complaint, oh my child has otitis media with effusion.

The issues here, again, there's opportunities to promote appropriate

treatment, which includes better diagnosis, using things like pneumatic otoscopy and tympanometry to diagnose this and distinguish it from ear infections or acute otitis media as well as hearing testing, which again is not something that is going to happen in an ED setting, but the measure that was put forth by the PCPI deals with documenting a child's hearing before surgical insertion of ventilating tubes, which after hernias in the U.S. is the second most common elective ambulatory procedure done in children, so it's a major, major condition, about 500,000 a year being placed, typically in ambulatory centers which I believe are also the topic of today's discussion.

So there is an opportunity before surgery to document that the child's hearing has been appropriately assessed and the measure requests that it be done six months before surgical placement of ear tubes and that would be very relevant and the ambi

centers would be a good place to really be an entry point to be sure this gets done because it's much more difficult in the physician's office than I think in urgent settings.

So those are the two appropriate areas. The inappropriate use abounds for otitis media with effusion so if you'd like ways to prevent inappropriate care this is a huge one. There's a couple of areas outlined in the measures. The first are antihistamine and decongestant preparations, which we have several Cochrane reviews, randomized trials, all of which are pretty old and all of which consistently say there is zero benefit to treating this condition with antihistamines and decongestants, even though it's nice to say they dry up the fluid. They don't dry up the fluid. They do nothing except cause adverse events and despite that, they are still used rather ubiquitously in primary care and urgent care settings to treat this condition.

The second is systemic antibiotics, which do have a very slight, transient benefit for treating middle ear fluid, otitis media with effusion, a rate difference of roughly about 14 percent, so a number needed to treat of about seven. The problem is about two weeks after you get treated, your body forgets that you had an antibiotic, you've got the same old lousy eustachian tube you had when you started and your fluid comes back, so there's no lasting benefit.

And the last are the systemic steroids, which actually do have a fairly good short-term boost, rate difference of about 30 some odd percent, so a number needed to treat of about three, but again your body has a lousy memory and after you've knocked it out for a week or two with steroids it comes back.

So you've got three things there, the antihistamine decongestants, the antimicrobials, systemic steroids, which are

used still fairly routinely in many practices and emergency settings to treat this despite a complete lack of lasting efficacy and well-documented harm, particularly for the systemic antibiotics and the steroids and even as we know, cases of deaths reported with use of antihistamine and decongestant preparations in kids, generally from improper dosing of the medications.

So that's the summary I have on why these are important and where we think the opportunities are reflected in the measures and certainly happy to address anything that's unclear. Yes?

DR. EISENBERG: I just have a question about the magnitude. I mean I know this is ambulatory but a lot of it is geared toward an emergency or urgent care. This is clearly a primary care, pediatrician, family doctor, med peds office visit kind of thing. Do we have any data looking at quality of care in either of those places in a comparison or

the number of kids or adults even that are treated in each specific realm and whether or not one realm is doing better than any other?

DR. ROSENFELD: You are referring to otitis media with effusion or swimmer's ear?

DR. EISENBERG: Well, actually both. Both are things that you are going to see -- I think acute otitis externa you are probably going to see a little bit more often in an urgent -- that's going to be like, I hurt, I need to come in. But otitis media with effusion that's an appointment kind of based thing oftentimes, it's something that's seen within 24 to 48 hours. You go see your doctor's office. How movable are these measures going to be into that realm and is there a difference in treatment or inappropriate treatment that we are seeing across the board?

DR. ROSENFELD: Understood. I do not have data to give you to answer the

question specifically. I can only give you opinion, which for swimmer's ear I would certainly agree with you, is probably going to be seen more in urgent care settings and emergency departments than the typical pediatrician primary care office. The measure for that, the guideline on which it was based, was developed with input from emergency physicians so I do believe it's relevant and the site of care wouldn't vary depending on that.

For the second one, otitis media with effusion, as you stated, and as I alluded to before, this is not something that you are likely to see as a primary diagnosis coming into either an ED or an urgent care setting. I do think you are likely to see mismanagement of it there on a regular basis, the typical thing being the child who comes in with a cold to an urgent center, or with a sinus infection, and they look and say oh, there's fluid in your ear, oh that's an ear infection,

even though you just have a cold, here's the antibiotic for the ear infection which you really don't have because they've misdiagnosed it, or here's the antihistamine, here's the steroid, whatever.

Those measures to my knowledge were not developed with emergency physicians involved. Again, I think the management would be the same if it was picked up in an ED but it's going to be a secondary diagnosis.

The hearing assessment one would be very relevant to ambulatory surgical centers and that's probably the optimal point of entry to pick up that metric, because it's difficult in pediatrician's offices as well as, to a lesser extent, otolaryngologists, it's not a problem but primary care it's a little difficult.

DR. EISENBERG: Do you see problems with, and again, it's a diagnostic dilemma, because we are going back and looking at data and saying all right, this kid came in with

upper respiratory infection, diagnosed with something other than otitis media with effusion, prescribed antibiotics, steroids, decongestants, whatever, but yet we have no way of really knowing what the true prevalence in that situation was or whether or not they were treated inappropriately. How do we get a better handle on that? I don't have an answer, I'm just --

DR. ROSENFELD: I don't have the answer. If it's documented as they came to the ED with an upper respiratory infection and otitis media with effusion -- and they got an antibiotic or a steroid -- it's clearly inappropriate for both conditions so, but beyond that I don't know. It's clearly a good point. Yes.

DR. BEVERLEY COLLINS: As far as the hearing test goes, I understand, I'm reading through the measure, that the hearing test can pick up any hearing problems that could lead to developmental problems, learning

problems down the road. What is the significance of the six months prior to the tubes being inserted? Why couldn't it be done after the tubes or is there some relevance to the timing of that test?

DR. ROSENFELD: Sure. The timing -- I think the six months itself is somewhat of an arbitrary period that was felt to be adequate to capture appropriate testing in advance of surgery, but the question as to why it would be say, before surgery not after surgery, it's roughly, it would be the equivalent of basically having cataract surgery without knowing your visual acuity before the surgery. You are doing an invasive procedure.

Even though it's a relatively innocuous procedure if done properly, it is an invasive procedure in the ear. It requires general anesthesia most of the time, and you need to really, from a quality perspective, understand the level of hearing before that

procedure, both in terms of prioritizing the need for the procedure -- since the level of hearing will affect that -- as well as determining if there is potentially an underlying hearing problem, in addition to what's going on just from the ear fluid, which could then be determined by testing afterwards and seeing the change.

But I think the fundamental issue is that it's an important aspect of surgical decision-making to know the child's hearing before scheduling a procedure that involves general anesthesia and it's also a question of documenting and knowing the baseline status so you can intelligently interpret a change in hearing after the fluid is removed.

DR. JEFFREY COLLINS: So would the results of the hearing test change the decision for inserting the tubes?

DR. ROSENFELD: It could potentially ahead of time. Certain children, particularly the otherwise healthy child with

no problems, a lot of these kids tolerate fluid in their ears very well, even with a hearing loss, and they can be doing great in school and doing just fine so you might not operate on a child like that, particularly if they have normal hearing.

A child with developmental delays, disabilities, other problems that put them at risk for delays, tolerate middle ear fluid poorly and certainly if they had any degree of hearing loss they would be candidates to be managed much more promptly and that's been addressed in guidelines from the AAP and the AAFP.

DR. JEFFREY COLLINS: Thank you.

DR. ROSENFELD: Okay? Thank you very much.

CO-CHAIR MOORHEAD: Are we ready to move to measure number eight? MS. MUNTHALI: Dr. Moorhead?

CO-CHAIR MOORHEAD: Yes?

MS. MUNTHALI: Ann Hammersmith is

here and so we will turn it over to her to lead the disclosures of interest. MS. HAMMERSMITH: Can you hear me now? Hi, I am Ann Hammersmith, I am NQF's general counsel. Sorry I am late, I was in another meeting. What?

DR. BURSTIN: You were early.

MS. HAMMERSMITH: Here early. All right, sure. Anyway, what we would like to do now is go through our disclosure of interest process. You have already filled out forms where you've disclosed various interests that you have, any consulting relationships, speaking relationships and so on. In the interests of transparency and openness, we'd like you to go around the table and share with your fellow committee members what you disclosed on your form. So you're sitting to my right, so you are our first contestant. Go ahead.

MS. MCCARTNEY: The only thing I have to disclose is I am a member of the American Heart and American Stroke

Association.

MS. HAMMERSMITH: Thank you.

DR. SALTZMAN: I just wanted to clarify, what were the disclosures -- I am new to the committee -- that you required, what, members of organizations?

MS. HAMMERSMITH: You didn't fill it out?

DR. SALTZMAN: I did fill it out but --

MS. HAMMERSMITH: Okay. Okay. I understand. It's a disclosure of interest policy and form. The idea behind it is that we ask you to reveal significant relationships you have.

DR. SALTZMAN: All right. Now I'm recalling.

MS. HAMMERSMITH: Okay.

DR. SALTZMAN: So, I'm the governor for the State of Massachusetts for the American College of Gastroenterology, the president of New England Endoscopy Society,

those were the two.

DR. EISENBERG: I am trying to think of any other societies. I'm an advisory board member, consultant and speaker for GlaxoSmithKline, Novartis and MedImmune, mostly on immunizations, in fact only on immunizations, American Academy of Family Physicians and ex-officio on Families Fighting Flu, I can't of any others that are really important.

MS. HAMMERSMITH: Okay, thank you.

DR. ROBERTS: Catherine Roberts. I don't have any corporate relationships or financial disclosures. I believe our form did ask for committee memberships. I'm certainly, let's see, I'm on the board of the directors for the Association of University Radiologists, I'm on educational committees for the American Roentgen Ray Society, the Radiological Society of North America. I'm a member of the ACR working on national quality improvement metrics at Mayo Clinic. I'm the

chair of patient safety for my institution for the Arizona campus, special interest in radiation safety. I'm the vice-chair of our quality review board on our quality council, I'm an editorial board member of the American Journal of Roentgenology, Radiology Case Reports and Academic Radiology and I do receive book royalties but unrelated to these.

MS. HAMMERSMITH: Okay thank you.

CO-CHAIR MOORHEAD: I am a member of the board of directors of the American Board of Emergency Medicine and the American Board of Medical Specialties and a member of the Quality Improvement Committee of the American College of Emergency Physicians.

CO-CHAIR STONE-GRIFFITH: I am a member of ENA, I chair their crowning committee and co-lead the stakeholder meeting that is trying to do measure harmonization and I'm also the ENA liaison to American College of Emergency Physicians Quality Performance Council.

MS. HAMMERSMITH: Thank you.

DR. JAUCH: Let's see, where to start. So I guess the best way is that through the NIH I have several grants that have corporate co-sponsorship with drug and device and kind and I also serve as a representative to a healthcare planning committee of General Electric, serving in the role of my university on that. I'm with the American Heart Association, I'm the incoming chair for the American Stroke and also serve as our guideline committee's chair and also on the editorial board of Stroke and with SAEM, the Society for Academic Emergency Medicine, I'm on the committee for industry relationships. I think just to be clear I'm not missing anything, I think that's largely it, and I'm also on the board of directors for the Emergency Medicine Foundation.

MS. HAMMERSMITH: Okay, thank you. Could everyone say their name before their disclosure? I think it would be easier for the

court reporter.

DR. JAUCH: That was a joke.

DR. ALTERAS: Tanya Alteras, I'll be quick. No disclosures.

MS. HAMMERSMITH: Thank you.

DR. ADAMS: Hello, I'm Jim Adams from Northwestern University. Aside from sitting on the board of the faculty foundation at Northwestern, I am on the medical advisory board for a company ALung, which is an extra-corporeal oxygen CO2 device that's in human trials. I have grant funding through AHRQ and a private Davy Foundation (phonetic) on communication patient safety, receive royalties from Elsevier for a number of publications, and am on boards or committees for the Society of Academic Emergency Medicine, Association for Academic Chairs of Emergency Medicine and I'm on the editorial board of the journal, Academic Emergency Medicine.

MS. HAMMERSMITH: Thank you.

DR. JEFFREY COLLINS: Jeff Collins from Mass General. I am on the board of directors for the Urgent Care Association of America. I am on the board for the Foundation for Urgent Care Medicine. I am on the editorial board for the Journal of Urgent Care Medicine and I serve on the Primary Care Executive Council for the Mass General.

MS. HAMMERSMITH: Thank you.

DR. NEWMAN: Nathan Newman, I'm the chief medical officer of Solantic. I'm also on the board of directors for the Urgent Care Association of America. I am also on the editorial board for the Urgent Care Journal. I am on the board of directors of Duval County Medical Society in Florida. I am also an active member of the Florida Academy of Family Physicians. I am a delegate of the AAFP and the FAFP.

MS. HAMMERSMITH: Okay. Thank you.

DR. BEVERLEY COLLINS: I am Beverly Collins. I am on the boards of both the

American College of Medical Quality and the Mid-Atlantic Business Group on Health. I am also a member of the Baltimore City Medical Society, MedChi, the state society in Maryland, American College of Preventive Medicine and since I work in an insurance company I am always in contact with vendors that are, you know, promoting pharmaceuticals, medical devices, quality improvement, any number of activities.

MS. HAMMERSMITH: Okay. Thank you.

DR. CHALIAN: I am Ara Chalian. I am on our academy's patient safety and quality steering committee and I'm also on our geriatrics committee and I've served on our academy's guideline committee but not on any guidelines related to the issues we are reviewing today.

MS. HAMMERSMITH: Okay. Thank you.

DR. ALESSANDRINI: I am Evy Alessandrini. I have no significant disclosures.

MS. HAMMERSMITH: Thank you.

DR. COHEN: I am Victor Cohen. I am here on behalf of American Society of Health System Pharmacists. I am also currently the chair of the emergency medicine PRN group for the American College of Clinical Pharmacy. I am also a speaker at times for Sanofi-Adventis and I do receive royalties for my text book in emergency medicine, Safe and Effective Medication Use.

MS. HAMMERSMITH: Thank you.

DR. O'CONNOR: I guess I'm next. I'm Robert O'Connor. My conflicts or interest are through my employment at University of Virginia. I'm on several clinical committees there. I am also one of the associate editors for Prehospital Emergency Care. I am on the board of directors of the Virginia Telehealth Network as well and my final conflict, I'm the immediate past chair of the Emergency Cardiovascular Care Committee for the American Heart Association.

MS. HAMMERSMITH: Okay. Thank you. Anybody in the back that needs to disclose? Oh, okay. All right. All right. Thank you all very much. Is there anything that you want to ask each other about any of these disclosures and anything you want to discuss? No? Okay. Thank you.

DR. BURSTIN: It is extraordinary how many committees you are all on, though.

CO-CHAIR MOORHEAD: Are we as a group comfortable with moving ahead? We are scheduled to have a break before we get into measures. It seems a little early. Are we okay going or what would you like to do? All right. So measure number eight, and Beverly I think you --

DR. BEVERLEY COLLINS: Hopefully this won't take 90 minutes, being the first one, so we can get a break. This is measure number ACP-008-10. It's otitis media with effusion hearing testing, which looks at percentage of patients aged two months through

12 years with a diagnosis of otitis media with effusion who received tympanostomy tube insertion who had a hearing test within six months prior to the tympanostomy tube insertion.

And I will go to the section on importance to measure and report. Do you want me to address each of the sub-criteria and pause for questions or discussion? Is that okay? Okay.

The first section talks about the summary of the evidence of high impact and it addresses 2.2 million diagnosed cases annually in the U.S. and about $4 billion of costs. And it talks about the children between the ages of six months to four years, and I had a concern here because the measure looks at testing children up to age 12 years of age. So, I think, sort of the impact the evidence doesn't really address that segment of what the measure is proposing.

And I had questions about how many

of the children that ended up with a diagnosis of otitis media with effusion actually end up hearing problems which is what this measure is addressing. And of those that do have hearing problems, how many end up with learning and developmental problems which is what this hearing test is supposed to look at the hearing problems that then impact the outcomes which are learning and developmental problems.

So on this sub-criteria the rating I gave was that it partially addressed the question or concern.

CO-CHAIR MOORHEAD: Any questions or comments? Move ahead unless someone has --

DR. BEVERLEY COLLINS: Okay. The opportunity for movement looked at, it said that the otitis media with effusion is often accompanied by hearing loss which can impair early language acquisition and so would the early language acquisition, again the age, the time frame I was looking at, does that talk about younger children or do the children up

to 12, are they also impacted here and that's the outcome that would be impacted.

When we talk about the summary of data demonstrating a performance gap, there was addressing that this measure is used by the PQRI which is a CMS measure set and I looked at that and that measure was retired by them January 1, 2010 and they said it was, I think because very few people reported on that measure and so they advised not moving forward with it again for this year.

Again looking at the gap, I didn't really see how often hearing tests are being performed at this point in time. There was addressing some surveys that were done and a guideline from ARHQ but I don't know if in those guidelines, hearing tests was part of the guideline that was actually questioned or measured. So on that section I gave it a rating of minimally addressed. Any questions?

DR. EISENBERG: Actually, can I, I'm not sure this is the right place to ask

the question but it occurs to me that if we're doing a hearing -- we're trying to link otitis media with effusion to hearing loss but there's other reasons for hearing loss, so a hearing test done six months prior to placement of PE tubes, which is presumably what we are trying to look at, are we identifying other potential causes of hearing loss and their relationship to placing the PE tubes as well? So is it inappropriate treatment for other causes of hearing loss, and is there something in the measure that allows us to determine whether or not that, in fact, is the cause of the hearing loss, and that the treatment is resolving the problem in measuring that outcome later on.

DR. BEVERLEY COLLINS: That was one of the questions that I have in the next section looks at outcome or evidence to support the measure and I think it's linking that process measure with outcomes is what the sort of link is missing, looks like, from what

I see.

DR. ALTERAS: Can I ask, when you did the research looking at how PQRI dropped the measure, was there any indication of why doctors were not using this measure in PQRI?

DR. BEVERLEY COLLINS: No, I just got a simple listing off their website and it says retired from PQI effective January 1, 2010. Analysis of 2007 and 2008 PQI results indicate there was a lack of significant reporting and usage was not considered. Maybe this will come up again in the feasibility, but is there a burden here of going back and checking patient files?

MS. BOSSLEY: Right, well, this, I should probably disclose, my prior job was working for the PCPI. I wasn't a part of the development of these measures but was involved with the PQRI components of it. PQRI mainly is a Medicare population so I think that is why you didn't see a lot of reporting on a pediatric measure and that's why they dropped

it from this system, you know, that reporting system. I believe that's the reason for it.

DR. BEVERLEY COLLINS: I think they expand a lot of their measures to look at all populations because there's a lot of other measures that don't address Medicare population. Any other questions about the opportunities for improvement?

The next section is outcome or evidence to support measure focus, relationship to outcomes. It talked about conductive hearing loss often accompanies otitis media with effusion but again there's no documented frequency, no statistics about how often that happens. They talk about hearing testing with severe cases of otitis media with effusion would lead to early identification and strategies for interventions to improve for developmental outcomes.

Again lack of evidence of the testing the impacts of these outcomes so I

don't really see the relationship to the process and the outcomes.

And I don't know if cost impact factors into this or not, again I didn't see anything addressing what the potential cost would be and how many tests would be performed.

And then the summary of the evidence addresses there's basically limited research that shows that the evidence that children experience greatest conductive hearing loss with the longest periods of time may likely exhibit more developmental and academic sequelae.

The rating of the strength of the evidence was grades B and C, which states that there's randomized control trials or diagnostic studies that have minor limitations. There is overwhelmingly consistent evidence from observational studies, case-control and cohort design.

And the rationale for using the

guideline over others wasn't really addressed in this section as well. It just said that the PCPI is using the guidelines and recommends evidence-based guidelines that are promoted by national specialty organizations or governmental agency. So in this section I also rated basically the outcomes of linking the process to outcome is not being met, not at all.

DR. BURSTIN: It would be useful to summarize the importance to measure and report before you move on because I think you've now done 1 b) and c) to see if, where you are.

DR. BEVERLEY COLLINS: For this whole section I didn't think that the importance to measure the report was not met because there's not a lot of statistical information here about what the importance is and the linking of process to the outcome measures.

CO-CHAIR MOORHEAD: Who was William Blom (phonetic)?

MS. MUNTHALI: William Blom could not be here. He dropped out just yesterday.

DR. BURSTIN: He was the seconder.

CO-CHAIR MOORHEAD: He was the seconder. So we don't have a seconder, then. We're totally dependent on you.

DR. CHALIAN: I have a question and I think Rich can comment on it as well. These are the process guidelines and they are kind of on the, in terms of the proximity to our outcome, these are the ones we were, in the introduction I think Helen was bringing up as where do we want to go with these? And from our perspective in otolaryngology, we still see the process outcomes for certain common disease sites that are treated by multiple specialists as very critical still in terms of minimizing cost and potential risk to the patient by delayed treatments or missing synchronous conditions.

And so I think that I struggled with this in the proposals I'm going to review

as well as you go into items two, three and four, we hit roadblocks but even if you look at outcome, these proposals don't strike on outcome. These are still in their early phases. And so from my perspective they still have validity in terms that they can really affect the kind of treatment the patient gets exposed to and they can definitely have a significant impact on cost and they get to the point where diverse groups of clinicians are treating diseases in the same way, either in the diagnostic step -- which, part of this is the diagnostic phase still -- or in the early treatment step, to minimize follow-up visits or repeat visits.

So part of this is a question, part of this is a comment, because I think this whole cluster of proposals fall into this little box.

DR. ALESSANDRINI: And Helen, I just want to, we talked about this before but I don't know if we talked about it today, is

that you know, it's sort of like the, for lack of a better term, the lowball measures, like we talked, like trying to elevate, you know, the relevance to the patient and I think we might be -- we want to make sure that we are looking at this in the right way.

This is a minimum thing. A child should not be having surgery unless it's indicated, you know, so I think we shouldn't be worried about getting an extra hearing test, I mean the important thing is that they're getting the hearing test and that the surgery is indicated. So I almost feel like we're a little bit, you know, upstream and this is sort of like, one of those lowball measures.

In some ways like Dr. Rosenfeld said, most of these kids do very well, they recuperate from this with very little even short or long term sequelae in that certainly the hearing test is sort of like the minimum thing that should be done before they have

surgery.

DR. ALTERAS: I am sorry if I missed this, but were there statistics in the form that talked about how often hearing tests are done on these patients?

DR. ALESSANDRINI: No there was no evidence of that, nothing documented, just the recommendation is that the hearing test be done within six months of the surgery.

DR. BEVERLEY COLLINS: I think what would help this is if there was more information background, and maybe bring it back and tell us what the incidence of these hearing problems are, the disability, the learning problems and all that, and really showing how many people don't have the hearing test, the follow-through.

DR. ALTERAS: So getting back to what you just said, I mean that's an issue that I mean, I struggle with personally, in always reviewing NQF measures that come through, is what do you do about the measures

that should be standard of care but maybe aren't standard, you know, that in reality are not being practiced. Do we endorse them and hope that they get implemented but then if you start paying doctors for doing, you know, if it gets implemented into a pay-for-performance type program, are we giving doctors bonuses for doing what they should be doing as just standard of practice, and I don't mean to offend anybody here, you know.

So that's, you know, something that I'm wondering about with actually all these otitis, acute otitis measures, and I'm just having a problem figuring out what, yes, like everyone has said so far, what the connection is between the hearing testing and having, you know, the tube surgery. Someone down at the other end of the table mentioned that there are so many other reasons why there could be hearing loss, so I just find this measure a bit confusing.

MS. MUNTHALI: Would anyone from

PCPI like to respond to any of these inquiries?

DR. ROSENFELD: Yes, I will just say a few words. I think that this sums up nicely, you know, as far as, the issue here is that this is extremely common surgery and anecdotal evidence, not hard-core evidence, suggests that a fair number of these kids end up undergoing surgery with general anesthesia without somebody taking the trouble to get a hearing test, which is inappropriate, whether it's 20 percent, 30 percent, 40 percent, I don't know. Nobody has done it and probably if we attempted to do it all the people who don't do it wouldn't admit that they're not doing it.

So I'm not sure we're ever going to get those data. But it is again to me the equivalent of you'd have a cataract surgery or strabismus surgery and do it on someone who never had a visual acuity test. So it is really, it is not so much to show that you are

going to have a better language outcome or that you're looking to improve some outcome. It's saying that the appropriate minimum due diligence has been done in getting a child ready for a surgical procedure. I think that's the best way to look at it.

DR. SALTZMAN: Rich, would it be fair to say that if the audiogram was normal that the child wouldn't have surgery?

DR. ROSENFELD: No, I don't think that's fair to say because there are children who have recurrent episodes of infection of fluid, particularly children who have other problems such as PDD, autism spectrum, perhaps others, are receiving early intervention speech therapy, who at least in observational studies we know do not tolerate middle ear effusion or otitis media very well.

So you wouldn't, it's not an appropriateness measure of the surgery, it's an appropriateness measure of doing the appropriate evaluation and due diligence

before the surgery, is really the issue here.

DR. ALTERAS: Can I just ask you one more question? I'm sorry, I don't have all the details of the measures in my head, but this is specified for children aged two to 12, right? What percentage of children who get this surgery are under the age of two, because I have little kids so I'm sort of obsessed with ear infections and things like that and knock on wood, nobody's really had many, but from what I understand, this is a surgery that happens when kids are sort of under the age of one, very often.

DR. ROSENFELD: I think the median age, at least from a study we had done years ago in the U.S., is around 14 months or so. There are two peaks. There are the very young kids, often infants, who get ear tubes because of frequent infections and there are just too many antibiotics, then there's an older, sort of preschool age group who have this persistent fluid and just aren't functioning

well.

So it's a bi-phasic peak. You can test hearing at any age. In a two-month old you can get -- there aren't many tubes being done in all fairness below six months of age in the U.S. It would be extremely rare. But there are quite a few between six and 12 months, and I would say the peak is probably a little under a year-and-a-half right now in the U.S.

MS. MCCARTNEY: I have a question. Going back to the data, are these formal hearing tests or hearing tests done by physicians in their offices? Because if they are, if there's a formal test and there's a charge, then there would be a way to abstract that data from charge data to see how many are getting the hearing test prior to the surgery. But if they are done in the office, you are right, it would be based on documentation not based on a charge.

DR. ROSENFELD: I believe it refers

to formal hearing testing because below the age of four years, the ability of a primary care clinician or anyone other than a licensed audiologist to really assess hearing in a meaningful way is not valid. So the majority of these kids are under four and in that setting you really need a licensed audiologist to do the testing properly.

CO-CHAIR MOORHEAD: This is obviously a key step because we don't move beyond this point we don't move. So the people that are listening to this, any other --

DR. BEVERLEY COLLINS: My personal recommendation was that it should be taken back and provide more information for us to make a clear decision. I think if really the developmental issues and things you say in the outcomes are not really important, maybe this needs to be rewritten to address preparation for surgery or make an evaluation that way, and then addressing the age recommendations because what you just said is it's really the

younger children but this goes up to age 12 so I honestly don't really see the link here.

CO-CHAIR MOORHEAD: Any other comments?

DR. ALESSANDRINI: I think this is a really tough one because the impact is great, you know, the prevalence is high. If not treated well, language disability is significant from patient-centered perspective. The hard part is I think what we really want, the evidence is lacking, and so you know, but I agree it's hard to move beyond this point because it seems like we're not really getting to what we want. I just don't know that if in 2010 we have the evidence to get really where we want to get. We certainly see a large degree of practice variation but when we look at the evidence it's not great.

CO-CHAIR MOORHEAD: What about the issue of the age?

DR. ALESSANDRINI: You know in my experience, and I spent years creating a

practice pathway at CHOP for this where we used a lot of local, expert consensus because of a lack of evidence and you know, we agreed that children younger than three were all tested with a formal audiologist and a sound booth. Other than that, older than three we were using, in the primary care doctor's office, a screening test. If a child passed the screening then that was considered adequate. If they didn't pass then they went off to an audiologist, although we did have the ability to track that testing in the primary care office based upon our electronic health record. So we were able to track it.

But I do think that there are significant issues with respect to who is at higher risk and those two peaks and not including the younger children but then, also the limitations of hearing testing in that age group. I am not an audiologist by any stretch of the imagination, but there are other opportunities for hearing testing in that age

group.

CO-CHAIR MOORHEAD: Ara.

DR. CHALIAN: It is one of these quality dilemmas and safety dilemmas, where do we need to prove there's a problem or do we sense a gap and do we want to build the bridge so that people don't fall through that gap. And I sense this proposal, respectfully, hearing Bev's idea that we should get better data to help us refine the data we are going to collect, for example if the group can provide where there's missing gaps in who's getting audiograms, who's not getting audiograms, and where the audiograms are being done, that will allow us to end up with a better composite of what we are going to pursue in our outcome measures and our process measures to refine.

Because ultimately this should help us define who gets tubes and who gets other interventions so I think in this way, the platform of setting the expectation that

an audiometric evaluation is done prior to surgery is very important. And I would maybe even go be the gadfly and say the window between the audiogram and the intervention should be much narrower.

And we as people who have developed the guidelines have allowed some wiggle room to allow the guideline to be successful, to allow clinicians to achieve success. As Tanya said, we don't want to pay people for getting it right, but we want to help them get it right. I would actually, on this side of the committee, would say we probably want to narrow that six-month interval to closer to the time of intervention.

CO-CHAIR MOORHEAD: Just to reflect, if we in fact wanted to do that, narrow this time, do we have to send it back?

DR. BURSTIN: Yes, so your options at this point you can approve the measure obviously we've only gotten through the first

criterion so far, but you could approve the measure, you could approve the measure with conditions, you could just ask a series of questions back, table it and re-discuss it if you feel like you can't even move beyond this first importance criterion or you can reject the measure. So it's still really that through the process but I think you have a bit of latitude. I just don't know from the part of, I guess -- are there specific, you know, based on these comments, are these things that you could potentially respond back to, for example addressing the time window, and what we'd like to do is get a list of specific questions so that we could ask PCPI to respond appropriately.

MS. TIERNEY: I guess I would just say that with regards to some of the information that's lacking here, there just wasn't available evidence you know, the information related to gaps is all that was out there in the literature. So we kind of

provided that to give some example of the fact that otitis media isn't being managed properly but it doesn't truly address the actual hearing test issue. And there isn't enough information available right now that would address that. So it was, as Dr. Rosenfeld said, somewhat anecdotal evidence that can apply to development measure.

So while we would certainly be happy, you know, if you, I guess that's a series of questions back, try to address them. I don't know if some of those issues where information is lacking if we can actually provide more. We did a fairly thorough review of the literature and what we have kind of presented for you in the document is what we were able to find.

CO-CHAIR MOORHEAD: What about the time gap issue, six months, and recommendation that that be shortened?

MS. TIERNEY: That's something we could certainly take back to the work group

for consideration.

DR. SALTZMAN: Could I just make a comment about the time issue? I mean I'm looking at the data you presented us here and this says, many episodes resolve spontaneously within three months. So if I do a test and I'm saying a three-month time period, well, in four months, you might have resolution of the problem. So it's a little bit more difficult than I think just saying there's a set time.

And I am still, I mean I agree that looking at don't do the procedure until you have a study, a hearing test done, but how efficacious, and how much relativity of doing that hearing test, or is it a series of tests that are needed? It seems like it's a more difficult, it's not an if a, then b kind of thing. So I'm having a lot of difficulty with the measure based on what's been presented so far, both the time issue and again, an appropriate work-up but does that really mean anything? If I do it within a month and

they've got an effusion, their hearing is decreased, how is that affecting the outcome? If they did it six months earlier, and their hearing was decreased and now it's resolved spontaneously, are we doing an appropriate intervention? So I think there's a lot of questions that are really left unanswered.

CO-CHAIR MOORHEAD: Anyone else? Well I guess this is as much philosophical in terms of approach, because I think there's agreement that the evidence isn't there, and we either want to push this or we don't, so I guess we need a sense of the committee, a vote on the importance issue here in order to move ahead. So Beverly your recommendation is not to move ahead on this one.

DR. BEVERLEY COLLINS: Yes, I think the suggestion to compile a series of questions and feedback to, you know, the sponsor would be appropriate and then maybe bring it back at another time. Is that all right?

CO-CHAIR MOORHEAD: How does that sit with the group? I'm seeing people nod. Do we need a formal vote? I mean I think what we're hearing is --

DR. BURSTIN: Although it might be helpful to just formally go through the questions that we want them to clarify as long as we've got them here.

DR. JEFFREY COLLINS: Right now?

DR. BURSTIN: Sure.

CO-CHAIR MOORHEAD: I think that would be helpful.

DR. BEVERLEY COLLINS: All right, well obviously the six-month time frame, the window is something that we asked about. I have questions about the ages, three months, six months, two months to 12 years. Also if we can get any information on how many children with otitis media with effusion actually end up with hearing problems. That would be important. I think you said that you investigated all the information about gaps

and couldn't find anything else so we don't really know if hearing tests are being done routinely or not. I think that would be an important thing to kind of know if we can get that. I think those are my main questions. Anybody else have any others?

CO-CHAIR MOORHEAD: Do you have anything with regards to the formal versus the, sort of what you --

DR. ALESSANDRINI: Yes, I think there might be some worth commenting on the location of the hearing testing, you know, whether screening in a pediatrician or a primary care office is adequate for decision-making and if that's the case, what would be the age cut-off that would be recommended for that.

CO-CHAIR MOORHEAD: So it can have an impact on the method of -- other questions?

DR. BEVERLEY COLLINS: I did look up the codes that were suggested for the hearing tests. There's actually, you can use

a CPT 2 code which you can document that the test was done but also there's CPT codes for hearing tests, it's under audiologic function test and there's a screening test, so it said in the books, and there's a pure tone audiometry air only and pure tone audiometry air and bone. I'm not an audiologist either so I'm not sure how those --

CO-CHAIR MOORHEAD: Any other questions that anyone else would like to raise? It sounds like there's consensus to send this back with these specific questions. Okay, at this point we wouldn't move ahead with this measure. Do we want comments on the other aspects of the evaluation or do we wait until we -- I mean I would think if you have some other specific questions with regards to the other criteria, I would probably take advantage of the opportunity to send it back if there are specific issues that you've come across.

DR. BEVERLEY COLLINS: Okay again,

just under the specifications, the measure specifications, again this six months, the significance of that, and the age criteria, something else I mentioned. I think the EHR specifications are still under development. I think that would be important to address, if anything has been developed in that area. Under data source they have electronic administrative data, or claims, electronic health and medical record, could be a source of data but again the specs have not been developed for that.

They also mentioned paper medical record, flow sheet and in special or unique data, which I don't know what that meant at all. So that might be clarified. I mean they do say the care setting would be office, clinic or hospital out-patient, so I'm not sure if that's where the testing would be done or not.

Validity testing wasn't really addressed. They just said that there was sort

of an assumption that if the public comment period had passed, because of the specialized expertise of the PCPI work group, it sort of sounded like, it was considered valid, which I didn't think was an objective way looking at the validity of the testing.

Under exclusions, it talked about, actually it brought up the pneumatic otoscopy and tympanometry and this measure is actually for the hearing test so I think they got sort of mixed up in some of the information there. And no real objective evidence on the exclusion assessment as presented.

Comparability of multiple data sources was not addressed. Under usability, again, it only addressed the CMS PQR program but as I mentioned, from what I saw, that that measure had been retired from there so I don't know that anybody else is actually using this measure. Doesn't seem to be. With harmonization --

CO-CHAIR MOORHEAD: Would you like

further information about why the decision was made to drop this measure? I mean we've had some decision maybe it's related or whatever but maybe it would be helpful to know specifically why that decision was made.

DR. BEVERLEY COLLINS: I think it's a good idea.

MS. TIERNEY: Could I just say, Heidi was talking about -- what she said, that's right -- several of the measures are no longer in the PQI program and it's because of the Medicare program and so there were no reports and no way to measure.

CO-CHAIR MOORHEAD: Okay.

DR. BEVERLEY COLLINS: Harmonization measures, that was not addressed. I don't know if there's other similar measures or not. Under feasibility, identifies susceptibility to inaccuracies, errors or unintended consequences of the measure, describe how these potential problems could be audited. I don't think that was

really addressed and that might be something that we could look into. Those were the main points I had.

CO-CHAIR MOORHEAD: Okay. Have we captured those? Yes. OK. Will they be included in the inquiry? All right. Well, we're staying on schedule.

DR. BEVERLEY COLLINS: Less than 90 minutes.

CO-CHAIR MOORHEAD: So any word on what number -- we have completed number eight and we'll move on to number nine.

DR. CHALIAN: That's me.

CO-CHAIR MOORHEAD: All right.

DR. CHALIAN: So this is NQF review number ACP 009-10, ambulatory care out-patient measures. It's acute otitis externa topical therapy, and the brief description is the percentage of patients aged two years and older with a diagnosis of acute otitis externa who are prescribed topical preparations. This is another process improvement measure and

assessment of the process. It did meet the conditions for consideration and I'll go into the area about importance to measure and report.

This is another high-impact condition as Dr. Rosenfeld described. It's a common condition. About one in 10 of us will have acute otitis externa. The statistics that were quoted is 1:100 to 1:250 of the general population will have this experience over the course of a year, which is around 3 million people or 3.5 million people in this country and the topical prescriptions that are currently prescribed are around 7.5 million prescriptions with a cost of $310 million approximately.

And the question here is, does that cost actually capture what's being prescribed for just this condition or some of the other draining ear conditions that go along with kids that get perforations. So some of this data gives you an idea of how

expensive and how costly this type of treatment is, but it actually may be the tip of the iceberg because if the guideline is followed, this cost will probably go up and the cost of oral antibiotics will go down or the prescribing of oral antibiotics will go down.

This is one of those diseases that is treated by many practitioners both in out-patient practices and emergency settings and ambulatory care kind of walk-in clinics. The most common pathogen is one that's in the ear canal skin and it is actually most responsive to topical treatment. And the data that was identified and used to qualify the performance gap showed that mean performance in prescribing topical antibiotics (topical preparations) was around 36 percent.

And Dr. Rosenfeld went over this in his presentation but about 55 percent of the patients in a data set that was from 2000 had received oral antibiotics only and about

40 percent of patients had received oral antibiotics and topical antibiotics (topical preparations) so there's a degree of over-prescribing of oral antibiotics. And the references were both from Pediatric Infectious Disease and from family practice literature. So in terms of this initial part of the importance, I felt that there was complete justification of the importance of this process, improvement and measure.

The evidence for the recommendation shows that the recommended treatment of topical antibiotics (topical preparations) works and it's based on grade B randomized controlled trials and diagnostic studies that are consistent with the observational studies as well. And so the recommendation for the treatment based on the USPSTF system would have been a strong recommendation.

The part of this application that I didn't, I needed some clarity was item 1c.12

and 1c.13. The way I read the data that had been entered there is a little discordance between recommendation and strong recommendation, looking at the proposing steward group's aggregate evidence which was aggregate level b I would have pushed this as a strong recommendation, but either way it's a recommendation.

And then so overall in terms of measure number one, I thought this was a high-volume condition with poor performance in terms of the recommended treatment and potential increased costs and toxicity of the current treatment that is being misused and a lower toxicity, higher potential compliance in terms of giving topical drops versus oral medications with the proposed process improvement. So I felt it met the first item's threshold in terms of importance.

CO-CHAIR MOORHEAD: Jeff, you were the secondary. Do you have any comments about this section?

DR. CHALIAN: And here as I tapped Jeff on the shoulder as I met him I need some help. And part of this is I think our challenge with obtaining data and collecting it. So as we went into the measure specifications, it seems logically clear that we could obtain the numerator, which is --

CO-CHAIR MOORHEAD: Could we just stop for a sec, is there anyone around the table who has any issue with regarding the importance criteria for this measure?

DR. CHALIAN: Sorry.

DR. ALESSANDRINI: I have a question, since it's really relevant to several measures. I mean I suspect that when I look at acute otitis externa, and I think about 20 years of practicing in the ED, you know, I don't really see it that often. I am sure that there are geographic pockets of, you know, places that may see it more than the places that I've practiced and if I look at the national priorities partners, I'm not

really sure where it fits in.

Because particularly this measure, you know, and I'm thinking of the intersection of the four different, you know, dimensions of this, and I actually think it's really not a high-impact aspect of care, granted it is painful, but I'm just struggling as we think about these measures, and if there are 600 measures that are out there, like, how do I know if I'm the medical director which one I want to report?

And should it only be endorsed if it's important and this, I think, it's also goes back to the standard of care. This is a standard of care. Giving somebody ear drops for otitis externa is standard of care. So I am sorry to keep bringing it up, but I'm just sort of struggling as, I'm not really sure it's that important. There's a heck of a lot of things that we do out there in the ambulatory, you know, practice that I think is more important, from variation in care, to

impact on a patient, to coordination of care.

So I think I wanted to bring it up now, because I think it goes across all, there's a lot of these otitis externa measures and on importance, I'm not jumping on board for importance for this one.

DR. CHALIAN: Thanks. Maybe I'll take Andy's comment.

DR. EISENBERG: I am going to comment on that because I am in one of those pockets in south-west Florida.

DR. ALESSANDRINI: You see a lot of it.

DR. EISENBERG: Every day. Every day. And I think it's one in terms of inappropriate treatment, is high priority, because it's often treated with oral antibiotics, which is clearly inappropriate therapy. So from that standpoint even though it may not have a huge impact in terms of people aren't going to die, the other part that might be interesting to look at as well

is gaps, disparity gaps, and who's being treated.

You see some older patients that come in. Are they treated as aggressively? Are the kids treated? Is it just like go take some Tylenol and the kid's wailing, so there are some issues that might come up but particularly from my standpoint it would be the inappropriate use of antibiotics, this is a relatively prevalent one in my community and would be a good measure. As to whether or not someone chooses to report it, that's a totally different issue.

CO-CHAIR MOORHEAD: You can look at Q-tip sales --

DR. CHALIAN: The firm doesn't encourage the use of those by the way.

CO-CHAIR MOORHEAD: Now that would be important.

DR. CHALIAN: I am not John Grisham. I think every point is well taken. And I'm in line with you on the issue of how

far do we go on setting basic treatment guidelines? As a safety officer I'm going to bring the other perspective in, patient advocate perspective. The assumption is when you come to either one of these domains, you will actually get the right treatment and the right diagnosis.

What we have identified actually is a gap. And so how much leverage do we want to give to setting the baseline standard and I feel that we are at a point where if it comes from the academy or it comes from the AMA, that the NQF has an opportunity to weigh in on it, this gives it the ultimate leverage. But as a newcomer I'm still learning so I'm all ears.

DR. NEWMAN: There's all sorts of gaps in background. There are 160 physicians. There are all types of medical educations that I encounter. There are all types of physicians with different experiences, with leaving clinical practice, coming back to clinical

practice, board-certified, non board-certified and I think that every opportunity that we have to focus clinical guidelines and try to teach and to even standardize somewhat, using them as guidelines, helping the individual practitioners is a good opportunity and I think we should go forward with that.

DR. BURSTIN: Just to make a process point, that it might just be useful to go through the sub-criteria rating for a, b and c and do the same as Dr. Collins just to give a greater sense of, you know, they did attempt to quantify some of the impact. Now the National Priorities Partnership is one area that that can be identified as being, obviously that would be highest priority, but also if there's a clear impact. So there is data here on impact. You need to assess whether that's sufficient.

DR. CHALIAN: I would feel there would be more impact data if we could show the cost of oral antibiotics that are prescribed

as well as the cost or the number of out-patient visits, as well as the follow-up visit and the short interval for the patient who's not responding. But these are data sets that I have to say, having served on a guidelines development committee, that we actually don't go into the databases to get, we look to the literature to get, because it requires new epidemiologic or database research. So these are some of the things that frequently are gaps in these couple of proposals.

DR. NEWMAN: Or even making sure that the antibiotics are appropriate, you know, targeted towards the organisms that are likely --

DR. BURSTIN: And the other thing to consider is there is a whole group of otitis externa measures and the question would be, you know, it sounds like you're all in agreement that not doing antibiotics is critical, but I think you sort of need to think of them collectively as a group as well.

DR. JEFFREY COLLINS: I had p, partial, as a measurement for the importance in terms of needing more information. The issue I did have is what we're really trying to get at is inappropriate, oral antibiotic use and what we're actually measuring is the total number of topical prescriptions with a denominator of O.E. you know, and so we're not actually getting at what we're really trying to get at from a measurement standpoint.

DR. ALTERAS: Yes, I mean, could someone be prescribed both, the topical treatment and antibiotics so it doesn't quite get you what you want to know?

DR. CHALIAN: The other part of this, and I think it goes into the exclusions, is this issue of being on both treatments could potentially be a reflection of otitis externa combined with the broader cellulitis and that's discussed loosely in the exclusions by talking about patients with complicated otitis externa but perhaps that could be more

clearly specified.

The question is, can we actually cull that out of the data that is out there and I think actually that's going to be difficult to pull out of the data without going directly into charts, because from the diagnostic code specificity, most people would just use an otitis externa code and using the cellulitis code is probably not going to be that common.

So I will give you my marks detail. Rethinking it, I would actually go with partial for 1a and in terms of 1b I thought there was complete and in terms of 1c, the outcome evidence and support measure focus I thought that was complete and then in summary I thought the threshold for number one was yes.

CO-CHAIR MOORHEAD: Jeff?

DR. JEFFREY COLLINS: Same.

CO-CHAIR MOORHEAD: So are we okay in terms of the importance criteria?

DR. ALESSANDRINI: Yes. I guess the question is, is this a time when we, does this come to a vote? You know, I mean --

DR. BURSTIN: We will finish the, well, we do need to have you vote on each criterion. We could do that at the end or we could do it, I mean, after the presenters present. It's your preference. If you want to just let the presenters go through the four criteria and then go do a vote we will try to get the votes up for you so you can review them but this is the time.

DR. CHALIAN: So moving forward in terms of the numerator, denominator and the measure specifications, it did appear that the guideline was listed on the National Guidelines Clearing House. I agree with Jeff that I would prefer to measure the number of patients getting the oral antibiotics because that's what we are trying to affect and then, but both measures could be incorporated into this and I don't think that's a big challenge.

And then at this point, and partly this may be that I'm a novice --

CO-CHAIR MOORHEAD: Could you just clarify that, both measures?

DR. CHALIAN: In other words, you could measure which patients are receiving only oral antibiotics and I think that would be a much more specific measure of what's going on with these patients, because if we measure the patients receiving topical antibiotics (topical preparations), we actually may be missing the patients who have both treatments offered to them, or prescribed to them.

And since we are really trying to track the outliers and affect that number and show success, I think I would rather see that number be driven down to zero, like the zero tolerance, and see the other number go up to 100 percent and then, that way, you would also not have that overlapping prescription issue to discern.

The denominator exclusions, and I think Andrew's point was a valid one, is the patients who are in for other conditions or other injuries that may require treatments, that somehow has to be factored into here and I didn't sense that that was, so the denominator formulas that were offered, I think, should include some cross-reference to another prescription that could be linked to another condition to rationalize why the patient is on the oral antibiotic.

It was felt that that there was no risk adjustment necessary and I defer to the group. There's this question of patients that are diabetic and they can have uncomplicated otitis externa and my perception is that those patients are sometimes viewed as exclusions and probably get treated with both treatments but we don't have any data to really go off of that. So I guess we would need a statistician's input as to how to get the cleanest information on this.

DR. JEFFREY COLLINS: And for completeness, it's any immuno-deficiency, so it's leukemia, it's people on chronic steroids, it's people with various degrees of immuno-deficiency so for completeness they would want to list all of those.

CO-CHAIR MOORHEAD: Okay.

DR. CHALIAN: What about patients with tympanostomy tubes?

CO-CHAIR MOORHEAD: That's a great question.

DR. CHALIAN: The question was what about patients with tympanostomy tubes, because you will end up with an external otitis picture, not necessarily from swimming, and the recommended treatment is topical antibiotics (topical preparations). Can I ask Dr. Rosenfeld a question?

DR. ROSENFELD: Sure.

DR. CHALIAN: How are we going to handle that? I mean is that something you think would be clouding this picture or would

those be diagnosed as acute otitis drain, you know, with otorrhea.

DR. ROSENFELD: Tympanostomy tube otorrhea? No, that's, I'm an otitis expert, and that is -- otorrhea with a tender tragus and that doesn't occur with tube otorrhea. I think several times the word topical antibiotics were used. I think that the words in the document are really topical preparations, which include antiseptics, so I don't want the word topical antibiotics to be what we're talking about here.

DR. CHALIAN: Correct. So actually for the transcription, if we can, if I use the word topical antibiotics it should be (topical preparations) because of the definition problem. Thank you.

DR. JAUCH: I have one question, being new to this whole process. Does this only look at the first presentation for this condition, or what about treatment failures where you have a progression of a disease or

there appears to be refractory to what we have considered standard of care on multiple visits?

DR. CHALIAN: The guideline is, as I read it, is written for the first presentation.

DR. JEFFREY COLLINS: I just wanted to probe one clinical wrinkle in here, as someone who sees this a lot like down in Florida. A lot of times what happens is you're looking at a goopy ear and so you can't distinguish between an acute otitis with a rupture and otitis externa necessarily. I've never prescribed Floxin Otic because it costs 80 bucks and so all I use is corticosporin. Oflox you can use for a perforate TM if you're not sure of your diagnosis and in that case what ends up happening with a lot of our docs is you do stick them on an oral antibiotic and a topical agent so it's a difficult clinical case sometimes, just to throw it out there.

DR. CHALIAN: And then in terms of

the settings and the data sources, this is all going to be culled from EHRs and paper medical records and flow sheets but there's no experience collecting this data and there's no reference to some small charts or data sets that have been abstracted. In a couple of the upcoming guideline proposals we will see that, and they have shown some success at looking at similar issues in terms of otitis media with effusion and conditions as such.

And then in terms of testing analysis, we don't have any data or references as to how this was validated or any testing of the compliance and the execution of studying this data set. So I thought there is minimal evidence in the proposal to support that at this point.

And then generally, as we go through the remainder of items 2, it's either m or n because of the fact that it hasn't really been trial collected. Jeff, anything you would add to that? Okay. Any questions

about that? Okay. Thank you.

And then in terms of usability, I think this would be valuable in terms of disclosure to the public. It would help people where this work is being done well. We don't have any samples or trials or examples of this data being collected so we don't really know that for sure.

In terms of its relation to other NQF-endorsed measures, there are several on the table today that link into this so there could be harmonization. They all will, the ones I've reviewed, will have similar challenges in terms of domains two, three and four.

Any questions? And then in terms of feasibility, I'm concerned about feasibility overall with these types of common disease measures that are treated in every domain from simple paper chart practices to different complex medical systems that have EHRs and on the other hand I do feel that

because of the systems do have EHRs, that representative data and practice patterns can be discerned, so I think it is feasible.

Will we have a true picture that will help patients and providers and payers and consumers know where to go? Not until we have meaningful use of records and that's going to be a big challenge for this type of data I think.

CO-CHAIR MOORHEAD: So maybe we can back up to the first question which is really the importance and I guess what I heard was is this really the right measure to get at what we're getting at or should we be sending it back with a recommendation that what we really want to see is avoid antibiotic use for patients with -- do you have a comment on that?

DR. CHALIAN: Exactly. And it may be splitting hairs so to speak, but from the perspective of capturing the outliers, which is what we're trying to measure, the proposal

makes the recommendation that you should use topical preparations. The measure would be, who does them? Because that would give us the cleanest data set to analyze and to base our next intervention on, from the perspective where I'm looking.

DR. JEFFREY COLLINS: I do think it's an important measure. It's very costly. We see a lot of kids who come back having been prescribed oral antibiotics with reactions to antibiotics and actually end up in the E.R.'s more than back to the urgent care and there's multiple studies to suggest that so I think it is a very important measure to keep on the table.

DR. BURSTIN: A question about, perhaps when we have finished looking at this whole set, I'd like the group to talk about whether there is some logical pairings or even combinations of measures that might make this a more meaningful measure overall.

DR. ALESSANDRINI: And in terms of

sort of getting at the whole composite measure idea, do you see this as lending itself to a composite measure, like we have a quality of otitis externa, and that you should you know, treat pain, not give oral antibiotics, you know what I mean, like, is that the better way to approach it?

DR. BURSTIN: I mean that's one possibility, essentially when we think about a composite in the framework of NQF, a composite is multiple measures brought together to have a single score.

DR. ALESSANDRINI: Right.

DR. BURSTIN: So that is something they would need to develop and bring back, probably not in this cycle, there's a lot of sort of methodologic work to do there. But you could potentially make the argument that you really only want to see these measures paired. So for example you wouldn't want to just look at somebody's rate of external, you know, the topical preps versus antibiotics, you'd

actually want to be able to see them in concert. Those are additional options as you run through the whole set I think.

DR. ALESSANDRINI: And I think the pain management, like everyone alluded to, is very important.

CO-CHAIR STONE-GRIFFITH: Helen, do we need to vote on each measure? Can we have these measures sort of open and go through them and then come back to them? Is that our option?

DR. BURSTIN: Those are options. We do want to get the committee's scores on yes/no for each of the criteria though for each measure. So any way you want to do it, later or now, whatever's easiest. It might just be easier while it's in your memory to just kind of run through the criteria and overall recommendation, knowing you'll then have enough to think about the recommendation with conditions and whether your conditions might be kind of putting them together.

DR. CHALIAN: I guess, to summarize, in item number one, the importance, the score was a yes. And then in item number two, the testing and analysis -- do you want me to go through 2a, 2b, 2c? Okay.

CO-CHAIR MOORHEAD: Can I just -- what I was hearing you say was what you really want to know are the patients who, okay --

DR. ALESSANDRINI: Not getting oral antibiotics.

CO-CHAIR MOORHEAD: Okay, not getting oral antibiotics. These are the ones that are. All right. Okay. So it'll be. I got it. So go ahead.

DR. CHALIAN: So to 2a. The numerator in 2a would be the patients receiving oral antibiotics and the --

DR. BURSTIN: That is a different measure.

CO-CHAIR MOORHEAD: For this measure, it's --

DR. CHALIAN: Oh, for this measure

it's topical, correct.

DR. BURSTIN: And I'm not sure we need to re-review that I think you kind of gave us that sense, we'll take your scores on this, because the steering committee at least needs to weigh in on the four criteria and vote and make an overall recommendation of approve, approve with conditions or reject or whatever the conditions might be.

DR. CHALIAN: So Helen do you need my yes, nos, for two, three and four or do we have them already?

CO-CHAIR MOORHEAD: Yes. The overall too.

DR. CHALIAN: The overall too? We wanted to change it so it would be no or do you want the CPM score, sorry. I'm unclear.

DR. BURSTIN: CPM would be good.

DR. CHALIAN: The overall for two would be a m.

DR. BURSTIN: Minimally focused.

DR. CHALIAN: Yes. And then for

three, we felt was, I felt was an M. and for four I think it's, I put feasibility as P.

DR. BURSTIN: Overall?

DR. CHALIAN: Overall.

DR. BURSTIN: What's your overall?

DR. CHALIAN: Oh, yes with conditions.

DR. ALESSANDRINI: What does the A stand for? Yes, no, and A.

DR. CHALIAN: Abstain?

DR. BURSTIN: Abstain.

DR. ALESSANDRINI: I couldn't find the definition, what the heck is the A?

CO-CHAIR MOORHEAD: So the specific conditions are, that you would recommend?

DR. CHALIAN: We would recommend the statistical numerator and denominator to be defined differently. Some usability examples in terms of abstracting charts and showing that we can actually obtain this data. And then the feasibility is I think, that's, I don't have a specific recommendation for

feasibility.

DR. BURSTIN: Were there also exclusions?

DR. CHALIAN: There was. The exclusion question of how to handle diabetes and other immuno-compromised states or complex patients. And I would actually, commenting on Jeff's point, the perforated tympanic membrane patient with external, otitis media that is complicated with a draining ear should be an exclusion. And I think that was obvious to the writers but may not be obvious to the general treating group.

CO-CHAIR MOORHEAD: Jeff, any, are you good with those scores?

DR. JEFFREY COLLINS: Yes.

CO-CHAIR MOORHEAD: Okay. So I guess for the committee, are we comfortable with the recommendation and those specific -- the recommendation is yes -- Okay. So we are done with nine. We may come back as part of the overall look at this group of four.

DR. BURSTIN: You actually need a vote, John.

CO-CHAIR MOORHEAD: Pardon me?

DR. BURSTIN: You actually just need a formal vote.

CO-CHAIR MOORHEAD: Oh we do? And we didn't do it on the last one.

DR. BURSTIN: You didn't finish the last one. You tabled it for more information. This one you've run through all four criteria, gotten your info, so yes, let's wrap this one up.

CO-CHAIR MOORHEAD: Thank you.

DR. BURSTIN: You are welcome.

CO-CHAIR MOORHEAD: So a hand vote on the vote of yes is yes on this measure. Those in favor? Opposed? Abstaining? Are you opposed or abstaining?

DR. ALESSANDRINI: I was opposed.

DR. BURSTIN: And it was recommended with conditions, right, that was -- and I wasn't sure those were clear

recommendations. Those sounded like tweaks you might want to the measure but the conditions were going to be, what would the developer come back with that would make you say yes, so if those were macro issues then --

DR. ALTERAS: Right, so we are not voting yes to recommend for endorsement without those conditions being met, right?

DR. BURSTIN: Correct, so that's exactly what those conditions are.

DR. CHALIAN: You think the conditions need more clarity, Helen?

CO-CHAIR MOORHEAD: Well, what I heard him say was really not conditions, but recommendations in terms of tweaking. Is that correct?

DR. CHALIAN: Yes. You know, I have a question actually, more it's a process question. Fire back.

DR. BURSTIN: This is really the first measure that's 90 minutes. Feel good about this.

DR. CHALIAN: Is it really 90 minutes? No wonder I'm getting hot. Strike that. So the data collection aspects of this, are other proposals more robust, are they more vetted out? When I look at this as a novice to this group I look at question number one and I don't really see the strength in going down to question g and h because a lot of these have no data.

DR. BURSTIN: Right. These measures are completely untested, so they would only go through as time limited, but that's your decision to make. Are you comfortable that they go through while they're being tested?

DR. CHALIAN: So it's reasonable.

DR. BURSTIN: It's reasonable for a time limited measure. That's your decision to make. But it sounds to me like there are some specific conditions where there are clarifying exclusions, if I was going to state that, and I guess the question would be, it still seems, I'm curious to hear, it might just be helpful

to have Jim and Evy give their sense of why they voted no or maybe there are conditions there that would perhaps explain the --

DR. ADAMS: Yes, sorry.

DR. BURSTIN: We'll have mics moved during the break.

DR. ADAMS: So my issue with this is, first I find it very disturbing if people are treating acute otitis media with just PO antibiotics, I just am disturbed about that. I do find, while it's a minor condition and not life-threatening, something that's absolutely useful to solve and have a measure around, I would be okay with that. But what I am also a little uncomfortable with is that it speaks only narrowly to the problem that we would have to have the exclusions of co-existing acute otitis media, exclusion of co-existing perforated membrane, exclusion of co-existing suspicion of malignant otitis, exclusion of co-existing complicating or cellulitis-like condition, especially you know

if there's a cochlear implant or other complicating medical conditions. So I think that that's just not clear.

The second part would be, in the treatment of acute otitis media, one of the things that I was just uncertain about, is how important is debridement and replacement of wicks in addition to the topical antibiotics. There seems to be varying opinions about that and is just the oral therapies sufficient? I'm sorry, topical treatments sufficient without debridement, without wicks, without anything else. I would be very happy to have a measure that just guides simple of simple, uncomplicated otitis media to make sure that the topical treatments are used if there is such a variation because that should be a real softball. But it would really have to be vetted out for my taste.

And then I would be also hesitant to start to build tons of measures on the soft issues because I don't think that that gets to

where we really need to go. So with those caveats, I would have shifted my vote to yes.

DR. JEFFREY COLLINS: In defense to the AMA there is a pretty specific passage here in section 2c related to exclusions.

MS. TIERNEY: I don't know if this is the perfect timing for me to speak or not, but if I could add, we have an extraneous analogy where we don't actually specify or provide an exhaustive list of possible reasons why a patient might be excluded from a measure. We just provide three broad categories, medical, patient or system as was determined appropriate by the records. In this case I think it's just a medical reason. I'm not sure, it might be a patient too.

So we would look for the physician to document in the medical record the patient was prescribed topical therapy because of some of the reasons that you mentioned and then, in auditing you could go back to the medical record to determine that there was actually a

valid reason why the patient couldn't get the topical therapy but we wouldn't ever provide an exhaustive list, so -- mostly for the reason that we probably wouldn't capture everything, that would be something else. So that's kind of our overall methodology.

So in all the measures that are from the AMA you won't see anything very exhaustive. We do include examples occasionally, just to kind of jog people's memory, but I don't know if that helps.

DR. CHALIAN: It does. And my fear of that approach, and I understand -- I think you did a good job with this by the way -- it just helps us clarify our kind of debate, but that forces the doctor to document against the measure to justify an action, which I just am philosophically -- you know, it then makes it harder for the doctor rather than just in the natural flow of events for something that's such a simple case.

DR. ALESSANDRINI: I think it just

also, the issue is that that's really good for improvement at the local level, to understand your decision-making processes, but there's a significant concern when you are public reporting, because it's opening up a big wide gap to game the system. And so unfortunately if you're going to be reporting these things publicly and benchmarking and comparing yourself against someone else, then you know, then I think we need to be more stringent about that. And that was one my comments about these measures. It's a little too loosey goosy for my opinion for public reporting.

And I think the other reason that I voted now was because I had the opportunity to review another otitis externa measure, that I thought that the definition of the measure and the validity and the reliability was better and so maybe I shouldn't have, but that's why I voted no as well.

DR. BURSTIN: So we can we just redo that count of hands, just so we have it

for the record.

CO-CHAIR MOORHEAD: Well, we could either redo it or we could go through the next, and then maybe come back and I think that might be helpful. There's two pools at this point but we're going to come back and kind of redo that once we've had the presentation of the next two, if that's okay. It's 12:15, let's forge ahead here a little bit before lunch if that's okay with folks and we'll go to number 10 and Jeff, I think that's yours.

DR. JEFFREY COLLINS: So I am the primary reviewer for measure ACP-010-10, title is acute otitis externa pain assessment. This is the percentage of patient visits for those patients aged two years and older with a diagnosis of acute otitis externa with an assessment for auricular or peri-auricular pain and this is a process measure.

It did pass the conditions for consideration by the NQF. In terms of number

one, importance, as was discussed before, this is a common infection with an incidence between 1:100 to 1:250 and a lifetime incidence of approximately 10 percent. Costs the U.S. approximately $310 million a year. The indirect costs of acute otitis externa haven't been calculated but are believed to be significant.

The mean performance measure was listed as approximately 34 percent so basically 66 percent of people aren't having pain addressed during a visit. Pain relief would be considered a major goal in the management of acute otitis externa. The frequent use of analgesics is often necessary to permit patients to achieve comfort, rest and resume normal activities.

In terms of relationship to outcomes, there was only one study reference from the British Medical Journal, suggesting that it's disabling enough to cause 36 percent of patients to interrupt their daily

activities for a median of four days and 21 percent requiring bed rest.

So I think from an importance standpoint, one would have to say that this is significant. Any question about importance?

CO-CHAIR MOORHEAD: Tanya. You are the seconder.

DR. ALTERAS: I was, but I apologize, I didn't receive the materials on Friday and so I have not had a chance to really look at them so you're on your own. Sorry about that.

DR. JEFFREY COLLINS: The one suggestion I did have in this section is that oftentimes based on JACO and other standards that healthcare facilities have, pain is sometimes considered a vital sign, it's sometimes assessed in triage, it's assessed as a general matter of activity so to all of a sudden say for this specific condition, we are considering a pain assessment, is something we'll have to talk about as a group after. So

I gave the evidence a partial for importance.

CO-CHAIR MOORHEAD: Okay.

DR. JEFFREY COLLINS: In terms of scientific acceptability, the numerator was going to be patient visits with assessment for auricular or peri-auricular pain with the denominator being all patient visits for those patients aged two years and older with a diagnosis of acute otitis externa and I thought based on level of importance that's an adequate measure.

In terms of usability, it's currently in use --

CO-CHAIR MOORHEAD: Could you just give us your scores --

DR. JEFFREY COLLINS: You want me to go to everything?

CO-CHAIR MOORHEAD: Just so we have those.

DR. JEFFREY COLLINS: Yes.

CO-CHAIR MOORHEAD: 2a.

DR. JEFFREY COLLINS: So for 2a I

had complete. In terms of reliability I had complete.

CO-CHAIR MOORHEAD: So 2b is complete.

DR. JEFFREY COLLINS: Yes. 2c, complete. And exclusion justification 2d, complete, and risk adjustment for outcomes, 2e, complete, and again that's based on just numerator and denominator.

DR. BURSTIN: You are right, denominator is one part of it, but there's no reliability in testing so all those subsequent 2s would be, you know, minimally or none.

DR. JEFFREY COLLINS: Right. Yes, yes. Usability again and feasibility would fall into that same category as minimal or --.

CO-CHAIR MOORHEAD: Okay. So the overall recommendation?

DR. JEFFREY COLLINS: From my standpoint I think it's very useful and if there was a composite measure where you wanted to put this stuff together and measure pain I

think that's one thing, but given all the pain standards that already exist in the field, I think there's a little bit of redundancy.

CO-CHAIR MOORHEAD: Comments or questions from the rest of the group? Anyone?

DR. CHALIAN: I have a question, I mean, if one of these data sets is out on the PQRI website then how does the formulating steward group get any of the data fed back to them, or do they?

DR. BURSTIN: Right because the measure is in use but yet we have no scientific acceptability, we have no report on what's actually happening to inform this committee.

CO-CHAIR MOORHEAD: I think that is part of our decision-making is, are we comfortable with that, knowing the testing will occur in 12 months, or are we not?

DR. ALESSANDRINI: Yes, I think everybody already knows how I feel about this now, but I think that, you know, I think that

ultimately the impact is low enough that the testing, I think we should be able to expect it a higher level of preparedness.

CO-CHAIR MOORHEAD: Well the recommendation is no from Jeff and I'm seeing some support of others.

CO-CHAIR STONE-GRIFFITH: Is this a no with recommendations as part of a, consideration as part of a composite or just no?

DR. JEFFREY COLLINS: I will defer to the group if they want to consider it as part of a composite or just say no outright.

DR. BURSTIN: So just to clarify, the issue is that you just don't think it's a stand-alone measure.

DR. JEFFREY COLLINS: A stand-alone, no.

DR. BURSTIN: Okay. Got it.

CO-CHAIR MOORHEAD: So why don't we just run the formal vote on that right now? Let's go through the last one and then we'll

come back to these three. So if we can go to number 11.

DR. ALESSANDRINI: I believe that is mine.

CO-CHAIR MOORHEAD: Yes.

DR. ALESSANDRINI: Okay. So, measure ACP-011-10 is titled acute otitis externa, systemic antimicrobial therapy, avoidance of inappropriate use and the brief description of this measure is the percentage of patients aged two years and older with a diagnosis of acute otitis externa who are not prescribed systemic antimicrobial therapy.

This is a process measure which is hitting a priority area of overuse and conditions for consideration by the NQF staff have been met. Because of let's see, so from an importance standpoint in terms of demonstrated high impact aspect of healthcare for 1a I gave that an M. I will tell you what I gave the measures and then I'll give you a summary. For 1b I gave that a P for partial

and that's demonstrating performance gaps and data on performance gaps because if you can see here, in the data it looks like there's, you know, variation in terms of using oral antibiotics for otitis media externa which ranges as high as 90 percent in their, 90th percentile of users.

Outcomes or evidence to support the measure focus, 1c, I gave that a P. So in terms of the summary for importance to measure and report, not a particularly high-impact diagnosis from a frequency or severity perspective, at least 10 times less common than otitis media with effusion.

It's important obviously to provide effective care and eliminate harm to the population but eliminating ways based on oral antibiotic overuse is probably the most important part. Evidence is good for lack of treatment with systemic antibiotics, it was a grade B recommendation, but as with other reviewers in some of these other measures,

diagnostic certainty does remain an issue and I had actually quoted also the age group for acute otitis media with ruptured tympanic membrane can be confused.

Variation in quality of care appears to exist based upon this measure specification sheet but it does conflict with the data submitted for measure ACP-032-10 and that measure demonstrates compliance and obviously a different set of nearly 85 percent of cases not getting systemic antibiotic treatment so I mean I think in the grand scheme of things, was the threshold criterion for importance to measure and report met, I would have to say yes. I'm a little schizophrenic.

CO-CHAIR MOORHEAD: Nathan, you're the secondary?

DR. ALESSANDRINI: In terms of scientific acceptability of the measure properties, I think that the information here again remains quite limited in terms of the

numerator statement and details and the denominator statement and details so for 2a, for specs, I gave this an M.

Let's see, again, no risk adjustment necessary as a process measure, a little bit of data provided on data source here and we go down to, and then nothing on reliability testing, nothing on validity testing, so I gave those Ns. Exclusions justified, here there's some fair documentation about the exclusions in 2d one, again talking about diabetes, HIV, immune deficiencies and a local cellulitis. So for 2d I gave that a P.

Risk adjustment, not needed, identification of meaningful differences in performance based upon the earlier information, gave that a P. Comparability of multiple data sources 2g is an N. Disparities has not been tested or reported at this point in time.

So overall I gave that an M, that

section 2, scientific acceptability an M.

CO-CHAIR MOORHEAD: Nathan?

DR. NEWMAN: I am in agreement.

CO-CHAIR MOORHEAD: Thank you.

DR. ALESSANDRINI: Usability. So again that's another measure that's reported to be currently in use however we have no data on how the measure is being used. A project is under way called cost savings from avoidance of inappropriate use, an application of AOE and OME, but no data so again that's an N for 3a. Harmonization, there needs to be harmonization with the multiple measures submitted by this group but it's not commented on in the specs sheet here, so that would be an N and distinctive or additive value for 3c, I gave that an M. There's nothing commented on here, but I do think thinking about the totality of the acute otitis externa measures, this one is probably one of the more important ones.

So the total score for section 3

is an M, like Mary. And then feasibility, this is really a tough one again. It seems like a lot of the data could be generated during the typical care processes, but we don't have complete documentation of that so I gave all of these an M except for 4e which I gave an N and overall for four I gave an M.

CO-CHAIR MOORHEAD: Nathan has been nodding down there, you would agree?

DR. NEWMAN: Yes.

CO-CHAIR MOORHEAD: So the overall?

DR. ALESSANDRINI: This is a tough one for me. So I think overall we could recommend this for a time-limited endorsement.

CO-CHAIR MOORHEAD: Nathan?

DR. ALESSANDRINI: And I guess I should just clarify that with the next measure, 32, which I think has a higher rating and so I guess, would we not recommend this one if we recommended that one, it would be important to hear the second measure to be able to make an informed decision since these

are competing.

DR. CHALIAN: I have a question. What makes this stronger than the other one?

DR. ALESSANDRINI: Stronger than the -- I think the other one is more standard of care and this one is really addressing overuse in a better fashion, with subsequent cost and patient ramifications from the overuse of oral antibiotics.

CO-CHAIR MOORHEAD: Nathan any comment?

DR. NEWMAN: I would have probably, you rated it, I would have probably rated it as a little bit higher and, because I feel like there is benefit to gain and probably overall would have put it as a P.

CO-CHAIR MOORHEAD: A P for which section?

DR. NEWMAN: I'm sorry, would have put it as a P for --

CO-CHAIR MOORHEAD: Section four?

DR. NEWMAN: Yes, for section four.

CO-CHAIR MOORHEAD: Okay. And --

DR. NEWMAN: But overall as a yes.

CO-CHAIR MOORHEAD: Okay. Jeffrey, you had a comment?

DR. JEFFREY COLLINS: I just had a clinical question about the denominator. The definition of chronic otitis or chronic otitis externa is basically an otitis externa lasting more than four weeks or four episodes over the course of a year and so I'm wondering how the clinician identifies each episode of OEE within a 12-month period as being a unique event versus saying that this is chronic, you know, otitis externa and something we may need another treatment option for.

DR. ALESSANDRINI: If I remember correctly I think that, sorry I'm getting them mixed up because there's two of them, is this the one that has, one of them has a 60-day window for the episode, is that this one? That's the other one. Yes. But I think this one has like two days subsequent. Let me go

back to the -- 30 day. So each episode of acute otitis externa, an episode of acute otitis externa, an episode is defined as a 30-day period from the onset as the first qualifying diagnosis in CPT codes.

So I guess if it falls outside multiple encounters during that third day episode it would be considered a no. You are right, there's not really a wash-out period or any type of period where there's no encounters for a certain period of time.

CO-CHAIR MOORHEAD: Any other questions or comments?

DR. CHALIAN: I have a question.

CO-CHAIR MOORHEAD: Yes.

DR. CHALIAN: It's a question of semantics. When you read these titles, you go to the NQF website and you say acute otitis externa, topical therapy and you read this one, which was acute otitis externa, systemic antimicrobial therapy, avoidance of inappropriate use. The question I am bringing

up is, what's the best way to change behavior and capture the clinician's mindset so they actually go down the right path. And maybe that's what we should discuss as we compile the composite concept, because is our goal to set a standard or a guideline immediately recognize, which requires rapid processing, or is our goal to do something else.

And my immediate quick answer is, my goal is to make it easy for the clinician and the family, consumer, to see what the goal is, what the standard is, and a lot of our proposals are actually phrased in a negative way. They are not in the active process, taking us forward, being advocacy oriented kind of proposals. So I put it on the table as something we should consider in our feedback to the stewards as well.

CO-CHAIR MOORHEAD: Okay. Other comments -- so this specific one, the consensus is yes. We are going to go back in a minute, but I'm seeing a consensus of yes.

So I'm just trying to get us through ones that are -- those are the four AMA ones. We can consider 32 if we want because it's pretty similar and then go back and look at the first five and we are getting towards lunchtime so I just want to make sure I'm okay with the group in doing that.

DR. BURSTIN: The food is right through that door.

CO-CHAIR MOORHEAD: Any sense from the group?

DR. ALESSANDRINI: I can do 32 pretty quickly because it really is essentially this --

CO-CHAIR MOORHEAD: Why don't we do 32, then we'll get our lunch, then we'll come back and talk about these as a group if that's okay. Okay?

DR. ALESSANDRINI: 32 is ACP-032-10 and the title of this one is a little bit different: Patients two years of age and older with acute otitis externa who were not

prescribed systemic antimicrobial therapy. The description is the same, two years and older with acute otitis externa who were not prescribed systemic antimicrobial therapy. Again a process measure focused on overuse and so, in reality, if we looked going back down at the importance to measure and report -- let me give you the numbers -- 1a is an M, this is the same as the last one 1b is an M, 1c is a P and you know, overall, the threshold criterion for importance is met.

Again the difference between the first measure and the second measure, the information remains the same you know, grade B, evidence, recommendation, here is the variation in quality of care that's reported in this particular measure specification sheet denotes that there's compliance with nearly 85 percent of cases so that's where the difference comes in in the two reports.

I'll stop there, if anybody has any comments about the importance, and who was

--

DR. CHALIAN: I would put the importance as P, as higher, overall, and you listed it as M, is that correct?

DR. ALESSANDRINI: Yes, I gave P to evidence, outcome or evidence.

DR. CHALIAN: Right, I agree.

DR. ALESSANDRINI: But I gave M for this one on performance gap because this is the one where 85 percent of people are complying with the measure. Should I keep going?

CO-CHAIR MOORHEAD: Nathan, are we okay?

DR. NEWMAN: Again, I gave it a P but --

CO-CHAIR MOORHEAD: Okay. Yes. We have got agreement that this is a yes in terms of importance.

DR. NEWMAN: Yes.

DR. ALESSANDRINI: For the importance, yes. The measure specifications,

this document is like 450-some pages long so they obviously gave every single inclusion and exclusion criteria possible for the inclusion and exclusion criteria so I gave that a P. Come on over here and I'll show you, sorry because I've got to try to get to the page where my next piece of information is. Sometimes it gets a little bit crazy to try to get. There we are. Page 425. Sorry got to go backwards from the bottom. Okay, let's see, sorry about that guys. Almost there.

MS. BOSSLEY: Try page 416 and 415.

DR. ALESSANDRINI: Thank you. That's where, I just hit it. So process measure without risk adjustment necessary, let me see if I can find 2b, reliability testing, so they have used three databases and have done a good deal of reliability testing. There are -- there's good detail on the analytic methods, and testing results so I gave 2b a C. I gave 2c a P. And 2d a C. And 2e a not-applicable. And 2f a P.

Comparability of multiple data sources is not commented upon here and nor are disparities in care. So overall, for scientific acceptability I gave it a P. The issue here is that, this is a measure using medications, this was associated with the highest error rates of all the testing that they did, 11 percent error rate, which unfortunately was based on a small sample of charts. So that's why I gave it a P instead of a C. That's all I have to say about scientific acceptability.

CO-CHAIR MOORHEAD: Nathan?

DR. NEWMAN: Yes, I agree.

CO-CHAIR MOORHEAD: Okay.

DR. ALESSANDRINI: From the usability perspective, in terms of meaningful, understandable and usable, useful information, I gave 3a a P and 3b, no comments on harmonization, no comments on distinctive or additive value and so despite the experience collecting the data and if the

measure is currently used we don't really have very much usability data that was reported to us from this measure steward. So I gave it an M. And that was for usability.

CO-CHAIR MOORHEAD: Nathan?

DR. NEWMAN: P.

CO-CHAIR MOORHEAD: P?

DR. NEWMAN: Yes, I think it's, it was easy to understand the results of the measure and I felt like most people would likely find a use for the medical systems.

CO-CHAIR MOORHEAD: Okay.

CO-CHAIR STONE-GRIFFITH: Now this is a proprietary steward, or it said that earlier, so if this were to be used for public reporting, how would we get the data in the public space? Are they going to have to do testing? Obviously they've done some testing in their internal system. But how would that be used outside?

DR. BURSTIN: Ingenix is actually here so they are certainly welcome to make

comments. They have signed the measure steward agreement so this measure will go in the public space is my understanding. This is not one of their proprietary, like, groupers and things like that, this is, so if this measure is NQF-endorsed, it'll be fully available, all the specs will be available.

CO-CHAIR MOORHEAD: Okay.

DR. ALESSANDRINI: Shall I go on to feasibility? And so for all the feasibility scores for 4a I gave it a C, 4b a C, 4c a C and 4d a P and 4e an M. But overall a recommendation for the feasibility I gave it a P.

CO-CHAIR MOORHEAD: Nathan? Okay. And then an overall?

DR. ALESSANDRINI: And my overall recommendation was for endorsement. Yes, for endorsement.

CO-CHAIR MOORHEAD: Nathan?

DR. NEWMAN: Yes.

CO-CHAIR MOORHEAD: Okay. Any other

comments or questions?

DR. ALTERAS: Can I ask you a question. It's not about the measure specifically, but I'm just wondering, is there any concern that having a measure like this -- and I'm all for overuse measures, that's one of the big things that we are advocating for -- is there just any concern that perhaps in cases where antibiotics are warranted, that they wouldn't be prescribed out of concern that a doctor would be dinged for doing it and --

DR. ALESSANDRINI: I think you bring up a really good question and I think that's like a lot of, as I talk about, we talk about these measures and thinking about the AMA measures with there's less of a strict exclusion criteria to really hone in on the denominator, and then at that point in time maybe you say, well, if I can you know, eliminate these antibiotics in 90 percent of cases that's good enough because the other 10

percent of them probably need them.

But in this particular kind of case I think that the exclusion criteria are so well defined that I feel like who's really included in the measure, it really seems to be fairly specific that those patients who have that uncomplicated, acute otitis externa, really feel like they shouldn't be getting systemic antibiotics.

CO-CHAIR MOORHEAD: Okay, so consensus is yes? All right. Do we have food?

DR. BURSTIN: Yes.

CO-CHAIR MOORHEAD: Okay. Food is next door, I guess you can take a break and get some food.

DR. BURSTIN: Just a clarification, if there's anybody on the phone, we'll grab people to comment when we get back.

CO-CHAIR MOORHEAD: Is anybody on the phone?

(Whereupon, the meeting was in lunch recess from 12:47 p.m. until 1:23 p.m.)

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

CO-CHAIR MOORHEAD: So we will wait for Helen but our idea is to go back over these last four and to give some thought into if our job is to promote the patient getting the appropriate care, is there some kind of combination that we'd like to see move forward.

So if that can be in the back of your mind we'll get going in just a couple of minutes here.

DR. ALESSANDRINI: We didn't necessarily agree, or we did not vote yes on all of them, is that correct?

CO-CHAIR MOORHEAD: I am going to review that before we go, I'm just going to wait for Helen. Thanks. Now that Helen is here we can begin. So what I have is our first measure was number eight and we voted to send that back with some specific recommendations. Number nine we voted a yes. Number 10 a no. Number 11 a yes. Number 32 a yes. So I think

what we'd like to do now, those are all the external otitis externa measures, but do we want to put any of the, do we want to put these together in some way that reflects what we thing is appropriate? Ara.

DR. CHALIAN: Maybe we could have a composite.

CO-CHAIR MOORHEAD: A composite. So if you're going to look at -- are people getting appropriate topical, do you also want to look at the same time that they're not getting oral, or whatever it comes --

DR. BURSTIN: Just to clarify, it probably is not something they could come back with a composite in this cycle. There's a fair amount of methodologic work in putting those measures together. One question we might be, we do have a fair number of measures that come in that are paired, that at least you'd say, looking at this one in isolation doesn't make sense. If we're going to look at these measures, look at them together. That I think

would be, in this cycle of measuring, probably the one --

CO-CHAIR MOORHEAD: So it would be a recommendation from the committee to look at --

DR. BURSTIN: So you want to talk about this, yes.

MS. BOSSLEY: Sure. How it would work would be it would be endorsed as a pair. The pair can be more than, you know, two or more.

CO-CHAIR MOORHEAD: Yes.

MS. BOSSLEY: And then they would be used together, so they'd be endorsed as a group or a bundle.

CO-CHAIR MOORHEAD: Okay.

MS. BOSSLEY: And that anyone who implemented one, should also implement the other ones as well and you'd have a separate report, you know, scores.

CO-CHAIR MOORHEAD: So we sort of took a consensus on what I, or at least what

I have was a yes on nine, no on 10, yes on 11, and 32. That's open again if anybody wants to change that and then any recommendations of what we would be pairing I guess would be the right word.

DR. ALESSANDRINI: So I think a nice recommendation would be, based upon reviewing 11 and 32, that we choose 32 because of the stronger measure specification and the scientific acceptability of the measures as well as its usability and feasibility testing. Perhaps taking Ara's comment that it actually may be nice to have that affirmative, positive title to it and perhaps use the title, something more similar to the title from 11, where it's, you know, avoiding systemic antimicrobial therapy in acute otitis externa or something, you know, more positive, and telling -- correct. Right. And if we --

CO-CHAIR MOORHEAD: How much discretion do we have in terms of --

DR. BURSTIN: Again, you would

recommend with conditions. It'll be up to the developer to go back to their work group, vet it and bring it back to you.

DR. ALESSANDRINI: Now I guess that's a tricky thing, now that I think about it, because 9, 10 and 11 are all AMA measures and then 32 is not but it would almost be nice to put together as a pair, you know, best practice therapy for acute otitis externa that you are, you know, treating pain, you're using topical therapy and avoiding antimicrobial therapy. So it would be nice to have those three together, it's just that in lieu of 11, I think we should do 32.

DR. BURSTIN: You do have some potential options. I guess the question would be, the scores were slightly higher for 32 over 11, broadly, so your option would be to say you could endorse 32, recommend endorsement of 32 as a stand-alone measure, which I think, it's a claims-based measure, it's a very different kind of measure, easy to

access. Then I think you are left with thinking about a recommendation back to PCPI about 9, 10 and 11.

And I think because the measures are -- I think you want the exclusions to be done in a similar way, so I think actually the same measure developer should put together those similar, that package, and perhaps that's the broader package of appropriate care for otitis externa. That's one possible way to think about it.

DR. ALESSANDRINI: And then I guess I would just ask the committee, given the lack of definitive denominator exclusion criteria, how does that make people feel about moving forward with 9 and 10? Ten I'm less worried about with the pain assessment thing, but with nine.

DR. CHALIAN: Nine actually has some exclusion and I maybe minimized it in terms of, but it's definitely in there and it's fairly detailed. The question I had after

Jim's comments was whether we need to go into more detail about the local debridement issue and wicks, and my impression is that not everybody that treats otitis externa actually feels comfortable debriding an ear and the wick issue.

So I think that kind of super-specific, a little bit more specialized recommendation is, makes it a harder guideline to implement.

DR. ADAMS: I think that's very reasonable, and somehow it would be nice, just, if it reflected, just some basic, appropriate guidelines, rather than some kind of comprehensive guideline for the management. But I think even at the simplest level, it would be useful.

CO-CHAIR MOORHEAD: Other thoughts?

DR. EISENBERG: Well, I'm not as concerned with the, I think what's going to happen when you extract the data, for anybody that's being prescribed antibiotics, the onus

is, why you prescribed them, or why you have done an intervention, and that's easy enough to find when you're looking back at the data, so I'm not as concerned that we're going to be having to have this exhaustive list of why somebody would be excluded.

Because I think it's going to be, I mean I gave antibiotics because, of local cellulitis, because of diabetes, because of whatever. I don't know, I mean I just don't see that as much of an issue.

DR. ALESSANDRINI: That is not easy to find out. That's a real issue in trying to understand what the, you know, especially in any type of a systematic fashion, to understand if you're making the right choice.

DR. BURSTIN: Currently all the PCPI measures come in with these general exclusion categories of medical systems and as they're all being reformatted to EHRs I think a lot of this is going to shift. This is a measure I think would very quickly, likely get

on the list for retooling if it's not already, in terms of retooling for EHRs, in which some of that specificity is easier to get at. But this is the general format of most of the measures.

DR. ALESSANDRINI: Right and it may be worthwhile to see if, again, my conflict is coming through in a sense, see if Sam has any information on what we found, they found through testing in the past, on those broader exclusions and bring that back and share that with all of you. That would be helpful.

DR. ADAMS: I think it's fair to say that if the diagnosis is simple and uncomplicated otitis externa, that this applies and if there should be another diagnosis or something broader, if there's concomitant otitis media, if there's some complication, if there's malignant otitis, that should be in the diagnosis. So I think it should be driven by the diagnosis itself in this measure. I think we should be okay.

DR. JEFFREY COLLINS: Is it redundant to say we're going to have a measure to say that we're using topical agents properly, we're not using oral, and then have another measure saying we're not using orals properly.

DR. ALESSANDRINI: Right. Right.

DR. JEFFREY COLLINS: You know, and having all those measures instead of just selecting --

DR. ALESSANDRINI: Right that's why I think we should just select the one.

DR. JEFFREY COLLINS: Right.

DR. BURSTIN: The only times I hear of we will bring two measures forward on a similar topic if they're harmonized and I think a question for you is the fact that they're on different data platforms and so there may very well be people out there who would actually prefer a measure that's purely off of claims and there may be others who want to really build this into their clinical

system. So I think a different data source is an opportunity for us that we could bring in two measures, but I think the issue is we have to feel comfortable that those two measures are in fact harmonized and I think they are, there's just perhaps not greater specificity in the exclusions around --

DR. ALESSANDRINI: I think they are as well.

CO-CHAIR MOORHEAD: So I am hearing -- the proposal is a combination. The specific issue is around 11 and 32 and your preference you know would be to use 32.

DR. ALESSANDRINI: Yes, I think my initial recommendation had been to use 32 in terms of getting at the avoiding systemic antimicrobial therapy for acute otitis externa. I guess what I'm hearing Helen say is that if 11 and 32 are harmonized, then potentially there could be, you know, a paired measure that includes any of 9, 10 and 11 and then 32 could stand on its own.

DR. JEFFREY COLLINS: Does this Ingenix provider database, does that limit us in some way? I mean who is in that database? Is that just a claims data? Is it --

MS. RIEHLE: It is all commercial, it's patient, it is limited to some patients but it is geographically diverse. It's all over the country.

DR. BURSTIN: So anybody could pick up this fax and run it in any system you have. It's not limited. The Ingenix database is just the way they have tested the measure.

MS. RIEHLE: Correct. Yes. That's correct.

DR. CHALIAN: So I am Mr. New Provider, I came from St. Somewhere and I read ACP-32. It says don't use oral antibiotics. Do I know what to use? Or I am Tanya. I am a mother. Just walked off the street, I go to the thing, it says don't use it, but does it help me? Is this more like a critique or is this more to guide and --

DR. ALTERAS: All right, I'll play the mother role.

DR. CHALIAN: Sorry, Tanya.

DR. ALTERAS: No, that's fine, I like playing that role. I would hope, and I am speaking, in my consumer advocate job, that this would spur a conversation between the new mother and the provider, and the provider says I'm not prescribing antibiotics even though you read online and all your mommy friends told you I should give them to you, this is why I'm not going to and educate the patient who's the child and the consumer who's the mother, and get the conversation started on overuse of antibiotics. I mean I feel like this is a perfect opportunity for that type of conversation to happen.

And those conversations, you know, they're not happening yet, and you know, over big issues, is how to get consumers to buy into the fact that there is huge overuse of you know, procedures, antibiotics and other

treatments and you know this is where I think a measure like this could really be helpful, other than the actual clinical aspect of it.

DR. CHALIAN: And then, just the devil's advocate, what's the root cause of people running for oral antibiotics, is it the patient's family, is it the patient, or is it the physician and physician-like providers that are writing for it? And who are we?

CO-CHAIR MOORHEAD: It's probably all of the above. I think part of it is, as Nathan was saying this morning, it could be here that you want to cover everything you've got.

DR. NEWMAN: I agree with Tanya, we wanted to promote communication through all users, but especially at the core, with the doctor-patient, or a patient's mother or a patient's family. I think that's the key.

DR. EISENBERG: I think we've had success with acute otitis media overuse too, watchful waiting and conversations that are

starting to take place with, you know, call me back, and I guess you might be able to do it, where you have follow-up in some ERs, who knows, so you might be more prone to treating, but I mean, I think from the consumer standpoint and from the physician's standpoint I think a lot of this is more uncertainty, I'm not going to see him again and I don't know what's going to happen, let me just do it.

DR. NEWMAN: It is a process. It is a process, because I get a lot of patients going to the emergency department saying, you know, I had to take my child, my six-year-old, because of this ear infection, the ER clearly would diagnose, give him an immediate antibiotic and why couldn't you have done that, or the same for pharyngitis and we try to arm our clinicians with enough information to help them make the case for not prescribing antibiotics, but nonetheless it's a process. We are certainly better than where we were 10 years ago but we have a long way to go.

DR. CHALIAN: So Mike, I think what I would say is the potential consideration for recommendation is for the specific guideline recommendation it says do not use systemic antibiotics. It should have a colon, you should use topical preparations. Or is the supposition that --

CO-CHAIR MOORHEAD: The problem is that we are talking about this as a stand-alone. If it were part of a three combination then it would be okay. It's looking at it as a stand-alone.

DR. EISENBERG: But that also argues for putting, letting the AMA group the three of theirs and have that, even though we're saying we like 32 better than 11, kind of having 11 as part of that composite score, with here's the appropriate treatment, here's the inappropriate treatment, here's the guidelines and the other one strictly like you said, from a data abstraction standpoint, I think it's meaningful data. How many people

got oral antibiotics?

DR. BURSTIN: I think they're quite complementary actually.

CO-CHAIR STONE-GRIFFITH: Helen can I ask you to make a point of clarification on the harmonization, because 11 and 32 is clearly, we like 32 because of the specificity, but we want 32 and 11 to be harmonized. And we want them to be grouped because that then gives us the ability to guide treatment, right? So if we were to say we like 32 better but we want 11 and 32 to be harmonized, does that then put responsibility back to AMA to harmonize 11 to complement or to be equivalent to 32?

DR. BURSTIN: It is not how much of that could actually happen just given the way the exclusions are done for the PCPI measures. They are not doing, they don't do specific exclusions in that way. So --

CO-CHAIR STONE-GRIFFITH: But that could be a recommendation?

DR. BURSTIN: But unlikely I think to be, they won't, Sam do you want to respond? I don't want to answer for you.

MS. TIERNEY: In general we do have this methodology of having the three broad categories. We'll ask for examples for effects on health to guide decision-making and to explain the rationale behind the decisions but we really do stick with those three kind of broad categories.

And Heidi brought up something earlier. We did do a study and I can't speak to it that well but I can certainly provide some more information --

DR. BURSTIN: Could you speak louder Sam or get closer to the mic?

MS. TIERNEY: Oh sure, sure. Related to, we did a study on practice sites for our heart failure and safety measures to actually examine the way that exclusions were used and we found that they were for the most part, the three broad categories were used

appropriately and that there was no kind of gaming of the system.

Because I know that is a lot of times a concern that we hear, by having the three broad categories, that you are just kind of leaving yourself open to that.

But in the study that we did in these five practice sites we found that that wasn't an issue. But I could provide more additional information. That was kind of just a quick and dirty of that.

DR. BURSTIN: And if nothing else I think, you know, if there are questions about the science you know, in terms of the actual measure itself, those I think would be a very reasonable recommendation that you should ask that those get harmonized if they're slightly different categories of age or risks or whatever the case may be. That would be an appropriate recommendation back to Ingenix and PCPI to try to harmonize, that you're not giving out strangely different messages that

say, do this, I want to measure, do this on another measure, and you know, I think potentially those could co-exist in that way. And the question would be would you even want number 11 to be a stand-alone or do you really want each of those only to be used in that broader context in which case the only stand-alone would be potentially 32 as an option.

CO-CHAIR MOORHEAD: Well and even then, I have a certain amount of discomfort with 32 just as a stand-alone. It could be the only one that a group would want to report on. And that doesn't really tell much of a story.

DR. BURSTIN: It tells the overuse story. It's very analogous to the other NCQA, for example we have NCQA measures that say not using antibiotics for an upper respiratory infection, not using antibiotics adults with bronchitis. I mean this is a classic overuse measure, getting at sort of least identifying what is inappropriate care. It may not give you the full picture of appropriate care but

again, it's that side of the picture that's potentially inappropriate care.

DR. EISENBERG: This might be a little bit of an aside but how much of that has really influenced behaviors? I mean do we know that by somebody does this, they do their measurement, is it changing behaviors? Is it more of a system problem, is it an individual provider problem, and if we're going to do that, don't we want to have some methodology or, that's probably beyond what we do, how do you do this right? Or how do we influence behaviors, and if so, what's the best methodology of doing that?

DR. BURSTIN: That is a really interesting philosophical question you guys can discuss over dinner. I am not going to give you -- I don't think there's a pat answer to that other than saying we are actually about to launch a contract to help us understand the impact of NQF-endorsed measures, does it make a difference out there.

But I think, you know, I was going to, you know, guess what's going to happen with process measures over the years. They're going to get built into clinical decision support and probably as a measurement tool fall to the wayside to more of a focus on outcomes. But again it's kind of crystal ball and don't really know yet.

CO-CHAIR MOORHEAD: So I am hearing some consensus that a composite measure including 9, 10 and 11 with some specific recommendations and a yes on 32 as a stand-alone. Is that agreeable to the group?

DR. BURSTIN: Just one clarification, a paired measure rather than a composite. A composite would require them to put it together into a single score. You could make a recommendation potentially that you would like them to work towards that.

CO-CHAIR MOORHEAD: I think paired is what we were --

DR. BURSTIN: Yes, good.

CO-CHAIR MOORHEAD: -- more accurately discussing.

DR. JEFFREY COLLINS: I thought it was nine and 11 and leaving 10 out.

DR. BURSTIN: That is your decision.

DR. JEFFREY COLLINS: Oh, okay.

CO-CHAIR MOORHEAD: Well, we had said 10 we didn't want as a stand-alone and then I thought I heard that as a pairing that it would be included, so what's your thought?

DR. JEFFREY COLLINS: I think we assess pain in so many different ways in all these different outpatient and inpatient settings that it's just redundant to track it without individual disease condition.

CO-CHAIR MOORHEAD: Even as a pairing with --

DR. JEFFREY COLLINS: Yes, but I do like the pairing of the other two.

CO-CHAIR MOORHEAD: Okay. Anyone else?

DR. O'CONNOR: Yes, I just thought, kind of a sort of a loose end because it doesn't require any action so I agree with what was just said. In other words, you can assess the pain but there's no treatment that's linked to it, so I'd argue for dropping it.

DR. EISENBERG: We have another measure, time to pain medication for long bone fracture, which isn't quite the same thing, but there's huge disparities in treatment for pain based on racial, ethnic, age and other considerations and I don't know if this is the appropriate mechanism to do that but I think if they were going to pair it, the pain component needs to be part of it not necessarily as a stand-alone. So I'm in favor of it as a paired process not to be left by the wayside but I would agree it's a difficult thing to measure. I think it's just a statement that I addressed it or told them to take Motrin or I mean some kind of

intervention was at least noted.

CO-CHAIR MOORHEAD: Okay. Anyone else? Well, I am hearing unanimity in including 9 and 11 as a pairing. And I'm hearing consensus on 32 and so I guess the vote is, is 10 part of the pairing with nine and 11. Are there any other comments before we vote?

DR. ALESSANDRINI: I would just say that I think it really makes the package complete if there were a treatment component of the pain but in the absence of doing something about the pain I think we're fine without it.

DR. JEFFREY COLLINS: A lot of institutions already have pain management guidelines in place so at our institution, one of the problems is who's actually assessing the pain, is this the triage nurse, is this the physician, is this somebody else in the process. But also what's the scale that you're using and so there's issues around that. And

then what we do is if somebody scales anything in the visit five or above, it has to be addressed in the discharge and so there's probably other institutions that do similar things so there may be some redundancy.

CO-CHAIR MOORHEAD: Okay. Those in favor of including 10 in the pairing with nine and 11. Hands up.

DR. BURSTIN: As is.

CO-CHAIR MOORHEAD: As is. Well that's clear. Those against including 10. Okay. So we have voted on a pairing with nine and 11 and there's agreement on 32 as a stand-alone. Is that correct? And we have some feedback. All right. Good work. Good discussion. We move to number 12.

DR. NEWMAN: That's me.

CO-CHAIR MOORHEAD: That's Nathan.

DR. NEWMAN: And what we are doing is we are measuring otitis media with effusion, OME, with antihistamines and decongestants to avoid the inappropriate use

of both of these types of medication. We are looking at patients between the ages of two months and 12 years with the diagnosis of OME that were not prescribed or recommended to receive either antihistamines or decongestants. It is a process-type measure and its focus is overuse.

As a background, certainly for the importance to measure and report, it's a high impact entity. There's over two million cases of OME annually, over 90 percent of kids have OME at some time before school age. There is certainly opportunity for improvement because the benefits that were hoped by the use of this measure revolves around the fact that OME usually resolves spontaneously and the indications for therapy are only if the condition is persistent and clinically significant and there's no data that exists to support antihistamines or decongestants in treating OME. As a result physicians really should not prescribe or recommend the over-

the-counter use of these medications, or prescribe use of these medications.

The use of antihistamines and decongestants will not lead to clinical resolution of OME and the measure aims to minimize the use of ineffective use of medication. The summary of evidence, that there's no data to support antihistamine/decongestant combinations in treating OME. There are well-known adverse affects of antihistamines and decongestants and therefore 1a under the high impact I listed C. 1b also C. 1c also C. And then overall I said yes to the threshold for importance to measure and report.

CO-CHAIR MOORHEAD: Ara?

DR. CHALIAN: I agree.

CO-CHAIR MOORHEAD: Okay. Anyone else? Okay. Nathan.

DR. NEWMAN: You know I'd also like to mention that I appreciate the opportunity to participate here and also my newness with

the forms and the guidelines. I did want to mention that before I started. Also, going further for 2, and we have the numerator and the denominator.

The numerator was patients not prescribed antihistamines or decongestants and of course the denominator, all patients two months to 12 years with OME I think are very straightforward and therefore I gave 2a a C.

MS. MCCARTNEY: Can I ask a general question?

DR. NEWMAN: Yes.

MS. MCCARTNEY: I have noticed in the measures that the numerators, when there's an age specification in the denominator it's not in the numerator. So this says all patients aged two months in the denominator but the numerator just says patients who were not prescribed. It doesn't give that age definition as well as in the measures I reviewed, if there's an age caveat it's not expressed in the numerator. To be consistent

don't we need those in the numerators? So if you're looking at a denominator of patients --

MS. BOSSLEY: I mean, some developers do include it in the denominator. Some don't. I think it's more a philosophy of how they describe it. Your description percentage of, should always include that. I think, you'll see variation across developers and whether they include that or not because I think you start with your pot of patients so it's already there in your denominator, no need to repeat it in the numerator. It varies across --

MS. MCCARTNEY: I just want it to be clear to people that are actually collecting this data that you know, that they're making sure they're collecting the right data.

MS. BOSSLEY. Sure, yes.

DR. EISENBERG: I have a question about measure. How do you measure patients who were not prescribed or recommended something? I mean seems like a very nebulous, you know,

to get the ones that weren't prescribed, I mean. And the other part of that is recommended. I mean oftentimes that is not included in, oh you know what you can go take so and so, and that's not necessarily going to be in the medical record. So it seems like it's a very nebulous figure.

DR. NEWMAN: Especially when you're dealing with some over-the-counter medication.

DR. EISENBERG: Go ahead and tried this but it's never documented and it's. I think it's more positive, you know, looking at it the other way and making the smaller number, the number who were prescribed, at least you can measure that. The recommended part is very difficult.

DR. NEWMAN: Well I think then again you're looking at the negative side, you know, are you reinforcing the negative side of what you're trying to accomplish and I personally like the positive side where, you know, you can track. I mean eventually we don't have the

processes in place yet. I mean, you know, it's very cumbersome to be going through handwritten charts certainly. But if as a physician, if you make those recommendations you should document it. I mean to me when you're looking in studies and you're trying to review care, then you have to assume that if it was there then it was done and if it's not there then it wasn't done and that falls out.

MS. TIERNEY: So have in our measurement applications we do have a CPT2 code that would be required to document this measure and just to kind of the point about the negative or the positive, that was a discussion that we had a lot at the work group meeting and I think that the general consensus was that some of this information is already being documented but documenting that you did not prescribe it kind of, sends a stronger statement and that was what they felt, the work group kind of generally felt, was sending a stronger message about the inappropriate use

of those medications.

With that said we have other overuse measures that are done the opposite way, you know with the positive statement and then aiming for a lower score but I think that the general consensus in the work group was that it was a stronger statement to say not, to use the negative statement. I don't know if that helps or not.

DR. NEWMAN: Didn't hear.

DR. BURSTIN: Sorry I was just saying that I know recently there was a FDA recommendation specifically not to use these in children at least so it's also I would think a safety issue but again I think the over-the-counter issue is going to be complicated to capture.

DR. NEWMAN: And you know again, with the criterion being not to prescribe antihistamine and decongestants, it felt like it was redundant to mention that. And the AAP and AAFP and FDA recent headlines, never use

less than two and then it's no recommended in older children, you know, four to six years old and less.

DR. ALTERAS: Can I just say one thing? You know I think we are starting sort of this new era of looking at inappropriate use and overuse measures and so while it might feel a little strange to measure the negative it's sort of like this new world that we have to start getting more comfortable with if we're going to really get to overuse measures that are effective.

CO-CHAIR MOORHEAD: At the end of the day we are all going to vote to make a recommendation whether you should or shouldn't use decongestants -- Suzanne, you had a --

CO-CHAIR STONE-GRIFFITH: I just wonder about the denominator and the episodes. We had a conversation several measures ago about a thirty-day window, the issue of 12 consecutive months. Are we comfortable with the episodes?

DR. NEWMAN: Which is defined as the 90-day period --

CO-CHAIR STONE-GRIFFITH: Right.

DR. NEWMAN: From the onset with effusion of OME, which of course is the first occurrence.

CO-CHAIR STONE-GRIFFITH: During the 12 consecutive months.

DR. NEWMAN: Right. What are your thoughts about that? I'm fine with that. Anybody else?

DR. CHALIAN: So in theory somebody could have three episodes and the denominator would go by, you know, and I think actually that's probably a good thing to capture in fact ideally you would want to capture patients that have had more than one episode and see if there's a refractory kind of drift towards changing your guidance, compliance with the guideline, which a database harvest would allow you to do.

DR. ALESSANDRINI: Yes I guess you'd

have to then, so it seems to me that the unit of analysis here is not a patient, it's an episode of OME, so in order to get at that you would have to stratify by number of episodes per patient or something, you don't need to say let's look and see if there are a certain number of patients that had two or more episodes and does your anti-histamine decongestant use go up with that, right, but the only way you would otherwise get it is to stratify, right? Because otherwise the unit of analysis looks to be an episode.

DR. CHALIAN: But actually it's conflicting. It would need to be clarified. It looks like it states patients would be the denominator, but then the time window would allow each patient to be considered more than once.

DR. ALESSANDRINI: Right.

CO-CHAIR STONE-GRIFFITH: And shouldn't we be consistent on that?

CO-CHAIR MOORHEAD: Yes. What did we

say this morning?

DR. NEWMAN: But wouldn't that negate that patient from being included in the study, or be removed, if they didn't fit that exact criteria?

DR. CHALIAN: Maybe looking for clarity -- it seems if 2a.7 implies if somebody had more than one episode, that each episode would count.

DR. ALESSANDRINI: In the denominator, right.

DR. CHALIAN: And in actuality I think our goal here is to look at episodes and breakdown of the recommendation as opposed to stratifying and altering our treatment based on somebody who's had multiple episodes over the course of a year. So we want to keep it simple.

DR. ALESSANDRINI: There's still no evidence whether it's the second time or the first.

DR. CHALIAN: Right. If we wanted to

keep it more simple and get more helpful, comprehensive data I would say each episode would be allowed to count and our measure is clinician behavior. We are not actually looking at an outcome on this, so --

CO-CHAIR MOORHEAD: So are we good with that?

DR. NEWMAN: I had felt like that that rating would be completely covered. However given new information we can make that partially covered, a P. This would be 2a. Reliability testing, it's interesting, and again I didn't get this document, it says in 2b.1 that a document was attached describing a study completed using the national colonoscopy data repository. I didn't receive that. I'm not sure how critical it was, did everybody else receive that written here?

DR. CHALIAN: There were pictures.

CO-CHAIR MOORHEAD: Ara, can you fill us in on the relationship there?

DR. CHALIAN: Well, there's a

deductive reductive process going on here.

DR. ALESSANDRINI: It's the oto-colic reflex.

DR. CHALIAN: Yes, it's the oto-colic reflex, my colleague to the right, I cede my minutes to the colleague to the right.

DR. NEWMAN: With reliability testing, you know, the measures are repeatable and they do produce the same results and a high proportion of the time when assessed, and the same population, same time period, I had given it a C however, with the definition being changed maybe we ought to change that to a P.

Validity testing, the exclusions, there are some exclusions with allergic rhinitis and associated diagnoses. I had given that also a P. The exclusions being justified, the PCPI-supported considerations of exceptions on a measure-by-measure basis, the exceptions, while the exceptions were removed from the denominator when calculating

performance rates of exceptions should be reported alongside performance rates. I didn't fully agree with that and I gave that also a P but I could be convinced to go to an M.

The rest of the two there wasn't much data and I gave 2e an M, 2f an M, 2g, 2h and I did note that the PCPI and the NCQA were developing a framework to stratify the measures and test for disparities in 2h but overall, you know, I did feel like that the measure as specified did produce consistent, reliable and credible valid results about the quality of care when it's implemented and would have given that a C however with the change in the statistical review and the denominator I would have changed that to a P.

DR. CHALIAN: The only comment I would add, I thought it was helpful in 2b that there was the work ongoing at the Cincinnati Children's Hospital assessing these charts and it should provide some valuable input into how robust the data is that can be obtained. In

terms of the validity testing, I thought that contributed also to the validity testing, and then in terms of the meaningful differences in performance, it seems like this should be black and white, you either are on or you are off. So I thought that was least a P or potentially a C depending on how it was defined. So I thought this, I agree with Nate, it is heading in the right direction.

DR. NEWMAN: Let's go with a P with that, the 2f, if that's agreeable. It's a good point. For usability the testing is not yet completed currently however I did feel like it was meaningful, I did feel it was understandable and useful. I gave that a C. Harmonization, I do feel like antihistamines and decongestants are not, should not be used in patients with OME except for the exclusions, and I think that can be harmonized with other measures and I also gave that a C.

Competing measures, I also gave that a C and overall with the intended

audience to be able to understand the results of the measure and are likely to find it useful, I gave for usability a C.

And then with four, with the issues with EHR not being uniform and data collection, standardized data collection being challenged I gave four Ms, which is only the limitation of EHR and the documentation that we currently use and therefore for feasibility I also rated that, I gave that an M. Ara?

DR. CHALIAN: I think the hardest part of this was touched on earlier, is how do you capture if there's not excellent documentation because we can't go to a prescription database but this may be one where its mere presence is good but if we actually harmonize this with the antibiotic use then it has more power because then we can go to prescriptions so this one I felt lent itself to harmonization as well or pairing, pairing sorry I used the wrong word.

DR. NEWMAN: And then overall the

recommendation was that we do recommend it for endorsement.

CO-CHAIR MOORHEAD: All right. Other comments, questions?

DR. COHEN: How would this be captured in charts in reference to whether it has some use to the physician or recommended and then my statement is wouldn't it be better to have a physician document, proactively counsel the patient against antihistamine use and that would it make clear, evident and the documentation is required perhaps by -- so again I was just recommending that physician, or clinicians proactively counsel a patient against the use of antihistamines as a method of capturing, that they made that proactive measure to avoid inappropriate use of the antihistamines as opposed to did not recommend antihistamines as a commentary that they may not put in the chart.

CO-CHAIR MOORHEAD: I think the answer to your first question I guess we can

ask our friends from AMA but it would have to be a specific extraction, that there was a statement and that you were not using it and I think that was the intent. And the second part is, is that correct?

MS. TIERNEY: Yes, I think that we originally had it as a counseling measure but I think we felt for feasibility reasons that it was better to change it. But we did recommend that they can be obtained over-the-counter so that's why we have the prescribed or recommended to receive language.

DR. ROSENFELD: Yes, if I could add to that too, the CPT2 code that they came up with says that you did not prescribe or recommend antihistamines, decongestants, it was a big debate about it because they are over-the-counter, people can get them, this counseling was wishy-washy so the CPT2 code is designed to really document that it was clearly stated don't get it and I'm not prescribing it.

CO-CHAIR MOORHEAD: All right so the recommendation is to recommend number 12? People comfortable with that? Heads are nodding. Okay. Move to number 13. Evy?

DR. ALESSANDRINI: Okay this is measure 13. This is otitis media with effusion, systemic corticosteroids, avoidance of inappropriate use and the description of the measure is percentage of patients aged two months through 12 years with a diagnosis of OME who are not prescribed systemic corticosteroids. This is a process measure and another overuse measure.

With respect to the importance, really just to reiterate, not to reiterate, as Nathan said, affects large numbers of kids, about 90 percent of kids by the time they hit school have had an episode of OME. I think that 1a the summary of evidence of high impact gets a C. Opportunity for improvement, there is some data to suggest that there are variations in practice here, perhaps not as

strong as the use of antibiotics in OME but that there is data on gaps. I gave that a P, that's 1b got a P. Outcome or evidence to support the measure focus gets a C. There's clearly grade A data demonstrating that corticosteroids do not work in otitis media with effusion in the long run.

And let's see, so overall in terms of meeting the threshold criterion for importance would be a yes. A high prevalence condition in which historically there's wide variation in practice and overuse, strong evidence, and guidelines that have been promoted and endorsed by multiple professional societies.

CO-CHAIR MOORHEAD: Okay any questions?

DR. ALESSANDRINI: Okay. Scientific acceptability, our numerator statement again would be similar to the decongestant antihistamine, patients who are not prescribed systemic corticosteroids, our denominator

statement again is the same, the episode of OME occurring within a 12-month time period. The CPT and the ICD codes are listed and EHR specifications are under development so as a result of that I gave 2a a P. Let's see.

CO-CHAIR STONE-GRIFFITH: So are you recommending the same change that we made to the other one, episodes versus patients?

DR. ALESSANDRINI: Right, we should be consistent I think, across these. They also are likely to be nice for pairing. Testing and analysis, again, is being initiated with the Quinn Project although no data is available. Certainly the potential to assess feasibility and reliability exists so I gave 2b as a P.

Validity testing, same rationale, 2c is a P. And exclusions justified, this is similar to the other PCPI measures and I gave that a P. Risk adjustment is not applicable for this process measure. We don't have any identification of meaningful differences in performance listed under this section so I

gave it an N as well as comparability of multiple data sources I gave 2g an N because nothing is reported.

Disparities in care, a framework is being developed so I gave that an M. And overall in terms of the scientific acceptability I gave it a P.

Okay. Usability, I think this is again something, the testing isn't completed, but it's sensible I think, it's actionable, and gave 3a a P. 3b at this point in time we didn't talk about any harmonization so I gave that an N/A. And I think it's the same thing with competing and distinctive for additive value, we haven't really discussed that at this point in time. And so overall, recommendation for the usability is a P.

Feasibility I gave a P as well. In most circumstances it should be, some of these may at this point in time require some chart review but a lot of it could be a by-product of care processes in terms of diagnoses and

treatment recommendations particularly since corticosteroids systemically would need to be prescribed.

And so I gave a P to 4a, b and c and d and e. And overall, for feasibility gave a P. One of the things that we haven't really talked about but would be relevant to this cadre of measures is that sometimes diagnosis coding for OME is not very good but I guess we could live with that right now.

And so my overall recommendation was yes for a time-limited endorsement.

CO-CHAIR MOORHEAD: Comments or questions? Everyone comfortable with a yes recommendation? We will come back to the pairing issue later.

DR. ADAMS: Is there a, since this is don't give, is there a CPT for this as well?

DR. ALESSANDRINI: Yes.

DR. ADAMS: Okay.

DR. CHALIAN: I have a question. Do

the stewards have to prove or demonstrate they have already shown facility in harvesting the data from prescription databases or is that an assumption that's easy to do? It's a question of information more for me.

DR. BURSTIN: Since it's mainly based on a CPT2 code I'm not sure it's directly, they're not really harvesting --

DR. CHALIAN: Okay.

MS. BOSSLEY: Right it would depend on what data source you're looking at so EHRs may be one way you'd be looking at some type of NDC coding and I think they're specified for that. Otherwise it's a category two code.

DR. CHALIAN: Okay. Thank you.

CO-CHAIR MOORHEAD: Okay. Number 14. Okay, that's a good idea, I'm sorry. Can we just, let's go to 15 and Ara can do that and we'll come back to 14.

DR. CHALIAN: Number ACP-015-10. Otitis media with effusion, systemic antimicrobials, avoidance of inappropriate

use, the percentage of patients aged two months to 12 years with a diagnosis of OME who are not prescribed systemic antimicrobials. It's an overuse issue. It's in the quality domain of effectiveness, efficiency and equity and it's a process measure.

It did meet the criteria for consideration and it really falls in line with the recent one that Evy reviewed. This is, we know the baseline of OME so I won't go over that again. We don't know how often antibiotics are prescribed percentage wise but we do know that in the data that was provided that many of the physicians, a very small percentage know the six items that were on a guideline from the 1990s and that over half of the physicians couldn't tell the next step in progression in terms of the work-up and the treatment plan.

So there is evidence of a gap here. And then also as Dr. Rosenfeld summarized, transient improvement with antibiotics has

driven many physicians or families to feel the need to implement this but there hasn't been a proven efficacy and we have already reviewed the impact of inappropriate use of antibiotics.

So at the risk of being quick on item number one, the summary data showing its importance, relevance and potential risk of the inappropriate use of antibiotics is appropriate and qualifies this for further review. And so I felt that one was a C.

And my co-reviewer I think is the person who's not here.

CO-CHAIR MOORHEAD: Everyone okay?

DR. CHALIAN: Okay. In terms of the numerator, for our measure specifications, the numerator would be the patients who were not prescribed antimicrobials. The patients would be those aged two months to 12 years. And again these patients could have multiple bouts or they could be counted -- more than one episode could occur during the course of a

year and the diagnostic codes and the CPT codes were listed. So I felt in this area the measurement was a C or a P with clarification about the denominator.

There was no -- the exclusion details and some of the EHR considerations are still in process so an exclusion detail that would allow for understanding of patients that have received antibiotics for another indication was mentioned. There was no risk adjustment required and the type of score you would be recorded as being better if you had a lower score. And in terms of these criteria, all the way down to 41, I felt that this met our goals and was at least a P.

CO-CHAIR MOORHEAD: All the way down to which one?

DR. CHALIAN: Up to three, up to testing and analysis. Actually, I'm sorry. No, that's correct. I'm actually still in domain B. In domain B, a goes up to item number 41 so now I'm on 2b.2. The Quinn Project again is

abstracting charts so we will have information as to the success of collecting this data so I felt that 2b was at the P level. And in terms of validity testing this should also help, the Quinn Project should also help with us understanding the validity of the data that is collected so I felt that was a P.

And in terms of justification of exclusions, provided the Quinn Project supports it, that could be a P or we could still be relatively uncertain in terms of the data that is collected.

And then in terms of 2e, which is adjustment for outcomes, I said this is a P but I didn't actually explain my logic there. So this is the resource use measures, tracking of risk adjustment, okay, that's actually probably not that applicable here. And then the meaningful differences in performance, this should capture it because we'll know which patients were prescribed and which were not, so for 2f it should be P.

And in terms of comparability of multiple data sources and methods, I felt this was still an unknown so we have no data on this at this point and in terms of disparities in care, the framework is being developed so we have no data so that's an N for 2h.

So as we wrap up on number two, again, the Quinn Project helps with this and the numerator and denominator are clear so I felt this was a P. Any questions?

I'll proceed into usability. This is currently in testing so we don't know if it's really a usable yet but it's a good sign that it's being tested so I felt that was a P.

And then we progress to harmonization and distinctive or additive values and I took these together. This does link itself to pairing. It is something that probably goes without explanation after what we've reviewed for the last two or three proposals. And I felt if this was paired successfully with the other projects this

would be very helpful in decision-making. So overall for section three I recommended a P rating.

And in terms of feasibility, this again seems feasible. The data elements are clear. They should be retrievable whether it's with a chart review or other databases and so I felt that was a P. Similarly I felt 4b was a P in terms of electronic resources. They may not be fully refined yet but it should be achievable. The exclusions did not require any additional data sources but we'll learn more about that from the Quinn Project so I felt that was a P as well so 4c would be a P.

And then susceptibility to inaccuracies item 4d, I felt was a minimal potential problem. And then the data collection strategies and implementations at this point seemed to be in the process of being built. We'll learn from the Quinn Project.

So overall I felt for item 4,

feasibility, that it's a P but in reality probably could be a C. So I felt this was a good metric for endorsement for time-limited and probably also would be ideally paired.

CO-CHAIR MOORHEAD: The recommendation is to --

DR. ALTERAS: Wait, can I ask you a question?

DR. CHALIAN: Yes.

DR. ALTERAS: Is it necessary to have two separate measures on avoidance and inappropriate us of antibiotics, one for otitis media with effusion and one for otitis media externa? I mean can we have one measure that is unstratified by whether, I just wonder, in terms of usability, like understanding these measures --

DR. ALESSANDRINI: One is just kids and one is all, just one issue so -- hard to put together.

CO-CHAIR MOORHEAD: Two different populations.

DR. ALTERAS: Okay, so.

DR. CHALIAN: Building on Tanya's question it may be another way of cataloguing though when you look at the website, would a search word cluster up appropriate and inappropriate --

CO-CHAIR MOORHEAD: Okay. Go to number 14, Beverly.

DR. BEVERLY COLLINS: This is measure ACP-014-10. It's otitis media with effusion, diagnostic evaluation assessment of tympanic membrane mobility. This is percentage of patient visits for those patients aged two months through 12 years with a diagnosis of otitis media with effusion, with assessment of tympanic membrane mobility with pneumatic otoscopy or tympanometry.

It's a process measure and it's geared toward population health. Excuse me. We go to the importance to measure. Under 1a, again I had the question about the evidence showing any impact for children older than

what's addressed in the evidence here. It only goes, it talks about children up to age four years of age but the measure looks at those through 12 years, so if we could get some clarification on that. I rated 1a as a P.

For the opportunity for improvement, it says that correctly diagnosing middle ear effusion is essential for proper management. That's why you can look at the mobility of the ear drum using these methodologies, pneumatic otoscopy or tympanometry. There has been some use of it with the PQRI. In this measure it's still present with CMS measures unlike the hearing test we talked about before, they got rid of that one. This one is still involved, so I don't think it was just pediatrics, I don't know why they got rid of the other one, I think it was because of the use.

They do talk about a survey from AHRQ where they questioned respondents about correct use of tympanometry and half of them

did respond it was the most accurate test to predict a normal middle ear. So I gave 1b a P rating.

And looking at outcome or evidence to support the measure. It quotes some information from some guidelines saying that pneumatic otoscopy had the best balance looking at nine different diagnostic methods for assessing OME of sensitivity and specificity but it did not give you what the actual results of that sensitivity and specificity were.

It said pneumatic otoscopy should remain the primary method of diagnosis but then it also talks about if there's an uncertain diagnosis, the tympanometry or acoustic reflectometry should also be considered as an adjunct.

So looking at the evidence, I'm not sure what the, I guess the measures use an either/or. It sounds like there's a hierarchy here but the measure doesn't differentiate

those. Maybe could you clarify that?

MS. TIERNEY: Yes, I think that again was a feasibility issue. The guideline is clear that pneumatic otoscopy is the preferred diagnostic tool but it also allows for tympanometry so in the development of a measure we felt that it was appropriate to allow for both and we couldn't specify that one would be used first over the other just from a measurement perspective.

DR. BEVERLY COLLINS: Okay, so either/or. And then one other thing they quoted is saying that pneumatic otoscopy is recommended and it's accurate in experienced hands so I'm wondering is that all practitioners. I was wondering when I first read this measure, I was thinking it was for primary care practitioners, or peds or something like that, but what are experienced hands? I mean, is that ENT people or is it still anyone that could do the test?

DR. CHALIAN: I would offer that

pediatricians see as many ears and that many ER physicians and primary care physicians see kids' ears as otolaryngologists do so --

DR. BEVERLY COLLINS: So any practitioner, this would apply to? Okay.

DR. EISENBERG: I just have a caveat. I work at about seven different facilities and I can't think of one that has a single pneumatic otoscopal device available to use.

DR. CHALIAN: Oh really?

DR. EISENBERG: They are stolen. They are missing. It's a little bulb that you can blow air with and they disappear very rapidly. It's a great thing to have but it's just not there most of the time.

DR. CHALIAN: I should sell them.

DR. BEVERLY COLLINS: And that's what this guideline statement says, that they are readily available in practice settings.

DR. EISENBERG: I mean it's a black rubber bulb with a tube attached to it. I mean

it's really hands on medicine but --

DR. NEWMAN: Back in the day it used to be just a tube.

CO-CHAIR MOORHEAD: Yours disappeared?

DR. O'CONNOR: I haven't seen one in years. Unless we carry our own, they vanish from -- there's nowhere I've worked I've seen one.

DR. NEWMAN: I am giving you all stocking stuffers.

CO-CHAIR MOORHEAD: That'll be about 32,000 of those we are going to need, okay?

DR. CHALIAN: As part of the stimulus package.

DR. BEVERLY COLLINS: Okay, I'll continue. So the pneumatic otoscopy was rated grade A, which is well-designed randomized controlled trials or diagnostic studies performed on the population and the tympanometry was a B, which is looking at randomized controlled trials or diagnostic

studies with minor limitations. So that whole category I rated as a P.

Measure specifications, we have the same issue here talking about episodes and visits.

CO-CHAIR MOORHEAD: So your overall on one is?

DR. BEVERLY COLLINS: Yes, yes. Even though we don't have the instruments.

DR. ALESSANDRINI: I think -- it is important, I just want to make sure that we bring up that I really struggle with a diagnostic test that can't be confirmed by anybody, you know what I mean like, this is a really tough one and so clearly a lot of times when we try to assess the quality of care provided for OME we are making the assumption that people are making the diagnosis correctly and then we base most of our quality measurement on that assumption, which is really what all the prior measures have been.

Making the diagnosis is a big issue

and I just, it's relying on somebody's documentation when they don't often have the appropriate equipment like we've all said here. So I think it's going to be tricky from the feasibility perspective.

DR. ALTERAS: Can I ask, sort of building on that, if you don't have the equipment in your exam rooms, is that an indication this isn't an important procedure to do? I mean it sounds like if you're not carrying one around in your pocket then you've sort of decided it's not really -- I just, I don't know it at all, so I'm just curious. Are we measuring something, I mean when you say it's important, I just, I mean, can someone educate me a little more on this?

CO-CHAIR MOORHEAD: I think they are missing and I think that in a lot of cases you make the diagnosis with an otoscope and what you're seeing and then in the difficult cases then you go find one because you want to see if the drum moves and you find out somebody

has got one in their pocket and so you, that's just the practical I think way that we deal with it. So I have a little issue with the importance here as well because there is a whole I don't know what percent, but there's a large percent I think in clinical practice that are diagnosed just because of what you see in the clinical picture and that I'm not sure that this really adds but in the difficult cases it's very helpful.

MS. ALTERAS: I just wondered, definitely there's value to process measures but I'm just wondering if this is one, if this is a process measure that really would add value.

DR. CHALIAN: I think hearing the viewpoints, it does probably add a few cases that we would miss and refine a few diagnoses that were in doubt that would have been overcalled, but the majority of these I think are based on the color of the fluid behind it or the air bubbles and you know, people make

the diagnosis so --

CO-CHAIR MOORHEAD: Bulging --

DR. CHALIAN: This may be more --

DR. BEVERLY COLLINS: More what?

DR. CHALIAN: More work than we need to do.

DR. ALESSANDRINI: And since the treatment is not to do anything but observe, that's what makes people, you know, it's like, well, I'm not supposed to do any of these treatments, I'm just supposed to have them come back so when they come back I'll have that bulb for them.

DR. EISENBERG: It goes back to the parent because I think what you're going to have is people that look, they don't have an otoscope, you know what it's dull, I can't really see anything and then the antibiotics are prescribed, so pairing it with the overuse of antibiotics is the appropriate way to look at it other than carrying them around in our pockets.

DR. BEVERLY COLLINS: I agree because maybe people haven't been using it because the inclination is just to prescribe antibiotics, that's been, you know, our way of practicing for the past couple of decades so it's just easier to write that prescription rather than doing a confirmatory test.

CO-CHAIR MOORHEAD: That may be true. I think in most cases you can make the diagnosis in other ways. It's not necessary. So I mean I think, some feedback here from the group, is this a yes or no, and if it's not a yes then --

DR. CHALIAN: Sounds like a no.

DR. BURSTIN: Again it may be a very useful measure for internal QI but does it reach the bar of a measure that you'd publicly report, that's what NQF is about, so maybe that'll factor into your thinking about it.

DR. ALTERAS: This isn't really like a consumer-friendly measure, so --

CO-CHAIR MOORHEAD: I think you're

being very consumer-friendly right now. Bob did you have a comment?

DR. O'CONNOR: I mean, I was just going to say if we had infinite measures we might consider this, but with limited measures I just don't think this is either widely-practiced or all that important in terms of treatment outcome.

CO-CHAIR MOORHEAD: There's a lot of nodding. Sounds like we can make this a no and then we don't go any further. Beverly, is that okay?

DR. BEVERLY COLLINS: I have no vested interest in this at all.

CO-CHAIR MOORHEAD: Everyone okay with that?

DR. CHALIAN: Sam are we missing a freight train?

Ms. TIERNEY: No I don't think so.

CO-CHAIR MOORHEAD: So at this point I think we'd like to go back and look at 12, 13 and 15 and look at the pairing issue and

look for a recommendation there from the group. Antihistamines, steroids and antimicrobials.

DR. ALESSANDRINI: I think it would be great to pair all of them because it's just a nice, you know, this is just really almost like an endorsement of watchful waiting, which is the right treatment for this.

DR. BURSTIN: And in some ways because the measures all go in the same direction, they're all don't do this, I would also actually think the committee might want to actually make, this seems like a perfect, true composite to develop, because you shouldn't actually do any of them. Right? I mean it could just be an all or none. That's one potential way to look at it, just to make it simpler.

CO-CHAIR STONE-GRIFFITH: So what would that be? Recommend back to the endorser to make it a composite?

DR. BURSTIN: I think you would

recommend with conditions. Again in this cycle, I don't think, I don't know that they'd be able to get it done as a composite, but that you'd recommend at least they be paired but perhaps a strong recommendation that by the time the measures are for maintenance or something you would expect to see a composite or something like that.

CO-CHAIR MOORHEAD: Is there agreement with that? We're nodding. Good. We're just, you're not nodding off? All right. Well, we're finished with ears. Okay well, good work, we're doing well. All right we're ready to move on. Number 16. I am ready for 16 but you are all ready for 29. Sorry, 29. Staying in the ENT. Twenty-nine is --

DR. JEFFREY COLLINS: That's me.

CO-CHAIR MOORHEAD: Jeff, okay.

DR. JEFFREY COLLINS: So I am reviewing ACPP-029-10, title is patients treated with an antibiotic for acute sinusitis that received a first line antibiotic. This is

a measure that identifies patients with acute sinusitis treated with antibiotic who received a first line antibiotic and it's a process measure. I have to say starting off that this one fascinated me so I'll try to leave my comments off to the side until the end.

It passed consideration for NQF, very clinically important topic, if you based on 1 billion viral ERIs in the United States every year you can extrapolate down to 20 to 30 million individuals diagnosed with sinusitis.

I think one of the things that needs to be clarified in the title is we're talking about acute bacterial sinusitis and to be very specific about that. Annual healthcare costs of close to $6 billion a year and over 73 million days of restricted activity and it accounts for 20 percent of antibiotic prescriptions in the United States each year so in terms of importance, I gave this a C. I just think it's a huge topic.

In terms of 1b, opportunity for improvement, benefits, summary of data and performance benchmarks, I gave it a partial. In terms of outcomes for evidence, important process in terms of really seeing who failed conservative therapy, who has a more severe illness and complications for acute sinusitis.

One of the issues is sort of looking at first line versus second line agents and the use of not using macrolides as first line agents and we can talk about that subsequently.

CO-CHAIR MOORHEAD: You want to go through all the ones and then --

DR. JEFFREY COLLINS: Sure.

CO-CHAIR MOORHEAD: I'm sorry, is it Leigh or Leigh Ann?

MS. MCCARTNEY: Leigh Ann.

CO-CHAIR MOORHEAD: Leigh Ann.

MS. MCCARTNEY: I agree so far.

CO-CHAIR MOORHEAD: Okay.

DR. JEFFREY COLLINS: So 1c I had a

complete.

CO-CHAIR MOORHEAD: Okay.

DR. JEFFREY COLLINS: If anybody has any, we'll talk as a group about the guidelines, but in terms of measure specifications, we're just looking at a numerator.

CO-CHAIR MOORHEAD: So your overall for 1, the importance, is a yes.

DR. JEFFREY COLLINS: Yes.

MS. MCCARTNEY: Yes.

CO-CHAIR MOORHEAD: Thank you.

DR. JEFFREY COLLINS: In terms of measure specifications you are looking at a numerator being patients who are treated with antibiotics for acute bacterial sinusitis that received a first line antibiotic. I didn't see any denominator data. I don't know if that wasn't --

MS. MCCARTNEY: It's way, way, way down. This is like 800 pages or something. It's like squeezed in the middle somewhere.

DR. JEFFREY COLLINS: Okay. I'm assuming it's all-comers with --

MS. MCCARTNEY: Whatever they have sent me to print out, actually had the denominator in it so, the denominator is all males or females that are three years of age or older at the end of the report period. And I mean there's quite a bit of, the sinusitis event will encompass the following period of time: 60 days prior to initiating sinusitis encounter through 21 days after the encounter.

So there is quite a bit of detail about the denominator.

DR. JEFFREY COLLINS: Right.

MS. MCCARTNEY: But it seems like they have, they've covered most of the information that would be included in it. There's quite a bit of detail on the exclusions.

DR. JEFFREY COLLINS: Right.

MS. MCCARTNEY: As well. But I honestly don't know what page because my --

DR. BURSTIN: It starts on page 891.

DR. JEFFREY COLLINS: Right. So I went from page 6 to page 890 so I may have missed the -- so I apologize.

MS. MCCARTNEY: Yes, it's a little difficult.

DR. JEFFREY COLLINS: I did think that testing analysis and everything that described getting to 2b and 2c were complete, that they were very thorough as far as the actual testing methodologies, that they suggested in terms of exclusion criteria, I thought those were appropriate too. Those are listed in section 2d, excluding people with recurrent episodes, chronic sinusitis, underlying immunodeficiencies or structural abnormalities, recent hospitalization or outpatient surgery and relevant head, neck and respiratory infections that might indicate a complicated case. I thought that was appropriate.

Risk adjustment, 2e I had not

applicable, identification of meaningful differences of performance, I thought that that was complete. You can holler if you have any differences.

MS. MCCARTNEY: No I agree.

DR. JEFFREY COLLINS: Comparability of multiple data source methods, I had an N. Disparities in care, I had an N also, there was nothing suggested. I do want to just toss out that when you look at first line agents, you know the cost of a generic amoxicillin versus the cost of Augmentin and a fluoroquinolone is pretty substantial so although people haven't studied it, it's something we might want to think about as far as community disparities.

In terms of usability, section 3a, meaningful and understandable and useful information, I had a partial. I think one of the difficult things here is, one of the clinical issues that happens with acute bacterial sinusitis is that you're diagnosing

it as a viral URI in a patient that's getting worse after five to seven days or a patient 10 days out who hasn't gotten better.

And so tracking that serially in a data source becomes difficult because how do you do that? Are you looking to identify viral URIs and then tracking a patient with a diagnosis of acute bacterial sinusitis subsequently? It's possible but it's incredibly cumbersome even with an electronic database and so I don't know if people have any ideas about that but I thought it was a cumbersome measure to get at.

And then in terms of feasibility, well I'll go through those. So for 3a I had partial, harmonization I had not applicable, distinctive or additive value I had not applicable or no. And then in terms of feasibility data generated as a by-product of care processes, they didn't list anything there. And then in terms of identifying susceptible inaccurate errors or unintended

consequences of the measure, they did have a reference to pen allergic patients and we can talk about that clinically. I had a partial.

In terms of data collection strategy and implementation, I thought that was partial.

DR. ALESSANDRINI: None of these seem to do any work on the cost of doing this and from working in the hospital setting quality center, I don't think people think about, just because it's electronic that doesn't mean there's not a body that has to pull it, analyze it, produce it on a regular basis. This is not, it's only data that you are getting out, it's not information, somebody still has to put a lot of work behind that information and sometimes I think that's what gets missed in these measures, is that amount of work and the bodies that it takes to really produce meaningful information from the data that is abstracted from these electronic means.

So in all the measures that I've looked at, the evidence of cost is missing and I think that's a very important piece that they need to consider when they're testing these and looking at the amount of time it takes and the resources it takes to really get this data and make it useful.

DR. BURSTIN: It's been a real struggle. We've asked for it. People analyze it completely differently. It's apples and oranges. So much of it depends on where you start in terms of the data systems in your institution so I mean for AHCA it's probably very different than some other institutions so that's been one of our challenges but I think it's still a valid point.

DR. ALTERAS: Can I ask a question? This isn't measuring whether a patient was diagnosed antibiotics inappropriately. It measures whether a patient who should be getting antibiotics is getting first line versus a too powerful one? Okay. How often

does it really happen that patients are prescribed a too powerful antibiotic, really?

DR. COHEN: I don't know. There are other factors though. Compliance issues, you know, in children is an issue, with MRSA resistance especially in Brooklyn, there's a significant multi-drug resistance issue. So there are issues to use the broader spectrum agents but not always. But it's overused I'm sure.

DR. CHALIAN: I have a question for the sponsor. I think there's some more recent sinusitis guidelines from the Academy of Otolaryngology and they don't seem to be referenced so I was -- and it's not my niche area so I can't give you the exact date but I think it was in the last two years.

DR. JEFFREY COLLINS: So the 2000 guidelines were updated in 2007 and those are referenced in there.

DR. CHALIAN: They're in there? Okay.

DR. ADAMS: And is that the source that we're using to draw the recommended first line antibiotics? Those guidelines? And then will be able to take into account the local -- as was discussed -- any kind of local recommendations if there's ID people that say something else? I mean they don't' typically do that for sinusitis but, you know, you brought up a good point and maybe it's just local custom and not evidence-based.

DR. NEWMAN: Right, so this is the nuance that I was referring to. So right now nationally about 30 percent of H flu, non-typeable H flu is beta-lactamase producing and almost 100 percent of M catarrhalis and so depending on what practice area you are in, you may opt for an agent just based on that and how do we get at that, you know, based on a chart review let alone documentation.

It's one thing to say that we're going to follow clinical guidelines set forth by these groups but to all of a sudden measure

people as a quality measure based on this I think is much more complicated.

DR. CHALIAN: Does the length of treatment enter in on the proposal?

DR. NEWMAN: I actually didn't see lengths of treatment.

DR. ALESSANDRINI: No I didn't see anything on length of treatment.

DR. CHALIAN: From the --

DR. JEFFREY COLLINS: It's 891 pages.

DR. CHALIAN: I'm not poking a hole in your bubble believe me. This is a tough one because I think the patient populations aren't homogenous anymore and so we're trying to induce thoughtful behavior but I'm not sure we have a guideline that will actually be one that's helpful and measurable and will guide behavior.

DR. ADAMS: And speaking to that, what I fear is the doctors who want to prescribe the second line agent will just

change the diagnosis. Acute febrile illness, I mean there's a whole lot of other things that they can --

DR. ALESSANDRINI: - the antibiotic --

DR. ADAMS: But I won't get dinged, right? I can --

DR. JEFFREY COLLINS: And again, the fact that you know, the guidelines build in treatment failure as being greater than or equal to 72 hours after the antibiotic has started. Now does that imply that they're going to come back to my institution or go to another institution or go to the primary care physician? How do I get at a treatment failure?

CO-CHAIR MOORHEAD: Just one or two --

DR. JEFFREY COLLINS: And again this is an incredibly serious topic as far as cost and over-prescription of antibiotics and all of these types of things but you know, as a

measure, I think it's really difficult to get a handle on.

DR. ADAMS: And then sometimes perfection is the enemy of the good and none of these are perfect but it may be it promotes the right behavior so we should do it anyway.

CO-CHAIR MOORHEAD: My computer still hasn't caught up with the 891 pages. So I have got to get to work on this so we got to the end of 4? Right? And so the overall, your recommendation is?

DR. JEFFREY COLLINS: The same, it's too complicated.

MS. MCCARTNEY: I think it is, you know, especially in the PCP setting, I think it's really going to be difficult to get this data. Go ahead.

DR BURSTIN: This measure is usually done at the health plan level where they have the data.

MS. MCCARTNEY: But I think the point is taken that the physician will change

it so even though the data is based on claims they may choose a different diagnosis so that they can use that so I think that's kind of what I was getting at, is that, you know, I think it would be, there's a lot of different diagnoses out there that they could choose that would still be appropriate but might get them a pass.

DR. EISENBERG: I would argue completely against that. I cannot think of any physician that's going to change their diagnosis from something simple that they have done because of how abstracted data is going to be used afterwards. I think that 99 percent do not think that far. They're going to just call it sinusitis whether it's the whole issue of --

MS. MCCARTNEY: They may.

DR. EISENBERG: Wrongful diagnosis to begin with but I mean there's probably, I mean your data probably shows what, 50 diagnoses that the average doctor uses and we

don't specify to the 5th digit, we don't, I mean we use this particular set of things, so I think your, that's a whole issue with claims data, are you really getting what they're doing and I don't see it going the other way at least until you've got a good enough EHR built in where it's either prompting you to do that, you know, to add a 5th digit or to make it more accurate, so I mean I don't think that's too big an issue.

DR. BEVERLY COLLINS: Even when EHRs are implemented though if they're not the same across all facilities you're not going to get all those prompts so I would agree, I think it's going to be difficult to get this data in an accurate manner.

MS. MCCARTNEY: I want to speak from the health plan perspective as well. You made it sound like it would be easy because everything is coded with claims and all that. If I had to code 800 pages of codes, there's no way I'd do it, unless this is a measure, a

metric or a program that's already delivered to us. It's just too confusing. I think it's overwhelming.

MS. GOVAN-JENKINS: I am a mother of a 14-month-old and a two-year-old and I'm an RN and I took my little girl to the doctor last week for a double ear infection and he did not prescribe the amoxicillin because she has been known to be, it has not worked for her in the past and every time he ordered it we had to go back and get more medication. So this time he ordered a three-day of Zithromax which worked perfectly and she is fine. So.

DR. JEFFREY COLLINS: Did they use a pneumatic bulb though?

MS. MCCARTNEY: I concur. I have had the same experience with my children, where amoxicillin hasn't worked and we've had to go back and then -- right.

DR. JEFFREY COLLINS: So just to summarize, what I would say is we at my practice, we use these guidelines, so these

are the guidelines we use, but as far as instrumentalizing these and using these as quality measures, I think would be incredibly cumbersome. The time it gets hardest for us to do is actually in the pen-allergic patients, where the nuances of antibiotic use become more specific and trying to get into the chart and who actually puts allergies in the right part of the electronic medical record rather than burying them in the note and trying to get that aggregate data is next to impossible for our group.

DR. BURSTIN: Well, this one is measures only specified for claims data, it's not specified for EHRs so those are you know, futuristic issues but for now it's purely taking pharmacy claims data, taking diagnostic claims data, and putting it together. It is what it is right now.

CO-CHAIR MOORHEAD: But it is for public reporting and we are recommending that this continue to be use QOM measure but not as

a -- I don't know -- Ara?

DR. CHALIAN: I guess my, when it's big aggregate data like that you can't tell if it actually applies and reflects on appropriate or inappropriate behavior. But it can give a misperception to the public or even the physician. So from that perspective I feel that it's important for the company to understand what's going on and maybe our organization to understand what's going on but it doesn't help the prescriber or the consumer without further definition of the cohorts.

DR. BURSTIN: Well the consumer also goes to those purchasers who are purchasing, you know, who are making purchasing decisions on the part of consumers, you can make the case that they want to be able to see different groups, they want to see different plans, so it often is on a higher level, aggregation.

DR. CHALIAN: It may help them who to identify who to invest with though, but not

necessarily that it affects their quality of care.

CO-CHAIR MOORHEAD: I am hearing consensus with the committee that we think that this should not be recommended as a measure that it continue to be used for quality improvement. Okay. Well thank you very much. We can move to number 30. Beverly.

DR. BEVERLY COLLINS: This measure is ACP-030-10. It is adults community-acquired bacterial pneumonia that had a chest x-ray and this measure identifies patients with community-acquired bacterial pneumonia treated as out-patients that had a chest x-ray.

It's peer coordination focus and it did meet the criteria for NQF to review it. We look at the importance of the measure, it has demonstrated high impact, it addresses almost 916,000 episodes of community-acquired pneumonia in the U.S. each year. This is in adults 65 years of age and older which is not really the population addressed by this

measure that is 18 and over. So that other segment of population is not addressed in this evidence. So I put partial, partially addressed.

The opportunity for improvement, speaks to the chest x-ray, is essential to confirm the diagnosis and it's also useful as suggesting the etiologic agent, determining prognosis and excluding alternative diagnosis and conditions. Did say that there was a compliance rate of almost 71 percent of the chest x-rays in the database that I guess the sponsor uses to do some validation and measurement, a commercial population less than 65 years of age, so it didn't really address if there were any settings of geographic locations that there might be more of an opportunity. So I gave this a P for partial.

It just said there were no disparities by this population group so I don't know, some of the other data, some of it was like no data, or there are no disparities

because I think there might be. Looking at the outcome or evidence, they rated the evidence as moderate level three, but in the rating methodology a level three is considered low and moderate is considered level two so I'm not sure really what the rating of this one is. I gave it a rating of a P as well. That also includes summary of controversy, contradictory evidence, they said there was none.

So I felt that it is an important measure so I gave it yes for importance.

With measure specifications there is a long description of the numerator. I was confused because there's a lot of exclusions in the numerator that seem like they would be in the denominator, or should be.

MS. RIEHLE: The reason why it's written it that way and I don't mean to interrupt you --

DR. BEVERLY COLLINS: Sure.

MS. RIEHLE: But the reason why it

is written that way is because after you start determining the numerator there are a few further exclusions so they're actually -- the first step of the numerator is to look for the CPT2 codes and then after that there's a few more exclusions so it's actually technically not part of the denominator because you've already started to define the numerator.

DR. BEVERLY COLLINS: Okay. I found it very confusing. And then, number five on the description of the denominator said, any remaining patients do not satisfy the numerator criterion and it's a whole long list of other types of pneumonia like, you know, histoplasmosis and a lot of others that I would think would be exclusions in the denominator starting out, because you're looking at bacterial pneumonia.

MS. MCCARTNEY: I agree.

DR. BEVERLY COLLINS: So I was like really confused.

MS. MCCARTNEY: I was confused with

the exclusions, or the, right, the remaining patients in five didn't match up to the denominator.

DR. BEVERLY COLLINS: Right. It's people, yes, who should not even be in the numerator, so if you're looking at the denominator. So I was really confused about how it is actually designed. And again there's 400 pages of codes that I found very complex and confusing. So let me skip to past the codes. Page 412 I believe it starts.

So I gave 2a.m. minimal because I couldn't understand it, the numerator and the denominator. All right so, let's see.

MS. MCCARTNEY: Can I just ask a question about this. So this would be built into some sort of, I know it's claims data, but with all of these codes, if this was going to be done this would be like some, it would be go through a software program, so that people -- but if they're looking at, you know, if they get their compliance with this and

they want to understand it they're going to have to go through all these codes. I mean I guess that's where it's kind of like okay, I'm Doctor X and I get this and says I'm not doing very well with this and I go and look at 400 pages of code I'm not going to think it's a very valid measure of my care for these patients just because there's so much and it's so complex.

MS. RIEHLE: I mean, I understand your concern, I mean in general, our customers who use these measures have people who provide support to people for the software so if they have a question, instead of having to pore through all this themselves they can ask a specific targeted question and then either our customers can help them or they can come back to Ingenix and eventually use their customer support. So we don't usually run into physicians you know getting a stack of codes they are more for, I mean we don't want them to have to do that.

CO-CHAIR STONE-GRIFFITH: Helen is this another situation where Ingenix will give specifications to anyone who wants to use it?

MS. RIEHLE: Absolutely.

CO-CHAIR STONE-GRIFFITH: Yes. Okay.

DR. BEVERLY COLLINS: Okay. Where I pick up on this next I think was risk adjustment which, none is necessary. Data source electronic administrative data and claims of pharmacy. So we skip to the reliability testing. Again it speaks to using multiple databases from Ingenix but it really doesn't give any of the results about how reliable their findings were. It talked about using regression analysis to verify reliability of the product across software releases so it looks like they're checking their software to see if it's reliable but not really the measure itself. So I gave that an M, minimal.

Validity testing basically had the same type of thing. It talked about the

software. It did talk about comparing to some claims as a gold standard, or looking at some record reviews, comparing the claims-based measure to some chart reviews as a gold standard, but it said they reviewed 726 measures were evaluated in this overall process and I don't really know if the measure we're looking at is one of the ones that were included in the study. It didn't really specify that. It says an overall error rate was less than five percent. So I really don't know what our measure here that we're addressing, how that fared.

And the exclusions, as I mentioned, sorry 2c I rated as P, partial. And then with the exclusions I gave that a C. I think they did capture a lot of those although it didn't talk about the exclusions from the codes, specifically all those 400 pages' worth.

And then the risk adjustment was N/A. That's 2e and 2f I rated as N, not at all, really didn't talk about the meaningful

differences in performance. And then comparability of multiple data sources was not addressed. I gave that an N. Age disparities I also gave an N. That was not addressed. So my overall score for this was P.

Under usability, it said they are currently in use and it really talked about all their, I think their clients that are using it, this measure. It's a similar measure I think with PCPI, I'm not sure if it's exactly defined the same way, but it doesn't seem to be any information about what the results and the usability are with their clients so I gave it an M for 3a. Harmonization was not addressed so I gave that an N. And the competing measures also was not addressed so I gave that an N with an overall score of N. For number three.

Feasibility talked about the data, how the data elements are needed. I think it was, I gave that a P, I mean they're listed but I think it's just an overwhelming amounts

of it. The electronic sources, I gave a P. The exclusions, I gave a C. They were all defined and accuracies or errors, I didn't really talk about how there would be an auditing process so I gave that a P, partial. And the data collection, I gave that a P. So an overall score for four of P.

MS. MCCARTNEY: I agree.

DR. BEVERLY COLLINS: And I think my overall recommendation is I think I would not accept it as defined. I was really confused with the numerator and denominator. I'm not sure what it's actually measuring. And it's very complex.

MS. RIEHLE: I agree it was confusing to understand exactly what they were measuring with all of the codes and then the -- well, it's way up at the top but it was very confusing.

DR. ROBERTS: Well, I certainly liked the premise. If someone has what they think is pneumonia I think the patient

deserves a chest x-ray so I liked the premise and I'd hate to see it just die but the recommendations maybe make it a little more understandable about the coding, is that the suggestion, and the numerator denominator?

MS. RIEHLE: The way we had to put our specifications in this format I guess was a little difficult to conform to and the fact that we do have so many codes, we do have to be up-front about the codes, you know, maybe putting them somewhere else so that they were not you know, so physical so they are not getting in your way when you're reviewing the measure. That might be, that might make it more helpful. I understand that it is a fairly complex measure but you know, we wanted t make sure that we did it, you know, in a way that was responsible.

DR. BEVERLY COLLINS: Can you speak to the discrepancy, maybe it's just a typo, about it being rated as a moderate level three evidence but then level three is considered

low.

MS. RIEHLE: You know what, I bet it is a typo. I am not sure but I could get back with that information.

DR. ALESSANDRINI: And can somebody just clarify the age range again?

MS. RIEHLE: It measures 18 and over.

DR. ALESSANDRINI: I guess I would just have to disagree and I practice in an emergency department so it's very easy to get a chest x-ray but I would suspect that a patient-centered primary care measure was that the patient clinically has pneumonia and has a normal pulse-ox and is hydrated and taking the oral antibiotics, were going overuse in some of these and my suspicion is an overwhelming majority of patients get better and those patients that need an x-ray subsequently because they don't respond, that's fine. And so I think this is not the tree that should be barking up.

DR. BEVERLY COLLINS: Can I ask, you know, the summary of evidence if high impact states that it's adults 65 years of age and older.

DR. ALESSANDRINI: That is a different --

DR. BEVERLY COLLINS: But then your denominator is 18 and older so can you explain the discrepancy there? Why do you quote that but then make it 18 and older?

MS. RIEHLE: I think that may have been just the available information. I think that we could probably try and find something that was more appropriate to the age range.

DR. BEVERLY COLLINS: Because I know that the data also that you guys quoted your database is for patients less than 65 so we're really not looking at the group that is the high-impact group. You're looking at the patients that are in that other grouping.

MS. RIEHLE: That's true.

DR. BEVERLY COLLINS: So you know I

would say there is some discrepancy in that and that maybe you guys would need to go back and provide some data on the 65 and older group and then revamp your denominator to make it more meaningful.

DR. ROBERTS: I like the 65 plus age group.

DR. BURSTIN: I just wanted to make, I thought this sounded familiar, this measure was evaluated before in our clinically rich initiative measures project and it didn't get through at that point. I think the idea was actually the point that was just raised. If you're seeing a patient who clinically has pneumonia and they're well and you're just going to treat and requiring the chest x-ray, particularly in the ambulatory, non-institution basis, was, didn't seem like it was guideline specific. I'll pull up the exact, the last steering committee deliberation on this, but I think they probably thought since this is more of an ED,

urgent care kind of oriented group this might have a different perspective.

CO-CHAIR MOORHEAD: Comments.

DR. NEWMAN: I find in emergent care there is enough fragmentation already in our processes and as we learn to integrate the different healthcare entities and so you have a chest x-ray as something that's tangible and can be tracked, can be digitally sent, it's a point in time, a marker and point in time, which can be referenced in the future and impact care. So I see a great benefit from getting a chest x-ray and an initial evaluation for pneumonia.

CO-CHAIR MOORHEAD: Jeff?

DR. JEFFREY COLLINS: Theoretically you can't make a diagnosis of community-acquired pneumonia without a chest x-ray so what ends up happening a lot of times if someone is diagnosed with chronic bronchitis ends up happening having a chest x-ray based on exam and those types of findings, hypoxia

and other things. But everybody if they are worried about pneumonia, make a diagnosis, that's billable as an x-ray.

DR. BURSTIN: I just briefly want to tell you what the committee before had gone through on this and they felt the evidence was fairly low-level evidence, it was mainly based on case studies and expert opinion. There were concerns about the measure being more robust. It was actually combined with a measure that I think was looked at and I think went through looking at specifically treatment for community-acquired pneumonia and they had actually recommended potentially putting those together and I don't think that happened.

There was also concern about the necessity of a chest x-ray each time of diagnosis and concerns about the ability -- there was something about measure the antibiotics 21 days before the episode start date was another issue they raised about the measure so it didn't, as I recall, it didn't

make it through the last project.

DR. NEWMAN: It is challenging. I mean you know, we're talking about pneumatic otoscopy and to try to go back and review tactile fremitus and other things with some of your clinicians, extremely challenging. Their oscillatory abilities are waning the further out they get.

DR. ADAMS: The additional problem though is that the radiographic findings of pneumonia lag the actual onset of the disease so it really is an imperfect test.

CO-CHAIR MOORHEAD: Just to be clear, this does apply to all settings, and so, if it applied to the ED only for example then they would get support for that.

DR. BURSTIN: Although there is already a measure about treatment in Eds.

CO-CHAIR MOORHEAD: I understand that I am just saying. So I heard a little bit difference of opinion but given that this applies to all settings are people comfortable

with the recommendation that this not be recommended?

DR. EISENBERG: No.

CO-CHAIR MOORHEAD: No.

DR. EISENBERG: No, I mean, I think this should not, is this a no recommendation?

CO-CHAIR MOORHEAD: Yes, no.

DR. EISENBERG: All right I'm comfortable. I'm sorry.

CO-CHAIR MOORHEAD: Yes, you're comfortable with no, not your recommending unless -- all right. I'm sensing a no. That's a no. All right it is 3:15. What I recommend is we take a 15-minute break and then we can come back and we can get started on some measures that were scheduled for tomorrow morning so we're ahead of schedule.

(Whereupon, the above-entitled matter went off the record at 3:19 p.m. until 3:38 p.m.)

CO-CHAIR MOORHEAD: For convenience we are going to try to do numbers 36 and then

35, two ED measures. 36 first.

DR. O'CONNOR: Just to read the number this is ACP-036-10. Patients with emergency medicine visit for non-traumatic chest pain that had an ECG. The summary of the conditions for consideration and then moving on to the importance to measure and report. This is a very important measure. You could read some of the summary of evidence but you know the point is that ECG is needed for non-traumatic chest pain in order to make the diagnosis of ST elevation MI which then should lead to a sequence of steps that result in reperfusion so it's an important test to obtain. So I gave it a C for importance.

Opportunity for improvement, there are a number of I guess data, a number of members of the database is what I'm trying to say, it shows there's a performance rate was 78.6 percent which leaves, it means that 21 percent, over 21 percent did not receive an ECG for non-traumatic chest pain so there's a

significant opportunity for improvement so I gave that a C as well.

Under outcome evidence to the support the measure focus I also gave a C. There's a number of national guidelines from either the AHA or ACC that emphasize the importance of the 12 lead in fact it is the only way by definition to make the diagnosis of ST elevation MI.

CO-CHAIR MOORHEAD: What year was this? I forget.

DR. O'CONNOR: Was which?

CO-CHAIR MOORHEAD: They had this 70 percent -- it does not seem --

DR. O'CONNOR: That's under 1b.2. Summary of data demonstrating performance gap variation.

DR. BURSTIN: So because it's claims-based is the question I guess so it requires to be a billing code for the ECG I assume.

MS. RIEHLE: A billing or a --

DR. BURSTIN: Okay and I guess the question is not an ED doc but how often to ECGs just kind of get done in the normal flow of things and perhaps not get charged I guess would be my only question.

DR. O'CONNOR: That is a great question.

CO-CHAIR MOORHEAD: It does happen when ordered by protocol and then for whatever reason the physician doesn't go back and put an order in and you can't bill it. Right?

DR. O'CONNOR: Yes.

DR. COHEN: That is captured by EHRs.

CO-CHAIR STONE-GRIFFITH: So it gets computerized, provide order --

DR. COHEN: Exactly.

CO-CHAIR MOORHEAD: We have --

DR. O'CONNOR: Okay well the problem with documentation I will get to in a minute in this sort of next section. So let's see for evaluation rating, now the scientific

acceptability of the measure properties, this is where --

CO-CHAIR MOORHEAD: Can we catch up with you just for a sec here.

DR. O'CONNOR: Sure.

CO-CHAIR MOORHEAD: So for 1b you gave that a C?

DR. O'CONNOR: For 1b I gave it a C.

CO-CHAIR MOORHEAD: And 1c?

DR. O'CONNOR: C also.

CO-CHAIR MOORHEAD: Okay. And then the overall?

DR. O'CONNOR: It was a C.

CO-CHAIR MOORHEAD: Overall would be a yes?

DR. O'CONNOR: Would be a yes, yes.

CO-CHAIR MOORHEAD: For importance? Okay. Thank you.

DR. O'CONNOR: All right the measure specifications, this is, just for reasons that were just pointed out, I gave this an M because not all 12 leads that are obtained get

charted or billed. In fact many emergency departments, when a patient comes in and says they have any complaint between their you know, I guess their naval and their chin, they get an ECG, pretty much, by protocol and unless those are documented, it may an elusive denominator.

The other part is the numerator by definition does not say whether this is a chief complaint of chest pain or something that's elicited under review of systems. So if it's a secondary complaint there may be some problems with it so for that reason I gave that an M.

Testing and analysis I gave a P. Because the quality assurance should be pretty easily obtained. But the ECG will wind up on the chart if it's performed.

Let's see I'm getting ahead of myself. The validity testing I also gave an M. Under summary of evidence N/A that's 2d. Because there were no exclusions. 2e is also

N/A. The method to identify statistically significant and practically meaningful differences, this is 2f, I gave a C because the measure will allow benchmarking between institutions.

The comparability of multiple data sources I gave a P. And 2h disparities gave an M. Disparities in obtaining an ECG haven't really been described. Overall it was a P for section 2. Usability --

CO-CHAIR MOORHEAD: Are there any comments or sections?

DR. O'CONNOR: Any comments on two?

CO-CHAIR MOORHEAD: Okay. Thank you.

DR. O'CONNOR: Usability, I figured it's something that's easily understood by providers so I gave a C for 3a. Harmonization that's with a number of other measures such as the AMA PCPI measure so I gave a C there as well. Under 3c distinctive or added value, I think this was the analysis described I gave an M. Feasibility -- I'm sorry, overall it's

a P for three.

Feasibility, 4a's a P, 4b P as well, although not all the data necessarily, I mean they're available electronically but unless, it depends what the EMR is, whether the EMR is being used. 4c I gave a C. 4d is P. 4e is C and then overall for 4 is a P.

So I guess just to summarize, I think it's a very good measure. It's can't be overstated how important it is to get an ECG for patients with non-traumatic chest pain. The problem is with identifying the true denominator as well as some problems with the numerator as well. But the true denominator is whether it's chief complaint-based or review of systems-based and the problems with the numerator are just whether or not the cardiogram gets into the billing information.

CO-CHAIR STONE-GRIFFITH: So, Elisa, maybe I have a question for clarification here. We have a measure, an active measure now, 009 I think it's in the document on page

whatever, 17. And so this is essentially, what you just said was that this was harmonized in terms of what we're measuring is harmonized, but we already have a measure both the 009 and the AMA, the PCPI measure. and those were both time limited and are they still, are they both still active? It sounds like from Helen's earlier they got another year added to this to make sure that they could move that into the EHR specifications. Okay. And so what would this new measure add value?

MS. BOSSLEY: Right, so this is a similar one as to what you looked at with the two antimicrobials, so different data sources. So in some way you can actually say, there's a few things you can say, you can say that this measure adds no additional value so don't recommend moving it forward, you can say it does because it is a different data source. There's a few things you can do but it is, this one is administrative claims and less.

MS. RIEHLE: It is. So it would be

in addition to the CPT2 code which the AMA uses. We'd also be using things that are found in claims data, CPT, regular CPT codes, that kind of thing.

DR. JAUCH: So this will be relevant to the next one as well. So you compare the two data sets. Have you actually shown that one is more rigorous or actually captures different data, or are they complementary and essentially part of the same for less or more amount of work? I guess I'm trying to get to the value added for having a different data set.

MS. RIEHLE: Well, I can only speak to using claims data but I know using CPT2 codes with claims data is at this point not very useful because the prevalence of them is less than one percent. They are not used very regularly at this point. So that, just using CPT2 codes alone would not be helpful in determining whether or not an ECG was done in terms of data.

DR. JAUCH: I know, at least for the, and not to steal Bob's thunder, but some of the supplemental information you provide for the syncopes states that 77 percent of patients who have syncopes actually had an ECG done. So I guess my question is are we expecting to capture another 10 percent and beyond that or is there some additive value to using a larger data set?

MS. RIEHLE: That 77 percent was using our benchmark database so that is not using the AMA specification that's using our specifications.

DR. JAUCH: So do you know what the AMA's benchmark showed? I mean do they have 50 percent that were captured, or? I guess I am just trying to get an understanding for the impact of having multiple --

MS. RIEHLE: I know in our data, and I can't speak to this particular measure, but I know in using claims data, the compliance rate that would be picked up by the CPT2 code

would be less than one percent because they are just not commonly used in administrative data at this point.

MS. BOSSLEY: I think what we could do is ask PCPI to provide what they have.

MS. RIEHLE: If they have anything to give you that additional information because it is using different, it's a different data source, different anything. So you could ask for that additional information before you make your final decision. That would be fine. But again, remember, you're not evaluating the one that's endorsed, you're evaluating this new one so it would just be added information to help you make a decision.

CO-CHAIR STONE-GRIFFITH: And the one that is endorsed is manually extracted for the most part.

MS. RIEHLE: What did we have here, if you look at it, we tried to provide the data source to use, so it's electronic data. This is a hard one to read. We've got paper,

administrative claims using category two codes, not just the pure administrative, and then also the electronic health record, so that's how the current one is specified.

CO-CHAIR STONE-GRIFFITH: Okay.

CO-CHAIR MOORHEAD: Bob, do you have an overall recommendation?

DR. O'CONNOR: Yes, I recommend yes for endorsement.

CO-CHAIR MOORHEAD: And your sense is that this would be additive, this would help to have these reported from a different data source, is that it?

DR. O'CONNOR: Yes, my understanding is it just broadens the net of data source and that would be, you know, for the reasons I mentioned before, I think that would be an improvement in terms of the reliability of the data.

CO-CHAIR MOORHEAD: Comments, questions, I'm sorry.

DR. ADAMS: Is there a way to

harmonize the two, vote to approve but then suggest that they --

MS. BOSSLEY: And I would recommend that be one of your conditions, that the two measures be harmonized.

CO-CHAIR MOORHEAD: Bob, is that okay?

DR. O'CONNOR: That's fine. Yes.

DR. ALESSANDRINI: No, but Heidi what would that mean? They'd have to choose which data source that they get to use right?

MS. BOSSLEY: What's happened in the past is in essence the measure that's endorsed is kind of the standard that then the other developer must show how they have or have not harmonized, given two different data sources, they may not be able to completely, but they need to provide that information back.

DR. ALTERAS: But if Ingenix were to harmonize with the AMA measure what would be the point of the Ingenix measure? I mean wouldn't it be, I just, is it just changing

the age or?

MS. BOSSLEY: No it would be harmonizing all the different aspects. You may collect it differently using category one codes from CPT and they may use CPT 2 but the age should be the same, you should be capturing similar visits, it should be the same ECG coding, that type of thing, to the extent possible.

DR. ALTERAS: Yes, that helps. I just, isn't there, there's a whole process going on now at NQF where you're having technical experts compare measures that are similar, practically the same measure, I mean I just feel like this is a case where that would have to happen before this could be endorsed, almost. I mean, I don't know that we would, you know. The last steering committee I was on there was a huge discussion over having two very, very similar measures on the books and then some providers using one, other providers using a different one, and you know,

whichever one suits, whichever one makes the most sense to them, whatever way you want to interpret that. So I just worry, you know, recommending this one for endorsement is just going to raise a lot of questions like what do we do with this once it's endorsed, why do we want to have two on the books?

MS. BOSSLEY: Well and I think you all need to decide whether you feel that by having two different measures using two different data sources is the way you feel it should be out there for the public to use for public reporting. I think that's what you all need to do. That's the question you need to answer. If it's not enough then you should say no. It's a little hard I know because you don't have testing results on the other one so it makes it very hard to make a really honest, good comparison. But unfortunately that's where we are right now. But we can ask PCPI to provide what they can, if they can provide. They may be able to provide some PQRI data or

something that would give you a little information. But it is, I mean it's difficult, but that is the question. Then it will go to the CSAC and they will decide whether or not, and the membership and everyone else, whether they agree with what your recommendation was.

DR. ALTERAS: Yes. I mean personally I feel, since there's already an endorsed measure on this, maybe this is irrelevant, I feel like ECG is, should be standard practice, so I have that issue with the measure in the first place. But second I just wouldn't feel comfortable recommending until we see the testing from AMA because I can just hear all the arguments down the line and you know, someone who works on all the comments and voting, I get all, I get lots of comments back. So --

CO-CHAIR MOORHEAD: So one of our options then would be to ask AMA for the data and then we could vote on this in a conference call or whatever. Jeff I think you were first

and then --

DR. JEFFREY COLLINS: I just am throwing this out, this would be an expectation in an urgent care setting also so I was just wondering if there was a reason why we were just saying emergency departments versus emergency departments and urgent care centers also.

CO-CHAIR MOORHEAD: Can you answer that?

MS. RIEHLE: I have to check that. I thought it did apply to urgent care but I would have to check.

CO-CHAIR MOORHEAD: I think it's just emergency.

DR. O'CONNOR: It's just emergency department.

MS. RIEHLE: Yes, we're using a code set that is defined by CMS but I mean we would be willing to entertain having the urgent care. If that was thought to be important then you could definitely take that to our

consultant panel and talk to them about that.

DR. CHALIAN: I had a question whether as NQF or any other organization that we could role model ourselves after has studied the way the consumer looks at two similar guidelines. Or a social scientist telling us what happens when you put conflicting or nearly similar however they're viewed out there. Or if it's an opportunity to study it.

DR. ALTERAS: Well I haven't done any research on this but it's confusing, I mean, this stuff is confusing to begin with for consumers and if you were to put two different measures up somewhere, the thing is, you know, a hospital wouldn't use both measures. They would use one or CMS would only use one so the only question is which one if there are two endorsed and I'm all for progress in measures and having the best one out there so I'm not saying that once there's an endorsed measure there should never be

another one brought up, but it's þ-

DR. O'CONNOR: I mean one argument to support that is under section three, it really does call for harmonizing this measure with the existing 009 and I think the difference is you've got an additive value in terms of more robust claims data and just so that everyone understands, I don't know if I said that very clearly, it's essentially basic codes, population, time frame etc as the existing code the difference is the expansion of the data set to avoid some of the problems with the numerator that we talked about earlier. If you look at section 3c it's pretty well described there.

CO-CHAIR MOORHEAD: So your recommendation is to support this with a request for harmonization?

DR. O'CONNOR: Yes.

CO-CHAIR MOORHEAD: And there's some thought about asking AMA first what their numbers are and there's some other thought

that there's some other thoughts, so -- the recommendation on the table is to support with a request for harmonization. Any comments?

DR. EISENBERG: Just for the ER?

CO-CHAIR MOORHEAD: This is just for the emergency room or we can make a recommendation that, was that a sense from urgent care that you would like this added or not? You would like this added. Like if we support this we'd like to request that this go back and your group would add on urgent care. Can we do that?

MS. BOSSLEY: Well typically yes, but you do have another measure that is endorsed but is not for that population so we would have to figure out if we could then go back to a developer even though it's an existing measure and do that. I don't think we've done that before. So we'll have to think through that one. Because then you don't have a harmonized one.

DR. JEFFREY COLLINS: Can't we

tackle it later for urgent care because we have enough on our plates.

CO-CHAIR STONE-GRIFFITH: Well on page 13 of 31, and now we're talking about 2a.36/37 care settings, it does not say there just emergency department. It lists -- page 13 of 21 on this measure. Ambulatory care clinic, ambulatory care emergency department, ambulatory care hospital out-patient, long-term acute care, nursing homes rehab. So do we need to get clarification of the care setting?

MS. RIEHLE: I will probably have to take a look at the specific code set. It's a CMS defined code set and it may include those codes. It's just, it's given kind of a --

CO-CHAIR MOORHEAD: Because up above the codes are all just --

CO-CHAIR STONE-GRIFFITH: Right, but they're not consistent with the care settings.

DR. EISENBERG: This measure has no time limitation on it. It's not a 10-minute measure which would be very difficult to do in

all of those other settings. I mean it was done or it wasn't done.

MS. RIEHLE: It actually gives you 24-hour leeway which I know is pretty generous but in claims data, you can't you know, look --

DR. EISENBERG: Yes, you just have a date. But if you did it at 11:45 at night, 24 hours ends in 15 minutes.

MS. RIEHLE: Well so we're not doing it by date, so let's say you present on the 2nd of the month into the ER, we look for a chest x-ray either on the 1st or the 3rd as well as the 2nd.

CO-CHAIR MOORHEAD: It seems to me that if we supported this with a request for harmonization it's implicit that it would be restricted to ED use only because that's the other codes, the other measures, is only for the emergency room.

MS. BOSSLEY: The other thing you can say too is when these measures come back

up you would like to see it expanded I think that's the other piece that we can include in a report and a recommendation.

CO-CHAIR MOORHEAD: Well the other one is coming up for, it says maintenance scheduled 5/1/2--, oh this got another year. It's coming up next month.

MS. BOSSLEY: So we should be getting it hopefully in the next few weeks.

CO-CHAIR MOORHEAD: So that would be the other option, is this is coming up in a few weeks.

DR. CHALIAN: Do those other sites that are listed actually fit more into your description of if the x-ray or I mean the ECG prior to leaving the ambulatory care or the nursing home on your way to the ER, you know some of the patients arrive with the ECG in hand and allows you to capture that because it would have been coded at that other site and it doesn't imply a defining practice at the other site.

CO-CHAIR MOORHEAD: Is that a statement or a question?

DR. CHALIAN: I guess I'm trying to clarify how you could, the question was should this apply to ambulatory sites that are not ED s and the question was how can you list all those sites if you're not implying that the behavior should occur there. My perspective was maybe those tests are being done there so this was their approach to capture the codes, the billing code, that would allow you to know the ECG was done there and not ding the ER for not having billed it because they actually have the ECG now.

CO-CHAIR MOORHEAD: I would think probably in practice it gets redone when it gets to the ED anyway so I think -- But you're looking for changes, so --

DR. JEFFREY COLLINS: Right.

CO-CHAIR MOORHEAD: I'm hearing a couple of different thoughts here. Potentially a request that this be part of their review

that's coming up for the 090 code, request to approve with the recommendation for harmonization, there's a couple of different ways to do this. Not to support it.

DR. CHALIAN: Going back to one of the prime points of how much confusion do we generate with two of these, my perspective would be that it would be ideal to have one recommendation or guideline on something so significant in terms of importance.

CO-CHAIR STONE-GRIFFITH: I'm looking back at one of the appendices and of course it talks about NQF 090 strictly electrocardiogram performed for non-traumatic chest pain. That's the one that we really harmonize. But when you start talking about ECG and other spaces, there's 0289 which came out in the ED transfer measures. Again it's different specifications but it's around obtaining ECG with AMI and chest pain. You also have it on your AMI core measures that we are publicly reporting as well so it's like

how many times and how many ways can we measure ECG? And is there really an opportunity to refine all of those?

DR. CHALIAN: Do these other measures meet the need to measure it, I mean do these other groups measure it adequately that we don't need to measure it?

CO-CHAIR STONE-GRIFFITH: Well, the ones, the 0289 is getting ready to go to hospital compare this year, right, June? Isn't that right? That'll be the first time it'll be reported. They've been collecting it for over a year now, hospitals have. I agree that this is very important. I am concerned with the number of ways that we are slicing the information to measure. Are we getting an ECG for appropriate cardiac-related complaints. And then to couple that I think we have the very setting the very settings that now we are saying well, it's important -- urgent care is important in the ED, where else might it be important?

CO-CHAIR MOORHEAD: So is your thought recommend that this be reviewed as part of the review this year? Or could this be considered as part of the 090 review that comes up with the 08s?

CO-CHAIR STONE-GRIFFITH: Right, I guess my recommendation would be that this should go back for further review and harmonization with what's coming up in May and to look at the other measures. I mean I guess what I heard Helen say earlier is we cannot have a new measure harmonized with an existing measure. Existing measure stands the way it is. So we have two measures that are out there, is that right -- being measured currently with specifications and reported so they are what they are so the only thing we can do is say this, we could recommend that this would be better or --

MS. BOSSLEY: I think the real thing would be it brings additive value because it's a different data source. That's really what I

think the question is before you. We can, the issue is, this is why this new maintenance process will make this much easier and you won't have to have this question to deal with again. Because in the review that will occur in the next few months on the existing measure, it really is looking at the testing and doing the full evaluation. Now they may look at, if this measure is in the process then you look at it, but again, the measure you have before you will not have gone through the whole process. So it's going to be a little messy.

So the key question I think that we need to have your input on is should this measure be harmonized with the existing one, does it bring additive value, and if so you're recommending to move it forward, and you still have member and public comment to get back and that can be a question that we specifically pose during the comment period to get input on and that may be what helps you make a final

decision.

In the meantime hopefully we'll have the testing information for the existing measure and that again may be helpful to you as you move through the process. This is a tough one.

CO-CHAIR MOORHEAD: Any thoughts?

DR. O'CONNOR: Just going back to my initial read of this, it was my understanding that this would replace the existing or somehow supplant it and given that information I think we need to consider this somewhat more carefully because the two measures in place could get you very different data.

CO-CHAIR MOORHEAD: A motion to consider carefully. With harmonization.

DR. O'CONNOR: I mean do we table this or --

CO-CHAIR MOORHEAD: Well our choices are to approve, to recommend this, we can ask for more information including the AMA information, public comment on having to

measures to get the public through that process and basically defer our recommendation until we get that. Or we can recommend that this just be included as a part of the review of the 090 and that that process could consider the same information could go to that group. Could we gather that information and somehow that would be then available through the 090 review?

MS. BOSSLEY: What will happen in the 090 review is looking at the testing information that's been put forward, that's it. And then that measure will either have endorsed and continue or not, and the time limited will be removed or not.

CO-CHAIR MOORHEAD: Okay.

MS. BOSSLEY: At that point in time it's not planned to have a full review of every measure that falls within the ED setting or with this specific aspect of care so that's where, it would be nice if we could do that because then you can just defer it.

Unfortunately you can't. Maybe the thing to do is to see what Elisa and I can get in the way of more background information, ask Ingenix to provide a little bit more information, harmonization, then you have a call coming up. Table it for right now, get you what we can and have you consider it again. Sounds like if we can get more information maybe you can make a more informed choice.

DR. JAUCH: So if the other one went forward and was approved, at what point then would there be the opportunity to harmonize and now a new approved measure and this one is being considered?

MS. BOSSLEY: Right, so we would first be right now asking Ingenix to harmonize with the existing endorsed measure. Hopefully there are no changes to the existing endorsed measure based on testing. But if there was then we would probably have a conversation with both developers and say we need to yet again do a little bit more harmonization. So

it may be two steps. It's not clean but that will probably be what it is.

CO-CHAIR MOORHEAD: So potentially we can defer this and gather more information. Would that be helpful in terms of making a decision or do you have enough information at this point?

CO-CHAIR STONE-GRIFFITH: And as part of that we want to validate the setting as well, is that right?

MS. BOSSLEY: Right. We will confer with both developers setting, yes.

DR. O'CONNOR: I would change my recommendation to table given that.

CO-CHAIR MOORHEAD: Is that okay with you? All right. Thank you. We will look forward to that, with harmony. Number 35.

DR. JAUCH: So 35, you can just basically leave 36 off and cut and paste syncope for chest pain. It really is. It's almost of comparable importance in the emergency setting, comparable prevalence in

the emergency setting as well as similar need probably to harmonize an endorsement that's in existence and it looks like will be also reviewed in the next month. So we can table this for --

We will go through this very quickly. I am not sure if I have a co-author or not. This obviously is an Ingenix supported measure looking at the use of ECG in the setting of syncope. This one is a little bit different in that it's an age group greater than the age of 60 so it makes it a little bit easier.

They do provide significant supporting data that this is an important metric including ASEP's position that all patients should receive an ECG in the setting of syncope. It's also part of the European cardiology society's recommendation for this and has now also been part of the NQF process for the last couple of years.

They do a test of the prevalence of

this disease and the potential ability for an ECG to identify life-threatening illnesses and again using their database Ingenix has shown that there is a compliance rate based on that recommendation from ASEP of 77.5 percent. A clear gap and opportunity for care improvement.

So with 1a I said that is fairly complete. For 1b opportunity for improvement, again, you know, it depends upon not knowing what you're missing, but I think it's certainly partial so I gave 1b a P. There's no mention of data on disparities. 1c I think is fairly complete but there are several bodies who give this overall evidence to support such a measure I gave that a C.

And so regarding was the threshold criterion for importance to measure and report met and I said yes especially in the age group that they are going to sub-select which is greater than 60.

And then we get the same number of

codes from before in terms of the numerator, again largely this is a little bit different, I think, and I don't obviously know all these codes. This is, I develop pseudo-seizures when I see things like this, but the appropriate codes are there so I gave that an M.

Regarding reliability I gave that a partial. Regarding analytical method again it's a little difficult but I think they showed that there's an 11 percent error rate and from chart review it approaches five percent so I gave that a P.

Exclusion criteria are largely again based solely on age otherwise there are none. And that's N/A for 2d. 2e similarly there is no risk adjustment in that so it's an N/A. For 2f let's see, now I have to harmonize with my paper copy. Comparability of multiple data sources and methods, again, that's N/A, we don't have what another data set would show.

Disparities in care, there are none

recorded here so that's an N/A. And I think overall the scientific acceptability of measure properties is met, I gave that a P.

Continuing with 3, in terms of data sample, from what they provided, I gave that a P. They don't have access to some of the reports but I think that what they proposed is reasonable. Regarding 3b, harmonization, this gets to not knowing what the other measure exactly states and some of the results that we'll have with the existing NQF measure which is up for review in June of this year. I gave it a P. Similarly we have the same issues as Bob mentioned about the endorsed AMA PCPI measure so I think once we get more information on that we'll have a better understanding of the harmonization potential. I gave that a P.

3c, for distinctive and additive value, again, without not knowing the exact information as contained in the two data sets and how they compare and contrast, I gave that

a P. I think that was probably generous.

And then again the overall usability criterion I gave a P for that. So again it would be very helpful to have, to be able to compare and contrast, the two data sets and the results thereof.

Regarding feasibility, they provide a little bit there regarding the coding abstraction performed by someone other than the person obtaining the original information. They have an electronic data source so I gave that an M for 4a and a c for 4b.

Regarding exclusions, there are none other than age less than 60. Susceptibility to inaccuracies, this is again inherent in their data sets and I'm not sure what their overall error rate, they've quoted five percent before so I really think it's really complete and I don't anticipate any great problems with inaccuracies.

Evidence of cost, this is all electronic, this is not going somebody else to

be hand extracting data from case report forms so I gave this a P. And overall, regarding the feasibility I gave that a P. But again we don't have any demonstration provided here but I think it's reasonable to expect that to be a P.

So similar to what we just heard regarding the issue of ECG s in a setting of non-traumatic chest pain I also view that this is an extremely valuable metric that we should be tracking, not only in the emergency department setting but also in other urgent care settings and perhaps other venues.

But the same caveats are held with the existing NQF guidelines or measure, performance measure as well as the one with the AMA and I think additional information will be very helpful in our ability to make a recommendation, certainly mine. So at this time I don't have a yes or a no. I have a waiting to be seen.

CO-CHAIR MOORHEAD: Thank you. We

don't have a secondary, any comments or questions?

DR. ALESSANDRINI: I just -- and I think it was probably the last time we did this and maybe I was tired of saying, this is relevant to people younger than 60. And I would just be very interested in hearing what other individuals in the room that you know, care for children and adolescents and young adults, but I think certainly this -- and I don't recall, I think it might have been last year, or two years ago or whatever, we had here that the steering committee felt that you know, vasovagal syncope doesn't require it.

DR. JAUCH: So their reference to Steve Huff's paper from ASEF were there was not an age specification nor is there one in European society of cardiology. It was the AMA one that had less than 60 would have started to include a fair number of vasovagal events that they were concerned about being compounders.

If you have somebody who has a clear, precipitating event, vasovagal event, and they really need an ECG, and whether or not they should be put in the same metric with patients who are over 60 where cardiac causes would be far more prevalent. So granted it's a problem it's just, do you lump them all together and say 90 percent is a good thing, or do you take subsets and say within the elderly everybody should get one, under 60, some proportion should get one, I think they were trying to make it a cleaner -- my interpretation is they were trying to make it a cleaner assessment.

CO-CHAIR MOORHEAD: You have a recommendation to defer.

DR. JAUCH: So recommend.

CO-CHAIR MOORHEAD: That's what I hear your recommendation and I'm seeing people agree. So we will go through the same process if that's okay. All right. I think we are at quitting time almost. We do need an

opportunity for public comment.

MS. MUNTHALI: I don't think we have anyone on the line. We don't. So we're also going to save the recap until tomorrow morning because we went through a lot of information today and we are fearful that we may all forget so we will have a detailed recap tomorrow morning before we start and we'll continue with the emergency department measures.

And I just wanted to remind everyone who presented if you have your hard copies of your evaluation results if you could turn those in, and if you have them by ecopy you can email those to us.

And thank you guys for today and see you tomorrow. Enjoy dinner.

CO-CHAIR MOORHEAD: So we have --

(Whereupon the above-entitled matter went off the record at 4:23 p.m.)

P

Q