

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, CNA, MSN, CO-
CHAIR

JAMES ADAMS, MD

EVALINE A. ALESSANDRINI, MD, MSCE

TANYA ALTERAS, MPP

ARA CHALIAN, MD, FACS

VICTOR COHEN, BS, PHARM, BCPS, CGP

BEVERLY COLLINS, MD

JEFFREY COLLINS, MD, MA

ANDREW C. EISENBERG, MD, MHA, FFAFP

WANDA GOVAN-JENKINS, RN

EDWARD JAUCH, MD, MS

LEIGH ANN MCCARTNEY, RN, MBA

NATHAN NEWMAN, MD, FFAFP

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

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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

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

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

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

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

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

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

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

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

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

1 geriatrician.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 MS. WEBER: I am Jessica Weber.

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

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

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

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

4 CO-CHAIR MOORHEAD: Well, I hope
5 everyone had uneventful travel. I am told some
6 of you guys sat on the runway in Chicago last
7 night for four hours while we got lightning
8 and some thunder and then the captain came on
9 and said, "Well, one of our indicators says we
10 have enough gas to get to Washington.
11 Unfortunately the other one says we are going
12 down in the Great Lakes. We all thought it
13 would be a good idea if we just checked that
14 out before we took off," so we pulled in about
15 2:30 this morning so, if I fade, Suzanne is
16 going to prop me up over here I know. He was
17 a very active captain, he went out and shut
18 the door and he was doing all these things
19 himself. I was pretty impressed actually. Nice
20 man.

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

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

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

11 MS. MUNTHALI: That's okay.

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

1 of overview of the project and help us get
2 going.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 to harmonize measures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MS. MUNTALI: Great. I just wanted
14 to talk a little about the measures that we
15 received. The steering committee will evaluate
16 27 candidate measures related to emergency
17 department and general urgent care, pediatric
18 ENT, urgent care, and procedures especially,
19 specifically endoscopy. Nearly 75 percent of
20 those measures are untested and may be
21 eligible for time-limited endorsement.

22 We handed out an attachment with

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

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

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

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

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

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

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

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

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

5 So those are the similar measures,
6 similar measures that are competing head-to-
7 head, measures that we received during this
8 project and similar measures, measures that we
9 received that are competing with currently
10 endorsed NQF measures.

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

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

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

3 DR. BURSTIN: We just sent her a
4 note.

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

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

16 CO-CHAIR STONE-GRIFFITH: Elisa?

17 MS. MUNTHALI: Yes.

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

1 Others have already passed, they came up in
2 2009. What became of them? Were they re-
3 endorsed for another time limited? How would
4 we know that?

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

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

1 data platforms.

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

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

14 CO-CHAIR STONE-GRIFFITH: Not yet.

15 DR. BURSTIN: Right.

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

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

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

9 CO-CHAIR MOORHEAD: Okay.

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

22 So we can't actually reduce the

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

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

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

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

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

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

1 mentioned.

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

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

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

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

1 is usually that the first one takes twice as
2 long as everything else so you should expect
3 90 minutes for the first one. I've been doing
4 this for about three years now. It's pretty
5 consistent and then it drops by about half at
6 that point. Again, we can do this some of this
7 work virtually. We'd like to get through as
8 much of it as we can again today. There's a
9 lot of similar measures so that usually makes
10 it move more rapidly as well.

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

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

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

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

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

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

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

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

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

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

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

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

19 DR. CHALIAN: Actually I have no
20 disclosures.

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

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

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

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

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

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

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

22 CO-CHAIR MOORHEAD: You haven't

1 worked with Suzanne I guess.

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

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

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

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

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

1 settings.

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

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

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

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

3 The big opportunity to avoid
4 inappropriate care here is with the systemic
5 antimicrobials. It's almost a reflex action in
6 many, certainly primary care offices and I
7 suspect in certain emergency departments and
8 urgent care settings as well that you show up
9 with otitis externa and you are given
10 amoxicillin or some other oral antibiotic,
11 often in combination with a topical product
12 just to cover all the bases, the problem here
13 being that number one, the oral antibiotics
14 are completely ineffective for the
15 overwhelming majority of otitis externa, which
16 is caused mostly by pseudomonas aeruginosa
17 and to a lesser extent staph aureus, both of
18 which, particularly pseudomonas, escapes the
19 overwhelming number of oral antimicrobials
20 that are given and more importantly the
21 adverse events and adverse effects of systemic
22 antibiotics, both in terms of common things --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 DR. JEFFREY COLLINS: Thank you.

16 DR. ROSENFELD: Okay? Thank you
17 very much.

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

21 CO-CHAIR MOORHEAD: Yes?

22 MS. MUNTHALI: Ann Hammersmith is

1 here and so we will turn it over to her to
2 lead the disclosures of interest. MS.

3 HAMMERSMITH: Can you hear me now? Hi, I am Ann
4 Hammersmith, I am NQF's general counsel. Sorry
5 I am late, I was in another meeting. What?

6 DR. BURSTIN: You were early.

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

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

1 Association.

2 MS. HAMMERSMITH: Thank you.

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

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

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

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

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

18 MS. HAMMERSMITH: Okay.

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

1 those were the two.

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

11 MS. HAMMERSMITH: Okay, thank you.

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

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

9 MS. HAMMERSMITH: Okay thank you.

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

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

1 MS. HAMMERSMITH: Thank you.

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

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

1 court reporter.

2 DR. JAUCH: That was a joke.

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

5 MS. HAMMERSMITH: Thank you.

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

22 MS. HAMMERSMITH: Thank you.

1 DR. JEFFREY COLLINS: Jeff Collins
2 from Mass General. I am on the board of
3 directors for the Urgent Care Association of
4 America. I am on the board for the Foundation
5 for Urgent Care Medicine. I am on the
6 editorial board for the Journal of Urgent Care
7 Medicine and I serve on the Primary Care
8 Executive Council for the Mass General.

9 MS. HAMMERSMITH: Thank you.

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

20 MS. HAMMERSMITH: Okay. Thank you.

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

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

11 MS. HAMMERSMITH: Okay. Thank you.

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

19 MS. HAMMERSMITH: Okay. Thank you.

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

1 MS. HAMMERSMITH: Thank you.

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

11 MS. HAMMERSMITH: Thank you.

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

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

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

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

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

1 12 years with a diagnosis of otitis media with
2 effusion who received tympanostomy tube
3 insertion who had a hearing test within six
4 months prior to the tympanostomy tube
5 insertion.

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

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

22 And I had questions about how many

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

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

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

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

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

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

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

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

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

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

1 I see.

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

6 DR. BEVERLEY COLLINS: No, I just
7 got a simple listing off their website and it
8 says retired from PQI effective January 1,
9 2010. Analysis of 2007 and 2008 PQI results
10 indicate there was a lack of significant
11 reporting and usage was not considered. Maybe
12 this will come up again in the feasibility,
13 but is there a burden here of going back and
14 checking patient files?

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

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

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

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

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

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

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

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

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

22 And the rationale for using the

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

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

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

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

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

3 DR. BURSTIN: He was the seconder.

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

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

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

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

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

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

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

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

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

1 surgery.

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

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

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

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

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

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

22 MS. MUNTHALI: Would anyone from

1 PCPI like to respond to any of these
2 inquiries?

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

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

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

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

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

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

1 before the surgery, is really the issue here.

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

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

1 well.

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

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

22 DR. ROSENFELD: I believe it refers

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

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

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

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

3 CO-CHAIR MOORHEAD: Any other
4 comments?

5 DR. ALESSANDRINI: I think this is
6 a really tough one because the impact is
7 great, you know, the prevalence is high. If
8 not treated well, language disability is
9 significant from patient-centered perspective.
10 The hard part is I think what we really want,
11 the evidence is lacking, and so you know, but
12 I agree it's hard to move beyond this point
13 because it seems like we're not really getting
14 to what we want. I just don't know that if in
15 2010 we have the evidence to get really where
16 we want to get. We certainly see a large
17 degree of practice variation but when we look
18 at the evidence it's not great.

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

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

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

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

1 group.

2 CO-CHAIR MOORHEAD: Ara.

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

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

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

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

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

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

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

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

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

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

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

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

1 for consideration.

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

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

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

8 CO-CHAIR MOORHEAD: Anyone else?

9 Well I guess this is as much philosophical in
10 terms of approach, because I think there's
11 agreement that the evidence isn't there, and
12 we either want to push this or we don't, so I
13 guess we need a sense of the committee, a vote
14 on the importance issue here in order to move
15 ahead. So Beverly your recommendation is not
16 to move ahead on this one.

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

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

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

9 DR. JEFFREY COLLINS: Right now?

10 DR. BURSTIN: Sure.

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

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

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

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

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

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

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

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

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

22 DR. BEVERLEY COLLINS: Okay again,

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

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

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

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

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

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

22 CO-CHAIR MOORHEAD: Would you like

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

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

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

14 CO-CHAIR MOORHEAD: Okay.

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

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

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

8 DR. BEVERLEY COLLINS: Less than 90
9 minutes.

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

13 DR. CHALIAN: That's me.

14 CO-CHAIR MOORHEAD: All right.

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

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

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

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

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

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

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

1 40 percent of patients had received oral
2 antibiotics and topical antibiotics (topical
3 preparations) so there's a degree of over-
4 prescribing of oral antibiotics. And the
5 references were both from Pediatric Infectious
6 Disease and from family practice literature.
7 So in terms of this initial part of the
8 importance, I felt that there was complete
9 justification of the importance of this
10 process, improvement and measure.

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

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

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

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

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

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

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

12 DR. CHALIAN: Sorry.

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

1 really sure where it fits in.

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

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

1 impact on a patient, to coordination of care.

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

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

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

12 DR. ALESSANDRINI: You see a lot of
13 it.

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

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

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

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

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

18 CO-CHAIR MOORHEAD: Now that would
19 be important.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 clearly specified.

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

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

19 CO-CHAIR MOORHEAD: Jeff?

20 DR. JEFFREY COLLINS: Same.

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

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

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

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

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

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

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

15 And since we are really trying to
16 track the outliers and affect that number and
17 show success, I think I would rather see that
18 number be driven down to zero, like the zero
19 tolerance, and see the other number go up to
20 100 percent and then, that way, you would also
21 not have that overlapping prescription issue
22 to discern.

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

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

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

7 CO-CHAIR MOORHEAD: Okay.

8 DR. CHALIAN: What about patients
9 with tympanostomy tubes?

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

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

19 DR. ROSENFELD: Sure.

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

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

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

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

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

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

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

7 DR. JEFFREY COLLINS: I just wanted
8 to probe one clinical wrinkle in here, as
9 someone who sees this a lot like down in
10 Florida. A lot of times what happens is you're
11 looking at a goopy ear and so you can't
12 distinguish between an acute otitis with a
13 rupture and otitis externa necessarily. I've
14 never prescribed Floxin Otic because it costs
15 80 bucks and so all I use is corticosteroid.
16 Oflox you can use for a perforate TM if you're
17 not sure of your diagnosis and in that case
18 what ends up happening with a lot of our docs
19 is you do stick them on an oral antibiotic and
20 a topical agent so it's a difficult clinical
21 case sometimes, just to throw it out there.

22 DR. CHALIAN: And then in terms of

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

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

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

1 about that? Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

22 DR. ALESSANDRINI: And in terms of

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

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

13 DR. ALESSANDRINI: Right.

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

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

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

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

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

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

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

9 DR. ALESSANDRINI: Not getting oral
10 antibiotics.

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

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

18 DR. BURSTIN: That is a different
19 measure.

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

22 DR. CHALIAN: Oh, for this measure

1 it's topical, correct.

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

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

13 CO-CHAIR MOORHEAD: Yes. The
14 overall too.

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

18 DR. BURSTIN: CPM would be good.

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

21 DR. BURSTIN: Minimally focused.

22 DR. CHALIAN: Yes. And then for

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

3 DR. BURSTIN: Overall?

4 DR. CHALIAN: Overall.

5 DR. BURSTIN: What's your overall?

6 DR. CHALIAN: Oh, yes with
7 conditions.

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

10 DR. CHALIAN: Abstain?

11 DR. BURSTIN: Abstain.

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

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

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

1 feasibility.

2 DR. BURSTIN: Were there also
3 exclusions?

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

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

16 DR. JEFFREY COLLINS: Yes.

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

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

3 CO-CHAIR MOORHEAD: Pardon me?

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

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

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

13 CO-CHAIR MOORHEAD: Thank you.

14 DR. BURSTIN: You are welcome.

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

19 DR. ALESSANDRINI: I was opposed.

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

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

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

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

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

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

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

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

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

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

15 DR. CHALIAN: So it's reasonable.

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

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

4 DR. ADAMS: Yes, sorry.

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

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

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

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

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

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

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

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

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

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

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

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

22 DR. ALESSANDRINI: I think it just

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

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

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

1 for the record.

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

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

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

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

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

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

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

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

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

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

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

1 I gave the evidence a partial for importance.

2 CO-CHAIR MOORHEAD: Okay.

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

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

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

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

18 CO-CHAIR MOORHEAD: Just so we have
19 those.

20 DR. JEFFREY COLLINS: Yes.

21 CO-CHAIR MOORHEAD: 2a.

22 DR. JEFFREY COLLINS: So for 2a I

1 had complete. In terms of reliability I had
2 complete.

3 CO-CHAIR MOORHEAD: So 2b is
4 complete.

5 DR. JEFFREY COLLINS: Yes. 2c,
6 complete. And exclusion justification 2d,
7 complete, and risk adjustment for outcomes,
8 2e, complete, and again that's based on just
9 numerator and denominator.

10 DR. BURSTIN: You are right,
11 denominator is one part of it, but there's no
12 reliability in testing so all those subsequent
13 2s would be, you know, minimally or none.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 DR. BURSTIN: Okay. Got it.

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

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

3 DR. ALESSANDRINI: I believe that
4 is mine.

5 CO-CHAIR MOORHEAD: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

22 So overall I gave that an M, that

1 section 2, scientific acceptability an M.

2 CO-CHAIR MOORHEAD: Nathan?

3 DR. NEWMAN: I am in agreement.

4 CO-CHAIR MOORHEAD: Thank you.

5 DR. ALESSANDRINI: Usability. So

6 again that's another measure that's reported
7 to be currently in use however we have no data
8 on how the measure is being used. A project is
9 under way called cost savings from avoidance
10 of inappropriate use, an application of AOE
11 and OME, but no data so again that's an N for
12 3a. Harmonization, there needs to be
13 harmonization with the multiple measures
14 submitted by this group but it's not commented
15 on in the specs sheet here, so that would be
16 an N and distinctive or additive value for 3c,
17 I gave that an M. There's nothing commented on
18 here, but I do think thinking about the
19 totality of the acute otitis externa measures,
20 this one is probably one of the more important
21 ones.

22 So the total score for section 3

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

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

10 DR. NEWMAN: Yes.

11 CO-CHAIR MOORHEAD: So the overall?

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

15 CO-CHAIR MOORHEAD: Nathan?

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

1 are competing.

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

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

10 CO-CHAIR MOORHEAD: Nathan any
11 comment?

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

17 CO-CHAIR MOORHEAD: A P for which
18 section?

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

21 CO-CHAIR MOORHEAD: Section four?

22 DR. NEWMAN: Yes, for section four.

1 CO-CHAIR MOORHEAD: Okay. And --

2 DR. NEWMAN: But overall as a yes.

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

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

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

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

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

12 CO-CHAIR MOORHEAD: Any other
13 questions or comments?

14 DR. CHALIAN: I have a question.

15 CO-CHAIR MOORHEAD: Yes.

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

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

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

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

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

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

10 CO-CHAIR MOORHEAD: Any sense from
11 the group?

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

15 CO-CHAIR MOORHEAD: Why don't we do
16 32, then we'll get our lunch, then we'll come
17 back and talk about these as a group if that's
18 okay. Okay?

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

1 prescribed systemic antimicrobial therapy. The
2 description is the same, two years and older
3 with acute otitis externa who were not
4 prescribed systemic antimicrobial therapy.

5 Again a process measure focused on overuse and
6 so, in reality, if we looked going back down
7 at the importance to measure and report -- let
8 me give you the numbers -- 1a is an M, this is
9 the same as the last one 1b is an M, 1c is a
10 P and you know, overall, the threshold
11 criterion for importance is met.

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

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

1 --

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

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

7 DR. CHALIAN: Right, I agree.

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

13 CO-CHAIR MOORHEAD: Nathan, are we
14 okay?

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

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

20 DR. NEWMAN: Yes.

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

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

12 MS. BOSSLEY: Try page 416 and 415.

13 DR. ALESSANDRINI: Thank you.

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

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

13 CO-CHAIR MOORHEAD: Nathan?

14 DR. NEWMAN: Yes, I agree.

15 CO-CHAIR MOORHEAD: Okay.

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

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

5 CO-CHAIR MOORHEAD: Nathan?

6 DR. NEWMAN: P.

7 CO-CHAIR MOORHEAD: P?

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

12 CO-CHAIR MOORHEAD: Okay.

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

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

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

8 CO-CHAIR MOORHEAD: Okay.

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

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

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

20 CO-CHAIR MOORHEAD: Nathan?

21 DR. NEWMAN: Yes.

22 CO-CHAIR MOORHEAD: Okay. Any other

1 comments or questions?

2 DR. ALTERAS: Can I ask you a
3 question. It's not about the measure
4 specifically, but I'm just wondering, is there
5 any concern that having a measure like this --
6 and I'm all for overuse measures, that's one
7 of the big things that we are advocating for -
8 - is there just any concern that perhaps in
9 cases where antibiotics are warranted, that
10 they wouldn't be prescribed out of concern
11 that a doctor would be dinged for doing it and
12 --

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

1 percent of them probably need them.

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

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

12 DR. BURSTIN: Yes.

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

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

19 CO-CHAIR MOORHEAD: Is anybody on
20 the phone?

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

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

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

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

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

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

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

6 DR. CHALIAN: Maybe we could have a
7 composite.

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

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

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

3 CO-CHAIR MOORHEAD: So it would be
4 a recommendation from the committee to look at
5 --

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

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

12 CO-CHAIR MOORHEAD: Yes.

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

16 CO-CHAIR MOORHEAD: Okay.

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

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

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

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

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

22 DR. BURSTIN: Again, you would

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

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

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

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

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

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

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

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

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

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

18 CO-CHAIR MOORHEAD: Other thoughts?

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

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

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

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

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

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

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

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

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

7 DR. ALESSANDRINI: Right. Right.

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

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

13 DR. JEFFREY COLLINS: Right.

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

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

8 DR. ALESSANDRINI: I think they are
9 as well.

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

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

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

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

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

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

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

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

3 DR. CHALIAN: Sorry, Tanya.

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

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

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

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

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

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

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

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

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

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

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

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

1 got oral antibiotics?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 DR. BURSTIN: Yes, good.

1 CO-CHAIR MOORHEAD: -- more
2 accurately discussing.

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

5 DR. BURSTIN: That is your
6 decision.

7 DR. JEFFREY COLLINS: Oh, okay.

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

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

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

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

21 CO-CHAIR MOORHEAD: Okay. Anyone
22 else?

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

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

1 intervention was at least noted.

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

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

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

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

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

9 DR. BURSTIN: As is.

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

17 DR. NEWMAN: That's me.

18 CO-CHAIR MOORHEAD: That's Nathan.

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

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

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

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

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

16 CO-CHAIR MOORHEAD: Ara?

17 DR. CHALIAN: I agree.

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

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

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

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

10 MS. MCCARTNEY: Can I ask a general
11 question?

12 DR. NEWMAN: Yes.

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

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

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

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

18 MS. BOSSLEY. Sure, yes.

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

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

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

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

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

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

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

1 of those medications.

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

10 DR. NEWMAN: Didn't hear.

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

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

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

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

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

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

1 DR. NEWMAN: Which is defined as the
2 90-day period --

3 CO-CHAIR STONE-GRIFFITH: Right.

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

7 CO-CHAIR STONE-GRIFFITH: During the
8 12 consecutive months.

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

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

22 DR. ALESSANDRINI: Yes I guess you'd

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

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

19 DR. ALESSANDRINI: Right.

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

22 CO-CHAIR MOORHEAD: Yes. What did we

1 say this morning?

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

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

10 DR. ALESSANDRINI: In the
11 denominator, right.

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

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

22 DR. CHALIAN: Right. If we wanted to

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

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

8 DR. NEWMAN: I had felt like that
9 that rating would be completely covered.
10 However given new information we can make that
11 partially covered, a P. This would be 2a.
12 Reliability testing, it's interesting, and
13 again I didn't get this document, it says in
14 2b.1 that a document was attached describing
15 a study completed using the national
16 colonoscopy data repository. I didn't receive
17 that. I'm not sure how critical it was, did
18 everybody else receive that written here?

19 DR. CHALIAN: There were pictures.

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

22 DR. CHALIAN: Well, there's a

1 deductive reductive process going on here.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 DR. NEWMAN: And then overall the

1 recommendation was that we do recommend it for
2 endorsement.

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

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

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

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

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

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

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

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

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

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

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

16 CO-CHAIR MOORHEAD: Okay any
17 questions?

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

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

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

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

16 Validity testing, same rationale,
17 2c is a P. And exclusions justified, this is
18 similar to the other PCPI measures and I gave
19 that a P. Risk adjustment is not applicable
20 for this process measure. We don't have any
21 identification of meaningful differences in
22 performance listed under this section so I

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

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

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

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

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

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

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

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

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

20 DR. ALESSANDRINI: Yes.

21 DR. ADAMS: Okay.

22 DR. CHALIAN: I have a question. Do

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

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

9 DR. CHALIAN: Okay.

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

15 DR. CHALIAN: Okay. Thank you.

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

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

1 use, the percentage of patients aged two
2 months to 12 years with a diagnosis of OME who
3 are not prescribed systemic antimicrobials.

4 It's an overuse issue. It's in the quality
5 domain of effectiveness, efficiency and equity
6 and it's a process measure.

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

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

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

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

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

14 CO-CHAIR MOORHEAD: Everyone okay?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So overall I felt for item 4,

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

5 CO-CHAIR MOORHEAD: The
6 recommendation is to --

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

9 DR. CHALIAN: Yes.

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

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

21 CO-CHAIR MOORHEAD: Two different
22 populations.

1 DR. ALTERAS: Okay, so.

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

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

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

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

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

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

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

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

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

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

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

1 those. Maybe could you clarify that?

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

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

22 DR. CHALIAN: I would offer that

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

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

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

11 DR. CHALIAN: Oh really?

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

17 DR. CHALIAN: I should sell them.

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

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

1 it's really hands on medicine but --

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

4 CO-CHAIR MOORHEAD: Yours
5 disappeared?

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

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

12 CO-CHAIR MOORHEAD: That'll be about
13 32,000 of those we are going to need, okay?

14 DR. CHALIAN: As part of the
15 stimulus package.

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

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

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

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

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

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

22 Making the diagnosis is a big issue

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

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

17 CO-CHAIR MOORHEAD: I think they are
18 missing and I think that in a lot of cases you
19 make the diagnosis with an otoscope and what
20 you're seeing and then in the difficult cases
21 then you go find one because you want to see
22 if the drum moves and you find out somebody

1 has got one in their pocket and so you, that's
2 just the practical I think way that we deal
3 with it. So I have a little issue with the
4 importance here as well because there is a
5 whole I don't know what percent, but there's
6 a large percent I think in clinical practice
7 that are diagnosed just because of what you
8 see in the clinical picture and that I'm not
9 sure that this really adds but in the
10 difficult cases it's very helpful.

11 MS. ALTERAS: I just wondered,
12 definitely there's value to process measures
13 but I'm just wondering if this is one, if this
14 is a process measure that really would add
15 value.

16 DR. CHALIAN: I think hearing the
17 viewpoints, it does probably add a few cases
18 that we would miss and refine a few diagnoses
19 that were in doubt that would have been
20 overcalled, but the majority of these I think
21 are based on the color of the fluid behind it
22 or the air bubbles and you know, people make

1 the diagnosis so --

2 CO-CHAIR MOORHEAD: Bulging --

3 DR. CHALIAN: This may be more --

4 DR. BEVERLY COLLINS: More what?

5 DR. CHALIAN: More work than we need
6 to do.

7 DR. ALESSANDRINI: And since the
8 treatment is not to do anything but observe,
9 that's what makes people, you know, it's like,
10 well, I'm not supposed to do any of these
11 treatments, I'm just supposed to have them
12 come back so when they come back I'll have
13 that bulb for them.

14 DR. EISENBERG: It goes back to the
15 parent because I think what you're going to
16 have is people that look, they don't have an
17 otoscope, you know what it's dull, I can't
18 really see anything and then the antibiotics
19 are prescribed, so pairing it with the overuse
20 of antibiotics is the appropriate way to look
21 at it other than carrying them around in our
22 pockets.

1 DR. BEVERLY COLLINS: I agree
2 because maybe people haven't been using it
3 because the inclination is just to prescribe
4 antibiotics, that's been, you know, our way of
5 practicing for the past couple of decades so
6 it's just easier to write that prescription
7 rather than doing a confirmatory test.

8 CO-CHAIR MOORHEAD: That may be
9 true. I think in most cases you can make the
10 diagnosis in other ways. It's not necessary.
11 So I mean I think, some feedback here from the
12 group, is this a yes or no, and if it's not a
13 yes then --

14 DR. CHALIAN: Sounds like a no.

15 DR. BURSTIN: Again it may be a very
16 useful measure for internal QI but does it
17 reach the bar of a measure that you'd publicly
18 report, that's what NQF is about, so maybe
19 that'll factor into your thinking about it.

20 DR. ALTERAS: This isn't really like
21 a consumer-friendly measure, so --

22 CO-CHAIR MOORHEAD: I think you're

1 being very consumer-friendly right now. Bob
2 did you have a comment?

3 DR. O'CONNOR: I mean, I was just
4 going to say if we had infinite measures we
5 might consider this, but with limited measures
6 I just don't think this is either widely-
7 practiced or all that important in terms of
8 treatment outcome.

9 CO-CHAIR MOORHEAD: There's a lot of
10 nodding. Sounds like we can make this a no and
11 then we don't go any further. Beverly, is that
12 okay?

13 DR. BEVERLY COLLINS: I have no
14 vested interest in this at all.

15 CO-CHAIR MOORHEAD: Everyone okay
16 with that?

17 DR. CHALIAN: Sam are we missing a
18 freight train?

19 Ms. TIERNEY: No I don't think so.

20 CO-CHAIR MOORHEAD: So at this point
21 I think we'd like to go back and look at 12,
22 13 and 15 and look at the pairing issue and

1 look for a recommendation there from the
2 group. Antihistamines, steroids and
3 antimicrobials.

4 DR. ALESSANDRINI: I think it would
5 be great to pair all of them because it's just
6 a nice, you know, this is just really almost
7 like an endorsement of watchful waiting, which
8 is the right treatment for this.

9 DR. BURSTIN: And in some ways
10 because the measures all go in the same
11 direction, they're all don't do this, I would
12 also actually think the committee might want
13 to actually make, this seems like a perfect,
14 true composite to develop, because you
15 shouldn't actually do any of them. Right? I
16 mean it could just be an all or none. That's
17 one potential way to look at it, just to make
18 it simpler.

19 CO-CHAIR STONE-GRIFFITH: So what
20 would that be? Recommend back to the endorser
21 to make it a composite?

22 DR. BURSTIN: I think you would

1 recommend with conditions. Again in this
2 cycle, I don't think, I don't know that they'd
3 be able to get it done as a composite, but
4 that you'd recommend at least they be paired
5 but perhaps a strong recommendation that by
6 the time the measures are for maintenance or
7 something you would expect to see a composite
8 or something like that.

9 CO-CHAIR MOORHEAD: Is there
10 agreement with that? We're nodding. Good.
11 We're just, you're not nodding off? All right.
12 Well, we're finished with ears. Okay well,
13 good work, we're doing well. All right we're
14 ready to move on. Number 16. I am ready for 16
15 but you are all ready for 29. Sorry, 29.
16 Staying in the ENT. Twenty-nine is --

17 DR. JEFFREY COLLINS: That's me.

18 CO-CHAIR MOORHEAD: Jeff, okay.

19 DR. JEFFREY COLLINS: So I am
20 reviewing ACP-029-10, title is patients
21 treated with an antibiotic for acute sinusitis
22 that received a first line antibiotic. This is

1 a measure that identifies patients with acute
2 sinusitis treated with antibiotic who received
3 a first line antibiotic and it's a process
4 measure. I have to say starting off that this
5 one fascinated me so I'll try to leave my
6 comments off to the side until the end.

7 It passed consideration for NQF,
8 very clinically important topic, if you based
9 on 1 billion viral ERIs in the United States
10 every year you can extrapolate down to 20 to
11 30 million individuals diagnosed with
12 sinusitis.

13 I think one of the things that
14 needs to be clarified in the title is we're
15 talking about acute bacterial sinusitis and to
16 be very specific about that. Annual healthcare
17 costs of close to \$6 billion a year and over
18 73 million days of restricted activity and it
19 accounts for 20 percent of antibiotic
20 prescriptions in the United States each year
21 so in terms of importance, I gave this a C. I
22 just think it's a huge topic.

1 In terms of 1b, opportunity for
2 improvement, benefits, summary of data and
3 performance benchmarks, I gave it a partial.
4 In terms of outcomes for evidence, important
5 process in terms of really seeing who failed
6 conservative therapy, who has a more severe
7 illness and complications for acute sinusitis.

8 One of the issues is sort of
9 looking at first line versus second line
10 agents and the use of not using macrolides as
11 first line agents and we can talk about that
12 subsequently.

13 CO-CHAIR MOORHEAD: You want to go
14 through all the ones and then --

15 DR. JEFFREY COLLINS: Sure.

16 CO-CHAIR MOORHEAD: I'm sorry, is it
17 Leigh or Leigh Ann?

18 MS. MCCARTNEY: Leigh Ann.

19 CO-CHAIR MOORHEAD: Leigh Ann.

20 MS. MCCARTNEY: I agree so far.

21 CO-CHAIR MOORHEAD: Okay.

22 DR. JEFFREY COLLINS: So 1c I had a

1 complete.

2 CO-CHAIR MOORHEAD: Okay.

3 DR. JEFFREY COLLINS: If anybody has
4 any, we'll talk as a group about the
5 guidelines, but in terms of measure
6 specifications, we're just looking at a
7 numerator.

8 CO-CHAIR MOORHEAD: So your overall
9 for 1, the importance, is a yes.

10 DR. JEFFREY COLLINS: Yes.

11 MS. MCCARTNEY: Yes.

12 CO-CHAIR MOORHEAD: Thank you.

13 DR. JEFFREY COLLINS: In terms of
14 measure specifications you are looking at a
15 numerator being patients who are treated with
16 antibiotics for acute bacterial sinusitis that
17 received a first line antibiotic. I didn't see
18 any denominator data. I don't know if that
19 wasn't --

20 MS. MCCARTNEY: It's way, way, way
21 down. This is like 800 pages or something.
22 It's like squeezed in the middle somewhere.

1 DR. JEFFREY COLLINS: Okay. I'm
2 assuming it's all-comers with --

3 MS. MCCARTNEY: Whatever they have
4 sent me to print out, actually had the
5 denominator in it so, the denominator is all
6 males or females that are three years of age
7 or older at the end of the report period. And
8 I mean there's quite a bit of, the sinusitis
9 event will encompass the following period of
10 time: 60 days prior to initiating sinusitis
11 encounter through 21 days after the encounter.

12 So there is quite a bit of detail
13 about the denominator.

14 DR. JEFFREY COLLINS: Right.

15 MS. MCCARTNEY: But it seems like
16 they have, they've covered most of the
17 information that would be included in it.
18 There's quite a bit of detail on the
19 exclusions.

20 DR. JEFFREY COLLINS: Right.

21 MS. MCCARTNEY: As well. But I
22 honestly don't know what page because my --

1 DR. BURSTIN: It starts on page 891.

2 DR. JEFFREY COLLINS: Right. So I
3 went from page 6 to page 890 so I may have
4 missed the -- so I apologize.

5 MS. MCCARTNEY: Yes, it's a little
6 difficult.

7 DR. JEFFREY COLLINS: I did think
8 that testing analysis and everything that
9 described getting to 2b and 2c were complete,
10 that they were very thorough as far as the
11 actual testing methodologies, that they
12 suggested in terms of exclusion criteria, I
13 thought those were appropriate too. Those are
14 listed in section 2d, excluding people with
15 recurrent episodes, chronic sinusitis,
16 underlying immunodeficiencies or structural
17 abnormalities, recent hospitalization or
18 outpatient surgery and relevant head, neck and
19 respiratory infections that might indicate a
20 complicated case. I thought that was
21 appropriate.

22 Risk adjustment, 2e I had not

1 applicable, identification of meaningful
2 differences of performance, I thought that
3 that was complete. You can holler if you have
4 any differences.

5 MS. MCCARTNEY: No I agree.

6 DR. JEFFREY COLLINS: Comparability
7 of multiple data source methods, I had an N.
8 Disparities in care, I had an N also, there
9 was nothing suggested. I do want to just toss
10 out that when you look at first line agents,
11 you know the cost of a generic amoxicillin
12 versus the cost of Augmentin and a
13 fluoroquinolone is pretty substantial so
14 although people haven't studied it, it's
15 something we might want to think about as far
16 as community disparities.

17 In terms of usability, section 3a,
18 meaningful and understandable and useful
19 information, I had a partial. I think one of
20 the difficult things here is, one of the
21 clinical issues that happens with acute
22 bacterial sinusitis is that you're diagnosing

1 it as a viral URI in a patient that's getting
2 worse after five to seven days or a patient 10
3 days out who hasn't gotten better.

4 And so tracking that serially in a
5 data source becomes difficult because how do
6 you do that? Are you looking to identify viral
7 URIs and then tracking a patient with a
8 diagnosis of acute bacterial sinusitis
9 subsequently? It's possible but it's
10 incredibly cumbersome even with an electronic
11 database and so I don't know if people have
12 any ideas about that but I thought it was a
13 cumbersome measure to get at.

14 And then in terms of feasibility,
15 well I'll go through those. So for 3a I had
16 partial, harmonization I had not applicable,
17 distinctive or additive value I had not
18 applicable or no. And then in terms of
19 feasibility data generated as a by-product of
20 care processes, they didn't list anything
21 there. And then in terms of identifying
22 susceptible inaccurate errors or unintended

1 consequences of the measure, they did have a
2 reference to pen allergic patients and we can
3 talk about that clinically. I had a partial.

4 In terms of data collection
5 strategy and implementation, I thought that
6 was partial.

7 DR. ALESSANDRINI: None of these
8 seem to do any work on the cost of doing this
9 and from working in the hospital setting
10 quality center, I don't think people think
11 about, just because it's electronic that
12 doesn't mean there's not a body that has to
13 pull it, analyze it, produce it on a regular
14 basis. This is not, it's only data that you
15 are getting out, it's not information,
16 somebody still has to put a lot of work behind
17 that information and sometimes I think that's
18 what gets missed in these measures, is that
19 amount of work and the bodies that it takes to
20 really produce meaningful information from the
21 data that is abstracted from these electronic
22 means.

1 So in all the measures that I've
2 looked at, the evidence of cost is missing and
3 I think that's a very important piece that
4 they need to consider when they're testing
5 these and looking at the amount of time it
6 takes and the resources it takes to really get
7 this data and make it useful.

8 DR. BURSTIN: It's been a real
9 struggle. We've asked for it. People analyze
10 it completely differently. It's apples and
11 oranges. So much of it depends on where you
12 start in terms of the data systems in your
13 institution so I mean for AHCA it's probably
14 very different than some other institutions so
15 that's been one of our challenges but I think
16 it's still a valid point.

17 DR. ALTERAS: Can I ask a question?
18 This isn't measuring whether a patient was
19 diagnosed antibiotics inappropriately. It
20 measures whether a patient who should be
21 getting antibiotics is getting first line
22 versus a too powerful one? Okay. How often

1 does it really happen that patients are
2 prescribed a too powerful antibiotic, really?

3 DR. COHEN: I don't know. There are
4 other factors though. Compliance issues, you
5 know, in children is an issue, with MRSA
6 resistance especially in Brooklyn, there's a
7 significant multi-drug resistance issue. So
8 there are issues to use the broader spectrum
9 agents but not always. But it's overused I'm
10 sure.

11 DR. CHALIAN: I have a question for
12 the sponsor. I think there's some more recent
13 sinusitis guidelines from the Academy of
14 Otolaryngology and they don't seem to be
15 referenced so I was -- and it's not my niche
16 area so I can't give you the exact date but I
17 think it was in the last two years.

18 DR. JEFFREY COLLINS: So the 2000
19 guidelines were updated in 2007 and those are
20 referenced in there.

21 DR. CHALIAN: They're in there?
22 Okay.

1 DR. ADAMS: And is that the source
2 that we're using to draw the recommended first
3 line antibiotics? Those guidelines? And then
4 will be able to take into account the local --
5 as was discussed -- any kind of local
6 recommendations if there's ID people that say
7 something else? I mean they don't typically
8 do that for sinusitis but, you know, you
9 brought up a good point and maybe it's just
10 local custom and not evidence-based.

11 DR. NEWMAN: Right, so this is the
12 nuance that I was referring to. So right now
13 nationally about 30 percent of H flu, non-
14 typeable H flu is beta-lactamase producing and
15 almost 100 percent of M catarrhalis and so
16 depending on what practice area you are in,
17 you may opt for an agent just based on that
18 and how do we get at that, you know, based on
19 a chart review let alone documentation.

20 It's one thing to say that we're
21 going to follow clinical guidelines set forth
22 by these groups but to all of a sudden measure

1 people as a quality measure based on this I
2 think is much more complicated.

3 DR. CHALIAN: Does the length of
4 treatment enter in on the proposal?

5 DR. NEWMAN: I actually didn't see
6 lengths of treatment.

7 DR. ALESSANDRINI: No I didn't see
8 anything on length of treatment.

9 DR. CHALIAN: From the --

10 DR. JEFFREY COLLINS: It's 891
11 pages.

12 DR. CHALIAN: I'm not poking a hole
13 in your bubble believe me. This is a tough one
14 because I think the patient populations aren't
15 homogenous anymore and so we're trying to
16 induce thoughtful behavior but I'm not sure we
17 have a guideline that will actually be one
18 that's helpful and measurable and will guide
19 behavior.

20 DR. ADAMS: And speaking to that,
21 what I fear is the doctors who want to
22 prescribe the second line agent will just

1 change the diagnosis. Acute febrile illness,
2 I mean there's a whole lot of other things
3 that they can --

4 DR. ALESSANDRINI: - the antibiotic
5 --

6 DR. ADAMS: But I won't get dinged,
7 right? I can --

8 DR. JEFFREY COLLINS: And again, the
9 fact that you know, the guidelines build in
10 treatment failure as being greater than or
11 equal to 72 hours after the antibiotic has
12 started. Now does that imply that they're
13 going to come back to my institution or go to
14 another institution or go to the primary care
15 physician? How do I get at a treatment
16 failure?

17 CO-CHAIR MOORHEAD: Just one or two
18 --

19 DR. JEFFREY COLLINS: And again this
20 is an incredibly serious topic as far as cost
21 and over-prescription of antibiotics and all
22 of these types of things but you know, as a

1 measure, I think it's really difficult to get
2 a handle on.

3 DR. ADAMS: And then sometimes
4 perfection is the enemy of the good and none
5 of these are perfect but it may be it promotes
6 the right behavior so we should do it anyway.

7 CO-CHAIR MOORHEAD: My computer
8 still hasn't caught up with the 891 pages. So
9 I have got to get to work on this so we got to
10 the end of 4? Right? And so the overall, your
11 recommendation is?

12 DR. JEFFREY COLLINS: The same, it's
13 too complicated.

14 MS. MCCARTNEY: I think it is, you
15 know, especially in the PCP setting, I think
16 it's really going to be difficult to get this
17 data. Go ahead.

18 DR BURSTIN: This measure is usually
19 done at the health plan level where they have
20 the data.

21 MS. MCCARTNEY: But I think the
22 point is taken that the physician will change

1 it so even though the data is based on claims
2 they may choose a different diagnosis so that
3 they can use that so I think that's kind of
4 what I was getting at, is that, you know, I
5 think it would be, there's a lot of different
6 diagnoses out there that they could choose
7 that would still be appropriate but might get
8 them a pass.

9 DR. EISENBERG: I would argue
10 completely against that. I cannot think of any
11 physician that's going to change their
12 diagnosis from something simple that they have
13 done because of how abstracted data is going
14 to be used afterwards. I think that 99 percent
15 do not think that far. They're going to just
16 call it sinusitis whether it's the whole issue
17 of --

18 MS. MCCARTNEY: They may.

19 DR. EISENBERG: Wrongful diagnosis
20 to begin with but I mean there's probably, I
21 mean your data probably shows what, 50
22 diagnoses that the average doctor uses and we

1 don't specify to the 5th digit, we don't, I
2 mean we use this particular set of things, so
3 I think your, that's a whole issue with claims
4 data, are you really getting what they're
5 doing and I don't see it going the other way
6 at least until you've got a good enough EHR
7 built in where it's either prompting you to do
8 that, you know, to add a 5th digit or to make
9 it more accurate, so I mean I don't think
10 that's too big an issue.

11 DR. BEVERLY COLLINS: Even when EHRs
12 are implemented though if they're not the same
13 across all facilities you're not going to get
14 all those prompts so I would agree, I think
15 it's going to be difficult to get this data in
16 an accurate manner.

17 MS. MCCARTNEY: I want to speak
18 from the health plan perspective as well. You
19 made it sound like it would be easy because
20 everything is coded with claims and all that.
21 If I had to code 800 pages of codes, there's
22 no way I'd do it, unless this is a measure, a

1 metric or a program that's already delivered
2 to us. It's just too confusing. I think it's
3 overwhelming.

4 MS. GOVAN-JENKINS: I am a mother of
5 a 14-month-old and a two-year-old and I'm an
6 RN and I took my little girl to the doctor
7 last week for a double ear infection and he
8 did not prescribe the amoxicillin because she
9 has been known to be, it has not worked for
10 her in the past and every time he ordered it
11 we had to go back and get more medication. So
12 this time he ordered a three-day of Zithromax
13 which worked perfectly and she is fine. So.

14 DR. JEFFREY COLLINS: Did they use
15 a pneumatic bulb though?

16 MS. MCCARTNEY: I concur. I have had
17 the same experience with my children, where
18 amoxicillin hasn't worked and we've had to go
19 back and then -- right.

20 DR. JEFFREY COLLINS: So just to
21 summarize, what I would say is we at my
22 practice, we use these guidelines, so these

1 are the guidelines we use, but as far as
2 instrumentalizing these and using these as
3 quality measures, I think would be incredibly
4 cumbersome. The time it gets hardest for us to
5 do is actually in the pen-allergic patients,
6 where the nuances of antibiotic use become
7 more specific and trying to get into the chart
8 and who actually puts allergies in the right
9 part of the electronic medical record rather
10 than burying them in the note and trying to
11 get that aggregate data is next to impossible
12 for our group.

13 DR. BURSTIN: Well, this one is
14 measures only specified for claims data, it's
15 not specified for EHRs so those are you know,
16 futuristic issues but for now it's purely
17 taking pharmacy claims data, taking diagnostic
18 claims data, and putting it together. It is
19 what it is right now.

20 CO-CHAIR MOORHEAD: But it is for
21 public reporting and we are recommending that
22 this continue to be use QOM measure but not as

1 a -- I don't know -- Ara?

2 DR. CHALIAN: I guess my, when it's
3 big aggregate data like that you can't tell if
4 it actually applies and reflects on
5 appropriate or inappropriate behavior. But it
6 can give a misperception to the public or even
7 the physician. So from that perspective I feel
8 that it's important for the company to
9 understand what's going on and maybe our
10 organization to understand what's going on but
11 it doesn't help the prescriber or the consumer
12 without further definition of the cohorts.

13 DR. BURSTIN: Well the consumer also
14 goes to those purchasers who are purchasing,
15 you know, who are making purchasing decisions
16 on the part of consumers, you can make the
17 case that they want to be able to see
18 different groups, they want to see different
19 plans, so it often is on a higher level,
20 aggregation.

21 DR. CHALIAN: It may help them who
22 to identify who to invest with though, but not

1 necessarily that it affects their quality of
2 care.

3 CO-CHAIR MOORHEAD: I am hearing
4 consensus with the committee that we think
5 that this should not be recommended as a
6 measure that it continue to be used for
7 quality improvement. Okay. Well thank you very
8 much. We can move to number 30. Beverly.

9 DR. BEVERLY COLLINS: This measure
10 is ACP-030-10. It is adults community-acquired
11 bacterial pneumonia that had a chest x-ray and
12 this measure identifies patients with
13 community-acquired bacterial pneumonia treated
14 as out-patients that had a chest x-ray.

15 It's peer coordination focus and it
16 did meet the criteria for NQF to review it. We
17 look at the importance of the measure, it has
18 demonstrated high impact, it addresses almost
19 916,000 episodes of community-acquired
20 pneumonia in the U.S. each year. This is in
21 adults 65 years of age and older which is not
22 really the population addressed by this

1 measure that is 18 and over. So that other
2 segment of population is not addressed in this
3 evidence. So I put partial, partially
4 addressed.

5 The opportunity for improvement,
6 speaks to the chest x-ray, is essential to
7 confirm the diagnosis and it's also useful as
8 suggesting the etiologic agent, determining
9 prognosis and excluding alternative diagnosis
10 and conditions. Did say that there was a
11 compliance rate of almost 71 percent of the
12 chest x-rays in the database that I guess the
13 sponsor uses to do some validation and
14 measurement, a commercial population less than
15 65 years of age, so it didn't really address
16 if there were any settings of geographic
17 locations that there might be more of an
18 opportunity. So I gave this a P for partial.

19 It just said there were no
20 disparities by this population group so I
21 don't know, some of the other data, some of it
22 was like no data, or there are no disparities

1 because I think there might be. Looking at the
2 outcome or evidence, they rated the evidence
3 as moderate level three, but in the rating
4 methodology a level three is considered low
5 and moderate is considered level two so I'm
6 not sure really what the rating of this one
7 is. I gave it a rating of a P as well. That
8 also includes summary of controversy,
9 contradictory evidence, they said there was
10 none.

11 So I felt that it is an important
12 measure so I gave it yes for importance.

13 With measure specifications there
14 is a long description of the numerator. I was
15 confused because there's a lot of exclusions
16 in the numerator that seem like they would be
17 in the denominator, or should be.

18 MS. RIEHLE: The reason why it's
19 written it that way and I don't mean to
20 interrupt you --

21 DR. BEVERLY COLLINS: Sure.

22 MS. RIEHLE: But the reason why it

1 is written that way is because after you start
2 determining the numerator there are a few
3 further exclusions so they're actually -- the
4 first step of the numerator is to look for the
5 CPT2 codes and then after that there's a few
6 more exclusions so it's actually technically
7 not part of the denominator because you've
8 already started to define the numerator.

9 DR. BEVERLY COLLINS: Okay. I found
10 it very confusing. And then, number five on
11 the description of the denominator said, any
12 remaining patients do not satisfy the
13 numerator criterion and it's a whole long list
14 of other types of pneumonia like, you know,
15 histoplasmosis and a lot of others that I
16 would think would be exclusions in the
17 denominator starting out, because you're
18 looking at bacterial pneumonia.

19 MS. MCCARTNEY: I agree.

20 DR. BEVERLY COLLINS: So I was like
21 really confused.

22 MS. MCCARTNEY: I was confused with

1 the exclusions, or the, right, the remaining
2 patients in five didn't match up to the
3 denominator.

4 DR. BEVERLY COLLINS: Right. It's
5 people, yes, who should not even be in the
6 numerator, so if you're looking at the
7 denominator. So I was really confused about
8 how it is actually designed. And again there's
9 400 pages of codes that I found very complex
10 and confusing. So let me skip to past the
11 codes. Page 412 I believe it starts.

12 So I gave 2a.m. minimal because I
13 couldn't understand it, the numerator and the
14 denominator. All right so, let's see.

15 MS. MCCARTNEY: Can I just ask a
16 question about this. So this would be built
17 into some sort of, I know it's claims data,
18 but with all of these codes, if this was going
19 to be done this would be like some, it would
20 be go through a software program, so that
21 people -- but if they're looking at, you know,
22 if they get their compliance with this and

1 they want to understand it they're going to
2 have to go through all these codes. I mean I
3 guess that's where it's kind of like okay, I'm
4 Doctor X and I get this and says I'm not doing
5 very well with this and I go and look at 400
6 pages of code I'm not going to think it's a
7 very valid measure of my care for these
8 patients just because there's so much and it's
9 so complex.

10 MS. RIEHLE: I mean, I understand
11 your concern, I mean in general, our customers
12 who use these measures have people who provide
13 support to people for the software so if they
14 have a question, instead of having to pore
15 through all this themselves they can ask a
16 specific targeted question and then either our
17 customers can help them or they can come back
18 to Ingenix and eventually use their customer
19 support. So we don't usually run into
20 physicians you know getting a stack of codes
21 they are more for, I mean we don't want them
22 to have to do that.

1 CO-CHAIR STONE-GRIFFITH: Helen is
2 this another situation where Ingenix will give
3 specifications to anyone who wants to use it?

4 MS. RIEHLE: Absolutely.

5 CO-CHAIR STONE-GRIFFITH: Yes. Okay.

6 DR. BEVERLY COLLINS: Okay. Where I
7 pick up on this next I think was risk
8 adjustment which, none is necessary. Data
9 source electronic administrative data and
10 claims of pharmacy. So we skip to the
11 reliability testing. Again it speaks to using
12 multiple databases from Ingenix but it really
13 doesn't give any of the results about how
14 reliable their findings were. It talked about
15 using regression analysis to verify
16 reliability of the product across software
17 releases so it looks like they're checking
18 their software to see if it's reliable but not
19 really the measure itself. So I gave that an
20 M, minimal.

21 Validity testing basically had the
22 same type of thing. It talked about the

1 software. It did talk about comparing to some
2 claims as a gold standard, or looking at some
3 record reviews, comparing the claims-based
4 measure to some chart reviews as a gold
5 standard, but it said they reviewed 726
6 measures were evaluated in this overall
7 process and I don't really know if the measure
8 we're looking at is one of the ones that were
9 included in the study. It didn't really
10 specify that. It says an overall error rate
11 was less than five percent. So I really don't
12 know what our measure here that we're
13 addressing, how that fared.

14 And the exclusions, as I mentioned,
15 sorry 2c I rated as P, partial. And then with
16 the exclusions I gave that a C. I think they
17 did capture a lot of those although it didn't
18 talk about the exclusions from the codes,
19 specifically all those 400 pages' worth.

20 And then the risk adjustment was
21 N/A. That's 2e and 2f I rated as N, not at
22 all, really didn't talk about the meaningful

1 differences in performance. And then
2 comparability of multiple data sources was not
3 addressed. I gave that an N. Age disparities
4 I also gave an N. That was not addressed. So
5 my overall score for this was P.

6 Under usability, it said they are
7 currently in use and it really talked about
8 all their, I think their clients that are
9 using it, this measure. It's a similar measure
10 I think with PCPI, I'm not sure if it's
11 exactly defined the same way, but it doesn't
12 seem to be any information about what the
13 results and the usability are with their
14 clients so I gave it an M for 3a.

15 Harmonization was not addressed so I gave that
16 an N. And the competing measures also was not
17 addressed so I gave that an N with an overall
18 score of N. For number three.

19 Feasibility talked about the data,
20 how the data elements are needed. I think it
21 was, I gave that a P, I mean they're listed
22 but I think it's just an overwhelming amounts

1 of it. The electronic sources, I gave a P. The
2 exclusions, I gave a C. They were all defined
3 and accuracies or errors, I didn't really talk
4 about how there would be an auditing process
5 so I gave that a P, partial. And the data
6 collection, I gave that a P. So an overall
7 score for four of P.

8 MS. MCCARTNEY: I agree.

9 DR. BEVERLY COLLINS: And I think my
10 overall recommendation is I think I would not
11 accept it as defined. I was really confused
12 with the numerator and denominator. I'm not
13 sure what it's actually measuring. And it's
14 very complex.

15 MS. RIEHLE: I agree it was
16 confusing to understand exactly what they were
17 measuring with all of the codes and then the -
18 - well, it's way up at the top but it was very
19 confusing.

20 DR. ROBERTS: Well, I certainly
21 liked the premise. If someone has what they
22 think is pneumonia I think the patient

1 deserves a chest x-ray so I liked the premise
2 and I'd hate to see it just die but the
3 recommendations maybe make it a little more
4 understandable about the coding, is that the
5 suggestion, and the numerator denominator?

6 MS. RIEHLE: The way we had to put
7 our specifications in this format I guess was
8 a little difficult to conform to and the fact
9 that we do have so many codes, we do have to
10 be up-front about the codes, you know, maybe
11 putting them somewhere else so that they were
12 not you know, so physical so they are not
13 getting in your way when you're reviewing the
14 measure. That might be, that might make it
15 more helpful. I understand that it is a fairly
16 complex measure but you know, we wanted t make
17 sure that we did it, you know, in a way that
18 was responsible.

19 DR. BEVERLY COLLINS: Can you speak
20 to the discrepancy, maybe it's just a typo,
21 about it being rated as a moderate level three
22 evidence but then level three is considered

1 low.

2 MS. RIEHLE: You know what, I bet it
3 is a typo. I am not sure but I could get back
4 with that information.

5 DR. ALESSANDRINI: And can somebody
6 just clarify the age range again?

7 MS. RIEHLE: It measures 18 and
8 over.

9 DR. ALESSANDRINI: I guess I would
10 just have to disagree and I practice in an
11 emergency department so it's very easy to get
12 a chest x-ray but I would suspect that a
13 patient-centered primary care measure was that
14 the patient clinically has pneumonia and has
15 a normal pulse-ox and is hydrated and taking
16 the oral antibiotics, were going overuse in
17 some of these and my suspicion is an
18 overwhelming majority of patients get better
19 and those patients that need an x-ray
20 subsequently because they don't respond,
21 that's fine. And so I think this is not the
22 tree that should be barking up.

1 DR. BEVERLY COLLINS: Can I ask, you
2 know, the summary of evidence if high impact
3 states that it's adults 65 years of age and
4 older.

5 DR. ALESSANDRINI: That is a
6 different --

7 DR. BEVERLY COLLINS: But then your
8 denominator is 18 and older so can you explain
9 the discrepancy there? Why do you quote that
10 but then make it 18 and older?

11 MS. RIEHLE: I think that may have
12 been just the available information. I think
13 that we could probably try and find something
14 that was more appropriate to the age range.

15 DR. BEVERLY COLLINS: Because I know
16 that the data also that you guys quoted your
17 database is for patients less than 65 so we're
18 really not looking at the group that is the
19 high-impact group. You're looking at the
20 patients that are in that other grouping.

21 MS. RIEHLE: That's true.

22 DR. BEVERLY COLLINS: So you know I

1 would say there is some discrepancy in that
2 and that maybe you guys would need to go back
3 and provide some data on the 65 and older
4 group and then revamp your denominator to make
5 it more meaningful.

6 DR. ROBERTS: I like the 65 plus age
7 group.

8 DR. BURSTIN: I just wanted to make,
9 I thought this sounded familiar, this measure
10 was evaluated before in our clinically rich
11 initiative measures project and it didn't get
12 through at that point. I think the idea was
13 actually the point that was just raised. If
14 you're seeing a patient who clinically has
15 pneumonia and they're well and you're just
16 going to treat and requiring the chest x-ray,
17 particularly in the ambulatory, non-
18 institution basis, was, didn't seem like it
19 was guideline specific. I'll pull up the
20 exact, the last steering committee
21 deliberation on this, but I think they
22 probably thought since this is more of an ED,

1 urgent care kind of oriented group this might
2 have a different perspective.

3 CO-CHAIR MOORHEAD: Comments.

4 DR. NEWMAN: I find in emergent care
5 there is enough fragmentation already in our
6 processes and as we learn to integrate the
7 different healthcare entities and so you have
8 a chest x-ray as something that's tangible and
9 can be tracked, can be digitally sent, it's a
10 point in time, a marker and point in time,
11 which can be referenced in the future and
12 impact care. So I see a great benefit from
13 getting a chest x-ray and an initial
14 evaluation for pneumonia.

15 CO-CHAIR MOORHEAD: Jeff?

16 DR. JEFFREY COLLINS: Theoretically
17 you can't make a diagnosis of community-
18 acquired pneumonia without a chest x-ray so
19 what ends up happening a lot of times if
20 someone is diagnosed with chronic bronchitis
21 ends up happening having a chest x-ray based
22 on exam and those types of findings, hypoxia

1 and other things. But everybody if they are
2 worried about pneumonia, make a diagnosis,
3 that's billable as an x-ray.

4 DR. BURSTIN: I just briefly want to
5 tell you what the committee before had gone
6 through on this and they felt the evidence was
7 fairly low-level evidence, it was mainly based
8 on case studies and expert opinion. There were
9 concerns about the measure being more robust.
10 It was actually combined with a measure that
11 I think was looked at and I think went through
12 looking at specifically treatment for
13 community-acquired pneumonia and they had
14 actually recommended potentially putting those
15 together and I don't think that happened.

16 There was also concern about the
17 necessity of a chest x-ray each time of
18 diagnosis and concerns about the ability --
19 there was something about measure the
20 antibiotics 21 days before the episode start
21 date was another issue they raised about the
22 measure so it didn't, as I recall, it didn't

1 make it through the last project.

2 DR. NEWMAN: It is challenging. I
3 mean you know, we're talking about pneumatic
4 otoscopy and to try to go back and review
5 tactile fremitus and other things with some of
6 your clinicians, extremely challenging. Their
7 oscillatory abilities are waning the further
8 out they get.

9 DR. ADAMS: The additional problem
10 though is that the radiographic findings of
11 pneumonia lag the actual onset of the disease
12 so it really is an imperfect test.

13 CO-CHAIR MOORHEAD: Just to be
14 clear, this does apply to all settings, and
15 so, if it applied to the ED only for example
16 then they would get support for that.

17 DR. BURSTIN: Although there is
18 already a measure about treatment in Eds.

19 CO-CHAIR MOORHEAD: I understand
20 that I am just saying. So I heard a little bit
21 difference of opinion but given that this
22 applies to all settings are people comfortable

1 with the recommendation that this not be
2 recommended?

3 DR. EISENBERG: No.

4 CO-CHAIR MOORHEAD: No.

5 DR. EISENBERG: No, I mean, I think
6 this should not, is this a no recommendation?

7 CO-CHAIR MOORHEAD: Yes, no.

8 DR. EISENBERG: All right I'm
9 comfortable. I'm sorry.

10 CO-CHAIR MOORHEAD: Yes, you're
11 comfortable with no, not your recommending
12 unless -- all right. I'm sensing a no. That's
13 a no. All right it is 3:15. What I recommend
14 is we take a 15-minute break and then we can
15 come back and we can get started on some
16 measures that were scheduled for tomorrow
17 morning so we're ahead of schedule.

18 (Whereupon, the above-entitled
19 matter went off the record at 3:19 p.m.
20 until 3:38 p.m.)

21 CO-CHAIR MOORHEAD: For convenience
22 we are going to try to do numbers 36 and then

1 35, two ED measures. 36 first.

2 DR. O'CONNOR: Just to read the
3 number this is ACP-036-10. Patients with
4 emergency medicine visit for non-traumatic
5 chest pain that had an ECG. The summary of the
6 conditions for consideration and then moving
7 on to the importance to measure and report.
8 This is a very important measure. You could
9 read some of the summary of evidence but you
10 know the point is that ECG is needed for non-
11 traumatic chest pain in order to make the
12 diagnosis of ST elevation MI which then should
13 lead to a sequence of steps that result in
14 reperfusion so it's an important test to
15 obtain. So I gave it a C for importance.

16 Opportunity for improvement, there
17 are a number of I guess data, a number of
18 members of the database is what I'm trying to
19 say, it shows there's a performance rate was
20 78.6 percent which leaves, it means that 21
21 percent, over 21 percent did not receive an
22 ECG for non-traumatic chest pain so there's a

1 significant opportunity for improvement so I
2 gave that a C as well.

3 Under outcome evidence to the
4 support the measure focus I also gave a C.
5 There's a number of national guidelines from
6 either the AHA or ACC that emphasize the
7 importance of the 12 lead in fact it is the
8 only way by definition to make the diagnosis
9 of ST elevation MI.

10 CO-CHAIR MOORHEAD: What year was
11 this? I forget.

12 DR. O'CONNOR: Was which?

13 CO-CHAIR MOORHEAD: They had this 70
14 percent -- it does not seem --

15 DR. O'CONNOR: That's under 1b.2.
16 Summary of data demonstrating performance gap
17 variation.

18 DR. BURSTIN: So because it's
19 claims-based is the question I guess so it
20 requires to be a billing code for the ECG I
21 assume.

22 MS. RIEHLE: A billing or a --

1 DR. BURSTIN: Okay and I guess the
2 question is not an ED doc but how often to
3 ECGs just kind of get done in the normal flow
4 of things and perhaps not get charged I guess
5 would be my only question.

6 DR. O'CONNOR: That is a great
7 question.

8 CO-CHAIR MOORHEAD: It does happen
9 when ordered by protocol and then for whatever
10 reason the physician doesn't go back and put
11 an order in and you can't bill it. Right?

12 DR. O'CONNOR: Yes.

13 DR. COHEN: That is captured by
14 EHRs.

15 CO-CHAIR STONE-GRIFFITH: So it gets
16 computerized, provide order --

17 DR. COHEN: Exactly.

18 CO-CHAIR MOORHEAD: We have --

19 DR. O'CONNOR: Okay well the problem
20 with documentation I will get to in a minute
21 in this sort of next section. So let's see for
22 evaluation rating, now the scientific

1 acceptability of the measure properties, this
2 is where --

3 CO-CHAIR MOORHEAD: Can we catch up
4 with you just for a sec here.

5 DR. O'CONNOR: Sure.

6 CO-CHAIR MOORHEAD: So for 1b you
7 gave that a C?

8 DR. O'CONNOR: For 1b I gave it a C.

9 CO-CHAIR MOORHEAD: And 1c?

10 DR. O'CONNOR: C also.

11 CO-CHAIR MOORHEAD: Okay. And then
12 the overall?

13 DR. O'CONNOR: It was a C.

14 CO-CHAIR MOORHEAD: Overall would be
15 a yes?

16 DR. O'CONNOR: Would be a yes, yes.

17 CO-CHAIR MOORHEAD: For importance?
18 Okay. Thank you.

19 DR. O'CONNOR: All right the measure
20 specifications, this is, just for reasons that
21 were just pointed out, I gave this an M
22 because not all 12 leads that are obtained get

1 charted or billed. In fact many emergency
2 departments, when a patient comes in and says
3 they have any complaint between their you
4 know, I guess their naval and their chin, they
5 get an ECG, pretty much, by protocol and
6 unless those are documented, it may an elusive
7 denominator.

8 The other part is the numerator by
9 definition does not say whether this is a
10 chief complaint of chest pain or something
11 that's elicited under review of systems. So if
12 it's a secondary complaint there may be some
13 problems with it so for that reason I gave
14 that an M.

15 Testing and analysis I gave a P.
16 Because the quality assurance should be pretty
17 easily obtained. But the ECG will wind up on
18 the chart if it's performed.

19 Let's see I'm getting ahead of
20 myself. The validity testing I also gave an M.
21 Under summary of evidence N/A that's 2d.
22 Because there were no exclusions. 2e is also

1 N/A. The method to identify statistically
2 significant and practically meaningful
3 differences, this is 2f, I gave a C because
4 the measure will allow benchmarking between
5 institutions.

6 The comparability of multiple data
7 sources I gave a P. And 2h disparities gave an
8 M. Disparities in obtaining an ECG haven't
9 really been described. Overall it was a P for
10 section 2. Usability --

11 CO-CHAIR MOORHEAD: Are there any
12 comments or sections?

13 DR. O'CONNOR: Any comments on two?

14 CO-CHAIR MOORHEAD: Okay. Thank you.

15 DR. O'CONNOR: Usability, I figured
16 it's something that's easily understood by
17 providers so I gave a C for 3a. Harmonization
18 that's with a number of other measures such as
19 the AMA PCPI measure so I gave a C there as
20 well. Under 3c distinctive or added value, I
21 think this was the analysis described I gave
22 an M. Feasibility -- I'm sorry, overall it's

1 a P for three.

2 Feasibility, 4a's a P, 4b P as
3 well, although not all the data necessarily,
4 I mean they're available electronically but
5 unless, it depends what the EMR is, whether
6 the EMR is being used. 4c I gave a C. 4d is P.
7 4e is C and then overall for 4 is a P.

8 So I guess just to summarize, I
9 think it's a very good measure. It's can't be
10 overstated how important it is to get an ECG
11 for patients with non-traumatic chest pain.
12 The problem is with identifying the true
13 denominator as well as some problems with the
14 numerator as well. But the true denominator is
15 whether it's chief complaint-based or review
16 of systems-based and the problems with the
17 numerator are just whether or not the
18 cardiogram gets into the billing information.

19 CO-CHAIR STONE-GRIFFITH: So, Elisa,
20 maybe I have a question for clarification
21 here. We have a measure, an active measure
22 now, 009 I think it's in the document on page

1 whatever, 17. And so this is essentially, what
2 you just said was that this was harmonized in
3 terms of what we're measuring is harmonized,
4 but we already have a measure both the 009 and
5 the AMA, the PCPI measure. and those were both
6 time limited and are they still, are they both
7 still active? It sounds like from Helen's
8 earlier they got another year added to this to
9 make sure that they could move that into the
10 EHR specifications. Okay. And so what would
11 this new measure add value?

12 MS. BOSSLEY: Right, so this is a
13 similar one as to what you looked at with the
14 two antimicrobials, so different data sources.
15 So in some way you can actually say, there's
16 a few things you can say, you can say that
17 this measure adds no additional value so don't
18 recommend moving it forward, you can say it
19 does because it is a different data source.
20 There's a few things you can do but it is,
21 this one is administrative claims and less.

22 MS. RIEHLE: It is. So it would be

1 in addition to the CPT2 code which the AMA
2 uses. We'd also be using things that are found
3 in claims data, CPT, regular CPT codes, that
4 kind of thing.

5 DR. JAUCH: So this will be relevant
6 to the next one as well. So you compare the
7 two data sets. Have you actually shown that
8 one is more rigorous or actually captures
9 different data, or are they complementary and
10 essentially part of the same for less or more
11 amount of work? I guess I'm trying to get to
12 the value added for having a different data
13 set.

14 MS. RIEHLE: Well, I can only speak
15 to using claims data but I know using CPT2
16 codes with claims data is at this point not
17 very useful because the prevalence of them is
18 less than one percent. They are not used very
19 regularly at this point. So that, just using
20 CPT2 codes alone would not be helpful in
21 determining whether or not an ECG was done in
22 terms of data.

1 DR. JAUCH: I know, at least for
2 the, and not to steal Bob's thunder, but some
3 of the supplemental information you provide
4 for the syncope states that 77 percent of
5 patients who have syncope actually had an ECG
6 done. So I guess my question is are we
7 expecting to capture another 10 percent and
8 beyond that or is there some additive value to
9 using a larger data set?

10 MS. RIEHLE: That 77 percent was
11 using our benchmark database so that is not
12 using the AMA specification that's using our
13 specifications.

14 DR. JAUCH: So do you know what the
15 AMA's benchmark showed? I mean do they have 50
16 percent that were captured, or? I guess I am
17 just trying to get an understanding for the
18 impact of having multiple --

19 MS. RIEHLE: I know in our data, and
20 I can't speak to this particular measure, but
21 I know in using claims data, the compliance
22 rate that would be picked up by the CPT2 code

1 would be less than one percent because they
2 are just not commonly used in administrative
3 data at this point.

4 MS. BOSSLEY: I think what we could
5 do is ask PCPI to provide what they have.

6 MS. RIEHLE: If they have anything
7 to give you that additional information
8 because it is using different, it's a
9 different data source, different anything. So
10 you could ask for that additional information
11 before you make your final decision. That
12 would be fine. But again, remember, you're not
13 evaluating the one that's endorsed, you're
14 evaluating this new one so it would just be
15 added information to help you make a decision.

16 CO-CHAIR STONE-GRIFFITH: And the
17 one that is endorsed is manually extracted for
18 the most part.

19 MS. RIEHLE: What did we have here,
20 if you look at it, we tried to provide the
21 data source to use, so it's electronic data.
22 This is a hard one to read. We've got paper,

1 administrative claims using category two
2 codes, not just the pure administrative, and
3 then also the electronic health record, so
4 that's how the current one is specified.

5 CO-CHAIR STONE-GRIFFITH: Okay.

6 CO-CHAIR MOORHEAD: Bob, do you have
7 an overall recommendation?

8 DR. O'CONNOR: Yes, I recommend yes
9 for endorsement.

10 CO-CHAIR MOORHEAD: And your sense
11 is that this would be additive, this would
12 help to have these reported from a different
13 data source, is that it?

14 DR. O'CONNOR: Yes, my understanding
15 is it just broadens the net of data source and
16 that would be, you know, for the reasons I
17 mentioned before, I think that would be an
18 improvement in terms of the reliability of the
19 data.

20 CO-CHAIR MOORHEAD: Comments,
21 questions, I'm sorry.

22 DR. ADAMS: Is there a way to

1 harmonize the two, vote to approve but then
2 suggest that they --

3 MS. BOSSLEY: And I would recommend
4 that be one of your conditions, that the two
5 measures be harmonized.

6 CO-CHAIR MOORHEAD: Bob, is that
7 okay?

8 DR. O'CONNOR: That's fine. Yes.

9 DR. ALESSANDRINI: No, but Heidi
10 what would that mean? They'd have to choose
11 which data source that they get to use right?

12 MS. BOSSLEY: What's happened in the
13 past is in essence the measure that's endorsed
14 is kind of the standard that then the other
15 developer must show how they have or have not
16 harmonized, given two different data sources,
17 they may not be able to completely, but they
18 need to provide that information back.

19 DR. ALTERAS: But if Ingenix were to
20 harmonize with the AMA measure what would be
21 the point of the Ingenix measure? I mean
22 wouldn't it be, I just, is it just changing

1 the age or?

2 MS. BOSSLEY: No it would be
3 harmonizing all the different aspects. You may
4 collect it differently using category one
5 codes from CPT and they may use CPT 2 but the
6 age should be the same, you should be
7 capturing similar visits, it should be the
8 same ECG coding, that type of thing, to the
9 extent possible.

10 DR. ALTERAS: Yes, that helps. I
11 just, isn't there, there's a whole process
12 going on now at NQF where you're having
13 technical experts compare measures that are
14 similar, practically the same measure, I mean
15 I just feel like this is a case where that
16 would have to happen before this could be
17 endorsed, almost. I mean, I don't know that we
18 would, you know. The last steering committee
19 I was on there was a huge discussion over
20 having two very, very similar measures on the
21 books and then some providers using one, other
22 providers using a different one, and you know,

1 whichever one suits, whichever one makes the
2 most sense to them, whatever way you want to
3 interpret that. So I just worry, you know,
4 recommending this one for endorsement is just
5 going to raise a lot of questions like what do
6 we do with this once it's endorsed, why do we
7 want to have two on the books?

8 MS. BOSSLEY: Well and I think you
9 all need to decide whether you feel that by
10 having two different measures using two
11 different data sources is the way you feel it
12 should be out there for the public to use for
13 public reporting. I think that's what you all
14 need to do. That's the question you need to
15 answer. If it's not enough then you should say
16 no. It's a little hard I know because you
17 don't have testing results on the other one so
18 it makes it very hard to make a really honest,
19 good comparison. But unfortunately that's
20 where we are right now. But we can ask PCPI to
21 provide what they can, if they can provide.
22 They may be able to provide some PQRI data or

1 something that would give you a little
2 information. But it is, I mean it's difficult,
3 but that is the question. Then it will go to
4 the CSAC and they will decide whether or not,
5 and the membership and everyone else, whether
6 they agree with what your recommendation was.

7 DR. ALTERAS: Yes. I mean personally
8 I feel, since there's already an endorsed
9 measure on this, maybe this is irrelevant, I
10 feel like ECG is, should be standard practice,
11 so I have that issue with the measure in the
12 first place. But second I just wouldn't feel
13 comfortable recommending until we see the
14 testing from AMA because I can just hear all
15 the arguments down the line and you know,
16 someone who works on all the comments and
17 voting, I get all, I get lots of comments
18 back. So --

19 CO-CHAIR MOORHEAD: So one of our
20 options then would be to ask AMA for the data
21 and then we could vote on this in a conference
22 call or whatever. Jeff I think you were first

1 and then --

2 DR. JEFFREY COLLINS: I just am
3 throwing this out, this would be an
4 expectation in an urgent care setting also so
5 I was just wondering if there was a reason why
6 we were just saying emergency departments
7 versus emergency departments and urgent care
8 centers also.

9 CO-CHAIR MOORHEAD: Can you answer
10 that?

11 MS. RIEHLE: I have to check that.
12 I thought it did apply to urgent care but I
13 would have to check.

14 CO-CHAIR MOORHEAD: I think it's
15 just emergency.

16 DR. O'CONNOR: It's just emergency
17 department.

18 MS. RIEHLE: Yes, we're using a code
19 set that is defined by CMS but I mean we would
20 be willing to entertain having the urgent
21 care. If that was thought to be important then
22 you could definitely take that to our

1 consultant panel and talk to them about that.

2 DR. CHALIAN: I had a question
3 whether as NQF or any other organization that
4 we could role model ourselves after has
5 studied the way the consumer looks at two
6 similar guidelines. Or a social scientist
7 telling us what happens when you put
8 conflicting or nearly similar however they're
9 viewed out there. Or if it's an opportunity to
10 study it.

11 DR. ALTERAS: Well I haven't done
12 any research on this but it's confusing, I
13 mean, this stuff is confusing to begin with
14 for consumers and if you were to put two
15 different measures up somewhere, the thing is,
16 you know, a hospital wouldn't use both
17 measures. They would use one or CMS would only
18 use one so the only question is which one if
19 there are two endorsed and I'm all for
20 progress in measures and having the best one
21 out there so I'm not saying that once there's
22 an endorsed measure there should never be

1 another one brought up, but it's p-

2 DR. O'CONNOR: I mean one argument
3 to support that is under section three, it
4 really does call for harmonizing this measure
5 with the existing 009 and I think the
6 difference is you've got an additive value in
7 terms of more robust claims data and just so
8 that everyone understands, I don't know if I
9 said that very clearly, it's essentially basic
10 codes, population, time frame etc as the
11 existing code the difference is the expansion
12 of the data set to avoid some of the problems
13 with the numerator that we talked about
14 earlier. If you look at section 3c it's pretty
15 well described there.

16 CO-CHAIR MOORHEAD: So your
17 recommendation is to support this with a
18 request for harmonization?

19 DR. O'CONNOR: Yes.

20 CO-CHAIR MOORHEAD: And there's some
21 thought about asking AMA first what their
22 numbers are and there's some other thought

1 that there's some other thoughts, so -- the
2 recommendation on the table is to support with
3 a request for harmonization. Any comments?

4 DR. EISENBERG: Just for the ER?

5 CO-CHAIR MOORHEAD: This is just for
6 the emergency room or we can make a
7 recommendation that, was that a sense from
8 urgent care that you would like this added or
9 not? You would like this added. Like if we
10 support this we'd like to request that this go
11 back and your group would add on urgent care.
12 Can we do that?

13 MS. BOSSLEY: Well typically yes,
14 but you do have another measure that is
15 endorsed but is not for that population so we
16 would have to figure out if we could then go
17 back to a developer even though it's an
18 existing measure and do that. I don't think
19 we've done that before. So we'll have to think
20 through that one. Because then you don't have
21 a harmonized one.

22 DR. JEFFREY COLLINS: Can't we

1 tackle it later for urgent care because we
2 have enough on our plates.

3 CO-CHAIR STONE-GRIFFITH: Well on
4 page 13 of 31, and now we're talking about
5 2a.36/37 care settings, it does not say there
6 just emergency department. It lists -- page 13
7 of 21 on this measure. Ambulatory care clinic,
8 ambulatory care emergency department,
9 ambulatory care hospital out-patient, long-
10 term acute care, nursing homes rehab. So do we
11 need to get clarification of the care setting?

12 MS. RIEHLE: I will probably have to
13 take a look at the specific code set. It's a
14 CMS defined code set and it may include those
15 codes. It's just, it's given kind of a --

16 CO-CHAIR MOORHEAD: Because up above
17 the codes are all just --

18 CO-CHAIR STONE-GRIFFITH: Right, but
19 they're not consistent with the care settings.

20 DR. EISENBERG: This measure has no
21 time limitation on it. It's not a 10-minute
22 measure which would be very difficult to do in

1 all of those other settings. I mean it was
2 done or it wasn't done.

3 MS. RIEHLE: It actually gives you
4 24-hour leeway which I know is pretty generous
5 but in claims data, you can't you know, look -
6 -

7 DR. EISENBERG: Yes, you just have
8 a date. But if you did it at 11:45 at night,
9 24 hours ends in 15 minutes.

10 MS. RIEHLE: Well so we're not doing
11 it by date, so let's say you present on the
12 2nd of the month into the ER, we look for a
13 chest x-ray either on the 1st or the 3rd as
14 well as the 2nd.

15 CO-CHAIR MOORHEAD: It seems to me
16 that if we supported this with a request for
17 harmonization it's implicit that it would be
18 restricted to ED use only because that's the
19 other codes, the other measures, is only for
20 the emergency room.

21 MS. BOSSLEY: The other thing you
22 can say too is when these measures come back

1 up you would like to see it expanded I think
2 that's the other piece that we can include in
3 a report and a recommendation.

4 CO-CHAIR MOORHEAD: Well the other
5 one is coming up for, it says maintenance
6 scheduled 5/1/2--, oh this got another year.
7 It's coming up next month.

8 MS. BOSSLEY: So we should be
9 getting it hopefully in the next few weeks.

10 CO-CHAIR MOORHEAD: So that would be
11 the other option, is this is coming up in a
12 few weeks.

13 DR. CHALIAN: Do those other sites
14 that are listed actually fit more into your
15 description of if the x-ray or I mean the ECG
16 prior to leaving the ambulatory care or the
17 nursing home on your way to the ER, you know
18 some of the patients arrive with the ECG in
19 hand and allows you to capture that because it
20 would have been coded at that other site and
21 it doesn't imply a defining practice at the
22 other site.

1 CO-CHAIR MOORHEAD: Is that a
2 statement or a question?

3 DR. CHALIAN: I guess I'm trying to
4 clarify how you could, the question was should
5 this apply to ambulatory sites that are not ED
6 s and the question was how can you list all
7 those sites if you're not implying that the
8 behavior should occur there. My perspective
9 was maybe those tests are being done there so
10 this was their approach to capture the codes,
11 the billing code, that would allow you to know
12 the ECG was done there and not ding the ER for
13 not having billed it because they actually
14 have the ECG now.

15 CO-CHAIR MOORHEAD: I would think
16 probably in practice it gets redone when it
17 gets to the ED anyway so I think -- But you're
18 looking for changes, so --

19 DR. JEFFREY COLLINS: Right.

20 CO-CHAIR MOORHEAD: I'm hearing a
21 couple of different thoughts here. Potentially
22 a request that this be part of their review

1 that's coming up for the 090 code, request to
2 approve with the recommendation for
3 harmonization, there's a couple of different
4 ways to do this. Not to support it.

5 DR. CHALIAN: Going back to one of
6 the prime points of how much confusion do we
7 generate with two of these, my perspective
8 would be that it would be ideal to have one
9 recommendation or guideline on something so
10 significant in terms of importance.

11 CO-CHAIR STONE-GRIFFITH: I'm
12 looking back at one of the appendices and of
13 course it talks about NQF 090 strictly
14 electrocardiogram performed for non-traumatic
15 chest pain. That's the one that we really
16 harmonize. But when you start talking about
17 ECG and other spaces, there's 0289 which came
18 out in the ED transfer measures. Again it's
19 different specifications but it's around
20 obtaining ECG with AMI and chest pain. You
21 also have it on your AMI core measures that we
22 are publicly reporting as well so it's like

1 how many times and how many ways can we
2 measure ECG? And is there really an
3 opportunity to refine all of those?

4 DR. CHALIAN: Do these other
5 measures meet the need to measure it, I mean
6 do these other groups measure it adequately
7 that we don't need to measure it?

8 CO-CHAIR STONE-GRIFFITH: Well, the
9 ones, the 0289 is getting ready to go to
10 hospital compare this year, right, June? Isn't
11 that right? That'll be the first time it'll be
12 reported. They've been collecting it for over
13 a year now, hospitals have. I agree that this
14 is very important. I am concerned with the
15 number of ways that we are slicing the
16 information to measure. Are we getting an ECG
17 for appropriate cardiac-related complaints.
18 And then to couple that I think we have the
19 very setting the very settings that now we are
20 saying well, it's important -- urgent care is
21 important in the ED, where else might it be
22 important?

1 CO-CHAIR MOORHEAD: So is your
2 thought recommend that this be reviewed as
3 part of the review this year? Or could this be
4 considered as part of the 090 review that
5 comes up with the 08s?

6 CO-CHAIR STONE-GRIFFITH: Right, I
7 guess my recommendation would be that this
8 should go back for further review and
9 harmonization with what's coming up in May and
10 to look at the other measures. I mean I guess
11 what I heard Helen say earlier is we cannot
12 have a new measure harmonized with an existing
13 measure. Existing measure stands the way it
14 is. So we have two measures that are out
15 there, is that right -- being measured
16 currently with specifications and reported so
17 they are what they are so the only thing we
18 can do is say this, we could recommend that
19 this would be better or --

20 MS. BOSSLEY: I think the real thing
21 would be it brings additive value because it's
22 a different data source. That's really what I

1 think the question is before you. We can, the
2 issue is, this is why this new maintenance
3 process will make this much easier and you
4 won't have to have this question to deal with
5 again. Because in the review that will occur
6 in the next few months on the existing
7 measure, it really is looking at the testing
8 and doing the full evaluation. Now they may
9 look at, if this measure is in the process
10 then you look at it, but again, the measure
11 you have before you will not have gone through
12 the whole process. So it's going to be a
13 little messy.

14 So the key question I think that we
15 need to have your input on is should this
16 measure be harmonized with the existing one,
17 does it bring additive value, and if so you're
18 recommending to move it forward, and you still
19 have member and public comment to get back and
20 that can be a question that we specifically
21 pose during the comment period to get input on
22 and that may be what helps you make a final

1 decision.

2 In the meantime hopefully we'll
3 have the testing information for the existing
4 measure and that again may be helpful to you
5 as you move through the process. This is a
6 tough one.

7 CO-CHAIR MOORHEAD: Any thoughts?

8 DR. O'CONNOR: Just going back to my
9 initial read of this, it was my understanding
10 that this would replace the existing or
11 somehow supplant it and given that information
12 I think we need to consider this somewhat more
13 carefully because the two measures in place
14 could get you very different data.

15 CO-CHAIR MOORHEAD: A motion to
16 consider carefully. With harmonization.

17 DR. O'CONNOR: I mean do we table
18 this or --

19 CO-CHAIR MOORHEAD: Well our choices
20 are to approve, to recommend this, we can ask
21 for more information including the AMA
22 information, public comment on having to

1 measures to get the public through that
2 process and basically defer our recommendation
3 until we get that. Or we can recommend that
4 this just be included as a part of the review
5 of the 090 and that that process could
6 consider the same information could go to that
7 group. Could we gather that information and
8 somehow that would be then available through
9 the 090 review?

10 MS. BOSSLEY: What will happen in
11 the 090 review is looking at the testing
12 information that's been put forward, that's
13 it. And then that measure will either have
14 endorsed and continue or not, and the time
15 limited will be removed or not.

16 CO-CHAIR MOORHEAD: Okay.

17 MS. BOSSLEY: At that point in time
18 it's not planned to have a full review of
19 every measure that falls within the ED setting
20 or with this specific aspect of care so that's
21 where, it would be nice if we could do that
22 because then you can just defer it.

1 Unfortunately you can't. Maybe the thing to do
2 is to see what Elisa and I can get in the way
3 of more background information, ask Ingenix to
4 provide a little bit more information,
5 harmonization, then you have a call coming up.
6 Table it for right now, get you what we can
7 and have you consider it again. Sounds like if
8 we can get more information maybe you can make
9 a more informed choice.

10 DR. JAUCH: So if the other one went
11 forward and was approved, at what point then
12 would there be the opportunity to harmonize
13 and now a new approved measure and this one is
14 being considered?

15 MS. BOSSLEY: Right, so we would
16 first be right now asking Ingenix to harmonize
17 with the existing endorsed measure. Hopefully
18 there are no changes to the existing endorsed
19 measure based on testing. But if there was
20 then we would probably have a conversation
21 with both developers and say we need to yet
22 again do a little bit more harmonization. So

1 it may be two steps. It's not clean but that
2 will probably be what it is.

3 CO-CHAIR MOORHEAD: So potentially
4 we can defer this and gather more information.
5 Would that be helpful in terms of making a
6 decision or do you have enough information at
7 this point?

8 CO-CHAIR STONE-GRIFFITH: And as
9 part of that we want to validate the setting
10 as well, is that right?

11 MS. BOSSLEY: Right. We will confer
12 with both developers setting, yes.

13 DR. O'CONNOR: I would change my
14 recommendation to table given that.

15 CO-CHAIR MOORHEAD: Is that okay
16 with you? All right. Thank you. We will look
17 forward to that, with harmony. Number 35.

18 DR. JAUCH: So 35, you can just
19 basically leave 36 off and cut and paste
20 syncope for chest pain. It really is. It's
21 almost of comparable importance in the
22 emergency setting, comparable prevalence in

1 the emergency setting as well as similar need
2 probably to harmonize an endorsement that's in
3 existence and it looks like will be also
4 reviewed in the next month. So we can table
5 this for --

6 We will go through this very
7 quickly. I am not sure if I have a co-author
8 or not. This obviously is an Ingenix supported
9 measure looking at the use of ECG in the
10 setting of syncope. This one is a little bit
11 different in that it's an age group greater
12 than the age of 60 so it makes it a little bit
13 easier.

14 They do provide significant
15 supporting data that this is an important
16 metric including ASEP's position that all
17 patients should receive an ECG in the setting
18 of syncope. It's also part of the European
19 cardiology society's recommendation for this
20 and has now also been part of the NQF process
21 for the last couple of years.

22 They do a test of the prevalence of

1 this disease and the potential ability for an
2 ECG to identify life-threatening illnesses and
3 again using their database Ingenix has shown
4 that there is a compliance rate based on that
5 recommendation from ASEP of 77.5 percent. A
6 clear gap and opportunity for care
7 improvement.

8 So with 1a I said that is fairly
9 complete. For 1b opportunity for improvement,
10 again, you know, it depends upon not knowing
11 what you're missing, but I think it's
12 certainly partial so I gave 1b a P. There's no
13 mention of data on disparities. 1c I think is
14 fairly complete but there are several bodies
15 who give this overall evidence to support such
16 a measure I gave that a C.

17 And so regarding was the threshold
18 criterion for importance to measure and report
19 met and I said yes especially in the age group
20 that they are going to sub-select which is
21 greater than 60.

22 And then we get the same number of

1 codes from before in terms of the numerator,
2 again largely this is a little bit different,
3 I think, and I don't obviously know all these
4 codes. This is, I develop pseudo-seizures when
5 I see things like this, but the appropriate
6 codes are there so I gave that an M.

7 Regarding reliability I gave that
8 a partial. Regarding analytical method again
9 it's a little difficult but I think they
10 showed that there's an 11 percent error rate
11 and from chart review it approaches five
12 percent so I gave that a P.

13 Exclusion criteria are largely
14 again based solely on age otherwise there are
15 none. And that's N/A for 2d. 2e similarly
16 there is no risk adjustment in that so it's an
17 N/A. For 2f let's see, now I have to harmonize
18 with my paper copy. Comparability of multiple
19 data sources and methods, again, that's N/A,
20 we don't have what another data set would
21 show.

22 Disparities in care, there are none

1 recorded here so that's an N/A. And I think
2 overall the scientific acceptability of
3 measure properties is met, I gave that a P.

4 Continuing with 3, in terms of data
5 sample, from what they provided, I gave that
6 a P. They don't have access to some of the
7 reports but I think that what they proposed is
8 reasonable. Regarding 3b, harmonization, this
9 gets to not knowing what the other measure
10 exactly states and some of the results that
11 we'll have with the existing NQF measure which
12 is up for review in June of this year. I gave
13 it a P. Similarly we have the same issues as
14 Bob mentioned about the endorsed AMA PCPI
15 measure so I think once we get more
16 information on that we'll have a better
17 understanding of the harmonization potential.
18 I gave that a P.

19 3c, for distinctive and additive
20 value, again, without not knowing the exact
21 information as contained in the two data sets
22 and how they compare and contrast, I gave that

1 a P. I think that was probably generous.

2 And then again the overall
3 usability criterion I gave a P for that. So
4 again it would be very helpful to have, to be
5 able to compare and contrast, the two data
6 sets and the results thereof.

7 Regarding feasibility, they provide
8 a little bit there regarding the coding
9 abstraction performed by someone other than
10 the person obtaining the original information.
11 They have an electronic data source so I gave
12 that an M for 4a and a c for 4b.

13 Regarding exclusions, there are
14 none other than age less than 60.
15 Susceptibility to inaccuracies, this is again
16 inherent in their data sets and I'm not sure
17 what their overall error rate, they've quoted
18 five percent before so I really think it's
19 really complete and I don't anticipate any
20 great problems with inaccuracies.

21 Evidence of cost, this is all
22 electronic, this is not going somebody else to

1 be hand extracting data from case report forms
2 so I gave this a P. And overall, regarding the
3 feasibility I gave that a P. But again we
4 don't have any demonstration provided here but
5 I think it's reasonable to expect that to be
6 a P.

7 So similar to what we just heard
8 regarding the issue of ECG s in a setting of
9 non-traumatic chest pain I also view that this
10 is an extremely valuable metric that we should
11 be tracking, not only in the emergency
12 department setting but also in other urgent
13 care settings and perhaps other venues.

14 But the same caveats are held with
15 the existing NQF guidelines or measure,
16 performance measure as well as the one with
17 the AMA and I think additional information
18 will be very helpful in our ability to make a
19 recommendation, certainly mine. So at this
20 time I don't have a yes or a no. I have a
21 waiting to be seen.

22 CO-CHAIR MOORHEAD: Thank you. We

1 don't have a secondary, any comments or
2 questions?

3 DR. ALESSANDRINI: I just -- and I
4 think it was probably the last time we did
5 this and maybe I was tired of saying, this is
6 relevant to people younger than 60. And I
7 would just be very interested in hearing what
8 other individuals in the room that you know,
9 care for children and adolescents and young
10 adults, but I think certainly this -- and I
11 don't recall, I think it might have been last
12 year, or two years ago or whatever, we had
13 here that the steering committee felt that you
14 know, vasovagal syncope doesn't require it.

15 DR. JAUCH: So their reference to
16 Steve Huff's paper from ASEF were there was
17 not an age specification nor is there one in
18 European society of cardiology. It was the AMA
19 one that had less than 60 would have started
20 to include a fair number of vasovagal events
21 that they were concerned about being
22 compounders.

1 If you have somebody who has a
2 clear, precipitating event, vasovagal event,
3 and they really need an ECG, and whether or
4 not they should be put in the same metric with
5 patients who are over 60 where cardiac causes
6 would be far more prevalent. So granted it's
7 a problem it's just, do you lump them all
8 together and say 90 percent is a good thing,
9 or do you take subsets and say within the
10 elderly everybody should get one, under 60,
11 some proportion should get one, I think they
12 were trying to make it a cleaner -- my
13 interpretation is they were trying to make it
14 a cleaner assessment.

15 CO-CHAIR MOORHEAD: You have a
16 recommendation to defer.

17 DR. JAUCH: So recommend.

18 CO-CHAIR MOORHEAD: That's what I
19 hear your recommendation and I'm seeing people
20 agree. So we will go through the same process
21 if that's okay. All right. I think we are at
22 quitting time almost. We do need an

1 opportunity for public comment.

2 MS. MUNTHALI: I don't think we have
3 anyone on the line. We don't. So we're also
4 going to save the recap until tomorrow morning
5 because we went through a lot of information
6 today and we are fearful that we may all
7 forget so we will have a detailed recap
8 tomorrow morning before we start and we'll
9 continue with the emergency department
10 measures.

11 And I just wanted to remind
12 everyone who presented if you have your hard
13 copies of your evaluation results if you could
14 turn those in, and if you have them by ecopy
15 you can email those to us.

16 And thank you guys for today and
17 see you tomorrow. Enjoy dinner.

18 CO-CHAIR MOORHEAD: So we have --

19 (Whereupon the above-entitled
20 matter went off the record at 4:23 p.m.)

21

22

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