

NATIONAL QUALITY FORUM

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MUSCULOSKELETAL MEASURES
STANDING COMMITTEE

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WEDNESDAY
MAY 7, 2014

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Roger Chou and Kim Templeton, Co-Chairs, presiding.

PRESENT:

ROGER CHOU, MD, FACP, Co-Chair
KIM TEMPLETON, MD, Co-Chair *
THIRU ANNASWAMY, MD, Dallas VA Medical Center
CARLOS A. BAGLEY, MD, FAANS, Duke University
School of Medicine
STEVEN BROTMAN, MD, JD, AdvaMed
SEAN BRYAN, MD, Greenville Health System
CRAIG BUTLER, MD, MBA, CPE, American Academy
of Orthopaedic Surgeons
KELLY CLAYTON, BS, Arthritis Foundation
LINDA DAVIS, BSN, Minnesota Health Action
Group
JAMES DANIELS, MD, MPH, FAAFP, FACOEM, FACPM,
Southern Illinois University
CHRISTIAN DODGE, ND, Bastyr University
ZOHER GHOGAWALA, MD, FACS, Tufts University
School of Medicine
V. KATHERINE GRAY, PhD, SAGE Health Management
Solutions, Inc.
MARCIE HARRIS HAYES, PT, DPT, MSCI, OCS,
Washington University in St. Louis
School of Medicine
MARK JARRETT, MD, MBA, North Shore - LIJ

Health System

PUJA KHANNA, MD, MPH, University of Michigan
WENDY MARKINOVICH, BSN, MPH, RN, Blue Cross
and Blue Shield Association
JASON MATUSZAK, MD, FAAFP, CAQSM, RMSK,
Excelsior Orthopaedics
CATHERINE ROBERTS, MD, American College of
Radiology
ARTHUR SCHUNA, MS, RPh, BCACP, American
Society of Health-System Pharmacists
JOHN VENTURA, DC, American Chiropractic
Association
CHRISTOPHER VISCO, MD, Columbia University
College of Physicians

NQF STAFF:

HELEN BURSTIN, MD, MPH, Senior Vice President
for Performance Measures
ANGELA FRANKLIN, JD, Senior Director,
Performance Measurement
KAREN PACE, PhD, MSN, Senior Director,
Performance Measurement
ANN PHILLIPS, Project Analyst
KATHRYN STREETER, CHES, Project Manager

ALSO PRESENT:

JOHN FITZGERALD, MD, American College of
Rheumatology
MELISSA FRANCISCO, American College of
Rheumatology
RACHEL MYSLINSKI, American College of
Rheumatology
JINOOS YAZDANY, MD, MPH, American College of
Rheumatology

* Present by teleconference

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

8:35 a.m.

MS. STREETER: Good morning. I'm
Katie Streeter, Project Manager for this
project.

I'd like to introduce Ann
Phillips. She's our Project Analyst.

Our Senior Director, Angela
Franklin, is on her way.

So I'll start us off here today.

The restrooms are out past the
elevators on the right. We will be breaking
today. These are actually incorrect times.
We had to switch our agenda around a bit. We
will be taking a break -- oh no, they are
correct -- at 11:00, lunch at 12:45 and then
another break at 3:30.

Helen, do you want to do -- okay.

MS. BURSTIN: Good morning
everybody, I'm Helen Burstin, Senior Vice
President here at NQF. Ann Hammersmith is our
General Counsel and I suspect she's in

1 traffic, so we'll go ahead and I don't want to
2 delay you guys.

3 So what we do is we actually
4 combine introductions and disclosures of
5 interest just for efficiency. And the idea
6 would be that we would ask you as part of the
7 introductions, to introduce who you are and
8 where you're from and then include for us any
9 information about your disclosures,
10 particularly your grants, your contracts,
11 anything that might be relevant to the
12 measures before the committee today.

13 We don't need to hear your full
14 CV. That would take the morning. I've read
15 them all. We've seen them, so thank you.
16 That's why you're seated here, so just --
17 brevity is fine but the major issue is to make
18 sure that as the measures come up, people feel
19 comfortable that everybody's disclosures are
20 on the table and you've all had a chance to
21 ask each other any questions of that.

22 So perhaps we'll begin with Roger.

1 CHAIR CHOU: Thanks.

2 I'm Roger Chou. My background is
3 internal medicine. I'm at the Oregon Health
4 and Science University. I direct the
5 Evidence-based Practice Center over there.

6 In terms of my conflicts and most
7 of my funding, or almost all of it, is from
8 the Agency for Healthcare Research and
9 Quality. I also have gotten some funding from
10 the American Pain Society, the Yale Open Data
11 Access Project, a few other things, but none
12 from industry.

13 I have also worked on guidelines,
14 so I've been on the ACP Clinical Guidelines
15 Committee. I've worked on guidelines for the
16 American Pain Society and we do systematic
17 reviews for the U.S. Preventive Services Task
18 Force and I think I'm here representing ACP.

19 Thanks.

20 MS. BURSTIN: Actually before you
21 move on, just one more quick thing since Roger
22 mentioned he's here representing ACP. He's

1 actually not. He's here representing Roger.

2 He was picked for his expertise.

3 So when you sit at this table --
4 you've been nominated by others. But when you
5 sit at this table, you're here as an
6 individual expert. You don't have to
7 represent the views of who you come from. We
8 really are relying on your personal expertise
9 and that's why you were selected.

10 So sorry to interrupt.

11 Craig?

12 DR. BUTLER: Okay, thank you. Hi,
13 I'm Craig Butler. I'm here nominated by the
14 American Academy of Orthopaedic Surgeons where
15 for the past few years, I've kind of tried to
16 lead our efforts in this area and we're kind
17 of relatively nascent in the area of
18 performance measurement development.

19 I co-chair the Orthopaedic Quality
20 Institute and I chair the Healthcare Systems
21 Committee.

22 By way of background, I'm a sports

1 medicine fellowship trained surgeon but I've
2 kind of walked away from clinical practice in
3 the last few years to do more on the
4 administrative side and most recently, I've
5 kind of ran a systems multispecialty group,
6 but I stepped down from that a few months ago
7 figuring that wasn't quite my cup of tea. So
8 I do some consulting now.

9 I don't have any real relevant
10 conflicts. I'm not working on any measures
11 currently. In fact, part of what I need to do
12 is to learn how I can help the Academy without
13 conflicting myself here and hope to have that
14 discussion as we continue the rest of the day.

15 DR. GHOGAWALA: My name is Zo
16 Ghogawala from Boston, Tufts and Lahey Clinic.
17 I'm a neurosurgeon and I have no relevant
18 conflicts.

19 I have funding for comparative
20 effectiveness research from the NIH and from
21 PCORI but no commercial conflicts of interest.

22 DR. JARRETT: Good morning, my

1 name is Mark Jarrett. I'm the Chief Quality
2 Officer of the North Shore - LIJ Health System
3 which is in the metropolitan area of New York.
4 I'm a rheumatologist by trade. I have no
5 conflicts in terms of any funding or other
6 measurements.

7 DR. HAYES: Marcie Harris Hayes
8 from Washington University in St. Louis. I'm
9 a physical therapist clinical investigator.
10 I do have funding through NIH but no conflicts
11 with the measures we're discussing today.

12 DR. ROBERTS: Good morning, I'm
13 Cat Roberts. I'm a musculoskeletal
14 radiologist at Mayo Clinic. I have no
15 disclosures. I was nominated by the American
16 College of Radiology.

17 DR. ANNASWAMY: Thiru Annaswamy,
18 Dallas VA Medical Center, nominated by the
19 American Academy of PM&R. I'm a PM&R
20 physician. I also work on the Evidence
21 Committee. I'm chairing that committee and
22 the evidence-based practice committee there.

1 No conflict of interest to disclose.

2 MS. DAVIS: I'm Linda Davis and
3 I'm from Minneapolis. I am a healthcare
4 consultant and I was nominated, I believe, by
5 the Alliance, which is the business coalition
6 in Madison, Wisconsin.

7 Most of my consulting these days
8 is with and for employers and the employer
9 coalition based in Minnesota called the
10 Minnesota Health Action Group. I have done
11 some consulting for Minnesota Community
12 Measurement which is a local measurement
13 organization as well.

14 I have no conflicts and I have not
15 received any funding.

16 DR. GRAY: Hello, I'm Katherine
17 Gray and I'm also from Minnesota, from
18 Minneapolis. I am the founder and president
19 of SAGE Health Management Solutions and that
20 provides clinical decision support for
21 imaging.

22 And my background is Ph.D. in

1 Individual Differences, so testing which is
2 reliability and validity and how you measure
3 things. And then I did a post-doc in
4 gerontology and the particular panel that I
5 was on is from CMS so it all does kind of hang
6 together.

7 And I have no conflicts of
8 interest, either.

9 Thank you.

10 DR. MATUSZAK: Hi, my name is
11 Jason Matuszak. I'm a primary care sports
12 medicine physician, family medicine trained up
13 in Buffalo, New York, nominated by the
14 American Academy of Family Physicians.

15 DR. BRYAN: Good morning, Sean
16 Bryan. I'm a family physician and primary
17 care sports medicine physician. I'm in
18 Greenville, South Carolina. I'm the chair of
19 the Department of Family Medicine for
20 Greenville Health System and also an associate
21 professor at the University of South Carolina
22 School of Medicine in Greenville.

1 I was nominated by the American
2 Medical Society for Sports Medicine and I also
3 serve on their Healthcare Transformation and
4 Quality Committee and I have no conflicts to
5 disclose.

6 MS. CLAYTON: Hi, my name is Kelly
7 Clayton and I was recommended or, yes,
8 recommended by the American College of
9 Rheumatology. I have done some advocacy work
10 with them for probably the last five years
11 when I sat on the National Public Policy
12 Committee for the Arthritis Foundation.

13 I'll finish my MPH in about three
14 weeks, but I'm kind of here to bring a patient
15 perspective to things.

16 MR. SCHUNA: My name is Art
17 Schuna. I'm a pharmacist at William S.
18 Middleton VA in Madison. I've spent my entire
19 career in rheumatology practice there and I'm
20 also a clinical professor at University of
21 Wisconsin School of Pharmacy and I represent
22 the American Society of Health System

1 Pharmacists and I have nothing to disclose.

2 DR. DODGE: Morning, Christian
3 Dodge, Bastyr University, Seattle, Washington.
4 I was nominated by the American Association of
5 Naturopathic Physicians.

6 I'm a clinical professor of
7 physical medicine in Seattle at Bastyr and
8 also in private practice. No disclosures.

9 MS. MARKINOVICH: I'm Wendy
10 Markinovich and I was nominated by Blue Cross
11 and Blue Shield Association, the national
12 trade association for all the Blue Cross and
13 Blue Shield plans nationwide and I am the lead
14 for our Blue Distinction Centers for Spine
15 Surgery and Knee and Hip Replacement and I
16 have no disclosures for the measures we're
17 evaluating today.

18 DR. VENTURA: I'm John Ventura. I
19 was nominated by the American Chiropractic
20 Association. I've served on the PQRS TEP for
21 Developing Chiropractic Measures and was part
22 of the NCQA Back Pain Recognition Program from

1 the pilot project and I have no disclosures.

2 DR. KHANNA: I'm Puja Khanna a
3 rheumatologist trained at UCLA and then moved
4 to the University of Michigan. My research
5 has been in gout, so I've worked on the
6 American College of Rheumatology's gout
7 guidelines and I have been on the task force
8 panel for measured development so that is my
9 only conflict of interest.

10 I have been funded by NIH,
11 American College of Rheumatology and just
12 recently submitted a PCORI grant, so here I
13 am.

14 DR. PACE: I'm Karen Pace. I'm on
15 NQF staff, another Senior Director.

16 Ms. Franklin: Angela Franklin,
17 Senior Director for this project.

18 MS. BURSTIN: And there's Dr.
19 Bagley, can you introduce yourself? You have
20 to push the red button that says speak.

21 DR. BAGLEY: I'm Carlos Bagley.
22 I'm a neurosurgeon at Duke University and I

1 was nominated by the North American Spine
2 Society.

3 MS. BURSTIN: And any disclosures
4 you'd like to share with them?

5 DR. BAGLEY: No disclosures.

6 MS. BURSTIN: Great, thank you.

7 And one more new addition. I
8 can't see your name tag. It's still not --
9 push the button the button that says speak.

10 DR. VISCO: Oh, just push it,
11 there we go, sorry.

12 Chris Visco, I've from Columbia
13 University. I'm a physiatrist and nominated
14 by the AAPM&R which is our academy.

15 MS. STREETER: Thanks and we also
16 have Kim Templeton on the line. Kim would you
17 like to introduce yourself?

18 CHAIR TEMPLETON: Hi, thank you.
19 I'm Kim Templeton, an orthopaedic surgeon,
20 Professor of Orthopaedic surgery at the
21 University of Kansas.

22 I believe I was nominated by the

1 U.S. Bone and Joint Initiative. I have no
2 disclosures and I apologize for not being able
3 to be there with you for the next couple of
4 days. We had some clinical issues here to
5 take care of.

6 MS. BURSTIN: All right, thank you
7 everyone.

8 Steve just joined us as well.
9 Steve Brotman, can you introduce yourself?

10 DR. BROTMAN: Hi, I'm Steve
11 Brotman from AdvaMed and I have no
12 disclosures.

13 MS. BURSTIN: All right. So thank
14 you for all those introductions and
15 disclosures. Just one thing we always ask of
16 committees is, you know, you had your
17 opportunity to give your opening disclosures
18 but if at any point during the course of this
19 meeting you have any concerns about potential
20 conflicts or disclosures, please come forward
21 to me or to the chair or any staff and we
22 really want to try to address those issues as

1 quickly as we can.

2 So of course, you've already
3 mentioned that you're on these measures for
4 gout, so we will ask you to recuse yourself
5 from that discussion. You don't have to leave
6 the room, but we can ask you not to
7 participate in those discussions, obviously.

8 And thanks everybody, I'll turn it
9 back over to Katie, I guess.

10 MS. STREETER: Thank you.

11 So just to set some ground rules
12 for today's meeting, NQF has been working to
13 improve the committee meetings based on input
14 from a variety of stakeholders. We've made a
15 few changes in our meeting process. Measure
16 developers will briefly introduce their
17 measures as they come up for discussion. They
18 do have two seats at the table.

19 Selected workgroup representatives
20 will then begin the discussion of the measures
21 in relation to the Measure Evaluation
22 Criteria.

1 So we'd really ask that as you're
2 walking through each measure, you keep your
3 comments and your discussion specific to that
4 criterion that we're on.

5 As is the case with committee
6 members, developers may put up their cards to
7 indicate when they wish to respond to comments
8 raised or correct any statements about their
9 measures.

10 During measure evaluation,
11 committee members often offer suggestions for
12 improvement to the measures. These
13 suggestions can be considered by the developer
14 for future improvements. However, the
15 committee is expected to evaluate and make
16 recommendations based on the measures per the
17 submitted specifications and testing.

18 Just some more ground rules. We
19 ask that you are prepared, having reviewed the
20 measures beforehand. We ask that you please
21 base your evaluation and recommendations on
22 the NQF Measure Evaluation Criteria.

1 Please remain engaged in the
2 discussion and attend the meeting at all
3 times.

4 Please keep your comments concise
5 and focused and avoid dominating the
6 discussion and allow others to contribute.

7 An overview of the NQF Consensus
8 Development Process, also know as CDP, this is
9 an eight step process for measure endorsement.
10 We are currently in the Standards Review step,
11 which is committee review of submitted and
12 maintenance measures, newly submitted
13 measures. This is when we'll make
14 recommendations for endorsement.

15 After this meeting, staff will
16 prepare a draft report that summarizes your
17 recommendation. We'll be posting that report
18 for a 30-day public comment period and NQF
19 member period. We ask that you suggest your
20 peers make comments and we will keep you
21 informed of the dates when that's posted. The
22 link to make comments and everything on our

1 website.

2 After comment period, the
3 committee will meet to discuss the comments
4 and prepare responses. We'll then have a 15-
5 day NQF member voting period followed by CSAC
6 review. CSAC is the Consensus Standards
7 Approval Committee.

8 The Board of Directors will then
9 ratify your decision followed by an appeals
10 period, 30-day appeals period.

11 So this isn't the NQF Measure
12 Evaluation Criteria, nothing new to you.
13 These are the conditions for consideration.
14 Importance to measure and report and
15 scientific acceptability are must pass
16 criteria. If measures do not pass these
17 criteria, they will not move forward through
18 the discussion.

19 If they do pass these criteria,
20 we'll discuss Feasibility and Use and
21 Usability followed by an overall
22 recommendation for endorsement.

1 And then tomorrow, if we do have
2 any identified harmonization issues, which we
3 may, with two of the measures, we'll have a
4 discussion at the end of the meeting to
5 discuss selection best of class or how we can
6 harmonize those measures.

7 And now we'll turn it over to
8 Angela to give an overview of our portfolio.

9 MS. FRANKLIN: Thanks, Katie.

10 So we'll move on through the
11 review of our Musculoskeletal Portfolio and
12 one of the new pilots that we're testing in
13 this particular project is the standing
14 committee concept.

15 And for those of you who may have
16 served with NQF before, this is a new concept
17 and we have a new function for the committee
18 and that is to oversee the Musculoskeletal
19 Portfolio.

20 Your responsibilities will
21 include, as you can see, providing input on
22 the portfolio which we'll step through in a

1 moment.

2 Be aware of which measures are in
3 the portfolio and how they fit into the
4 context of the measures before you for review.

5 Be aware of other NQF measurement
6 activities that relate to musculoskeletal. At
7 this time, we are the only musculoskeletal
8 activity at NQF, but we anticipate, as the
9 committee goes forward, additional activities
10 will become relevant.

11 Be open to external input on the
12 portfolio. That means public comments that
13 come in during the public comment period,
14 following this meeting as well as future
15 comment periods.

16 Provide input from your
17 perspectives as to how the portfolio should
18 evolve over time. And that includes providing
19 your input on gaps that you recognize in the
20 portfolio, areas that you recommend for future
21 measure development.

22 And again, as I mentioned earlier,

1 consider the measures already in the portfolio
2 when evaluating individual measures.

3 At this time, I just want to step
4 through the musculoskeletal disease and the
5 definition that we have right now currently
6 for musculoskeletal disease.

7 And as you can see on the slide,
8 that covers injuries or disorders, including
9 inflammatory and degenerative disorders
10 affecting the muscles, nerves, tendons,
11 joints, cartilage and supporting blood
12 vessels, disorders of nerves, tendons, muscles
13 and supporting structures for the upper and
14 lower limbs; neck, lower back that are caused
15 or participated or exacerbated by sudden
16 exposure to sudden exertion or prolonged
17 exposure to visible factors such as
18 repetition, force, vibration or awkward
19 posture.

20 Just to give you some context,
21 movement for nearly half of Americans over the
22 age of 18 and many children is restricted by

1 musculoskeletal disorder that includes
2 arthritis, back pain, fractures, osteoporosis,
3 sports traumas and any other elements that
4 affect mobility and function.

5 Prevalence of musculoskeletal
6 disease is significant. It's the leading
7 cause of disability in the U.S. and the
8 prevalence of disease requiring medical care
9 has increased by more than two percentage
10 points over the last decade and includes now
11 more than 30 percent of the population.

12 And this is a graphic that we have
13 sourced from the U.S. Bone and Joint
14 Initiative publication, The Burden of
15 Musculoskeletal Disease in the U.S. And this
16 just graphically shows the increasing
17 prevalence of musculoskeletal diseases in
18 proportion to the total population.

19 Some additional context, 89.7
20 million individuals have cited musculoskeletal
21 disease as a primary health concern in
22 response to the Medical Expenditures Panel

1 Survey that was conducted during 2004 to 2006
2 and in 2008, the number of adults reporting
3 musculoskeletal disease increased to 110.34
4 million in the National Health Interview
5 Survey.

6 So, there's been more than a 47
7 percent increase in the total aggregate direct
8 cost to treat persons with musculoskeletal
9 disease during the same time and some
10 estimates place annual direct and indirect
11 costs at \$287 billion, again, that's from the
12 National Health Interview Survey.

13 Over the period of 1996 to 2004,
14 the proportion of persons with one or more
15 major subgroups of the musculoskeletal
16 diseases has risen along with arthritis, joint
17 pain, spine conditions being the most
18 prevalent.

19 And again, I have a graphical
20 representation of these facts. And again, we
21 sourced this from the U.S. Bone and Joint
22 Initiative, Burden of Musculoskeletal Disease.

1 So I wanted to give you a little
2 history of work so far by NQF in the area of
3 musculoskeletal disease and this is comprised
4 of Consensus Development projects that have
5 been held over the years from 2009 to present
6 beginning with our Outpatient Imaging
7 Efficiency Project in 2009, our Ambulatory
8 Care Standards using clinically enriched data
9 in 2010 and our Ambulatory Care Project which
10 endorsed additional outpatient measures also
11 in 2010.

12 From all fo these projects, we
13 ended up with 26 endorsed musculoskeletal
14 measures as of 2011. However, for various
15 reasons, most of those measures have since
16 been retired.

17 So that leaves us with actually
18 four existing measures in the portfolio. Two
19 measures were endorsed in the Clinically
20 Enriched Administrative Data Project and they
21 are the Measure Number 0054 related to
22 arthritis and the use of DMARDs as well as

1 0052 low back pain use of imaging studies,
2 both developed by NCQA and they are part of
3 the NCQA Back Pain Recognition Program.

4 The next two measures that we have
5 in the portfolio are Number 662, median time
6 to pain management for long bone fracture.
7 And that was endorsed during our additional
8 outpatient measures that were endorsed in
9 2010.

10 And in our Imaging Efficiency
11 Project, the measure number 0514, MRI of
12 lumbar for low back pain which was developed
13 -- both of these measures were developed by
14 CMS.

15 So as we've defined our portfolio,
16 we are focused on arthritis and related
17 conditions as well as musculoskeletal
18 injuries. You might also think about
19 congenital and developmental conditions,
20 neoplasms of bone and connective tissue and
21 osteoporosis and bone health as well as spinal
22 deformity and related conditions under this

1 umbrella.

2 However, those conditions are
3 divided amongst our other portfolios with
4 spinal deformity and related conditions are
5 considered in the Child Health and Material
6 Portfolio. Neoplasms are considered in the
7 Cancer Portfolio and osteoporosis is included
8 in the Endocrine Portfolio.

9 So that leaves us with our current
10 portfolio up for review during this phase in
11 the areas of arthritis and related conditions
12 as well as musculoskeletal injuries.

13 Our measures fall into the topic
14 areas of Timely Pain Management, Imaging,
15 Screening and Assessment for Rheumatoid
16 Arthritis as well as Therapy for RA.

17 We're also considering gout
18 measures in the areas of Assessment,
19 Monitoring and Therapy.

20 So we have a total of 12 measures
21 for review and in the portfolio, so that will
22 certainly be the topic of discussion as we

1 move into Day Two.

2 And again, this is a listing of
3 the particular measures as they fall into the
4 topic areas.

5 And for the context within the
6 National Quality Strategy, musculoskeletal
7 disorders measures in this portfolio fall
8 within the Safety and Affordable Care domains
9 of the National Quality Strategy which also
10 serves as our north star as we conduct our
11 work today.

12 So, as a product of our previous
13 projects, prior priority areas for gap filling
14 have been identified in the areas of Disease
15 Modifying Anti-Rheumatic Drugs, or DMARDs,
16 osteoarthritis, care for low back pain
17 including appropriate utilization for low back
18 pain treatments and the management of low pain
19 including manipulative treatments, oral
20 steroid use, narcotic use and functional
21 status outcomes.

22 So as we go through our portfolio

1 and, again, we'll get to this more on Day Two,
2 here are your questions to consider.

3 What are the high leveraged
4 improvement opportunities in this area?

5 Why are the measures current in
6 the portfolio important?

7 And do the measures adequately
8 address quality issues?

9 And also, primarily consider other
10 areas of musculoskeletal disease and disorders
11 and whether you're aware of any measures or
12 concepts that should be brought forward for
13 consideration or considered by a measure
14 developers for future development?

15 MS. BURSTIN: And just one thing
16 quickly to add to that, we really are very
17 interested in finding out measures already in
18 use and there are places where you've got
19 measures that we are using now that we would
20 like to increasingly look at the prospects for
21 those measures and try to bring them in and
22 make them into national standards rather than

1 them starting from scratch in that very long
2 development cycle.

3 So especially because this is a
4 standing committee, we'll be with you for a
5 while so we'll continue to ask you to
6 recommend even measures, for example, used in
7 research. Many of you have grants for NIH or
8 hopefully PCORI.

9 You know, as some of those
10 measures potentially are very useful in
11 research, some of those might be things we
12 could apply and bring forward for national
13 standards as well since, as you can see, there
14 are a lot of gaps in this area.

15 MS. FRANKLIN: Thanks, Helen.

16 And that will move us to our
17 consideration that's key for today's measures
18 and that's our eMeasures Trial Implementation
19 Pathway which we are piloting in this project.
20 And there are several measures within the
21 project that could fall into the pilot.

22 Most notably, we have the four

1 gout measures which are also eMeasures that
2 will fall into this pathway, as well as a
3 rheumatoid arthritis measure that will be a
4 potential candidate for this pathway.

5 And Karen, I don't know if you
6 wanted to speak a little bit to the pathway
7 and how we conceived it or is we want the
8 trial measure

9 DR. PACE: Right, so basically the
10 reason for this pilot eMeasure Trial
11 Implementation, and I think we're calling it
12 Trial Measures.

13 But the reason for it is with
14 eMeasures, given the current uptake of EHRs
15 inability to embed eMeasures and find testing
16 sites, that that's been a limiting factor of
17 bringing eMeasures to NQF.

18 There's not enough sites to
19 implement the eMeasure even for limited
20 testing. And so, in an effort to continue
21 progress in this area, the thinking was that
22 we would look at a process for approving

1 eMeasures as Trial Measures so these would not
2 be considered endorsed but they would
3 essentially have to meet all of the criteria
4 except the scientific acceptability formal
5 testing for reliability and validity.

6 So it has to already be completely
7 specified as an eMeasure, meaning the HQMF,
8 using the HQMF standards for specifying an
9 eMeasure. They would have had to have done
10 the eMeasure feasibility assessment and that
11 includes kind of the data element feasibility
12 as well as testing once this project actually
13 runs.

14 So the idea is that these
15 eMeasures are ready to implement and by giving
16 it approval as a Trial Measure, hopefully can
17 facilitate the testing that would then occur
18 getting enough sites to participate in the
19 testing and since they would data to actually
20 then come back with formal reliability
21 measures.

22 So that's the issues and we're

1 going to be pilot testing it I mean with some
2 measures in this current project.

3 MS. FRANKLIN: Perfect, thank you,
4 Karen.

5 So with that, questions? Yes,
6 Mark?

7 DR. JARRETT: On the eMeasures,
8 would you consider, because I know on one of
9 them there's an eMeasure and there's the same
10 thing in a non-eMeasure. Would we run
11 parallel because that would be a really good
12 test because on the abstracting it the old-
13 fashioned way while electronically trying to
14 measure it to look for reliability and
15 validity?

16 DR. PACE: Yes, that's a
17 possibility. I don't know, are they different
18 measure developers?

19 MS. FRANKLIN: No, they're all the
20 same.

21 DR. JARRETT: They're the same.

22 DR. PACE: Interesting. So,

1 generally that is how eMeasures are being
2 tested right now is to look at the data that
3 is generated through applying the eMeasure
4 compared to record abstraction, you know,
5 using the full record to abstract the same
6 elements.

7 So there's definitely some
8 possibility, especially with it being the same
9 measure developer.

10 Go ahead, yes?

11 DR. JARRETT: No, just because
12 there's a warning and I imagine some of the
13 other people in the room have the same thing
14 as we look through meaningful use and we start
15 paralleling our eMeasures that we send in for
16 meaningful use with what we do by abstraction.

17 The numbers we sent to CMS are
18 very different and some of us get very nervous
19 sending CMS two sets of data because, even
20 though they claim and they sent us a letter
21 saying it's not a problem, we worry about
22 that.

1 So it we have to keep that into
2 consideration why you may want to pilot it in
3 selective places.

4 MS. BURSTIN: That's exactly what
5 we're actually hoping to learn more from. I
6 actually am chair of the Quality Measures
7 Workgroup for the Health IT Policy Committee,
8 so it is in fact true that the measures you're
9 sending in for meaningful use are simply based
10 on whether you could report not the levels or
11 performance.

12 But nonetheless, we all want to
13 understand what those differences are between
14 tarp-based measures, claims-based measures,
15 other approaches and eMeasures. So lots to
16 learn there. Both ambulatory as well as in
17 the hospital.

18 MS. FRANKLIN: Any other questions
19 about anything we've discussed so far?

20 Okay. So that moves us to
21 consideration of our measures and, as I
22 mentioned earlier, we will start with the gout

1 measures and the developer for those measures
2 are the American College of Rheumatology and
3 we do have two seats at the table for
4 representatives from ACO.

5 MS. STREETER: Actually, I think
6 this is a good time to pause and go over who
7 we'll do the voting using the clickers that
8 you have there.

9 Ann will walk us through that. We
10 can even do a practice run to make sure that
11 everyones clicker is working and your vote is
12 registered.

13 MS. PHILLIPS: So, I'll explain to
14 you how the vote stamped devices work. I
15 think all of you should have a fob that I've
16 passed out to you. You'll need to point your
17 votes snap device at -- it works on line of
18 sight at this computer. There is a USB
19 dongle, so just point it here.

20 It works on line of sight. You
21 should see a red light on your device. We
22 give you 60 seconds for voting. The device

1 only records you last input. So if you vote
2 and want to change your input, just press the
3 next button. There's no need to clear it,
4 just press the next button. But it has to be
5 done in that period.

6 So we can go ahead and try a
7 sample vote right here. Okay.

8 DR. PACE: So the voting slides
9 are on the two screens at the end of the room.

10 MS. PHILLIPS: I don't know why
11 this just crashed. Hang on just one second.

12 DR. PACE: So while we're making
13 sure the program gets up and running, I just
14 wanted to -- I know you've been through this
15 on some of your calls, but again, as we talked
16 about at the beginning, we really want you to
17 follow the criteria in terms of your
18 recommendations and you've seen these before
19 but they are at your seat.

20 The algorithms for going through
21 the evidence, the clinical evidence criterion
22 and also the reliability and validity.

1 So, I'll just make a few comments
2 about this and then we can see if you have any
3 questions because I know you've all been
4 reviewing measures and probably have
5 encountered some questions as you've been
6 going through those and thinking about how
7 they meet or don't meet our criteria.

8 So, I think, are most of these
9 measures process measures? So we have a
10 different way that we look at outcome measures
11 but most of these measures will be process or
12 structure measures, so we really do want to
13 look at the strength of the clinical evidence
14 for the focus in that performance measure.

15 So, the idea is direct evidence
16 and also what's the quality, quantity and
17 consistency of that body of evidence? One of
18 the things that we want to distinguish is that
19 clinical practice guidelines may be the source
20 of a systematic review of the evidence where
21 the quantity, quality, and consistency of the
22 body of evidence has been reviewed.

1 Not all guidelines are equal and,
2 you know, so if it's, you know, we have on the
3 submission form where we've really asked the
4 developers to indicate what was the source of
5 the systematic review of the evidence to
6 provide information about the grading of that
7 evidence and actually to provide the summary
8 of the systematic review of the evidence.

9 So one thing to keep in mind is if
10 it's based on a guideline and there is no
11 summary of the quantity, quality and
12 consistency of the evidence, that the highest
13 possible rating would be moderate and that's
14 only if the grading and evidence really
15 indicate that it's fairly strong evidence.

16 Guidelines that are basically
17 recommendations that doesn't fit into our
18 evidence criteria and those would need to be,
19 if they're considered at all under the
20 exceptions to the evidence.

21 And in the algorithm at the very
22 end, beginning with Box 10, we have -- kind of

1 walk through how you might consider and
2 exception to the evidence.

3 So the first question is, are
4 there or could there be performance measures
5 of a related health outcome or evidence based
6 intermediate clinical outcome or process
7 instead of what's being presented? And then
8 again, is there a systematic assessment of
9 expert opinion that that should be done and
10 does the steering committee agree that it's
11 okay to or beneficial to hold providers
12 accountable for performance in the absence of
13 empirical evidence?

14 So, the other thing I'll just make
15 a distinction about is this idea of direct
16 evidence. So a lot of times, we may see
17 measures that come in, assess a lab value,
18 assess a label value, assess a blood pressure
19 value. And obviously, you have to do those
20 things, but the evidence is really about, you
21 know, the relationship of the actual blood
22 pressure value to the health outcomes and

1 mortality/morbidity or there's evidence about
2 treating something.

3 So there's really not going to be,
4 and we don't expect, that there's going to be
5 body of evidence about the need to assess
6 blood pressure.

7 But again, that's an example of
8 where we would much prefer to have measures
9 about how you treat blood pressure or what the
10 control fo blood pressure is rather than
11 measures of Just assessing it.

12 So, just keep that in mind and we
13 can certainly answer questions as you go
14 through this.

15 The other algorithm is for the
16 reliability and validity and we will, again,
17 we can go through these maybe more
18 specifically as you're going through the first
19 measure if you have questions. But I think
20 tow key things about reliability and validity
21 is that the high rating is reserved only as
22 potentially eligible for measures that have

1 been tested at the performance measure level
2 of the performance measure score, not the data
3 elements.

4 So, just a quick example is that
5 if people are looking at the data that are
6 used in the measure, for example,
7 interabtractor reliability, that's at the
8 data element level. What we're talking about
9 when we talk about reliability of the
10 performance score, it's really a signal to
11 noise analysis, being able to distinguish
12 between provider versus within provider
13 differences.

14 So obviously, the performance
15 scores are what's going to be used in
16 accountability applications so that's why that
17 would be eligible for a high rating than any
18 of the testing and how the performances score.

19 Again, it's not just that they did
20 the test, but was it an appropriate test,
21 appropriate sample and adequate results.

22 So, high might be the highest but

1 maybe the results are in the mid-range and you
2 might want to still rate it as moderate.

3 One other point about validity,
4 testing is face validity testing would only be
5 eligible for a moderate reading. It's the
6 weakest form of testing and that's where it
7 would fall with the rating scale.

8 So I'm going to just stop there
9 and see if you have any specific questions
10 about our criteria that I can answer or things
11 that you noticed as you were reviewing
12 measures before we get started and then we
13 can, you know, all obviously work through
14 these things as they come up during your
15 evaluation.

16 MS. FRANKLIN: We'll be able to
17 demonstrate voting with you shortly, but in
18 the meantime, just to follow on to Karen's
19 comments, we do have a format for going
20 through the measures today that's quite
21 specific regarding how the measures are teed
22 up.

1 So, as the committee members may
2 be aware, we're going to ask that you follow
3 the process of first letting the developer
4 provide a brief overview of their measure and
5 rationale behind the measure and then we'll
6 ask for the lead discussants to introduce
7 their measure including the measure number,
8 the title, the description and the level of
9 analysis, if that hasn't already been covered
10 by the developer.

11 And then we'd ask you to walk
12 though each criterion beginning with evidence
13 to discuss the committee's discussion and then
14 throw open the floor to the full steering
15 committee for comments and questions. And
16 we'll proceed in that same fashion through the
17 rest of the criterion and at the end of the
18 discussion of each criterion, we will conduct
19 a committee voting.

20 So that's the step wise fashion
21 that we'd like to proceed in today.

22 Dr. Chou will help guide us

1 through that discussion and facilitate
2 discussion amongst the committee members.

3 Any questions about that process?

4 Yes?

5 DR. ANNASWAMY: Could we test the
6 voting clickers?

7 MS. FRANKLIN: We will be testing
8 the voting clickers. I was just giving them
9 a little time to get that all set up for you.
10 But we'll definitely be conducting a test
11 vote.

12 Are there questions about the
13 process or anything that was discussed?

14 So, as we get the voting materials
15 ready, I think we can go ahead and begin
16 discussion of the first measure, voting by
17 that time, we should be able to have a test
18 vote and then an actual vote following
19 discussions of criterion. So, yes.

20 So our first measure for
21 discussion today is Measure Number 2549
22 entitled Gout Serum Urate Target and our

1 measure steward who is at th at the table is
2 the American College of Rheumatology. Our
3 lead discussants are James Daniel and Steven
4 Brotman who will tee off after the developer.

5 DR. YAZDANY: And so, Katie, can I
6 just ask you to bring up the introductory
7 slides?

8 I'll go ahead and get started here
9 and I'll ask you to advance the slides since
10 you have the controls over there. Yes, yes.

11 So I am Jinoos Yazdany. I am an
12 Associate Professor of Medicine at UCSF and
13 we're practicing rheumatologists and a health
14 services researcher. I have co-chaired the
15 ACR's Quality Measures Subcommittee. I am the
16 principle investigator on the Rheumatoid
17 Arthritis Measures Project.

18 My research funding comes from the
19 NIH NIAMS as well as from PCORI. I have no
20 other financial disclosures. In particular,
21 I have no financial relationships with any
22 entity that makes products or provides

1 services for rheumatoid arthritis or anything
2 else in rheumatology.

3 I am joined here by Dr. John
4 Fitzgerald who is Associate Professor of
5 Medicine at UCLA. He is the Chief of the
6 Division of Rheumatology at UCLA. He chairs
7 the ACR Guidelines Committee.

8 He's the principle investigator on
9 our Gout Measures Project. And John also has
10 no financial disclosures.

11 John and I are volunteers, we are
12 not employed or we are not paid by the
13 American College of Rheumatology.

14 We're also joined here today, I'll
15 just introduce Rachel Myslinski who is our VP
16 of Quality and Registries as well as Melissa
17 Francisco who is Senior Staff.

18 Next slide?

19 So I thought what I would do today
20 is just in a few minutes provide an overview
21 of the methods to provide context for how we
22 arrived at this point.

1 The very first thing and this was,
2 you know, many years ago, was that as a
3 professional society, we actually set
4 priorities for Quality Measure Development and
5 that was through the development of a white
6 paper on quality measurement which was
7 published in 2010. And through that process,
8 we came up with rheumatoid arthritis and gout
9 as top priorities.

10 And the reason for that was
11 because of the prevalence, the perceived gaps
12 in quality and the fact that we felt that
13 measures would have a big impact.

14 We then went on to define methods,
15 and our methods Actually begin with the
16 writing of guidelines. And so both of the
17 measured projects that are being presented
18 today happened after the development of a
19 guideline in rheumatoid arthritis that was in
20 2012 and in gout in 2013 and workgroups that
21 were multidisciplinary in nature with very
22 strict conflict of interest policies were

1 assembled.

2 Next slide?

3 The workgroups defined the measure
4 concepts and really, we tried to build on the
5 lessons that we'd learned from quality
6 measurement over the last decade. And the
7 central task was how to push measurement
8 forward to decide what's meaningful and figure
9 out how the measure that.

10 After those initial measure
11 concepts were developed, we assembled expert
12 panels and this was a multistakeholder
13 participatory effort where we had practicing
14 rheumatologists. We solicited a nominations
15 from other professional societies.

16 So for example, the American
17 Academy of Orthopaedic Surgery, the American
18 College of Physicians and others were
19 involved. There were patient pairs, so for
20 example, a Medical director for Medicaid
21 Managed Care Plan was on our panels,
22 rheumatologists and also allied health

1 professionals.

2 We used the RAND/UCLA
3 Appropriateness Method for ratings and
4 provided the panelists with evidence reviews,
5 pre-conference anonymous ratings and then
6 post-conference ratings.

7 Next slide?

8 Measures that passed the expert
9 panel then went on to a public comment period
10 and the ACR represents 90 percent of U.S.
11 rheumatologists and every member gets an email
12 through the Rheumatology Morning Wire as we
13 call it, every morning so through that and
14 also through newsletters and other efforts, we
15 asked for public comment on the measures and
16 we also targeted a request for responses from
17 other stakeholders, including other special
18 societies and especially societies and
19 patients.

20 And then finally, the various
21 levels of leadership at the American College
22 of Rheumatology approved the measures.

1 So as you can you see, this was a
2 very intensive consensus process arriving at
3 this point.

4 Finally, we got to the -- for the
5 rheumatoid arthritis measures, the e-
6 specifications as well as the recruitment of
7 testing sites to do the feasibility testing,
8 the query building and the validity testing.

9 And I just want to take a moment,
10 actually if you could advance the slide, just
11 to thank the AMA PCPI who were instrumental in
12 helping us navigate the testing since we are
13 the new measure developers and this process is
14 quite intensive, so it was nice to have their
15 expertise and also the NQF staff who provided
16 feedback from the measures concept audit.

17 I'm almost done here, next slide.

18 This is a very brief overview of
19 rheumatoid arthritis.

20 About 1.3 million American have
21 RA. It's more common in women. It's a
22 chronic disease that has no cure and without

1 treatment, one-third of patients will have
2 permanent disability in five years. And as
3 rheumatologists before the modern era where we
4 have so many medications to pick from, it was
5 not uncommon for our waiting rooms to be
6 filled with lots of assistive devices and even
7 wheelchairs.

8 And with modern treatment, most
9 patients can expect that their pain will be
10 well controlled and this joint damage will be
11 prevented.

12 Next slide?

13 You may be wondering why
14 rheumatoid arthritis is a top-20 Medicare
15 prioritized condition by the National
16 Priorities Partnership. Well, I think that if
17 you're CMS, you see that the main age in this
18 disease is 67. This is a chronic disease and
19 so with the prevalence is actually going to
20 increase in our Medicare population as the
21 population ages.

22 We have good treatments and so

1 providing effective care is obviously a
2 priority and I think we would be dishonest if
3 we didn't acknowledge that fact that the cost
4 of treatment is very high and just to
5 illustrate this point, I made this table with
6 the top ten best selling drugs in 2013 by
7 sales and revenue. So these are the ten in
8 the entire healthcare system and four of them
9 are in the area of rheumatoid arthritis.

10 So, you know, there have been lots
11 of debates about Hepatitis C and the cost of
12 those medications recently, but we've had to
13 struggle with drug costs in RA for a really
14 long time.

15 Next slide?

16 The past decade, really the
17 primary RA quality measure has been the use of
18 DMARDs. I call this an equity measure because
19 it has really been an area where we've
20 identified the severities and monitoring has
21 increased use.

22 But new measures that we're

1 proposing today are attempting to build a
2 measure and an infrastructure that's patient
3 centered and aligns with the National Quality
4 Strategy to enable the measurement
5 infrastructure will allow us to look at
6 effectiveness, safety, population health and
7 eventually value.

8 And our measures address three
9 main areas. The first is what is the most
10 important outcome to patients? That's the
11 first measure, functional status.

12 What's the most important outcomes
13 to clinicians?

14 What is it that we base our
15 clinical decisions on?

16 What are the outcomes of clinical
17 trials? That's disease activity.

18 And what's the most critical thing
19 for patients safety that we can measure? And
20 that's TB screening.

21 Next slide?

22 Gout. Gout is interesting because

1 the prevalence is increasing and we think that
2 this has something to do with the epidemic of
3 obesity in this country and a recent NHANES
4 survey, a remarkable 3.9 percent of adults
5 reported gout.

6 I think sometimes we underestimate
7 how severely gout can affect people. It's
8 associated with excruciating pain, it can
9 destroy joints and lead to disability. And as
10 rheumatologists, we see widespread quality and
11 safety problems in this disease more than any
12 other. And so that's why this was a priority.

13 And our gout quality measures --
14 next slide, this is my last slide -- address
15 these questions.

16 What are the cornerstones or
17 appropriate treatment? That's urate-lowering
18 therapy and prophylactic therapy.

19 What is an important intermediate
20 outcome? That's the uric acid target.

21 And how should drugs be dosed?
22 Uris monitoring.

1 So with that, I will turn it over
2 to Dr. Fitzgerald. To introduce the very first
3 measure.

4 DR. FITZGERALD: Thank you,
5 Jinoos.

6 What I'd like to do is, I've
7 prepared a handout for the group that was
8 distributed focusing on responses to the
9 questions that were addressed at the tele-
10 conference, tele-meeting two weeks ago.

11 MS. FRANKLIN: So, first, if you
12 could just introduce the measure that we have
13 coming up next and then as the committee
14 discusses the measure and those questions are
15 raised, we will be happy to have you respond.

16 DR. FITZGERALD: Okay. So, my
17 understanding is we'd have an intro that we
18 can give an overview before the discussion.

19 MS. FRANKLIN: Yes, of this
20 particular measure.

21 DR. FITZGERALD: Okay. So for the
22 first measure which is 2550, the title is Gout

1 ULT Therapy, again prepared by the American
2 College of Rheumatology and a brief
3 description of the measure.

4 It's a measure of the percentage
5 of patients age 18 and older with the
6 diagnosis of gout and either and either tophus
7 or tophi or at least two gout flares or
8 attacks in the past year who have a serum
9 urate level greater than six milligrams per
10 deciliter who are then prescribed a urate-
11 lowering therapy.

12 And so, in introducing this, I
13 wanted to use this measure as a chance to
14 introduce some of the rationale for the gout
15 measures in general and as RA was described as
16 a disease that there's no current cure, gout
17 has often been called a curable disease, yet
18 we all see patients with advanced tophaceous
19 gout on occurrence and attacks and the reason
20 for this is there's a lot of gaps in the
21 quality of care. And some of those gaps are
22 highlighted on Page 2 of the handout.

1 One of the notable problems is
2 that adherence to urate-lowering therapy is
3 quite poor. In several studies, it's been
4 documented that adherent rates of allopurinol
5 for up to 30 percent of the population
6 revealed that patients are only taking their
7 allopurinol ten percent of the time as
8 prescribed.

9 Other documented studies by
10 Halpern and Colleagues have shown that 50
11 percent of patients are described as
12 nonadherent meaning a medical possession ratio
13 of less than 80 percent.

14 In those patients who are
15 nonadherent there are higher serum uric acid
16 levels and in those higher serum uric acid
17 subgroups, there are higher rates of gout
18 attacks.

19 In addition to poor adherence,
20 it's also been noted that there's very little
21 titration of urate-lowering therapy. Patients
22 are often prescribed a single dose. I can

1 cite three studies here where 300 milligrams
2 or less are often initially prescribed and
3 there's no titration that follows up.

4 Furthermore, there's no serum
5 urate monitoring or there's very poor serum
6 urate monitoring done. In studies anywhere
7 between ten or 20 percent of patients might
8 have a serum urate check in the following
9 year.

10 This is problematic because Perez
11 Ruiz and colleagues have noted have noted that
12 most patients require a dose of over 300
13 milligrams to achieve the serum urate target
14 of six.

15 In a study by Annemans and
16 Colleagues, it was a large study looking at
17 4,000 UK patients and 3,000 patients in
18 Germany, there was a greater adherence in the
19 UK with better serum urate control and fewer
20 flares, but again, poor adherence in both
21 countries was noted.

22 I'd like to address some of the

1 concerns about serum urate here at this time
2 as well. I wanted to point out with the
3 charts that are on Page 4 is that the
4 prevalence of gout and the instance of gout is
5 rising over the years but despite that, there
6 has been no change in the prescription rates
7 and the treatment of patients with
8 hyperuricemia gout and those have remained at
9 20 percent.

10 So on the following page, another
11 author has proposed a quality model, a
12 conceptual model, this is by Dr. Lin and
13 Colleagues and there are many areas that could
14 be addressed in the management of gout. We're
15 not able to address those areas.

16 We focused on the physician-
17 patient provider intervention and I want to
18 highlight a couple of things on this chart.

19 On the left side of the chart in
20 the system description of things that could be
21 improved for gout, one thing that these
22 doctors noted is that gout doesn't have any

1 quality indicators and we're hopefully going
2 to address that here.

3 In the areas that have been
4 described for improvement, it's under use of
5 urate-lowering therapy and unsure knowledge
6 about the indications for urate-lowering
7 therapy, the lack of prophylaxis, unaware or
8 lack of knowledge about the target and
9 duration of therapy and lack of dose
10 escalation.

11 The next point that I'd like to
12 address is there were a lot of concerns about
13 the validity of some serum urate as a marker.
14 And two -- actually, I'll table that until we
15 get to the discussion on that.

16 So with that, we'll open it up for
17 discussion.

18 MS. FRANKLIN: Thanks Dr.
19 Fitzgerald. So that moves us to our lead
20 discussants for the measures and that's Drs.
21 Daniel and Dodge, if you could give your
22 overview of the measure from the workgroup

1 perspective and then we'll -- yes, go ahead.

2 DR. DANIELS: Were we supposed to
3 do 2549 or 2550? Because he just --

4 MS. FRANKLIN: 2550, I'm sorry.

5 DR. DANIELS: Okay.

6 MS. FRANKLIN: 2550.

7 And just a reminder that these are
8 Measures that are candidate for the Trial
9 Measure Approval that we discussed earlier.

10 DR. PACE: So, we're going to go
11 through the subcriteria evidence first or --

12 MS. FRANKLIN: Yes, we'll be going
13 through -- we discussed the procedures and
14 measures and then we'll start with the main
15 criteria evidence, importance to measure -- of
16 importance to measure and report and then
17 we'll be voting, but we will conduct a test
18 vote prior to your actual vote.

19 DR. DANIELS: I just want to use
20 people on the panel here and I don't know if
21 I'm the best person to start this, but I'll
22 give it a shot.

1 So am I supposed to review the
2 element of the workgroup first and then I read
3 the --

4 MS. FRANKLIN: Yes, if you could
5 just, yes, give an overview of the measure,
6 the description, a quick description which we
7 have and then the workgroup summary regarding
8 evidence.

9 DR. DANIELS: Okay, a brief
10 discussion was percentage of adults greater
11 than 18 years with a gout diagnosis, being
12 prescribed a urate-lowering therapy and there
13 was a lot of discussion right at the beginning
14 of the measure on the 1(a) evidence report as
15 the measure.

16 And the first, I won't read it
17 verbatim, but, there was comments made that
18 they felt that people felt that there probably
19 were some more information but it wasn't
20 presented, and it looks like more that was
21 done.

22 And then there were a number of

1 questions around how these would attacks would
2 define measurement of -- and they also felt
3 that with the performance gap that there was
4 some evidence of under treatment in this
5 population and they felt that it would have an
6 impact, if it was proven that this was there.

7 And the workgroup agreed that the
8 evidence presented did not directly support
9 the measure focus and the study showed that
10 between patients on a urate-lowering therapy
11 reduces the number of attacks should be cited
12 and strengthen the rationale for measure.

13 There was also some questions
14 about clarification on why the serum levels
15 was chosen, how that happened.

16 MS. STREETER: I just wanted to
17 jump in and ask everyone to speak really close
18 directly into your mic. We've been asked by
19 our court reporter, he's having some problems
20 picking up the voices. Thank you.

21 CHAIR CHOU: Does Dr. Dodge have
22 any additional comments?

1 DR. DODGE: No additional
2 comments.

3 CHAIR CHOU: So maybe we'll open
4 it up now for questions or discussion from the
5 panel. I believe you have something you
6 wanted to say first?

7 DR. FITZGERALD: I can respond to
8 those questions if you'd like at this time or
9 wait.

10 CHAIR CHOU: That would be great.

11 DR. FITZGERALD: Okay.

12 So we responded to the request for
13 additional data on Page 6 of the handout. We
14 have cited the three studies -- no, not that
15 one. There's a Word document, roughly 12-
16 page. The first page is a summary of the
17 measures and if you go past the fish on Page
18 6 to the 2550 Gout ULT Therapy Heading.

19 And what I've done is posted the
20 questions that were addressed to us and so one
21 of the questions was about evidence and we're
22 providing the citations for the three studies

1 looking at febuxostat, these were two
2 randomized controlled trials and an open label
3 follow-up trial demonstrating that febuxostat
4 lowered serum uric acid and reduced the
5 frequency of gout attacks.

6 Also provided here are articles
7 documenting the efficacy about allopurinol.
8 Not surprisingly, these are older articles
9 dating back to the 1960s, but they describe
10 the effect of allopurinol on lowering both
11 uric acid and frequency of attack and tophus
12 reduction.

13 There's a single article also
14 cited for the use of probenecid and then two
15 articles that are cited for the use of
16 pegloticase and the intravenous uricase that's
17 used specifically for patients with advanced
18 tophus.

19 Regarding questions about attack
20 definition, that's been updated. I don't have
21 that on my copy but Melissa provided updates
22 for that.

1 We are going into, this is the
2 eMeasure for the proposal for the trial
3 testing and we are going into testing. We are
4 proposing to use ICD-10 coding and so we'll be
5 looking at that during the specification phase
6 of our study.

7 The performance gap was
8 acknowledged and the last question was about
9 the serum uric acid as a level of six
10 milligrams per deciliter. I do have some more
11 data on that but briefly, the six milligrams
12 per deciliter has been recommended and
13 endorsed by the British Society of
14 Rheumatologists going back to 2004. EULAR,
15 the European League Against Rheumatism and
16 their guidelines in the 2006 and again, by the
17 American College of Rheumatology.

18 The rationale for a level of six
19 is that in an article by Soji and Colleagues
20 --

21 CHAIR CHOU: Can I stop you for a
22 second? I think we'll wait to talk about the

1 uric acid targets until we get to those
2 measures then we can focus on the treatment
3 piece first, if that's okay.

4 Do people have other comments or
5 questions to ask about the supporting
6 evidence?

7 DR. DANIELS: If you want, I don't
8 know, I didn't get this until last night.

9 But I did go through those so if
10 anybody would like a summary I can help with
11 that.

12 CHAIR CHOU: That would be great.

13 DR. DANIELS: Okay. What they did
14 was, at least to me -- what they did is I
15 thought they did a good job on clarifying what
16 they were measuring. It was a little more
17 clear and what they basically said to be in
18 the study, you have to either have typhus or
19 tophi. You have to have two gout flares in
20 the last year and you have to have erosions on
21 a radiograph.

22 And the way the presented seemed

1 at least to me to clarify things a bit better.

2 The big study has been brought on
3 by Halpern, it was like almost 2,500 patients
4 and what it really studied was if the patient
5 might take the allopurinol, it really didn't
6 talk about it, it was prescribed, it's just
7 that the people who they prescribed didn't
8 take it.

9 The second one by survey basically
10 looked at medication possession rate, so of
11 the 30 percent of patients that had
12 medication, less than 10 percent kind of were
13 still using it. So it looks like that there
14 are any of them prescribed and not given.

15 And then the last one talked about
16 patients who have received medication and it
17 was only 300 milligrams, but the dose rate was
18 below six was only 370, excuse me, it was 370
19 is what they said the average to bring it up,
20 so it wasn't that far off.

21 The Japanese guidelines, you know,
22 were kind of mentioned and had gotten sent out

1 in an email and that had a summary where they
2 actually used their definition was seven
3 milligrams and that kind of goes along with I
4 think with 2011 some of the later guidelines
5 on that.

6 And then we've had a real big
7 study in the general practice research
8 database which eight percent of the UK
9 population were followed. And out of those,
10 there was really no change in proportion to
11 the people that were adherent.

12 The fishbone diagram, I thought
13 really brought out a lot of the good points
14 that they were trying to bring out. And then
15 they gave a lot of their studies talked about
16 the latest ones with the -- I'm going to
17 mispronounce this, with the febuxostat.

18 And the allopurinol was
19 surprisingly how low studies were. They were
20 all old and they were like 106 patients and
21 the average was like 30, 33 and 12.

22 And with the probenecid, there were only

1 82 patients.

2 When they talk about feasibility,
3 they basically referred to the other
4 guidelines that had been used and the quality
5 and care of patients.

6 CHAIR CHOU: Are there questions?

7 I had a couple.

8 So one is that at least in the
9 febuxostat trials, you know, you have to have
10 pretty high uric acid levels to get into the
11 study, I think over eight, and then you know,
12 a lot of the other studies focus on people
13 with pretty advanced gout.

14 And so, I guess one of the
15 questions is, you know, what is the evidence
16 in people with minor or less severe attacks of
17 gout?

18 And the other related issue is
19 something that came up on the call which is
20 about, you know a lot of, in primary care,
21 frankly, a lot of people are kind of given a
22 clinical diagnosis of gout and it's often not

1 confirmed. So with, you know, a joint fluid
2 analysis and a lot of them are pretty soft
3 calls.

4 And, you know, somebody says my
5 foot hurts and they get treated like they've
6 got gout. And I guess the concern is about
7 possible potential over treatment is that --
8 or some people -- with some people getting
9 treated who don't really have gout. We've
10 given a lot of these patient, I don't think
11 that -- I mean the guys you see are, you know,
12 different than the ones that are seen in a lot
13 of primary cares.

14 So I guess two questions about
15 kind of the populations studied in the trials
16 and then kind of the reliability of the
17 diagnosis, particularly in primary care
18 settings.

19 DR. FITZGERALD: Okay, thank you.
20 I'll take those in order if you don't mind.

21 So I believe the first question
22 was about the Japanese study. The Japanese

1 guidelines are interesting, they're nicely
2 written. In Japan, they treat asymptomatic
3 hypertyrosinemia and so part of the Japanese
4 guideline measure was to develop the spectrum
5 of patients with gout through patients where
6 they had asymptomatic hyperuricemia.

7 And they developed a novel
8 nomogram looking at what they defined as a
9 normal serum urate as less than seven and
10 hyperuricemia as greater than seven. And so
11 that became their threshold.

12 It has been argued by many about
13 which threshold is used. The problem I have
14 with the Japanese guidelines is that they
15 recommend treatment of patients with
16 hyperuricemia who don't have gout and that's
17 not something that's been accepted here as
18 showing a clear benefit.

19 So, I wouldn't focus on the seven
20 milligram definition from the Japanese
21 guidelines other than to say that there is
22 some variability out there but the three major

1 --

2 Actually, I'll even go back and
3 add the Dutch guidelines which were the first
4 ones that are out. But the four major
5 guidelines that have focused on this have used
6 six milligrams per deciliter and the Europeans
7 have even used five milligrams per deciliter
8 in the more severe cases as the DACR
9 guidelines.

10 For the second question about the
11 less severe patients, one of the -- part of
12 the specification is that this is trying to
13 capture patients who have more severe disease
14 by those patients who are having frequent gout
15 attacks, two or more per year. Those who have
16 tophi or those that have a erosions.

17 For the patient who's having an
18 attack every 14 months or even just one attack
19 per year, they wouldn't be included in these
20 guidelines.

21 So I think the less sever patients
22 would be -- I mean they would not be included

1 in this measure and, you know, hopefully then
2 that wouldn't create the concern about over
3 treating the rest of your patients.

4 And finally, regarding the
5 clinical diagnosis of gout. Gout can be tough
6 to diagnose even in rheumatology practices,
7 the majority of the patients were not needle
8 confirmed cases.

9 In fact, if you look at the
10 criteria, several of the criteria have sprung
11 up over the years to get around the needle
12 confirmation. And now there are clinical
13 indications for the diagnosis of gout which
14 have high likelihood ratios in the 10 to 30
15 range when you're looking at them.

16 And so, criteria such as podagra,
17 rapid response to therapy, limited duration
18 are all included in making a clinical
19 diagnosis of gout.

20 And again, because we're looking
21 for patients who are more severe, not the
22 subtle gout, I hope that and think that a lot

1 of that would be excluded.

2 CHAIR CHOU: Yes, I think that's
3 helpful. I mean I guess I still, you know the
4 tophi and erosions are fairly easy when
5 somebody comes in with obvious podagra it's,
6 you know, fairly straightforward.

7 But I guess my concern are these,
8 you know, I mean I'm a primary care doc, so I
9 see patients who come in and they've been
10 given a diagnosis of gout and I often am not
11 sure that they have gout. They may come in
12 twice a year saying, you know my foot hurts
13 and I --

14 You know, sometimes I'll even just
15 ask, you know, when we kind of do the history,
16 we'll talk about their gout and they'll say,
17 oh yes, I had a few flares and I took a little
18 bit of Naproxen.

19 I have no idea what that means or
20 how reliable that is, is that really a flare?
21 That's really what I'm talking about. And are
22 we really saying that those are patients who

1 we should put on uric acid-lowering therapy?

2 I guess.

3 So anyway, is there a question?

4 DR. MATUSZAK: Yes, I just had a
5 question for the developers on this and maybe
6 I'm misinterpreting this a little bit, but did
7 you say in the evidence supporting this, only
8 about ten percent of patients are actually
9 taking the prescribed meds?

10 So is the outcome that we're going
11 -- I mean is the bar that we're setting just
12 prescribing meds or is it actually that we
13 would like to see the quality outcome being
14 actually driving down the uric acid levels in
15 patients regardless of what method it takes.

16 I mean, is that kind of like going
17 back to some of the analogies we've used
18 saying that we're, you know, going through --
19 we're not going to target hemoglobin A1c for
20 diabetes, we're going to target whether or not
21 you prescribe an insulin for it.

22 So, is this really what you think

1 is going to be an effective target for getting
2 the quality outcome we're looking for?

3 DR. FITZGERALD: I think you
4 nicely set the stage for some of the follow-up
5 measures but in the follow-up measures, we do
6 specify the importance of trying to reach and
7 to measure uric acid and to reach a uric acid
8 target.

9 Uric acid levels and targets are
10 well correlated with patient outcomes. But
11 the first step is getting patients on therapy.

12 The British study showed that
13 patients aren't on it and then patients
14 aren't taking it but the way you would
15 encourage adherence is by trying to get
16 patients to a uric target.

17 DR. MATUSZAK: Yes, it certainly
18 seems that that probably as the bigger
19 obstacle and barrier to overcome and I think
20 how you position this one, this particular
21 measure in the prescribing of the med being
22 the process that we're looking at, again,

1 looking at the available evidence that's out
2 there I think that really the evidence is
3 driving at lowering the uric acid level, not
4 necessarily just by making the prescription,
5 actually getting patients to take it, actually
6 getting them to do the dietary modifications
7 and everything else seems to be a much bigger
8 yield for the quality outcome.

9 DR. FITZGERALD: I think this
10 measure by itself wouldn't address all those
11 issues. There is interesting evidence on
12 adherence in how the drugs are prescribed or
13 what gets patients to they to stay on their
14 drugs.

15 CHAIR CHOU: I see a question over
16 there.

17 I Just wanted to make one follow-
18 up comment first.

19 I think in order to improve
20 adherence, you first have to get people to
21 start prescribing the med, I think that's
22 generally where we start with the quality

1 measures.

2 The second point is that this is
3 the same for many chronic conditions. I mean
4 hypertension, management of hyperlipidemia,
5 management of diabetes, it's less than 50
6 percent adherence rate so this is not unique
7 to this condition.

8 Any comments here or questions
9 here?

10 MS. DAVIS: I was just thinking
11 about what Jason was saying is why don't we
12 just go to the end point here and figure out
13 what the levels, you know, measure the levels.

14 I'm representing the consumer and
15 the purchasers perspective and maybe one way
16 of getting there is by actually publishing or
17 reviewing the levels of different
18 practitioners, comparing them to each other
19 rather than going through -- letting them
20 figure out how to get the patients to keep
21 compliant, letting them figure out how to
22 change their behavior.

1 CHAIR CHOU: Are there any other
2 questions or comments?

3 DR. JARRETT: This is a related
4 question. Disclosure, I'm not a
5 rheumatologist, but could you tell us a little
6 bit about why the compliance is low? Is there
7 a financial barrier to the patients? Is there
8 cause and side effect barrier for patients?
9 Why are patients who are prescribed these
10 medications not taking them?

11 DR. FITZGERALD: So when you look
12 at the cited evidence, and I have that later
13 in one of our discussions, education is a big
14 component. It's been postulated that not
15 checking levels and not giving patients
16 feedback is another component.

17 When urate-lowering therapy is
18 prescribed, there's an expected increase rate
19 of gout attacks during the first three to six
20 months. That has a potential negative
21 feedback and so if patients aren't educated
22 about that and if patients aren't prophylaxed

1 against those attacks, there is a risk of loss
2 of adherence.

3 And so those are the reasons cited
4 with lack of adherence and the flare rate
5 during the first three to six months was one
6 of the strongest associations. It had a
7 twofold increase. Those patients who flared
8 were less likely to stay on their drugs.

9 So there's important education and
10 then we think of prophylaxis is important as
11 well.

12 DR. JARRETT: Is there a financial
13 barrier?

14 DR. FITZGERALD: Well, there
15 shouldn't be. You know, allopurinol is dirt
16 cheap. It's been around forever. Coltrazine
17 used to be dirt cheap but no longer the case,
18 hopefully again.

19 The newer drugs are quite
20 expensive. We're really not interested in the
21 big loaded case. We're not addressing that
22 with any of these patients. We're not looking

1 at the severe or refractory cases really, but
2 the cost of allopurinol, it doesn't cost a
3 lot.

4 But again, the asymptomatic period
5 between attacks, it's very much like
6 hypertension. You know, RA, there's a good
7 feedback, if you don't take your drugs you
8 hurt. And with gout, if you're feeling well,
9 a lot of patients want to try and come off
10 their drugs and they just don't feel they need
11 anything.

12 The problem is that those urate
13 crystals, as long as the levels are above six,
14 they're going to start forming and those
15 crystals are auto-inflammatory and can cause
16 erosion and damage.

17 DR. CHOU: Yes?

18 DR. DANIELS: Just a follow-up
19 that just from a primary care standpoint.

20 What happens is most of the time
21 people go to the doctor when they have a
22 problem and they want that fixed and then

1 otherwise, getting them to come in is a little
2 bit tough.

3 So there's a lot of confusion
4 because there's a bunch of issues here that
5 are sort of all intertwined and so, you know,
6 they really care, I don't want my toe to hurt.
7 Okay? And so then the doc gives them, you
8 know, an anti-inflammatory which really has no
9 effect on the long-term deposits of tophi and
10 all that to happen.

11 And I also know we're discussing
12 other issues here besides the level of the
13 uric acid because there are people that come
14 in with attacks of low and often people with
15 higher acid levels, that don't have gout
16 attacks but they end up having damage to other
17 organ parts.

18 So and then when it comes into it,
19 there's even, I think among providers, a
20 question on, you know, how do you actually
21 diagnose gout? Because for along time, it was
22 like you've got to stick a needle in the joint

1 and those who have in a primary care setting,
2 you don't get much and then when you get the
3 fluid, that's very difficult, if you're not in
4 the right center to identify. And so they're
5 kind of hesitant to stick a needle in
6 someone's toe and then, you know, what do you
7 do? So there's a lot of guessing.

8 And so if you're a doctor, you're
9 saying I'm not really sure about this and they
10 come in every so many years because their toe
11 hurts, we probably know that's going to get
12 measured. I'm not saying that's right, I'm
13 just saying that's kind of how it works.

14 (Whereupon, the above-entitled
15 matter went off the record briefly at 10:00
16 a.m.)

17 However, worrying about quality
18 over a large scope of physicians, I worry
19 about the measure because we are measuring
20 something that, quite frankly, we haven't done
21 the education to really teach people how to
22 respond.

1 And although it is good to say
2 that, all right, this is where our baseline
3 is, and it would provide baseline, and maybe
4 as a trial that is good, I worry about the
5 fact many of the primary care physicians out
6 there do not know how to deal with the first
7 six months when the flareups occur. They
8 don't know how to deal with which drug to use
9 and how to titrate the drug.

10 And although these measures are
11 good to serve as baseline, I worry that we
12 will spend three-four years seeing terrible
13 results, seeing if the results are valid, et
14 cetera, and that it can't go without a
15 concomitant program. Otherwise, we are just
16 measuring the fact that we don't do well. And
17 I know that we all know that in the general
18 community we don't do well.

19 DR. FITZGERALD: I am not sure how
20 to solve the education problem. There has
21 been over a decade with four agencies putting
22 out guideline recommendations.

1 As fantastic as I think the ACR
2 guidelines were, in all honesty, they are not
3 that novel. They really restate what has been
4 stated for years. And yet, the ball hasn't
5 moved on that.

6 I think there is some lack of
7 appreciation of gout and what it can do. We
8 may have to indirectly thank some of the
9 pharmaceutical companies for promoting gout.
10 It has become more -- you see it on
11 commercials, the guy walking around with that
12 big beaker of green juice. And some of that
13 is motivating patients to ask more about gout.

14 So, gout really hasn't been on the
15 radar screen. It has sort of been thought you
16 can treat it intermittently. But we do see
17 the patients that advance to damage, erosion,
18 tophi. They undergo surgeries. There is
19 significant morbidity, and the drugs can be
20 quite toxic, as you advance with renal disease
21 and NSAIDs and steroids. And so, it is
22 important to try to treat these earlier.

1 And a greater public awareness is
2 needed. I am not sure that we are going to
3 have a public campaign.

4 CO-CHAIR CHOU: I think there is a
5 comment there, and then, Carlos.

6 MEMBER ANNASWAMY: Has ULT been
7 defined? What are the drugs that count as
8 ULT?

9 DR. FITZGERALD: So, it would be
10 allopurinol, febuxostat, and probenecid, which
11 are the available agents right now. We are
12 not including pegloticase.

13 MEMBER BAGLEY: I guess the
14 question I had was, how are the number of
15 flares defined? Is it, as you were alluding
16 to, just what the patient reports or is it
17 that the patient actually has sought medical
18 attention to it? Because I think that is
19 somewhat of a concern for me.

20 DR. FITZGERALD: Yes, we will be
21 refining that in the specification phase.
22 But, with the ICD-10 coding, there is a code

1 for gout flares. So, it would probably be,
2 our measure would probably be low on
3 sensitive, meaning that some patients would be
4 sliding by, but the specificity should be
5 good.

6 CO-CHAIR CHOU: Yes, I think we
7 will talk about that some more when we get to
8 the specifications.

9 So, maybe are there other, one or
10 two more comments?

11 MEMBER GHOGAWALA: Just one last
12 question. What number of patients are we
13 talking about here? This sounds like a more
14 severe segment of the people who have two
15 flares a year of tophi. Could you give us
16 some perspective of this population that we
17 aim to study with this measure?

18 DR. FITZGERALD: I don't know the
19 exact numbers for that, but, of all the gout
20 patients -- and gout patients, again, you saw
21 the 4 percent; it is 8.4 million people. The
22 cocktail napkin calculation is I had 20

1 percent and Dr. Gardner had 30 percent. So,
2 20 to 30 percent of patients might be that
3 more severe form. Most patients are really
4 going to be the milder for. That model is
5 difficult.

6 CO-CHAIR CHOU: Yes, one more
7 comment.

8 MEMBER SCHUNA: Yes, my question
9 was with regard to it looks like you are
10 recommending urate-lowering therapies, maybe
11 not addressing appropriate therapies in some
12 cases.

13 For example, a patient with tophi
14 or renal dysfunction or a history of kidney
15 stones probably shouldn't be on probenecid.
16 Is there any cost for that or is an
17 efficiency?

18 DR. FITZGERALD: I think probably
19 for future development we were trying to keep
20 it simple without going to too many
21 specifications.

22 CO-CHAIR CHOU: I have a quick

1 process question before we move on. So, we
2 said earlier that we want to vote on the
3 measures as they are presented.

4 But, if, for example, there was a
5 motion to limit this to people with tophi
6 erosions or something like that, does that
7 mean that this has to kind of go through the
8 whole process again or is it still possible
9 for it to move forward with some modification?

10 MS. FRANKLIN: We generally have
11 to look at the measures as they are presented
12 to us. If there were evidence that the
13 developer could present that that modification
14 would be supported within the measure within
15 the timeframe of this project --

16 DR. FITZGERALD: Our measure is
17 specified for erosions, tophi, or frequent
18 attacks. This is just the summary
19 description.

20 MEMBER MATUSZAK: Actually, it is
21 in the denominator. When they discuss the
22 denominator later on, that is where they

1 actually said that --

2 CO-CHAIR CHOU: Right. Well, what
3 I was referring to was, could the denominator
4 be modified.

5 MEMBER MATUSZAK: Can I just ask
6 one more question on the evidence before we
7 move on?

8 I just noticed that the articles
9 here that you cited in this additional piece
10 that you gave us today, this lead author on
11 all three of those. Just so I am clear on
12 this, does that author have any conflicts or
13 any disclosures or anything that might be
14 relevant to the discussion at hand on the
15 evidence?

16 DR. FITZGERALD: I don't know Dr.
17 Becker's conflicts, but if he was the lead
18 author on all the febuxostat trials, I am sure
19 he received some benefit from authorship.

20 CO-CHAIR CHOU: Maybe we will have
21 Dr. Daniels kind of look at the evidence and,
22 then, see if we are ready for a motion or a

1 vote.

2 DR. PACE: To just do a
3 clarification, from what I have looked at in
4 the submission form, this is an example of
5 where it is based on a guideline. This isn't
6 a systematic review, you know, of a rating
7 review, and consistency wasn't provided. So,
8 we would start at the bottom rating.

9 CO-CHAIR CHOU: Yes, are you
10 saying we start at the moderate and, then,
11 what has been presented additionally since
12 then?

13 MEMBER ANNASWAMY: Are we using
14 moderate as the highest it can be?

15 DR. PACE: Without a systematic
16 review that has been systematically reviewed
17 and rated. So, there is no doubt that there
18 some evidence, that the evidence is here, but
19 there hasn't, at least from what I have seen,
20 there isn't the systematic review where the
21 studies have been graded on the quality of the
22 studies and, then, gone through the whole

1 process of quantity, quality, consistency.

2 MEMBER ANNASWAMY: My question
3 was, you said you can start at moderate. I
4 was wondering, is moderate the ceiling or the
5 floor?

6 DR. PACE: The ceiling.

7 MEMBER ANNASWAMY: Okay.

8 MEMBER BUTLER: So, just for
9 clarification, we are walking our way through
10 this algorithm, correct, and we are basing it
11 on this second block, No. 3. And we are
12 saying no to that on the evidence?

13 DR. PACE: Correct. Well, we are
14 saying -- yes, right.

15 DR. FITZGERALD: Could I just ask
16 for a point of clarification? So, these
17 measures were based on the ACR 2012
18 guidelines. They were derived from that.
19 That was based on a guideline review that did
20 grade all the evidence.

21 DR. PACE: We understand that, and
22 that is the reason that they can at least get

1 a moderate rating. But we have asked the
2 developers, because all guidelines are
3 different, we asked the developers to provide
4 a summary of that systematic review of the
5 evidence where they summarized the quantity,
6 quality, and consistency from a systematic
7 review.

8 And so, we understand from
9 developers that a lot of times guideline
10 developers don't make that available. But if
11 it has been a guideline that is evidence-
12 based, that is where we say, well, then, go
13 ahead and at least give it a moderate rating.
14 But, without really knowing the details of the
15 systematic review, that is the thinking behind
16 this algorithm.

17 MEMBER DANIELS: I feel like the
18 young country fullback that is a freshman
19 going against the UCLA Bruins All-American
20 linebacker here.

21 But what I am going to say is I
22 think moderate is okay. I mean, this

1 percentage of patients I think is something
2 that has been shown.

3 And then, I will kind of make it
4 complex and say, if they picked the six, I
5 think that is probably a low. I will split
6 moderate to low; you can pick which one you
7 want.

8 CO-CHAIR CHOU: Yes, I think,
9 again, we can address the targets when we get
10 to the target measures. I think here
11 essentially we are talking about do we think
12 there is evidence support use of urate-
13 lowering therapies in people with more severe
14 gout. So, what we think the evidence behind
15 that would be.

16 DR. PACE: And the question about
17 where we are in the algorithm, actually, the
18 answer to No. 3 is that there is evidence, but
19 No. 4 is, is there a summary of the quantity,
20 quality, and consistency? And that is where
21 the "no" is. So, you are kind of looking in
22 Box 6 now, based on the guideline

1 recommendation.

2 I also didn't see in this
3 submission the definition of what those grades
4 mean, which we can ask for. But it was stated
5 it was grade A.

6 Each guideline developer tends to
7 have different descriptions of what those
8 mean, but the idea is, do you agree that that
9 is sufficient evidence?

10 MEMBER BROTMAN: Can you provide
11 an explanation of what "insufficient
12 evidence," the conception, is and how it
13 parses out at the end of that chart to a go-
14 or-no-go status?

15 DR. PACE: Good question. I know
16 that this gets a little complicated.

17 So, basically, what we think
18 insufficient evidence means is, if it is based
19 on more of an expert or consensus opinion
20 versus actual empirical evidence, that is
21 where we would say insufficient, versus low
22 would mean there is evidence, but it indicates

1 you really shouldn't do whatever is being
2 suggested. That is pretty unlikely that
3 people will bring those kinds of things
4 forward.

5 The other way you could get at a
6 low is if the evidence is really inconsistent.
7 So, there may be evidence -- and this is where
8 the systematic review is very useful because
9 there may be evidence, and, ultimately, when
10 you look at the whole body of evidence, it may
11 be inconsistent and conflicting. And the
12 thinking there is, then, it is really not the
13 right time to move forward with a performance
14 measure.

15 But insufficient with exception
16 would mean that it is primarily a consensus
17 recommendation without a body of evidence
18 behind it. But there are reasons that you, as
19 the Steering Committee, thinks that it merits
20 having a national performance measurement,
21 which means, you know, maybe there isn't a
22 better measure at this point in time; that the

1 recommendation is based on a group consensus;
2 that that is the way to move forward versus
3 just one small group, and the Steering
4 Committee agrees.

5 So, someone brought up the
6 question, well, why not just measure the uric
7 acid? Maybe there is reason not to or that is
8 too difficult. But you all are experts in the
9 area and know where things are at and the
10 possibilities.

11 MEMBER BROTMAN: Yes, just a
12 followup. So, if that category is voted on,
13 the same effect as low and insufficient
14 evidence or --

15 DR. PACE: Yes. Okay, that is a
16 good question. We have been kind of deciding
17 how best to present this. We have done it
18 different ways.

19 But low would mean it doesn't go
20 forward. Insufficient evidence, it would not
21 go forward. Insufficient with exception, it
22 could go forward.

1 And if this becomes an issue, we
2 may have to split it and first have you just
3 vote on the evidence that is there, and then,
4 come back and ask you to vote on whether you
5 want to move forward with an exception. But
6 we will kind of see how that goes.

7 CO-CHAIR CHOU: Yes, just to
8 follow up on that, I mean, I have been
9 involved with stuff with ACP, for example,
10 with end-of-life care and counseling where
11 there is no studies that show that that
12 improves patient outcomes, but there are
13 ethical and other reasons why people think
14 that is a good thing to do. So, that is one
15 possible example.

16 Another is in the area of safety,
17 where we often don't have good studies. I
18 have done a lot of work with opioids where we
19 don't actually have any good data showing that
20 doing urine drug screening and PDMP
21 monitoring, and all this other stuff, actually
22 reduces abuse or addiction rates. But people

1 think it is a good idea because people are
2 dying from overdoses.

3 So, those are a couple of examples
4 where we may not have good evidence, but
5 enough of a consensus.

6 DR. PACE: And I think that is a
7 good point. You know, the benefit should
8 outweigh potential harm. And the reason we
9 have this in here, and we should have
10 mentioned this to begin with, is that these
11 recommendations are for national standard
12 performance measures, which puts in place, in
13 motion, a whole infrastructure for people to
14 make sure they are doing them, to collect the
15 data, to report the data, et cetera.

16 And so, we want to make sure the
17 evidence warrants, or in the cases that we
18 talked about exception, warrants really
19 putting that all into motion.

20 MEMBER GRAY: I would also like to
21 ask a question, a clarifying question.

22 Roger just restated this: that

1 what we were voting on in terms of the
2 evidence was that, if the medication was
3 prescribed, it would lower the measures. But
4 isn't the way this is written more focused on
5 getting the doctors to prescribe it? Isn't
6 that really kind of the key? Or which way
7 does it provoke?

8 DR. FITZGERALD: So, if the
9 patient has one of these three conditions and
10 a high serum uric rate, then the doctor should
11 prescribe the medication. And so, it is
12 really about the doctor prescribing the
13 medication under right conditions.

14 MEMBER GRAY: But do we have, I
15 mean, in the evidence do we have that they
16 don't prescribe it in those conditions?

17 DR. FITZGERALD: Yes, there is a
18 big British study that is saying only 20
19 percent of patients might be getting that. It
20 wasn't the exact same specifications. So, it
21 wasn't a perfect fit. But there are lots of
22 examples and citations where there is low use

1 of urate-lowering therapy.

2 DR. PACE: So, that would be about
3 the performance gap.

4 CO-CHAIR CHOU: Yes. So, I was
5 going to say that, I think, is the next step,
6 opportunity for improvement.

7 For this first piece with the
8 evidence, what we are looking for is that
9 there is a link between an action and an
10 outcome, right? So, we are looking for
11 whether prescribing a therapy improves
12 outcomes or reduces harms or both. So, I
13 think that is where we are focusing on with
14 the evidence.

15 We will talk about the performance
16 gap I think next.

17 DR. PACE: I think you are asking,
18 it is this what we talk about, the kind of
19 pathway which has it has to be prescribed,
20 but, then, as we have talked about, the
21 patient has to take it before you are actually
22 going to see the impact on the uric acid

1 levels.

2 Again, ideally, you want to
3 measure things, the outcome or things closest
4 to it, but this may be the best you can get at
5 this point in time. So, you need to do that.

6 CO-CHAIR CHOU: So, I think we
7 have one --

8 MEMBER MATUSZAK: I just want to
9 make sure. So, this measurement that we are
10 using here, we can only grade this as moderate
11 if it meets grade criteria high or U.S.
12 Preventive Services Task Force -- I'm sorry --
13 A levels, right? If it doesn't meet that
14 criteria in either case, then we can't rate it
15 as moderate? It has to go to low or
16 insufficient?

17 DR. PACE: That is the way the
18 algorithm is, that it really should be,
19 without that quality, quantity, and
20 consistency, that it should be based on that.
21 But that is where the guidelines graded it
22 Grade A. I don't know if you can speak to

1 what Grade A means for that guideline.

2 DR. FITZGERALD: We used the
3 American College of Cardiology ratings for
4 evidence A, B, or C. A was either a meta-
5 analysis or more than one randomized
6 controlled trial.

7 And so, in this instance,
8 febuxostat studies would be two randomized
9 controlled trials showing that the allopurinol
10 data would probably be under that data as
11 well. It is probably evidence B. It is
12 multiple series.

13 DR. PACE: So, could you clarify,
14 are you saying "you," as the measure
15 developer, graded the evidence or the
16 guidelines?

17 DR. FITZGERALD: The Guidelines
18 Committee graded it.

19 DR. PACE: Okay. Oh, okay.

20 DR. FITZGERALD: Yes.

21 DR. PACE: Okay.

22 DR. FITZGERALD: So, the

1 guidelines would have been the recommendations
2 related to the development of this being rated
3 A based on the febuxostat studies.

4 CO-CHAIR CHOU: We have a moderate
5 on the table.

6 One more comment here or?

7 MEMBER BROTMAN: I just wanted to
8 state that, just for clarification, the rest
9 of, I think 20 percent of the guidelines are
10 based on level Grade A and the rest were Grade
11 C, if I am not mistaken.

12 DR. FITZGERALD: I couldn't give
13 you the percentages on the breakdown, but the
14 majority of the gout data was B and C data.
15 It certainly wasn't all C. But there was a
16 lot of B, and the minority -- there are not a
17 lot of gout randomized trials.

18 DR. YAZDANY: But I think it
19 warrants repeating one more time that this
20 reflects the fact that the data is old, and
21 that the incentive to do a randomized
22 controlled trial in the last 20 years on the

1 drug that costs cents is not there. And so,
2 we just have to take that into consideration.
3 It requires a nuanced look at the data. No
4 one is going to do a randomized controlled
5 trial of allopurinol at this point because
6 there is no financial incentive to do so.

7 But that doesn't mean that the
8 drug doesn't work. We have used it for 60
9 years, and it is just common knowledge and
10 standard of care that it works.

11 CO-CHAIR CHOU: Yes, I mean, the
12 strength of evidence, when we do our evidence
13 reviews, we really look at that as a measure
14 of certainty. And the way we think about it
15 is, do we think if there are other trials that
16 come out, will it change what our conclusions
17 are? If somebody did a trial of allopurinol
18 today, do we think it would tell us that this
19 stuff doesn't work for gout?

20 And even if you don't have huge
21 randomized, you know, placebo-controlled RCTs,
22 you can still be fairly certain about that.

1 I have done reviews on vision screening for
2 the Task Force where there is no trial of
3 cataract surgery versus a placebo. You don't
4 need one, right? You take out somebody's
5 cataract and they can see, and they couldn't
6 see before.

7 So, there's plenty of examples
8 like that where, you know, we can use, I
9 think, evidence that isn't as high on the
10 hierarchy, or whatever, and still have pretty
11 certainty of what the effects of the
12 intervention is going to be.

13 I thought there was a question
14 here.

15 MEMBER DODGE: I have concerns
16 just about how the state of all the ledgers
17 are and how contingent the evaluation of, say,
18 this measure is on the others that actually
19 didn't follow through on evaluating evidence
20 and whether this actually helps people with
21 gout as part of the short-term, especially if
22 there is an increase in flares and people

1 initiate urate-lowering therapy. And if they
2 aren't given these other prophylactic pieces,
3 we could be doing net harm by just
4 implementing this measure alone.

5 And so, how do we manage those
6 contingencies when we are trying to take each
7 measure as its own standalone?

8 DR. FITZGERALD: I think that is a
9 good point. Again, I think in the more severe
10 patients, the risks of not treating are a
11 little bit higher. And again, we will work on
12 educating. We will continue to try to do
13 that, so that this is used in the most
14 effective way.

15 I still think that in a patient
16 who has had frequent attacks or evidence of
17 damage, that getting them started on
18 therapy -- those patients who are having
19 attacks a lot, hopefully, they are on
20 prophylaxis, and if they are not, there is a
21 common custom on how to treat their attacks.
22 So, I think in this select group, there is a

1 little less concern. I think in the group
2 where there is little risk of progression to
3 damage, then there would be harm. But that is
4 not being applied to this measure.

5 CO-CHAIR TEMPLETON: This is Kim.
6 If I could make a comment, too?

7 I guess making sure that the
8 measure also is still focused on drug
9 treatment when we know that the more holistic
10 approach is to also look at lifestyle factors.
11 So, would this potentially, then, result in
12 less patient education about the other things
13 that are part of gout care, with the full
14 focus on medication/medicine?

15 DR. FITZGERALD: Lifestyle is
16 important. There have been studies showing
17 that lifestyle can lower uric acid levels as
18 much a milligram per deciliter.

19 In fact, in the Japanese study
20 that has been reported for patients with mild
21 hyperuricemia, they recommend lifestyle.

22 The ACR guidelines do address

1 lifestyle and recommend that every patient
2 should be counseled on lifestyle and changes.

3 For the subgroup of patients here
4 with more progressive and advanced disease,
5 there are studies that show that lifestyle
6 alone is probably not efficacious enough in
7 this subgroup.

8 CO-CHAIR CHOU: Yes, again, this
9 would be another one where I would have a
10 question about whether the denominator
11 exclusion might incorporate whether lifestyle,
12 you know, things that are identified to work
13 first.

14 Again, I am not sure how strictly
15 we have to adhere to the measure as presented.

16 DR. FITZGERALD: We really wanted
17 to try to include -- that was both in the
18 guidelines and in the measure development.
19 But the complexity of trying to abstract from
20 the chart lifestyle interventions and
21 counseling we thought was going to be
22 complicated. And so, we focused for a

1 simpler, cleaner measure.

2 CO-CHAIR CHOU: Yes. Okay. Well,
3 again, we have a moderate on the table. Why
4 don't we test the clickers? And then, we can
5 see if there is a motion and make a vote on
6 the evidence.

7 DR. PACE: Why don't you go back
8 to just the one or two one? Yes. Yes, that
9 one.

10 Okay. We are going to test the
11 FOBs, so that we have got everybody's vote
12 registered. And you have got 60 seconds to
13 aim your FOBs.

14 CO-CHAIR TEMPLETON: And this is
15 Kim. How do I vote?

16 MS. STREETER: Kim, if you want to
17 text Chad and me through the webinar your
18 vote?

19 CO-CHAIR TEMPLETON: Okay. Just
20 hit the Send thing at the bottom?

21 MS. STREETER: Yes.

22 DR. PACE: And in this case, your

1 options are 1 or 2.

2 MS. PHILLIPS: Your options are 1
3 or 2.

4 CO-CHAIR TEMPLETON: And what is 1
5 again?

6 DR. BURSTIN: One is yes; two
7 is --

8 DR. PACE: This is just a test.
9 It really doesn't matter what it means.

10 CO-CHAIR CHOU: With your
11 microphone on, repeat the instructions.

12 Just push 1 or 2 and point it to
13 her.

14 MS. PHILLIPS: And point right
15 here.

16 One more.

17 MEMBER GHOGAWALA: We don't have
18 to say Send?

19 MS. PHILLIPS: No.

20 There we go; we have 22 now.

21 Okay, so the voting works.

22 This is what a voting slide will

1 look like. So, back to the beginning of this.

2 MEMBER DANIELS: Can I ask, is it
3 a strict majority? Is there a supermajority?
4 What are the rules here?

5 Could I ask for a question before?
6 Because I weighed-in. I wondered if the
7 sophomore running backs wants to -- I'm
8 pointing to Dr. Doge. Do you have an opinion
9 on this?

10 MEMBER DODGE: My earlier comment
11 was not just to the developer, but also to
12 process, where if we are evaluating this
13 measure and there are multiple contingencies
14 about how likely this measure is to be
15 effective that are based on other measures yet
16 to be discussed, how can we evaluate that
17 evidence?

18 MS. FRANKLIN: So, we still have
19 to evaluate the measure just as it stands
20 alone at this point and based on the input
21 that we have received from the developer on
22 their ability to modify or not modify the

1 measure.

2 CO-CHAIR CHOU: I guess, do we
3 have a motion to vote on this as a moderate?

4 MS. FRANKLIN: Someone did ask
5 whether this was a majority vote, and we do do
6 voting by percentage. And if the vote falls
7 within this 40-to-60-percent range, this is
8 supposed to be reached and we consider the
9 measure in the gray area. To the extent that
10 it is 40 percent and above, the measure can
11 continue through the process, to public
12 comment, and then, consideration by the
13 Steering Committee.

14 If the percentage of vote falls
15 below 40 percent, then that would be for low
16 or insufficient evidence. At this point the
17 measure would not pass.

18 Are there still questions about
19 the voting and the percentages?

20 (No response.)

21 Okay. I turn it over to Dr. Chou.

22 CO-CHAIR CHOU: All right. Do we

1 have a motion to vote on the evidence?

2 We don't need to? Okay, let's
3 just do it.

4 MS. FRANKLIN: So, for this
5 measure, you would be voting high, moderate,
6 low, insufficient. And then, if the Committee
7 feels like we should exercise an exception to
8 the evidence, if there is an insufficient
9 vote, then we would look at --

10 DR. PACE: Well, no. Right now,
11 let's try this, unless we get caught up on the
12 insufficients.

13 But, basically, 1 is high, and we
14 have already kind of talked about that, only
15 eligible if the summary of the quantity,
16 quality, consistency submitted -- 2 is
17 moderate; 3 is low, meaning the evidence would
18 really indicate you shouldn't do what is being
19 suggested. Four would be insufficient
20 evidence, but you think it meets the
21 exception, that even though the evidence isn't
22 strong, it really is something that, you know,

1 for consensus opinion and benefits outweigh
2 harms. And then, 5 would just be there's
3 insufficient to make a decision one way or the
4 other. You just can't tell because there
5 wasn't enough evidence. Okay?

6 MS. PHILLIPS: We will have 60
7 seconds, and the voting starts now.

8 (Vote.)

9 MS. PHILLIPS: We will be taking
10 22. We have one remote who is voting via
11 chat. That's right, we are 21; that is
12 correct.

13 So, we can see that 67 percent is
14 moderate. Low was 10 percent. Okay.

15 Fourteen, moderate; 2, low;
16 insufficient evidence with exception, 1, and
17 insufficient evidence, 4. And that means the
18 measure can go on.

19 CO-CHAIR CHOU: So, I think we now
20 move into this performance gap issue, the
21 opportunity for improvement.

22 Dr. Daniels or Dr. Dodge, would

1 you like to present? We have already talked
2 about it a little bit, but maybe just
3 summarize it real quick?

4 MEMBER DANIELS: Well, basically,
5 you know, the new evidence that they have
6 here, there is probably some room to improve
7 that, you know, with patient compliance.

8 It is pretty clear. So, I guess I
9 will keep it short. That's all I will say.

10 Basically, the Work Group came out
11 and said that, overall, less than optimal
12 performance of quality of care; providers will
13 kind of already know. And there is disparity
14 among groups, and then, with the information
15 from the study and, also, the UK
16 information --

17 CO-CHAIR CHOU: I guess my only
18 question is that most of the data presented
19 seem to be about adherence and not about
20 prescribing rates, but I assume that they are
21 both an issue.

22 DR. FITZGERALD: Yes, I would

1 think the evidence that best addresses the
2 prescribing rates is what I would provided in
3 the handout by Quo and colleagues. It was a
4 2013 publication, and it was looking at the
5 trends of the incidence and prevalence of
6 gout, which is the two left charts.

7 And the chart in the right column
8 shows the proportion of patients that had been
9 prescribed urate-lowering therapy. That has
10 remained low. These are patients who are
11 diagnosed with gout. That has remained low,
12 and it has actually even fallen off over
13 recent years.

14 CO-CHAIR CHOU: Any other
15 discussion or questions or comments?

16 (No response.)

17 All right. It sounds to me like
18 it is time to vote on the performance gap
19 issue here.

20 MS. PHILLIPS: You have four
21 options, 1 for high, 2 for moderate, 3 for
22 low, and 4 for insufficient.

1 You may begin voting now.

2 (Vote.)

3 We have 20. We need one more.

4 There we go.

5 Okay. We have 4 for high. We
6 have 15 for moderate. We have zero for low,
7 and we have 2 for insufficient.

8 CO-CHAIR CHOU: So, I think that
9 means that we agree that this is high-enough
10 priority in terms -- or excuse me -- there's
11 enough opportunity for improvement to move on.
12 Correct?

13 All right. So now, we are into
14 the priority discussion. And again, Dr.
15 Daniels or Dr. Dodge, could you briefly tell
16 us what you think about how this measure
17 addresses a healthcare priority? Again, we
18 have heard a lot of this before. So, it can
19 be pretty quick.

20 MEMBER DANIELS: It's there. You
21 know, the stuff that I read from, actually,
22 stuff they gave me last night, some of the

1 things that I thought were linked aren't, or
2 at least there's not good evidence. You know,
3 I always thought that the metabolic syndrome
4 and all that really affected it, and there
5 really isn't any direct evidence. There is
6 some association, but there is no direct
7 evidence. But there is pretty good evidence
8 that there are problems with the tophi and
9 that.

10 The number of patients, you know,
11 how big this hits on the National Priority, I
12 kind of bow to the group here. It probably
13 knows more than I on what you need to do, on
14 how many people this will affect when they
15 come into the doctor's office. By the time
16 they go through the things they want to go
17 through, you want to go through, and then,
18 what the guidelines go through, is there
19 enough time?

20 So, I will leave it at that.

21 MEMBER DODGE: I think the only
22 addition -- and this came up on the call -- is

1 that there was a study or there were numbers
2 about gout in general, but not necessarily
3 what subgroup this particular criteria
4 represents of that 8 million Americans that
5 suffer from gout. I think 20 to 30 percent
6 sounds like the estimate, which is still is
7 substantial. But that wasn't clearly
8 specified.

9 CO-CHAIR CHOU: Any other
10 questions or comments?

11 (No response.)

12 All right. I think we are ready
13 for a vote here. So, this is on healthcare
14 priority.

15 MS. PHILLIPS: You have four
16 options, 1 for high, 2 for moderate, 3 for
17 low, and 4, insufficient.

18 And the voting begins now.

19 (Vote.)

20 And we are at 21.

21 We have 1 for high, 14 for
22 moderate, 3 for low -- I'm sorry -- 2 for low,

1 and 4 for insufficient.

2 CO-CHAIR CHOU: So, I think it
3 passes for that criterion as well.

4 So, then, I think we move on to
5 kind of more the kind of implementation stuff.
6 I don't think the quality construct is
7 relevant for this measure.

8 And so, the next area that we need
9 to address is the reliability. The testing
10 isn't relevant, right, because it hasn't
11 been --

12 DR. PACE: Right, and good point;
13 we probably should have added a new slide for
14 the trial measure.

15 So, basically, what we need to
16 look at here are it is HQMF specifications.

17 And did Chris or the team look at
18 the specs and say that they were sufficient?
19 I am not sure we need to go beyond that, but,
20 Angela, I am not sure what has been done.

21 MS. FRANKLIN: I believe, based on
22 our review of the specifications, the HQMF

1 specifications, they were sufficient with the
2 measure.

3 DR. PACE: And that's confirmed?

4 MS. FRANKLIN: Yes. So, that was
5 what we look at.

6 CO-CHAIR CHOU: So, does the
7 Committee vote? I mean, I am not clear
8 exactly what we are voting on.

9 DR. PACE: So, it is a good
10 question. So, it is an excellent question.
11 We need to think this through here and ask you
12 to think it through with us.

13 So, I guess what we could do, you
14 know, we did have staff that reviewed the HQMF
15 specifications. We don't really expect all
16 the Steering Committee members to be able to
17 do that.

18 We will be asking you to vote on
19 feasibility, which gets into the feasibility
20 of the data elements of the measure logic,
21 which the developer should have presented
22 something for you.

1 So, I guess what we could do is
2 just ask if anyone had any questions about the
3 HQMF specifications or any concerns about the
4 specifications that we should address. But I
5 am not sure -- I will ask you if anyone has
6 anyone has any suggestions. I am not sure
7 that we would really need to vote on those.
8 But were there any issues with them?

9 Yes?

10 MEMBER VISCO: I guess maybe just
11 a point of clarity then. Since there is
12 nothing under exclusion criteria ends, and I
13 know there is some wording in there regarding
14 the specific -- if a patient declines a
15 medication, then there has to be some evidence
16 behind that.

17 And again, I am not as familiar
18 with this evidence. And if there is evidence
19 behind patients deferring or declining
20 medication, you know, they want to put arnic
21 on their feet for three weeks before you give
22 them the prescription, or whatever.

1 And then, the second thing would
2 be contraindications to oral administration of
3 medication.

4 DR. PACE: So, I think you raise
5 some good points. I think we should have the
6 Committee at least look at the English
7 language of the specification and raise any
8 issues you have about it, exclusions and
9 things of that nature. So that we can make
10 sure that those are clarified and we can think
11 about voting regarding this while you are
12 talking about them.

13 But, you know, there really are
14 two issues about specifications. One is that
15 they are precise, and that is part of what the
16 HQMF review would do, and, also, that they are
17 in appropriate HQMF format.

18 But the other part is, are the
19 specifications consistent with the evidence
20 that was presented? And I think that is part
21 of what you are getting at.

22 So, why don't you just have a

1 brief conversations about those issues?

2 CO-CHAIR CHOU: So, it looked to
3 me like the reliability is just whether they
4 report what they want us to measure. But the
5 validity is where we get into this evidence,
6 you know, what the match is and whether there
7 should be different exclusions, et cetera.

8 DR. PACE: Right. So, I think
9 what we are just going to do is focus on
10 specifications. And there are two issues
11 about specifications. It is really do you
12 have any questions about the specifications
13 that need to be clarified. We already know
14 that the HQMF works, but if you have questions
15 about the specifications and whether they are
16 appropriate, then I think we should bring them
17 up here.

18 CO-CHAIR CHOU: Right. So, the
19 one thing that came up earlier was that people
20 with frequent attacks, it will only be people
21 who basically present to the office and the
22 doctor codes it as a gout attack. So, there

1 will be probably a lot of people that either
2 don't come in or it is not coded, and they are
3 going to be missed in the denominator,
4 correct?

5 DR. FITZGERALD: Correct.

6 CO-CHAIR CHOU: Okay. And then,
7 we had already talked earlier about just the
8 question about how somebody defines a gout
9 attack or clinician, but I don't think we are
10 really going to be able to get into that here.

11 Are there other questions or
12 issues in terms of the specifications?

13 MEMBER ANNASWAMY: Validity of
14 including -- there is no denominator exclusion
15 specified in this measure. So, as my
16 colleague here mentioned, shouldn't we exclude
17 patients who voluntarily say, "No, I don't
18 want to be treated with drugs."? Or are there
19 contraindications to them? Are those
20 denominator exclusions?

21 DR. YAZDANY: So, traditionally --
22 and Karen can correct me if I am wrong -- but

1 patient preference, we have guidance that that
2 is not an appropriate exclusion, based on NQF
3 materials and sort of the national climate.

4 DR. PACE: So, exclusions or
5 exceptions has gone back and forth. And so,
6 the NQF criterion guidance on the patient
7 preference really shouldn't be part of
8 exclusions unless they can be appropriately
9 identified, because that is something -- a lot
10 of this comes from the idea, you know, it is
11 something that is easy to check off.

12 You know, the question with
13 exclusions is really, is there any reason to
14 think it should be different across providers?
15 So, things that are infrequent, kind of random
16 events, or that there's going to be a certain
17 small percentage across providers, where that
18 happens, then it is not going to appreciably
19 affect the measure.

20 MEMBER ANNASWAMY: Can you give an
21 example?

22 DR. PACE: Of a small random thing

1 or --

2 MEMBER ANNASWAMY: Of an exclusion
3 that is not a patient preference?

4 DR. PACE: Yes. When you are
5 talking about drugs and allergy to drugs. And
6 that is directly supported by the evidence, I
7 mean the clinical evidence.

8 And again, I guess one could argue
9 that that is going to be a small percentage.
10 And that is part of what, you know, when they
11 actually bring a measure forward for
12 endorsement, if there are exclusions, we ask
13 for some analysis of those exclusions.

14 But my understanding with eMeasure
15 is also that these kind of broad, general
16 categories are very difficult to specify as
17 eMeasures. So, in the past we have seen with
18 some of the measures like a general category
19 of patient preference, system issues, or
20 medical reasons, without any specificity.

21 First of all, you have a problem
22 with standardization, but, also, they have

1 been very hard to operationalize in an
2 eMeasure environment.

3 But go ahead.

4 MEMBER DANIELS: I just want to
5 chime-in that I agree with you, Roger, that
6 really the crux of this whole thing is in this
7 validity area that I hope gets sort of sorted
8 out, because I think there are lots of
9 studies, but they don't actually hone-in on
10 the exact question that we are doing. So,
11 that would be the part, at least for me, that
12 would be real important.

13 CO-CHAIR CHOU: Right.

14 I was just going to comment that,
15 you know, ACR I don't believe has adopted
16 grade yet, but the way that grade rates the
17 recommendations is that strong recommendations
18 are really not affected by patient
19 preferences. I mean, they are, basically, we
20 think this is what should be done pretty much
21 all the time, unless there are really
22 extenuating circumstances.

1 Whereas, the weak recommendations
2 are much more conditional or based on shared
3 decisionmaking kind of aspects. And those are
4 ones where grades would actually say they are
5 probably not candidates for quality measures.
6 Because if patient preferences are that big of
7 an issue, then we probably shouldn't be
8 measuring clinicians on how they perform on
9 this.

10 So, in general, we want the
11 quality measures to be the equivalent of a
12 strong recommendation. So, if there is a
13 concern that there is a huge patient
14 preference component, I think it does call
15 into question whether it should be a quality
16 improvement measure.

17 MEMBER ANNASWAMY: How about
18 contraindications?

19 DR. PACE: Yes, I think those are
20 certainly fair game for exclusions.

21 But do you want to address that?

22 DR. FITZGERALD: So, with urate-

1 lowering therapy, there are three options:
2 the allopurinol, febuxostat, and the
3 probenecid. And each of them has some
4 specific inclusions, but we had in our
5 prophylaxis measure, because the prevalence of
6 those contraindications are higher, we listed
7 all those.

8 For this one, allopurinol
9 hypersensitivity is really fairly low.
10 Febuxostat is an option for those patients.
11 Probenecid has contraindications. Probenecid
12 is not used all that frequently. So, we
13 didn't specify those. We can certainly look
14 into those areas during the testing period.

15 MEMBER ANNASWAMY: Even if there
16 are contraindications? Is that something you
17 can capture by an eMeasure?

18 DR. FITZGERALD: We will look into
19 that, but we should be able to capture, for
20 example, an allergy for allopurinol. For
21 probenecid, we could capture a creatinine
22 level or a history of stones. Febuxostat,

1 again, an allergy would be something, but the
2 allergy for febuxostat and allopurinol is
3 quite low, the allopurinol clearly more
4 concern. The febuxostat can have some similar
5 outcomes.

6 CO-CHAIR CHOU: So, again, a
7 process question. So, if we do think that
8 there should be a contraindication exclusion
9 or something, that is okay?

10 MS. FRANKLIN: Yes. We would
11 capture that in our discussion that will be
12 sent out for public review and our report.

13 So, the concerns that are being
14 raised around the table would be included in
15 our evaluation of this measure, although we
16 are not voting on this particular criterion at
17 this time, and be open for public comment.

18 CO-CHAIR CHOU: Okay. So, I think
19 we are really in the validity discussion. I
20 mean, I think we have kind of moved a little
21 bit beyond the reliability.

22 And again, I think the discussion

1 is around the denominator and the exclusions
2 and these kinds of things, whether we think it
3 is specified the way that we wanted to or
4 whether we have questions or comments to make.

5 So, I will open up the floor and
6 see if people have questions or comments here.

7 DR. PACE: Right. Very good.

8 So, this is a measure that is
9 coming to us that we are considering for this
10 approval as a trial measure, which means it
11 really has not had formal reliability and
12 validity testing.

13 So, the only thing that you would
14 be voting on are specifications. So, I guess
15 what we could do -- would you move to the
16 reliability slide.

17 So, in this case, maybe we can do
18 it this way: you would only be voting on 2a1,
19 precise specifications. So, that is part of
20 our reliability criteria. And normally,
21 reliability is mostly hinged on what the
22 testing actually shows. In this case, there

1 is no testing.

2 We have had a review of the HQMF
3 specs, and those are sufficient. So, I would
4 say that --

5 MS. FRANKLIN: The voting speaks
6 only to the human-readable specifications --

7 DR. PACE: Right.

8 MS. FRANKLIN: -- we have in the
9 measure as specified now. Does that make
10 sense?

11 DR. PACE: Yes. Or we could just
12 skip these and just offer comments. I think
13 that is probably a more reasonable thing to
14 do.

15 MS. FRANKLIN: Yes.

16 DR. PACE: So, let's just say
17 let's move on and talk about the
18 specifications in terms of whether you think
19 there are any issues with them being the right
20 specifications, which normally would fall
21 under validity.

22 But we are not going to really

1 have you vote on either reliability or
2 validity, but certainly offer any suggestions,
3 because these measures are going to be
4 approved as trial measures, which means they
5 are going to be tested and, then, eventually
6 brought back for full endorsement, where you
7 would be actually looking at the empirical
8 reliability and validity testing.

9 So, does that make sense to
10 people? And I apologize, we are kind of
11 working through this with you as we are
12 looking at this first measure for a trial
13 measure. Okay.

14 CO-CHAIR CHOU: Comments or
15 questions?

16 (No response.)

17 So, I still have some concerns
18 about the potential exclusions in the
19 contraindications piece. So, I would suggest
20 that that is something that should be added,
21 or at least I would like for that to be added.

22 And then, I also wonder if there

1 should be built in some kind of lifestyle
2 trial or something. I mean, this basically
3 obligates clinicians to start treatment, the
4 drug. And I wonder if there should be some
5 period at least where you are warned in
6 lifestyle and other therapies. So, that would
7 be my other concern.

8 Then, my last thing that I brought
9 up before is the denominator. I mean, I am
10 fairly comfortable with what it is going to be
11 for tophi and erosions. I am not quite as
12 comfortable with drug therapy for everybody
13 that has a couple of minor attacks a year,
14 however they are defined.

15 And so, I think I can live with it
16 because of the terms of what the denominator
17 should be. I just wanted to put that on the
18 table.

19 I think you had a comment?

20 MEMBER VENTURA: I was under the
21 impression that the denominator captures that
22 by only addressing the people that are more

1 severe, because you have to have the serum
2 urate 6 or greater plus the two frequent
3 attacks.

4 CO-CHAIR CHOU: I don't think it
5 specifies the uric acid level.

6 DR. FITZGERALD: It does.

7 CO-CHAIR CHOU: It does? Okay.
8 So, a serum uric acid of 6 or greater. The
9 tophi and erosions are specified.

10 So, I guess if people are
11 comfortable with a uric acid level of 6 with
12 people who have monoarticular arthritis a
13 couple of times a year or what we think is
14 monoarticular arthritis, that is fine. Like
15 I said, I just wanted to put it on the table.

16 MEMBER DANIELS: I would like you
17 to split it because I think we have sort of
18 two issues here. If you put the gouty erosion
19 and the tophi, that is sort of looking at like
20 long-term damage type of thing versus the
21 gouty flares. But even if you look at
22 treatment, you know, in practice, we have got

1 people who have gouty flares often getting
2 anti-inflammatory medication. It is sort of
3 like a different pathway.

4 So, I would almost like to see it
5 clear to me. And then, I would have a lot
6 more comfort with the levels you have taken
7 because, you know, I do actually have --
8 people who have the gouty flares, that was
9 recommended for a whole series. The reason
10 that I had read is that the complication rate
11 was higher with the higher levels. So, the
12 higher levels, like maybe up around 8 or 9,
13 may be associated with the things that could
14 really affect people's health, not that having
15 a gouty attack isn't fun. I understand.

16 To me, that would really clean it
17 up as far as being able to sort of support it
18 with the evidence. Because, right now, it is
19 just like a whole bunch of targets kind of
20 mixed up in there. And it is not your fault,
21 but the studies that you have don't exactly
22 address those sort of perfectly. And so, you

1 are making some inferences. So, the cleaner
2 we can get it, the better I would feel.

3 DR. FITZGERALD: So, you're right,
4 the studies that identify patients with poor
5 outcomes, tophus is a poor outcome; high serum
6 urate is a predictor of poor outcome and
7 higher medical costs.

8 Patients who are having frequent
9 attacks are more likely to have serum urates
10 in those high levels. I think we are thinking
11 about the odd character who is having frequent
12 attacks and has a marginal urate. Those
13 people are just less common.

14 If you are having to address the
15 recurrent podagra, if you are having frequent
16 attacks, the natural history of gout, it
17 progresses from an intermittent basis of
18 attacks to a chronic phase, where there starts
19 to become chronic pain, chronic inflammation,
20 damage, and erosion.

21 And the people who are more likely
22 to go on to that are those who are having the

1 frequent attacks.

2 MEMBER DANIELS: And again, I know
3 the waters will get muddy a lot more in the
4 future because, as your specialty has sort of
5 done, now the residents are getting trained on
6 office ultrasound on a lot of people. And so,
7 that is going to change like the sensitivity
8 of that. Right now, it is kind of hard to
9 pick that up. So, I think that in the future
10 that may become an issue.

11 DR. FITZGERALD: It may. Again,
12 gout is still primarily treated in the primary
13 care office. Eighty percent of patients don't
14 make it to a rheumatologist.

15 MEMBER ANNASWAMY: There was a
16 mention of erosions in the inclusion criteria,
17 but it is not actually on your enumerator
18 statement. And you just mentioned tophi in
19 your enumerator statement. Is there a
20 difference between tophi and erosions?

21 DR. FITZGERALD: In the last
22 revision I guess erosions came out.

1 MS. MYSLINSKI: So, when we were
2 working on the e-specification, it was not
3 really feasible to assess that in an
4 electronic way, those erosions on a
5 radiograph.

6 DR. PACE: So, I think the
7 question that you are asking is whether the
8 specifications are consistent with the
9 evidence. So, for example, does the guideline
10 for giving this med or prescribing med, is it
11 specified for these specifications?

12 DR. FITZGERALD: The guideline
13 from the 2012 ACR guidelines is -- and,
14 actually, so have been the other guidelines,
15 including the British Society and EULAR -- has
16 been two or more attacks per year tophi or
17 erosions.

18 MEMBER GRAY: Just one more point
19 of question here. Is the target, then, for
20 the accountability to the physician, it is
21 really primary care then as opposed to -- like
22 once they get to the rheumatologist, you

1 believe they are prescribing, right? Is that
2 sort of the deal, the 20 percent that is going
3 there?

4 DR. FITZGERALD: I think
5 assumptions about rheumatologists doing things
6 properly are assumptions. And there is some
7 data that there is better adherence and more
8 prescription use, but you would expect that.
9 They are also a different group of patients
10 that is being seen. So, it is a little bit of
11 apples and oranges.

12 But the goal of these measures is
13 really to try to improve the care for all gout
14 patients. And since most gout patients are
15 being seen by the primary care doctor, that is
16 the target.

17 Again, the infrequent minor gout
18 patient is not being targeted by the measure,
19 but, hopefully, their quality of care improves
20 as well.

21 MEMBER ANNASWAMY: A couple of
22 questions. One is age 18, is that specified

1 because less than 18 doesn't happen? That is
2 more of a clarification.

3 And the second is, what does the
4 lead discussant have in terms of the motion
5 for the specification?

6 DR. FITZGERALD: In general, under
7 age 18 is very unusual, yes.

8 MEMBER DANIELS: And I guess this
9 is where the country boy gets hammered by the
10 outside linebacker.

11 I am going to put 3 down for this.
12 This is where I have my issues with it.

13 MS. FRANKLIN: Okay. So, at this
14 time, we are not actually voting, but we can
15 capture the Committee's sense right now in the
16 discussion about where -- we are not looking
17 at feasibility; we are looking at reliability
18 and validity -- validity at this point.

19 DR. PACE: The question is,
20 though, ultimately, you are going to be asked
21 to approve this as a trial measure. So, if
22 you think the measure is not specified

1 correctly, then I guess that would be a
2 stopping point.

3 So, do you agree that we need to
4 have them vote on this?

5 CO-CHAIR CHOU: Yes, maybe let's
6 take a second. Do people -- I mean, I have
7 already said some of my concerns, and I think
8 James has also -- do other people have
9 thoughts about whether some of the
10 specifications, we should consider
11 modifications, or want to support the
12 specifications as is?

13 MEMBER GRAY: Can we hear from the
14 Committee or the key people, JD and Christian?

15 CO-CHAIR CHOU: Okay. Who?
16 Chris?

17 MEMBER DANIELS: Yes. Basically,
18 I would feel much more comfortable -- I will
19 just repeat it -- if they sort of split it, if
20 like this gouty flare was sort of thrown out
21 and they are looking at erosions and tophi,
22 because that is kind of more of a problem.

1 And the other issue I have is with
2 the level. I almost wish we wouldn't check in
3 that particular level because I think that
4 opens up a whole can of worms.

5 You know, those are my two issues,
6 and the other thing is that they have got some
7 big studies here, but they are not exactly
8 asking the same question. They are close.
9 So, there is a lot of sort of inference in
10 this. That is why I am putting it low.

11 CO-CHAIR CHOU: Thank you.

12 John?

13 DR. FITZGERALD: So, we can feed
14 back after we get our specification. When we
15 test these measures, we could feed back the
16 differences between gouty flare being included
17 or excluded. We could look at that.

18 And then, the reason to put a 6-
19 milligram threshold is we don't want to ding
20 -- so, people who have tophi and gouty
21 attacks, even if their uric acid is 4.8, they
22 should still be put on therapy. But that,

1 again, is sort of that "rare hen" that we
2 don't want to ding people for. So, we put a
3 minimum threshold to make sure we weren't
4 expecting people to go beyond that.

5 MEMBER DANIELS: Then, on 2549,
6 you are using 6.8, on your other. That is
7 where the confusion is.

8 DR. FITZGERALD: Yes, I can go
9 into -- there was a lot of data on that -- and
10 I can go into the rationale on it.

11 On that one, we didn't want to
12 hold people to try to get -- one is an
13 indication to use the prescription; the other
14 one is a target. And so, a higher target is
15 more lenient. And so, we chose a higher
16 target with rationale behind that, to be more
17 tolerant of the patient who is having two
18 attacks per year, and they come back with a
19 uric acid of 6.2. We didn't want to ding
20 someone for that.

21 CO-CHAIR CHOU: Again, we are
22 going to talk about the targets later. I

1 don't want to get too caught up in that.

2 But there is one thing I noticed
3 when I looked at the Becker trial, the
4 enrollment criteria was you had to have a uric
5 acid of over 8. And so, again, this uric acid
6 level thing is just all over the place.

7 DR. FITZGERALD: Okay. So, just
8 my comment on the outcome to try to get the
9 drug approved was serum urate. So, the
10 pharmaceutical company is going to want to
11 enroll people who have high serum urates.
12 They are not going to enroll people with, you
13 know, a serum urate of 6.8 with a goal of
14 trying to get an answer. This affects their
15 image and their population.

16 CO-CHAIR CHOU: No, I understand
17 that. I was just trying to connect the
18 evidence with what we are actually
19 recommending in the quality measure.

20 DR. FITZGERALD: Again, trying to
21 get the evidence to exactly match this, the
22 wording and the specificity and the levels,

1 there is going to be a limit on what the
2 randomized trials can provide.

3 CO-CHAIR CHOU: Yes?

4 MEMBER BRYAN: I'm sorry, getting
5 back to JD's comment earlier about the gouty
6 erosions, it seems like in the specifications
7 it is strictly related to radiographic
8 erosions, but it can also seen on ultrasound
9 and MRI.

10 DR. FITZGERALD: So, Rachel
11 reminds me that we put the erosions at the
12 very end, when we started looking at the
13 feasibility.

14 To answer that, the guidelines
15 have looked at erosion, ultrasound and dual-
16 energy CT findings, and those are really too
17 new to put in and expect people to use as
18 targets. And so, those were left out of the
19 measure.

20 CO-CHAIR CHOU: All right. So, I
21 guess I need to get some guidance on what we
22 are doing now.

1 (Laughter.)

2 So, we are now voting, I heard.

3 DR. PACE: So, again, you will be
4 ultimately voting at the end on whether this
5 measure should go forward as a trial measure,
6 meaning that it is ready to do testing.

7 So, I think there was a suggestion
8 that the denominator specification should be
9 looked at, and the developer mentioned that
10 that is something that could be analyzed
11 through their data when they obtain that
12 through testing.

13 So, one way we can do this is for
14 you to offer recommendations in terms of what
15 the testing should or some analysis that you
16 might want to take a look at with the
17 specifications.

18 I think what we might do is move
19 forward through the other criteria. At the
20 end, you will be asked to do a yes/no on
21 approval as a trial measure, meaning it still
22 has to go to testing and would have to come

1 back to NQF with testing results in order for
2 it to pass endorsement.

3 So, that is where you will really
4 weigh-in on reliability and validity, but I
5 think this is a good opportunity to tell the
6 developer the kinds of issues or concerns you
7 have, so that they adequately look at it
8 during their testing period.

9 Does that satisfy people, if we
10 move on to the other criterion?

11 Go ahead.

12 CO-CHAIR CHOU: Yes, I mean, I
13 think at least James and I have expressed some
14 suggestions about analyzing the people with
15 recurrent attacks separately, however you guys
16 want to do. I think getting data separately
17 would be good. The contraindications for it
18 in terms of exclusions would be something else
19 to consider.

20 And then, at least in the people
21 without tophaceous gout and erosions,
22 considering whether you can somehow

1 incorporate this kind of non-drug therapy
2 trial, or whatever, would be my other
3 suggestion.

4 Are there others?

5 MEMBER DANIELS: I'm sorry. And
6 just to clarify, maybe even considering just
7 saying we are just testing, not asking seeing
8 what -- just kind of tying two things in there
9 in a way, just to see if they are measuring
10 it. It is not actually saying it has to be
11 this level.

12 CO-CHAIR CHOU: Thank you.

13 All right. Are we supposed to
14 break or do we want to finish this one?

15 DR. PACE: Let's go through this,
16 because I think we should be able to get, and
17 we need to get, through these last.

18 Let's move on to feasibility.

19 CO-CHAIR CHOU: Okay.

20 DR. PACE: And then, we will do
21 usability and use, and wrap this up and take
22 a break.

1 Is that okay, Angela?

2 MS. FRANKLIN: Yes.

3 DR. PACE: Okay.

4 CO-CHAIR CHOU: James, any
5 comments about feasibility? I mean,
6 personally, it is hard, it is, I think, more
7 difficult for the panel members who will judge
8 some of these, because these are more kind of
9 technical issues. I think we would like to
10 hear if you guys think there are feasibility
11 issues as well.

12 DR. PACE: So, Angela, did Chris
13 review the feasibility?

14 MS. FRANKLIN: I believe we found
15 the feasibility to be sufficient, and the
16 developer also provided additional information
17 around feasibility assessment that they can
18 docket for the Committee to review.

19 And I guess we would ask the
20 discussants if they have any discussion that
21 they have or comments that they have regarding
22 feasibility, and then, concerns or questions

1 from the Committee.

2 MEMBER GRAY: I have one, and that
3 has to do with, since the ICD-10 will be put
4 off for another year, how does that impact
5 your ability to clarify this data?

6 DR. FITZGERALD: So, we have
7 picked testing sites based on ICD-10
8 implementations. And they were all ahead of
9 the deadlines. And I don't know if we have
10 had updates since the new factors.

11 CO-CHAIR CHOU: Yes?

12 MEMBER VENTURA: Can I ask the
13 developer about a feasibility table, an Excel
14 spreadsheet? I am not sure what those numbers
15 mean.

16 DR. FITZGERALD: So, a survey was
17 done of the sites, and there were questions to
18 each of the leaders at the various test sites
19 about the ability to abstract the data from
20 their records.

21 MS. FRANCISCO: So, I think a
22 primary issue is that whatever you were

1 looking at during the call that we were on was
2 not the actual feasibility assessment that we
3 submitted prior to the discussion. And we
4 actually submitted an entire --

5 CO-CHAIR CHOU: Can you speak
6 closer to the microphone?

7 MS. FRANCISCO: I'm sorry.

8 We actually submitted an entire
9 workbook that runs through each of the
10 questions that were asked, each of the data
11 elements that we asked the sites to look at,
12 and a summary of feasibility based on all
13 those questions that we asked on the specific
14 data elements.

15 So, we sent that in. We have
16 resubmitted it, and I am hoping that you have
17 all actually have had a chance to look at
18 that.

19 MEMBER BROTMAN: So, does the
20 scoring table, the results that are in that --
21 it was a 3x3 grid -- does that have an
22 explanation of what those numbers mean?

1 MS. FRANCISCO: You will find the
2 guidance provided by NQF in terms of the
3 feasibility numbers. We sent the feasibility
4 assessment. And I am not sure if I can quote
5 them off the top of my head. But I think we
6 included in the worksheet the definitions,
7 maybe in the overview tab.

8 DR. FITZGERALD: Yes, Dr. Ventura
9 just has that little final table, not the
10 explanations.

11 MEMBER BROTMAN: We only have
12 numbers, 1, 3, 2.

13 MS. FRANCISCO: The very small
14 table that you are referring to, I think it is
15 a 3x3 that has an overview summary. That was
16 submitted very, very early on, before we went
17 through this entire process. So, this
18 document was uploaded and submitted to you for
19 review, and I don't know why, but you were all
20 given the original table that we submitted
21 very, very early on. So, these are the actual
22 results from the full feasibility assessment

1 that we conducted.

2 DR. YAZDANY: Melissa, would you
3 just provide an overview of the results,
4 because it sounds like maybe people have not
5 had a chance to look at it. So, just a high-
6 level summary, maybe the high points?

7 MS. FRANCISCO: Sure. I think it
8 would be helpful if you could just put the
9 overview tab up. Then, I can kind of speak to
10 that.

11 So, we went through testing of
12 critical data elements that were identified,
13 that we needed to assess the feasibility of,
14 in order for us to even proceed with testing
15 of these measures as they are specified.

16 And so, you don't all have to look
17 at the screen. We looked at five critical
18 data elements relating to certain comorbid
19 conditions, chronic kidney disease and
20 diabetes. We looked for a diagnosis/finding
21 for tophus and gout attacks, contraindications
22 for a certain list of medications that are up

1 there, as well as lab results for serum urate,
2 and active medications, ULT and NSAIDs, the
3 corticoids and colchicine, with a standard set
4 of questions that we asked that are based on
5 NQF.

6 And the rating scale that we have
7 included on each of these data elements also
8 is based on NQF's standards and speaks to
9 feasibility rated 1 through 3, based on, "Is
10 this data element feasible to collect at this
11 time? And if not, is it feasible to collect,"
12 I believe it is within the next three to five
13 years.

14 CO-CHAIR CHOU: Okay. So, it
15 seems like we are getting there, I mean in
16 terms of the general directions to go. And
17 so, hopefully, it will be helpful for our gap
18 discussion, too. Measures like the Minnesota
19 total cost of care endorsed measure do get at
20 those buckets that you were just describing.

21 In addition, we have talked about
22 breaking those measures down by payments from

1 third-party sources.

2 And in addition, we have also
3 talked about the episode-based measures, the
4 measures that are more centered on location,
5 doc conditions, and specific applications of
6 care that make up these buckets.

7 So, this is helpful for an
8 overview framing, and we do have, can look at
9 least the top two measures, the total-cost-of-
10 care measure and the knee replacement measure
11 that both fit into this framework. So, this
12 is getting somewhere.

13 MS. FRANCISCO: So, there are
14 specific ICD-10 codes. If you look through
15 the value sets, there is an extensive list of
16 codes just on tophus alone that get into the
17 granular detail of how that is defined.

18 CO-CHAIR CHOU: And we expect
19 people will be using to that degree of
20 specificity? Anyway, I guess we don't get
21 into all of that. But that is one of the
22 questions I have. Are we actually really

1 going to be able to identify people with
2 erosions and tophi?

3 MEMBER MATUSZAK: I would just
4 also submit that I don't know if we can
5 determine feasibility if we still have a lot
6 of questions about what the measure is
7 actually going to include and what it is not
8 going to include.

9 If we start talking about more
10 exclusions and they are rewriting parts of it
11 to maybe handle more exclusions, then do we
12 really have a good handle on how feasible it
13 might be, once you have started to add some
14 more into the denominator?

15 DR. FITZGERALD: We will certainly
16 test for the exclusions, as requested. We are
17 going to be collecting the data anyway.

18 Some of the exclusions, you know,
19 the contraindications, those are going to be
20 fairly infrequent. It is an infrequent event
21 over multiple providers. I don't think it is
22 going to be a concern.

1 So, I don't want to speak for NQF,
2 but I would vote on it as --

3 DR. PACE: Yes, I would vote on it
4 as it is specified. You know, the developers
5 is going to take your suggestions to heart
6 when they do their testing. This measure is
7 not going to be endorsed. You're basically
8 saying this measure is ready to go and be
9 tested, and you are offering some suggestions
10 for additional information that you need to,
11 that you would expect to see when this comes
12 back.

13 This is a standing Committee,
14 which means that this is the Committee it will
15 come back to.

16 So, I think when the testing comes
17 back, if it indicates they hardly identified
18 any patients, that will tell you something.
19 Perhaps it won't even come back if it really
20 doesn't make it sufficiently through their
21 testing.

22 MEMBER JARRETT: Yes, it gets to

1 the issue, you know, if I look at the table,
2 a lot of the feasibility is three to five
3 years, which is a long time in the electronic
4 world that we are living in today because
5 everything will be different.

6 And philosophically, I mean, what
7 would be the timeframe that the testing would
8 occur? Because, clearly, if it is three to
9 five years before they will be able to pull
10 down a lot of this data from large groups of
11 populations, then are we setting something up
12 now that may just completely change in three
13 years again because of the fact that the
14 electronic world is changing?

15 DR. FITZGERALD: We do have a
16 calendar. Do you want to describe that,
17 Rachel, the testing? Maybe go to the history
18 with like RA and other experiences.

19 MS. MYSLINSKI: So, we are
20 anticipating the testing over the next 12
21 months, so over the next year, which is
22 consistent with RA testing.

1 CO-CHAIR CHOU: Sorry, I was going
2 to say, the one other thing, just in terms of
3 feasibility, is I am just not sure how well
4 you will be able to distinguish what an acute
5 gout attack is. Because, again, when I see
6 patients with gout, I have just coded it
7 "gout". And it could be just a followup or it
8 could be an acute attack. I don't think you
9 can tell necessarily from the coding. So,
10 just another thing.

11 DR. FITZGERALD: I think with
12 ICD-9 you are limited on that, but ICD-10 does
13 have specific gout, acute gout, as a code.
14 So, if you were giving someone an NSAID
15 prescription for acute gout management, in the
16 future you will be coding that with ICD-10 for
17 gout.

18 And the sites we are going to be
19 looking at, it is going to be primary care
20 practices who are using ICD-10.

21 CO-CHAIR CHOU: So, I guess we are
22 voting -- oh, sorry.

1 MEMBER ANNASWAMY: Well, that
2 brings to question about whether you're voting
3 on whether it is feasible now or feasible when
4 ICD-10 comes in.

5 DR. PACE: It is specified for
6 ICD-10. So, it is an eMeasure specified for
7 ICD-10, and that is what the feasibility
8 assessment reflects. And they are going to
9 test it in sites that are using ICD-10.

10 MEMBER ANNASWAMY: To borrow the
11 football analogy, we are voting on potential,
12 not on --

13 DR. PACE: Yes, yes, exactly,
14 because this is an untested measure. So,
15 basically, the bottom line for these trial
16 measures is that it meets our importance
17 criterion, because there is no point in going
18 forward if it doesn't meet our importance
19 criterion, even for testing.

20 And they have already done their
21 homework on feasibility, that they think that
22 they can actually implement it in these test

1 sites, so that they can accumulate data to do
2 formal testing on reliability and validity.

3 And that under usability and use,
4 when we get to it, it is that, basically,
5 there would be a use for this in improvement
6 and accountability, and what is the plan for
7 that to put it into use.

8 And all of this endorsement will,
9 then, hinge on whether the testing actually
10 demonstrates that it can be a reliable and
11 valid quality indicator.

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

14 (No response.)

15 So, I guess, if there are none, we
16 will be voting on whether we think it is
17 feasible enough to test.

18 So, I guess we will go ahead with
19 the vote.

20 MS. PHILLIPS: Okay. We are
21 voting on feasibility. You have got four
22 options. One is high; 2 is moderate; 3 is

1 low, and 4 is insufficient.

2 You may begin voting now.

3 (Vote.)

4 MS. PHILLIPS: We have 14 for
5 moderate. We have 5 for low, and we have 2
6 for insufficient.

7 CO-CHAIR CHOU: I believe that
8 passes.

9 And our last issue or criterion is
10 this usability and use.

11 Some of these I think aren't
12 really relevant in terms of we know the
13 measure isn't being currently used and it is
14 not being publicly reported. And we don't
15 know if there is going to be any improvement
16 over time since it hasn't been implemented
17 yet.

18 I guess the one major issue would
19 be this unintended consequences piece, which
20 we have talked about before.

21 Would the lead discussants want to
22 comment on those before we open it up to the

1 rest of the panel?

2 MEMBER DANIELS: No.

3 DR. PACE: The other thing is
4 whether there is a rationale how it could be
5 used for improvement and that there is a plan
6 for it to be used in accountability.

7 DR. YAZDANY: So, I can comment on
8 that.

9 The ACR has been collaborating
10 with the people who developed the American
11 College of Cardiology's PINNACLE Ambulatory
12 Care Registry. So, I think that is one of the
13 successful examples of an ambulatory registry
14 in the United States.

15 They are in the process of scaling
16 our Pennsylvania Registry, which is gotten
17 certification by CMS to be a Qualified
18 Clinical Data Registry. And these gout
19 measures will be part of beta data, eventually
20 a part of that program in the coming year, we
21 are hoping, and the measures have also been
22 submitted to CMS for use in 2016 programs.

1 So, on many different levels, we
2 are trying to get more experience with the
3 measures and trying to get more data on gaps
4 in care and potential for improvement.

5 CO-CHAIR CHOU: Thanks.

6 Yes?

7 MEMBER MATUSZAK: I want to echo
8 what you brought up earlier, Roger. But I do
9 think that there is a high potential for
10 unintended negative consequences with this.
11 You are talking about that you are
12 specifically gearing this towards the practice
13 in primary care providers and the community.

14 And now, you are telling them that
15 we are going to judge your quality based on
16 whether or not you are starting urate-lowering
17 therapy on the cost of at least two gouty
18 attacks, and we are going to grade you on
19 this.

20 I understand right now we are just
21 testing, actually, but now you are probably
22 going to have a significant in the number of

1 people who are experiencing untoward effects
2 from the initial period of time, that they are
3 not getting adequately educated and just being
4 thrown en masse onto these meds to try to meet
5 these numbers for the quality measure. I
6 think we will see a significant increase in
7 the number of people a lot of side effects or
8 a lot of increased flares during that acute
9 period of time because of inadequate
10 education.

11 CO-CHAIR CHOU: Yes, I mean, I
12 think I said something similar before, and I
13 think the other aspect that I am concerned
14 with is unnecessary treatment and this issue
15 of really pushing people to drugs without
16 considering other lifestyle stuff first.

17 I know that NQF, they must have
18 dealt with this with things like diabetes
19 management and hypertension and
20 hyperlipidemia, because these are all
21 conditions where you would like to do
22 lifestyle stuff first.

1 So, there must be precedent for
2 this kind of thing. But I do think it is
3 worth considering.

4 I think one of the challenges will
5 be how do you actually measure the unintended
6 consequences. I am not sure how we can do
7 that, which is a little bit of a concern
8 because we would like to be able to know what
9 the consequences are. But I think it is
10 actually going to be very hard to measure
11 that.

12 DR. BURSTIN: Just one more
13 caution. The criterion actually makes the
14 case that there is evidence of unintended
15 consequences. So, we are really talking
16 theoretical.

17 I think your point is really well-
18 taken, though, Roger. We need to have a
19 better system of understanding feedback on the
20 ground. Perhaps that is something that is
21 getting better, because our registries are
22 really beginning to understand that, and

1 perhaps put in what some people call
2 "balancing measures" to kind of keep an eye on
3 what might be measures that would suggest that
4 there might be a problem beginning, as part of
5 your ongoing surveillance.

6 CO-CHAIR CHOU: Yes. Well,
7 there's a couple of people I wanted to
8 comment.

9 I was going to say there could
10 actually be a measure about, is lifestyle
11 stuff tried first? I mean, that could
12 actually be a separate measure, but we don't
13 need to talk about that right now.

14 So, a couple of comments. I think
15 you had one.

16 MEMBER BRYAN: It is just to
17 dovetail on what Jason said and what you had
18 said earlier, Roger, the concern that how many
19 of these folks are being labeled with gout,
20 presumptively, when it truly isn't gout.

21 And then, we are going to be
22 telling these primary care docs that they will

1 be measured on quality for putting people on
2 a med. And I just worry about people being
3 put on urate-lowering therapy that don't
4 actually have gout.

5 Now, hopefully, the fact that it
6 does say that they have got to have
7 hyperuricemia will help guard against that,
8 but I still worry about that a little bit.

9 MEMBER ANNASWAMY: My comment is
10 more of a clarification. The measure
11 information form, like Helen was saying,
12 clearly asks whether there has been evidence
13 of unintended consequences.

14 So, the ACR is saying that at this
15 point it doesn't apply. So, they have
16 provided no information. But we are talking
17 about hypotheticals. So, I am not even sure
18 if we are voting on the information provided.

19 DR. PACE: So, the unintended
20 consequences mostly comes into play with
21 measures that have been tested and mostly
22 implemented, because that is when you really

1 have the opportunity to see unintended
2 consequences.

3 I think these are certainly things
4 that are worth discussing and noting to the
5 developer, that if they can look at any of
6 this, because we do say, was there any
7 evidence of it during testing. So, I think it
8 is worth noting. And I think you should vote
9 the way you think.

10 Yes?

11 DR. FITZGERALD: Yes, just to
12 address the concerns. We do agree about the
13 lifestyle recommendations. In our education,
14 in our guidelines, all patients with gout,
15 whether it is minor or severe or tophaceous,
16 are advised and recommended that their
17 physicians guide them and educate them on
18 therapy.

19 For those patients who are not
20 severe, lifestyle alone may be appropriate.
21 For those patients who are severe with
22 frequent attacks, lifestyle alone is likely

1 not to be effective and urate therapy will be
2 needed for that.

3 And so, by looking at just the
4 more severe patients, those patients who are
5 with or without lifestyle likely are going to
6 need urate-lowering therapy. And in those
7 patients, you know, one of the main side
8 effects is, as has been brought up here and
9 discussed, is a gout attack. These are
10 patients who are already defined as having
11 frequent gout attacks.

12 In the short-term, increased risk
13 of gout attacks for long-term reduction is a
14 tradeoff. And again, hopefully with
15 education, I mean, that can be moderated.
16 These are patients who are having gout
17 attacks. So, hopefully, they have therapies
18 for their gout attacks, which would minimize
19 potential harm.

20 The other harm is not treating and
21 letting them go on to continue to have attacks
22 and further progressive damage.

1 CO-CHAIR CHOU: If there are no
2 other comments, I guess we are voting. Again,
3 I think we are voting on whether we think it
4 is usable for testing, but not for endorsement
5 yet, but just whether we would think that they
6 should go ahead and test this measure.

7 So, why don't we go ahead and do
8 the vote?

9 MS. PHILLIPS: Now you are going
10 to vote on usability and use. Your options
11 are 1 for high, 2 for moderate, 3 for low, and
12 4 for insufficient.

13 You may begin voting now.

14 (Vote.)

15 DR. PACE: Okay, we have 21
16 responses, and 1 for high; 12 for moderate; 4
17 for low, and 4 for insufficient.

18 CO-CHAIR CHOU: So, I think that
19 barely makes our 60-percent threshold with the
20 combination of high and moderate. So, I think
21 that means that they can move forward with
22 testing in terms of the usability and use

1 issue.

2 Now do we do an overall vote now
3 on the whole measure? I think now that what
4 we do is get an overall vote, with all the
5 considerations, the evidence, the priority,
6 the gaps, the measure specification stuff, and
7 the feasibility.

8 And again, I think we are not
9 voting to endorse at this point. We are
10 voting to move forward with testing.

11 Any final comments before we do
12 this vote?

13 MEMBER VISCO: If this comes out
14 as a "no," can it still be tested?

15 DR. PACE: So, if this comes out a
16 "no," first of all, it goes out for public
17 comment to see what the public comments say
18 about it and, also, if there are issues that
19 the developer wants to bring back to you.

20 But by no means, it wouldn't carry
21 the NQF approval, and we should tell them what
22 needs to be fixed to get NQF approval as a

1 trial measure.

2 So, you know, it really is a
3 question whether any of the issues that were
4 brought up are kind of fatal flaws for moving
5 forward with testing.

6 CO-CHAIR CHOU: And can I just
7 ask --

8 DR. PACE: Yes.

9 CO-CHAIR CHOU: So, really, the
10 testing, it is just a resource thing. It is
11 not going to have a clinical impact at this
12 point. It is whether we think that it is
13 worth the resources of the NQF and the
14 partners to go forward with testing. Is that
15 correct or are there other --

16 DR. PACE: Right. It really is
17 whether this is a measure that is going to be
18 useful and it bears further testing. The
19 developer already thinks that. They have
20 already invested a fair amount into specifying
21 it to get to this point and submitting it.

22 And so, I think, you know, it

1 really is whether there is any fatal flaws
2 that you think, you know, as you have said, it
3 is not worth the resources to proceed with
4 further testing.

5 So, we will correct this next
6 slide for the next trial measure we have. So,
7 disregard that it is -- well, let's just go to
8 the last slide that is the yes or no.

9 Yes, yes. So, we will have a
10 specific slide about whether you want to
11 approve it as a trial measure. So, this is
12 just a generic yes/no slide, and we will fix
13 that on the break.

14 So, it is, basically, you will be
15 voting on whether this measure should be
16 approved as a trial measure, meaning you think
17 it should proceed with testing.

18 Again, the testing would have to
19 come back before this measure would ever be
20 considered endorsed. And this, as well as any
21 of the recommendations you make later, are
22 things that will go out for public comment.

1 So, this is the first phase of the process.

2 So, why don't we go ahead? A yes
3 would mean approval as a trial measure, and no
4 would be not approved.

5 MS. PHILLIPS: Okay. We are
6 voting on Measure 2550 for approval for trial
7 use.

8 You may begin voting now.

9 (Vote.)

10 MS. PHILLIPS: We have 20
11 responses.

12 Okay, 14 say, yes, go ahead with
13 the trial measure, and 7 say no.

14 CO-CHAIR CHOU: All right. So, I
15 guess that passes and it meets our 60-percent
16 threshold again.

17 And I think it is time for a
18 break.

19 (Whereupon, the foregoing matter
20 went off the record at 11:39 a.m. and went
21 back on the record at 11:56 a.m.)

22 CHAIR CHOU: Just wanted to let

1 everyone know, we're going to talk about 2521
2 first before 2549. I think that it makes a
3 little more sense clinically to talk about
4 wether to measure before we talk about
5 targets. I believe these are both trial
6 measures. Is that correct?

7 MS. FRANKLIN: Yes. These are
8 measures that will also be considered for
9 cross measure approval. So they are not
10 measures to be approved for ambility purposes.

11 CHAIR CHOU: And I'll turn it over
12 to the developer, John, to give us a little,
13 a brief overview.

14 DR. FITZGERALD: And thank you.
15 So 2521 is titled, Gout: Serum Urate
16 Monitoring. And the numerator statement is
17 that patients measured with serum urate within
18 6 months after the date of a new or a change
19 in dose onto urate lowering therapy
20 prescription.

21 The denominator would be adults
22 over 18 with established Gout initiating or

1 changing a dose of urate lowering therapy.
2 The rationale for this is we want to look at
3 patients who are given either a new
4 prescription for urate lowering therapy or a
5 change in dose. And we want a follow up urate
6 measure.

7 The evidence shows that the
8 majority of patients are given a prescription
9 of uric acid and then, depending on the
10 studies usually it's only about 20 percent of
11 patients get a follow up urate level checked.

12 And so without a urate level being
13 checked, you don't know if the patient's
14 adherent, if the drug is effective and so you
15 really need to connect the outcome of the
16 urate lowering drug, which is the urate
17 measurement. And if we have questions later
18 about the data I can answer those.

19 CHAIR CHOU: Great. I think Steve
20 was going to be the initial lead discussant
21 and just provide an introduction.

22 DR. BROTMAN: Right. So, again,

1 this is item 2521 Gout: Serum Urate
2 Monitoring. steward is the American College
3 of Rheumatology. And a brief description of
4 the measure once again is percentage of Gout
5 patients who have started on or changed urate
6 lowering therapy who's serum urate is measured
7 within 6 months after dose change.

8 The numerator statement is that
9 the patients with serum urate measured within
10 6 months after date of new or changed urate
11 lowering therapy prescription. And the
12 denominator is adults more than 18 years of
13 age with established Gout initiating a
14 changing dose of urate lowering therapy.

15 There are no exclusions. It's a
16 process measure. It is another one of the
17 electronic type of trial measures where the
18 reliability and validity testing will be done
19 at a later time.

20 And we'll start with a discussion
21 of the evidence. The workgroup had a robust
22 discussion of the evidence and I'm going to be

1 very brief because I want to get to a full
2 discussion here.

3 But basically the discussion
4 entailed that there's no direct evidence to
5 support the proposed measure. Namely, there's
6 no cited trials of uric acid monitoring versus
7 no monitoring or treating to uric acid level
8 targets or other strategies.

9 And the evidence is based largely
10 on the association between uric acid levels
11 and recurrent Gout. And given a lack of some
12 of that evidence, it was hard for a lot of us
13 to determine how high a priority this should
14 be.

15 Some other workgroup comments.
16 Some of us noted that while clinical
17 guidelines were presented to support the
18 measure, very little of the evidence directly
19 addressed the impact of and the linkage
20 between monitoring serum urate levels and
21 improved outcomes.

22 Again, these measures are based on

1 the American College of Rheumatology
2 guidelines in which some of their
3 recommendations are level A but the majority,
4 I believe are grade C recommendations. And
5 that was noted in our final workgroup as well.
6 And that other evidence would support that the
7 measure focus is not available.

8 Other comments that there are not
9 randomized controlled trials of uric acid
10 monitoring versus no monitoring was mentioned
11 before or treatment for uric acid therapies or
12 other strategies. Although the developer
13 noted that there are observational studies
14 that patients with more monitoring have better
15 uric acid outcomes.

16 And I believe they supplied some
17 additional evidence yesterday that was
18 forwarded to the committee, if I'm correct.
19 And also the workgroup members were concerned
20 that Gout is not always treated with uric acid
21 lowering therapy.

22 And some of the members noted that

1 other treatments and patient education about
2 Gout may also have a significant impact on
3 outcomes. So I wanted to just go back to JD,
4 if you had any comments before we discuss a
5 little bit more of the evidence.

6 DR. DANIELS: Thank you, Steve.
7 And I'll be brief here. I'll try to be like
8 Johnny, may as well just quit scrambling and
9 throw the ball. So what they did was they
10 gave us some more information. We went
11 through that last night.

12 And they kind of, I think, at
13 least helped me try to identify the inclusion
14 criteria a little bit. And so they wanted
15 someone who was 18 or older, had an active
16 diagnosis of Gout that does not end during the
17 measurement period, one health encounter with
18 a health care provider for Gout and a
19 medication order for uric acid lowering
20 therapy.

21 As far as validity, they used the
22 ICD-9 codes and they quoted a Herald, which

1 was a big paper. And they basically thought
2 they had a positive predictive value of 61
3 percent and that they thought that they would
4 have a good way of kind of capturing this.

5 They also quoted a guy, this
6 Jackson fellow, who basically the potential of
7 unmet need for Gout diagnosis and treatment
8 capture, recapture analysis of national
9 administrative debt. I read that three times,
10 had a headache. I'm unclear on what that adds
11 to it and maybe it will edify us.

12 Other additional evidence they
13 gave was that serum urate lowering is endorsed
14 by a number of guidelines including UR, the
15 Brit and the American guidelines. And the FDA
16 use serum lowering data as the primary outcome
17 for drug approval when the new drug came out
18 and that they thought that there was improved
19 patient outcomes that correlated with these
20 lower levels.

21 And then it really wasn't
22 referenced but it was basically sort of like

1 a comment about during the discussion at the
2 workgroup level there was talk about how this
3 has had some same of the issues as measuring
4 hemoglobin A1c cholesterol and not really
5 linking to outcome.

6 And basically their response was
7 that there's no literature in the
8 rheumatological arena to support this argument
9 and that there are much more robust resources
10 for the American heart than they do for Gout.

11 They don't think that they're
12 going to be able to approve that. And they
13 felt that it was unfair to compare the two.
14 And that as basically what I got out of the
15 last one.

16 CHAIR CHOU: Jonathan, did you
17 want to respond?

18 DR. FITZGERALD: Sure. I can go
19 through those points. So, again, there was
20 more in common about this case of the
21 patients. If patients are not on urate
22 lowering therapy then they're not going to be

1 in this measure. So if someone's put on diet
2 or lifestyle, there's not a requirement to
3 check the urate.

4 What we're asking is if physicians
5 or providers start a urate lowering therapy or
6 change a dose then there's a measure. And the
7 rationale for that is to look for the changes.
8 It is true there's no monitoring trials but we
9 are going off the data showing that urate
10 levels are tightly correlated with outcomes.

11 And so that is important to follow
12 urate levels. When we had our telemeeting,
13 the teleconference, there was a lively
14 discussion about serum urates and this gets to
15 the next level also. But the value of serum
16 urates and whether it was postulated that
17 patients could just be put on urate therapy
18 and not monitored and not have the serum urate
19 monitored.

20 And the argument was in the
21 atherosclerosis and with the lipid literature
22 getting away from lipids, there was also

1 concerns about in diabetes where hemoglobin
2 Alcs were presented as the target that then
3 there was, you know, adverse events from
4 people titrating down too low.

5 And a good bit of the conference
6 had focused on that. And so we wanted to
7 respond to that. You know, we think that
8 these situations are quite different between,
9 well, we're certainly trying to make an
10 analogy that this is an important intermediary
11 outcome and so there's some similarities.

12 There are important differences.
13 Serum urate is tied with outcomes and these
14 drugs, the urate lowering drugs work primarily
15 through lowering the serum urate. So that's
16 the rationale for monitoring.

17 Gout is not atherosclerosis. And
18 there aren't the resources that are going to
19 be put into it. And there have not been any
20 trials. And it's unlikely that there would be
21 trials randomizing groups of patients to
22 whether they're going to be monitored with

1 their serum urate or not monitored.

2 We do have observational data
3 looking at international studies. British and
4 German large population samples showing that
5 patients who aren't getting monitored tend to
6 have more gouty attacks. Also have, when they
7 do get monitored, they have higher urates.

8 And in contrast to the hemoglobin
9 A1c, there's not a known risk for driving down
10 urate below six, five or four. In fact, when
11 the Pegloticase studies, they're really
12 driving the urates down to undetectable
13 levels. And we don't have adverse outcomes.
14 We have the treatment goal.

15 So I think there are differences
16 between the other intermediary outcomes. The
17 other point that was being discussed was on
18 validity of the Gout diagnosis.

19 So the primary study, looking at
20 that, is the Arroll study looked in a VA
21 database looking for the Gout diagnosis alone.
22 All of our measures are Gout plus urate

1 lowering therapy. So it's not a direct
2 comparison.

3 The positive predicted value was
4 61 percent, which was similar to other
5 rheumatic conditions. It's not great. The
6 concern with these studies and doing eMeasures
7 is not so much the sensitivity but the
8 specificity. You don't want to incorrectly
9 put people into your measure. So the
10 specificity is more important.

11 If the sensitivity is off, that's
12 okay as long as you're looking at big samples.
13 If you're missing people, as long as it's
14 fairly random, that shouldn't be as harmful.

15 Because our measures are using the
16 ICD-9 codes for Gout plus a prescription for
17 a urate drug, it will increase the
18 specificity. Now, admittedly the Jackson
19 article is close to torture. It's very
20 difficult to get through.

21 The point of that study is that
22 they had done the same thing. They had used

1 a urate diagnosis to increase the specificity.
2 Now they didn't do formal testing on that.
3 But they said it would have been near 100
4 percent, which is sort of, I think, the
5 author's opinion.

6 But there have been studies that,
7 again, have looked at the ICD-9 codes. There
8 have been other studies that have used a
9 prescription for a "Gout-specific" medication.
10 And those would be urate lowering therapies.

11 Other authors have used
12 colchicine, which I would argue is not Gout-
13 specific because there's others. We're
14 looking at the urate lowering agents. The
15 concern with, particularly allopurinol is that
16 it can be used with patients with leukemia or
17 lymphoma to prevent.

18 And so authors have excluded to
19 leukemia or lymphoma and it has been suggested
20 to us that we consider excluding those. We
21 haven't specified that but we can certainly
22 test that when we go into the testing phase.

1 The rationale for not excluding is
2 because we're not using allopurinol as a urate
3 lowering therapy or a Gout-specific medicine
4 as a criteria for the diagnosis. We're using
5 it joined with the Gout diagnosis.

6 So it would really be a small
7 number of patients who were Gout and lymphoma
8 or leukemia and on urate lowering drugs. So
9 we hadn't specified it that way but we can
10 certainly look into that when we're doing the
11 testing. So I think those are the various
12 questions that were raised.

13 CHAIR CHOU: Questions for either
14 John or lead discussants or comments? Yes.

15 DR. MATUSZAK: So, just
16 hypothetically speaking, if this is your
17 quality measure and you've got a patient that
18 you started onto urate lowering therapy
19 because they've had multiple gouty attacks and
20 they started off with the serum uric acid
21 level of eight and they come back to you to
22 get their test and it's four or five months

1 later and it still shows eight but they
2 haven't had any gouty attacks, are you
3 treating the number or are you treating the
4 gouty attacks? And, you know, is actually
5 getting that number improving the outcome for
6 the patient?

7 DR. FITZGERALD: So rather than go
8 with a specific patient, I'd go with what the
9 data shows for groups of patients. And if you
10 looked at groups of patients, patients whose
11 uric acid remained at eight would have a
12 higher proportion and the data would say it's
13 about a 50 percent higher risk of having a
14 Gout attack versus those patients who it was
15 reduced down to six.

16 And if you go up higher, it can go
17 up for patients who their uric acid that was
18 in the range of ten or higher, the odds very
19 sure would be 2.5, based on some other
20 studies. So there is evidence to argue that
21 you should be treating the number in that
22 specific sort of case instance. I think it's

1 best to think about what the data is.

2 CHAIR CHOU: Yes?

3 DR. GHOGAWALA: This is a
4 feasibility question. But it relates to
5 something that we experience in our health
6 center. Many of times we have patients who
7 are seen by a rheumatologist or an
8 endocrinologist or a specialist started on
9 medical treatment and then referred back to
10 their primary care physician.

11 And the question that I have here
12 is, and we're under enormous pressure to do
13 that, as I think a lot of us are. How would
14 we be able to, from a feasibility standpoint,
15 measure whether the physician was doing a
16 follow up study or not.

17 Because at least in our case, many
18 of these doctors are not using the same
19 electronic health records as we are. They are
20 primary care doctors.

21 DR. FITZGERALD: The sites we're
22 looking at have unified health records, you

1 know, for the eMeasures you're really reliant
2 on testing and applying those in a situation
3 where you could capture data.

4 The patient's going to outside
5 labs or paper charts, that will create
6 problems. But that's true of any eMeasure.
7 And from a practical point of view, whoever,
8 you know, as long as the uric acid was drawn,
9 it doesn't matter who drew it if the lab
10 measurement was there after the prescription
11 or dose change.

12 DR. GHOGAWALA: Understood. Thank
13 you. From a quality perspective, if the
14 measure of quality here is the initial
15 prescriber and if that initial prescriber has
16 no control over beyond a recommendation, I
17 think this may be more common if you look at
18 this from a natural scale than you realize.

19 And in fact our scenario here is
20 not that people that have paper charts. Most
21 people have electronic charts but it's just
22 different and not compatible with our central

1 health care system in all cases. And we are
2 under pressure for, you know, independent
3 medical groups to send those patients back to
4 us.

5 And in fact I would think that
6 Gout would be an example where you wouldn't
7 necessarily keep it in a tertiary health
8 center. You would send it back.

9 DR. FITZGERALD: So that concern
10 would be, for example, to the rheumatologist
11 who might start a urate lowering therapy.
12 Personally I would have a higher expectation
13 about that prescribing physician following up
14 on lab measures for a new drug they're
15 starting before signing back. So I think the
16 responsibility would still be there.

17 DR. ANNASWAMY: So from the
18 comments and the evidence provided, it seems
19 like there was no direct evidence to suggest
20 that monitoring a change in uric level leads
21 to better outcomes. So there is indirect
22 evidence. And also the six month project,

1 also there is no direct evidence.

2 To the question of clarification
3 here about whether it's the highest it can,
4 what's the highest ceiling that we can
5 potentially raise this evidence because there
6 is no direct evidence to this recommendation.

7 DR. PACE: Right. And maybe we
8 can go to that slide and let's look at our
9 algorithm here. So the focus of this measure
10 is follow up serum testing after prescribing
11 the drug or changing the drug.

12 And the evidence that was provided
13 is about, I was just looking at this, it's not
14 directly focused on that topic. So basically
15 you're saying there's insufficient evidence
16 for what they're measuring in the topic.

17 DR. ANNASWAMY: There's indirect
18 evidence.

19 DR. PACE: Indirect evidence.

20 DR. ANNASWAMY: So there's
21 indirect evidence going in a particular
22 academy?

1 DR. PACE: Right. Good question.
2 Go ahead. Do you want to?

3 CHAIR CHOU: Yes. I mean, I was
4 hearing people saying, you know, indirectness
5 is something we deal with. And grade deals
6 with that as well and so does the task force
7 and others. And there's many different types
8 of indirectness, of course.

9 So what we're talking about here
10 is that we basically have correlational
11 studies but studies of the actual
12 intervention, which in this case is uric acid
13 monitoring.

14 And I think that there's, you
15 know, if you use grade you basically, you
16 know, look at the overall body of evidence and
17 ding it for indirectness and you can ding it
18 lower or less severely depending on how
19 indirect we think it is.

20 So it requires some, you know,
21 subjective, you know, judgement there. You
22 know, the degree of indirectness, essentially

1 here. But I think it would be tough to get
2 above a moderate. I mean, to me at least it
3 would be tough to get above moderate without
4 a study, you know, showing that monitoring
5 actually improves outcomes.

6 DR. PACE: Right. And that's
7 consistent with what our guidance is and what
8 the evidence task force had identified. So
9 the evidence is not directly about what's
10 being measured and, you know, the highest it
11 would be is moderate. But even, I don't know
12 if they gave a grade in this. But someone was
13 talking about C level, which is probably
14 expert consensus, so.

15 CHAIR CHOU: Yes. I was going to
16 say that John mentioned some of these cohort
17 studies or whatever that looked at monitoring
18 versus no monitoring. That's direct evidence.

19 I mean, they're observational but
20 it still, you know, would more directly
21 address this so it would be nice to see that
22 because I too am troubled with the lack of

1 direct evidence at least in what's been
2 provided so far.

3 I also have a question about what
4 about people who start, you know? So two
5 issues, one is that people with acute Gout
6 often have, you know, normal uric acid levels.

7 And what's the rationale for, I
8 don't know, I mean, or they have, or even
9 with, you know chronic Gout they have uric
10 acid levels maybe of less than six. And
11 what's the utility of monitoring in those
12 situations.

13 Also just to note that again in
14 the febuxostat trial, they didn't monitor the
15 -- I mean, monitoring may have been part of
16 the protocol but the way they treated was
17 just, you just treat. If somebody meets these
18 criteria you treat. And they were able to
19 show that they had a lot less Gout attacks on
20 either dose of the febuxostat.

21 And so at least if you're going to
22 go by the trial data, it seems to me that, you

1 know, whether treating is what we have the
2 clearest evidence that if you start somebody
3 on one of these uric acid lowering therapies
4 that you do impact Gout outcomes.

5 DR. FITZGERALD: Is used as a
6 monitoring versus nonmonitoring. It was
7 really designed to show the efficacy of their
8 drug.

9 So, some of the other points I
10 wanted to get back. So, the serum uric acid,
11 Lesson 6, I think we'll defer some of the
12 level discussions to the next point, where we
13 do specify where we think a target should be.

14 This really is, if the provider
15 has started or changed the drug, it means that
16 they are unhappy with where their current gout
17 management is and they're trying to move to a
18 new state. And uric acid levels change within
19 14 days and what we're asking is that there be
20 a follow-up, so there's information about that
21 new state.

22 So, regardless of what the level

1 was, the provider thought that the urate
2 needed to be managed or changed. And, so,
3 that's the rationale for that.

4 And, then, the final point about
5 the direct and indirect, some of this measure
6 was designed for phase validity. Construct is
7 the provider is writing a prescription for a
8 change in urate therapy and the natural
9 follow-up would be, then, to measure that
10 urate level to see if the change in the
11 therapy was effective.

12 And, then, it had been previously
13 mentioned about supporting measures that had
14 precedent and, in preparing for this, I went
15 back and was reviewing the data. And there
16 was a group that proposed gout quality care
17 indicators back in 2004. It was Ted Miklus,
18 Ken Saag and Kathy Mclain group.

19 And they came up with a measure,
20 really matched a lot of our measures. But
21 theirs was a gout patient is given a
22 prescription and, at the time, it was just the

1 xanthine oxidase inhibitor was just the
2 primary indicator.

3 Then a serum uric level should be
4 checked at least once during the first six
5 months of continued use, because periodic
6 serum uric measurements are required for
7 appropriate dosage estimates of those xanthine
8 oxidase inhibitor for escalations or
9 reductions. So, there's been some precedent
10 for this type of measure.

11 DR. PACE: So, I want to just go
12 back to the question that was posed to me, in
13 terms of where this falls in the algorithm.
14 What's been provided is not necessarily even
15 graded. So, it's either going to be moderate
16 or insufficient. And, then, the question
17 would be whether it's insufficient with, you
18 know, justification for an exception.

19 But even with the moderate, there
20 should be a grade of the evidence and it
21 should be a fairly high grade or strong
22 recommendation. So, from what I'm hearing you

1 talking about, it doesn't even seem like it
2 fits in that box. But that's certainly your
3 judgment.

4 CHAIR TEMPLETON: Yes. Go ahead,
5 Steve?

6 DR BROTMAN: Yes. Can I just ask
7 for a clarification? There's two contrasts.
8 One is going on clinical practice guidelines,
9 which does look at some evidence and,
10 depending upon what that is, it's graded.

11 But we still have a hybrid here,
12 if I'm correct, where they provided some other
13 evidence and, at that point, is it our job to
14 look at the quality, consistency and quality
15 of that evidence and grade it accordingly?

16 DR. PACE: Well, we basically
17 don't think that's a Committee job. The
18 Committees aren't constructed to do systematic
19 reviews of the evidence. And, typically, it's
20 not a measure developer job and, so, we ask
21 the developers to use graded evidence.

22 However, you know, when you're in

1 this area where maybe there isn't a systematic
2 review or they've submitted kind of individual
3 studies, it is going to fall to your judgment,
4 you know. The question that always comes up,
5 when we have individual studies submitted is,
6 is that really representative of the body of
7 evidence or is it selected study?

8 We just don't know, because it
9 wasn't a systematic review and approach to
10 gathering all the evidence. But I think Dr.
11 Chou can guide us more on that.

12 DR. CHOU: Yes. I mean I was
13 going to say that. But it seems to me that
14 we're both in Box 6 and Box 7, that there is
15 a guideline and the evidence isn't quite what
16 we're looking for. And, so, we're also in Box
17 7, which is not really captured in this
18 algorithm, being in both places at the same
19 time.

20 You know, Box 7, 8 and 9 do allow
21 you consider other stuff. So, I mean I think
22 it's possible. I think we need to be cautious

1 about that because, you know, without a
2 systematic review, you don't know what's
3 missing or whether it's selective, you know,
4 how they pick the studies and all that kind of
5 stuff.

6 I guess, Steve, you're going to
7 follow up?

8 DR. VENTURA: It seems to me that
9 several of the other measures would face the
10 same thing, that there's no direct evidence
11 that the process measure itself improves the
12 outcome. There is a lot of indirect evidence
13 about the steps in the process.

14 DR. CHOU: Right.

15 DR. VENTURA: So, we could still
16 use Box 7, couldn't we --

17 DR. CHOU: I think so.

18 DR. VENTURA: -- if it's still
19 happening?

20 DR. CHOU: Yes. Yes.

21 DR BROTMAN: So, then, does the
22 question become is there a sufficient amount

1 of evidence or insufficient amount of
2 evidence? It almost seems that way sometimes.

3 DR. CHOU: Yes and I think that's
4 what the discussion right now is. If we don't
5 think the evidence is there, we don't move
6 forward. I mean we kind of stop there. And,
7 so, I think we want to have a little bit more
8 discussion here, before we go on.

9 I just wanted to just comment on
10 the positive predictive values and stuff. I
11 mean because this is relevant to the first
12 measure we looked at, actually. That's pretty
13 terrible. That means that one out of every
14 three people who has an ICB9 Code of gout
15 doesn't actually have gout. I mean that's
16 pretty bad.

17 And it may be the same for RA and
18 OA, but it just means it's bad for all of
19 these conditions. So, that's concerning to
20 me. I mean I hope that that's something
21 that's considered in the testing also, to
22 really look at whether we're really actually

1 getting people with gout. I mean everyone's
2 brought this issue up previously.

3 DR. FITZGERALD: Yes. Again, that
4 would be sort of the floor, because we're
5 looking at all their measures are gout plus a
6 urate lowering. There could still be errors
7 there.

8 But the Jackson study that was
9 provided, again, hadn't done a formal testing.
10 But they had argued that the specificity on it
11 to be very high. They claimed a higher
12 specificity.

13 DR. CHOU: Yes. Yes. I tried to
14 look at that study, too. It's hard to really
15 determine. And it's not clear to me how, just
16 because somebody's being prescribed it, how
17 suddenly the diagnosis becomes.

18 It just means somebody's
19 prescribing the drug because, if they already
20 gave an incorrect diagnosis and are
21 prescribing the drug, it doesn't make the
22 diagnosis any more correct. So, that's why I

1 have some questions about that study.

2 But, again, I think this is
3 important from a reliability kind of issue.
4 That's problematic. So, other comments or
5 concerns about the evidence?

6 DR. DANIELS: Just one quick
7 clarification.

8 DR. CHOU: Yes.

9 DR. DANIELS: I might have gotten
10 this wrong. Basically, what I'm getting is
11 that Jackson reports that the addition of
12 allopurinol and colchicine improves the
13 sensitivity to 84 percent?

14 DR. CHOU: The sensitivity is not
15 the part it predicted. The part of the
16 predictive value is how many people you say
17 have the condition that actually have it. The
18 sensitivity is how many people with the
19 condition you can identify.

20 And, so, the part of the
21 predictive value is really what we're looking
22 at, in terms of the accuracy of our ability to

1 identify the denominator.

2 DR. DANIELS: I'm sorry. I was
3 talking about the inclination to move closer
4 to 100 percent S values.

5 DR. FITZGERALD: I think I also
6 pasted a comment. So, they reported the
7 sensitivity and they fully tested for the
8 sensitivity and that had gone up to 84 percent
9 with their methodology. They had this
10 separate comment and I pasted it, just so I
11 was using their words and not an
12 interpretation and they described that the
13 specificity was increased.

14 DR. DANIELS: I see what you're
15 saying. So, as far as the reimbursement is
16 dependent on submitting returns, 100 accurate
17 isn't likely. They didn't actually get it,
18 then.

19 DR. FITZGERALD: It's a
20 nonspecific statement.

21 DR. DANIELS: Yes.

22 DR. FITZGERALD: But they were

1 arguing for a higher specificity.

2 DR. JARRETT: Getting to the issue
3 of, you know, this is really bordering on
4 whether or not the population that we're
5 dealing with is not a homogeneous population.
6 So, there will be groups of patients where,
7 perhaps, you know, lowering them from 7 to 6.5
8 may have no clinical significance.

9 However, as a process measure, if
10 we don't kind of have broad stroke with this,
11 we're going to miss that large group where
12 really truly the number and the measuring of
13 the number really has impact.

14 So, I think we have to look at the
15 broader population, realizing that we're not
16 going to be able to slice and dice it the way
17 we ideally would like to and maybe ten years
18 from now we can. But we'll have to take a
19 broader view and say, yes, it should be
20 measured. There is enough evidence.

21 Of course, there is a large
22 segment that that measurement and making sure

1 the number then eventually does come down to
2 the appropriate number really does make a
3 difference.

4 CHAIR TEMPLETON: Yes?

5 DR. DODGE: This strikes me as
6 similar to the examples you gave earlier about
7 insufficient evidence but with a exception,
8 because you've already set the bar as the
9 criteria for inclusion are that you have
10 initiated therapy or changed therapy.

11 Then the urate is in the
12 discussion as important. And it would seem
13 completely obvious that you would want to see
14 what that effect of the intervention has been.
15 And I don't know. It would be so limited to
16 try to find a study that proves that just that
17 measure is enough.

18 But it is a prerequisite I think
19 to seeing if the other things like a serum
20 uric target are actually effective. So, this
21 is one of those ones where I don't know as the
22 burden of evidence for me had to be very, very

1 high because it just seems like a very
2 straightforward accountability to the decision
3 that is an inclusion criteria.

4 DR. CHOU: I just wanted to
5 respond to that a little bit. I was one of
6 the people that brought up the issues with
7 lipid treatment and diabetes treatments, where
8 there's a clear correlation with A1c levels
9 and bad outcomes. There's a clear correlation
10 with lipid levels and cardiovascular outcomes.

11 But you can take two drugs that
12 have the same lipid lowering affects and
13 statins reduce heart attacks and other drugs
14 don't. And same thing with diabetes that, if
15 you take Metformin, you can reduce, you know,
16 events. If you take Rosiglitazone or
17 whatever, it doesn't. They have the same
18 exact effect on the A1c level.

19 So, there's more than one type of
20 indirectness here. So, now, not only are we
21 looking at indirect evidence in the sense that
22 we're just looking at correlational

1 observations, we're also looking at
2 intermediate outcome.

3 And this is what I was talking
4 about is that there is degrees of
5 indirectness. And, again, I just think that
6 this is something we have to be careful about,
7 because many groups have gone down that path
8 before.

9 I'm certainly not arguing that
10 their path of physiology is the same. I don't
11 know that, you know, maybe allopurinol and
12 probenecid and all these other drugs have
13 exactly the same mechanism and it's all uric
14 acid. The evidence I don't believe is very,
15 you know, sound on that. So, I just want to
16 make that point. Yes?

17 DR. MATUSZAK: And I think if I
18 understand, our function here is not to
19 necessarily say that, I mean something might
20 be very, very good to do in clinical practice,
21 but if the evidence doesn't support us
22 measuring it as a quality outcome, if the

1 evidence doesn't support that, then I don't
2 know that we necessarily have to say.

3 I mean it might still be a great
4 thing to do clinically but I don't know that
5 we need to endorse or support measures that
6 don't have the evidence behind the process.

7 DR. FITZGERALD: If I may comment,
8 as you pointed out, it seems incredibly
9 obvious to check a urate after you've started
10 a urate drug. And that doesn't happen. In
11 only 20 percent of patients who were given a
12 prescription get uric acid checked in the next
13 year.

14 It would be akin to finding
15 someone who has hypertension starting a anti-
16 hypertensive and, then, not checking a blood
17 pressure measurement. You're not going to do
18 a trial on that and I think we're likely not
19 going to see a trial on whether you should
20 check a uric acid after starting or the
21 benefits of or the timeframe or the window.

22 So, I think we're going to be

1 challenged with that. So, I think a lot of
2 this is dependent on phase validity and
3 documentation that there are gaps in what
4 would seem to be obvious care.

5 There are fewer treatment
6 alternatives for lowering urate therapy. Uric
7 is used only about ten percent of patients.
8 So, it's really primarily allopurinol and
9 febuxostat has been growing. So, there are
10 only a couple treatment options.

11 The data suggests, through a
12 randomized trial, when they did the
13 allopurinol versus febuxostat, had similar
14 outcomes as far as gout. And that's not
15 saying that that explains everything. But the
16 mechanism, when you look at the data, is
17 patients who respond to the drug with urate
18 lowering are less likely to have attacks.

19 So, it does seem to be really an
20 intermediary and the way these drugs work is
21 by lowering the levels down below solubility.
22 And we've seen that with ultrasound studies,

1 when patients are put on the medications, that
2 there is resolution of the findings of the
3 crystals in the joints, again, indirect.

4 MR. SCHUNA: I'm not sure it's
5 akin to blood pressure lowering and
6 hypertensive treatment in that you can start
7 uric acid lowering therapy and the patient no
8 longer has gout attacks or has less frequent
9 gout attacks. Maybe that's the goal for the
10 patient in many cases.

11 DR. FITZGERALD: We did not tie
12 indications into this measure. Simplified,
13 again, conceptually, we're thinking these are
14 patients who are having frequent attacks. The
15 problems that are reported with adherence and
16 with patients who respond to the drugs have
17 dose titration, Perez Ruiz presented the
18 article that most patients are on 300, but
19 only a proportion of those meet what would be
20 considered the target for having levels less
21 than six.

22 And it's because monitoring is not

1 being done or is not being done in a timely
2 manner or there's not responses to monitoring.
3 So, there's several problems in the process of
4 care between getting the test, responding to
5 the test, titrating the drug.

6 And what we're trying to do here
7 is get people on that first step as far as
8 monitoring the change that was initiated.

9 DR. YAZDANY: Can I just make one
10 more point?

11 CHAIR TEMPLETON: Yes, go ahead.

12 DR. YAZDANY: So, I think with the
13 pathophysiology of gout, although it wasn't
14 discussed in our submission materials, is very
15 relevant here. The question is how good of a
16 surrogate intermediate outcome is uric acid?

17 And I think, unlike many of the
18 other parallels that people are drawing, uric
19 acid is actually found in the tophus. It's
20 actually found in the joint that's having a
21 gout attack with incredibly high sensitivity.

22 We have sort of a human model of

1 gout where, if somebody has cancer and we give
2 them chemotherapy, cells release uric acid, so
3 you get a huge load of uric acid and you get
4 an acute gout flare in the setting of
5 chemotherapy and we have prophylaxis.

6 So, gout is not only at the crime
7 scene. It's found, you know, consistently
8 with high sensitivity in the joint. So,
9 unlike things like say cholesterol or even
10 with hemoglobin A1c, where the distance
11 between an outcome, say a myocardial
12 infarction and intermediate outcome are far,
13 I would argue that, in gout, the intermediate
14 outcome and the final outcome are actually
15 very closely linked.

16 And that's why there won't be a
17 trial of monitoring uric acid or not
18 monitoring uric acid because it probably would
19 be challenging for an IOB to approve that.

20 DR. DANIELS: I'm going to say
21 something to that and I'm going to use that
22 Perez Ruiz article that they had. And one

1 thing that I found was, you know, only three
2 percent of the patients with gout received
3 doses over 300. However, and this is where
4 it's kind of saying all the way to below six,
5 which some people would say a low level, that
6 they only needed 370 milligrams.

7 So, you know, there's obviously
8 some other things happening here besides just
9 the uric acid level. You know, there are some
10 things that are left out that we don't really
11 understand because that tells you there. It's
12 almost to what Art just said that, you know,
13 there's going to be a certain number of
14 patients that you're going to put on medicine
15 and it lowers and they kind of do okay.

16 So, you know, it looks like we're
17 kind of under-treating but it's still, at
18 least according to this study, not that bad.

19 DR. FITZGERALD: That was the
20 average dose requirement and I have to go back
21 and look at the proportion of patients who had
22 met target, even if we just assume an average

1 dose, it would imply somewhere around half
2 weren't reaching the target. I'd have to go
3 back though.

4 DR. CHOU: Karen?

5 DR. PACE: Yes. I just wanted to
6 emphasize what Dr. Chou said, in terms of kind
7 of the whole causal pathway, one of the things
8 that we do ask the developers to do that I see
9 wasn't in these forms is to lay that out, the
10 pathway between what they're suggesting be
11 measured and the ultimate health outcome.

12 So, the way I understand this is
13 that you're talking about measuring uric acid
14 levels that should result in looking at the
15 uric acid level and what's the connection of
16 that uric acid level to decreased gouty
17 attacks and symptoms and, you know, if you lay
18 out that causal pathway, where do you actually
19 have the evidence?

20 So, I think we've been talking
21 about the evidence of giving these meds and it
22 lowering the uric acid level. But the

1 question that seems to be coming up, then,
2 what's the relationship between that level and
3 the attacks.

4 DR. CHOU: Yes. I was going to
5 say I mean there's a lot of assumptions that
6 physicians will act on the level and that
7 patients will actually take the medicines and
8 all these other things. I mean there's a
9 whole slew of other things that would have to
10 happen, which is why it would be nice for
11 someone to actually study it to see what the
12 impacts are. But go ahead.

13 DR. FITZGERALD: I think this
14 measure is as subjectives are modest, because
15 we're trying to get physicians to do the first
16 step, as far as checking the level. And, as
17 far as laying out the causal pathway, I'll
18 just highlight the studies that were
19 submitted.

20 The Soji article is the one and
21 that's in here showing the uric acid levels
22 and proportion of patients who have attacks.

1 There's a Perez Ruiz article who describes the
2 rate of tophi reduction and the velocity of
3 tophi reduction is highly correlated with uric
4 acid levels.

5 As mentioned, Tio and colleagues
6 have purported resolution of crystals with
7 improvement in the management of
8 hyperuricemia. So, those are scattered
9 through here.

10 DR. CHOU: And I'm still not
11 entirely clear about the rationale for
12 monitoring somebody who has a uric acid of
13 six, say, to start with. What would be the
14 rationale for that?

15 DR. FITZGERALD: So, that might be
16 better addressed in a different section. In
17 the guidelines, if someone has a level of six,
18 we would be happy with where that is and there
19 would not be a dose change and they would fall
20 into this. I mean, if their symptoms are
21 doing well --

22 DR. CHOU: What I'm saying is

1 someone has six when they have their first
2 gout attack or their second gout attack. You
3 start them on uric acid lowering therapy. Why
4 would you need to check their uric acid level
5 again?

6 DR. FITZGERALD: So, again, we're
7 coming up with patients who are really at the
8 margins of what we're describing in these
9 measures. There are several issues that I can
10 address with them.

11 DR. CHOU: About a third of
12 patients with gout have uric acid levels that
13 are around six. I mean they're not very high.
14 It is my understanding that there's quite a
15 few patients, actually, that don't have highly
16 elevated uric acid levels.

17 DR. FITZGERALD: So, again, if
18 we're talking about patients with frequent
19 attacks, the majority of patients will have
20 levels of eight or ten, so, significant
21 hyperuricemia. It's certainly possible to
22 have gout patients with uric acids of six or

1 even lower. Those are really the exception.

2 There is also the known phenomenon
3 that, during the attack, the uric acid level
4 can be dropped and artificially low. So,
5 there are several issues in there. I mean
6 correct me if I'm misunderstanding the
7 question, but I'm not sure that they're on top
8 of the measure.

9 DR. ANNASWAMY: I think I can add
10 to what Roger is saying. The denominator is
11 essentially patients who had a new drug
12 initiated or change in drug. So, among those,
13 perhaps there is reason to exclude those that
14 do not have high uric acid levels.

15 They may not need monitoring of
16 their levels as much as others may. And the
17 evidence does not support such a robust need
18 for those patients and they have not been
19 excluded in this denominator.

20 DR. FITZGERALD: I think that's a
21 very good suggestion. We certainly weren't
22 looking toward that in excluding patients who

1 had levels lower than someone would act on,
2 because you're right. At those points, if
3 someone has a level of five and they're still
4 having attacks and it's determined that they
5 need more urate therapy, it's not necessary to
6 check that.

7 I do think that is a small
8 minority of patients. Those are more likely
9 ones that are getting to the rheumatologist.
10 So, you know, 20 percent. And then, for the
11 rheumatologist, that's an unusual patient
12 still. That would be two percent of that.
13 So, I think it's a small number but I think
14 it's a very reasonable proposition.

15 DR. CHOU: Other comments? I
16 think it's time for us to take a vote on the
17 evidence. So, again, this is a trial measure.
18 So, we'd be kind of voting whether there's
19 enough evidence to move forward with testing.
20 And let's go ahead.

21 MS. PHILLIPS: We've got one for
22 high, two for moderate, three for low, four

1 for insufficient, four for insufficient with
2 exception and five for insufficient evidence.
3 We're voting on Measure 2521, points to
4 measure and report. Starting now.

5 We have 21 responses: five for
6 moderate; five for low; six for insufficient
7 evidence with exception; and five for
8 insufficient evidence.

9 DR. CHOU: So, do the two and four
10 go together, is that how it works?

11 CHAIR TEMPLETON: Yes.

12 DR. CHOU: So, it still doesn't
13 quite meet the 60 percent threshold. So, it's
14 40 to 60 percent. Can you remind me what
15 happens here? Does this mean we wait for a
16 public comment to come back and then
17 reconsider?

18 MS. FRANKLIN: Yes. I think at
19 this point it means that it would continue on
20 and, of course, we've taken public comments on
21 the measure and the Committee reconsiders the
22 measure after the public comment period.

1 DR. CHOU: All right. So, the
2 next area is opportunity for improvement. I
3 think this is related to a lot of the stuff
4 we've already talked about. So --

5 MS. FRANKLIN: We'll have to pause
6 it for a public comment.

7 DR. CHOU: Oh, okay. Sorry.
8 Pause for a public comment.

9 MS. STREETER: I'm just going to
10 try to keep us on a schedule here. We'll take
11 a quick break for public comment and then
12 we'll have our lunch break and continue on to
13 a performance step after that. Operator, at
14 this time, can you open the lines and see if
15 we have any public comments?

16 OPERATOR: If you have a public
17 comment, please press 4-1 on the phone keypad.
18 And there are no comments at this time.

19 MS. STREETER: Okay.

20 DR. CHOU: I think we get to break
21 for lunch. Where is lunch?

22 MS. STREETER: Lunch is

1 (Whereupon, the foregoing matter
2 went off the record at 12:49 p.m. and went
3 back on the record at 1:16 p.m.)

4 CHAIR CHOU: It's 1:15, so we're
5 going to reconvene here, try to get back on
6 schedule.

7 So we're still discussing Measure
8 2521, serum urate monitoring. We have just
9 finished the evidence discussion and we heard
10 public comments, of which there were none. So
11 I think we can move on. Do we need to --
12 okay.

13 So we're now at the kind of
14 opportunity for improvement piece. Maybe,
15 James or Steve, if there are additional
16 comments. I think we've already all heard
17 much of the evidence about potential
18 performance gaps, but if there's anything that
19 you wanted to add here.

20 DR. BROTMAN: I don't have
21 anything. I think we've had the discussion
22 mostly.

1 CHAIR CHOU: Okay. And, JD said
2 the same.

3 So I think it's time for us to
4 vote on whether we think there's opportunity
5 for improvement here.

6 MS. PHILLIPS: Okay. We're voting
7 on 1B, performance gap. Your options are one
8 for high, 2 for moderate, three for low and
9 four for insufficient. Voting begins now.

10 We have 20 responses. Has
11 everyone voted who's going to vote?

12 Still at 20.

13 We may need to redo this. There
14 we go. Twenty-one. Thank you.

15 Okay. The results are 2 for high,
16 11 for moderate, 2 for low and 6 for
17 insufficient.

18 CHAIR CHOU: I think we're right
19 at our cutoff with moderate and high, right at
20 60 percent. So I think we move on.

21 The next area is priority. Again,
22 any additional comments from Steve or JD about

1 priority that we haven't discussed previously?

2 DR. BROTMAN: Priority is still
3 similar in terms of the work group discussion
4 that gout may be a high priority, but not sure
5 if the lack of monitoring represents a high
6 priority gap and a high priority.

7 CHAIR CHOU: Open it up for any
8 other comments?

9 (No audible response.)

10 CHAIR CHOU: I think it's time for
11 a vote here.

12 MS. PHILLIPS: Okay. Voting on
13 priority. Your options are one for high, two
14 for moderate, three for low and four for
15 insufficient. The voting begins now.

16 We are at 19 responses, so can
17 everybody try again?

18 There we go. Twenty-one. Thank
19 you.

20 All right. Zero for high, eight
21 for moderate, six for low and four for
22 insufficient.

1 CHAIR CHOU: All right. So I
2 think this is the first time we haven't met at
3 least the -- is that -- that's below the 40
4 percent cutoff, right?

5 MS. PHILLIPS: It's below.

6 CHAIR CHOU: So what do we do
7 here?

8 MS. FRANKLIN: At this time that
9 would mean that this is a must pass criteria,
10 so the measure would not continue forward for
11 consideration. However, this will also go out
12 for public comment and the Committee can react
13 to comments received from the public after the
14 period is closed.

15 CHAIR CHOU: Do we take public
16 comments now or do we --

17 MS. FRANKLIN: No.

18 CHAIR CHOU: -- wait?

19 MS. FRANKLIN: No.

20 CHAIR CHOU: No? Okay. So I
21 think we are -- we don't go any further, so
22 maybe we move on to the next measure at this

1 point. So that's 2550 -- no, not 2550, 2549.

2 This one is of course related to the prior
3 measure. Instead of being about monitoring,
4 it's about targets.

5 I guess I'm not quite sure how to
6 proceed here. I mean, if we're not going to
7 suggest monitoring, I'm not sure how much
8 sense -- I mean, if we're not going to move
9 forward with that one, do we still want to
10 discuss this one?

11 MS. PHILLIPS: Yes, we still have
12 to discuss this one --

13 CHAIR CHOU: Okay.

14 MS. PHILLIPS: -- as a stand-alone
15 measure.

16 CHAIR CHOU: Okay. So, John?

17 DR. FITZGERALD: And I would argue
18 that -- I mean, this is separate and we
19 designed it separately, so this was not meant
20 to be conditional on the prior one. And the
21 rationale for this one is quite different than
22 the last one also.

1 So this is our serum urate target.

2 The brief description is the percentage of
3 patients with a gout diagnosis who have been
4 treated with a urate lowering therapy for at
5 least 12 months, that the serum urate checked
6 is at least once yearly and with the most
7 recent result being less than 6.8 milligrams
8 per deciliter.

9 And the numerator statement is
10 that adults, patients 18 years or older, in
11 whom a serum urate level has been checked at
12 least once yearly with the most recent being
13 less than 6.8 milligrams per deciliter. The
14 denominator is the patients with a gout
15 diagnosis who have been treated with a urate-
16 lowering therapy for at least 12 months. And
17 we had no exclusions.

18 CHAIR CHOU: Steve, do you want to
19 give an overview?

20 DR. BROTMAN: Well, I think that
21 was a good overview of the measure title for
22 2549 gout serum urate target as well as the

1 developer rationale and the numerator and
2 denominator statement. This is a process
3 measure, another EHR measure where this is on
4 a trial basis where their reliability and
5 validity testing is not done yet. And they
6 state that they will be doing it later and
7 submitting for full NQF endorsement at a later
8 time.

9 Just to go onto the evidence
10 section, similar types of discussion, but a
11 little bit more related to the targets.
12 Related to the evidence is indirect, but the
13 association -- it's basically an association
14 between uric acid levels and gout, but no
15 studies cite compared effects of targeting of
16 less than 6.8 versus other targets. And other
17 comments about they would rank the evidence as
18 low or possibly insufficient.

19 The work group noted that the
20 clinical guidelines are presented to support
21 the measure. It's indirect based on that
22 association of the levels and the gout attacks

1 and rather than the impact and the linkage
2 between the monitoring of the serum urate with
3 a target of 6.8 or less -- or less than 6.8
4 versus other targets in improved incomes.

5 So work group questioned whether
6 the required quality and consistency of any
7 evidence that had been put forward other than
8 the guidelines had been met and noted that the
9 evidence presented again was level C grade.

10 JD, did you want to chime in with
11 anything?

12 DR. DANIELS: Yes, stuff that they
13 gave us on top of that was basically they kind
14 of talked about the Halpern study. Again,
15 it's one of these things that doesn't exactly
16 kind of match what they're measuring. It's
17 the non-compliance of urate lowering drug.

18 And then they -- I'm confused
19 about this, because they're saying we're doing
20 -- ICD-10 will be used to identify patients
21 with gouty attacks. So I didn't know if
22 that's something -- they're going to use this

1 to actually collect their data for them? Is
2 that what they're -- it doesn't look like
3 there's any new data that they're giving us,
4 but I don't know if they're saying that
5 they're going to use -- if we say it's okay,
6 that they're going to use this process to
7 collect their data. That I guess would be
8 my --

9 DR. FITZGERALD: So, sorry, I
10 think there's some confusion on that. This
11 form was -- I structured this form based on
12 the question feedback we had received from the
13 work group.

14 DR. DANIELS: Okay.

15 DR. FITZGERALD: And this question
16 fell under here about how gout attacks were
17 going to be defined. I think that question
18 actually relates to the urate lowering therapy
19 indication. So this answer -- the question
20 and answer should probably be in another
21 section. So we could disregard that here.
22 Gout attack is not part of this measure.

1 DR. DANIELS: Okay. I'm just --

2 DR. FITZGERALD: Yes, sorry for
3 that. Yes, I understand the confusion and I
4 apologize.

5 DR. DANIELS: Okay. That's all
6 right. A lot of this overlaps. And really
7 nothing else.

8 DR. BROTMAN: And I just wanted to
9 add that there was some discussion in the work
10 group that this is possibly just a check box
11 measure and just capturing a snapshot in time
12 that may not actually reflect the compliance
13 of someone on ULT.

14 CHAIR CHOU: So, John, do you want
15 to respond to some of their comments?

16 DR. FITZGERALD: Sure. So there's
17 a lot in there to respond to. A lot of this
18 is related to some of the discussions we've
19 had before. There is not evidence with a, for
20 example, randomized trial looking at 6.8
21 versus 7 versus 6, and we're not going to have
22 that. The data to support this measure is

1 that serum urate levels that are brought down
2 lead to improved outcomes. And there have
3 been the febuxostat randomized control trials
4 looking at that showing improvements in
5 patient outcomes associated with improvements
6 in the serum urates.

7 I think the best evidence, again
8 indirectly, is the Soji article, And I put a
9 picture of the figure in the responses that we
10 provided is the relationship between serum
11 uric acid and future gouty attacks. The
12 authors themselves had specified that at
13 levels above 6 milligrams per deciliter there
14 is increased attacks. In the 4,000-patient
15 British and 3,000-patient German studies
16 higher urate levels again were associated, and
17 that's where I gave you the numbers before.
18 People in the serum urate 8 had a 1.5 odds
19 ratio of having more frequent attacks. Serum
20 urate levels of 10 had a 2.5.

21 So when you look at Soji, even
22 though -- I mean, they did pick six, and other

1 people who have picked six milligrams per
2 deciliter includes the ACR, the gout
3 guidelines, which was based on RAND/UCLA
4 methodology. The EULAR guidelines, the
5 British Society of Rheumatologists, the Dutch
6 General Practitioners have all chosen six as
7 well, some of them even choosing five for
8 certain indications.

9 When you look at the data, even
10 the Soji, even though it's somewhat sigmoidal,
11 it is fairly linear. The Perez Ruiz study,
12 that's also looking at velocity of tophi
13 reduction, which is tightly correlated with
14 serum urate levels, is also fairly linear. So
15 it's admittedly very hard to pick a level.

16 Now, we had considered the six
17 milligrams per deciliter because there was so
18 much consensus on that, however, that would
19 then penalize anybody who was getting close or
20 close enough and we thought, again because
21 it's a quality measure, we ought to pick a
22 higher level, to be a little bit more

1 permissive so as not to ding someone who gets
2 a uric acid of 6.4 and is doing well.

3 So we picked a higher level. We
4 didn't want to pick an arbitrary level. And
5 so 6.8 milligrams per deciliter is the
6 solubility level for serum urate. So that
7 level has been picked. That level has been
8 cited frequently, is sometimes used as the
9 definition. Seven is also sometimes used as
10 the definition for hyperuricemia. We do plan
11 during the testing phase to look at different
12 thresholds to see if that's going to make a
13 big difference in our outcomes.

14 And I think those were most of the
15 questions. Were there --

16 CHAIR CHOU: I'll open it up to
17 the rest of the panel. Other questions or
18 comments about the evidence here?

19 MS. DAVIS: This seems to me to be
20 an intermediate outcome in a way. I mean,
21 it's actually a level and not a process
22 measure. Is that accurate?

1 And then just a comment. I'm
2 wondering if you just collect the data on the
3 actual level on every one and then do some
4 comparative analysis on it rather than setting
5 it at 6.8 with a yes or no. Would give you
6 more information.

7 CHAIR CHOU: Go ahead, John.

8 DR. FITZGERALD: I mean, we'll
9 certainly look at that. We weren't aware of
10 to be determined proposal as far as level. So
11 we felt we needed to pick a level and now we
12 just wanted to give you the background on how
13 the 6.8 was picked.

14 CHAIR CHOU: Can I ask? So one of
15 my questions is what's the rationale that --
16 if you've checked say once and their uric acid
17 is 6.5 and they don't have any more gout
18 attacks, what's the rationale for requiring a
19 yearly level?

20 DR. FITZGERALD: So this -- yes,
21 this was conceptualized for getting people
22 started, so for the incipient year. I guess

1 as stated, it's continuing years if patients
2 became -- if they're doing well. Lost
3 adherence, levels would go up and they'd be
4 likely to have attacks again. So --

5 CHAIR CHOU: Yes, but I guess
6 clinically if they weren't having attacks why
7 would there be any reason to recheck again
8 once you've gotten their level down?

9 DR. FITZGERALD: I can't -- the
10 only data I can cite for that is there have
11 been trials looking at stopping urate lowering
12 therapy, and even patients who've been well
13 controlled after many years will typically
14 flare after stopping therapy. So I think
15 those were some of the earlier allopurinol
16 studies. So I think there is value in
17 continuing to follow.

18 CHAIR CHOU: Yes?

19 DR. GHOGAWALA: This is going to
20 be just ignorance on my part, but is there any
21 need to monitor any blood work for somebody
22 who's say on urate lowering therapy for say

1 five years and is stable? Is there any other
2 reason to be measuring blood work on them for
3 that purpose? I just don't know.

4 DR. FITZGERALD: Yes, there's some
5 safety monitoring recommendations as far as
6 LFTs, renal function and, to a lesser extent,
7 CBC.

8 CHAIR CHOU: Other questions?
9 Yes?

10 DR. ANNASWAMY: I have a question
11 about 6.8 versus a range. If less than six is
12 associated with good outcomes and greater than
13 seven is associated with bad outcomes, and
14 you're looking for a snapshot and there is
15 variability in uric acid levels day-to-day,
16 time-to-time, and you have a range that is
17 acceptable, perhaps a range is what you should
18 be looking at given those variabilities.

19 DR. FITZGERALD: Well, we've said
20 less than 6.8, so our range is 0 to 6.8. If
21 we said less than seven, then we'd be -- I
22 mean, some of this we will look at with the

1 testing data to see if there is meaningful
2 differences. But again, we're picking -- our
3 objective here was to pick a threshold, if the
4 guideline is to try and to do something else.
5 But even the range really is a threshold
6 still.

7 CHAIR CHOU: I have another
8 question just about -- again, this is one
9 where I think that people with tophaceous gout
10 and with erosions -- I would view them a
11 little bit differently where the target or
12 achieving a target may be clinically much more
13 important than somebody who, for example, has
14 a couple of attacks that are easily treated
15 and you have them on uric acid lowering
16 therapy and they're not having any more
17 attacks. Why do you need to monitor those
18 patients with a yearly uric acid? And so I
19 just wonder if there was any consideration to
20 focusing on people with kind of more severe
21 gout.

22 DR. FITZGERALD: So in developing

1 this we tried to stay away from the
2 indications and leave those as implied is that
3 the urate lowering therapy has been prescribed
4 for this patient, and therefore there are
5 underlying indications. We hadn't specified
6 the indications like we did in the first
7 measure. Sorry, the rest of your question?

8 CHAIR CHOU: I think it was
9 just --

10 DR. FITZGERALD: Oh, yes, for the
11 patient that --

12 CHAIR CHOU: Yes.

13 DR. FITZGERALD: Yes, so urate
14 levels -- well, urate levels are associated
15 with tophus reduction, so, yes, clearly in
16 those patients. And if it's aggressive tophus
17 you want even lower levels. Urate levels are
18 associated with recurrence of attacks. Again,
19 for the patient at the edge or the margin, I
20 have less data to support arguing that. We
21 could try and again look at that and define
22 some tighter -- we could put the indications

1 back in like we did on the other measure.

2 CHAIR TEMPLETON: And this is Kim.
3 If I could ask a question, please?

4 So, I understand that the uric
5 acid is the easy thing to measure, the easy
6 thing to find in electronic health records,
7 but wouldn't a more -- and this is ignorance
8 on my part. Wouldn't a more patient-centered
9 outcome be whether or not the patient had had
10 a gouty attack during the period of time?
11 Because that's really the goal of treatment
12 is, not targeted at a number, but what the
13 patient's symptoms are.

14 DR. FITZGERALD: That is harder to
15 get at, and those two values, the uric acid
16 and the recurrence of attacks, are well-
17 correlated.

18 CHAIR CHOU: Yes, that's an
19 interesting point that Kim brings up. I think
20 it's a little tricky because even with the
21 febuxostat trials, there is still -- it's like
22 it reduced their gout flares by 50 percent or

1 something. So there's still a -- people are
2 still having flares even if they were being
3 treated. And so, I think that's a little
4 tricky in terms of measuring. For example,
5 rheumatologists might see people who have more
6 severe disease and more refractory to
7 treatment. And so, do you want to measure the
8 process or do you want to measure the outcome,
9 and how can you kind of case mix adjust and
10 those kinds of things? But I think it's an
11 interesting point.

12 DR. FITZGERALD: Yes, the patient
13 outcomes would be challenging to measure. As
14 you know, a lot of these happen at home. Can
15 be self-reported. So that would be a
16 challenging measure for feasibility/validity
17 reasons.

18 With tophus, even gouty
19 rheumatologists aren't regularly measuring
20 tophus size to document progression. So
21 again, I think a very difficult measure unless
22 you're in a clinical trial where that's a

1 specific outcome.

2 What we have is a highly-
3 correlated intermediate outcome, the uric
4 acid, which predicts tophus and tophus
5 progression and gout attacks. So, if you
6 bring that down, you're more likely that the
7 patient outcomes are going to come down as
8 well.

9 CHAIR TEMPLETON: And again, I
10 realize that this is easier to measure,
11 however, in one of the previous measures that
12 we discussed this morning one of the
13 definitions of more severe active gout was the
14 number of gouty attacks, and 2 or more in 12
15 months. So at some level that's got to be a
16 measure because we're using that as a
17 criterion for treatment.

18 DR. FITZGERALD: That was an
19 inclusion criteria for the measure, which if
20 you miss some people, I think that's okay. As
21 an outcome measure that becomes harder.

22 CHAIR CHOU: Yes, I mean again, I

1 think it's -- most quality measures are not
2 predicated on those kind of outcome measures
3 because of this case mix problem. I mean,
4 there are some that are designed like that.
5 But even, for example, like HIV quality
6 measures and diabetes and things like that you
7 can certainly measure outcomes, but without
8 being able to adjust for case mix it's pretty
9 hard to interpret. How do you benchmark a
10 primary care university tertiary care center
11 versus something out in the community? All
12 those kinds of things.

13 So anyway, at least to my
14 knowledge most of the quality measures are
15 focused in general on process things. There
16 are some exceptions, things like pressure
17 ulcers and stuff like that where it may be
18 more kind of outcome-driven. But anyways --

19 DR. MATUSZAK: So if I'm
20 understanding the process correctly, what
21 happens when a patient comes in to be treated
22 for gout is that you're initiating --

1 potentially if they've had severe occurrences
2 and things, that you're starting urate
3 lowering therapy. And then you're actually
4 obtaining these uric acid levels in that acute
5 treatment phase anyways and you're targeting
6 the treatment to some number.

7 So if you're doing that in the
8 acute phase of disease management, what
9 rationale do you have for doing it once a year
10 or once in 12 months if you've already kind of
11 accomplished that with your initial phase of
12 disease management?

13 DR. FITZGERALD: So urate lowering
14 therapy is more of a chronic gout management
15 rather than the acute gout management. The
16 acute gout management is pretty much
17 restricted to the NSAIDS and the anti-
18 inflammatories.

19 DR. MATUSZAK: I'm sorry, I mis-
20 spoke. When you guys were talking about that
21 they're coming in to start urate lowering
22 therapy, you're actively managing people to

1 bring down their uric acid level. So you're
2 starting at a standard dose, 150 or 300 of
3 allopurinol and then you're titrating up based
4 on what their uric acid level is. So if
5 you're doing this on a biweekly or semi-weekly
6 basis or monthly basis to titrate them to the
7 point where they're under control, what
8 evidence do you have for doing it just once a
9 year? Doesn't it make sense that you would do
10 it to -- treat to a target in the acute -- in
11 the early management of it? I mean, what does
12 it matter 11 months from now if you started
13 uric acid lowering therapy now? Eleven months
14 from now why obtain that value?

15 DR. FITZGERALD: And so the
16 evidence that I presented earlier in the gaps
17 of care is that patients aren't getting their
18 urate levels monitored and they're not getting
19 their allopurinol or febuxostat titrated.

20 The goal of this is to try and get
21 people to do that, to try and get to the
22 target. So your goal is to get to 6.8 or

1 lower, however you do that through the
2 monitoring or titrations, whether it's done
3 however frequently. We set the one year as a
4 reasonable amount of time for someone to
5 follow up with a primary care physician.

6 If they're in for their gout,
7 maybe they get titrated aggressively like
8 you're describing, which would be fantastic.
9 Maybe they just get put on the 300 that's
10 typically done. But a level gets checked to
11 see if the therapy is effective. And if it's
12 not, then they have a chance to respond. And
13 so they have at least a year to try and get to
14 that rate.

15 DR. MATUSZAK: In the previous
16 outcome measure that we just addressed
17 previously then you wanted them if you're
18 changing the dose to do it within six months.
19 But if they're on a standard dose, then just
20 to do it once a year. Is that --

21 DR. FITZGERALD: I'm not -- no,
22 we're not -- so now we're not asking them.

1 Now we're not telling them how we want them to
2 get there. We're saying you want you to get
3 there.

4 DR. MATUSZAK: Got you.

5 DR. FITZGERALD: We had previously
6 suggested that --

7 DR. MATUSZAK: Thank you.

8 DR. FITZGERALD: -- if you start a
9 change, you check it and then do that
10 iteratively.

11 DR. MATUSZAK: Perfect.

12 DR. FITZGERALD: This is now just
13 saying, okay, get there how you get there,
14 whether you give them 300 off the bat, or
15 preferably you give them 100 or 150 and
16 titrate to the target.

17 CHAIR CHOU: And do you have any
18 information? I mean, with statins and Alcs,
19 for example, we know that we can't get some
20 patients below whatever target no matter what.
21 You can treat people maximally and they just
22 don't get to the target. Is the same true --

1 I mean, I know there's that one new drug that
2 we're not talking about here, but with
3 allopurinol and febuxostat are there patients
4 that you really can't get below a target of
5 6.8 if they start with a uric acid level of
6 12, that kind of thing?

7 DR. FITZGERALD: So we talked
8 about this in committee a lot about where the
9 exclusions might be. And again, those are the
10 rare patients more than the exceptions, but
11 patients with renal disease can be more
12 challenging. Dose titration is perhaps not
13 always done ideally. And again, patient
14 adherence, which we've on instruction excluded
15 as part of the design process, are issues.

16 So there are challenges there.
17 For the majority of patients they really ought
18 to be able to get their uric acid down. The
19 drugs work well. The -- you know, when
20 titrated are effective in lowering urate.

21 DR. VISCO: Just help me get my
22 head around this a little bit more. If we are

1 really talking about an intermediate health
2 outcome and not a process measure here, and
3 long-standing high levels of uric acid may
4 lead to chronicity of gouty symptoms, wouldn't
5 it make more sense to measure this in a two-
6 phase way and say -- ask people not only to
7 report the numerator when it's less than 6.8,
8 but also when it's over 6.8, much like you've
9 reported hemoglobin A1c that's been
10 chronically elevated, you know, over 9 or
11 whatever?

12 DR. FITZGERALD: So we had talked
13 about that and group-level versus patient-
14 level quality measures. And I think the
15 diabetes one that you're referring to, the
16 poorly controlled, that -- I think that's a
17 group level measure. And I think we were
18 directed to me more individual patient
19 measure. And so we focused on trying to treat
20 the target, again because there was rationale
21 in that and there's less -- we would have --
22 I mean, we could certainly come up with a bad

1 definition as well. But we focused on trying
2 to get patients to treat to target. It is
3 partly educational.

4 CHAIR CHOU: If there are no more
5 comments, let me just try to I think summarize
6 kind of where we are at.

7 So I think like some of the
8 previous measures we've noted that this is --
9 a lot of this is based on epidemiologic, kind
10 of correlational data without direct evidence.
11 We are looking at an intermediate outcome.
12 Some questions came up about the denominators
13 and the time kind of criterion that are in the
14 measure. I think those were kind of the main
15 issues. And I think maybe we're ready to do
16 a vote on the evidence.

17 DR. FITZGERALD: Sorry, Roger. I
18 just have the numbers. You were talking about
19 how effective therapy is. And in the
20 febuxostat trials 80 to 90 percent of patients
21 on either of the febuxostat groups had met a
22 serum urate level of six. And that included

1 patients with CKD up to three. So four was
2 excluded.

3 CHAIR CHOU: Okay. So we expect
4 people who can't get down to be fairly low
5 because we're using a higher threshold here of
6 6.8. Less than 10 percent maybe, something
7 like that.

8 Okay. I think it's time to vote
9 on the evidence. Again, this is a trial
10 measure, so we're voting to whether this
11 should proceed in terms of our evaluation to
12 be tested.

13 MS. PHILLIPS: Okay. We're voting
14 on measure 2549, the evidence. Your options
15 are one for high, two for moderate, three for
16 low, four for insufficient evidence with
17 exception, and five for insufficient evidence.
18 The voting begins now.

19 We're at twenty. There. Twenty-
20 one. Great.

21 All right. Nine for moderate,
22 four for low, four for insufficient evidence

1 with exception, and four for insufficient
2 evidence.

3 CHAIR CHOU: So this barely
4 crosses 60 percent.

5 MS. PHILLIPS: Yes.

6 CHAIR CHOU: Let's just -- is
7 there anything new that we need to discuss
8 here, Steve, JD?

9 (No audible response.)

10 CHAIR CHOU: I think we've --

11 DR. BROTMAN: -- think so.

12 CHAIR CHOU: Okay. Any other
13 comments from the rest of the panel?

14 (No audible response.)

15 CHAIR CHOU: All right. I think
16 it's time to put this one to a vote as well.

17 MS. PHILLIPS: All right. We're
18 voting on measure 2549, 1b, the performance
19 gap, with one for high, two for moderate,
20 three for low, four for insufficient. Voting
21 begins now.

22 We're at 19, so -- there we go.

1 Twenty. We need one more. You could all vote
2 again. You may have jumped the gun. There we
3 go. Twenty-one. Thank you.

4 All right. One for high, eleven
5 for moderate, three for low, and six for
6 insufficient.

7 CHAIR CHOU: That's in our gray
8 zone, I think. Fifty-seven percent. So
9 again, what do we do here?

10 MS. FRANKLIN: So it's within the
11 40 to 60 percent range, which is our gray
12 zone. It means that the Committee technically
13 has not reached consensus on this measure. It
14 goes forward though FOR consideration.

15 CHAIR CHOU: Okay. So I think
16 that's been noted.

17 The next area is priority. Again,
18 anything to add here, Steve or JD?

19 DR. BROTMAN: Just the same
20 comment that appeared, previously appeared in
21 this work group, that although gout is a high
22 priority, the work group is not sure that

1 monitoring to this target represents a high
2 priority gap.

3 CHAIR CHOU: Any other comments
4 from the rest of the panel?

5 (No audible response.)

6 CHAIR CHOU: All right. I think
7 it's time for a vote on priority.

8 MS. PHILLIPS: Okay. We're going
9 to vote on high priority for 2549. One for
10 high, two for moderate, three for low, four
11 for insufficient. The voting begins now.

12 We're at 20. So if you can all
13 vote again. We're still at 20.

14 (Laughter.)

15 MS. PHILLIPS: Okay. We may have
16 to redo this one. Okay. All right. Well, we
17 were at 20. So -- yes. Okay. This is not a
18 vote, but starting now let's -- everybody vote
19 again and we'll see if we can get to 21.

20 MS. STREETER: Also when you look
21 at the clicker as you push the button, if you
22 see a red light, I think that means the

1 battery is either out or going out. So let us
2 know and we can replace it.

3 MS. PHILLIPS: We're still at 20.
4 There we go. Twenty-one.

5 Okay. Now we're actually going to
6 vote.

7 (Laughter.)

8 MS. PHILLIPS: All right. Now
9 we're going to vote, starting now. This is
10 the real vote.

11 (Laughter.)

12 MS. PHILLIPS: All right. We're
13 still at 19. We're still at 20 anyway, so --
14 is it you, Katie?

15 Does everybody have a green light
16 on their -- all right. Well, we're still at
17 20. I'm not sure what's going on with this.

18 Yes, but let's vote on the actual
19 measure. Yes, maybe we'll get all 21 this
20 time. All right. Now.

21 Now we're at 20. Twenty-one.
22 Okay. Great.

1 All right. One for high, nine for
2 moderate, five for low, and six for
3 insufficient.

4 CHAIR CHOU: Okay. So we're still
5 in the 40 to 60, so this moves forward without
6 consensus.

7 Then I think we need to move on to
8 the next area. So quality construct isn't
9 relevant, I don't think, for this one.

10 And we're going to do the
11 specifications a little bit differently. I
12 think basically we just want to -- instead of
13 trying to use the stuff that's on the script,
14 we're going to be focusing on whether we think
15 that the things that are being measured are
16 what should be measured, basically. Is that
17 correct?

18 MS. PHILLIPS: That is correct.
19 We'll be voting on trial -- on whether the
20 specifications are consistent with the
21 evidence. We won't be of course looking at
22 any of the testing at this time. And this is

1 not a must pass criterion. It's more just a
2 vote indicating the Committee's feeling about
3 the specifications as presented by the
4 developer.

5 CHAIR CHOU: So, first before we
6 do the voting, Steve or JD, anything to
7 mention here?

8 (No audible response.)

9 CHAIR CHOU: Anything from the
10 rest of any other members of the panel?

11 (No audible response.)

12 CHAIR CHOU: I had previously just
13 mentioned some of my thoughts about, you know,
14 potential exclusions. For example, somebody
15 who is stable and doesn't have -- is on uric
16 acid lowering therapy and is having no gout
17 attacks, whether they really need to be in the
18 denominator. And the other one might be
19 people -- considering looking at people with
20 tophaceous gout or erosions separately, or
21 somehow stratifying those populations.

22 All right. So I think we're

1 voting on whether we think that as specified
2 it can move forward, right?

3 MS. PHILLIPS: That's correct.

4 CHAIR CHOU: Okay.

5 MS. PHILLIPS: Okay. We are
6 voting on 2549, trial measure specifications.
7 One for high, two for moderate, three for low,
8 four for insufficient. Voting begins now.

9 We are at 20. We're at 21.
10 Great.

11 We've got 1 for high, 11 for
12 moderate, 5 for low, and 4 for insufficient.

13 CHAIR CHOU: So, taken under
14 advisement. That's still in the gray kind of
15 40 to 60 range.

16 The next area is feasibility. Any
17 comments about feasibility from Steve, JD or
18 the folks who looked at feasibility?

19 DR. BROTMAN: Yes, I believe this
20 was the same data feasibility testing summary
21 that we saw before in some detail, unless
22 there's a correction to be made.

1 DR. FITZGERALD: No, that would be
2 it, but the data summary that you saw before.

3 CHAIR CHOU: Any questions or
4 comments?

5 (No audible response.)

6 CHAIR CHOU: All right. Let's
7 vote on feasibility.

8 MS. PHILLIPS: All right.
9 Feasibility for 2549. Your options are high
10 one, two for moderate, three for low, or four
11 for insufficient.

12 We're at 20. There. Twenty-one
13 now. Great. Thank you.

14 We've got 5 for high, 11 for
15 moderate, 2 for low, and 3 for insufficient.

16 CHAIR CHOU: Okay. So that
17 passes. It's over our 60 percent. The last
18 criterion is useability and use.

19 Steve or JD, any comments here?

20 DR. DANIELS: Just so you know,
21 it's not the after lunch lull. We're just
22 being quiet.

1 (Laughter.)

2 DR. DANIELS: Is that it's sort of
3 some of the same stuff on it. It's going to
4 be hard to do this when the finding on what is
5 gout and the levels are kind of all over. So
6 some of the same things. That's where I think
7 they're having trouble.

8 CHAIR CHOU: Yes, I mean I guess
9 my concern is again about the unintended
10 consequences, whether this is going to lead to
11 unnecessary testing and/or treatment and
12 whether that can be measured, or how that can
13 be measured. So just put that on the table
14 there.

15 Anything else to add to what's
16 been said already?

17 DR. FITZGERALD: Just to address
18 that concern that the burden or the cost of a
19 uric acid level wouldn't be prohibitive and
20 most -- the patients would be on urate
21 lowering therapy already, so it might be a
22 dose change.

1 MS. PHILLIPS: Okay. Voting on
2 measure 2549, useability and use. Your
3 options are one for high, two for moderate,
4 three for low, and four for insufficient
5 information. Voting begins now.

6 We're still at 20, so if everybody
7 can just make sure. There we go.

8 Okay. One for high, eleven for
9 moderate, four for low, and five for
10 insufficient.

11 CHAIR CHOU: All right. This is
12 again in the 40 to 60 percent range. So a
13 process question: So we have several things
14 that fell into this 40 to 60. Does that mean
15 we don't do the final vote, that it just -- we
16 still do the final vote?

17 Okay. So now we do our vote. Do
18 we want this to move forward as a trial
19 measure?

20 MS. PHILLIPS: 2549, overall
21 suitability for trial measure. You've got
22 option one for yes and option two for no. And

1 voting begins now.

2 Okay. We are at 21.

3 And 11 for yes and 10 for no.

4 MS. FRANKLIN: So it's still in
5 the gray zone and we'd still continue forward
6 with consideration of the measure. Again,
7 keep in mind that these deliberations of the
8 Committee would be summarize and report and go
9 out for a public comment and we'll come back
10 and reconsider the measure.

11 CHAIR CHOU: Okay. So when we
12 reconsider it, are there opportunities for
13 them to revise it, the measure after all the
14 public comments and things, or do we end up
15 voting on the exact same measure again?

16 DR. PACE: Typically it's the same
17 measure. During that time period of the
18 comment, if the developer has something to
19 offer that you should consider when you have
20 all the other comments and make your final
21 decision on whether to recommend this or not,
22 they can do that during that 30-day comment

1 period as well. But typically it's the same
2 measure, but there may be some clarifications
3 or potential changes. I mean, the tricky
4 thing is these measures are already specified
5 as e-measures, so it's not something that can
6 change quickly. And so, that's something that
7 we'll have to deal with if they want to make
8 any changes.

9 DR. VENTURA: Roger?

10 CHAIR CHOU: Yes?

11 DR. VENTURA: I guess it was a
12 concern voiced by a couple other people also.
13 I'm not sure that using this algorithm is
14 appropriate for a test measure. Maybe we're
15 being -- the rigor we're expecting is too high
16 for something to be submitted as a test
17 measure.

18 CHAIR CHOU: Yes, I mean, I don't
19 know if the NQF folks want to address that.
20 I mean, to me it's seems like it is very hard
21 for us to assess some of the latter things
22 that really -- where we're really able to

1 provide a lot of input before it's been tested
2 is in the evidence kind of performance gap,
3 health priority kind of areas and it's a lot
4 harder for us to really make informed
5 judgments about some of these other things.
6 So I'll see what the NQF folks have.

7 DR. PACE: Yes, I think -- and we
8 specifically said these measures should meet
9 the importance to measure and report criterion
10 because if they don't meet it now, it's not
11 going to meet it when they come back after
12 testing. And so, that bar should be the same
13 as for any measure that's coming to us for
14 consideration for endorsement.

15 Regarding the specifications, it
16 has to be an HQMF, which of course it is, and
17 we've already checked that. And I think the
18 big question about specifications is really a
19 connection back to the evidence. So if the
20 evidence the presented; and occasionally we
21 see this, evidence is presented fine, but then
22 the way the measure is specified doesn't

1 really sync with the evidence. So that's a
2 problem then that you should flag.

3 And then the feasibility is mostly
4 going to be about can the data be obtained
5 from EHRs and does the measure logic work,
6 which again should be tested. And then
7 useability and use is really, as you've been
8 talking about, it's the potential for use as
9 improvement and accountability.

10 So the big one is really the
11 importance to measure and the evidence
12 criterion.

13 CHAIR CHOU: So when you submit a
14 new measure, it's always a trial measure?

15 MS. FRANKLIN: No, this is only
16 being piloted for e-measures that are in --
17 without testing, that have not yet been
18 tested.

19 DR. PACE: And not every e-measure
20 has to go through this. So if an e-measure
21 has already been tested, it just comes in and
22 is assessed against all the criteria.

1 CHAIR CHOU: All right. I think
2 we're moving onto our next measure, which is
3 2526, anti-inflammatory prophylaxis with urate
4 lowering therapy.

5 I think I'll hand the mic to John
6 to give an overview from the developer.

7 DR. FITZGERALD: Thank you. So
8 the brief description is this is looking at
9 the percentage of patients with gout who are
10 initiated on ULT who are also receiving
11 concomitant anti-inflammatory prophylaxis, be
12 it either low-dose colchicine, NSAID or
13 glucocorticoid to reduce flares.

14 The numerator would be patients
15 co-prescribed low-dose colchicine, NSAID or
16 glucocorticoid. The denominator 18 years old
17 or greater with established gout initiating
18 urate lowering therapy. Denominator exclusion
19 were patients with contraindications to all
20 co-therapies. That would include the NSAIDs,
21 steroids and colchicine. And those are
22 specified.

1 CHAIR CHOU: So, Christian and I
2 were the lead discussants on this. So, I'll
3 just give a really brief overview. I'm not
4 going to repeat what John just said.

5 It's basically as when you're --
6 because people with -- are at risk for a gout
7 flare when the uric acid level changes,
8 whether it's going down or up. This one is
9 about starting an anti-inflammatory during
10 that initial period.

11 There were several -- I think the
12 main concern that came up in the work group
13 discussion was that really there was only one
14 trial of anti-inflammatory meds versus
15 placebo. It was small; 43 patients, and it
16 used colchicine. So it didn't address the
17 other drugs that are specified in the measure

18 There was a much larger trial that
19 was also cited, but it actually compared
20 different durations of anti-inflammatory
21 prophylaxis. It didn't compare prophylaxis
22 versus no prophylaxis. So even though that

1 was a much bigger study, it didn't directly,
2 I think, address the -- whether to use it. It
3 was more about how long to use it. And that
4 much larger trial was also colchicine, so
5 there was really no evidence presented about
6 NSAIDS and/or glucocorticoids.

7 There was a denominator exclusion
8 for people with contraindications. So as you
9 all know, NSAIDS and steroids have lots of
10 contraindications, and colchicine has some as
11 well. I think this would be -- I mean, you'd
12 have to have a contraindication to all three,
13 I guess, to be excluded.

14 I don't know that there was a
15 whole lot of other stuff here. I guess the
16 one thing I would add is at least in the
17 febuxostat trial they did put everybody on
18 anti-inflammatory prophylaxis. I think it was
19 with colchicine. I actually don't remember
20 what they did. But they did something for the
21 first eight weeks. And so at least the trials
22 have been designed to use anti-inflammatory

1 prophylaxis.

2 DR. FITZGERALD: Yes, they had
3 used naproxen during that study. So there's
4 evidence of NSAIDs being used, but it's
5 indirect. There's a known risk of a gout
6 flare anytime there's a change in uric acid,
7 so if you go out and have your shrimp and beer
8 dinner, shrimp and lobster, you're going to
9 raise your uric acid and you'll have a gout
10 attack. By the same example, if you were
11 having shrimp and beer every night and you
12 went vegetarian, you would suddenly lower your
13 uric acid and you'd also be at risk for having
14 a gout attack. So a change in uric acid will
15 increase your risk of having an attack.

16 And so, the baseline risk of --
17 let's say someone had a 15 to 20 percent risk
18 of having an attack during a six-month period.
19 We'll go up to 30 percent on the initial
20 treatment. So this has been recognized and
21 co-therapy has been recommended, again not
22 just by the ACR, but by other gout mine groups

1 including EULAR and BSR.

2 And when studies have been done --
3 so Sarawate, who we described earlier, looked
4 at reasons for non-adherence. Gout flare
5 after initiating therapy had a twofold risk of
6 non-adherence in patients. So there are risks
7 to ongoing therapy. And so the
8 recommendations have been to use an anti-
9 inflammatory. And we were providing any of
10 the anti-inflammatories that are used as
11 either being colchicine, NSAIDs or steroid.

12 And it's true that there is only
13 the one small placebo-controlled trial. Given
14 the known risk I think it's very unlikely to
15 do a large trial. The other trial though,
16 however, the short versus long, is on a large
17 study.

18 Do you remember how many patients?
19 Was it 2,000?

20 Yes, I think it's 2,000 patient.
21 And so it was three months versus six months
22 and there were flares after discontinuation

1 after three months. And so the recommendation
2 there was for the six months. So we're not
3 going to be able to get a placebo versus
4 prophylaxis trial. I think the short versus
5 long is the best that we're going to be able
6 to get.

7 CHAIR CHOU: Christian, do you
8 have anything to comment or add?

9 DR. DODGE: Just echoing what was
10 brought up in the work group, just that the
11 evidence is mainly for colchicine. And the
12 inclusion of the other options I think makes
13 this a little harder to justify in terms of
14 evidence.

15 CHAIR CHOU: Comments from the
16 rest of the panel? I see one up over there.

17 DR. MATUSZAK: Just two quick
18 questions. First one is the most important
19 question I'm going to ask you all day, which
20 is does it appear to be the hops or the barley
21 in the beer --

22 (Laughter.)

1 DR. MATUSZAK: -- that seem to be
2 the bigger problem with gout?

3 And actually the second one; and
4 I'll let you answer the first one, is actually
5 what about the over-the-counter NSAIDs? Is
6 there any way to take those into account?
7 Obviously if people have Aleve, do I have to
8 write them a script for naproxen in order to
9 get credit for this quality measure? Thanks.

10 DR. FITZGERALD: I think I'll take
11 the first.

12 (Laughter.)

13 DR. FITZGERALD: I'll take the
14 Fifth on the first.

15 Yes, so over-the-counter Aleve
16 twice a day would be sufficient. During the
17 specificity testing we'll see how well we do
18 at capturing that. The EMRs are designed to
19 capture those. If this is specified, people
20 will be noting it more. Again, some of the
21 coding and documentation will be driven by
22 some of these measures.

1 CHAIR CHOU: Other comments?

2 MR. SCHUNA: You don't specify
3 duration, but yet one of your studies suggests
4 there's a difference in duration. And I guess
5 I'm wondering why that was. And would one
6 week be sufficient for this prophylaxis?

7 DR. FITZGERALD: Yes, we had
8 debated about duration. And there was
9 concerns about holding everybody to the six
10 months, and so it was left off. And so, as
11 long as there was some documentation of
12 prophylaxis being done with the initiation,
13 that would be sufficient.

14 CHAIR CHOU: Other comments or --
15 and I guess just to follow up on the specific
16 drugs issues, I mean, there really is very
17 little data about use of steroids, is that
18 correct? I mean, not just for this purpose,
19 but just for use -- I mean, there's anecdotal
20 stuff, but in terms of published research
21 stuff there's not very much.

22 DR. FITZGERALD: Steroids would be

1 the least published, or at least the NSAIDS we
2 do have evidence of it being used in trials.
3 But again, it was to permit prescribers -- if
4 they would use any of the three anti-
5 inflammatories. In practice it's not used
6 really as a prophylactic agent, and I don't
7 think we would see much of it.

8 CHAIR CHOU: Well, I mean, I guess
9 I have some concerns about putting a patient
10 on eight weeks of prednisone, for example, for
11 prophylaxis of flares. And I would -- I think
12 it would make me more comfortable at least if
13 it was restricted to colchicine and NSAIDS.

14 DR. FITZGERALD: Yes, I think we
15 had debated that also because nobody likes the
16 idea of prolonged steroid. And it was left in
17 there for patients who are on existing --
18 there are a lot of patients who might be one
19 existing steroids for polymyalgia, asthma or
20 other indications.

21 CHAIR CHOU: Comment?

22 DR. ANNASWAMY: My question is

1 more about sort of the specifications, but I
2 guess I'll hold it until then.

3 CHAIR CHOU: Okay. Other
4 questions about the evidence?

5 (No audible response.)

6 CHAIR CHOU: Okay. I think we can
7 move to a vote. So just to summarize, we have
8 the one placebo-controlled trial. It's small,
9 but definitely showed a decrease in acute
10 flares. And then we have that bigger study,
11 which was six months versus eight weeks, I
12 believe, and the six month group had fewer
13 flares. We've already discussed the issues
14 about most of the data really being colchicine
15 with some data on NSAIDs and potential
16 concerns about the corticosteroid component.
17 I think those were the main things.

18 I guess there was a question about
19 whether there should be a duration-kind of
20 component to the measure, because there
21 currently isn't. That's not within the
22 evidence thing. No, I don't think.

1 So I think we can move ahead with
2 the vote.

3 MS. PHILLIPS: Okay. We're voting
4 on measure 2526 for the evidence. One for
5 high, two for moderate, three for low, four
6 for insufficient evidence with exception, and
7 five for insufficient evidence. And voting
8 begins now.

9 Okay. We're at 21.

10 MS. PHILLIPS: Eight for low,
11 seven for insufficient evidence with
12 exception, and two for insufficient evidence.

13 CHAIR CHOU: So, I think we're in
14 the 40 to 60 percent if you add up high,
15 moderate and insufficient with exception.

16 MS. FRANKLIN: No, we don't count
17 the --

18 MS. PHILLIPS: High, moderate and
19 insufficient with exception.

20 CHAIR CHOU: Yes, one, two and
21 four together. So, yes, so we're at 52
22 percent, so we proceed. So, no, we don't have

1 consensus yet, but we have enough consensus to
2 keep moving forward.

3 So the next area is opportunity
4 for improvement. So in the measure work sheet
5 and what was presented to us and in our work
6 group discussion the main evidence presented
7 was this VA study that showed that few
8 patients, 10 percent of whatever, of the VA
9 patients received prophylaxis during acute --
10 I mean, during the initial treatment phase.
11 I think that was the primary evidence
12 presented, but it was implied that there's a
13 lot of other -- that there's other evidence of
14 similar performance gap there.

15 Christian, did you have anything
16 to add there?

17 DR. DODGE: I think the
18 differential between on-demand treatment
19 versus prophylactic treatment wasn't totally
20 clear. What the magnitude of impact was, and
21 just taking these 30 percent increased risk of
22 flares and treating those acutely versus

1 taking the bulk of people where most of them
2 are being unnecessarily; we just don't know
3 which ones, and burdening them with these --

4 CHAIR CHOU: Other comments from
5 the rest of the panel?

6 (No audible response.)

7 CHAIR CHOU: And, John, did you
8 want to respond to the --

9 DR. FITZGERALD: I think the main
10 argument for the prophylaxis is the loss of
11 adherence with patients who do have a flare
12 because they then tie -- the data shows that
13 there's a twofold risk of dropping out. And
14 I think what they do is they tie the ULT
15 treatment to their gout getting worse.

16 DR. DODGE: Understood, but I
17 think that that would be an education piece.
18 When you're starting a therapy you'd want to
19 make sure that they could expect that and then
20 had contingencies for acute management versus
21 -- what strikes me is -- not that it's
22 unreasonable, but I think it strikes me as

1 heavy-handed to make that a performance
2 measure.

3 CHAIR CHOU: Other comments?

4 (No audible response.)

5 CHAIR CHOU: All right. I think
6 we're ready to vote on the opportunities for
7 improvement performance gap issue.

8 MS. PHILLIPS: Okay. 2526. You
9 have four options. One for high, two for
10 moderate, three for low, and four for
11 insufficient. And voting begins now.

12 Okay. We're at 21.

13 One for high, eight for moderate,
14 nine for low, and three for insufficient.

15 CHAIR CHOU: All right. We're 40
16 to 60 percent, so again we haven't reached
17 consensus, but we have enough to keep moving.

18 So the next area is priority. I
19 think this touches on what Christian said,
20 just how big of a clinical impact is this of
21 avoiding flares but having patients take a
22 drug versus having them treat flares acutely.

1 And John mentioned that one of the other
2 consequences of having the flares may be that
3 people stop taking their uric acid lowering
4 therapy completely.

5 And then there's been evidence
6 presented previously about how common gout is
7 and how -- the impact in terms of productivity
8 and health outcomes and all that.

9 Other comments? Christian?

10 DR. DODGE: Just the idea that
11 citing costliness of gout flares versus
12 prophylaxis for a much broader group of
13 people, I'm not sure how that would offset the
14 cost of the flares.

15 CHAIR CHOU: Yes, John, do you
16 want to respond to that?

17 DR. FITZGERALD: I don't have any
18 data on that. NSAIDs wouldn't be that costly.
19 Colchicine is no longer an inexpensive option,
20 unfortunately. Hopefully will be again soon.
21 And potential side effects I couldn't state.
22 So, gout flares are costly as far as lost

1 work, visits to the ER. The average cost of
2 a gout patient is usually \$300 per year or
3 more than non-gout patients for just their
4 gout-related activities. When you add in all
5 the other sort of comorbidity conditions, then
6 the cost of gout patients go up quite a bit.
7 They can be in the \$3,000 or more per patient.
8 So gout flares are costly. It would be hard
9 to say how that one would shake out.

10 DR. ANNASWAMY: Just to clarify,
11 what is the issue with colchicine?

12 DR. FITZGERALD: So, colchicine
13 used to be \$0.30 a pill, and three years ago
14 the FDA -- and colchicine has been around
15 since Egyptian days originally as an emetic
16 drug, because of that known side effect. In
17 the, I think, it was 1600s it's effect on gout
18 was starting to be used.

19 In 2009 the FDA branded it for one
20 single manufacturer, who then -- the centuries
21 of research that went into that were then
22 reaped. The price went up to \$3 a pill. So

1 used twice a day, it's now a \$6 therapy
2 instead of a \$0.60 therapy. And the hope is
3 that once it goes -- it was given a short run
4 of branding, initially three years, but that
5 was extended, I don't know for how long. But
6 colchicine is currently not the cheap option
7 it used to be.

8 CHAIR CHOU: Other questions or
9 comments?

10 DR. YAZDANY: Can I just make one
11 comment.

12 CHAIR CHOU: Sure.

13 DR. YAZDANY: It's sort of a soap
14 boxy comment. So forgive me, but I do think
15 that as a person who chaired the ACR's
16 Choosing Wisely campaign, sometimes some of
17 the subconscious decisions that we make drive
18 up health care costs. So we want a randomized
19 controlled trial that shows that prophylaxis
20 works. So a company did a randomized
21 controlled trial of colchicine, which
22 rheumatologists have known literally for

1 decades and decades, and if not centuries, as
2 a medicine that works. And the same thing for
3 NSAIDs.

4 So, I just think we have to be
5 careful. For a lot of the things that we
6 would have RCTs for drug therapy there has to
7 be a really strong financial incentive for
8 something that's known to be an expensive
9 drug. Some of these things that are very
10 inexpensive and yet very effective based on
11 sort of decades and decades of clinical
12 experience we are throwing out because there
13 isn't an RCT, even though there's very, very
14 strong international and national consensus.
15 So I'm just going to say that. I'm not trying
16 to sway your decision, but I just want to
17 point that out.

18 CHAIR CHOU: Well, did you want to
19 say something, Karen, or -- okay.

20 DR. PACE: No, it's been sitting
21 there a long time.

22 CHAIR CHOU: Yes, I mean, the

1 point is well taken. I mean, one response
2 would be that. That's what people always say
3 when there isn't evidence. And there are a
4 lot of things in medicine where if we hadn't
5 pushed for the studies we wouldn't have
6 learned that they didn't work or they didn't
7 work as well as we thought they should. And
8 I would argue that a trial of colchicine would
9 be pretty cheap --of colchicine prophylaxis of
10 a couple hundred people would be pretty cheap
11 and not that hard to do. Or a trial with
12 naproxen. But I think some of this is beside
13 the point here.

14 Let's come back to the voting. So
15 we're voting on the priority. And again, just
16 the high, moderate, low or insufficient here.
17 I think we can move forward.

18 MS. PHILLIPS: Okay. We're voting
19 on measure 2526, priority. We've already got
20 our options for voting. And voting starts
21 now.

22 Okay. We're at 21.

1 We have 2 for high, 5 for
2 moderate, 12 for low, and 2 for insufficient.

3 CHAIR CHOU: So I think this is
4 just below our 40 percent threshold. Is that
5 right? Sixty-seven percent low, so 33 are --
6 actually it's less than that. Eighteen and --
7 ten and twenty-four -- thirty-four percent for
8 high and moderate. So we're a little bit
9 below our 40 percent threshold. So what does
10 this mean? This means that we stop here?

11 MS. FRANKLIN: Yes, it would not
12 continue forward.

13 CHAIR CHOU: Okay. All right. So
14 I think we're down with the gout measures.

15 And now we're moving onto the
16 rheumatoid arthritis measures. And the first
17 one is going to be functional status
18 assessments.

19 Oh, yes, go ahead. Sorry.

20 DR. FITZGERALD: Well, I do want
21 to thank all members. It's clear that we
22 could put a lot of time and effort into this.

1 And thanks to the NQF staff. Throughout the
2 process you've helped get this through.

3 I do not want this to reflect on
4 my interest on RA. I'll be leaving shortly to
5 catch a plane to the airport.

6 I just had a procedural question.
7 Was there public comment on the last two?

8 MS. FRANKLIN: Oh, we don't do
9 public -- well, you explain.

10 MS. PHILLIPS: Yes, we don't do --

11 DR. FITZGERALD: Okay.

12 MS. PHILLIPS: -- public comment.
13 We do it at specific times in the agenda.

14 DR. FITZGERALD: Oh, okay. With
15 that, thank you.

16 CHAIR CHOU: All right. Thanks,
17 John, for being in the hot seat --

18 (Laughter.)

19 CHAIR CHOU: -- and answering all
20 the questions. I know how that feels.

21 DR. ANNASWAMY: John, I think
22 you're batting a 500, so you should feel

1 great.

2 (Laughter.)

3 CHAIR CHOU: I heard a request for
4 a bathroom break.

5 PARTICIPANT: A bio break, a very
6 short one.

7 CHAIR CHOU: Yes, okay. A bio
8 break. I haven't heard that term before --

9 (Laughter.

10 CHAIR CHOU: -- but, yes, I think
11 we can take one.

12 (Whereupon, the above-entitled
13 matter went off the record at 2:29 p.m. and
14 resumed at 2:36 p.m.)

15 CHAIR CHOU: All right. So, we're
16 going to try to reconvene here. The next
17 measure we'll be talking about, we're moving
18 away from gout to RA now. It's about
19 Functional Status Assessment, again nominated
20 by ACR.

21 This is an eMeasure but it's been
22 tested so this is different from the others,

1 and now we're not voting on whether to test,
2 we're voting on whether to fully endorse. So,
3 I'm going to hand it over to Jinoos to give us
4 a brief overview.

5 DR. YAZDANY: Great. Thanks,
6 everyone. So, the first measure is 2524, and
7 this is Functional Status Assessment in
8 rheumatoid arthritis. This is a process
9 measure in which the requirement is that
10 functional status is assessed using a
11 standardized assessment and that the result is
12 recorded in an electronic health record.

13 I just have a few introductory
14 slides. So, rheumatoid arthritis can lead to
15 destruction -- actually, if you can go back
16 just one for me, destruction of the joints,
17 and there's often rapid functional decline.
18 And simple tasks that many of us take for
19 granted, writing, cooking, dressing, walking
20 can become very painful. And we asked the
21 question why is it important to measure
22 functional status? And it all comes down to

1 one single point, which is that this is the
2 single most important thing to patients. And
3 that capturing Patient Reported Outcomes I
4 think has become a priority nationally. Next
5 slide.

6 This is a very important study,
7 and it was published in 2011. And it was a
8 very well done analysis that surveyed both
9 patients and rheumatologists, and looked at
10 what things to consider when they're
11 considering changing therapies.

12 And you'll see that there is some
13 discordance in the things that physicians
14 value and the things that patients value. And
15 you will see that for patients the number one
16 thing is physical function and mobility. For
17 the rheumatologist it is many of the things
18 that we consider under the general concept of
19 Disease Activity, so things like the swollen
20 joint count, the DAS 28 which is a measure of
21 disease activity, and so forth. Next slide.

22 So, what you may not know is that

1 rheumatology has really pioneered the use of
2 Patient Reported Outcomes in clinical trials,
3 and in clinical practice over the last 40
4 years. We've probably been using PROs longer
5 than just about anybody. We have the legacy
6 measures that the Health Assessment
7 Questionnaire, called the HAQ in all of its
8 various revisions, and building on these
9 legacy measures the NIH PROMIS system now has
10 sort of these state-of-the-art versions of
11 these that incorporates some of the old items
12 and adds new items so that we get rid of
13 things like ceiling and floor effects, and we
14 can more carefully tailor the functional
15 status assessments to our patients.

16 The psychometric evidence base is
17 very strong. It's a method that was very hard
18 to put this type of evidence into the forms
19 which are really more about the process. But,
20 again, there's been decades of psychometric
21 work, probably more in rheumatology than just
22 about anything else showing that these

1 measures are valid, and they have content and
2 concept validity, that they're responsive to
3 changes, that they're reliable, feasible. And
4 there's been, I think, a lot of work done in
5 health literacy, low literacy populations.
6 Also, they're available in many different
7 languages. And there's also advice by the
8 national/international consensus guidelines
9 that recommend this process of care. Next
10 slide.

11 Most rheumatologists do not use a
12 formal PRO to assess functional status in
13 practice, although many may do the full in a
14 more cursory way. And measurement
15 infrastructure does enable next steps so we
16 see this as a stepping stone measure. We can't
17 get to outcomes assessment until people are
18 actually measuring this, and we'll talk about
19 why later. We can't do bench marking, we can't
20 go to risk assessment model or do quality
21 improvement without the basic infrastructure
22 of this superhighway of measurement, if you

1 will. And I think that we can learn a lot from
2 other countries, especially our European
3 colleagues in Sweden, and Denmark, and France,
4 and the UK, and others who really have used
5 this type of measure as the backbone for a
6 National Quality measurement improvement and
7 for a value-based health care design. Next
8 slide.

9 I decided to clean out because
10 there were lots of issues raised on the
11 testing, but a lot of the workflow challenges
12 were overcome in our testing, and we'll talk
13 about that in more detail. And I want to point
14 out that many EHRs are increasingly including
15 PRO capacity. This is an example, one of the
16 largest EHR developers, Epic, is providing its
17 customers with a PRO application in the 2012
18 release. There's a library of PROs that are
19 available and you can select or you can add
20 your own PROs, the common short forms and many
21 of the ones that we're discussing are included
22 in that, and the local Epic user books can

1 program the software for clinical user to
2 define an event and to direct the
3 administration of such PROs. So, this is a
4 rapidly changing field and we recognize this,
5 but there's some challenges to be overcome.
6 But I think that slowly the superhighway is
7 being built, and we'll talk about the validity
8 ratings. Next slide.

9 I just wanted to mention this
10 because I don't feel it was totally clear in
11 our submission materials that this measure was
12 reviewed and recommended by the Measure
13 Applications Partnership for use in 2015 CMS
14 programs. It's currently in use and programmed
15 into the Rheumatology National Registry which
16 is a chief qualified clinical data registry
17 CMS.

18 Somebody on one of the
19 teleconferences asked well, if these things
20 are already happening why is NQF endorsement
21 important? And as a professional society, we
22 share the vision that endorsement accelerates

1 a coherent harmonized measurement status group
2 across the U.S. health care system, so we're
3 motivated to get these things endorsed. So,
4 those are my introductory comments. Thanks.

5 CHAIR CHOU: So our leads on this
6 one are John Ventura, Kelly Clayton, and Jason
7 Matuszak. Do one of you want to do the
8 overview to start?

9 DR. VENTURA: Sure, I'll start and
10 then turn it over to Jason and Kelly. I'm not
11 going to repeat the measure. I think it's
12 worth mentioning relative to the rationale
13 they couldn't face the same issue on this one,
14 and that is there's no direct evidence that
15 the process measure itself leads to better
16 outcomes, although there's a lot of indirect
17 evidence relative to the steps in the process
18 such that it's a way to measure responsiveness
19 to treatment, it's a predictor of future
20 disability and mortality, and it provides
21 feedback to both the patient and the
22 provider. And it's associated with an

1 increased mortality, also, as evidence for the
2 rationale for why this shouldn't be done. When
3 we got to the first -- the comments, it was
4 basically just what I had mentioned, that
5 there isn't direct evidence about the
6 relationship to health outcomes, but indirect
7 evidence for it. There was one question about
8 health literacy, and I think that was
9 addressed by them having multiple tools that
10 had been valid and reliable measures. And
11 anything else you want to add to that, Jason
12 or Kelly?

13 CHAIR CHOU: Kelly or Jason, do you
14 have additional comments?

15 DR. MATUSZAK: I guess a couple of
16 the other things that came up was the
17 difficulty of all these patients because a
18 lot of rheumatoid arthritis patients have
19 significant co-morbidities that also are going
20 to affect the functional status assessments.
21 Obviously, we do think they are very
22 important. I think they have to -- I agree

1 that I think it's the single biggest factor
2 for the patient and for the treatment
3 providers. But I also found it interesting
4 that these treatment guidelines that you guys
5 pulled this from actually didn't recommend
6 specifically doing Functional Status
7 Assessments, it only recommended doing it as
8 part of the global assessment on patients. And
9 then even in the ACR guidelines that they
10 recommended doing it every three to six months
11 in remission or low-activity states, and every
12 one to three months during the active state.
13 So, I was wondering kind of why the
14 discrepancy, why it set a bar at one level,
15 and then describe the quality measure as
16 something entirely different over what the
17 clinical guidelines are recommending. Is it
18 just a set of, you know, artificially low bar
19 even though it's not what your standard of
20 care is, or what you guys determined should be
21 good care.

22 DR. VENTURA: I'm sorry. I didn't

1 address the numerator and denominator, the
2 numerator is the percentage of patients 18 and
3 older with a diagnosis of RA for whom a
4 functional status was performed at least once
5 every measurement period, which was 12 months.

6 CHAIR CHOU: Jinoos, did you want
7 to respond to some of the comments?

8 DR. YAZDANY: Sure, I'd be happy
9 to. So, let me start with the question about
10 health literacy. This is an area that actually
11 going into testing we were very concerned
12 about because one of our testing sites in
13 particular has a population that draws at
14 least partly from a safety net and there are
15 a large proportion of people that we actually
16 know from other studies that have low health
17 literacy. It's also a population in which are
18 both Spanish and Chinese speakers so there's
19 the added issue of language. So, as we think
20 about handing surveys to patients I think we
21 can't ignore these things.

22 Now, one interesting glimpse about

1 what the magnitude of missing data in a
2 setting like that might be, came from the fact
3 that the workflow at this particular site is
4 that every patient fills out something called
5 a Patient Global in which over time they learn
6 that there's a digital analog scale that goes
7 from zero to 100, a happy face, or not happy
8 face -- but anyway, we all have to read to be
9 able to do that, and people just sort of mark
10 how they're doing. So, we
11 have had the experience of 100 percent of
12 patients are able to fill out that Patient
13 Global Assessment, and there was a discrepancy
14 of 6.3 percent between the PROMIS physical
15 function survey and that Patient Global
16 Assessment, so what that means to us is that
17 about 6.3 percent of this population was
18 unable to fill out the PRO. And in those
19 instances there's an additional burden on the
20 staff that have to read the PRO to the
21 patient, or have a family member help them, so
22 I think that's a small number, but it's

1 something to be considered.

2 Co-morbidities do affect
3 functional status, and I'm trying to remember
4 what the exact question was about - oh, yes,
5 okay. So, we had many debates over a period of
6 over a year about which functional status
7 assessments to recommend, and they occurred
8 among dozens and dozens of rheumatologists and
9 experts. And in the end we decided that
10 because co-morbidities can affect functional
11 status so profoundly that there needs to be
12 some flexibility in giving clinicians the
13 opportunity to offer different ones. So, for
14 example, you know, if there's a geriatric
15 patient with a severe disability and one who's
16 a geriatric functional status PRO, that's
17 fine. They should get credit for that.

18 We did recommend four based on
19 expert consensus that would be sort of the
20 default recommendations coming from an archive
21 of rheumatology, but we wouldn't ding people
22 because of co-morbidities that were going to

1 do something else, so the measure leaves some
2 flexibility.

3 And then in terms of guidelines
4 and the timing of assessment, if you read
5 through the guidelines, and we know there's 20
6 different guidelines that recommend functional
7 status assessment, some of them say that this
8 should be offered to patients at least once a
9 year, other ones say that you should do it at
10 every visit. There's disagreement on that, and
11 the reason that we came down at once per year
12 was that nobody said to it less than that, so
13 that is a bar on which everybody can agree.
14 And partly, that has to do with the
15 psychometric properties of these functional
16 status measures. They tend to decline slowly
17 in the chronic phase of the disease, and if
18 something is declining slowly, so for example
19 with the HAQ, if somebody only loses one point
20 or less per year you probably will get that
21 valuable information by just measuring it once
22 a year. Many people do it more often. That

1 should be applauded. I think that's great, but
2 we're not going to ding people for not doing
3 it every time.

4 CHAIR CHOU: Other comments or
5 questions from the rest of the panel or from
6 the lead discussants? Yes?

7 DR. ANNASWAMY: Yes, I think
8 functional assessment as an outcome measure is
9 easy to understand and comprehend, but
10 functional assessment as the intervention is
11 hard to study. So, it is near impossible to
12 overcome the problem of looking for studies
13 where doing a functional assessment has
14 improved outcome. The analogy I can think of
15 is cake. If you are trying to figure out if an
16 outcome of making a cake is good, you would
17 want to eat it, but you really can't assess
18 the outcome of eating without eating it unless
19 you're comparing it to looking at it. And then
20 you're dealing with having your cake and
21 eating it too.

22 (Laughter.)

1 DR. YAZDANY: Can I just make a
2 comment about outcomes measures? We - to make
3 another analogy, I think we need to walk
4 before we can run. I'm going to say that for
5 a lot of these measures, so we are in a
6 situation where most people are not even
7 walking, are not even measuring functional
8 status which is the number one most important
9 thing to patients. And although I understand
10 and share the enthusiasm for moving towards
11 outcome measures, we're in a situation where
12 it's hard to even test these measures because
13 people aren't using them, so that's one thing.
14 It's just like building a superhighway.

15 The other thing that variables for
16 risk adjustment, and we actually went through
17 this exercise so we said if we were going to
18 develop a risk adjusted functional status
19 outcomes measures, and part of this work was
20 actually with CMS because they're very
21 interested in this for meaningful use stage 3.
22 You know, what are the variables that we might

1 need? Disease duration, fixed deformities,
2 detailed information about co-morbidities. For
3 example, what if someone just had a joint
4 replacement or has another issue? In
5 rheumatology we have a compounding issue of
6 access to drugs. With many of our biologic
7 agents patients have a 30 percent coinsurance
8 so how do you factor in access to drugs on
9 socio economic status? I know the NTHROP has
10 had a big debate about that, which we don't
11 need to talk about today. So, at the
12 conclusion of all of that we decided that we
13 want them motivated to work towards that, and
14 we actually commissioned a paper on Outcomes
15 Measurement in Rheumatology which our
16 colleague, Lisa Sutter, is actively writing
17 right now to sort of set the stage of how
18 we're going to go from here to there, and why
19 we can't do that right this second. But there
20 was universal agreement that this was the
21 right starting point.

22 CHAIR CHOU: Kelly or Mark have a

1 comment?

2 DR. JARRETT: My comment really
3 relates to over 30 years of struggling to take
4 care of tons of rheumatoid patients, and the
5 reality is that you need this measure because
6 it does not coincide necessarily with all our
7 other objective measures, like joint counts.
8 And it is the most important thing. Patients
9 who have to get up four hours earlier to get
10 dressed so that they can button their clothes
11 and go to work, that's what's important to
12 them, not how many warm, swollen joints they
13 have. And it really truly is a measure of how
14 they feel, and it is the most important thing
15 to them. And, yes, it doesn't relate right now
16 directly to outcomes, but I agree 100 percent,
17 if you don't start measuring this now, you get
18 uniformly measured, you can never get to the
19 next step.

20 CHAIR CHOU: Okay. Kelly, do you
21 have a comment?

22 MS. CLAYTON: I have to agree with

1 Mark. Like I said, I come both from the
2 researcher perspective but also the patient
3 perspective, and having done this for almost
4 15 years, I think the biggest key to filling
5 out some of these functional status
6 assessments and the instruments used is
7 getting the conversation flowing between the
8 patient and the rheumatologist. Yes, these
9 instruments tend to only look at a snapshot in
10 time as them, you know, being unable to do
11 this in the last week versus, you know, the
12 last few months, but it gets the conversation
13 flowing between you and the rheumatologist
14 that hey, you know, over the last three months
15 I've had this decline, or, you know, that
16 leads to a change in therapy, so change in
17 additional prescriptions, things like that,
18 and physical activity changes.

19 CHAIR CHOU: Thanks. Other
20 comments?

21 MS. DAVIS: In my department, we
22 work with various outcomes, and in Minnesota

1 we're actually doing quite a bit of work as
2 well on functional status for surgical
3 procedures. But in all of the work we're doing
4 in Minnesota it is accompanied by qualify of
5 life surveys, as well as functional status
6 because they're different based on the
7 perception of the patient. I'm wondering if
8 that's something you would consider. It's
9 probably not totally relevant to our
10 conversation, but you laid the stage for it,
11 so -

12 DR. YAZDANY: So, there's overlap
13 of course between physical function and
14 quality of life assessment. In fact, some
15 quality of life assessments include physical
16 function as a single domain. And, you know, I
17 think in a more advanced performance
18 measurement system we would in a much more
19 sophisticated way capture all of the aspects
20 that are important to patients. And,
21 obviously, quality of life is part of that.
22 Within this narrow disease, though, the reason

1 that we started the functional status is
2 because we have information that that's the
3 single thing that patients care about the
4 most. I agree, that's an important goal,
5 forward thinking, great to hear you're doing
6 that.

7 CHAIR CHOU: Yes, Zoher.

8 DR. GHOGAWALA: So, I, too, I want
9 to applaud the effort to sort of
10 systematically collect patient reporting
11 functional status. The numbers that you quoted
12 for the percentage of patients that are unable
13 to complete these forms reliably is very, very
14 low. However, in monitoring of European
15 registries, as well as efforts in the United
16 States where registries incorporate patient
17 reported outcomes type of data the compliance
18 rate is, in fact, low. And one of the things
19 that at least we've seen on spine side is that
20 in academic centers in areas where there's
21 nurses or study coordinators who have helped
22 patients to get these outcome assessments

1 completed, answer questions and so forth, the
2 compliance rate is much higher. But as we look
3 more broadly at community practice, small
4 private practice and so forth where the time
5 demands on clinicians are enormous, adding
6 this to the workflow may be a challenge. And
7 I'm just curious to hear your perspective,
8 understanding full well that I think that no
9 matter what the hurdles, we must do this. But
10 our challenge is to getting patients to
11 complete these forms reliably, and we probably
12 should think about that.

13 DR. YAZDANY: Those are all really
14 important comments. I can share our
15 experience in rheumatology, which is that
16 those people who are motivated to measure this
17 have just come up with amazing grassroots
18 innovative ways to do this in clinical
19 practice. I mean, we have people doing
20 everything from literally having like those
21 old-fashioned scantron machines, and people
22 sort of using a number 2 pencil and sort of

1 feeding it through and getting the outcome, to
2 startup companies that are pushing these
3 things to patients phones, and touch screens,
4 and people getting it through the Epic My
5 Chart, emailed to them. And I think what's
6 really interesting is that if you build the
7 will and the infrastructure, I think we can
8 leave it to people to come up with a solution
9 that will work for them.

10 We have exact times on each of
11 these measures that are recommended, so in
12 most cases for the patient it's between three
13 and five minutes to fill out the form. And in
14 most cases it's less than one minute to score
15 the form. So, again, I don't want to minimize
16 that. In a 15-minute visit, that one minute
17 might be a challenging thing for a clinician
18 who doesn't have any support staff. But we
19 also know that it's not a huge amount of time
20 either, so at least there's some calibration.

21 CHAIR CHOU: Other comments?

22 DR. ANNASWAMY: In your literature

1 review assessment has PRO been compared to a
2 provider-based assessment?

3 DR. YAZDANY: So, there's two forms
4 of evidence. One is for randomized controlled
5 trials, and one is from just observational
6 studies. And based on recommendations from
7 Omar Act, functional status assessments are
8 actually now included in a standard way in
9 RCTs in RA. So, we know from those trials that
10 drugs that work move these PROs, so they move
11 in the same direction as objective measures of
12 disease activity, and these composite measures
13 which we'll talk about later. And that data is
14 summarized in some of the psychometric papers
15 that were cited, and that the measures are
16 responsive to change.

17 There's also observational
18 studies. The largest one is the CORRONA
19 Database. This is a Consortium of Rheumatology
20 Researchers of North America. It's actually
21 based in community practices, and there it's
22 not a randomized controlled trial. There

1 people just agree to measure. And what we see
2 in that observational study, and I can forward
3 you the citation, is among these 17,000
4 patients that have been followed for over a
5 decade, we again see that the functional
6 status assessments are moving in the same
7 direction as the more objective disease
8 activity assessments. And that, in fact, just
9 the measurement, which is the only
10 intervention in that observational study seems
11 to lead to no further declines in function,
12 which is really important, and maybe even an
13 improvement. That's a study by Greenberg that
14 was actually relatively recently published in
15 the American Journal of Medicine in late 2013.
16 And I'm sorry it's not included in the
17 materials, partly it's because we started the
18 materials before that paper was public.

19 DR. ANNASWAMY: So, in these
20 examples you cited there functional assessment
21 reported by the patient compared to provider-
22 based assessment of disease activity. I was

1 more wondering along the lines of provider-
2 based assessment of function versus patient-
3 reported assessment of function.

4 DR. YAZDANY: There has been some
5 work done in that area, and as a general rule
6 one thing that's interesting is that if
7 patients are just - and this is based on a
8 study by Jeff Curtis. If patients are just
9 asked about their function without doing a
10 formal survey, so you just say how are you
11 getting along? Which is usually how it goes in
12 clinical practice. I would say that that's the
13 usual care. Physicians will then tend to over-
14 estimate their function, as opposed to having
15 a standard way of collecting it. So, that's
16 the best information that we have in that
17 regard, and I think it makes sense.

18 CHAIR CHOU: I have a question. You
19 know, the measure is specified as being in
20 counters for RA. And, for example, a lot of
21 patients with RA may have a primary care
22 doctor, but really their RA care is somewhere

1 else. So, this - you know, it's - I guess
2 what I'm asking, this isn't being targeted at
3 kind of the routine kind of primary care
4 follow-up. It's really people that are being
5 managed, and it's really going to be mainly at
6 rheumatologists the way it's written.

7 DR. YAZDANY: So, that's a very
8 important point. Again, we went back to both
9 the literature and some qualitative studies.
10 There's a really nice one that Dan Solomon's
11 group did at the break on where they surveyed
12 the primary care community and just asked them
13 whether they are comfortable diagnosing RA,
14 managing RA, starting DMARDs, a whole range of
15 questions along those lines. And I think the
16 results are consistent with our clinical
17 experience, which is that although in the
18 primary care setting many feel comfortable
19 diagnosing them, so I guess the vast majority
20 don't feel comfortable actually managing the
21 DMARDs, so I think for that reason, and the
22 fact that we really wanted to have

1 accountability measures for rheumatologists,
2 we wanted to limit this to rheumatologists.

3 CHAIR CHOU: My other question is
4 just how - you know, the numerator specifies
5 using a valid and reliable instrument. I'm
6 just wondering how that's going to be
7 operationalized.

8 DR. YAZDANY: So, Rachel may be
9 able to speak more to this, but we've applied
10 for LOINC codes for the various recommended
11 measures. There's really four recommended
12 measures. They include the HAQ-2, the PROMIS
13 physical function short form 10, the PROMIS
14 physical function short form 20, and the
15 PROMIS physical function computer-assisted
16 technology testing. Oh, I guess, and there's
17 a fifth one, which is the Rapid 3, which is
18 the MD HAQ. So, those are the ones that we're
19 going to primarily capture. And then I guess
20 there's also an option for other, something
21 like that.

22 CHAIR CHOU: Right. And I guess my

1 question, so when it says I use this other
2 measure, how is that judged? Who judges that,
3 and how is that - I mean, there's many, many
4 functional status measures both disease-
5 specific and non-disease specific and, you
6 know, I think that to me poses a challenge in
7 terms of figuring out what meets the criteria
8 or not.

9 MS. MYSLINSKI: Yes, it is a
10 challenge. The way that we have specified it
11 we're looking for the result of an assessment.
12 So, if it was just, for example, somebody
13 saying - a conversation between a provider
14 and patient, that wouldn't necessarily be
15 captured in that way.

16 CHAIR CHOU: But it sounds like any
17 measure basically you would accept, so you're
18 not really - the validity and reliability
19 thing won't really be -

20 (Off microphone comment.)

21 CHAIR CHOU: All right. Other
22 questions or comments?

1 DR. VENTURA: I was going to ask
2 the same question. I thought they would come
3 up -

4 CHAIR CHOU: Yes, the availability
5 -

6 (Off microphone comment.)

7 CHAIR CHOU: So, let me just
8 summarize where we're at. I think everyone -
9 I mean, there's no direct evidence about how
10 measuring outcomes impacts patient outcomes,
11 but I think there's a rationale for doing it.
12 But, you know, kind of clinically it makes
13 sense that in order to trap outcomes and all
14 this other stuff - and then a lot of the
15 evidence is, you know, really about
16 reliability, you know, responsiveness to
17 disease state, things like that. That's really
18 where a lot of the evidence, I think, is
19 coming from. It's almost like looking at a
20 diagnostic test where we're looking at
21 diagnostic accuracy rather than how doing the
22 test impacts outcomes.

1 I'm not sure if we have to use the
2 kind of the algorithm for evidence rules a
3 little bit differently because to me it
4 doesn't really seem to fit the algorithm,
5 unless we drop to the very end.

6 (Off microphone comment.)

7 CHAIR CHOU: With exceptions, okay.
8 So, that means we kind of drop to the bottom
9 there.

10 PARTICIPANT: Box 7, just going on
11 to box 10.

12 CHAIR CHOU: Yes. So, I think we're
13 probably ready to move to a vote on this
14 measure.

15 MS. PHILLIPS: Okay. So, you're
16 going to vote on Measure 2524 for the
17 evidence. Your options are one for high, two
18 for moderate, three for low, four for
19 insufficient evidence with exception, and five
20 for insufficient evidence. Giving in just a
21 second, the mouse cursor is being
22 uncooperative. All right. We can start the

1 voting now.

2 (Voting.)

3 CHAIR CHOU: Okay, it passes the
4 evidence. Next is opportunity for improvement.
5 Jinoos already summarized some of that.
6 Anything to add from the lead discussants?

7 DR. VENTURA: No, other than they
8 did use three test sites to insure variation
9 in implementation and so forth, and 7 percent
10 there was definitely room for improvement.

11 CHAIR CHOU: Other comments from
12 the rest of the panel? And you can do the
13 vote.

14 MS. PHILLIPS: Okay. On the
15 performance, one is fine, two moderate, three
16 low, and four insufficient. And voting can
17 begin now.

18 (Voting.)

19 CHAIR CHOU: All right. This one
20 passes with flying colors also. These votes
21 are a lot more clear cut than the gout votes.
22 Next area will be priority, so again think

1 Jinoos already addressed that. I'd see if John
2 or any of the other lead discussants have
3 other comments to add?

4 DR. VENTURA: No, just to add that
5 it's been added as a CMS top 20 condition.

6 MS. PHILLIPS: Okay, we're going to
7 vote on priority for 2534, one is high, two
8 moderate, three low, and four insufficient.
9 Voting begins now.

10 (Voting.)

11 CHAIR CHOU: Okay. So we keep
12 moving. The next area is the reliability and
13 validity stuff. Essentially, the
14 specifications. Again, I think we're kind of
15 voting, but not really, I guess.

16 MS. PHILLIPS: Oh, no, this is a
17 full -

18 CHAIR CHOU: Oh, this is for a
19 full. Okay. So, this is a full measure. Sorry.
20 So, let's step back, sorry. So, this actually
21 has been tested. Maybe, John, if you want to
22 summarize some of the testing information.

1 DR. VENTURA: Sure. Reliability was
2 assumed to be 100 percent because it's the
3 extraction from EHR. So, they assumed a
4 reliability component, and then used three
5 validity checks. The first was actually using
6 check values or reliability measure between
7 the hand pulled data and the automatic on the
8 EHR pulled data. And it was very, very high
9 correlation between the two.

10 We also measured face validity by
11 virtue of expert handling census, using what
12 was appropriate, which was considered very
13 high. And then they also did do a - I believe
14 it was like a cap value on diagnosis of RA
15 between the EHR and the hand pulled, and that
16 came out with very little disagreement.

17 CHAIR CHOU: Anything to add from
18 the other leads?

19 DR. VENTURA: And according to NQF
20 case validity is sufficient.

21 CHAIR CHOU: Okay. So, we haven't
22 done this yet, so do we vote on the

1 reliability first, and then validity? Okay.

2 DR. PACE: So, in this case, so I
3 know that this gets into our quirky little
4 aspects about criteria, they're right, that we
5 - the Measure Testing Task Force report,
6 because if you're looking at data element
7 reliability and validity, they're very closely
8 connected. So, that's why we accept data
9 element validity to suffice for reliability,
10 as well. So, I would say use those results of
11 the data element validity as your doing your
12 reading for reliability. And because that
13 would be at the data element level, not the
14 performance score, moderate would be the
15 highest score - rating that it could get.

16 DR. ANNASWAMY: If you go down the
17 algorithm you're at number ten through twelve
18 on the validity level.

19 DR. PACE: Yes. We're actually
20 going to use the - if you look at the
21 reliability algorithm, I'm just saying we'll
22 use the same for the data element validity as

1 - you'll use that same information in making
2 your decision about data element reliability.

3 DR. ANNASWAMY: What would be an
4 example of the reliability -

5 MS. STREETER: Can you please turn
6 on your mic. Sorry to interrupt.

7 DR. ANNASWAMY: My bad. What would
8 be an example of a reliability testing that
9 would be at number 2 or 1. We have number 4.

10 DR. PACE: Okay. So, at the level
11 of the performance score?

12 DR. ANNASWAMY: Yes.

13 DR. PACE: Typically, what we see
14 with this is a signal to noise analysis where
15 you actually have the performance scores for
16 a lot of the providers, and you could do a
17 signal to noise analysis. Sometimes we've seen
18 developers do split half reliability analysis,
19 but the idea is that you actually have
20 computed performance scores for enough
21 providers that you can actually do those kinds
22 of analyses. And I don't have it in front of

1 me, but how many sites did you test this in?

2 DR. YAZDANY: There were three
3 sites, and multiple providers at each site.
4 And we did not do signal to noise, but instead
5 we look within sites to see whether there was
6 variability between the providers of
7 individual sites, and then also between the
8 sites. And I can tell you that one of the
9 sites that had something like 12 providers had
10 statistically significant differences in
11 performance between the providers at that
12 site, and then others there were no
13 differences between them. I don't know if
14 that's all that you're looking for -

15 DR. PACE: Yes. No, that's
16 different.

17 DR. YAZDANY: Okay.

18 DR. PACE: That's looking at the,
19 you know, distinguishing performance. But, I
20 mean, they're sometimes related. But, anyway,
21 those are the two that we typically see,
22 signal to noise analysis, or split half, you

1 know, or using some kind of ICC analysis. But,
2 basically, looking at that computed provider
3 level score, not the data, you know, the
4 agreement in the data from two different ways
5 of abstracting.

6 CHAIR CHOU: Okay. I still don't
7 really get all this stuff, but I think it
8 would helpful at least for me if kind of the
9 NQF people could tell us if they think there
10 are issues with reliability, because I'm not
11 sure that we always know all this random split
12 half stuff, and the signal to noise, and all
13 these other things. I mean, I don't know - I
14 mean, we're often not presented that data,
15 number one. And number two, just how to
16 interpret it I think is going to be difficult
17 for many people. But I'm not hearing that
18 there are any concerns that you guys
19 identified. Is that correct?

20 DR. YAZDANY: That is correct.

21 CHAIR CHOU: Okay. And then the
22 lead didn't really identify concerns here

1 either, so -- and I'm talking about both
2 reliability, as well as the validity
3 component, as Karen said, that these are
4 interrelated.

5 DR. PACE: And the ceiling is
6 moderate.

7 CHAIR CHOU: Say that again.

8 DR. PACE: The ceiling is moderate.

9 CHAIR CHOU: Okay. Why is the
10 ceiling moderate, again?

11 DR. PACE: Because the testing is
12 done for the data, not the computed
13 performance score. So, our hierarchy is that
14 that's a foundation but it doesn't tell us
15 exactly about the performance score. And that
16 often happens when you have few sites on which
17 you can actually do the testing.

18 CHAIR CHOU: All right. So, I
19 believe we're ready to vote on reliability,
20 and then we'll vote on validity.

21 MS. PHILLIPS: Okay. There are four
22 options. One for high, two for moderate, three

1 for low, and four for insufficient. We're
2 voting on Measure 2524 for reliability. Voting
3 begins now.

4 (Voting.)

5 CHAIR CHOU: We can move to
6 validity now.

7 MS. PHILLIPS: All right. We are
8 now voting on validity for Measure 2524. Your
9 options are one for high, two for moderate,
10 three for low, and four for insufficient.
11 Voting begins now.

12 (Voting.)

13 CHAIR CHOU: So, this passes, so we
14 can move on to the next, which is feasibility.
15 Any comments from the lead discussants?

16 DR. VENTURA: They did set up
17 especially to look at feasibility, and they
18 were a little bit confused between the two -
19 there were some concerns voiced by the sites.
20 Two of the three said that they didn't think
21 it would be feasible from a technical standpoint,
22 although they said it did meet the standard,

1 and that there is some challenge relative to
2 workflow also. The technical component they
3 thought they could overcome in a matter of
4 weeks, but the workflow they thought might
5 take a few months. They did support it, but
6 there were some challenges.

7 CHAIR CHOU: Does any ACR folks
8 want to comment on that?

9 DR. YAZDANY: Just to say that I
10 don't think that we should minimize the fact
11 that this will require workflow changes for
12 individual clinicians. And I feel like I'm
13 very sensitive to that, because I take care of
14 patients, so sometimes it's easy for us to say
15 and hard for people to do.

16 That being said, it's interesting.
17 When we started this process the subjective
18 feasibility assessments where people just say
19 do you think you can do this, and people sort
20 of typed what they thought were much more
21 negative than the actual implementation of
22 testing. And that was just interesting,

1 because I think people thought maybe there's
2 a lot of inertia, people are scared of their
3 IT divisions, they don't want them to change
4 the EHR. They think it's going to be hard and
5 expensive, and often I think that those things
6 are true. But on the other hand, many of the
7 testing sites, and actually we continue to see
8 this as we roll out the registry, they are
9 able to overcome many of those things.

10 And I'll just make a point that,
11 you know, if this measure does get NQF-
12 endorsed and is part of CMS programs, there's
13 going to be a really strong incentive for EHRs
14 to make this easier for docs so that they
15 don't have to reinvent the wheel one at a
16 time, you know, vocally to build this stuff.
17 So, I think that's the vision. I hope it's
18 realized. And I think we have to support, I
19 guess as the ACR part of the job in supporting
20 the members just to make sure that we provide
21 education, tools, and support to make this
22 easier.

1 CHAIR CHOU: Over here and then
2 down there.

3 DR. JARRETT: I just have a
4 question for you in the feasibility study that
5 you guys looked at. They did raise concerns
6 about the technical and the workflow changes,
7 but it was interesting because they also -
8 maybe there was a little hesitation on
9 whether or not it accurately differentiated
10 the quality of performance across providers,
11 you know, that there are certain categories
12 that, as you guys did these feasibility things
13 like, you know, they said oh, yes, strong
14 agreement that this will retain its value, and
15 then this one they kind of said ahh, maybe, I
16 guess. Did you get a sense of why the sites
17 felt that it might not be a good
18 differentiator of quality amongst providers?

19 DR. YAZDANY: It's some of the
20 issues that we've talked about before, which
21 is I think that, you know, this measure is a
22 foundational step, and if we were going to use

1 the score to differentiate between providers
2 performance without looking at risk adjustment
3 I think, you know, there should be hesitation.
4 But that's not the plan, so I think part of it
5 may be that. Part of it may be that people
6 feel like they're doing this with the are you
7 able to get along kind of question, so they
8 think most rheumatologists on a subjective
9 level think that this part of taking care of
10 patients. You ask them how they're
11 functioning, and maybe they don't believe that
12 doing a standardized assessment is going to be
13 any different than usual care, even though we
14 have some data to show that actually there is
15 a difference. So, I think those may be two
16 issues that are reflected in those qualitative
17 comments.

18 CHAIR CHOU: Zoher.

19 DR. GHOGAWALA: So, if I understood
20 correctly, the pilot aspect of this was three
21 sites, in which all three were extracting the
22 data from the electronic health record. The

1 fact of the matter is that that's not reality
2 in the United States today. So, to look at
3 this from a feasibility standpoint today, to
4 me I think it's very, very worrisome because
5 while it's important to do, while I think that
6 it ultimately must be done, to sort of make
7 this a measure is going to present a hardship
8 for the vast majority of practicing
9 physicians. And an unexpected consequence of
10 this is that the initial enthusiasm and the
11 initial forward momentum on this will be lost.
12 And I'll give you an example.

13 This is from many, many years ago
14 in Europe with the Spine Tango Registry. The
15 initial pilot study of that showed outstanding
16 patient compliance because it was a group of
17 very, very motivated sites. But as it was
18 brought out to 50 sites with 20 or 30,000
19 patients, the compliance fell to 30 percent,
20 and the value of that registry is low. So, I
21 think this is something that we need to think
22 about very carefully, because today while Epic

1 does have a drop-down menu for sure about the
2 common patient-reported outcome measures, it's
3 not in fact installed in the vast majority of
4 sites that have Epic today. And it takes a
5 highly motivated group of people to make it
6 happen, so I don't think this is feasible at
7 least today. That's my view.

8 CHAIR CHOU: Yes. You know, my only
9 thought is that I have patients who are, you
10 know, any way measured are disabled and are
11 always going to be disabled no matter what I
12 do, and how many times I measure it. And it
13 just raises some questions about, you know, is
14 some of this kind of wasted energy in some
15 patients, at least. And I don't think we need
16 to get into that here but, I mean, I - you
17 know, not necessarily with RA, but patients
18 with, you know, disabilities or other chronic
19 pain conditions and things like that where
20 literally there's nothing - I mean, you
21 know, they've been treated maximally and
22 there's nothing that's going to change their

1 functional status.

2 But in terms of kind of the
3 implementation piece, I think my - you know,
4 I already raised the other - the concern I
5 had about what instruments are going to be
6 accepted, and it sounds like you guys are
7 thinking this would be a very broad, basically
8 if somebody uses an instrument that's
9 essentially been published and studied in some
10 way, then that's going to meet the criteria.
11 I think.

12 Any other comments or questions?
13 All right. I think it's time to make a vote on
14 feasibility.

15 MS. PHILLIPS: We're voting on
16 feasibility for 2524. One is high, two is
17 moderate, three is low, four is insufficient.
18 And voting begins now.

19 (Voting.)

20 CHAIR CHOU: So, we're over 60
21 percent for high and moderate so we can move
22 on to usability and use. I think some of this

1 overlaps with the feasibility issues. Are
2 there other comments that the lead discussants
3 wanted to make?

4 DR. VENTURA: I think just one.
5 There was some overlap with the function
6 measure as a part of PQRS, and the feeling
7 that this is, I guess, pertaining to my
8 question about only using valid and reliable
9 measures.

10 It was noted that this would add
11 specificity to our PQRSs. I mean, if you open
12 it up to any tool that's possible, how are you
13 adding specificity to the PQRS measure?

14 CHAIR CHOU: I have a question,
15 actually. I'm a little surprised that this
16 isn't, you know - like for low back pain, for
17 example, we know that people don't measure
18 function and stuff very well in primary care,
19 but in - if you go to specialty clinics they
20 do. That's built into their workflow already,
21 so I'm curious why this is not the case with
22 rheumatology for RA. Is there - you know, it

1 seems like that would be -- it would be the
2 same kind of situation where there would be a
3 disconnect between primary care management and
4 specialty management, but you'd think that the
5 specialist would kind of be on top of it
6 already.

7 DR. YAZDANY: I think that there's
8 some clinical inertia on it. I don't know
9 what else to say.

10 CHAIR CHOU: Other comments or
11 questions here?

12 DR. ANNASWAMY: One of the
13 unintended consequences that the gentleman
14 over there, I can't see his name, was talking
15 about, but the other is the unintended
16 consequence of setting the bar so low, could
17 it be that, you know, you're finding a lot of
18 people are reaching it, and there may not be
19 an incentive to keep going shooting for a
20 higher bar? That may be one unintended
21 consequence.

22 DR. YAZDANY: This is more, again,

1 a vision than the current state of affairs,
2 but the way that the registry is being built
3 is with those nightly uploads of data, and so
4 you are going to be able to sort of create,
5 hopefully, move towards some kind of model
6 that's more learning health care system where
7 you're going to have some people that are
8 measuring it more often, and some people that
9 are measuring it less often, and hopefully get
10 to a point where you can generate data about
11 this. And I know that NQF has, you know, an
12 endorsement and maintenance process, and
13 hopefully, you know, with each iteration of
14 this there's going to be the ability to make
15 this more sophisticated and useful. So, we
16 know this is just a baby step.

17 DR. DANIELS: Yes, maybe - I'm
18 going to call him Dr. Z, sorry doc. You had
19 some good points and everything but, you know,
20 this kind of tugs at your heart. You kind of
21 want to get this to go through, and I know
22 that just in our setting we sometimes have to

1 sort of make a quick-draw shot like, you know,
2 this person is presented to you and the family
3 brings him in. Do they go to the nursing home,
4 or they can stay home, they're going to fall
5 and break their hip. And there's a couple of
6 real quick things that we'll do, stand up, sit
7 down, tests that I can do. But to get
8 something that's kind of more complex than
9 that, I guess my question is with -- we're
10 talking about working with groups of people
11 and that. What would be wrong with this,
12 sorry, doc, with just having like an OT or a
13 PT consult. So, if there's a person - I mean,
14 you go and have them see it, and they know a
15 lot more about the function. I mean, you guys
16 are giving people drugs, but as far as
17 functional stuff, they're kind of better than
18 us. So, I mean, what would be wrong with just
19 asking them to do that?

20 DR. YAZDANY: There is nothing
21 wrong with that. And I think, you know,
22 getting a little bit off topic, but we've

1 heard a lot about team-based approach to
2 health care, and there are many examples of
3 rheumatologists around the country, and in
4 particular with the care of rheumatoid
5 arthritis where there is a team-based
6 approach. And in that practice is a physical
7 therapist, an occupational therapist, and
8 there's a nursing visit, and some of these
9 things are not done necessarily by the
10 physician, but are done by the co-staff. And
11 I think that in that situation as long as it's
12 in the EHR, there's no reason that the
13 rheumatologist that's affiliated with that
14 practice shouldn't get credit, as well. And,
15 you know, as you move up levels of
16 accountability that practice will look good,
17 and that health system will look good. So, I
18 think there will be incentives, hopefully, you
19 know, depending on how this measure actually
20 is used in the health care system for that to
21 happen.

22 DR. DANIELS: Do you use a measured

1 option?

2 DR. GHOGAWALA: I think that's
3 actually a great idea. The only trouble that
4 I see on this may be a surgeon bias, is
5 oftentimes we see the PT and the OT reports
6 which are very useful for a physical therapist
7 or an occupational therapist to follow
8 someone's care, but we don't really know how
9 to understand it. That sounds silly at one
10 level, but there's no way to quantify the
11 level of disability. And that's something
12 that's very appealing about these validated
13 patient-reported outcome tools. Whichever one
14 you use there are some numbers that have
15 meaning, and you can compare how, you know,
16 one group of patients is doing versus another.
17 And you compare how your patient is doing over
18 time. So, I think there's real value in the
19 patient-reported outcomes approach, as opposed
20 to the PT or OT report, which also has great
21 variability, incidentally, in terms of
22 different therapists and how they fill these

1 forms out.

2 But I still continue to - I have
3 real concerns over, you know, how - and I say
4 this as center, we have Epic, so I could see
5 how we could do this, but I have real concerns
6 about programs that don't have an electronic
7 health record that would permit this, so how
8 that would be in the figures.

9 MS. BURSTIN: Just a quick comment.
10 That's a very fair piece of advice, it's only
11 specified for those who have it, so no one
12 else can be held accountable for using the
13 measure unless you already have EHR. So,
14 again, it's that thinking towards the future,
15 having measures in place when more and more
16 people are on EHRs, but you couldn't do it if
17 you didn't have it. No one will force you to
18 use the measure.

19 DR. GHOGAWALA: So, this is
20 verified.

21 MS. BURSTIN: Yes.

22 DR. GHOGAWALA: Then my concerns

1 are much less. But there's EHRs and there's
2 EHRs.

3 MS. BURSTIN: Yes.

4 DR. GHOGAWALA: So, Epic, and
5 Serner, and so forth have these capabilities,
6 but a lot of people practice with an EHR
7 system that simply doesn't have this
8 capability. So, how would that apply to those?

9 CHAIR CHOU: I saw some hands up
10 here, and then we'll come back to you.

11 DR. ANNASWAMY: Another of the
12 unintended consequence, Roger, you talked
13 about earlier which is since, again, this is
14 such a low bar, if a lot of providers started
15 using the other and end up doing a non-
16 validated, non-standardized functional
17 assessment, then we're kind of shooting
18 ourselves in the foot, and we are really not
19 measuring function properly.

20 DR. YAZDANY: So, thinking again,
21 the onus is on the ACR and the rollout of the
22 registry. And I can tell you that, you know,

1 they have very dedicated staff that are there
2 to support practices. And I think by putting
3 these tools on line - and, by the way,
4 actually all of the ones that we selected are
5 non-proprietary. Nobody has to pay for using
6 any of these tools, which is really important.
7 For example, the SFM-6 you have to pay for.
8 Right? So, we took all that into
9 consideration, so I think we need to encourage
10 people to use the four recommended tools
11 unless they have a really good reason for
12 using something else.

13 CHAIR CHOU: And I think that's
14 something that can be measured. Right? We can
15 see how many people are checking off box 4,
16 whatever, and if it's 80 percent, then you
17 know there's a problem, and you need to kind
18 of readdress what we're looking at.

19 The only other thing I'll mention,
20 and I hope this isn't really applicable here
21 but, you know, this reminds me of when pain
22 was added as an outcome measure to be done as

1 a fourth vital sign or whatever, the fifth
2 vital sign, which everyone thought was a great
3 idea. And it's probably contributed to the
4 massive, you know, increase in use of opioids.
5 And, you know, so you don't always know what's
6 going to happen with these things, and when
7 you don't have strong evidence linking the
8 intervention with the outcome it really is, I
9 think, important to really follow through and
10 see what's actually happening. Are patients
11 getting better care as a result of the
12 functional assessment, et cetera? There are a
13 couple of other comments here.

14 DR. MATUSZAK: It certainly sounds
15 like you guys have hit on some usefulness
16 criteria there in terms of some of the overlap
17 with what you're doing with CMS and stuff,
18 which I think is really nice if you can get
19 that type of alignment. I think that's really
20 big, and must be a little concussion piling up
21 on me because I can't remember what the other
22 thing was.

1 (Laughter.)

2 DR. MATUSZAK: But, actually, a
3 question for JD. Exactly how far south in
4 southern Illinois are you from?

5 PARTICIPANT: It depends on the
6 date.

7 (Laughter.)

8 CHAIR CHOU: John had a comment.

9 DR. VENTURA: Yes, I just have
10 experience more with back pain and functional
11 outcome measures, and even two experiences
12 with implementations of the EHR. And while
13 logistically it's a bit problematic, it's
14 definitely the trend, and I think it's going
15 to become logistically much easier. That's
16 been my experience.

17 CHAIR CHOU: All right. I think
18 we're ready for a vote. Are we ready? Oh,
19 Karen, sorry.

20 DR. PACE: That's all right. I was
21 just going to say if that's a problem about
22 the specifications and any standardized tool,

1 I mean, that is an issue. They've got four
2 recommended ones, that's something that the
3 committee can factor into their discussion, or
4 their vote on this measure. But I guess the
5 other thing is, it wasn't clear in the kind of
6 English language specifications, but the
7 measure is specified so that they can't just
8 check that they used, or identify a code for
9 an instrument. They actually have to record a
10 score from that instrument. Is that correct?

11 DR. YAZDANY: Correct.

12 DR. PACE: So, that probably needs
13 to be clear in the specifications, because
14 then the point is you will have that data as
15 you've been talking about, so I just wanted to
16 ask basically the committee how they would
17 initiate that.

18 CHAIR CHOU: At least for me, I
19 think it's acceptable to have the option to
20 use other measures. I just wanted to see
21 follow-up data and if it's a high proportion,
22 then I think it needs to be revisited. If it's

1 10 or 15 percent, or whatever then, you know,
2 it may not be an issue. So, at least that's my
3 perspective. I wouldn't ask the measure to not
4 go forward or something because of that. Other
5 - yes?

6 MS. CLAYTON: One last thing to
7 add. One of the articles that was cited in our
8 measure specifically even pointed out that the
9 self-reported measures may be influenced by a
10 patient's mood, self-efficacy, cultural
11 beliefs, so on, but over time you'll see more
12 of a reliable measure versus those random kind
13 of up and down episodes.

14 CHAIR CHOU: All right. Let's vote
15 on usability and use. And then we'll go from
16 there.

17 MS. PHILLIPS: We're voting on
18 usability and use for 2524. You've got four
19 options, one high, two moderate, three low,
20 and four for insufficient evidence. The voting
21 begins now.

22 (Voting.)

1 CHAIR CHOU: So, this passes and we
2 come to the final vote. And this time we are
3 voting for full endorsement, so not just to
4 test it.

5 MS. PHILLIPS: All right. We're
6 going to use the additional question slide for
7 that.

8 (Off microphone comment.)

9 MS. PHILLIPS: This is for overall
10 suitability for 2524 for endorsement. One is
11 yes, two is no. Voting starts now.

12 (Voting.)

13 CHAIR CHOU: All right. We're done
14 with that measure. We have two more. Are we
15 taking a little five or ten minute break? So,
16 maybe we'll reconvene at 5 til, and then
17 finish out the day.

18 (Whereupon, the proceedings went
19 off the record at 3:43 p.m., and went back on
20 the record at 3:55 p.m.)

21 MS. STREETER: Thank you. So, as
22 many of you probably know, Ann sent out an

1 email just announcing that we made dinner
2 reservations for those who are interested in
3 going somewhere after dinner, we thought it
4 would be nice just to have somewhere already
5 booked for you, if you'd like to go. It's two
6 blocks away, and basically we just want a head
7 count now so we can update our reservation.
8 For those who are interested in going to the
9 dinner, if you could raise your hand.

10 (Off microphone comment.)

11 MS. STREETER: Okay, thank you.

12 CHAIR CHOU: All right. So we're
13 going to move into the last couple of
14 measures. I just wanted to apologize because
15 I'm going to have to leave probably after the
16 first measure because I have another phone
17 call I have to be on. But we're going to do
18 Measure 2522 first, so this is rheumatoid
19 arthritis, tuberculosis screening. Again,
20 developed by ACR. The lead discussants are Kim
21 Templeton on the phone, and Linda Davis. And
22 this is for a trial measure, so not fully

1 endorsing it, just endorsing for further
2 testing. And I'll turn it over to Jinoos for
3 an overview.

4 DR. YAZDANY: Sure. So, Katie, I'll
5 just have you queue up that slide for me. So,
6 this is tuberculosis testing in people who are
7 newly starting a biologic DMARD.

8 This is a key patient safety
9 measure, and the rationale is the biologic
10 DMARDs increase the risk of reactivation of
11 latent tuberculosis; that is, tuberculosis
12 that's dormant or asleep and doesn't have any
13 symptoms, and reactivation of tuberculosis is
14 a dreaded event. It can lead to severe
15 morbidity or death, and as someone who took
16 care of somebody who had this two months ago
17 who didn't have screening for tuberculosis
18 before starting a biologic, I can tell you
19 that there was just a tremendous amount of
20 suffering in a patient who almost lost his
21 life. So, this is something that perhaps
22 should be a never event.

1 Screening detects tuberculosis,
2 and simple treatment regimen generally is
3 effective. Just to give you some perspective
4 because I think some questions were raised
5 about this on the telephone conferences about
6 burden. We think that about, based on CDC
7 estimates, that about 4 percent of the
8 population of the United States has latent TB.
9 It's a much higher percentage among certain
10 racial ethnic groups. So, for example, among
11 African Americans it's thought to be as high
12 as 18 percent, among Hispanics probably 9
13 percent or higher, and definitely much higher
14 among foreign-born immigrants, as well.

15 The risk of hepatotoxicity with
16 treatment the usual regimens of either
17 monotherapy with isoniazid or rifampicin in
18 the more recent literature is between about
19 zero to 1 percent, although our experts tell
20 us that with monitoring for liver function
21 tests and early discontinuation if there's a
22 problem, the risk of anything serious

1 happening is negligible.

2 Biologics increase the risk of TB
3 reactivation by at least 5 percent, I'm sorry,
4 five times. The signal was initially detected
5 in randomized controlled trials, so this is a
6 serious adverse event happening in the context
7 of over 10 randomized controlled trials. So,
8 I don't think that there's any question that
9 there's an increased risk. Next slide.

10 We already talked about why this
11 is important. In terms of the evidence, I just
12 wanted to point out that it I think would be
13 unethical to perform a randomized controlled
14 trial of screening. The recommendation is
15 really based on the biology of the disease,
16 and just to tell people a little bit about
17 that.

18 Our bodies control tuberculosis by
19 forming something called a granuloma. There's
20 a picture of that on the previous slide. And
21 when you give somebody a biologic DMARD, you
22 actually stop that containment mechanism, so

1 the organism that's asleep is able to wake up
2 and cause all sorts of trouble. There's very
3 strong guideline-based consensus about this.

4 And then in terms of, you know,
5 people were wondering well, is there evidence
6 that the process of care, so just the
7 screening itself does anything. The closest
8 that I could find is from our Swedish
9 colleagues that have a national registry, and
10 they did a very clever study. And they looked
11 at the background rate of tuberculosis in
12 rheumatoid arthritis patients in two time
13 periods, 2002 to 2006 before there was
14 widespread screening, and then in 2007 and
15 2011, so that was sort of the background rate.

16 Biologic starters had a higher
17 rate as expected of tuberculosis, but
18 interestingly over time the biologic users had
19 a decreased risk, so that demonstrates that
20 screening, which is the only intervention.
21 This is not a trial, this is not the regional
22 registry, seemed to protect patients. And they

1 actually went back and did a chart review in
2 the cases of active tuberculosis that they
3 found, and 16 of the 18 did not have
4 tuberculosis screening documented. So, I think
5 that's probably the best we're going to get in
6 terms of observational evidence.

7 The gap in care, next slide. The
8 rheumatology registry data which is based on
9 the PQRS measure shows that measuring this has
10 improved performance. We started out at 74
11 percent performance, and we're up to 93
12 percent. There were a lot of questions about
13 who's currently participating in the registry,
14 and I just wanted to take a moment and answer
15 that question, because I know that people had
16 questions about that.

17 So, our current registry has 810
18 active users. There are 373 unique active
19 sites. There are 31,800 RA encounters, so we
20 estimate that there's about 5,000
21 rheumatologists in the United States, and I
22 just told you that there's 800 active users.

1 So, we don't believe that the data from the
2 RCR is necessarily representative of the
3 entire U.S. rheumatology population, and we
4 know that those practices are early adopters,
5 so there's likely more room for improvement
6 from our best guess. Next slide.

7 I just want to point out in terms
8 of feasibility and validity that this measure
9 is very similar to an NQF-endorsed measure
10 that was put forward by the NCQA in the area
11 of HIV. Their measure reads, "Percentage of
12 patients aged three months and older with a
13 diagnosis of HIV or AIDS from whom there was
14 a documentation that a TB screening test was
15 performed and results interpreted at least
16 once since the diagnosis of HIV infection."

17 So, although the numerator is similar, they
18 actually had a lookback period of forever,
19 which is really hard in performance
20 measurement. But, nevertheless, that's an
21 endorsed measure. We were able to test this
22 measure at one site, and in that one site we

1 were able to calculate performance. And this
2 had very high expert panel ratings.

3 Planned uses, next slide. This
4 also has been reviewed and recommended by the
5 Measures Application Partnership for use in
6 2015 CMS programs. And this is also programmed
7 into our QCDR. That's all.

8 CHAIR CHOU: Thank you. Kim, would
9 you be able to provide an overview of the
10 measure and the evidence? And then we'll get
11 - have additional comments from Linda.

12 CHAIR TEMPLETON: Sure. And as was
13 stated, there really isn't evidence directly
14 addressing this from the standpoint of a
15 randomized controlled trial on whether
16 patients are tested or not tested because (a)
17 it would pose a serious ethical issue, and you
18 couldn't do it. And (b) even if you could, the
19 numbers that you would need in a study would
20 be so large that it would be an unwieldy study
21 to do because of the rare incidence of the
22 condition. So, this is something that the

1 evidence is primarily expert opinion,
2 understanding the risk, as was just mentioned,
3 of putting someone on the DMARD who has latent
4 TB that's not detected and treated initially.
5 So, there isn't direct evidence. However, the
6 consequences of somebody activating latent TB
7 if they're placed on DMARD is so substantial
8 that perhaps we can waive any direct evidence
9 in this area. At least that was part of our
10 discussion when we had our conference call.

11 CHAIR CHOU: Thanks, Kim.

12 CHAIR TEMPLETON: Sure.

13 CHAIR CHOU: Linda, do you have
14 anything to add?

15 MS. DAVIS: The concern was that
16 the measurement, actually - I mean, this is
17 not unlike all the other measures we've been
18 talking about, the actual process of
19 measurement hasn't been linked to the actual
20 improvement in outcomes, but it has been
21 linked, associated to the implementing the
22 measurement. So, by measuring we improve the

1 testing of it, which we hope then will be
2 connected to outcomes.

3 CHAIR CHOU: Thanks. Before taking
4 other comments, I just wanted to note that,
5 you know, this is really a patient safety
6 issue. And it's actually quite rare to have
7 evidence, direct evidence that doing many of
8 the things we do for patient safety like, you
9 know, when we start an anti-arrhythmic
10 checking EKGs and all this other stuff,
11 monitoring LFTs in patients who were put on a
12 potentially hepatotoxic drug, checking their
13 creatinine on somebody who was on metformin.
14 There's no study showing that those things
15 work, but our threshold when it comes to
16 patient safety tends to be different than when
17 it comes to, you know, intervening and doing
18 something. And I would, you know, also point
19 out that the FDA, for example, will pull
20 studies based on case reports and things like
21 that, sometimes very few case reports. So, I
22 do think we look at the evidence a little bit

1 differently when we're looking at patient
2 safety issues.

3 Yes, Jason, do you have a comment?

4 DR. MATUSZAK: Two questions, and I
5 don't remember reading in your guide - or the
6 recommendation, but did you have a preference
7 as to the type of screening method. And did
8 you exclude or take into account in terms of
9 the sensitivity specificities, the percentage,
10 if you know what I mean, like with the
11 Mantelle, for instance, I mean, you're talking
12 about sensitivity sometimes in the .59 range.
13 So, I just wanted to know how you guys decided
14 on what you were going to use, or what you
15 were going to look at, and exclusions for, you
16 know, people with BCGs or stuff like that.

17 DR. YAZDANY: Those are really good
18 questions. I can tell you that the road to
19 this process measure was long and extremely
20 painful, so just to be perfectly honest.

21 In our first version of this
22 measure, we really wanted it to be the did you

1 test, and then did you react appropriately to
2 what that result was? So, it was going to be
3 a more complicated measure, and we really
4 wanted to get there. And we actually wrote the
5 specifications to be able to do that, or
6 tried to write them, and it just failed. So,
7 we couldn't, because of the nuances in terms
8 of different cutoffs, and different labs, and
9 different places that the results are found,
10 and there's just sort of problem after problem
11 in terms of being able to do that second step.
12 So, I think that that's something that we need
13 to work toward, and that's going to require
14 some standardization among laboratories in the
15 U.S., and assays, and just TB screening as a
16 field, in general.

17 So, therefore, this measure, the
18 only thing that we could actually make work in
19 the current EHR environment is just whether a
20 screening test was performed. And people that
21 have developed workflows to make this work,
22 like for example the testing site, have a

1 structured place in their EHR where this is
2 recorded. So, I think that's what the workflow
3 is going to end up looking like. Does that
4 answer your question?

5 DR. MATUSZAK: Kind of. And I was
6 just - the other piece of it that I just had
7 concerns about is just, you know, the
8 prevalence in the population that you're
9 looking at, and then the lack of - I mean,
10 it's a fairly good screening test to begin
11 with, and then, you know, if there is really,
12 truly a horrible outcome that can occur for
13 people, you know, is this actually - does it
14 give us a false sense of security, does it
15 actually accomplish what we want it to, does
16 it actually identify these people when you're
17 looking at these low prevalences, and a
18 sensitivity that's not great. So, is it
19 accomplishing what you're setting out to do,
20 I guess would be a big thing.

21 DR. YAZDANY: I think those are
22 good points. TB screening is not perfect. You

1 can have a negative PPD and actually have
2 active disease. You can have a negative
3 QuantiFERON and have active disease. There's
4 a false positive rate, but we had an expert
5 from the CDC participate on the guideline
6 process, and these recommendations follow what
7 the current state-of-the-art is, limited, I
8 agree, and there needs to be more work in this
9 area. But I think the Swedish data are really
10 compelling, and it's showing that there are
11 patient safety gains in an entire country. And
12 I think that that's probably good enough for
13 something that's sort of a devastating outcome
14 for patients.

15 DR. MATUSZAK: Last piece, and I
16 think that you said in the previous 12 months
17 prior to starting the biologic, why not right
18 at the time you're going to start the
19 biologic?

20 DR. YAZDANY: So, this has to do
21 with the complicated way that our health care
22 system works. So, let's say that you come in

1 to see me as a patient and I decide that I'm
2 going to start a biologic on you, and I order
3 a PPD, and you need to have that read 48 hours
4 after you get the test, so that means you
5 might not be able to come back for it until
6 next week. Meanwhile, I'm filling out a prior
7 authorization for the biologic, and that might
8 take months to come back. So, this is based on
9 our qualitative experience, that if it was
10 done in the last year, it's good enough. And
11 you're going to obviously at the clinical
12 encounter see if there are new risk factors or
13 new exposures, but there's just there's all
14 these moving parts, and we didn't want to make
15 it too strict.

16 DR. ANNASWAMY: What about employee
17 health testing, because this is a very common
18 employee health. Would the availability of
19 that data count falsely towards provider's
20 performance, and if so, if there has been a
21 positive test previously, that is not enough.
22 You've got to now do another test to detect

1 that latent infection. So, how would you hold
2 the provider accountable for that?

3 DR. YAZDANY: So, through the
4 consensus process we agreed upon sort of among
5 the rheumatology community that the
6 rheumatologists who prescribes the biologic
7 agent should have documentation of the TB
8 testing or in the case of a person who's not
9 eligible for testing because they've had a
10 previous result, that status documented in
11 their electronic health record.

12 And, you know, it's imperfect,
13 right, because some people will get it at an
14 employee health center, some people will get
15 it in their primary care office. But, you
16 know, as with all things patient safety we
17 have to have accountability somewhere, and it
18 seems like the person who's prescribing the
19 biologic is a reasonable place for that to
20 land. So, they don't have to do it, they just
21 have to have it in their EHR.

22 CHAIR TEMPLETON: This is Kim. It's

1 also noted in there that, you know, if it's in
2 the note it may be based on patient self-
3 report. Is there any data as far as how
4 accurate that is?

5 DR. YAZDANY: Whether patients
6 accurately report whether or not they've had
7 a PPD test?

8 CHAIR TEMPLETON: Right.

9 DR. YAZDANY: I'm sure that that
10 data exists but I don't know it off the top of
11 my head. I can try to look that up.

12 CHAIR TEMPLETON: Okay, thank you.

13 DR. JARRETT: Yes. Just a comment
14 again getting back to the utility of the TB
15 test, and just remember that the CDC and most
16 State Departments of Health, if there's a TB
17 exposure in a hospital, that's what we use,
18 that's what we make clinical decisions on, so
19 this is really the state of the science, which
20 is not great, but it is the best we have. And
21 the ramifications of not using the best we
22 have right now are still serious enough that

1 this has to be done.

2 And on the self-report side, you
3 know, my personal opinion is much like
4 employee health in hospitals, nobody is going
5 to by self-report, and we don't even let the
6 docs any more read their own PPDs. We make
7 them go to respiratory or someplace to get it
8 done, so I think we have to - we may allow
9 PPDs to be done by somebody else, but there
10 has to be documentation of it.

11 CHAIR CHOU: Yes, Linda?

12 MS. DAVIS: I'll reveal my learning
13 curve on RA and DMARDs, but this does not
14 apply to non-biologic DMARDs. Right? Okay. And
15 I trust that that's evidence-based, and
16 everything. Okay.

17 CHAIR CHOU: Are there other
18 comments or questions? I think that we should
19 be ready to vote on the evidence then.

20 MS. PHILLIPS: Okay. We're voting
21 on the evidence. One high, two moderate, three
22 low, four insufficient evidence with

1 exception, and five is insufficient evidence.
2 I'll tell you when you can start. And you can
3 start voting now.

4 (Voting.)

5 CHAIR CHOU: I think that's 100
6 percent that we should move forward. That's a
7 first.

8 All right. Let's go on to the next
9 criterion. This is performance opportunity for
10 improvement. I think Jinoos presented some of
11 that data. Kim, did you want to comment on
12 that? Did you want to say anything else about
13 this piece?

14 CHAIR TEMPLETON: No, this again
15 came up during our conference call discussion
16 with the current ACR register reporting.
17 Almost a 93 percent compliance rate, I guess
18 that would be a question for the ACR
19 representatives. How much higher do we think
20 this can go, and will this performance measure
21 continue to drive that higher, or what would
22 they anticipate?

1 CHAIR CHOU: I thought it was
2 like it went up to 93 percent after they
3 implemented it.

4 CHAIR TEMPLETON: Right, it went up
5 to 93 percent. Right? But will this change
6 anything by - if we approve this measure?

7 DR. YAZDANY: So, I think the best
8 guess that we can make just based on the PQRS
9 experience and our registry, so less than one
10 in five U.S. rheumatologists participate in
11 that program, but use of this measure
12 increased performance from the 70s to the 90s.
13 So, that's just - it's just an interesting
14 observation. And what we would anticipate just
15 based on what we know about users of the
16 registry who are early to adopt a lot of these
17 quality improvement initiatives is that
18 performance may be lower in other settings,
19 and that the measurement seems to have driven
20 improvement. So, there's reason to think that
21 there is additional room for improvement,
22 especially if there's more widespread

1 implementation.

2 And this is a measure for which,
3 although it's very hard to get to 100 percent,
4 I realize, for really anything, but the goal
5 for this measure actually is 100 percent.

6 CHAIR CHOU: Linda, do you have
7 anything to add?

8 MS. DAVIS: I have a question,
9 clarification. The experience that you're
10 describing from the 70s to the 90s was in the
11 registry. Is that accurate? What happened with
12 PQRS data?

13 DR. YAZDANY: Registries used to
14 report PQRS data. Is that what you mean?

15 MS. DAVIS: I guess I was under the
16 impression they're two different physician
17 groups that -

18 DR. YAZDANY: So, people use -
19 people can report PQRS measures outside of
20 the registry, but most people actually use the
21 registry because it makes it easier. Do you
22 know the numbers on that Rachel, like what

1 percentage of people, rheumatologists use the
2 registry versus not?

3 MS. MYSLINSKI: We have over 200
4 providers a year that use it to report.

5 CHAIR CHOU: Comments or questions
6 from the rest of the panel? All right. We're
7 getting to the end of the day, everyone's
8 tired. I think we can vote on the performance
9 gap issue.

10 MS. PHILLIPS: Okay. We're voting
11 on performance gap for 2522. Your options are
12 one for high, two for moderate, three for low,
13 four for insufficient. You may begin voting
14 now.

15 (Voting.)

16 CHAIR CHOU: Another 100 percent.
17 The next area is health care priority. I think
18 Jinoos already covered this. Kim and Linda, do
19 you have other things you want to add? So,
20 nothing from Linda. Kim?

21 CHAIR TEMPLETON: No, I don't have
22 anything.

1 CHAIR CHOU: All right. Other
2 questions or comments from the rest of the
3 panel? All right. I think we can vote on this
4 issue.

5 MS. PHILLIPS: And you're voting on
6 Measure 2522, priority. One for high, two for
7 moderate, three for low, four for
8 insufficient. Voting starts now.

9 (Voting.)

10 CHAIR CHOU: All right, moving
11 right along. So, now we're to the reliability,
12 validity. And I think we go back to how we
13 were doing it for the other trial measures.
14 It's really the specifications, do we think
15 it's measuring the right stuff I think is
16 basically what we're talking about. And I
17 think Jason already brought up an issue, is
18 whether measuring - you know, how people are
19 interpreting the PPD, is the PPD really the
20 correct measure? Do you want to follow-up on
21 that, or have other thoughts about that?

22 DR. MATUSZAK: I'd let the lead

1 discussants answer first, and then I'll -

2 CHAIR CHOU: Okay. Linda and Kim,
3 do you have additional comments here? Nothing
4 from Linda. Kim?

5 CHAIR TEMPLETON: Nothing, no.

6 CHAIR CHOU: Okay.

7 DR. MATUSZAK: I think that the -
8 well, I guess the - let me think for a
9 second. Hold on a second.

10 CHAIR CHOU: It was just a follow-
11 up on what you had brought up earlier about
12 whether measuring PPD is really what we want
13 to be doing, are there other measures that
14 would be better for screening people, I think
15 is what you were bringing up before; that
16 there's difficulty in interpreting PPDs, that
17 the test itself is not perfect, et cetera.

18 DR. MATUSZAK: Yes. No, I think
19 that summarizes what I was saying before.
20 There's a couple of different methods,
21 obviously, for screening for TB. And, you
22 know, we don't say any one particular method,

1 we don't even talk about whether it's a two-
2 stage PPD, or a one-stage PPD, or anything
3 else like that. We kind of leave it up to the
4 individual clinicians to make a judgment on
5 that, you know, so that's part of it.

6 The other piece of it, too, is the
7 -- you know, even I think some of your sites
8 mentioned this, again, in your feasibility. I
9 guess we haven't gotten to feasibility yet,
10 but is it really accurately portraying the
11 quality differences between the providers? You
12 know, they might be getting a number of
13 patients that have already been pre-screened
14 for other reasons or something else, because
15 whatever it was, like most of your sites
16 actually indicated that they felt like it
17 actually lost validity when it was translated
18 into a quality measure, and that it did not
19 accurately reflect quality differences between
20 providers.

21 DR. YAZDANY: So, I think that
22 those comments reflect sites that have not yet

1 worked out the workflow to capture this
2 information reliably. We talked about that a
3 little bit before, so if you just take an EHR
4 that's not trying to sort of move the patient
5 safety needle on this measure, there may be
6 instances where a PPD result is scanned as a
7 PDF, there may instances where the QuantiFERON
8 was done at an outside lab, but there may be
9 - so I think that, you know, as currently
10 structured if you were just going to, you
11 know, apply this and the gold standard was,
12 was the test done anywhere in the health care
13 system, then it's true that it would not
14 reflect accurately the quality of care that
15 was being provided.

16 Now, that being said, I think that
17 our testing site that has established workflow
18 to get this done demonstrates that it actually
19 can be done, and that there is a slight
20 performance gap. I think that they were in the
21 80s. This is a research interest of mine, so
22 I can share with you additional data since

1 this submission that we did at our VA Hospital
2 in San Francisco, and that we did - you know,
3 this was a quality improvement project, 138
4 patients who had started a biologic in the
5 last year. Of those, 27 percent had not gotten
6 a PPD that was findable through looking for
7 either a PPD that was administered or a
8 QuantiFERON test. And of those, 13 percent
9 were really not completed, and 14 percent was
10 presumed completed but the biologic was
11 started outside the VA, so we think that it
12 might have been done at some other site. So,
13 we had a lot of discussions among the
14 clinicians, if the person at the VA is
15 prescribing the biologic, even if they're
16 renewing it, should the documentation of a PPD
17 reside at that facility, or is it good enough
18 to just continue a medication someone else
19 started somewhere else. And I think that, you
20 know, for patient safety you have to avoid the
21 Swiss cheese, and we decided that a redundant
22 system in which the prescriber of a biologic

1 has documentation within their EHR would be
2 the safest strategy for patients. So, there
3 are feasibility issues. They want to
4 acknowledge them and not minimize them. But I
5 think that the vision in terms of making
6 health care safer is to make the prescribing
7 doctor accountable by building in the workflow
8 to put it into the EHR.

9 DR. MATUSZAK: But does just the
10 having to have a test documented in the EMR
11 actually make the provider more accountable?
12 I mean, what's - there's no follow-up
13 afterwards to insure that it wasn't a false
14 negative test, and that your latent TB didn't
15 activate, presumably. So, how do you
16 translate this into actually meaning that the
17 providers are providing better care?

18 DR. YAZDANY: That gets back to the
19 original comment where, you know, I think in
20 the future the goal is to do the measure
21 that's - we found it, and then this is what
22 we did about it. But we just couldn't actually

1 make that work in the testing, so I understand
2 the desire for that. We shared it, but we just
3 couldn't make it work yet. So, I think as more
4 people implement this maybe we'll actually
5 through the registry or whatever be able to
6 figure out an innovative way to do that.

7 CHAIR CHOU: Mark?

8 DR. JARRETT: I see your point
9 about attribution of the quality factor to the
10 provider, the rheumatologist, but I think it
11 gets to the concept that we need to think not
12 in terms of attribution, that you actually do
13 something, but that you've reviewed the data,
14 had the data, and that's the whole purpose of
15 meaningful use and transfer information is the
16 fact that if it does exchange, and the fact
17 that you documented it and hopefully paid
18 attention to it if it was positive, means that
19 that is a quality factor, because up until now
20 documentation in the charts of what went on
21 any place else other than your own office, let
22 alone in your own office, has been poor to

1 less than poor. So, I think really at this
2 stage for American health care, I think that
3 that actually is an attribute of quality.

4 CHAIR CHOU: Other comments about
5 reliability and validity, or again about the
6 test specifications? So, just following up
7 again on one of Jason's points. So, I mean,
8 would there -- it seems like to me it would
9 be fairly easy to require a two-stage PPD or
10 some - you know, you could add some stuff
11 into the measure fairly easily, it seems to
12 me, but you guys just decided you can't go
13 there? Okay.

14 DR. YAZDANY: We actually really
15 did try. We can share those results with the
16 committee if they are interested.

17 CHAIR CHOU: Other comments? All
18 right. I think we're ready to vote on the
19 reliability and validity piece.

20 MS. PHILLIPS: Okay. We're voting
21 on 2522.

22 CHAIR CHOU: Specifications, sorry.

1 MS. PHILLIPS: Trial measure
2 specifications, or the specifications
3 consistent with the evidence. One is high, two
4 moderate, three low, and four insufficient.
5 And you may begin voting now.

6 (Voting.)

7 CHAIR CHOU: So, this passes. The
8 next area is feasibility. Kind of touched on.
9 Kim and Linda, do you have other comments you
10 want to make about this? Nothing from Linda.
11 Kim, other additional comments on feasibility?

12 CHAIR TEMPLETON: There was a
13 discussion, I know, what happens as we talked
14 if this test is done elsewhere, but it was
15 thought that that could be accommodated with
16 the EHR.

17 CHAIR CHOU: Great. Other comments
18 from the group? I'll just say one thing, and
19 that's that I'm not convinced that people read
20 the induration correctly, that they'll read
21 the redness and stuff like that, so I do think
22 that the likelihood of false positives is

1 there, but that's a problem with TB testing in
2 general, not specific to this measure.

3 All right. Do we want to go ahead
4 and vote on the feasibility then, if nobody
5 has other things - anything else to bring up?
6 All right, let's do it.

7 MS. PHILLIPS: Okay. We're voting
8 on feasibility for 2522. One is high, two
9 moderate, three low, four insufficient. And
10 voting begins now.

11 (Voting.)

12 CHAIR CHOU: That passes the
13 feasibility test, and now we're to usability
14 and use. Jinoos already presented some data
15 about, you know, its implementation in the
16 survey she cited, and some evidence about
17 improvement in testing rates. And I think
18 Jason and I have both alluded to unintended
19 consequences. Are there other comments from
20 Linda or Kim?

21 CHAIR TEMPLETON: One of the
22 comments that came up in discussion is if, you

1 know, someone has a negative TB test and is
2 started on a biologic, and needs to switch to
3 a different biologic, does the TB test need to
4 be repeated, or is the initial test adequate?

5 CHAIR CHOU: Jinoos.

6 DR. YAZDANY: So, the eSpecs would
7 indicate that the initial TB test is -
8 there's a measurement year, and if a biologic
9 is discovered in the measurement year then we
10 look back one year from the start of that
11 initial biologic.

12 CHAIR TEMPLETON: Okay.

13 DR. YAZDANY: It would not - just
14 to be clear, they don't need another test if
15 they switch their biologic.

16 CHAIR TEMPLETON: Okay. All right,
17 thank you. That's it for me.

18 CHAIR CHOU: So, I was just
19 thinking why wouldn't you - so, if somebody's
20 been on a biologic for five years, why
21 wouldn't they - I mean, is there no - I
22 mean, can't you get TB? I mean, it's just like

1 a health care worker has to be tested every
2 year, or whatever.

3 DR. YAZDANY: So, at some point,
4 you know, another quality measure might be
5 that you document that you've assessed new TB
6 risk factors every year.

7 CHAIR CHOU: Other comments? Yes?

8 DR. ANNASWAMY: This is where I
9 think, again, unintended consequences could be
10 an issue. For example, the false positive test
11 results could be an issue, false negative test
12 results could be an unintended consequence.
13 This is also a safety of the safety measure.
14 TB testing has adverse reactions. In a setting
15 of a previously unknown exposure, a TB test
16 can cause skin sloughing, and so - and
17 QuantiFERON is preferable, so you might end up
18 causing harm trying to minimize harm. So,
19 unintended consequences can be a problem with
20 this.

21 CHAIR CHOU: Jason?

22 DR. MATUSZAK: And I think it was

1 my point, too, is that I think that you guys
2 actually put in here that there were no risks
3 of unintended - or no risks associated with
4 this, and I think that there could be. I mean,
5 you're talking about, you know, positive test
6 leads to six months of INH, liver problems,
7 and those types of things when it might not
8 even have been a true positive test. And I
9 think that you do have to consider that.

10 But just incidently, just so I
11 know, if they've been treated with six months
12 of INH, can they then start on some biologic,
13 can they do it at the same time? Do they have
14 to wait? What's the -

15 DR. YAZDANY: That's great. So, I
16 want to apologize for not filling out the
17 unintended consequences section appropriately
18 enough. In retrospect after everybody pointed
19 it out, I think there is actually more
20 literature that could have been cited there,
21 including the exact incidence of side effects
22 with TB therapies and all of that, so I

1 apologize for that. That data is available,
2 and I've cited some of it for you.

3 In terms of safety of starting
4 biologics after TB treatment has commenced,
5 the ACR guidelines, the 2012 Sing, et al
6 guidelines say that any time after one month
7 of completing TB therapy consensus is that you
8 can start. Some people wait longer, few people
9 wait shorter, but that's the guideline.

10 CHAIR CHOU: If there are no other
11 comments, I think we can vote on the usability
12 and use issue.

13 MS. PHILLIPS: Okay. We're voting
14 on usability and use for 2522. One is high,
15 two moderate, three low, and four insufficient
16 information. Voting begins now.

17 (Voting.)

18 CHAIR CHOU: So, this passes, and I
19 think we're to the final vote. So, this is
20 whether to recommend as suitable for a trial.
21 So, again, not for full endorsement, but for
22 further testing. Any final comments? All

1 right, let's do the vote.

2 MS. PHILLIPS: All right. Does the
3 measure meet NQF criteria for a trial measure?
4 One yes, two no. Voting starts now.

5 (Voting.)

6 CHAIR CHOU: All right, this one
7 passes. So, we've got one final measure. I
8 have to step out, so I'm sorry about that, but
9 I will see you all in the morning.

10 MS. FRANKLIN: Thank you, Dr. Chou.
11 So, that moves us on to our next measure, and
12 if we can have a brief overview of the
13 measure. This is Measure 2523, Rheumatoid
14 Arthritis.

15 DR. YAZDANY: Great, thank you.
16 And, Katie, I'll just you queue that up for me
17 again. So, this is a measure requiring that
18 patients, adult patients with rheumatoid
19 arthritis have a standardized disease activity
20 measurement greater than 50 percent of the
21 time in their outpatient RA encounters. So, I
22 think it is worth it to spend just a minute

1 talking about what we mean by disease
2 activity, because I do think that this is a
3 somewhat complex concept.

4 This is key outcome in rheumatoid
5 arthritis. It's the cornerstone for advancing
6 therapy. It's the outcome that's used in all
7 randomized controlled trials. It's what we use
8 either using a standardized form or
9 subjectively to advance treatment in clinical
10 practice and judge the effectiveness of our
11 medications. And there's strong consensus that
12 this is something that should be measured in
13 national and international guidelines. Next
14 slide.

15 So, what is RA disease activity?
16 Well, what's interesting is that because
17 there's no biomarker for rheumatoid arthritis,
18 we don't have a blood pressure or hemoglobin
19 A1C. What has evolved over many decades are
20 these composites of different values. So, for
21 example, it might include swollen and tender
22 joints, inflammation on laboratories,

1 declining or poor function. And just to give
2 everybody a visual representation of this
3 concept of RA disease activity - oh, I'm
4 sorry, if you could advance the slide one more
5 for me. You'll see that there are six ACR-
6 endorsed measures, and each contains different
7 components. All six include a patient-reported
8 outcome. Some of them also include laboratory
9 features, some of them also include a
10 provider's global assessment. And I know that
11 this is somewhat confusing, and I'll explain
12 a little bit more about this in just a second.
13 Next slide.

14 So, it has taken us a very long
15 time, and it's been an arduous process to
16 actually just get rheumatologists to agree on
17 what the endorsed measures for RA outcomes
18 should be in terms of the ACR's endorsements.
19 And in this document, which I cite in the
20 materials by Jackie Anderson, citing the ACR's
21 endorsement process, there is a three-year
22 national effort to define and agree upon valid

1 disease activity measures in rheumatoid
2 arthritis.

3 And to just give you a sense of
4 the scope of this work, there were 63 existing
5 measures, and we took those through
6 psychometric evaluations, and did surveys of
7 rheumatologists, and saw which ones people
8 were actually using, and which ones were
9 feasible for use in clinical practice, which
10 ones actually had cut points for remission,
11 low, moderate, and high disease activity so we
12 could do some comparisons across the measures.
13 So, that's how we arrived at the six measures.
14 So, even though they include different
15 components, it was felt that they captured
16 this concept of disease activity using these
17 different data elements. Next slide.

18 There has not been a randomized
19 controlled trial comparing measuring disease
20 activity to not measuring disease activity.
21 What we have is randomized controlled trials
22 that look at a treat to target strategy, and

1 it's been very interesting because over the
2 last decade, trial after trial demonstrating
3 that it doesn't even matter how you reach that
4 target, but as long as you aim for a target it
5 seems to be that patients do better. And
6 there's new data from the CORRONA Registry,
7 again, this is this observational study with
8 17,000 patients in which really the only
9 intervention was measurement, because people
10 actually have to submit the disease activity
11 measures. And we see this really nice
12 improvement in disease activity scores over
13 time.

14 This table shows that this is a
15 disparities sort of sensitive measure, and
16 that disease activity is higher both at the
17 start of the study and later in the study in
18 racial and ethnic minorities; although, over
19 time there was improvement in all groups with
20 measuring, even though the disparity persisted
21 just in terms of the absolute levels. Next
22 slide.

1 A majority of rheumatologists
2 don't routinely measure disease activity in
3 clinical practice. And in the most recent
4 study at Brigham, you know, one of our
5 academic institutions we found that only 29
6 percent of the time was one of these
7 standardized measures actually used in
8 clinical practice. Next slide.

9 This is another thing where
10 although there was concerns about
11 implementation of workflow, all of the testing
12 sites were able to implement this over a
13 period of weeks. And I'll just point out that
14 there's a range of options, so some of these
15 measures require that there's laboratories
16 available at the point of care, not everybody
17 is going to be able to implement that. Some of
18 these have only a patient-reported component,
19 so for sites where the workflow implementation
20 might be a challenge, that's an option, so
21 leaving that flexibility was really important.

22 Next slide, the planned uses. This

1 measure has been reviewed and recommended by
2 MAP for use in 2015 CMS programs. It's also
3 programmed into the registry. And this is the
4 one measure that CMS is actually working on to
5 include in meaningful use Stage 3. They've
6 contracted with Mathematica Policy Research to
7 develop this measure. Mathematica has been
8 consulting with the ACR, and they've agreed
9 that these six disease activity measures
10 should be the base of this measure as we work
11 towards a strategy of outcomes measurement.
12 Although, I think that they agree that it's
13 hard to do that right. And I'll stop right
14 there.

15 MS. FRANKLIN: Okay, thank you. So,
16 our lead discussants for this measure are Puja
17 Khanna and secondary is Marcie Harris Hayes.
18 And, also, I wanted to check and see if I have
19 Kim Templeton still on the line?

20 CHAIR TEMPLETON: Yes, I am.

21 MS. FRANKLIN: And, I also wanted
22 - if you wanted to help facilitate this,

1 please feel free to do so. I wanted to give
2 you that opportunity.

3 CHAIR TEMPLETON: Thank you. I
4 appreciate that.

5 MS. FRANKLIN: Other than calling
6 on people, which I can do.

7 (Laughter.)

8 MS. FRANKLIN: Thanks, Kim.

9 CHAIR TEMPLETON: Sure.

10 DR. HAYES: So, actually I'm going
11 to take the ball on this one, and Puja is
12 going to step in to save me when needed.

13 So, Jinoos did a really nice job
14 of basically doing what I'm supposed to do
15 next, but I'll just try to point out a few
16 things.

17 So, this is a process measure at
18 the clinician level. And, again, the
19 description of the measure you have up on the
20 slide. I think she represented it nicely. As
21 far as the evidence is concerned, she also
22 presented that, as well. And from the Work

1 Group meeting we felt that the evidence to
2 support the actual process itself is not
3 available, but the evidence to support tight
4 control of disease activity was strong and
5 appropriate, we felt. Dr. Khanna, do you want
6 to add anything?

7 DR. KHANNA: One of the things that
8 was brought up, Jinoos, was one of the members
9 thought why was the cut off of 50 percent of
10 the patients used? So, if you can elaborate a
11 little bit on that, I think that would be
12 helpful to the group.

13 DR. YAZDANY: So, although it seems
14 somewhat arbitrary, we based that on a couple
15 of things. The first thing, and perhaps the
16 most important factor is that we have a range
17 of adoption of this in the U.S. health care
18 system right now. And there are facilities,
19 Geisinger is a wonderful example, that have
20 implemented this workflow over the period of
21 a number of years, so they really had time to
22 sort of test this and improve. And it's

1 interesting to see that performance at those
2 sites is not 100 percent, nor are they aiming
3 for it to be 100 percent. And the reason is
4 that there may be instances where a rheumatoid
5 arthritis patient is coming in follow-up where
6 they just need an injection, or they have an
7 acute issue, and you don't need to do the
8 whole disease activity assessment. So, this
9 provides room for those instances where people
10 don't need to have a full evaluation, which
11 comes up not infrequently, and sort of
12 empirically based on evidence ruling this out.

13 The other piece of this is that I
14 think health care is messy, so asking for a
15 complicated workflow to be done at every
16 single visit when, you know, the patient may
17 not want to do it, and the MA may not be able
18 to give them their patient-reported outcome to
19 fill out, that's a really, really high bar.
20 But if you're at 50 percent, it means that
21 you're doing it most of the time. And we felt
22 like that was - it's actually really pushing

1 the field forward, but not being unreasonable.
2 So, anyway, that was the justification for the
3 greater than 50 percent.

4 CHAIR TEMPLETON: Any other
5 questions or comments?

6 MS. FRANKLIN: Marcie had a
7 question, and then - Thiru?

8 DR. ANNASWAMY: The measure
9 worksheet summary of all the Work Group calls,
10 the assessment of evidence is all over the
11 place. What is the summary of the assessment
12 of evidence by the lead discussants?

13 MS. FRANKLIN: Marcie.

14 DR. HAYES: So, I can address that.
15 So, when we went through the work - as we
16 were going through the process up to our first
17 meeting we weren't really certain about how to
18 judge the evidence when it wasn't - the
19 evidence wasn't directly measuring the
20 process. So, it's my understanding that those
21 individuals that rated the evidence low, they
22 were basing it on there isn't evidence,

1 evidence hasn't been given on the specific
2 process measuring this to all does it affect
3 outcomes? That's my understanding. The Work
4 Group can jump in and -

5 DR. KHANNA: That is correct. So,
6 if you want a straight answer, the evidence
7 supporting this measure is strong. But it's
8 just that we needed a little bit more
9 clarification on how the evidence was derived.

10 CHAIR TEMPLETON: Does that answer
11 your question?

12 DR. ANNASWAMY: Yes, Kim. Thanks.

13 CHAIR TEMPLETON: All right,
14 thanks. Any other questions or comments?

15 MS. FRANKLIN: I don't see any
16 around the table either.

17 CHAIR TEMPLETON: So, are you ready
18 to vote on the evidence?

19 MS. PHILLIPS: So, we're voting on
20 the evidence for Measurement 2523, one high,
21 two moderate, three low, four insufficient
22 evidence with exception, and five insufficient

1 evidence. And hang on just one second. Okay,
2 voting begins now.

3 (Voting.)

4 CHAIR TEMPLETON: So, it sounds
5 like we have enough to proceed.

6 MS. FRANKLIN: That's correct.

7 CHAIR TEMPLETON: All right, good.
8 Now, I'll turn back over to lead discussants
9 on gaps in care and opportunities for
10 improvement.

11 DR. HAYES: So, the developers
12 provided some information on performance
13 scores that they measured three different
14 entities, and there was variable performance
15 in meeting this criteria that ranged from 35
16 to 61 percent. They also reported on some data
17 through the ACR's Clinical Registry to show
18 that there was some improvement from CY 211,
19 43 percent up to 54 percent in 2012, so it
20 appears there is a gap and that it could be
21 improved.

22 CHAIR TEMPLETON: Okay, great. Any

1 other comments or questions? Okay. Sounds like
2 we're ready to vote on gaps in care at this
3 point, opportunities for improvement.

4 MS. PHILLIPS: Okay. Measure 2523,
5 performance gap, one high, two moderate, three
6 low, four insufficient. And the voting begins
7 now.

8 (Voting.)

9 CHAIR TEMPLETON: Okay. Moving on
10 to priority, and turn it back over to the lead
11 discussants on priority.

12 DR. HAYES: For priority it looks
13 like the Work Group rated it at moderate or
14 above. National Priorities Partnership, as
15 mentioned before, has listed RA is one of the
16 top 20 high-impact conditions.

17 CHAIR TEMPLETON: Okay. Any further
18 comments or discussion regarding priority?
19 Okay. If not, we can go ahead and vote.

20 MS. PHILLIPS: Measure 2523,
21 priority. One is high, two moderate, three
22 low, four insufficient. Voting begins now.

1 (Voting.)

2 CHAIR TEMPLETON: Okay, wonderful.
3 Move on to reliability and validity. Turn this
4 back over to the lead discussants.

5 DR. HAYES: So, we are - this is
6 for endorsement. Right? So, we will go through
7 these steps. So, for reliability, again, this
8 is an eMeasure, so we are to look to validity
9 to make our assessment about reliability. Is
10 that true?

11 DR. PACE: Right. They did validity
12 of the data elements which is acceptable.

13 DR. HAYES: Okay.

14 DR. PACE: And we'll use those
15 results for both the reliability and validity.
16 They did the agreement between the eMeasure
17 data and instruction.

18 DR. HAYES: So, validity testing
19 similar to what was reported previously, they
20 tested it in three different ways. Performance
21 measures for validity where they abstracted
22 data from randomly selected records. The

1 second was critical data element validity.
2 This is the part where I struggled with a
3 little bit because the validity I'm used to is
4 very different than this validity, so help
5 walk me through this.

6 And then, also, systematic
7 assessment of face validity, which there was
8 strong face validity based on expert opinion.
9 And then - and part of the validity measure
10 that did demonstrate it that sites actually
11 did perform differently with the measure;
12 however, there were some questions raised
13 about how specifically you can demonstrate how
14 each site performed differently.

15 CHAIR TEMPLETON: Any additional
16 comments or questions, discussion?

17 DR. PACE: So, I'll just answer
18 your question about why this is at least
19 thought of as validity, is that for some of
20 these measures if you're looking at the data,
21 the question is are the data the correct data?
22 So, typically, we've seen this with claims

1 data. So, the question is when you look at
2 claims data, is that - if you would compare
3 that to "the authoritative source," which
4 would be the medical record, would you get the
5 same result? So, we typically have seen this
6 kind of analysis with claims data often
7 reported as sensitivity and specificity rather
8 than CAPAs. So, that has - that kind of
9 concept has been extrapolated in this eMeasure
10 environment where you're looking at eMeasure
11 -- data that's pulled using the eMeasure
12 specifications, and comparing it to data that
13 would be abstracted from the entire medical
14 record. So, in one place you've got a computer
15 program pulling the data and computing the
16 performance measure, and you're comparing that
17 to some human actually going through the whole
18 record to looking for the data to see if
19 they're convergent. And that's, you know,
20 maybe not totally satisfying, but it's kind of
21 where we're at right now with eMeasure
22 testing. So, if anyone has better ideas, I'm

1 sure all the measure developers would love to
2 hear it and so would NQF. So, that's kind of
3 where things are in terms - so, it's really
4 the concept of that data being used in the
5 measure compared to the authoritative source,
6 which in this case would be really having
7 access to the full record, not just what the
8 computer program is dealing with.

9 And just to remind - same as our
10 last conversation, because these are tested at
11 the data element level according to our
12 algorithm the highest rating is eligible, four
13 is moderate. And that would be for both the
14 reliability and validity, because even though
15 they've done face validity, we don't bump it
16 up because of doing face validity.

17 CHAIR TEMPLETON: Any additional
18 comments or discussion?

19 DR. KHANNA: So, if I may, this is
20 Puja here. The CAPA was reported as .81 so
21 that's pretty decent.

22 CHAIR TEMPLETON: So, we're ready

1 to vote on reliability?

2 MS. PHILLIPS: Voting on
3 reliability for 2523. One high, two moderate,
4 three low, and four insufficient. Voting
5 begins now.

6 (Voting.)

7 CHAIR TEMPLETON: Okay, thank you.
8 Discussion on validity, any further discussion
9 on that?

10 MS. FRANKLIN: None here in the
11 room.

12 CHAIR TEMPLETON: Okay. Let's go
13 ahead and vote on validity.

14 MS. PHILLIPS: Voting on validity
15 for 2523. One high, two moderate, three low,
16 and four insufficient. And voting begins now.

17 (Voting.)

18 CHAIR TEMPLETON: Okay, great.
19 Thank you. Now, turn the discussion back over
20 to the lead discussants on feasibility.

21 MS. FRANKLIN: So, for feasibility
22 I think we've already kind of talked about

1 some of the feasibility issues here, so Zo
2 mentioned some earlier. So, those are the only
3 comments that came up with the Work Group.

4 CHAIR TEMPLETON: Okay. Any further
5 comments or discussion regarding feasibility?
6 Okay, we can go ahead and vote on feasibility.

7 MS. PHILLIPS: Feasibility for
8 2523. One high, two moderate, three low, four
9 insufficient. Voting begins now.

10 (Voting.)

11 CHAIR TEMPLETON: Okay, great.
12 Thank you. And then usability and use, again
13 we'll turn back over to the lead discussants.

14 MS. FRANKLIN: For usability and
15 use, some of our previous comments have been
16 addressed already during this discussion. And,
17 in general, the Work Group had no major
18 concerns.

19 CHAIR TEMPLETON: Okay, great.

20 MS. FRANKLIN: Other than what
21 we've already discussed.

22 CHAIR TEMPLETON: Any other

1 comments or discussion regarding usability and
2 use? Okay, let's go ahead and vote on that.

3 MS. PHILLIPS: Okay. We're voting
4 on usability and use for 2523. Your options
5 are one high, two moderate, three low, and
6 four insufficient information. Voting begins
7 now.

8 (Voting.)

9 CHAIR TEMPLETON: Okay, great.
10 Thank you. Any other comments or discussions
11 on 2523? If not, I guess we'll proceed to
12 voting on the measure overall.

13 MS. FRANKLIN: There's none in the
14 room.

15 CHAIR TEMPLETON: Okay. All right.
16 Let's go ahead and proceed with the vote then.

17 MS. PHILLIPS: Okay. We're voting
18 for overall suitability for endorsement for
19 2523. Your options are one for yes, and two
20 for no. And voting begins now.

21 (Voting.)

22 CHAIR TEMPLETON: Okay, great.

1 Thank you.

2 MS. FRANKLIN: So the measurers
3 passes and that concludes our measure review
4 process for today. But at this time, we want
5 to open the line for public comments or
6 comments in the room.

7 OPERATOR: At this time if you
8 would like to ask a question please press *1
9 on your telephone keypad. There are no further
10 comments at this time.

11 MS. FRANKLIN: All right. So,
12 hearing none I'd like to thank the Committee
13 members and the developers for a very
14 productive day, and we look forward to seeing
15 you tomorrow morning at 8:30 for breakfast, 9
16 a.m. we'll start with the measure evaluation
17 again. Tomorrow we'll also be addressing
18 harmonization issues, as well as going around
19 the table to discuss gaps scenarios that we'd
20 like to see future measure development.

21 I'd also like to thank you, Kim,
22 our Co-Chair for being on the line and hanging

1 in there all day.

2 CHAIR TEMPLETON: Thank you. I
3 appreciate it.

4 MS. FRANKLIN: And thanks to Dr.
5 Chou in absentia. With that, I'll give you
6 some time back. We finished early.

7 DR. DANIELS: Should we leave our
8 clickers and our name tags just here?

9 MS. FRANKLIN: Yes, please leave
10 everything here except your computers.

11 (Whereupon, the proceedings went
12 off the record at 5:04 p.m.)

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\$0.30 291:13	abstraction 35:4,16	achieving 248:12	351:21 358:20	278:16 281:8
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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Musculoskeletal Measures Standing
Committee

Before: NQF

Date: 05-07-2014

Place: Washington, D.C.

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