

NATIONAL QUALITY FORUM

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MUSCULOSKELETAL MEASURES
STANDING COMMITTEE

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THURSDAY
MAY 8, 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 9:00 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, MD, 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

PRESENT:

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:

KELLY ANDERSON, Lewin Group
MARY BARTON, MD, MPP, National Committee for
Quality Assurance
DALE BRATZLER, DO, MPH, Oklahoma Foundation
for Medical Quality*
CHARLIE BRUETMAN, MD, Lewin Group
JOHN FITZGERALD, MD, American College of
Rheumatology
MELISSA FRANCISCO, American College of
Rheumatology
COLLEEN MCKIERNAN, MSPH, Lewin Group
RACHEL MYSLINSKI, American College of
Rheumatology
JENNA WILLIAMS-BADER, MPH, National Committee
for Quality Assurance

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

9:03 a.m.

MS. FRANKLIN: Hello and welcome to Day 2 of the Musculoskeletal Standing Committee Consideration of Candidate Measures and I just want to do a quick check and see if we have one of our co-chairs on the line. Kim Templeton. Okay.

And, operator, can you check to see if we have her dialed in by any chance?

OPERATOR: She's not dialed in at this time.

MS. FRANKLIN: Okay. Thank you. So, with that, I will turn it over to our Co-Chair Dr. Chou.

CHAIR CHOU: Welcome to Day 2. Thanks, everyone, for coming back after a long day yesterday.

So, I think just wanted to do a -- are there any kind of logistic things we need to talk about today? Cabs or anything like that? Okay. Not yet.

1 Just wanted to do a quick recap of
2 yesterday and then talk about what we're going
3 to go over today.

4 So, yesterday, we reviewed I think
5 a total of nine measures or seven measures.
6 Four gout measures and three RA measures.

7 One of the gout measures was
8 passed as a trial measure and a second one
9 also passed. Kind of that gray 40 to 60
10 percent. Not quite consensus yet and two of
11 them didn't get passed our initial three
12 screening criteria.

13 All of the RA measures passed and
14 we have a couple more to consider today.

15 I understand we have five more
16 measures today. We'll be starting off with
17 the Disease Modifying Anti-Rheumatic Drug
18 Therapy Measures. There's one on pain
19 management for long-bone fracture and then a
20 couple on imaging for low-back pain.

21 So, I think unless there's other
22 issues that we needed to discuss, we can

1 probably move on.

2 Great. So, do we have the
3 developers for the Anti-Rheumatic Drug Therapy
4 Measure?

5 MS. FRANKLIN: Please feel free to
6 come to the main table.

7 CHAIR CHOU: Those two spots are
8 reserved and if you can give us a brief
9 overview of the measure, that would be
10 fantastic.

11 MS. WILLIAMS-BADER: Hi, everyone.
12 My name is Jenna Williams-Bader. I am
13 Assistant Director of Performance Measurement
14 at NCQA.

15 Mary, would you like to --

16 DR. BARTON: And I'm Mary Barton,
17 Vice President for Performance Measurement.

18 MS. WILLIAMS-BADER: That was
19 brief. Thanks.

20 All right. This morning, we are
21 going to start talking about the Disease
22 Modifying Anti-Rheumatic Drug Therapy for

1 rheumatoid arthritis. This measure is
2 specified at the health plan level and I think
3 we covered the importance of this measure
4 quite well yesterday.

5 Just so you know, in this measure,
6 we do look for at least two claims with a
7 rheumatoid arthritis diagnosis to try to
8 verify that the patient does indeed have
9 rheumatoid arthritis. We're also looking for
10 the DMARD to be dispensed rather than ordered
11 or prescribed and we do have exclusions for
12 HIV and pregnancy.

13 Oh, I think -- as I said that we
14 did a good job of covering yesterday the
15 importance of rheumatoid arthritis, it is a
16 rare condition, but it does have quite a
17 significant impact on patients who have the
18 condition.

19 The guidelines very strongly
20 indicate that patients should be prescribed
21 and put on DMARD as early as possible.

22 However, the guidelines also

1 continue to recommend DMARD therapy even for
2 patients that have had the condition for a
3 while. There is actually no recommendation to
4 completely stop DMARD therapy for those
5 patients and at the moment, there isn't much
6 evidence to show that non-medication remission
7 is really possible in these patients. So,
8 while the guidelines do recommend scaling back
9 the DMARD therapy, they do say that patients
10 should continue to stay on DMARD therapy.

11 This measure was first developed
12 in 2002/2003. The concept was actually
13 supported by and recommended by two different
14 panels that NCQA had brought together. One
15 being to define measures for rheumatoid
16 arthritis and another to define measures for
17 pain.

18 When that measure was eventually
19 developed, we pulled together a
20 musculoskeletal expert panel to help inform
21 the development of the measure.

22 It was field tested in 2003 and

1 you'll see the results of those -- of that
2 field test in the information that we gave to
3 you. The measure did perform well during
4 field testing. We saw that there was
5 variation across the plans and the rate was
6 not as high as we would hope. You will have
7 noticed that during the field test we found
8 that the diagnosis of RA was -- there was high
9 agreement between medical record review and
10 claims.

11 There was unfortunately a bit of a
12 discrepancy in one of the plans for the actual
13 dispensed DMARD. However, I would remind you
14 this is from 2001/2002 data and these plans
15 have had much more experience to date with
16 dispensing data. So, we do expect that the
17 plans are performing better now and actually
18 as you can see, the rates are relatively good.

19 However, we do still see variation
20 between plans and we do see variation between
21 the different lines of business as well. The
22 commercial plans are performing better.

1 However, we do still see that
2 there's variation between the plans at the
3 10th and 90th percentile and the importance of
4 this measure I think is emphasized by the fact
5 that the Medicare Stars Program has picked it
6 up.

7 The measure is also included at
8 the physician level and the physician quality
9 reporting system and there is strong interest
10 in the physician level measure as well as
11 we'll hear about during the next presentation.

12 I think that covers it. Thank you
13 very much.

14 CHAIR CHOU: Thank you. Puja and
15 Art, do you want to provide a brief overview
16 from the Committee.

17 DR. KHANNA: Sure. Thank you.
18 That was actually a great start to it.

19 So, to briefly describe what we
20 said is as far as the evidence goes, we
21 thought it was high and it was based on a
22 systematic review of empirical evidence

1 presented to us. So, we did not have any, you
2 know, concerns about it.

3 One of the things that was brought
4 up was that the work group members questioned
5 whether there is, you know, a continued
6 opportunity for improvement in this measure.
7 Because like you pointed out, 90 percent of
8 the commercial plans are already meeting the
9 measure. Whereas, you know, although the
10 Medicare and Medicaid plans were not quite
11 there yet.

12 So, the thought was that how much
13 do you really think we can get to 100 percent
14 because that would be the ideal. So, if you
15 could, you know, --

16 MS. WILLIAMS-BADER: Yes, I can
17 certainly speak to that.

18 So, as you point out, the average
19 is high. However, even in the commercial --
20 across the commercial plans, we do see that
21 there is variation and actually the variation
22 -- there is variation by region as well.

1 So, while there are some regions
2 where the average is around 90 percent, there
3 are others where it's as low as 82 percent and
4 then between the -- as I said, between the
5 10th and 90th percentile, there is also still
6 variation.

7 So, in different regions, the 10th
8 percentile is as low as 75 percent and the
9 90th may be as high as 95 or 90 to 95 percent.

10 So, while plans are performing
11 well even across all three lines of business,
12 there is variation indicating that there's
13 room for improvement still.

14 CHAIR CHOU: Thanks. Art, do you
15 have anything to -- any additional comments?

16 MR. SCHUNA: No, it's just that I
17 think this is a very important measure and
18 clearly, there's data supporting the
19 importance of this. So, I think the evidence
20 is pretty strong on this one compared to some
21 of the things we looked at yesterday.

22 CHAIR CHOU: Great. Any questions

1 for the stewards at this point? Jason.

2 DR. MATUSZAK: The way I
3 understood the literature and the evidence
4 that's out there, there actually is a
5 significant body of evidence that shows that
6 people can take at least long holidays off
7 their DMARDs or even up to a year without
8 having a significant increase in some of their
9 flares.

10 How do you guys address that
11 evidence?

12 DR. BARTON: I think the issue is
13 that the best way that we can be sure that
14 patients are receiving attention for their
15 rheumatoid arthritis is to use a measure that
16 looks over a period of time and I think, you
17 know, your point raises the good question of
18 whether one year is the ideal period of time
19 to look for evidence of a prescription to
20 address disease modification.

21 Unfortunately, we're -- in a
22 programmatic way, we're kind of tied to that

1 kind of interval. But, it may be that it's a
2 -- as close an approximation as we can get to
3 the perfect interval which might be longer.
4 I don't think that the evidence would suggest
5 that people should be taking several years
6 long holidays.

7 DR. MATUSZAK: Actually, the study
8 I'm looking at right here shows that they can
9 take up to five years in some cases without
10 taking their DMARDs and stuff.

11 So, I think that the evidence does
12 exist out there that certain people and you
13 can predict in some cases who those people
14 might be that might be able to do better.

15 But, if we're doing something like
16 a functional status assessment on their people
17 on a routine basis, is that enough for
18 outcomes on these patients as opposed to a
19 prescription for a DMARD every year?

20 CHAIR CHOU: We have a couple of
21 rheumatologists on the panel. Maybe they can
22 help address this. Puja or Mark? Yes.

1 DR. JARRETT: It is true, you
2 know, in practical terms, there are patients
3 who go into a natural remission and go years
4 without taking a DMARD and what I would look
5 to say -- ask is I don't know if ICD-10, if it
6 ever comes to fruition, would help us because
7 that might allow us to differentiate if it
8 goes down another level in terms of active
9 versus inactive disease and if you had that,
10 then you'd be able to do that. Differentiate
11 those patients you've seen twice a year who
12 are doing great basically on nothing or a non-
13 steroidal and coasting and then wouldn't get
14 counted then in the denominator.

15 So, I don't know if you can
16 explore that in terms of seeing if ICD-10 will
17 help you with that.

18 But, I still think overall this
19 measure is very critical. Because even with
20 those exceptions, you still need to get the
21 bulk of the patients, 95 percent, on a DMARD.
22 So, you know, that -- the small group, we got

1 to figure out how to get them out of the
2 denominator.

3 CHAIR CHOU: Anyone have any other
4 questions or comments? Oh, Thiru.

5 DR. ANNASWAMY: Just a quick
6 question about what changes to the measures
7 has been made, if any, since 2009 because this
8 is a maintenance measure.

9 MS. WILLIAMS-BADER: This measure
10 was reevaluated in 2012 and when we do every
11 evaluation, we look at the performance data,
12 we look at the guidelines to see what updates
13 are there and we also look to see if we've
14 received a number of -- if we've received
15 questions from the plans that are reporting
16 the measure to make sure that we've covered
17 all of our bases.

18 When we did the reevaluation of
19 this measure in 2012, there were no
20 significant changes. I think we might have
21 made a few tweaks around the edges for coding,
22 but nothing significant to the measure

1 specification and that was supported by a bone
2 and joint measure advisory panel that we
3 pulled together as well.

4 DR. BARTON: I think we would also
5 say every year we review the pharmacy data
6 that's in the measure.

7 CHAIR CHOU: Linda.

8 MS. DAVIS: Have you looked at
9 what health plans do to actually try and
10 improve their score on this measure and what
11 impact that has and what there is variation
12 from plan to plan?

13 MS. WILLIAMS-BADER: That is an
14 excellent question and there's definitely
15 strong interest from our Committee on
16 Performance Measurement which is a large and
17 multi-stakeholder group that reviews all of
18 our measures that are reported by plans and
19 they've asked the same question.

20 We do try to do that for certain
21 measures. We have over 70 in our set and that
22 kind of review does take quite a lot of time.

1 So, I think as I said there's
2 interest in that, but we haven't done it for
3 this particular measure.

4 DR. BARTON: I think I would say
5 we have anecdotal evidence from a couple of
6 experts who have provided us with some insight
7 about how their plans use internal monitoring
8 of this to actually provide feedback to the
9 clinicians who are caring for patients with
10 rheumatoid arthritis. Which in some managed
11 care plans is, you know, entirely
12 rheumatologists, but there are places where
13 there's a mixture of internists or
14 geriatricians who are also taking care of
15 these patients and so, by providing feedback
16 to them, they can at least ask the question
17 for someone who might not have had the thought
18 raised, you know, to encourage them to
19 consider.

20 I think to Mark's point every
21 clinician is in the position of having to sort
22 between the 95 percent and the 5 percent and

1 make that individual decision. But, if they
2 haven't even thought to consider the question,
3 you know, they're not going to -- there's no
4 opportunity for the patient to get on a
5 therapy.

6 CHAIR CHOU: I just had a question
7 about the exclusions. Just kind of
8 harmonizing with some of the stuff we talked
9 about yesterday about the PPD kind of
10 exclusion. People who haven't been tested or
11 for whatever reason or who have a positive PPD
12 and haven't been treated yet. Seems like that
13 should be an exclusion. It's going to be a
14 small number of people, but yes. Yes.

15 MS. WILLIAMS-BADER: Mary's
16 indicating that's a very small number. Also,
17 we are including -- this measure does not only
18 look at biological DMARDs. So, there are
19 still options for those patients as well.
20 Making it an even smaller number.

21 CHAIR CHOU: Why don't we move
22 into the evidence? We're already, I think,

1 talked about most of the evidence. Again,
2 this is for re-endorsement. Right?

3 If there are additional questions
4 or comments about the evidence, this is one of
5 the required sub-criteria.

6 If there isn't more discussion, I
7 think we can go ahead and take a vote on this
8 one.

9 MS. PHILLIPS: Okay. We're voting
10 on measure 0054. You have five options. One
11 for high. Two for moderate. Three for low.
12 Four for insufficient evidence with exception.
13 Five for insufficient evidence and the voting
14 begins now.

15 Okay. We have all 22. We've got
16 13 high, 8 moderate, 1 low, 0 for insufficient
17 with exception and 0 for insufficient.

18 CHAIR CHOU: So, this one passes.
19 Let's move to the opportunity for improvement.
20 Again, we've already discussed this. That the
21 average rates are high, but there is variation
22 both among the different health plans and then

1 among the different types of health plans.

2 Other additional questions or
3 comments regarding the opportunity for
4 improvement piece.

5 All right. I think we're ready to
6 do a vote on this as well.

7 MS. PHILLIPS: Okay, 0054, for the
8 performance gap, you've got four options. One
9 for high. Two moderate. Three low and four
10 for insufficient. Voting begins now.

11 Okay. We're at 22. And we've got
12 six high, 13 moderate, 3 low and 0 for
13 insufficient.

14 CHAIR CHOU: So, this passes here
15 as well.

16 Let's move on to health care
17 priority. Again, we've discussing RA the last
18 afternoon and this morning.

19 Are there other comments or
20 additional things to say about the health care
21 priority? Puja.

22 DR. KHANNA: So, this is actually

1 data that has come from CDC as well. That
2 it's considered one of the leading causes of
3 morbidity/mortality in the country. So, it is
4 one of the top 20 priorities. So, and
5 definitely a cause to treat -- start DMARDs
6 early and treat the disease aggressively.

7 CHAIR CHOU: Additional comments
8 or questions? Yes, Linda.

9 MS. DAVIS: So, this measure has
10 been in place for several years and have you
11 seen improvement over those several years and
12 how much improvement has there been?

13 MS. WILLIAMS-BADER: Again, this
14 is one where the performance has -- there's
15 been shifting among the plans that are
16 reporting. We don't see a large amount of
17 improvement from when it was first reported to
18 now, but we do see incremental increases and
19 especially for the plans at, you know, at the
20 edges.

21 So, we have seen some improvement.
22 Because it started at a somewhat higher rate

1 than some of our other measures, there hasn't
2 been as large of an improvement as there might
3 be.

4 MS. DAVIS: And that's just
5 improvement in the actual measure and
6 actually, the number of prescriptions that are
7 written for people with DMARDs? None of the
8 outcomes --

9 MS. WILLIAMS-BADER: The number of
10 patients that have been -- that have been
11 dispensed at DMARDs.

12 MS. DAVIS: But, not in morality
13 or outcomes or any other?

14 MS. WILLIAMS-BADER: Oh, I see.
15 No, we don't do that type of analysis. The
16 plans aren't reporting that data to us.

17 MS. DAVIS: So, I'm wondering if
18 the continuation of this measure will continue
19 to have the kind of mixed improvement in the
20 actual utilization measure, the process
21 measure over time and how impactful that
22 actually is.

1 MS. WILLIAMS-BADER: And I think
2 that's actually a very good idea to think
3 about comparing that to rates of
4 morbidity/mortality to see if there is some
5 connection for those plans where they are
6 improving their rates.

7 CHAIR CHOU: Great. Thanks. So,
8 some of that discussion I think we'll consider
9 later when we get to the usability and use
10 criterion.

11 Are there other comments about the
12 health care priority?

13 Okay. I think we're ready to take
14 a vote on this as well.

15 MS. PHILLIPS: Okay. Measure 0054
16 for high priority are your four options. One
17 for high. Two moderate. Three low and four
18 insufficient and voting begins now.

19 Okay. We're at 21 and we've been
20 holding for a couple of seconds. We have 22.
21 Thank you.

22 Sixteen for high, 3 for moderate,

1 2 for low and one for insufficient.

2 CHAIR CHOU: Okay. So, we passed
3 the three initial criteria. So, we're going
4 to move on here.

5 The next area is the reliability.
6 So, I think we've kind of touched on this
7 already.

8 Puja and Art, did you have other
9 questions or comments about either the
10 specifications or the liability testing?

11 MR. SCHUNA: I guess one question
12 I have regarding this is the patient factors
13 which might influence whether patients will
14 get a prescription or not. There can be a big
15 variance in copay fees from place to place.
16 Some patients may be paying \$200 to \$300 or so
17 for biologics a month and they may choose not
18 to be treated for that reason and the question
19 comes then should that be the plan's
20 responsibility or the provider's
21 responsibility in that setting. That's a
22 concern I have about this.

1 CHAIR CHOU: Did you guys want to
2 comment on that?

3 DR. BARTON: Well, I think
4 demonstrating the fact that many plans are
5 able to get rates up as high as the 90s would
6 say to me that there are ways to -- either
7 those are, you know, completely made up of
8 populations that are -- have benefits that
9 are, you know, well designed or they found
10 ways to address and equalize the opportunity.

11 And I think that if we are -- as
12 we see this being used in the Stars Rating
13 Program, there will be more of an appetite for
14 plans that are doing really well to talk about
15 how they're getting high rates and for, you
16 know, sharing of best practices. Because I
17 think you're pointing out something that's
18 really currently, you know, a tremendous issue
19 in this country, but not necessarily going to
20 be fixed by a measure.

21 MR. SCHUNA: So, you say that
22 plans can go up to 90 percent or better, but

1 you also mention that certain plans do not
2 come close to meeting those goals and certain
3 regions of the country didn't do -- perform as
4 well and I have to wonder whether patient
5 factors may be responsible for that and not
6 the institution.

7 MS. WILLIAMS-BADER: I guess I
8 would also say that at the health plan level
9 we definitely think that the plan should be
10 responsible for making sure that patients are
11 getting the medications that they need to get
12 and as has been verified and discussed by this
13 Committee today, DMARDs are very important for
14 patients with rheumatoid arthritis. So, I do
15 think that we hold the plans accountable for
16 making sure that the patients are getting
17 medications that they need.

18 If the patients are refusing for
19 reasons besides cost, maybe they just -- they
20 choose not to, then we do think that that
21 might be some that would apply across the
22 plans and those might be the ones that -- I

1 see you shaking your head. I'll let you --

2 MR. SCHUNA: Well, I mean there's
3 differences between plans. I mean some plans,
4 for example, in the VA system, \$8 is all a
5 patient pays for any drug per month. Patients
6 going to some outside insurance company pays
7 hundreds of dollars a month.

8 You know, so, those kind of
9 variations exist and I guess what I'm
10 concerned about is that this doesn't
11 necessarily deal with those questions and it
12 becomes the plan's fault or the provider's
13 fault that the patient doesn't -- chooses that
14 they can't afford \$300 a month.

15 DR. BARTON: If it's not the plan
16 that creates the benefit design, who is it?

17 I would say that the plan is the
18 place where you should hold the accountability
19 for insuring the fair opportunity to access
20 therapies.

21 CHAIR CHOU: Mark had a comment.

22 DR. JARRETT: One last comment

1 following up on what Art's saying and we also
2 have to look at it. This is saying that
3 they're going on a DMARD. It doesn't say
4 which DMARD and many patients because of their
5 plans and they can't afford the copays wind up
6 being stuck on just methotrexate which is
7 relatively inexpensive rather than getting a
8 DMARD which might cost them because of their
9 copays \$600/\$700 a month and they can't afford
10 it.

11 So, at some point not in the
12 purview of here, but we need to think about
13 asking the clients if they're collecting this
14 data to slice and dice it and then compare it
15 to what their copay structure is. Because I
16 would bet that we'll find lots of patients are
17 on a DMARD, but probably not the appropriate
18 DMARD. Something is better than nothing.

19 So, we should measure it and get
20 the docs to do it, but then I think that
21 information is a treasure-trove that we should
22 look into to really see to really truly

1 improve the care.

2 CHAIR CHOU: Linda.

3 MS. DAVIS: I heard verbally that
4 this does not include biologics. Is that
5 accurate or does it also include biologics?
6 I'm on biologics.

7 MS. WILLIAMS-BADER: Oh, I just
8 meant to say that it includes all DMARDs both
9 biologic and nonbiologic.

10 MS. DAVIS: Okay. All right. So,
11 that changes. So, the price variation is
12 substantial and can be up to, you know,
13 thousands a month. Right?

14 And I work for a employer
15 coalition and they're all self-funded and they
16 all make their own decisions about their
17 benefit designs. They're all very concerned
18 about specialty drugs and biologics and scared
19 to death of what's going to happen with that
20 in the future. So watching it very carefully.

21 But, almost all of them to a T
22 accept those with unions have high-deductible

1 health plans and I see those deductibles
2 increasing and increasing nationally and
3 locally and I don't see any trend changing
4 that anywhere. So, I'm wondering about the
5 implications for high-deductibles in this cost
6 that's also been factored into some of the
7 variation that you're seeing.

8 DR. BARTON: May we answer? So,
9 this is a problem that's larger than this
10 measure clearly and so, the NCQA holds the
11 health plans responsible and the HEDIS
12 reporting to include their ASO patients within
13 there. Which is the self-funded employers set
14 of patients that they're administering. So
15 that the health plan would be actually held
16 accountable for, you're right, a range of
17 benefit plans and designs. Some of which it
18 had actually designed and others which it had
19 not.

20 Right now, that's the model for,
21 you know 25 years that NCQA has used. It's
22 the -- health plans are the locus that were

1 willing to take accountability and where we
2 have found it feasible to hang accountability.

3 But, I would bet, you know, a
4 quarter that you're right. That over the next
5 ten years, we're going to have to find new
6 models to address accountability so that the
7 -- you know, whatever the organizations within
8 the delivery system that are actually
9 responsible for caring for patients are the
10 ones who are being held accountable. But, I
11 would say it's premature to know yet what
12 that's going to look like.

13 DR. MATUSZAK: I just wanted to
14 ask about some of your reliability studies
15 that you had done again and I can't find the
16 exact passage right now where I read it, but
17 I jotted down a note here that shows that some
18 of your field tests showed as little as only
19 57 percent concordance with the medical record
20 and the data that you guys were pulling.

21 Can you maybe speak a little bit
22 more about your field tests and what the

1 accuracy has been?

2 MS. WILLIAMS-BADER: Absolutely.

3 So, the reason you might have had a difficult
4 time finding it is that the field test data is
5 actually under the validity section.

6 So, back in 2002/2003, we did a
7 field test with three health plans. We do try
8 to get a range of health plans and a range of
9 lines of business if we have -- if we are
10 specifying a measure for multiple lines of
11 business.

12 As you do point out, particularly
13 for the DMARD therapy itself, we did see that
14 there were -- that the numbers on the rate of
15 agreement between the medical record and the
16 claims was lower than we would like. There
17 was one plan where the rate of agreement
18 between the administrative claims and the
19 medical record was around 58 percent.

20 However, as I mentioned, this was
21 quite a few years ago. Plans have had now --
22 particularly the ones participating in HEDIS

1 have had more than a decade to improve the
2 ability to get claims -- the prescription data
3 and I'd also say it's in their best interest
4 to make sure they can because that's for the
5 numerator event and we do know that plans are
6 able to get that data since we have some plans
7 that are performing so well.

8 The actual RA diagnosis, the
9 validity and rate of agreement was much higher
10 for the diagnosis. So, we see that the
11 denominator is valid. Whereas, we did a
12 little bit of discrepancy there on the
13 numerator event.

14 DR. MATUSZAK: How do you know
15 those high-performing plans are not part of
16 the 57 percent that are having reporting
17 errors and maybe are over reporting the -- or
18 under recognizing perhaps the number of
19 patients with rheumatoid arthritis, you know?

20 MS. WILLIAMS-BADER: So, like I
21 said, the rate of agreement for the RA
22 diagnosis was quite high. There was one plan

1 in the field test out of three that had a
2 large number of missing medical records. So,
3 their n was quite small. It was only 30.

4 However, in the other two plans
5 where they had over a hundred patients
6 included in the sample where they were able to
7 identify the medical record, the rate of
8 agreement between the medical record and the
9 claims for the diagnosis was 94 percent and 99
10 percent.

11 So, again, we think that the
12 denominator's being identified correctly.

13 On the numerator side with the
14 DMARD therapy, yes, there are some plans --
15 there was one plan where they only had 58
16 percent agreement, but as I said -- and
17 actually, the place where we're seeing the
18 discrepancy is that there were about 35
19 percent the DMARD therapy was identified in
20 the medical record only.

21 I would point to -- I would just
22 reiterate that it's in the best interest for

1 the plans to get better access to the pharmacy
2 data if they're not able to, if that's the
3 problem and we do see that plans are able to
4 since their rates are high.

5 DR. BARTON: I would add that
6 HEDIS has a pretty rigorous audit that would
7 be -- that would make me say that it's
8 unlikely that health plans are committing
9 fraud on a measure like this because of the
10 way that we use both statistical methods and
11 actually chart review methods to audit
12 performance as it's reported.

13 CHAIR CHOU: Linda.

14 MS. DAVIS: So, PBM data is what
15 they're dealing with. Right? For the
16 numerator when they're looking for the
17 prescriptions from the pharmacy benefit
18 managers. That's where pharmacy claims come
19 from.

20 You know, Kaiser probably has
21 their own data. So, it's not uniform. It's
22 not everybody doing it that way.

1 But, most have PBMs and the PBMs,
2 they can have carved out PBMs which are --
3 they may have members on their medical plan
4 that have up to eight to ten different PBMs
5 across their population and so, they need to
6 get data from all of these other PBMs as well.

7 Do you know the completion rate?
8 Like how many of those other outside PBMs
9 they're able to get the data from in order to
10 have accurate and complete information about
11 the data.

12 DR. BARTON: I guess the two ways
13 that we have access to this information are
14 one, when plans don't have a sufficient sample
15 size of patients, we expect them to report
16 that fact rather than reporting a rate. So,
17 that's one kind of non-report that they're
18 permitted to categorize and then another would
19 be if they had enough patients.

20 So, if the denominator, you know,
21 ascertainment went well, but they were somehow
22 not reporting because they didn't have access

1 to data. Plans are rarely using that option.

2 So, the only information that I
3 have would be to say that somehow by whatever
4 method is appropriate to their setting,
5 they're getting the data.

6 CHAIR CHOU: Karen.

7 DR. PACE: Yes, I just want to do
8 a little clarification here so that we can
9 kind of move through our criteria.

10 The reliability testing that was
11 done was done at the plan level and those data
12 are provided and indicate pretty high
13 reliability and what that is telling us is
14 that the scores can distinguish among the
15 health plans and that is -- the reliability
16 question is about systematic error and the
17 ability to identify differences between the
18 measured entities.

19 A lot of what you're talking about
20 gets into the validity question. At the data
21 element level, are the data valid that are
22 going into the score? Are the appropriate

1 exclusions, et cetera?

2 So, you may want to kind of deal
3 with the reliability question first and then
4 move on to validity and, you know, that's
5 possible. I mean you can have a very reliable
6 measure and still have concerns about validity
7 or may not be valid, but we try to kind of
8 split those out because they are -- they're
9 related, but different properties.

10 CHAIR CHOU: Yes, Puja or Art
11 might want to comment on this, but the
12 reliability testing they had mean scores of
13 like .87 to .93. Which are supposedly quite
14 high. I guess it's on a -- up to a 1.0 scale.

15 And then I mean the other piece of
16 the reliability is just the specifications.
17 If we have -- you know, if we think that the
18 numerator, denominator and exclusions are
19 specified clearly in what we want them to say.

20 Yes. Go ahead, Puja.

21 DR. KHANNA: So, the numerator and
22 denominator are definitely specified. I think

1 we had some questions about the exclusions.

2 The work group members thought
3 that malignancies could be potentially put in
4 as an exclusion because there are -- you are
5 including biologics and in that case, you will
6 have, you know, patients who have had
7 biologics.

8 DR. PACE: And again, I know this
9 may sound like splitting hairs, but the
10 reliability question on the specifications is
11 are they precise? Are they defined? Are they
12 identified?

13 The question about whether
14 something should be in as an exclusion and
15 isn't really does again come to validity. You
16 know, what does the evidence say about, you
17 know, is this the right denominator
18 population? Are the right people excluded and
19 included? So, I know it kind of splits it a
20 little bit, but, you know, the specifications
21 related to both reliability and validity.

22 DR. KHANNA: So, I guess no

1 questions about the numerator or denominator.

2 CHAIR CHOU: Okay. Thanks. Other
3 comments or questions about reliability
4 aspects?

5 All right. Why don't we go ahead
6 and take a vote on this?

7 MS. PHILLIPS: Okay. Measure
8 0054, we're voting on reliability. You have
9 four options. One high. Two moderate. Three
10 low. Four insufficient. Voting begins now.

11 We are up to 22. We've got 11 for
12 high and 11 for moderate.

13 CHAIR CHOU: Okay. Let's move on
14 to the validity piece. So, that passed there.

15 We already started the discussion
16 on validity. There was some discussion about
17 the variations. It sounded like there was
18 some -- that some prescriptions were missed.
19 So, you had to capture that in the medical
20 records. They weren't in the electronic
21 record or whatever. But, you guys were pretty
22 confident about the denominator.

1 Yesterday, actually one of the ACR
2 folks presented some data that showed that
3 ICD-9 codes were very inaccurate for various,
4 you know, rheumatological conditions. They
5 said the positive predictive value was like 60
6 percent. Which just seemed very shockingly
7 low to me.

8 But, it sounds like that hasn't
9 been an issue when you guys have checked the
10 -- when you guys have done your checks. Is
11 that correct?

12 MS. WILLIAMS-BADER: Right. I --
13 yes, I would say that. Yes, we haven't found
14 that and again, we are using two claims. So,
15 they -- and they need to be on different dates
16 of service.

17 And I think we also think that
18 this is some -- an issue in which it is
19 beneficial for the plan to make sure that the
20 patients are really being diagnosed accurately
21 so that they're not having false diagnoses in
22 their denominator. Because those would be

1 patients you'd want to -- wouldn't want to
2 necessary give this prescription to.

3 CHAIR CHOU: So, let's say that a
4 PCP calls something RA which isn't really RA.
5 That gets picked up somehow and thrown out?
6 There's a way to do that?

7 DR. BARTON: No, there would -- if
8 it appeared in two different visits on two
9 different days, they would be included in the
10 denominator.

11 But, I would imagine that we would
12 be hearing from plans if they were -- because
13 of our -- the feedback loop that we utilize
14 and the opportunity for plans to ask questions
15 during the measurement year. That we would be
16 hearing about that.

17 We certainly hear about that kind
18 of issue on other measures. So, it may be
19 that that's a generic ICD-9 problem, but
20 perhaps less so in plans that have chosen to
21 address this as a quality issue.

22 CHAIR CHOU: Karen.

1 DR. PACE: Yes. So, maybe you
2 want to just -- because I know and I think
3 this was your question that the validity
4 testing was done on three plans and you have
5 the sample sizes for those plans. But, you
6 also -- so, I think that's where the question
7 has come in with the one out of the three.

8 But, you also mentioned some
9 ongoing auditing. Do you have data related to
10 this measure from your ongoing auditing or
11 how --

12 MS. WILLIAMS-BADER: I don't
13 believe that we provide that information.
14 That's part of our accreditation process and
15 it's to make sure that we have confidence in
16 the results that we're getting from the plans.
17 But, I don't believe that information is
18 publicly available because it's -- it goes
19 back to how we're accrediting the plans.

20 DR. BARTON: But, the published
21 rates are the published rates.

22 MS. WILLIAMS-BADER: Exactly. The

1 published rates have been audited. So, we
2 have confidence that those are the right
3 rates.

4 DR. PACE: Okay. Right. So, then
5 what they have is these kind of -- the small
6 actual empirical validity testing and then
7 also their face validity.

8 So, according to our criteria,
9 this would be eligible for a moderate rating
10 on validity or less if there were issues.
11 But, that would be where it would fall in our
12 algorithm.

13 CHAIR CHOU: Are there --

14 MS. WILLIAMS-BADER: Sorry. Can I
15 just say? When the measure was reevaluated in
16 2012, like I said, we pulled together another
17 measure advisory panel and then we also
18 discussed this with the multi-stakeholder
19 group, the Committee on Performance Measure,
20 that I referenced earlier and there are plans
21 on that panel as well as a number of different
22 stakeholders including you. We have

1 Government representatives. We have consumer
2 representatives. We have physician
3 representatives.

4 And the misdiagnosis of RA was not
5 one I believe that came up during that
6 reevaluation. So, about -- that would be
7 seven or eight years after the measure was
8 first introduced into HEDIS. That wasn't
9 something that came up during that reeval.

10 CHAIR CHOU: I just have another
11 denominator question. So, are people -- and
12 this is for the rheumatologists in the group.
13 Are people with seronegative RA managed
14 differently?

15 I've had at least one patient
16 where we've had trouble getting biologics
17 approved. It's been a -- kind of a battle,
18 you know, just to get prior authorization and
19 stuff.

20 DR. KHANNA: Right. So, usually
21 the seronegatives get treated with a
22 nonbiologic DMARD to begin with and it is hard

1 to get prior auth for the biologics and that's
2 across the board, across all health plans and
3 the rationale obviously is that you're not
4 seeing disease progression and we don't have
5 markers.

6 But, there are patients who they
7 still get a DMARD. Absolutely. It depends on
8 the clinical presentation of the patient.

9 CHAIR CHOU: So, earlier, just to
10 remind everyone of a few, I think, issues that
11 were brought up with the validity. Whether
12 patients with malignancies should be excluded.
13 This issue about people who are in remission
14 with. Whether there should be somehow
15 something built in for them and then this
16 issue about patient preferences particularly
17 related to out of pocket cost and things like
18 that.

19 So, just to remind everyone that
20 these issues had come up and then this -- kind
21 of this measurement thing particularly with
22 getting the claims data for the drugs.

1 Are there other issues or things
2 that people wanted to bring up here? Art.

3 MR. SCHUNA: Yes. I'm not too
4 sure about the malignancy as an exclusion
5 because you can use rituximab. You can use
6 nonbiologic therapy in those patients.

7 I guess the people I'd be
8 concerned about would be patients who might be
9 under active treatment for their cancer in
10 which they -- but, I guess I don't see that
11 necessarily as a denominator issue and even if
12 it were, it would probably be a fairly small
13 percentage of patients.

14 DR. JARRETT: No, I agree with
15 Art. It's a small number. The ones who don't
16 want to take the nonbiologicals, it becomes
17 more patient preference or sometimes their
18 oncologist will say I don't want you taking
19 anything. But, most of them are -- you know,
20 if they have active disease, they'll usually
21 take a nonbiologic. It's usually not a
22 problem.

1 Methotrexate's about the only one
2 that they're not going to rush to take because
3 it might interfere obviously with perhaps
4 previous chemo that they've gotten and such.

5 But, there are enough other
6 choices that most will take something.

7 CHAIR CHOU: Great. Other
8 questions or comments from the panel? Go
9 ahead, Linda.

10 MS. DAVIS I have seen lots of
11 advertisements for biologics and get support
12 from the drug companies for coverage for
13 these. I don't know how many people get that
14 actual coverage.

15 Have you done any analysis to see
16 how that might impact the numbers of people
17 you're missing in your claims data because
18 they're getting money from some other
19 manufacturer?

20 MS. CLAYTON: Throwing the patient
21 side out there, a lot of the nonbiologic
22 DMARDs, you're looking at the copays of

1 anywhere from 100 to 300. The biologics,
2 however, you're looking at anywhere from \$500
3 to \$2500 a month.

4 So, as patients, we rely heavily
5 on those copay assistance cards and I
6 typically I mean you're on a biologic for
7 maybe two/three years and you're --
8 essentially, it fails treatment. So, then you
9 end up switching.

10 But, I've had cases, you know,
11 that I've encountered and other patients have
12 encountered where, you know, it may take up to
13 three months to get a copay assistance card
14 from a pharmaceutical company. Therefore,
15 you're not being treated those three months or
16 four months while you're waiting and then most
17 of them, it'll cover nine to ten months of
18 coverage only.

19 So, for many of us, it's like
20 paying an additional mortgage payment. Which
21 we can't afford. So, then you're on the --
22 not on the treatment.

1 There's cases -- United
2 Healthcare, they will no longer allow their
3 patients to use a copay assistance card up
4 front. So, they're forced to pay their
5 copayments up front and be reimbursed directly
6 by the pharmaceutical companies rather than
7 using that at the time the prescription's
8 filled. So, once again, that leaves patients
9 who are -- unable to fill their prescriptions
10 as well. So.

11 I would say most people --
12 patients I've encountered through the ACR and
13 Arthritis Foundation, you're probably looking
14 at what 60, 70, 80. Most patients I would say
15 rely heavily on these copay assistance cards.
16 So.

17 DR. KHANNA: Majority of patients,
18 it's not 10 or 20 percent.

19 MS. DAVIS: Those data aren't in
20 the claims date.

21 CHAIR CHOU: Other questions or
22 comments? Jason.

1 DR. MATUSZAK: I just wanted to
2 ask how the plans have responded to provider
3 panels not having enough rheumatologists in a
4 given coverage area and stuff and how valid do
5 you think this measure is if the majority of
6 rheumatoid arthritis care is being provided by
7 primarily care physicians in a given area as
8 opposed to rheumatologists because of access
9 issues?

10 MS. WILLIAMS-BADER: I know that
11 we have had some discussion about this with
12 experts. The measure certainly doesn't
13 specify what type of provider needs to be
14 seeing the patient and we believe that, as the
15 evidence shows, these patients should be
16 receiving the DMARD therapy.

17 So, if there is a lack of
18 rheumatologists in a particular area, then I
19 think we hold the plans accountable for
20 insuring that these patients still are able to
21 access care and receive the medications that
22 evidence tells us they should be receiving.

1 CHAIR CHOU: Karen, did you have a
2 comment or is that old? Okay.

3 All right. Are there additional
4 comments or questions or I think we may be
5 ready to put the validity criterion to a vote.
6 All right. Let's do the vote.

7 MS. PHILLIPS: Okay. We're voting
8 on validity for 0054 with four options. One
9 for high. Two for moderate. Three for low
10 and four for insufficient. The voting begins
11 now.

12 We're at 22. We have 0 for high.
13 We have 16 for moderate, 4 for low and 2 for
14 insufficient.

15 CHAIR CHOU: All right. So, we've
16 passed the validity criterion. So, we're
17 going to move on to feasibility.

18 Puja or Art, do you have comments
19 for the feasibility criterion?

20 DR. KHANNA: So, the work group
21 thought that feasibility would not be an
22 issue. Obviously, the data elements are being

1 already captured and generated in the EHR.

2 One issue that I thought, you
3 know, thus far since we are still dealing with
4 ICD-9 codes is that we should be able to
5 capture that under ICD-10 as well and
6 obviously, we wouldn't be going into ICD-10
7 for a little while. So, that's something to
8 keep in mind.

9 But, otherwise, no issues.

10 CHAIR CHOU: Art, anything to add?

11 MR. SCHUNA: No, it's just that
12 they've already been doing this for some years
13 and it appears like it is feasible.

14 CHAIR CHOU: Questions or comments
15 from the rest of the panel?

16 Okay. I think we're ready to do a
17 vote on the feasibility issue then.

18 MS. PHILLIPS: Feasibility for
19 0054, you have four options. One for high.
20 Two for moderate. Three for low. Four for
21 insufficient. Voting begins now. Yes, we do.

22 We have one Committee Member who

1 stepped out of the room. So, we have 21
2 votes. We have 13 for high, 8 moderate, 0 for
3 low and 4 insufficient.

4 CHAIR CHOU: All right. We're
5 going to move on. That passes. Then let's
6 move on to usability and use.

7 I think some of this information
8 has already been provided, but again, I'll
9 turn the mike to Puja for additional comments.

10 DR. KHANNA: No, we thought that
11 it was definitely usable. You know,
12 commercial plans are using it and the benefits
13 definitely outweigh the negative consequences.
14 So, no issues regarding that.

15 CHAIR CHOU: Art, anything to add?

16 MR. SCHUNA: No, nothing further.

17 CHAIR CHOU: I just had one
18 question. Have you seen improvement in the
19 places that had low rates? I mean over time
20 has that -- I think you alluded to that
21 earlier, but the numbers have come up a little
22 bit.

1 MS. WILLIAMS-BADER: They have and
2 if I -- just a second here to see how they are
3 coming up. Let's see.

4 Yes, we have seen that the lower
5 plans are increasing over time. I'm --

6 DR. BARTON: I would just say
7 that, you know, statistically, of course,
8 that's going to happen. More likely that the
9 70 percent plan will show the ability to
10 improve more than a 90 percent plan.

11 So, I'm not sure how much to make
12 of it, but we have seen improvement in the 10
13 percentile over time.

14 CHAIR CHOU: Yes. I mean I think
15 it's just you'd like to see something.
16 Whether it's -- you know, whether it's just a
17 statistical aberration or what. But, it's
18 nice to see a move in the right direction at
19 least.

20 Okay. Other questions or comments
21 regarding the usability and use criterion?

22 All right. I think we can do a

1 vote then.

2 MS. PHILLIPS: Okay. For 0054
3 usability and use, you have four options. One
4 for high. Two moderate. Three low. Four for
5 insufficient. Voting begins now.

6 Okay. We're at 22. We have 12
7 for high, 9 for moderate, 1 for low and 0 for
8 insufficient.

9 CHAIR CHOU: All right. We've
10 passed all of the criteria. So, now, we're
11 going to the final vote.

12 So, this is a recommendation for
13 reendorsement. Yes or no.

14 MS. PHILLIPS: Okay. We're voting
15 for overall suitability. One for yes. Two
16 for no. Voting begins now.

17 Okay. We're at 22 and we have 21
18 yes and 1 no.

19 CHAIR CHOU: I think Thiru was
20 trying to get in a final comment. We'll see
21 if he sways the -- turns the whole group
22 around here.

1 DR. ANNASWAMY: No, I was
2 wondering if there was any discussion to be
3 had similar measures.

4 MS. FRANKLIN: We've identified
5 this measure as related to our next measure
6 and we will be discussing those differences at
7 the end of the day.

8 DR. KHANNA: You keep stealing my
9 questions, Thiru.

10 CHAIR CHOU: Sorry. We can move
11 to the next measure which is 2525. Which is
12 also on DMARDS and this is a new measure.
13 Okay. And it's for full endorsement. Okay.
14 Great.

15 So, I would invite the developers
16 to present the measure.

17 DR. YAZDANY: Right. Good
18 morning, everybody. All right.

19 So, this is the last measure
20 submitted by the American College of
21 Rheumatology for this session.

22 And this measure, unfortunately,

1 there was actually a typo in the submission
2 materials on the very first page in which we
3 made it sound like this was for newly
4 diagnosed patients. Actually, the wording was
5 for newly prescribed DMARD therapy and I'm
6 sorry, but we didn't catch that earlier.

7 But, the measure should actually
8 read percentage of patients greater than 18
9 years with rheumatoid arthritis which we
10 define as two face-to-face encounters with a
11 diagnosis of RA. I'm sorry. Say that again.
12 Who are prescribed, administered or ordered a
13 DMARD in the measurement year.

14 So, this is prevalent RA and we're
15 looking at DMARD use and this is actually the
16 way that we tested this measure.

17 We've already talked about the
18 rationale for this measure and in terms of the
19 why is this important criteria, I think the
20 most important thing that we've learned over
21 the last decade of using the DMARD measure in
22 the health care system is that this is a

1 disparity sensitive measure and we now have,
2 I think, very good data to show that racial
3 ethnic minorities, low income individuals,
4 older patients and also certain geographic
5 regions are much less likely to be dispensed
6 a DMARD. That's based on the NCQA measure.

7 I just wanted to take a moment and
8 point out that we are interested in
9 harmonizing this measure. It's -- we have no
10 intention of creating duplication.

11 The difference with the NCQA
12 measure is that this is an electronic measure.
13 It's an eMeasure and that we are intending
14 this for physician level accountability.

15 But, what's the same is that we've
16 aligned the DMARD list. We've aligned our
17 definitions of rheumatoid arthritis. I think
18 the measure concepts are the same.

19 What's different is that the
20 specifications reflect the data source. So,
21 for example, whereas the NCQA measure is
22 looking at pharmacy claims and whether or not

1 a medication was dispense to the patient, not
2 all EHRs are connected to pharmacy data and
3 so, therefore, we find DMARDS by looking at
4 whether they were prescribed, administered or
5 ordered.

6 The other thing is that for
7 physician level accountability, we've included
8 a code for inactive rheumatoid arthritis.
9 This is not a code that's commonly used we
10 admit. It means that the diagnosis that was
11 on the problem list is no longer active. It
12 has an end date and it uses the diagnosis
13 inactive quality data model element.

14 I think people need to learn how
15 to use this code. I don't think a lot of
16 people are using this code. I just wanted to
17 point that out up front.

18 However, up to 10 percent of
19 patients with RA over time may go into
20 remission and so, I think that's something
21 that we've heard loud and clear from
22 clinicians. Is that we need to include that

1 and performance is not expected to be 100
2 percent at the clinician level.

3 Our exclusions are aligned with
4 the NCQA measure HIV and pregnancy. The only
5 difference is its inactive disease clause.

6 There are a lot of questions which
7 I'd be happy to answer in more detail about
8 including all possible contraindications to
9 DMARDs and our expert panels had extensive
10 discussions about these issues. But, we sort
11 of went, you know, item by item and I think
12 there were good reasons not to include a long
13 list of exclusions.

14 For example, with TB testing, some
15 DMARDs are safe for people that have latent
16 TB. Even biologics can be started one month
17 after initiation of TB therapy. So, that one
18 was out.

19 Cancer, some DMARDs are safe in
20 patients with cancer and the literature
21 regarding the relationship between DMARDs and
22 cancer even with biologics is evolving and we

1 couldn't reach agreement about that being a
2 universal exclusion.

3 I will stop there.

4 CHAIR CHOU: Thank you. So, Art
5 and Mark are the lead discussants on this.
6 They're trying to defer to each other, but I
7 think Mark has the hot potato.

8 DR. JARRETT: All right. I'll
9 guess get started.

10 I mean a lot of the issues have
11 already been discussed on the -- in the last
12 measure. I'll say something politically
13 incorrect, but I would actually like to see
14 this done by ACR because perhaps there will be
15 more slicing and dicing of the data and
16 figuring out why some people aren't getting
17 it.

18 So, for example, filling a
19 prescription is great. But, a lot of
20 physicians won't write the order even because
21 they know it's not covered if it's a
22 biological. So, we know that's the reality of

1 what goes on.

2 So, getting down to that level
3 will be helpful and will also help us figure
4 out why people are not prescribing certain
5 things. So, I think it is useful in that
6 regard.

7 One of the -- you know, the work
8 group had looked at things and it's the same
9 questions that came up before.

10 One of the issues had come up
11 about when the diagnosis is made. If it's in
12 that measurement period and they got seen, you
13 know, almost at the end of the measurement
14 period and then got seen once more, perhaps a
15 DMARD wasn't -- the first visit was that was
16 the diagnosis clinically. Second visit was
17 let's talk about the drugs and, you know,
18 there may be some slip up on that in that
19 regard in why it wasn't started right away.

20 The TB testing and everything,
21 although it was brought up, I agree with all
22 the discussion and the same thing with the

1 cancer issues.

2 And the last thing was the DMARD
3 list. Although it's very long and very
4 inclusive and matches with the NCQA, it is a
5 little bit of a problem. That some of the
6 drugs many of us would look at and say is that
7 really appropriate therapy for somebody who's
8 got active rheumatoid arthritis. It does
9 offer an option for that small select few
10 perhaps that do have a malignancy and are
11 afraid of taking certain drugs or where the
12 oncologist may prevent it.

13 But, many of us would feel that
14 for people with real active RA that's not
15 really the appropriate decision. But, again,
16 I think that's delving down deeper.

17 Art, anything else?

18 MR. SCHUNA: No, I don't think so.

19 CHAIR CHOU: John has a question.

20 DR. VENTURA: Yes, if I could just
21 ask for clarification. How does capturing
22 this data at an individual level allow you to

1 dig deeper versus capturing it at plan level?

2 DR. YAZDANY: I'll take that one.

3 So, this is another measure that is programmed
4 into our qualified clinical data registry and
5 through that effort, we will be collecting
6 much more data than just these quality
7 measures and that's really going to be the
8 primary reason and I actually think that the
9 ACR's been very proactive about getting
10 qualitative feedback from membership and, you
11 know, sort of building that into our quality
12 measurement loop and so, I think we can expect
13 to see some granularity in the future.

14 CHAIR CHOU: So, just so I can be
15 a little bit clearer on the difference between
16 this and the prior measure, so neither of them
17 are focused on how quickly you started. It's
18 just whether you've been on it within the last
19 12 months. Right?

20 And so, the main difference is
21 that one is an eMeasure focused at individual
22 clinicians and the other one is really health

1 plan level. Is that correct? Okay.

2 Are there other examples of
3 quality measure you guys do this kind of thing
4 for?

5 MS. BURSTIN: There are many like
6 that. Some of which are actually both at the
7 health plan and at the clinician level NCQA,
8 but there are some others where NCQA has the
9 health plan level measure and the clinician
10 level measure is done by the specialty
11 society.

12 And the key thing there is, of
13 course, the harmonization which is why that's
14 what's been brought up. The last thing you
15 want to do is have two measures out there at
16 different levels that, in fact, are different
17 enough or just different enough that what
18 you're seeing is measured in noise as opposed
19 to really getting at the details that you
20 want.

21 So, appreciate the efforts already
22 to date to try to get them permanent.

1 DR. YAZDANY: Just one question
2 that I have and this is really for the NQF
3 staff is I think it may lead to maybe a
4 cleaner perception of measurements if there
5 were sort of umbrella measure concepts, but
6 then with different pathways to application or
7 implementation and I think that would lead to
8 the perception perhaps from the health care
9 system and clinicians in particular that this
10 is not just a proliferating of many, many
11 different measures and it seems like this
12 measure is a perfect candidate for something
13 like that.

14 I understand there isn't
15 precedent, but if there's a way that we can
16 participate in this being the first example,
17 I think we'd be very motivated to help with
18 that.

19 MS. BURSTIN: That's exactly what
20 we try to do on these harmonization examples.
21 Perhaps not that explicit about seeing this as
22 the umbrella concept, but that is very much

1 what we try to.

2 CHAIR CHOU: Other comments or
3 questions from the rest of the panel? Jason.

4 DR. MATUSZAK: I just want to ask
5 the same question I asked to the previous
6 group and again, in reviewing the evidence
7 that you guys submitted for this measure, I
8 didn't see any mention of the studies that
9 talk about long-term remission off of drug
10 therapy and I'm just wondering, you know, why
11 that piece is often times or not really
12 accounted for well in this measure.

13 And completely off topic, how are
14 you guys -- in your registry, how are you
15 eliminating patients that have passed away?
16 Are you continuing to keep their information
17 in your registry in perpetuity? Are you
18 resetting the data every year? Are you kind
19 of pulling those patients back out? Are those
20 going to continue to count in your
21 denominator, but not in your numerator because
22 you're not prescribing for them? Just --

1 DR. YAZDANY: Good questions. So,
2 this issue of long-term remissions off of
3 drugs, we do have some medical literature
4 regarding that and in some studies, it's as
5 low as 9 percent. In other studies, it's as
6 high as 29 percent. I'm not sure I believe
7 that because that doesn't actually coincide
8 with any of our clinical experience.

9 But, in any case, it was very
10 important to include that inactive disease
11 data element because we need to capture the
12 fact that some people go into remission and
13 don't need drug therapy. That's our baby step
14 in dealing with this issue.

15 But, I think that this Committee
16 actually took an important step in endorsing
17 a concept that will allow us to do that in a
18 much more sophisticated way in the future.
19 Because if we actually are able to capture
20 disease activity scores and those fall into
21 the remission range, that's actually the true
22 denominator that you want, you know, and in

1 the future when everybody's doing disease
2 activity and recording the score, then we can
3 actually calculate something that's more
4 meaningful.

5 But, I think this is the first
6 step, inactive code and then eventually, the
7 registry, you know, hopefully will be able to
8 do that in a more sophisticated way.

9 In terms of patients who have
10 passed away, we have not explicitly dealt with
11 that issue. With our registry developers,
12 obviously, at some point, we will have to
13 actually test whether or not the electronic
14 health record is reliably capturing that
15 information and is transmitting that as a data
16 element to the registry.

17 I don't think that testing has
18 happened yet, but it's really important.

19 CHAIR CHOU: Linda.

20 MS. DAVIS: I just keep thinking
21 about what we were talking about yesterday
22 where the actual process of measurement

1 improves outcomes and the connection between
2 the two and we haven't really talked that much
3 about that with these two measures and I'm
4 wondering if there's been any kind of analysis
5 or thinking about how to learn more about
6 that. Whether actually measuring this will
7 make an impact on the outcomes of the patient.

8 DR. YAZDANY: So, I think that we
9 have two types of evidence in terms of the
10 relationship between DMARDs and outcomes.

11 The first is randomized controlled
12 trials in which there was a placebo arm.
13 Admittedly, many of those are old and the
14 newer trials have combination therapy as the
15 comparison.

16 But, from those older trials of
17 which there are actually a substantial number,
18 we know that for disease activity damage,
19 often it's radiographic erosions and function
20 DMARDs improve outcomes and I would argue that
21 those are outcomes that matter. So, those are
22 the randomized controlled trial data.

1 Newer data that's really based in
2 claims at the population level using, for
3 example, Medicare fee for service data show
4 that patients who are not on DMARDs -- so, for
5 example, if the comparison is people that are
6 treated with steroids alone have higher number
7 of -- greater health care utilization and more
8 hospitalizations even when you do a case mix
9 adjustment for all of their co-morbidities and
10 where they live and socio-demographic factors
11 and so, I think the observational data also
12 support the fact that DMARDs are actually
13 perhaps decreasing health care costs.

14 And we can argue about the
15 biologics because those are very expensive.
16 I'm not sure I can make that claim with the
17 biologics, but I think in general DMARDs are
18 cost effective and they improve outcomes in
19 both observational and randomized control
20 trials.

21 CHAIR CHOU: Yes, Linda, were you
22 asking if there would be efforts to see how

1 patients do in these -- I mean if they're --
2 I mean did that answer your question?

3 MS. DAVIS: Well, it did kind of I
4 mean, but we looked at the actual process of
5 measurement and does that have an impact on
6 outcomes? Not whether or not giving DMARDs
7 and improving that has improvement.

8 So, let's assume that increasing
9 DMARDs improves outcomes. Does measuring use
10 of DMARDs increase use of DMARDs?

11 DR. YAZDANY: I'm not aware of any
12 study that's looked at that.

13 CHAIR CHOU: Other questions or
14 comments before we kind of move into the
15 criteria?

16 All right. So, the first sub-
17 criterion is evidence. I think we've covered
18 this for the most part, but if there are other
19 comments, Mark or Art. Others on the panel.

20 All right. Let's go ahead and do
21 a vote on evidence.

22 MS. PHILLIPS: Okay. We're voting

1 on the evidence. You have five options. One
2 for high. Two for moderate. Three for low.
3 Four for insufficient with exception and five
4 for insufficient. Voting begins now.

5 Okay. We've got 22. We've 9 for
6 high. We've got 10 for moderate. Zero for
7 low. Two for insufficient with exception and
8 1 for insufficient.

9 CHAIR CHOU: So, this passes. The
10 evidence criterion. Let's move on to the
11 performance gap.

12 Again, I think we've covered this
13 evidence. Do the lead discussants have
14 anything additional to add? Other questions
15 or comments from the rest of the panel?

16 I think we can move to a vote.

17 MS. PHILLIPS: Okay. We're voting
18 on performance gap for measure 2525. One for
19 high. Two for moderate. Three for low. Four
20 for insufficient. Voting begins now.

21 Okay. We're at 22. We've got 4
22 for high, 16 moderate, 2 for low and 0 for

1 insufficient.

2 CHAIR CHOU: That passes also.

3 So, we move on to priority. So, again,
4 anything from the lead discussants to add to
5 what's already been discussed? Anything from
6 -- any other comments or questions from the
7 rest of the panel?

8 Let's do a vote.

9 MS. PHILLIPS: Voting on priority
10 for measure 2525. One for high. Two for
11 moderate. Three for low and four for
12 insufficient. Voting begins now.

13 Okay. We're at 22. We've got 12
14 for high, 10 for moderate, 0 for low and 0 for
15 insufficient.

16 CHAIR CHOU: That's passes as
17 well. So, we move on. So reliability is the
18 next and let me see if I describe this
19 correctly.

20 So, we want to make sure that we
21 -- we're looking at the specifications,
22 whether they're clearly specified and then if

1 there's been reliability testing. Which I'm
2 not sure if we talked for this. Is it -- it's
3 not the same as for the last measure. Right?
4 Because it's a -- okay and is this -- because
5 this is new there hasn't been reliability
6 testing?

7 DR. PACE: So, this measure has
8 had limited testing in only two sites in two
9 EHRs and this is the eMeasure. So, they're
10 using data element validity like what we saw
11 yesterday. Which will suffice also for data
12 element reliability. So, we can look at those
13 results and again, it would only be at the
14 data element level and in this case, it was
15 only two sites instead of the three that we
16 saw yesterday.

17 CHAIR CHOU: Okay. And the
18 results? Can you summarize what the results
19 were?

20 DR. PACE: Yes. So, let me pull
21 up the -- yes, our -- right. Why don't you
22 summarize your results?

1 MS. PHILLIPS: All right. Let me
2 get my -- let me just pull this up. All
3 right. So, part of the reason that we only
4 testified this in two sites was that there was
5 still a discussion going on at the NQF and at
6 the national level regarding how many EHRs
7 were required and so, therefore, we weren't
8 from the start planning to do additional and
9 given that this was done on a shoestring
10 budget, it just gets very expensive. So,
11 that's why there's only two sites.

12 We did data element validity
13 testing and so, we were looking for agreement
14 about the diagnosis of rheumatoid arthritis as
15 well as the performance score overall. So,
16 whether or not a DMARD was found in these two
17 face-to-face encounters.

18 There was actually some
19 disagreement or instances in which the patient
20 was in a DMARD as recorded in the note, but it
21 was not found in the three places in terms of
22 administered, ordered or prescribed fields in

1 which we were looking at this and I think this
2 does reflect that medication reconciliation is
3 still not perfect, far from perfect in
4 electronic health records. But, I think that
5 there are lots of efforts to try to improve
6 that and I suspect that agreement will
7 increase just as that increases in electronic
8 health records. It was still within the
9 substantial range. Which I think is adequate
10 for the purposes of testing.

11 The other piece of validity
12 testing was just the expert panel ratings and
13 those had a median validity score of 9 out of
14 9. Which is the highest rating.

15 CHAIR CHOU: Thank you. So, for
16 yesterday for some of these new measures, we
17 were kind of looking at reliability and
18 validity together. Is that what we're doing
19 here? Okay.

20 MS. PHILLIPS: Yes.

21 CHAIR CHOU: Because we weren't
22 doing that correctly for the last one.

1 DR. PACE: No, this one's fine.

2 CHAIR CHOU: Okay.

3 DR. PACE: And again, it's because
4 of -- we say if you're doing data element, you
5 could do the validity, too.

6 CHAIR CHOU: Okay. Thank you.
7 And then, Mark had brought up some issues with
8 the exclusions and things. Did you want to
9 comment on that some more? Yes.

10 DR. JARRETT: No, I think that at
11 this point I think I would -- I think it's
12 fine and I think we can't let perfection get
13 in the way of success. I think we're all
14 struggling with eMeasures all over and we're
15 not going to find the correlation, the R value
16 we would like, for probably another two or
17 three years, but that doesn't mean we
18 shouldn't start the process and gather
19 whatever information we can where we can and
20 I think I could still support doing this.

21 CHAIR CHOU: Great. Art, anything
22 else you wanted to comment on with the

1 reliability/validity?

2 MR. SCHUNA: No, not really.

3 CHAIR CHOU: Okay. Anyone from
4 the rest of the panel with questions or
5 comments here?

6 All right. Let's go ahead and
7 vote. So, this I believe is going to be both
8 the reliability and validity.

9 MS. PHILLIPS: So, we were just
10 having a sidebar. We're talking about looking
11 at this potentially as a measure that's for
12 trial use --

13 CHAIR CHOU: Okay.

14 MS. PHILLIPS: -- potentially.

15 CHAIR CHOU: Okay.

16 MS. PHILLIPS: Because there's
17 only two sides tested which may not meet the
18 sufficiency of testing.

19 CHAIR CHOU: Okay. How does that
20 impact what we're doing right now?

21 DR. PACE: So, we should move on
22 to just the question about the specifications.

1 CHAIR CHOU: Okay. So, we're just
2 talking about the specifications.

3 DR. PACE: Sorry.

4 CHAIR CHOU: That's all right.
5 So, I think we're ready to do the vote.

6 MS. PHILLIPS: All right. Voting
7 on trial measures specifications for 2525.
8 You have four options. One high. Two
9 moderate. Three low and four insufficient.
10 Voting begins now.

11 Okay. We are at 20. Been holding
12 here so we can vote again. We're at 21.
13 There we go. Twenty-two. Thank you.

14 We've got 3 for high, 17 for
15 moderate, 0 for low and 2 for insufficient.

16 CHAIR CHOU: All right. We pass.
17 So, we move to the last couple of criteria.
18 So, feasibility. Again, lead discussants,
19 Mark or Art, do you have comments to make
20 about the feasibility issue?

21 DR. JARRETT: It was the same
22 issues about defining the onset of the disease

1 and the process over the year and that may
2 throw things off. That was brought up by the
3 work group. But, everybody kind of felt --
4 and the TB question was brought up again, but
5 again, that -- I think it's been resolved in
6 multiple discussions and those are the only
7 issues from the work group.

8 Unless I left something out, Art.

9 MR. SCHUNA: Nothing further from
10 me.

11 CHAIR CHOU: Comments from the
12 rest of the panel?

13 All right. I think we can vote on
14 the feasibility.

15 MS. PHILLIPS: Okay. Voting on
16 feasibility for 2525 four options. One for
17 high. Two for moderate. Three for low. Four
18 for insufficient. Voting begins now.

19 Okay. We've got 22 responses.
20 We've got 6 for high, 15 for moderate, 1 for
21 low and 0 for insufficient.

22 CHAIR CHOU: That's passes and

1 then we move to the usability and use area.

2 Again, Mark and Art, any comments --

3 additional comments here?

4 DR. JARRETT: No additional
5 comments that haven't been covered that I know
6 of.

7 CHAIR CHOU: Thanks. Art,
8 nothing? Any additional discussion or
9 comments from the rest of the panel?

10 Okay. I think we're ready to vote
11 on usability.

12 MS. PHILLIPS: Usability and use
13 for measure 2525, you have four options. One
14 high. Two moderate. Three low and four
15 insufficient. Voting begins now.

16 We are at 21. So, if you can all
17 vote again. Okay. We're at 22. We've got 4
18 for high, 17 for moderate, 0 for low and 1 for
19 insufficient.

20 CHAIR CHOU: So, again, we pass
21 and we move to the overall vote. So, this is
22 a vote for testing for trial measure. Yes.

1 Okay. So, this is a vote for trial measure.

2 Yes or no.

3 MS. PHILLIPS: Measure 2525 for
4 overall suitability trial measure. You've got
5 two options. One for yes and two no. Voting
6 begins now.

7 Okay. We are 19. So, if you
8 would all vote again. Okay. Now, we've hit
9 22. We've got 21 yes and 1 no.

10 CHAIR CHOU: All right. So, that
11 passes. Thiru really wants to talk about
12 harmonization, but we're waiting for that for
13 later.

14 MS. FRANKLIN: I think we're
15 saving that for later.

16 CHAIR CHOU: Okay. All right.
17 So, you got to hold your horses. We're going
18 to talk about it later.

19 MS. FRANKLIN: Actually, since
20 we're --

21 CHAIR CHOU: You want to hear
22 about it.

1 MS. FRANKLIN: It's fresh in our
2 minds. We can do it right now.

3 CHAIR CHOU: Okay. Did you want
4 to make some comments?

5 DR. ANNASWAMY: I want to see what
6 the others thought about it.

7 CHAIR CHOU: What was that?

8 DR. ANNASWAMY: I would like to
9 listen on the discussion.

10 CHAIR CHOU: Okay.

11 MS. FRANKLIN: Sure and there's
12 just a -- just technically speaking, we have
13 handouts and discussions from the developers
14 that they sent to us regarding harmonization
15 that we're going to pull up on the screen and
16 we'll pull those up for you to take a look at
17 and we also have a side-by-side identifying
18 the differences between the measures and yes.

19 And we'd also like to have the two
20 developers, if they could, come sit at the
21 table for this discussion.

22 DR. PACE: And just to note to the

1 Committee, the reason we wait until after
2 you've evaluated each measure individually
3 because if for some reason or another one of
4 the measures would not actually be recommended
5 for endorsement, it's kind of a moot point.
6 So, we first think that each measure needs to
7 stand on its own of meeting the criteria and
8 then if we have two measures that are related
9 or competing, then to move to the next phase.
10 If they're competing, which one's better or if
11 they need to be harmonized in some way.

12 MS. FRANKLIN: So, we're pulling
13 up the side-by-sides of the two DMARD
14 measures. One from NCQA and the new measure
15 from American College of Rheumatology and the
16 developers have already provided us their
17 discussions, information about their
18 preliminary discussions.

19 If you could review those for us
20 and then we'll have a discussion about the
21 differences between the measures.

22 DR. YAZDANY: I'm be happy to do

1 it. All right. So, like I mentioned before,
2 we've already actually tried to harmonized a
3 vast majority of the data elements.

4 So, for example, the measurement
5 period in both measures is 12 months. Both
6 require two encounters. We've gone through
7 the medication list line by line and
8 reconciled everyone so that they match.

9 We have aligned the exclusions
10 which are HIV and pregnancy with the one
11 exception which is the inactive disease NR
12 measure and at this time, we are not able to
13 capture that in claims data. Otherwise, we
14 would put it into the NCQA measure as well.
15 But, it's just not possible.

16 And then the other difference is
17 how we actually find DMARDs and we talked
18 about that. So, one is dispensed. The other
19 is ordered, prescribed or administered NR.
20 So, I think that the concepts and the
21 measurement period and the numerators and
22 denominators actually align as best they can

1 given the data -- the different data sources.
2 I don't think that we had any piece of this
3 where we couldn't come to agreement.

4 Am I remembering that correctly,
5 Jenna?

6 MS. WILLIAMS-BADER: That does
7 sound right. Yes. Good summary. Thank you.

8 CHAIR CHOU: Questions or comments
9 about the harmonization of these two measures?
10 Mark.

11 DR. JARRETT: Do you see two years
12 from now retiring one of them and just being
13 an eMeasure and that's it?

14 MS. WILLIAMS-BADER: Again, ours
15 is specified at the health plan level. We are
16 developing a long-term plan for eMeasures. It
17 would actually take quite a bit of work and as
18 someone who also exclusively works on
19 eMeasures, I understand the difficulty in that
20 work.

21 So, it's not something that we can
22 say in the next couple of years we'd be able

1 to do and we do think that the plan level
2 measure is important because of the reasons we
3 stated earlier. Which is that we do see the
4 plan as an accountable entity that would
5 really be able to influence this particularly
6 given the issues around cost of the
7 medications and access to care.

8 So, probably not within the next
9 couple of years. Let's think maybe five or
10 ten and see how we're able to do with the plan
11 level eMeasures when we're able to start
12 rolling that out.

13 CHAIR CHOU: Jason.

14 DR. MATUSZAK: I do think that
15 it's valuable to hold the plans accountable
16 and the physicians accountable and however we
17 need to do that.

18 I guess my biggest struggle with
19 all of this is still the idea that we're not
20 holding people accountable to getting patients
21 into remission or low-activity status or
22 anything else.

1 We're holding people and plans
2 accountable for the actual prescribing of a
3 drug and to me, that kind of -- it's -- yes,
4 they're effective, but we also know that
5 there's ways to treat many people without
6 using drugs and you know and I'd always just
7 encourage us, you know, is it enough to treat
8 our hypertensive patients by giving them
9 hydrochlorothiazide or do you treat to some
10 target and actually work towards, you know,
11 holding people accountable for getting these
12 people these functional outcomes that you
13 really want to have and so, I struggle with
14 that part of it.

15 DR. YAZDANY: I think those are
16 important points and I think it's important to
17 articulate what the vision for the future is
18 and what we're doing to get there and I think,
19 you know, the first step is endorsement of the
20 measures which require measurements of the
21 outcome, functional status and disease
22 activity. That's the walking before you can

1 run.

2 If we can reliably actually get
3 our health care system to do that, then that
4 future that you're envisioning where there's
5 an outcome measure that's risk adjusted and
6 that actually, you know, really drives quality
7 improvement quickly becomes possible.

8 So, I think it's a great vision.
9 We just can't there before we have the
10 measurement in place.

11 CHAIR CHOU: Can I ask a
12 clarification? So, I thought you said that
13 inactive RA was an ICD-9 code. It's just not
14 used very much. Is that right?

15 DR. YAZDANY: It's not an ICD-9
16 code.

17 CHAIR CHOU: It's not an ICD-9.
18 So, it's a code that you guys made up that
19 nobody --

20 DR. YAZDANY: It's not an ICD-9
21 code. This is a problem that begins and then
22 is --

1 CHAIR CHOU: It's an ICD-10 code.

2 DR. YAZDANY: Yes.

3 CHAIR CHOU: Okay.

4 DR. YAZDANY: So, it's an ICD-10
5 code and --

6 CHAIR CHOU: So, it will be an
7 ICD-10. But, if it will be an ICD-10, there's
8 no reason that it couldn't be on the NCQA
9 measure. Right? Even if -- just people won't
10 necessarily know to use it right away.

11 MS. WILLIAMS-BADER: Yes, over the
12 past two years, we've been preparing for the
13 ICD-10 and transforming our ICD-9 list into
14 ICD-10 list. So, this is definitely something
15 that we can think about and consider as we're
16 developing those.

17 CHAIR CHOU: I think that would
18 help address Jason's concerns in some ways.
19 If there is -- you know, if that's -- if
20 they're not included in the denominator,
21 somehow people who have inactive disease
22 however that's defined.

1 Just a couple of other
2 clarifications for me is you had already
3 talked that the title is going to be -- the
4 description is different. Right? This is the
5 old description. We are no longer talking
6 newly prescribed or diagnosed or whatever RA.
7 It's really the same patient population.

8 And then this numerator is really
9 not people who received a DMARD as it says up
10 here, but it's people who were prescribed
11 whatever, whatever DMARD.

12 MS. WILLIAMS-BADER: I apologize
13 for those errors leading to mass confusion.

14 CHAIR CHOU: Okay.

15 MS. WILLIAMS-BADER: Sorry about
16 that.

17 CHAIR CHOU: Okay. All right.

18 DR. PACE: So, that is a
19 difference. Right? Your NCQA is dispensed.
20 Yours is just that there was a written
21 prescription or the --

22 MS. WILLIAMS-BADER: That's right.

1 That's right. So, we talked about that.

2 And the error is in that -- it's
3 newly prescribed. Which just we need to take
4 out the word newly because I think it's
5 confusing everybody.

6 DR. PACE: So, do you have any --
7 did you discuss that difference and what it
8 relates to? I mean, you know, dispensed is
9 actually more specific than there was an order
10 in a chart.

11 MS. WILLIAMS-BADER: Yes, we did
12 discuss that. I think part of this is
13 definitely coming down to the data source.

14 I will say that NCQA has
15 transformed some of our HEDIS measures into
16 eMeasures and we stayed true to the intent of
17 the HEDIS measure. Which is that medications
18 should be dispensed and I will say it's been
19 very unpopular among the users of those
20 eMeasures. It's an eMeasure in stage -- there
21 are a few in stage 2 of meaningful use.

22 So, we are hearing quite a lot of

1 push back from EHR vendors and physicians
2 saying they just don't have access to that
3 dispensing data yet. But, it's certainly
4 somewhere I think we'd like to go. It's just
5 that field is rapidly evolving and there are
6 a lot of connections that need to be made and
7 sharing of information that's just not done
8 yet.

9 DR. YAZDANY: To give people a
10 sense, you know, from the clinical front line,
11 current ePrescribing is a one-way street. So,
12 you write a prescription and it goes to the
13 pharmacy, but you don't actually get any
14 information back to your EHR and people are
15 trying to close that loop. But, until they
16 can, it's not going to be possible. But,
17 maybe in the next iteration, we'll be there.

18 MS. BURSTIN: Just one suggestion
19 perhaps for ACR in terms of the ability to
20 harmonize particularly since this is going to
21 be out there. You're testing. You're working
22 on it. Actually to stratify your rate by

1 dispensed and ordered. So, you can actually
2 match the level of dispensed to the NCQA
3 measure, but then we can address some of those
4 issues we just heard earlier about how often
5 it's ordered and perhaps the patients don't
6 have the financial means to actually get it.

7 So, you'd learn a lot to Mark's
8 point about being able to dive deeper. If you
9 actually had those two rates, perhaps
10 something you could test separately.

11 And then just one more point. Not
12 so much about this measure, but as long as
13 you're on the topic of harmonization, the two
14 you, I know NCQA's also working on a --
15 because I chair the Quality Measures Work
16 Group, the Policy Committee functional status
17 has been a goal achievement for patients with
18 RA and as you know, ACR just put forward a
19 measure yesterday on functional status
20 assessment for RA. So, even though they're
21 not directly -- this measure is not done yet,
22 I would just again encourage you guys to as

1 you're working through your measure be sure
2 that the registry-based measure and the
3 eMeasure are coming together.

4 DR. YAZDANY: So, just to give
5 people an update on that effort which we've
6 been involved in, even though the title of
7 that is functional status, the measures listed
8 are disease activity measures. It's
9 confusing, but so, that measure will actually
10 map. At least the disease activity
11 measurement tools map to our disease activity
12 measurement.

13 I just want to make that clear
14 because I think it's confusing in the title
15 and we've responded it's not functional status
16 and we're working on, you know, the ACR saying
17 get the disease activity measures into the EHR
18 and record a score and what we're working to
19 is setting a shared goal about what the target
20 should be. Sort of an untested and
21 interesting idea. So, hopefully, we'll hear
22 more about that in the coming years.

1 MS. BURSTIN: I just would
2 encourage that continued collaboration because
3 I think that's your real opportunity there.

4 CHAIR CHOU: Yes.

5 DR. GRAY: Yes. Can you explain
6 what harmonization means? I mean what's the
7 point of the discussion exactly? Have the two
8 entities come together and harmonized this and
9 we're just looking at the end product or are
10 we supposed to suggest something or what are
11 we -- what's the goal?

12 MS. FRANKLIN: So, the Committee
13 can review the differences in the measures and
14 make suggestions as to how the two developers
15 should work together to make sure the measures
16 are harmonized so that the reporting burden in
17 the field is reduced. But, I think that's the
18 ultimate end goal here.

19 CHAIR CHOU: Linda.

20 MS. DAVIS: I keep thinking about
21 public reporting and patients like Kelly and
22 others who might want some of this

1 information. Is that on the road map for
2 either of -- I mean I know NCQA is kind of out
3 -- I don't think it's available to consumers
4 who are the good arthritis health plans, but
5 it would be -- I always think about the
6 ability for people to actually see the results
7 of all this work as consumers as well.

8 MS. WILLIAMS-BADER: So, I will
9 say our measures are actually -- you can
10 access data. I unfortunately am hazy on the
11 details and my NCQA staff over there are going
12 to be really disappointed in me.

13 But, you can actually access
14 information on the rates. I do believe you
15 need to license that data, but it is available
16 and we do rank the -- we rank the health
17 plans. I don't know if that goes into the
18 level of detail of each measure and their
19 scores. But, that's one way in which the data
20 is publicly available.

21 I think we both agree, both our
22 organizations agree, that we'd like to get to

1 a point where the physician level measures are
2 publicly available as well.

3 I know that in PQRS average score
4 or summary scores across all the physicians
5 that are participating in the PQRS program are
6 available, but we've not gotten to the point
7 yet where we are or CMS has not gotten to the
8 point yet where they're reporting those PQRS
9 measures at the physician level.

10 But, I hope that's the direction
11 we're all going.

12 MS. DAVIS: But, it doesn't sound
13 like it's in the road map. It's not a
14 specific plan at some point in the future yet.

15 DR. YAZDANY: I think there is a
16 road map and I may be getting the details
17 wrong, but even in terms of the qualified
18 clinical data registry, you know, the more
19 advanced functions are fully transparent data
20 eventually. So, I think we're working towards
21 that, but we're not there yet.

22 CHAIR CHOU: Thanks. Are there --

1 Thiru.

2 DR. ANNASWAMY: I guess we still
3 don't have the answer on what exactly we are
4 doing with the harmonizing task and then the
5 other one is going to Jason's point earlier.
6 I think in the long-term vision of this whole
7 idea of tying performance to outcomes perhaps,
8 you know, I heard of the ICD-11 being planned
9 which will directly be interfaced with the
10 ICF, the International Classification of
11 Function, to where coding will be matched with
12 the functional stratification of patients.

13 So, perhaps that vision will come
14 together in the long run.

15 MS. BURSTIN: In terms of your
16 first question, in terms of what we're
17 expecting today, we want to have this
18 opportunity for the Committee to look at the
19 side-by-side, see if there are any obvious
20 differences there you think beyond what they
21 haven't harmonized that they should work on.
22 What we usually expect is that within one year

1 by the annual update for the measures that any
2 suggestions made by the Committee will be re-
3 reviewed to be sure that they've met those
4 harmonization goals.

5 So, at this point, we've just --
6 this is really a preliminary conversation to
7 see if there's anything obvious here that you
8 think they need to specifically continue to
9 focus on and apply.

10 For example, I raised this issue
11 of dispensing versus prescribed.

12 If there are any other issues you
13 think they should work on, otherwise, you
14 know, we'll just let them continue to work on
15 this and we'll kind of assess again as the
16 measure moves forward and again, since the ACR
17 measure is still being tested, there's a nice
18 opportunity there to see if anything else
19 emerges that may require further
20 harmonization.

21 CHAIR CHOU: Jason.

22 DR. MATUSZAK: Just really quickly

1 and you guys probably already touched on this,
2 but how come the differences between the drug
3 lists and what are the individual differences?
4 Why does one plan or why does one measure
5 count certain drugs and others doesn't or are
6 they included in there? Just summarize in a
7 different place. Because I don't see some of
8 these on both sides of the --

9 DR. YAZDANY: So, this is the
10 first pass of the medication list side-by-side
11 and some differences. For example, if I'm
12 remembering correctly, the ACR list didn't
13 include some Gold formulations or
14 mycophenolate. For example, this is two
15 differences and we just -- we reconciled those
16 differences.

17 Like for example, the clinical
18 discussion regarding the Gold formulations was
19 that it would be preferable to have a
20 harmonized measure rather than argue about the
21 efficacy of, you know, one Gold formulation
22 versus the other. Especially since claims

1 data tell us that, you know, there are two
2 patients in the U.S. taking gold anyway. So,
3 it's just -- you know, it doesn't make sense
4 to argue about Ns that small.

5 And that's actually -- you know,
6 that was true for anything that we disagreed
7 on. So, no one's using it anyway. It's
8 almost like, you know, what's the point.
9 But --

10 DR. PACE: So, what does that mean
11 then? Are you going to have lists that are
12 the same? I guess that's the question.

13 DR. YAZDANY: We actually --
14 somebody made a spreadsheet. Right. And I
15 don't know where that is. With the harmonized
16 sort of side-by-side. I think we should, you
17 know, email that out at some point then.
18 Right.

19 CHAIR CHOU: It would be fairly
20 straightforward just to make sure that the
21 drug list is the same. So, that, I think, is
22 an easy fix.

1 Other questions or comments? I
2 mean I guess my other thing would just be that
3 it would be nice for the exclusions to match
4 up precisely especially with this, you know.
5 However, you guys end up handling the inactive
6 disease piece. So, that would be the other
7 thing.

8 Jason.

9 DR. MATUSZAK: And one more. I
10 see that on the ACR measure that you guys
11 highlight that it's got to be two visits with
12 the same clinician. Whereas, the plan measure
13 is two visits with a diagnosis of RA
14 regardless of the provider. Is that correct?

15 MS. WILLIAMS-BADER: That is
16 correct. I guess I should speak that. Again,
17 I will look for signs over there from NCQA
18 staff to -- if I state anything incorrectly.

19 We don't have any measures that
20 indicate it needs to be with the same
21 clinician.

22 So, I know Mary's not at a

1 microphone. So, I'll repeat what she says and
2 just add to that.

3 What Mary was saying is that at
4 the health plan level, we're not using it for
5 accountability of the physician. A physician
6 level measure you do want to try to insure
7 that the patient is really in that physician
8 patient panel. So, you would want those
9 visits to be with the same clinician.

10 On the plan side, we are using
11 those multiple claims to insure the diagnosis
12 correctly represents the diagnosis the patient
13 has. So, it doesn't -- because we're holding
14 the health plan accountable for the measure,
15 it doesn't matter if that was with the same
16 clinician. We're just saying that if the
17 patient truly has RA as represented by two
18 claims for the RA diagnosis, they should be
19 receiving this medication.

20 Because as Mary pointed out, they
21 might be treated by a team. So, it doesn't
22 mean that the patient has to see the same

1 clinician.

2 DR. YAZDANY: So, let me just make
3 one more comment. I think that's great. I
4 agree with that.

5 And in terms of accountability,
6 one thing that came out during testing is that
7 it's not uncommon for a rheumatologist on the
8 first visit evaluating somebody for
9 inflammatory arthritis to have a code of
10 rheumatoid arthritis and what they mean out --
11 what they actually mean is rule out rheumatoid
12 arthritis and so -- and there were instances
13 where we found that in testing and so, in
14 order to increase specificity which is
15 important if it's going to be a provider level
16 accountability measure, we were able to do
17 that with the two codes. So, it sort of
18 reflects sort of the clinical practice style
19 and coding I guess that exists right now.

20 DR. MATUSZAK: One more piece on
21 the two clinicians thing. If it's you and
22 your nurse practitioner or PA, do you count as

1 the same clinician or you count as different
2 clinicians?

3 DR. YAZDANY: So, the measure
4 authoring tool as far as I understand it which
5 granted I may reveal my ignorance here, but we
6 actually can't assign attribution in the
7 measure authoring tool and so, that is done in
8 implementation of the measure at the practice
9 site.

10 MS. WILLIAMS-BADER: I might
11 actually be able to help out here.

12 If the measure is being considered
13 for the Meaningful Use Program, otherwise
14 known as the CMS EHR Incentive Program, then
15 the eligible professional is the one who is
16 reporting the measure and except for some
17 differences in Medicaid, I believe that is
18 going to be physicians.

19 But, that doesn't mean that if
20 other members of the care team provide the
21 care that the eligible professional won't get
22 credit for it. As long as the information is

1 available in the EHR, then the eligible
2 professional gets credit.

3 So, you're sort of holding the
4 eligible professional accountable for the care
5 team and making sure the care team is
6 delivering the care to the patient. But, I
7 don't believe that it -- that they would be
8 dinging in a sense the provider if it is a
9 nurse practitioner who provides one of those
10 visits.

11 CHAIR CHOU: I think Thiru had a
12 comment and then Kelly and then Art.

13 DR. ANNASWAMY: So, at the end of
14 this discussion, is there an action item that
15 you expect this Committee to do like we did
16 for the approval or the endorsement of the
17 measure? Do we just discuss and say guys,
18 work it out or do we say work it out with
19 option A, option B, option C? That's kind of
20 what I was asking earlier.

21 DR. PACE: No, I think it's
22 primarily about making recommendations. So,

1 where -- that you still expect some
2 harmonization and probably identifying if it's
3 short term versus long. Like the medication
4 list. Maybe that's a short term thing versus
5 something that might be longer term.

6 But, ultimately, I will say if
7 there's something that is really just a huge
8 problem that you see, it could result in you
9 going back and saying well, we don't think we
10 should recommend the measure for endorsement.
11 That would be kind of an extreme situation and
12 probably relates to one not really closely
13 following the evidence that exists versus
14 something else.

15 But, I mean generally it's really
16 about improving it and recommendations for
17 them to accomplish that by the time it comes
18 back.

19 DR. ANNASWAMY: -- the
20 recommendation then?

21 MS. FRANKLIN: Not at this time.
22 No. We're not voting today. We would capture

1 the suggestions for the developers so far that
2 we've had around harmonization in terms of the
3 denominator. I heard something about the
4 exclusions as well as the descriptions of the
5 measures in the medication list and we would
6 capture that in that report, put that out for
7 public comment and come back with crisp
8 recommendations for the measure developers
9 mostly likely after the comment period has
10 ended.

11 CHAIR CHOU: Yes, so, I think
12 we're into our break. So, I want to try to
13 wrap this up. A couple of other people wanted
14 to say something and then I think we can
15 summarize recommendations from the panel and
16 then hopefully close this out.

17 But, Kelly, I think you had your
18 hand up.

19 MS. CLAYTON: I just had a quick
20 question. For the ACR measure, is the only
21 reporting party rheumatologists? Because, you
22 know, sometimes patients are diagnosed by the

1 family practitioner, get referred to a
2 rheumatologist, wait three to six months for
3 a visit, don't receive a DMARD on that first
4 visit and I didn't know if there was a
5 percentage of the population that could
6 potentially be lost in reporting.

7 DR. YAZDANY: So, our measure for
8 performance at the rheumatologist level, but
9 I think your point is a really important one.
10 There are many areas of the United States
11 where there are not rheumatologists and access
12 has been a problem with long wait times.

13 Now, one thing that's interesting
14 about going forward with implementation both
15 at the health plan level and at the
16 rheumatologist level is that our more
17 groundbreaking health systems have figured out
18 that those two entities actually need to work
19 together and use tools like telemedicine,
20 electronic referral systems and other
21 innovative things to do, population health
22 management and actually in some ways having

1 both of these measures go forward allows for
2 that because the rheumatologists learn
3 population health management through the
4 registry and the health plans have an
5 incentive to increase DMARD use.

6 So, we need to work towards an
7 access measure, but in the meantime, I
8 actually think that there's some interesting
9 things happening on the ground to move this
10 field forward.

11 CHAIR CHOU: Art wanted to make a
12 comment.

13 MR. SCHUNA: Yes, I think it will
14 be interesting to see how these two compare
15 when you begin getting results because there
16 are differences in data collection with one
17 being electronic, the other including paper
18 records.

19 The differences in these drug
20 lists don't seem that great to me. I think in
21 some cases they have listed drugs by category
22 rather than exact name and when you consider

1 that, they tend to be pretty similar to me.

2 I see down the road eventually
3 though that this could just be one measure
4 because if the ACR criteria evaluation tool
5 included plans, you could group the plan data
6 and you'd have both pieces of information in
7 one criteria and I think that was -- there was
8 one other point, but I can't remember it right
9 now.

10 CHAIR CHOU: All right. Thanks.
11 So, let me just try to summarize and let's
12 wrap this up here.

13 I think, you know, the description
14 -- this isn't a harmonization issue, but just
15 that they're going to, you know, fix it to
16 what the current description is and then those
17 will be fairly well harmonized.

18 We had talked about, you know,
19 even though the lists are very similar, it
20 would just be nice if they just looked the
21 same so that it's easy for people to see that
22 and I think that's a very easy fix there and

1 then I think that the other main issue was
2 just how to deal with this inactive RA issue.
3 If that could be something for the two groups
4 to work on moving forward.

5 Were there other suggestions from
6 the group for harmonization?

7 DR. PACE: I think the other thing
8 that came up was the dispense and order.

9 CHAIR CHOU: Yes.

10 DR. PACE: Just to at least note
11 it or --

12 CHAIR CHOU: Yes, that's one of
13 the other things to look at.

14 All right. So, I think we are
15 past break time. So, we'll take what? Ten
16 minutes or something and then reconvene here
17 at 12 after or so. Thanks.

18 (Whereupon, the above-entitled
19 matter went off the record at 11:01 a.m. and
20 resumed at 11:11 a.m.)

21 CHAIR CHAO: All right, we are
22 going to move on to our next measure. It's

1 number is 0662. It's median time to pain
2 management for long bone fracture. The
3 measure steward is CMS, and this is a measure
4 for reendorsement.

5 We have someone from CMS on the
6 line.

7 Can you give us a brief overview
8 of the measure?

9 MR. BRATZLER: This is Dale
10 Bratzler. I'm not from CMS, but I work with
11 the contractor, Acoma Foundation Medical
12 Quality, for the measure. This measure was
13 developed as a part of a group of performance
14 measures for emergency departments that
15 focuses on timely access to healthcare.

16 There were a number of performance
17 measures for the emergency department that
18 focused on throughput times, time to see a
19 provider, provider decision to admission, and
20 this particular measure focused on timeliness
21 of pain management for patients because, as we
22 know, many patients end up sitting in a

1 waiting room for prolonged periods of time.

2 So the measure focuses on the median time from
3 arrival at the emergency department until the
4 patient receives pain medications.

5 We delimited the denominator of
6 the performance measure to patients with long
7 bone fractures for two reasons. The first was
8 that there was little controversy that the
9 vast majority of patients who have a long bone
10 fracture need pain medications.

11 Secondly, we didn't want to have
12 some vague description of pain or some pain
13 syndrome that might have unintended
14 consequences of getting people to pursue, you
15 know, going to the emergency room because they
16 knew there was a performance measure requiring
17 timely administration of pain medications. We
18 wanted to avoid that.

19 So, working with the Emergency
20 Department Technical Expert Panel, we focused
21 on long bone fractures because, as one of our
22 ER docs said, if somebody consciously breaks

1 a long bone just to get pain medicines, so be
2 it; we're going to give them pain meds.

3 So it is a median time procedure.
4 Patients are excluded from the denominator if
5 they've already received pain medications, if
6 they refused to get pain medications, or if
7 there is some explicit contraindication to
8 getting the pain medication.

9 That's just a brief overview.

10 CHAIR TEMPLETON: Thank you.

11 Sean, Wendy, and Chris are the
12 lead discussants on this.

13 I don't think we need to repeat
14 the overview, so I think we can start talking
15 about the evidence. Do one of you want to
16 take the first --

17 DR. VISCO: Sure, I'll take the
18 jump right in there.

19 Just to go back to the type of
20 measure here, I note it's being listed as an
21 efficiency measure. We were of the feeling
22 was this was a process measure. And

1 certainly, we all felt that way on this unless
2 we were, you know, missing something overall.

3 In terms of the evidence for 1A,
4 we felt that there was moderate evidence
5 supporting a delay in treatment. There is
6 very good moderate evidence for ethnic
7 disparities, especially in analgesia delivery.
8 However, we felt that there was very weak
9 evidence regarding a particular time frame for
10 treating the pain, and there was really no
11 clinical guidelines to support a particular
12 time frame for treatment. So, in this
13 particular measure, that's a 35-minute
14 benchmark, and we really couldn't find the
15 evidence to support that.

16 Shall I go into performance gap?

17 We're going to focus on evidence
18 first.

19 And then Wendy or Sean, did you
20 have additional comments to make your?

21 DR. BRYAN: No. I think Chris
22 summed it up nicely. You know, the feeling of

1 the work group was that there probably is,
2 taken in total, probably moderate evidence.

3 CHAIR TEMPLETON: Is there
4 anything from the rest of the panel?

5 DR. BUTLER: Can I just have some
6 clarification on this, from my understanding
7 as to what an efficiency measure is. I
8 understand it has two components, the resource
9 use and the quality component, and there's no
10 evidence required for the resource use
11 component.

12 Beyond that, I'm having, I guess,
13 trouble distinguishing really from the process
14 of measure.

15 Sorry.

16 CHAIR TEMPLETON: Sorry, if you
17 could be just a little bit closer to the mic,
18 I think. And there was a helicopter or
19 something.

20 So, if you could, repeat your
21 comment.

22 DR. BUTLER: Okay. Let me see if

1 I can remember about I just said.

2 (Laughter.)

3 DR. BUTLER: So I guess I'm having
4 a little trouble with the -- you know, they
5 said they thought this is a process measure.
6 And I tend to agree, especially when those
7 different components are broken out to
8 identify it an efficiency measure. So that's
9 what I'm trying to distinguish.

10 Is there a higher guide rule?

11 MS. PACE: This is Karen Pace.

12 I would say that I guess we would
13 tend to agree. I mean this is kind of about
14 getting the right treatment at the right time
15 for the patient, and if someone's in a pain,
16 sooner is better than later.

17 I think -- Dale can speak to this
18 -- they may have been thinking of efficiency
19 in terms of the efficiency of their systems to
20 make this happen. But, you know, it is about
21 patients getting the right treatment.

22 Dale, do you want to comment on

1 why you are thinking efficiency?

2 DR. BRATZLER: Well, again, this
3 is just one measure in a whole set that had
4 been discussed by other committees looking at
5 timely management of patients who present to
6 the emergency department. This is just one
7 piece of a group of measures that focus on
8 efficient movement of patients from arrival at
9 the emergency department through the emergency
10 department.

11 There was a perceived need to
12 focus on management of pain, and we spent long
13 periods of time talking about this, about how
14 we develop a measure to promote unintended
15 consequences of inappropriate use of pain
16 medications for patients seeking medications,
17 and yet, looked at a group of patients where
18 there was general consensus that timely
19 treatment of pain is a reasonable exclave
20 expectation.

21 DR. PACE: Right; I don't think
22 anyone is disagreeing with the timely -- and

1 the classification of it, we can handle.

2 We probably need to look across
3 some NQF measures about the timeliness. By I
4 don't think it will change your evaluation of
5 the measure at this point.

6 DR. BRATZLER: I don't think we
7 ever tried to argue that there was an outcome
8 other than patient satisfaction, perhaps,
9 related to the median time to pain management
10 and patient outcomes. I don't know that it
11 changes the outcome for a patient and so I
12 don't we ever tried to make that argument.

13 DR. PACE: Right, and you haven't
14 really baked in a certain benchmark. It
15 strictly is the median time for each
16 institution; correct?

17 DR. BRATZLER: That is correct.

18 CHAIR CHOU: I guess a question I
19 have for NQF is, is there a different
20 algorithm for efficiency measures? I mean I
21 don't really see that on here.

22 DR. PACE: No, there isn't.

1 I think you're well point is well
2 taken. For strict resource measures, if it's
3 just cost or number of visits et cetera, we
4 don't have the evidence component. But if it
5 were an efficiency measure that included cost
6 and resource use plus quality, the quality
7 component would still need evidence. So I
8 think it's okay to just proceed.

9 CHAIR CHOU: So I think we treat
10 it as a process measure, I think, is just
11 basically my take from that. I think this was
12 mentioned before, that most of this is
13 indirect in the sense that it's based on
14 evidence that, you know, some people don't get
15 pain medications immediately and are therefore
16 having some suffering. I know there's also
17 some evidence about disparities.

18 Do other people want to make
19 comments about -- oh, yes, Kim.

20 CHAIR TEMPLETON: This is Kim --
21 yes; I'm sorry. This is Kim.

22 I just have three questions. One,

1 in the definition of pain medications, does
2 this also include regional blocks? There's
3 increasing information in the elderly with hip
4 fractures about the efficacy of using ileal
5 fascial another regional blocks. Would that
6 be included?

7 DR. BRATZLER: Yes, it is,
8 including intrathecal, regional, nerve blocks,
9 Biers procedure. All of those are included.

10 CHAIR TEMPLETON: Okay, and two
11 other questions. One, what if you have
12 someone who comes in with pain who does have
13 an injury, but yet, when you're trying to make
14 a diagnosis, you get a plain x-ray and your
15 picking up an old fracture. This is not an
16 acute fracture; their pain is due to something
17 else.

18 Would those be included within
19 this?

20 DR. BRATZLER: Here, it would
21 depend on the billing for the diagnosis, so I
22 can't tell you for sure whether it would or

1 not. But these cases are selected based on
2 the diagnosis codes.

3 CHAIR TEMPLETON: And then I guess
4 the last question would be, you'll have some
5 young kids who will come in, as well as the
6 elderly who are osteoporotic, who have a
7 mechanism of injury, but because of their
8 metallization of their bone, you can't detect
9 a fracture on plain film. And so you're down
10 to MRIs, CT, some other imaging modality to
11 confirm the diagnosis, which is going to take
12 time. And would it be beyond your time frame
13 that's delineated for this.

14 How would that be accounted for?

15 DR. BRATZLER: Well, of course it
16 is a median time, so that addresses some of
17 the outlier issues, that if the case came into
18 this denominator, perhaps it should be, you
19 know, could extend to --

20 (Simultaneous speaking.)

21 CHAIR CHOU: Okay, thanks -- I
22 wanted to try to stick with the evidence right

1 now we can talk about the speculation --

2 (Simultaneous speaking.)

3 CHAIR CHOU: Thanks for those
4 comments.

5 Mark, would you go ahead?

6 DR. JARRETT: The rest of the
7 specifications that --

8 (Simultaneous speaking.)

9 DR. JARRETT: I'm just getting a
10 little -- especially because --

11 CHAIR CHOU: I have Dale on the
12 phone.

13 Do you want to respond to that?

14 DR. BRATZLER: I can't say much to
15 --

16 (Simultaneous speaking.)

17 DR. BRATZLER: -- by the American
18 College of Emergency Physicians --

19 The PPE approach --

20 (Simultaneous speaking.)

21 CHAIR CHOU: Do you -- patient
22 satisfaction is a reality. Do you have data

1 showing that -- whatever, whatever measurement
2 -- some of that kind of kind of thing?

3 DR. BRATZLER: I don't know. I
4 don't have any particular patient satisfaction
5 data.

6 Again, this is part of an
7 efficiency group looking at timeliness of care
8 for a whole group of emergency department
9 measures.

10 CHAIR CHOU: Okay.

11 Are there other comments from the
12 group?

13 John, and then Jason.

14 DR. FITZGERALD: Yes, I guess it's
15 to kind of tie in to what Merck said. And
16 that is, it was originally endorsed in 2011,
17 and now, three years later, we're going to
18 keep this same work for the emergency
19 department staff. I don't see that it's
20 moving towards an outcome improvement.

21 CHAIR CHOU: Jason?

22 DR. MATUSZAK: I guess I just had

1 more of a question about for the developer
2 about the research that they cited.

3 Which particular long bone
4 fractures did you guys find that pain
5 management was not being adequately addressed?
6 And how do you address those long bone
7 fractures?

8 I mean which long bones are we
9 talking about? Everything the long bone?
10 Hands? Feet? Distal fibula? Give me an idea
11 here.

12 DR. BRATZLER: So it's primarily
13 humorous, radius, ulna, femur, tib, fib.

14 I'm not sure if Wanda or somebody
15 from NQF has an open mind. They know the
16 denominator codes. It's all based on codes.
17 So, hands, foot, would not be in the long bone
18 group.

19 CHAIR CHOU: Are there other
20 comments or questions?

21 (No response.)

22 CHAIR CHOU: All right.

1 So I'm just going to sum up where
2 we're at. Although there is a reendorsement,
3 there are some questions about the evidence
4 supporting the measure. I'll just stop there.
5 There are some questions about the evidence
6 supporting it, and it sounds like it's quite
7 indirect.

8 At this point, I see that a couple
9 of the workgroup members did try to rate it,
10 and some people -- I mean there's at least one
11 moderate or high in the workgroup comments --
12 but again, there are quite a few questions
13 that have been already reflected, I think, in
14 the discussion.

15 So I'm going to pause there. If
16 there are no further questions or comments, we
17 need to put this to a vote. Remember, it
18 needs to pass the evidence criteria to be able
19 to move on.

20 So let's pause here and let's do
21 the vote.

22 MS. PHILLIPS: All right. We're

1 voting on 0662. We're voting on the evidence.

2

3 You have five options: "1" for
4 high, "2" for moderate, "3" for low, "4" for
5 insufficient evidence with exception, and "5"
6 for insufficient evidence.

7 The voting begins now.

8 Okay, we're at 21, and we have 21
9 in the room.

10 So we have zero for high, three
11 for moderate, seven for low, two for
12 insufficient evidence with exception, and nine
13 for insufficient evidence.

14 CHAIR CHOU: This is below the 40-
15 percent cut off -- yes -- we have three
16 moderate and two insufficient with the
17 exception, so that still comes out to 24-
18 percent.

19 So I think we stop here, unless
20 there's other --

21 MS. MARINKOVICH: We can stop
22 here.

1 DR. MATUSZAK: Yes, just one more
2 comment.

3 It was mentioned earlier, care
4 coordination --

5 (Simultaneous speaking.)

6 DR. MATUSZAK: -- simple item
7 direct from the patient.

8 John Watson once again -- in
9 Kaiser Health -- has fielded a single item of
10 patient report of harm. And once again, the
11 rates are fairly high, and they do vary quite
12 widely. So it's another potential way of
13 looking at harm, using patient reports through
14 some database on that from John Lawson.

15 CHAIR CHOU: So I'm going to open
16 up open it up, maybe first to the lead
17 discussants, and then to the rest of the
18 panel, for further discussion here.

19 DR. MATUSZAK: Sure. I think part
20 of the challenge was the complexities and
21 subtleties in the evidence with regard to
22 level of care and type of ER that care is

1 involved in.

2 For instance, in tertiary care
3 centers in the Friedland study, head injury
4 was associated with lower analgesic use, but
5 that wasn't necessarily a bad thing. In
6 multi-trauma cases, which -- I think it was,
7 and I can't remember of the top of my head; I
8 think the Brown study in 2003 -- at least 10-
9 percent or maybe more of patients had complex
10 cases, and these are cases where the potential
11 administration of analgesia would either
12 complicate the diagnosis or would also involve
13 missing something with visceral or other
14 traumatic causes. We can't really address
15 underestimate those 10-percent because those
16 are real dangerous types of cases that need,
17 you know, a lot of thoughtful care.

18 So there was a potential for that,
19 and again, that gets into a lot of subtlety,
20 which mostly related to some thought that it
21 was difficult to look at this without thinking
22 about risk stratification for -- and that came

1 up with in a workgroup as well, which gets
2 outside of the evidence -- but it's still
3 related in terms of how the data kind of pans
4 out.

5 I had a couple other thoughts, but
6 I'll turn it over to Wendy and Sean.

7 MS. MARINKOVICH: So a couple of
8 things I'll add is that we didn't see a lot of
9 movement in the measure. There was a slight
10 movement, but we didn't see a lot of movement,
11 and that was one of the discussion groups that
12 we had.

13 DR. PACE: That's right. Yes, we
14 would just say that, what were the evidence
15 issues?

16 MS. FRANKLIN: The evidence issues
17 -- okay -- no, go ahead.

18 DR. PACE: So let's break it down.

19 This measure is about timely
20 administration of analgesia for patients with
21 long bone fractures. So the evidence they
22 provide -- and we should talk about the

1 evidence they provided. And if we look at
2 that of the process, getting the right
3 treatment at the right time, the desired
4 outcome for this would be, first, symptom
5 control, pain control, and patient
6 satisfaction, are probably the two desired
7 outcomes.

8 So, you know, we can think about
9 evidence of pain treatment, and does that
10 influence pain control and patient
11 satisfaction. We can look at if they provided
12 any evidence about, you know, the time that
13 that should occur.

14 But I think some of the other
15 issues you're bringing up at the do with the
16 performance gap, which, if there is none,
17 that's where you should vote that down, or how
18 the measure is actually is constructed,
19 whether it needs solutions and risk
20 stratification, et cetera.

21 But I think we need to really
22 focus on the evidence first and then talk

1 about these other things under the appropriate
2 criteria.

3 DR. BRYAN: And that's why I
4 brought that up the way that I did, because we
5 as a workgroup did kind of feel like, in
6 general, this sort of hit at a moderate, and
7 a couple of us felt that it was on the low
8 side. But if this got to 1B and 1C, I think
9 that we would see that's where we had more of
10 this kind of discussion, which is why I wanted
11 to bring in some of performance issues that we
12 had, that maybe people are looking at that and
13 already bringing this down to a low rating.

14 But that's, again, where we were
15 going to come in and say, this is probably low
16 in that realm.

17 DR. PACE: Right, and I think
18 that's fair. But, you know, we really do want
19 you to evaluate the criteria as they're stated
20 because it's helpful for other reviewers to
21 understand where potential differences in the
22 measure are for the measure developer.

1 You know, the fact that this
2 really isn't based on a systematic review of
3 the evidence, it probably would fall into the
4 'moderate' category to begin with, or it could
5 be, you know, perhaps meet the exception. But
6 I think we just need to be clear on what
7 criteria you're basing your vote on.

8 CHAIR CHOU: Yes, I mean I'll
9 summarize some of the stuff that I've heard
10 and my take on it.

11 You know, really, no direct
12 evidence has been presented. So, at best,
13 this can be moderate to begin with. But even
14 the indirect evidence, I think, is
15 problematic, to me at least, in that we don't
16 really don't know what the optimal time for
17 administration is.

18 I mean there's this kind of
19 assumption that a sinister patient hits the
20 door, they should be given analgesics, and I'm
21 not sure that's necessarily the case. And
22 then this in issue about heterogeneity, it's

1 kind of tied in with the specifications, but
2 I also think it's also tied with the evidence
3 because there is heterogeneity in the patient
4 presentations, and not everybody should be
5 getting analgesics within 10 minutes of
6 walking into the ER, or whatever.

7 So I think that the indirectness,
8 at least to me, is an issue and then, related
9 to the indirectness, some of these assumptions
10 that are being made. I think it's difficult.
11 I actually think it's difficult to interpret
12 what it means that the median time went down
13 by three minutes. I don't know if that's bad.
14 If it's good, it's only a slight improvement,
15 but I don't even really know, really, how to
16 interpret that.

17 So, I'll open it up to see what
18 other people, with the other takes have been
19 from either the leads or other folks on the
20 panel.

21 DR. JARRETT: No, I agree with
22 Roger. I think that if we just follow the

1 algorithm, you know, it's not a patient-
2 oriented health outcome, and that takes us
3 down that path. You know, I mean the evidence
4 that they present is not a systematic review
5 per se. So we're looking at these individual
6 studies. Individual studies don't actually
7 look at what the measure is testing.

8 And then the only thing we're
9 really left with is whether or not that
10 actually should be considered for an exception
11 --

12 (Simultaneous speaking.)

13 CHAIR CHOU: Marcie?

14 DR. HAYES: So my comments would
15 be similar to Jason's and may not --

16 (Simultaneous speaking.)

17 DR. HAYES: And what we concluded
18 and recommended was that was a good measure
19 for use within hospital over time for not
20 sufficiently accurate for a cross hospital
21 comparisons, given the results I just
22 mentioned.

1 (Simultaneous speaking.)

2 CHAIR CHOU: I can't remember what
3 the vote was, but were there people who did
4 feel that the evidence was better, moderate at
5 least, and wanted to comment on how kind of
6 where they came to that?

7 MS. MARINKOVICH: I was one of
8 them with the moderate.

9 CHAIR CHOU: Yes.

10 MS. MARINKOVICH: In going down
11 the algorithm, I agreed that there was no
12 systematic review, where they had a body of
13 literature that they turned in.

14 And so, with the information
15 presented, there did appear to be an issue,
16 and this literature supported that there was
17 disparities between them, that there was a
18 need for pain medication in these large bone
19 fractures.

20 I don't disagree, as well, with
21 the, if it's trauma, you know -- but that was
22 for specifications where I felt that there

1 would be some additional thoughts, you know,
2 with exclusions of patients that had issues
3 with other areas.

4 But with the evidence itself, I
5 did read it as moderate following the
6 algorithm that was in the indicia.

7 DR. BRUETMAN: Yes, I looked at it
8 in much the same that Wendy did, and it was
9 kind of between low and moderate. But I felt
10 that overall, the evidence, although indirect,
11 probably fell at a moderate level. However,
12 you know, when you go down the priority,
13 reliability, validity, usability, and just the
14 fact that, you know, there is really is no
15 direct evidence that giving the pain
16 medication sooner really is a proving the
17 quality of the care or the outcomes.

18 I felt, you know, there were
19 enough issues with this measure that I was
20 going to vote low on a lot of other things,
21 but this was the one thing where I felt that
22 it did need to meet that kind of minimum bar.

1 CHAIR CHOU: Thanks.

2 Are there any other comments or
3 questions?

4 Mark.

5 DR. JARRETT: Since didn't get to
6 specifications, looking at median time really
7 doesn't address the issue of disparate care
8 because, although the median may drop, there
9 may be a large segment on one side of the
10 curve that is still getting poor care. And
11 looking at the median time, you may come out
12 looking really good but still be giving
13 disparate care to certain populations. So I
14 think it's not achieving the purpose of what
15 the measure was supposed to do.

16 CHAIR CHOU: That's a great point,
17 thanks.

18 DR. JARRETT: And during our
19 discussions, the developer agreed with us that
20 this was really a reflection on time to
21 diagnosis as well.

22 And you know, furthermore, one of

1 the discussions that came out -- just to give
2 information back at this point in the
3 developer -- one of the discussions that came
4 out was that long bone fractures are such a
5 small portion of pain in the emergency room
6 that they really should think about the
7 problem when thinking about this. It didn't
8 seem to stand alone as a measure, to us.

9 Again, it's further down the
10 algorithm. It's not speaking to the evidence,
11 but it's speaking how the developer could
12 consider this particular measure.

13 CHAIR CHOU: Marcy?

14 DR. HAYES: So I'm just trying to
15 kind of -- I thought I heard the developer say
16 that there was some consensus with a
17 particular committee, but I'm not seeing that
18 in the documentation.

19 Did I hear that incorrectly?

20 CHAIR CHOU: I think they worked
21 with some of emergency room group.

22 Is that correct?

1 I think that's what he was talking
2 about. I don't think there was necessarily
3 ACER or whatever, that it was a professional
4 society necessarily.

5 DR. BRATZLER: Yes. So most of
6 the members of the tech technical expert panel
7 -- not all, but most -- are members of the
8 American College of Emergency Physicians.

9 CHAIR CHOU: Did you want more
10 from us, or what is the process here now?

11 MS. PHILLIPS: We were just
12 discussing if the committee, after this
13 discussion, if the committee's concerns were
14 with evidence or with some other part of the
15 criteria.

16 That was our only discussion. I
17 don't whether we wanted to tease that out
18 more, or.

19 CHAIR CHOU: I think I heard
20 expressed concerns about the performance gap
21 as well as the priority things. We could do
22 votes on those if you wanted feedback there.

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DR. PACE: I think the only question is, after this discussion, whether anyone would change the vote that they gave on evidence. If not --

CHAIR CHOU: We can revote.

DR. PACE: That's up to --

CHAIR CHOU: If that's the appropriate procedure, we can revote and see what's happened.

DR. PACE: Either way -- I mean if people want to indicate whether they would change. If everyone feels like it's going to be the same -- you know that, I mean --

CHAIR CHOU: Well, that kind of puts people on the spot.

Why don't we just your revote and just vote how you feel.

MS. PHILLIPS: All right, we're voting on 0662 on the evidence.

You have five options -- starting now.

1 Okay, we have all 22 responses.

2 Zero for high, two for moderate,
3 six low, one for insufficient evidence with
4 exception, and 12 for insufficient evidence.

5 CHAIR CHOU: Okay.

6 (Laughter.)

7 Thank you, Dale.

8 CHAIR CHOU: I think we're going
9 to move on to the next measure now, which is
10 0052, use of imaging studies for low back
11 pain. The developer is NCQA.

12 Let me pull this one up. We have
13 -- oh, there we are -- Mary.

14 (Off microphone comment.)

15 CHAIR CHOU: So, actually, I guess
16 I should mention that.

17 I wasn't involved with the
18 development of this measure, but I have been
19 involved with a lot of ACP stuff related to
20 low back pain imaging. So I don't know if I
21 need to recuse myself from voting or anything
22 -- no? Okay -- so, just as a disclosure.

1 Mary, can you give us an overview
2 of the measure?

3 DR. BARTON: I'll just start by
4 saying that among the measures in the HEDIS
5 set, a very small number are focused on
6 overuse, and this is one that has been around
7 for several years. We've seen some progress
8 on this, but really, my hope is that over the
9 future, as issues like choosing wisely gain
10 steam, and as clinicians think about how they
11 might apply care most judiciously to patients
12 who need it, that these kind of measures will
13 be more successful in changing practice.

14 But I'm going to let Jenna give an
15 intro to the measure.

16 MS. WILLIAMS-BADER: Thanks, Mary.
17 You did cover a little bit of what I was going
18 to say.

19 This is, as Mary pointed out, an
20 overuse measure. Here, we're looking for the
21 percentage of patients with a primary
22 diagnosis of low back pain who did not have an

1 imaging study within 28 days of diagnosis.

2 A couple of things to note about
3 the description: We are looking for a patient
4 who did not have an imaging study, and we do
5 this by actually -- we create an inverse
6 measure where we actually look for claims of
7 the images, but then we subtract that from one
8 to come up with the measure weight. So,
9 although it is an overuse measure, a higher
10 score is actually better because we are
11 looking for those who did not, and that would
12 be the appropriate treatment for those
13 patients.

14 Again, it is a health plan-level
15 measure, and we are relying on claims data for
16 the measure reporting. This measure was
17 actually developed that a similar time as the
18 DMARD measure that we were discussing earlier.
19 It was actually developed by a panel that had,
20 or, it was informed by a panel that had been
21 developed that had come up with pain measures
22 before. I mentioned them during the DMARD

1 discussions.

2 So this was identified as an
3 important topic by a group that was looking at
4 possible pain measures, and that was the group
5 of NCQA, the American Medical Association, and
6 the joint Commission. It has been and
7 continues to be an area of strong interest,
8 and the guidelines continue to support that
9 imaging within the first few weeks of a
10 diagnosis is not indicated, and that it is
11 better to engage in watchful waiting until
12 those four to six weeks have elapsed. we do
13 have exclusions for red flags, however, which
14 would indicate that imaging is appropriate,
15 and those red flags are that there are signs
16 of neurologic impairment, trauma, IV drug
17 abuse, and cancer.

18 Other points about this -- we do
19 ask for plans to identify the earliest
20 encounter for the episode, and we have a 180-
21 day, what we call negative diagnosis history
22 in which we look back at claims to ensure that

1 there was not a low back pain diagnosis in the
2 180 days before the index encounter, index
3 episode. So, while we recognize that low back
4 pain is a chronic condition and it may flare
5 at certain times, we're trying to identify the
6 patients at the beginning of their episodes so
7 that we are addressing the acute back pain.

8 The measure was reevaluated in
9 2012, as was the DMARD measure, and was
10 reviewed by the same measurement advisory
11 panel. They strongly supported this measure
12 moving forward. We again looked at the
13 guidelines, and the guidelines had not
14 changed. There does continue to be strong
15 support. And as Mary noted, this measure is
16 actually, or, this concept is actually in the
17 choosing wisely recommendations; it was one of
18 the first ones that was recommended. So it
19 continues to be of strong interest.

20 There is some flatness in the
21 scores. Although, we do see a variation when
22 you start looking at the percentiles. And

1 again, we do hope to see some more renewed
2 interest in improving the scores for this
3 measure in that it is, because of the choosing
4 wisely initiative and also because this
5 measure has been included in CMS's HER
6 incentive program.

7 So we do feel that it continues to
8 be important. There's room for improvement.

9
10 I think that covers it.

11 CHAIR CHOU: Thanks, Jenna.

12 So we have three lead discussants.
13 I think Zoher was going to start off, and then
14 we'll take comments from the others.

15 DR. GHOGAWALA: Thanks, Roger.

16 So we have a number of comments
17 about this measure. This measure is, as
18 stated, a process measure that is used to look
19 at the overutilization of lumbar spine imaging
20 -- plain films, CT, and MRI -- for
21 uncomplicated low back pain.

22 You know, the first thing we do is

1 we'll look at the evidence and what our study
2 group said about the evidence. But the big
3 picture here is that, you know, low back pain
4 as an overall health expenditure in the United
5 States is an enormous issue, and the
6 developers shared some of that data.

7 I think one of the most widely
8 quoted is the Brook Martin study in JAMA from
9 2008, which looked at the cost of all spinal
10 disorders being in the range of \$80- to \$100
11 billion a year, compared to patients in the
12 United States who don't have low back pain
13 disorders. As you drill down on that data
14 further, the outpatient costs associated with
15 low back pain are \$20- to \$30 billion. Now,
16 a lot of that is the cost of pain medications,
17 but certainly, a lot of that is certainly the
18 cost of diagnostic imaging; in particular,
19 MRI. So the workgroup felt that the
20 significance of this matter, as a matter of
21 overutilization, I think, is very, very clear
22 based on the data.

1 The opportunities are also there
2 in terms of the variation in care. They show
3 a difference -- and again, Jenna, you
4 described the score being one minus the
5 numerator over the denominator -- so a higher
6 score is better. But the difference between
7 a 10th percentile and the 90th percentile was
8 75 to 90, so a 15-percent differential, and
9 for a healthcare matter as big as this, that's
10 a significant matter.

11 One thing that is disappointing as
12 we evaluate this measure is that over time,
13 that practice or performance variation has not
14 changed, and there are many issues behind why
15 that might be.

16 But the first order of business is
17 the evidence, and they present six randomized
18 studies from which two meta-analyses were
19 performed and guidelines have been generated.
20 I think the important point about this is that
21 high-quality studies have been performed that
22 have asked the question, if you use early

1 imaging for low back pain versus not, you
2 don't see a difference in outcome. Okay? So
3 one can then infer that perhaps that early
4 imaging is not required.

5 However, if you look at this
6 measure, one of the things that is different
7 -- I think it's always important when you're
8 looking at randomized studies and then looking
9 at process measures to ask the question -- is
10 the process measure in fact directly related
11 to the randomized study evidence? And here,
12 it's close, but it's not directly related.
13 And let me just explain why that is.

14 Usual care implies that there's
15 still follow up with these patients so that,
16 if somebody had a significant problem that was
17 not imaged initially, they could be imaged
18 because there would be further care.

19 If you look at this measure, this
20 is looking at patients who are coming to
21 either a clinic or to an emergency room with
22 a diagnosis of low back pain absent these red

1 flags, and the measure is advocating that
2 these patients not be imaged. Now, if these
3 patients in a single event are not followed,
4 it's possible that some of these patients in
5 fact had a problem that would require imaging.

6
7 So the big picture -- when you
8 look at it, the evidence base is there, the
9 guidelines have been generated, and I think
10 there's very little question that there's
11 overutilization of imaging for low back pain.
12 But you know, our committee felt that this is
13 a moderate degree of evidence that directly
14 relates to this measure, but a systematic
15 review has been generated in terms of the
16 evidence.

17 Overall -- we'll get the other
18 points -- the other major issue, from our
19 study group perspective, is that the study
20 population that is defined by this measure,
21 our study group felt, was inadequate. Again,
22 the point here of usual, uncomplicated low

1 back pain and overutilization of imaging is
2 all true. But how you define that study
3 population is critical.

4 I think some of the red flags that
5 are included in this study population --
6 history of cancer, history of trauma within a
7 year, IV drug abuse, and neurological
8 impairment in the last year -- are all
9 reasonable.

10 But maybe, Cat, if I can turn this
11 over to you, the American College of Radiology
12 has published and studied this type of study
13 population and has come up with some other
14 very important criteria for identifying
15 patients that may in fact not have
16 uncomplicated low back pain, which would be
17 excluded in this measure.

18 DR. ROBERTS: I think some of my
19 comments refer to validity, so I might hold
20 those and bring those up then.

21 But just speaking to the evidence,
22 there is a very large body of very high-

1 quality literature on this topic, including
2 systematic reviews. So this could be rated as
3 highest high. Our group together had a
4 consensus of moderate.

5 I will speak to the other topics
6 on the validity later.

7 CHAIR CHOU: Thanks, Cat.

8 Again, just for full disclosure,
9 we did one of the systematic reviews. It was
10 published in Lancet a few years ago, so I'm
11 one of the authors, or the lead author.

12 Carlos, did you have additional
13 comments?

14 DR. BAGLEY: I would agree with
15 that. I think, because they didn't get the
16 imaging early doesn't mean they didn't get the
17 imaging, and I think there's no direct study
18 the shows that.

19 So, again, I think the data is
20 there, but based on the specificity of this
21 particular measure, it's kind of more of a
22 moderate level.

1 CHAIR CHOU: JD?

2 DR. DANIELS: Are the other
3 speakers done talking?

4 CHAIR CHOU: Those were the three,
5 yes.

6 DR. DANIELS: Okay, sorry.

7 I may have just sort of missed it,
8 but I just sort of went on my own -- you know
9 more about this than I do, Roger -- Gilbert,
10 from the UK, "Does early imaging in influence
11 management and improve outcome in patients
12 with low back pain," a programmatic randomized
13 controlled study, which is actually a little
14 bit larger than a Kendrick study. And what
15 they ended up doing, you know, just to kind of
16 mix things up again -- but they actually found
17 that, although it did not appear to affect
18 management, it did improve cost of clinical
19 outcome. I don't know how much a pound is
20 now, but it was 870 British pounds per
21 quality.

22 I just wanted to mention it

1 because most of my job all day is to convince
2 most people that back pain is part of the
3 human condition and that you can prove that no
4 one's perfect; just look at an MRI.

5 The main thing that I'm worried
6 about with this measure is what you're looking
7 at. If you go and say, you know, how you're
8 going to pull this out if somebody comes into
9 a primary care office, most docs, I don't
10 think, want to do an x-ray. And so what
11 happens is that there's a whole bunch of other
12 issues, psychosocial issues, and sometimes,
13 that's what really ends up adding the cost up.

14
15 And if you're going to measure,
16 like, say, you've got a guy who -- just last
17 week, this happened -- a firefighter comes in
18 and he has night pain and he's a tough guy and
19 you kind of know him, and he's got a tumor.
20 Okay?

21 So when I get x-ray him -- so it
22 was like, boom, I'm going to x-ray him that

1 day, and he didn't fall off a ladder or
2 anything; so how do you justify that? What
3 I'm probably not going to do is, Charlie, I'm
4 going to x-ray your back because I'm worried
5 you've got cancer, and you know, that's
6 probably not going to be the diagnosis. It
7 going to be, like, nonspecific kind of back
8 pain. And you'll say, well, those are far and
9 few in between.

10 But you know, you could get
11 populations -- let's say you've got a
12 geriatrician, and you've got nursing home
13 people, and they fall, and they're on a lot of
14 meds, you're probably going to want to do
15 that, especially if they can't kind of express
16 that they're having pain.

17 So, you know, I think that
18 although I agree with this whole kind of issue
19 here, maybe part of the reason that nothing's
20 moved is what you're measuring -- I'm talking
21 a little bit too much; sorry.

22 CHAIR CHOU: Yes, thanks, JD. No,

1 that was great.

2 Just a few comments about the
3 evidence. One is both the Kendrick and
4 Gilbert studies were done in the UK, where
5 care is very different from here; for example,
6 they do five times less spinal fusion
7 surgeries than we do in the United States.

8 If you actually look at the costs
9 across the studies that have been done in
10 different places, it's actually all over the
11 place. In some places that increases costs;
12 in others, it decreases. So I think it's very
13 hard to interpret the costs, especially for
14 the non-US studies.

15 And then if you look at other
16 outcomes, like anxiety -- right? There's this
17 idea that you would reassure patients by
18 showing them that they don't have cancer or
19 whatever. You actually don't show that
20 there's any positive effect, that in some
21 cases, it actually gets worse because you see
22 all these degenerative things, and so many

1 patients think there's something wrong with
2 them.

3 And so, you know, really, it's
4 essentially a wash with any outcome if you
5 look across all these studies -- pain;
6 function; quality of life; patient
7 satisfaction -- and if anything, there's a
8 trend towards worse outcome in people who get
9 immediate imaging. So, hopefully, that
10 clarifies things a little bit.

11 I think there are still issues in
12 terms of how you manage patients day to day
13 and all that kind of thing.

14 The other piece of this, I think,
15 is that the RCTs don't capture some of these
16 downstream harms, but we have other studies
17 that people who get early imaging are much
18 more likely to undergo surgery and things like
19 that without any clear beneficial impact.
20 Right? It would be fine if they were doing
21 better, but they're also not doing better. So
22 there are a lot of downstream costs that

1 aren't captured aren't really captioning many
2 of these studies.

3 So I just wanted to make a couple
4 comments.

5 There are a bunch of hands up.
6 We'll get to you. I think John had his up
7 first.

8 DR. VENTURA: I think Webster's
9 study addressed that issue of cost well and
10 showed a fivefold increase if you have early
11 unindicated MR, as well as a delayed recovery
12 --

13 DR. DANIELS: I'm sorry; I was
14 misspeaking; x-ray, not MR.

15 DR. VENTURA: Oh, okay. Yes, I
16 thought he was addressing the MR issue, also.

17 DR. MATUSZAK: I guess what I
18 worry about with this measure is that you're
19 not really looking at what they're looking at
20 in most of these studies. In the studies,
21 you're looking at the time from the onset,
22 really, in saying that most back pain resolves

1 within four to six weeks, uncomplicated if you
2 work it. But really, you're not; you looking
3 at claims data.

4 And nowadays, especially with high
5 deductible plans and things, I couldn't tell
6 you the last time I saw an acute back pain
7 that came on acutely. I mean most of the
8 patients I've seen have already had it for
9 three to six months, and there's nothing in
10 here that really accounts for that.

11 You know, you talk about radicular
12 findings and stuff, but I work with the young
13 athlete population, and actually, in my 18- to
14 21-year-olds, my most common ultimate cause of
15 back pain is a stress fracture in the spine,
16 and that's not something that, you know,
17 again, is caused by a trauma, and it has this
18 long course before it comes up.

19 So, without having any information
20 about being able to subtract out for the long
21 lead time before that initial diagnosis is
22 made, I worry about how accurately this

1 reflects the evidence that's being presented.

2

3 CHAIR CHOU: Again, I can help
4 answer that little bit. So, in the six trials
5 or so that are out there, the inclusion
6 criteria are actually really varied. So a few
7 of them were focused on people who truly had
8 acute low back pain, but several of them
9 actually included patients with subacute or
10 even chronic back pain; so, longer than 12
11 weeks. And we tried to stratify by duration,
12 and there's really no difference. I mean
13 there are not a lot of studies, so it's hard
14 to see anything. But it's as far as we can
15 tell, there's no real difference.

16 Now, that being said, there is not
17 a whole lot of data about what to do with
18 somebody who's had back pain for two years.
19 I mean that's considered a red flag in a lot
20 of places. And so you're right; somebody
21 could present with back pain, and even though
22 it's their initial presentation, they could

1 have had it for two years or something, and
2 they would be -- I don't think they're
3 captured directly by the evidence. But we
4 also have no evidence showing that, you know,
5 they need to have an x-ray or whatever.

6 So anyways, there were a few
7 comments here.

8 Zoher?

9 DR. GHOGAWALA: So, just one point
10 of clarification because, JD, I see you're
11 concerned with the geriatric population. But
12 this measure -- correct me if I'm wrong -- is
13 18 to 50. So I think we should just
14 understand what, the measured population
15 group.

16 CHAIR CHOU: Are there other
17 people -- yes, John?

18 DR. FITZGERALD: I just have a
19 question about -- so we want to bring up an
20 issue about the exclusions. Is that under
21 specifications, or?

22 (Off-microphone comment.)

1 DR. FITZGERALD: I think Cat
2 raised some issues there too.

3 Are there other comments or
4 questions about the evidence?

5 Yes, Linda?

6 MS. DAVIS: Where is the data that
7 50 is the right upper limit?

8 CHAIR CHOU: So I can speak to
9 that, I think. I mean it, it's simply based
10 on the fact that the red flags -- being over
11 50 is a red flag for cancer. It's not a
12 specific red flag. We've traditionally had a
13 bunch of "red flags," and together, they have
14 a very high sensitivity, and age has been one
15 of them, traditionally. So that's the reason
16 for it.

17 Are there other questions?

18 Yes, JD?

19 DR. DANIELS: I don't want to
20 belabor the point, but I guess this is more of
21 a question to the staff.

22 When you say you've screened for

1 cancer or like that, when you do the
2 selection, so I assume that what happens is,
3 the way you found out is that someone had an
4 x-ray is that the diagnosis for back pain was,
5 like, rule out cancer, and that didn't count.

6
7 But otherwise, if the clinician --
8 what kind of happens is that when you're
9 worried about something -- it has to do with
10 the type of population you take care of. And
11 so, if you take care of a mostly healthy
12 population, and you see a serious problem,
13 most of the time, you don't just say, well,
14 Ms. Jones, I think you have cancer; we're
15 going to do these tests and find out.

16 Usually, what we do as we say, I'm
17 concerned about this. And so, when we do this
18 diagnosis -- it would be like a nonspecific --
19 we're going to kind of come back and kind of
20 talk to you. Where, if you go with a
21 different population, where most of the people
22 who are walking in your door presumably have

1 the disease or have a higher prevalence of the
2 disease just because they're there, it kind of
3 almost works backwards.

4 So I guess my question really, or,
5 my concern -- because I really agree with
6 everything Roger has said -- is not so much
7 that it's the wrong thing to do. It's more on
8 how you're collecting your data. And that
9 might have a reason why it hasn't moved,
10 because, I think there are some cases where,
11 if you came in with certain physical or
12 history-type findings than the one that Dr.
13 Dao had his big one a long time ago, where he
14 kind of went through and said, here's the
15 meta-analysis, and what really counts, and
16 that's one of them. So that's my comment.

17 CHAIR CHOU: JD, I want you to
18 hang onto those thoughts because I think we're
19 going to get to that when we get to the
20 feasibility and use kind of stuff. I think
21 those are kind of important questions, and I'm
22 going to have you guys respond to this when we

1 get there.

2 Are there other comments or
3 questions about the evidence. I think we'd
4 probably like to move it towards a vote here.

5

6 (No response.)

7 CHAIR CHOU: All right, let's vote
8 on the evidence.

9 MS. PHILLIPS: We're voting on
10 Measure 0052. We're voting on the evidence.

11

12 You have five options, "1" for
13 high, "2" for moderate, "3" for low, "4" for
14 insufficient evidence with exception, and "5"
15 for insufficient evidence.

16 The voting begins now.

17 Okay, we've got 22. We've got
18 five for high, 15 for moderate, one for low,
19 one for insufficient with exception, and zero
20 for insufficient.

21 CHAIR CHOU: All right, so this
22 passes the evidence criteria, and let's talk

1 about performance gap now.

2 I'll hand it over to Zoher:

3 DR. GHOGAWALA: The workgroup felt
4 there is a performance gap. Again, as I
5 mentioned before, they've looked at the rates
6 here. Whichever way you want to look at it,
7 the way they've scored it, it's a 75 for the
8 10th percentile and 90 for the 90th
9 percentile. So there is a range of practice
10 and probably for proof.

11 CHAIR CHOU: Cat or Carlos, do you
12 have additional comments to make here?

13 DR. ROBERTS: There were
14 additional disparities noted for minorities
15 and other ethnic populations.

16 CHAIR CHOU: Thanks.

17 In addition to the data that was
18 presented, I'm aware, at least, of other
19 published data showing that there are high
20 rates of imaging in Medicare populations, for
21 example, which I guess would mostly be
22 excluded from this measure. But other studies

1 have shown that as well.

2 Are there other comments or
3 questions about the performance gap issue from
4 the rest of the panel?

5 (No response.)

6 CHAIR CHOU: All right, let's go
7 ahead and vote.

8 MS. PHILLIPS: Okay, we're voting
9 on 0052 for performance gap.

10 You have four options, "1" for
11 high, "2" for moderate, "3" for low, and "4"
12 for insufficient.

13 The voting starts now.

14 We're up to 22.

15 We've got 10 for high, 12 for
16 moderate, zero for low, and zero for
17 insufficient.

18 CHAIR CHOU: So this passes that
19 criterion as well.

20 Let's talk about the high
21 priority.

22 Again, Zoher.

1 DR. GHOGAWALA: So, again, the
2 workgroup here felt like this is a very high-
3 priority item. Overutilization of
4 radiographic imaging for low back pain has
5 been identified in the literature repeatedly.

6
7 The other thing that was pointed
8 out by the developers is that the rate, in
9 particular, of CT imaging is sufficiently high
10 enough that if you look at a broad perspective
11 across the American population, there is
12 probably a meaningful oncologic risk
13 associated with that.

14 So, again, we felt it was a high-
15 priority item.

16 CHAIR CHOU: Are there additional
17 comments?

18 Carlos or Ted?

19 (No response.)

20 CHAIR CHOU: How about the rest of
21 the group?

22 (No response.)

1 CHAIR CHOU: All right, why don't
2 we go ahead and vote on the priority
3 criterion.

4 MS. PHILLIPS: Okay, we're voting
5 on priority for 0052.

6 There are four options, "1" for
7 high, "2" for moderate, "3" for low, and "4"
8 for insufficient.

9 Voting begins now.

10 We are at 22. We've got 19 for
11 high; we've got three for moderate.

12 CHAIR CHOU: All right, so we
13 passed the three must-pass criteria, and now
14 we're moving into the others.

15 First, we'll do reliability, and
16 again, I think we want to try to separate out
17 reliability and validity, which had been a
18 challenge for me. But I think the
19 specifications are mostly referring to whether
20 they are clearly specified. Right? So, not
21 whether we think this is necessarily the right
22 specifications -- that will come later -- but

1 whether it's clearly specified and whether
2 they're, and then the reliability is just how
3 reliable the testing is. And then we'll talk
4 about the validity stuff in the next section.

5 So, Zoher?

6 DR. GHOGAWALA: So, from a study
7 group perspective, again, separating the two
8 issues, from a reliability perspective, data
9 was presented by the developers from, I
10 believe, two sites. And the reliability, we
11 judged to be moderate based on our assessment
12 of the data.

13 CHAIR CHOU: Thanks.

14 Carlos or Cat, are there other
15 comments here?

16 (No response.)

17 CHAIR CHOU: Are there comments
18 from the rest of the panel regarding
19 reliability?

20 (No response.)

21 CHAIR CHOU: Would you be able to
22 briefly summarize what the reliability testing

1 showed, just so that everyone is kind of on
2 the same page here?

3 MS. WILLIAMS-BADER: Sure, happy
4 to.

5 We did the same type of analysis,
6 beta-binomial, as we did in the DMARD measure,
7 looking at and comparing the signal-to-noise,
8 and here we see that in the commercial plans,
9 there's actually a very high reliability score
10 of 0.99. In Medicaid, the reliability score
11 is, the average is the 94.

12 We also see that even in the
13 ranges of between 10th and 90th percentile,
14 that for commercial plans, it's .81 to .99,
15 with .7 being the threshold as high. It's
16 showing that the range for the 10th to the
17 90th as high reliability. For Medicaid, we do
18 see a lower end for the 10th to 90th of .64
19 to .98. But again, .7 is the threshold here
20 that we're looking at.

21 If you look at the histograms that
22 we provided, you can see that there are still

1 the majority of the plans falling at the .7
2 and above.

3 CHAIR CHOU: Thanks.

4 Are there any questions or
5 comments about reliability?

6 (No response.)

7 CHAIR CHOU: Let's go ahead and
8 vote on this criterion.

9 MS. PHILLIPS: Okay, we're voting
10 out reliability for Measure 0052.

11 You have four options, "1" for
12 high, "2" for moderate, "3" for low, and "4"
13 for insufficient.

14 Voting begins now.

15 Okay, we're holding at 21. So if
16 everyone could vote again, that would be
17 great.

18 We're still at 21 -- there we go.
19 Thank you. Okay. We have eight at high, 14
20 at moderate, zero at low and zero at
21 insufficient.

22 CHAIR CHOU: That passes.

1 Moving on to validity, this is
2 where I think there are more concerns or
3 issues to discuss. So again, I'll start with
4 Zohar, and then we'll move to Cat and Carlos.

5 DR. GHOGAWALA: I think I'll turn
6 this one directly to Cathy.

7 The workgroup, just as a summary,
8 had significant concerns about low validity
9 here.

10 DR. ROBERTS: Thank you.

11 So I'd like to refer to the
12 American College of Radiology appropriateness
13 criteria from 2011, and this is on appropriate
14 imaging of low back pain.

15 Those appropriateness criteria
16 list the exclusions that are listed in this
17 measure. However, they include several more,
18 and we feel that the absence of these
19 exclusions make the data that's being
20 collected less meaningful. Some of those
21 exclusions, which we think are missing and
22 should be there, are unexplained weight loss,

1 insidious onset; unexplained fever; history of
2 urinary or other infection; immunosuppression;
3 diabetes mellitus; prolonged use of
4 corticosteroids; osteoporosis; and prior
5 lumbar spine surgery.

6 Our group felt that it was
7 important to exclude any clinical findings
8 that suggest neoplasm or infection, and the
9 way that this is currently written, it does
10 not.

11 CHAIR CHOU: Are there other
12 comments from the group before we let the
13 developers respond?

14 DR. GHOGAWALA: You rock, Cat.

15 (Laughter.)

16 CHAIR CHOU: Jenna, would you like
17 to respond?

18 MS. WILLIAMS-BADER: Absolutely.

19 I definitely welcome those
20 comments, and I think they are worthwhile for
21 us to think about in the future. To give you
22 history, we did actually look at some of those

1 during our field testing, and we found that
2 their rates for those were quite low.

3 Now, one reason why they might
4 have been low is that claims might not be the
5 appropriate place to capture some of those
6 types of exclusions. Unexplained weight loss
7 is jumping out at me as one, and we actually
8 did look at that one during field testing and
9 only found 28 cases out of 22,000. So I'm not
10 saying that it's not more common than that.
11 It's just that in claims, that might be
12 difficult to capture.

13 We're actually really interested
14 to see how the e-measure performs. Again, we
15 do have an e-measure that's included in
16 meaningful use. And the electronic health
17 record does give us the opportunity to look at
18 symptoms and other types of information that's
19 not readily available in claims.

20 I will say, though, that as much
21 as we want the EHR to be telling us about
22 symptoms, it does not, as well as it should.

1 The availability of that information is
2 actually quite low. But we do think that it's
3 a promising data source for these types of
4 overuse measures, where the claims may not
5 help us to identify all of the key exclusions.

6 CHAIR CHOU: Go ahead, Cat.

7 DR. ROBERTS: Thank you.

8 I really appreciate those
9 comments, and I'm glad you that you'll look
10 into them. I do feel it's important for these
11 measures to be as meaningful as possible, and
12 I really feel bad for practices that might
13 have a disproportionate number of post-op
14 patients or immunosuppressed patients. And if
15 we look at the metric, it will show that they
16 are giving substandard care, when they're not;
17 they're giving appropriate care.

18 So people spend an enormous amount
19 of time writing these. They spend an enormous
20 amount of time collecting data for these. So
21 I still believe we should endeavor to be as
22 meaningful as possible when these are written.

1 CHAIR CHOU: Go ahead, Mary.

2 DR. BARTON: One of the things
3 that we have found in health plan measurements
4 is that the threshold of potential exclusions
5 that we try to incorporate in measures -- we
6 usually use two percent as sort of a rough
7 estimate.

8 So things that happen super-
9 rarely, it doesn't, the health plans have told
10 us it's actually not worth their while to
11 track down, because it's not going to affect
12 -- and also, when we imagine across health
13 plan -- I'm not saying this is true for
14 provider groups. I think you make an
15 excellent point about provider groups -- but
16 across health plans, the idea that
17 immunocompromise in people under the age of 50
18 with sort differentially and one health plan
19 could have more than another, that's hard to
20 imagine.

21 So I think that, you know, while
22 these are issues that absolutely play into

1 clinician decision-making on a one-on-one
2 basis, they have not been at the level, at a
3 health plan level, where we have heard
4 feedback. And believe me, when health plans
5 believe that we are measuring something that
6 is unfair, they're so not shy about letting us
7 know that.

8 (Laughter.)

9 DR. BARTON: So I would be
10 curious, and I think I'd be interested to go
11 back to some of our health plan partners and
12 find out about their thoughts about these
13 issues because, certainly, you make a
14 compelling case. And I think, you know, in
15 particular, the provider group assessment or
16 the individual physician assessment, those
17 exclusions would help immensely with the
18 credibility of the measure.

19 CHAIR CHOU: So Helen and Jenna
20 and Zoher all want to say something.

21 I just wanted to say -- this isn't
22 going to help because it just makes more

1 things more complicated -- the risks factors
2 are very complex. I mean some of these are
3 very weak risk factors. So, unexplained
4 weight loss, insidious onset -- the predictive
5 values are very low. You know, you increase
6 your likelihood of cancer from .8 percent to
7 like 1.2 percent. It's trivial, almost.
8 Whereas, having a history of cancer is
9 actually a much stronger risk factor. It
10 brings you to 1 percent from 1 percent to 10
11 percent.

12 And so it's very hard, actually,
13 to do this in a measure to try to incorporate
14 all of these different risk factors, some of
15 which are very minor and uncommon -- you know,
16 having vertebral infection is actually quite
17 uncommon, but having a stress fracture is
18 relatively common in people who have risk
19 factors for it. And how do you kind of put
20 all this stuff in? So this just speaks to
21 some of the challenges that measure developers
22 face in trying to deal with this, and kind of

1 some of the decisions that have to be made in
2 terms of what they can do and what they can't.
3 I mean it's a huge issue.

4 We struggle with this trying to
5 even provide clinical guidance; what we tell
6 somebody if you have a patient over 50? Do we
7 say that they all need to be imaged? They
8 used to say they should, and we've actually
9 came back, the ACP at least, has said it's
10 reasonable to manage them first if they don't
11 have any other red flags and that kind of
12 thing.

13 But, Helen?

14 MS. BURSTIN: Thanks very much,
15 and actually, just to bring us back to the
16 criterion, specifically that the exclusions
17 are supported by clinical evidence and that
18 there should be evidence of sufficient
19 frequency of occurrence, such that the results
20 are distorted without the exclusion. So what
21 we don't want to do is overburden the measure
22 with lots of things that may be clinically

1 logical, and at the doc sitting in front of a
2 patient, you would consider some of those.
3 But in terms of fairness and measurement, you
4 don't want to overburden the measure.

5 We specifically want to make sure
6 that it would only be those exclusions you
7 would include that, otherwise, if you didn't
8 have them, the results would be distorted. So
9 I think that gets at some of this issue of the
10 key issues around sensitivity analysis,
11 essentially, and understanding issues of
12 positive predictive value.

13 MS. WILLIAMS-BADER: Yes, I just
14 have one more thing to say, and that's
15 actually, going through this NQF process and
16 initiating some discussions with the woman
17 group about their MRI measure, which is coming
18 next, has given us the chance to compare the
19 exclusions that are in their measure to the
20 ones in ours, and we do want to continue those
21 discussions?

22 We think that making those changes

1 to our measure or us are significant enough
2 where we would need to run them through our
3 typical process, which is to pull together
4 experts and discuss them, and potentially even
5 put it to public comment. But we do see that
6 there is an opportunity for us to think about
7 some of these other exclusions.

8 DR. ROBERTS: I'll just say I'm
9 surprised that lumbar spine surgery is a rare
10 event.

11 CHAIR CHOU: JD?

12 DR. DANIELS: Oh, again, I'm just
13 going from the stuff I saw. I think they are
14 urinary thing did pan out, and I also thought
15 it sort of is, you know, in how you word this.
16 You might need a different word. But night
17 pain -- those were two that I thought
18 separated out.

19 Part of the reason that at least
20 I'm bucking so hard on this is that I think
21 what you've got here is you've got a problem.
22 There's a hole in the boat, and instead of

1 trying to fix the hole, you're throwing a
2 bail. And you're not really fixing the
3 problem.

4 So what happens is, in primary
5 care, you know, they talk about shooting
6 zebras and all this stuff, so we don't really
7 see -- you know, the way we decide if it's a
8 zebra is -- we're not up on the high bluff
9 with a high-powered rifle that can see the
10 zebras like the specialists, if you want to
11 say it that way. What we really know is what
12 a horse really, really looks like. So what
13 happens is, these people come in and they go,
14 you're not a horse. I'm not really sure what
15 you are today, and you may just be a weird
16 looking horse.

17 But the big thing is that most
18 people come in with back pain, they just need
19 to be reassured. But what happens is the
20 thing that kind of keeps me sane when I get up
21 in the morning and look in the mirror -- it's
22 a hard job -- is that, you know, I really try

1 to do with the best. And so, on those cases
2 that kind of pop up, you almost have to do it.

3
4 And I think what this may be doing
5 is kind of -- you know, doctors pay attention
6 to this stuff. I know you guys are looking at
7 the big healthcare level in stuff, but you
8 know, it's sort of like part of the fiber of
9 what makes you do what you do. That's my
10 whole issue on this because we're spending a
11 lot of time and effort measuring this, but I
12 think you're looking in the wrong spot.

13 CHAIR CHOU: So JD was doing all
14 the football allusions yesterday, and now we
15 are to animals and boats.

16 (Laughter.)

17 DR. DANIELS: Yeah, the Navy,
18 yeah.

19 CHAIR CHOU: So I think what
20 you're saying is that it has to do with, there
21 has to be some additional exclusions, that
22 you're concerned that the denominator is

1 incorrect. Is that right, basically?

2 Did the developer -- Zoher, and
3 then we'll -- go ahead.

4 DR. GHOGAWALA: You know, one of
5 the things, just to follow on what JD is
6 saying, is that this is a really hard problem
7 because the patient population here is
8 incredibly heterogeneous, and one of the
9 issues, I think, is if you're trying to
10 improve quality in this area -- and I would
11 submit to you that so far, it looks like
12 you're not -- is that you need to do something
13 that actually is giving the type of feedback
14 that would improve quality. And one of the
15 ways to do that, I think, is rather than
16 saying will come up with this complex list of
17 inclusions and exclusions for a very
18 heterogeneous population, is to recognize, I
19 think, that there is a role for judgment. I
20 think that's what JD was getting at. There's
21 a role for physician seeing a patient with
22 back pain, and exercising judgment. Okay?

1 And certainly, there are very well
2 known risk factors, and there's good evidence
3 here, but it seems to me, if I were just sort
4 of stepping back from this after looking at
5 the entire measure, what we want to do is we
6 want to avoid imaging patients that don't have
7 anything wrong with them that need further
8 treatment.

9 And so -- again, looking at the
10 RCT data, which is slightly different from
11 this measure, to me it seems that what you
12 want to do is you want to sign a measure that
13 allows for the identification of patients, the
14 number of patients of the percentage of
15 patients, that were imaged that didn't have
16 anything wrong, and that requires follow-up.

17
18 There's some more recent data from
19 Canada, which I think is doing this very, very
20 nicely. They're looking at nurse triage or
21 nurse practitioner-type triage mechanisms
22 where the patients are evaluated, no red

1 flags, no imaging, but they're followed up
2 four to six weeks, mandated. Okay? And then
3 they determine whether in fact there is
4 something that's not the usual course, and
5 then they make those decisions. That has
6 reduced MR utilization dramatically. That was
7 published a few months ago. So I think
8 there's an opportunity here. But I worry that
9 in its current iteration, it does just as
10 invalid.

11 Furthermore, relying on claims
12 data to say that certain things are very, very
13 incompetent uncommon, I think, is dangerous
14 because certain things may be in fact more
15 common than we can cull from administrative
16 data.

17 But my concerns are significant
18 with validity.

19 CHAIR CHOU: I'll let the Jenna
20 respond to that.

21 I just wanted to say I understand
22 everyone and I agree with a lot of these

1 issues. But I also think that this is an
2 issue with all measures. I mean there's
3 always exclusions that aren't accounted for,
4 and that's why you're going to get to 90
5 percent. There's going to be 10 percent of
6 patients without an obvious red flag who are
7 imaged, and we'll actually say that those
8 patients are probably doing pretty good if 90
9 percent of the patients -- but there's a
10 problem with 50 percent of the patients with
11 no red flags are getting imaged.

12 My understanding is that that's
13 how a lot of these measures are designed to
14 work. You know, that it's not expected the
15 places won't necessarily get to 100-percent.
16 There is a way to compare one site versus
17 another. There is this case mix issue, of
18 course, but there's ways that that can be
19 addressed and, you know, with the way that
20 things are set up.

21 But anyway, I'll let Jenna respond
22 if you have any other responses to Zoher's

1 comments.

2 MS. WILLIAMS-BADER: I think you
3 actually covered what I was going to say,
4 which is that we don't expect performance to
5 be 100 percent, and so what we are looking for
6 is differences between variation among plans.
7 And there is that variation, indicating that
8 that while we don't know what the upper rate
9 should be, we know some plans are able to get
10 to a certain rate, and if there are plans
11 below that, then we see that there's room for
12 them to improve.

13 CHAIR CHOU: I think Thiru and
14 then Jason.

15 DR. ANNASWAMY: Just along the
16 lines of what you just said, Roger, I think
17 the way we can reconcile this and introduce
18 the possibility of judgment and uniqueness of
19 your health plan your practice would be the
20 usability and use area. So we're not saying
21 that we're going to come down with a big sword
22 or axe on your health plan if you are at 75 or

1 85, but maybe there is opportunity for
2 education, introduction of new practice
3 patterns, like a nurse practitioner follow-up,
4 et cetera, to know to that number up.

5 So the measure is a measure of the
6 measures; right? I mean how you use it would
7 be where some of these other factors would be
8 introduced to make a difference to the
9 outcome.

10 DR. MATUSZAK: Yeah, those
11 interventions are every time I have to get on
12 the phone to get a prior authorization and
13 talk with some doctor in a distant place
14 because I want to get an MRI scan for somebody
15 less than 28 days after the ICD-9 code goes in
16 for the first time. You know, those are the
17 interventions that they put in place, which
18 really just burdens us even more, which I
19 think does factor into this.

20 But I'd submit that I think that
21 maybe some of the movement that you're not
22 seeing in this is because we've reached that

1 noise level here where the heterogeneity has
2 reached a point where there's so much that
3 comes down to the doctor's discretion, that
4 these are patients that, I don't know how much
5 better we're going to do with these. I think
6 that most docs do a pretty good job of trying
7 to do this, and maybe the randomized
8 controlled trials that show that the outcomes
9 don't matter is beside the point.

10 But I don't know that these few
11 catchall ICD-9 codes that kind of get used for
12 any imaging study that we want to do is
13 concerning the low back, in most cases, is the
14 most valid method of capturing the type of
15 information that you're trying to capture, and
16 that, I would submit, is almost fatal flaw
17 with this.

18 I just don't feel that the
19 validity is there for what you're trying to
20 accomplish.

21 MS. WILLIAMS-BADER: Yes, I did
22 want to speak to the face validity because I

1 haven't covered that well.

2 When the measure was first
3 developed, as I said, there was one panel on
4 pain that recommended it, and went through
5 musculoskeletal workgroup. It went to public
6 comment period. Then those results were
7 discussed both with our musculoskeletal expert
8 workgroup as well as with our committee on
9 performance measurement.

10 When the measure was reevaluated
11 in 2012, again, we pulled together bone-joint
12 measurement advisory panel and also took the
13 measure to CPM as well. I think there was an
14 acknowledgment that we are approaching a time
15 where we might want to think about whether
16 this is as good as we're going to get. But
17 because we are still seeing variation -- and
18 I'll just point you to the fact that both the
19 10th and 20th percentile are 70 to 75-percent
20 across the two lines of business -- that is
21 showing the, I don't know that the CAC would
22 be at 70-percent.

1 Lastly, as we mentioned before,
2 this is a choosing-wisely topic, indicating
3 that even though physicians think they might
4 be doing this, they're still not quite
5 encouraging the watchful waiting, as we would
6 hope.

7 DR. BARTON: To say that the
8 societies who put this forward under choosing
9 wisely didn't think that it's been solved
10 already because they're saying to patients
11 that they should rethink and ask the question,
12 do I really need to be imaged?

13 So I can't imagine who, other than
14 the ordering clinicians, would know better
15 whether they are using this at a frequency
16 perhaps higher than is clinically indicated.

17 DR. MATUSZAK: But that's not
18 really what you're measuring here. You're
19 measuring from the time that ICD-9 code gets
20 going, and whether or not there's an imaging
21 study in the next 28 days. You're not
22 measuring from the time of onset. You're not

1 measuring, you know, anything else other than
2 that. That's why I'm saying I don't know if
3 that's the most valid way of capturing the
4 data, which I agree support, but I don't know
5 that that's it.

6 CHAIR CHOU: Doesn't that 180-day
7 exclusion prior to the first visit prevent
8 that?

9 DR. MATUSZAK: Only on the ICD-9
10 codes. If it's not input in the 180 days
11 prior to that, then -- you know, again, so
12 your patients are coming to see you not
13 anymore because they have an acute back strain
14 that happened a few days ago. Because of the
15 high deductible plans, now they're coming in
16 six months afterwards, and they've already
17 tried three different things to try and work
18 through the problem themselves. But you're
19 not capturing a lot of that. And I would
20 submit that I think that's an increasing
21 problem, especially with the way people have
22 been delaying care more so in recent years,

1 with these high deductible plans.

2 CHAIR CHOU: Christian?

3 DR. BARTON: I guess my concern --
4 I agree with all the points, but what is the
5 concern about the measure going into place
6 without these caveats and these additional
7 exclusions? I mean I think we would all
8 acknowledge that the over-utilization is
9 absolutely a problem, that the amount of yield
10 we're getting from these images is relatively
11 low. So, sure, we can all cite examples of
12 times where we found that the zebra and it was
13 really important to that individual patient.
14 But if we include these exclusions, we're not
15 fundamentally changing the yield on all those
16 other exams that come out without clinical
17 significance.

18 And so, while I agree with all of
19 those comments -- I also agree with the
20 limitations logistically and including low
21 prevalence exclusions -- I was wondering if
22 you could just articulate what is the end

1 deliverable here is that you're looking for.

2 DR. ROBERTS: Sure, and that's a
3 great point because I get what you're trying
4 to do. I do. And I completely agree with,
5 you know, the standards that are in the
6 literature I absolutely do.

7 My concern is eroding provider
8 confidence in our metrics. We've all come
9 together today, we've come long distances,
10 we've spent a lot of time, to try to make
11 these measures as good as they can possibly
12 be. And I don't know if you've had the
13 personal experience, but I certainly have,
14 where my institution gets a metric back that
15 says I'm giving substandard care. And it's
16 the way they do the metric.

17 At that point, some people just
18 turn off. You know? They say forget it. The
19 way you do that metric, you're not even
20 counting people who -- they have cancer? I'm
21 not going to let my patient be hurt. Of
22 course I'm going to image them. And when

1 these metrics are messy, that's what happens.
2 We erode confidence of our providers, of our
3 patients, and that's why it's important, I
4 think, we bring this up and we talk about them
5 and try to hold everyone to the highest level
6 we possibly can.

7 People are getting more and more
8 savvy about this every day, and it's not just
9 the providers, not just the health plans, it's
10 the consumers too. So, if they realize that
11 these aren't meaningful measures, it's a
12 slippery slope. So that's my concern.

13 CHAIR CHOU: Linda?

14 MS. DAVIS: I would echo that for
15 employers as well.

16 I work with employers, and they
17 look at, in our market in particular, and we
18 have several health plans -- not several; a
19 few -- that all overlap in terms of their
20 provider networks, but there are different
21 NCQA ratings, and they look at that and
22 scratch their heads going, so we've got the

1 same providers in every network and they're
2 all doing kind of the same thing, and we can't
3 really tell the difference, but why are there
4 differences in the scores of various health
5 plans? The health plans get to dance and
6 explain what that is.

7 But it's still kind of a scratch-
8 your head kind of thing and lack of
9 confidence in the measures.

10 CHAIR CHOU: I think we're going
11 to try to close because we're overdue for
12 lunch.

13 Just to summarize, I think, where
14 we were at, there is some concerns about the,
15 you know, how the denominator was defined in
16 terms of, you know, presentation -- ICD-9
17 code, I should say, rather -- necessarily
18 knowing exactly when the pain started. And
19 then there were some concerns expressed about
20 not having some exclusions on there. Those
21 are the main issues that were brought up.

22 And then we also kind of talked

1 about how the measures used.

2 I actually, you know, I actually
3 think 75 to 90 percent is pretty good for a
4 measure in terms of people being able to
5 comply with it, so it doesn't seem like most
6 places have had a terrible time trying to --
7 I mean those numbers are actually better than
8 I would expect looking at the literature in
9 terms of inappropriate imaging rates. So, if
10 anything, it seems like it's underestimating
11 inappropriate in imaging, you know, however.
12 But I think there were concerns that it would
13 be overestimating inappropriate imaging by not
14 having some of these exclusions and things
15 like that.

16 But let me pause there. Are there
17 final comments before we go to a vote?

18 I think we need to vote. Yes,
19 solar?

20 DR. GHOGAWALA: Sure, Roger, just
21 to follow up on that because there was a
22 comment in the review from someone outside the

1 review group.

2 I think one of the problems here
3 is that this an administrative coding kind of
4 data, and so it probably does underestimate
5 the problem. And I would submit, therefore,
6 that it is not helping to address the problem
7 because, when a clinician writes down, you
8 know, spinal stenosis as the cause of the
9 back, or herniation, it's not captured whether
10 they know that that's the case or not. And a
11 lot of people, on their MRI, will have these
12 things.

13 So it is a tough one because this
14 is relying on coding information to solve a
15 problem that may not be solvable with a code.

16 CHAIR CHOU: Yes, I can't put
17 suspected radiculopathy; it's not an ICD-9
18 code. You have to either put low back pain or
19 some other, something else that you know won't
20 cause a flag.

21 Cathy, do you want to say
22 anything? And then I think there was a

1 comment everywhere.

2 (No response.)

3 CHAIR CHOU: No.

4 All right, so I think we're going
5 to have to put this to a vote.

6 Remind me again -- they've done
7 the must-pass things, but they still have the
8 pass these, though, before everything is
9 passed.

10 Okay, so we're voting on the
11 validity now.

12 MS. PHILLIPS: We're voting on
13 0052, validity.

14 You have four options, "1" for
15 high, "2" for moderate, "3" for low, and "4"
16 for insufficient.

17 The voting begins now.

18 Okay, we are at 22. We got one
19 for high, seven for moderate, 10 for low, and
20 four for insufficient.

21 CHAIR CHOU: That seems to be our
22 30 percent threshold. We keep going, though;

1 right? Or do we stop here? All right.

2 MS. BURSTIN: We should probably -
3 - this does stop it in terms of our evaluation
4 today, though, but just in terms of the
5 exclusions that are actually included in the
6 measure, I just want to get a sense of the
7 committee's appetite.

8 Certainly, some of the exclusions
9 we've been talking about, like cancer, are
10 actually exclusions in this measure. So it
11 might be helpful to see if NCQA can go back
12 and actually provide additional data back to
13 the committee, if you'd like to see it, on the
14 other rate of exclusions. What's included?
15 What's not? How do the rates change? Because
16 I think it's been, it's a great discussion,
17 and your points are well taken, and we don't
18 want to erode confidence in the measures. We
19 don't want to erode confidence in the
20 measures.

21 We also want to be sure there's a
22 fair opportunity to look at what the data

1 actually shows in terms of the proportion of
2 some of those exclusions that may already be
3 included or may not be excluded and just get
4 a sense of it.

5 CHAIR CHOU: Thanks, Helen.

6 It seems to me like you guys would
7 have some of this data, so it would be
8 interesting for me to see how many people who
9 are, you know, being flagged as getting
10 inappropriate imaging have had prior back
11 surgery or have some of these other things.
12 If we know what those percentages are, I think
13 that helps in terms of assessing, you know,
14 their importance.

15 And then the other piece of this -
16 - I don't know if you're able to do this -- if
17 you're actually able to see, you know, and
18 patients are classified as not meeting this
19 criteria -- so they get an image when they
20 don't have any red flags -- how many of these
21 actually end up having cancer, an infection,
22 or something like that. I don't know if you

1 can do that, but that would be the other side
2 of it.

3 Are there other comments?

4 I mean I'm not sure how to address
5 Jason's concern about time from onset. That's
6 not just an issue with measure development;
7 that's an issue with just trying to do studies
8 on low back pain. Like, if you have an
9 administrative database or something, it's
10 extremely difficult to sort out when the back
11 pain started. So I'm not sure that these guys
12 can solve that, but I think that was the other
13 big concern.

14 Yes, Thiru?

15 DR. ANNASWAMY: perhaps if there
16 are more data like that to where you can tell
17 what is the difference, the true difference,
18 between what you're trying to measure, which
19 is uncomplicated low back pain, and the
20 muddied water of complicated low back pain
21 that presents as uncomplicated, potentially.
22 If there is a percentage difference, then

1 perhaps the recommended benchmark would be a
2 way to resolve this.

3 I can only give an analogy. For
4 example, inpatient rehabilitation -- there is
5 a 60-percent rule for admission. So 60-
6 percent of the patients admitted into
7 inpatient rehab units have to meet and
8 inclusion diagnosis of five or six. There is
9 a proposal to make it a 75-percent rule, which
10 would be more restrictive. But that's being
11 pushed back by inpatient rehab providers
12 saying there's just not, we don't want to be
13 too restrictive, or we're going to have to
14 turn away patients that are not in these
15 diagnoses, because we potentially see more of
16 them in our facility than otherwise. So the
17 60 to 75-percent makes a huge difference in
18 the amount of pushback you get.

19 Perhaps there is a benchmark that
20 you could use to say, because we understand
21 there's differences between different health
22 plans and mixes, this is what we think we

1 should shoot for.

2 DR. PACE: But the measure as it's
3 constructed doesn't set any benchmark.

4 DR. ANNASWAMY: Right.

5 DR. PACE: Okay -- so it's not
6 saying what it has to be. It's a comparative
7 performance -- okay. All right.

8 CHAIR CHOU: JD?

9 DR. DANIELS: I'd just like you to
10 kind of go back because I may just be all
11 wrong on this. But some of this stuff Cat
12 mentioned, I thought, had shown -- it didn't
13 use the exact words, but it may have shown
14 that it made a difference. Like, urinary
15 symptoms and night pain, those kinds of
16 things, which, they're kind of indirectly --
17 but that's not an ICD-9 code.

18 So, you know, as far as you
19 capture it, I'd feel a lot more comfortable
20 with it if you kind of had that as an
21 exclusion. I'd be fine.

22 CHAIR CHOU: So there are several

1 issues with the red flags. One is how well
2 they actually predict the condition, so
3 essentially, the likelihood ratios and
4 positive predictive values with them. And
5 with UTIs at least, there isn't a lot of data
6 because we don't have a lot, there's not a lot
7 of vertebral infections. That's what you'd be
8 concerned about. But at least for
9 constitutional symptoms, it's quite weak.

10 DR. DANIELS: Yes, and even just
11 urinary symptoms, remember, they'll cover more
12 than just a UTI. It covers other neurological
13 things.

14 CHAIR CHOU: Yeah, with cauda
15 equina or something like that. But my second
16 point is it's not just the positive predictive
17 value. It's how frequently frequent the
18 condition is. So cauda equina is quite
19 uncommon, and vertebral infections are quite
20 uncommon.

21 So, even if you have something
22 there, then I might not be particularly -- it

1 might be for a condition that just doesn't
2 occur very much. And so both of those issues,
3 I think, is what makes this complicated.
4 There is a whole slew of things. I mean if
5 you took all the red flags, you know, you
6 would end up with, most people should be
7 imaged, and we know that's clearly not the
8 case. So that's the problem, is that there's
9 so many that have been described and so many
10 of these predictors that, how do you, you
11 know, separate out the ones that are the most
12 important?

13 I think that's what makes it --

14 DR. DANIELS: Well, there's a
15 whole set of predictors we're not looking that
16 wasn't even brought up.

17 The New Zealand folks are, I
18 think, light years ahead of us. They've got
19 the yellow flags, which are basically the
20 psychosocial things that hit because I think,
21 in real life, sometimes what happens is the
22 average doc that sees them, they're not just

1 doing the x-ray to get the patient out of
2 their hair. It's like the patient goes, I'm
3 having trouble, and you've got to kind of
4 convince them to go back and work or do
5 whatever. And so that one might be a good
6 one. I mean there's pretty good data about,
7 that that's more like longitudinal, but kind
8 of looking at that, you know, and that might
9 be helpful so that there's, like adding that
10 code.

11 CHAIR CHOU: Yes, I this is not
12 addressing yellow flags. These aren't imaging
13 things. But we certainly have yellow flags,
14 too; we have purple flags and other things
15 also. There's all sorts of colors.

16 But I would -- just one thing in
17 terms of the evidence -- and again, a lot of
18 my work has been in low back pain, and so the
19 idea that imaging somebody, you know,
20 reassures them just hasn't been proven, and it
21 actually has been shown that it causes harm
22 because people feel like they can't -- you

1 know, they start worrying about their back.

2 It's an attractive kind of idea,
3 but it just -- if you look at the literature,
4 if anything, it's a wash, or it makes people
5 worse -- so I think I'd just be cautious about
6 presenting that as a reason for imaging.

7 But I think all of these other --
8 you know, there are a lot of potential red
9 flags. I think that beta would help to figure
10 out which ones need to be in and which ones,
11 you know, we don't have to worry about so
12 much. And then, like I said, this issue about
13 how do you define, you know, the population --
14 the 28 day thing -- or the onset of low back
15 pain. I think that's a real challenging one.
16 I'm not sure the best way to do that because
17 I know that we deal with that just trying to
18 do research and that in this area as well.

19 So are there other comments?

20 (No response.)

21 CHAIR CHOU: All right.

22 Are we supposed to take public

1 comments now, or do we break for lunch?

2 MS. STREETER: Operator, at this
3 time, could you please open up the line and
4 see if we have any members of the public that
5 would like to make a comment?

6 OPERATOR: If you would like to
7 make a comment, please press *1 on your
8 telephone keypad.

9 (No response.)

10 OPERATOR: And there are no
11 comments at this time.

12 MS. STREETER: Also, real quick,
13 just one more process point.

14 As part of our new standing
15 committee policy, we are appointing you two-
16 or three-year terms. So this is a stagger on
17 when people join them leave the committee.

18 You may have the chance to renew
19 after your term, so don't get upset if you'd
20 like to stay for three and we give you two.

21 Basically, during lunch, we will
22 be walking around and asking you to draw a

1 number out of the cup, and that's how we will
2 be appointing your term.

3 DR. ROBERTS: And two-year terms
4 are renewable, of course, so don't worry
5 you'll be with us forever.

6 CHAIR CHOU: So let's break for
7 lunch, and then we have one more measure.

8 (Whereupon, a lunch recess was
9 taken at 12:52 p.m.)

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

1:17 p.m.

CHAIR CHOU: The level of analysis and the care setting were reversed, so the level of analysis should be health plan, integrated delivery system, and the care setting or those other things, ambulatory care, clinician office, clinic, urgent care hospital, acute care facility, so I just wanted to make sure everybody knew that.

If there's a feeling that that would change your decision regarding the validity thing, please speak up. Otherwise we'll just move on here. Any concerns or issues here?

I think people are pretty clear on the conversation. We just want to make sure people - you know there wasn't confusion there.

Okay, so we're moving to our last measure which is Measure 0514, MRI lumbar spine for low back pain. This is CMS and we

1 have the developers here. Could you give us
2 a brief overview.

3 DR. BRUETMAN: Okay, yes, I don't
4 know if CMS is on the line, so good afternoon.
5 I'm Dr. Bruetman, Charlie Bruetman, from
6 Lewin, and we've been developing this measure
7 with CMS.

8 With me I have my colleagues Kelly
9 Anderson and Colleen McKiernan, and on the
10 phone I believe is Dr. Nicholas Staedtler if
11 we have any questions as well. Maybe Dr. - I
12 think Dr. Nakano was going to try to join, but
13 with the change in schedule, I'm not sure, and
14 Fiona Larbi is on the phone.

15 So I will give an overview on the
16 measure, and I know there is - hopefully it's
17 not going to create more confusion because
18 it's very similar to the prior measure that
19 was discussed, so we'll clarify any issues as
20 we go along.

21 Basically this measure is -
22 calculates the percent of MRI lumbar spine for

1 low back pain without any prior evidence of
2 conservative treatment. It is a claims-based
3 measure and there's a very high prevalence of
4 this low back pain, and it is based on, as was
5 discussed previously and Choosing Wisely was
6 selected as a top priority by the American
7 Academy of Family Physicians, it is considered
8 the fourth most common reason for office
9 physician visits as they state, and as I said
10 it was selected in Choosing Wisely initiative
11 it is great - they are Number One and I'm not
12 saying it's rated Number One, but it's top on
13 the list of the 15 things they consider for -
14 that physicians and patients should question.

15 They state that basically that you
16 should not do imaging for low back pain within
17 six weeks unless the presence of a red flag,
18 for example a progressive neurological
19 impairment.

20 American College of Radiology also
21 states that uncomplicated acute low back pain
22 is a benign self-limited condition that

1 warrants no imaging, and having the test
2 performed soon after the start of a low back
3 pain and this is evidence that was one of the
4 reasons it was selected for Choosing Wisely is
5 that if you do have that fares no better for
6 the patient and they also state that an MRI in
7 just a month increases by almost eight times
8 the chance of having the surgery and five
9 times the medical expenses incurred and with
10 no faster recovery is seen.

11 The goal of the measure is to - I
12 would say is twofold. On one hand it is -
13 there is no benchmark on the measure so we do
14 a calculation of the rate, and it is to
15 decrease the overutilization of this MRI for
16 low back pain without conservative treatment,
17 and it also - we are also are looking at the
18 outliers and try to reduce the outliers
19 getting them closer to the mean as it is a
20 publicly reported measure by CMS.

21 This measure was endorsed in 2008
22 by NQF, and was re-endorsed in 2011 and has

1 had very strong support from the medical
2 community either expressed through comments or
3 discussions we've had along the way.

4 All our measures when we discussed
5 it it's not only it's based on the evidence of
6 literature reviews that we do, but also we
7 have a technical accurate panel that's been
8 working with us of clinical experts, and they
9 have been supporting - very supportive of this
10 measure.

11 Along the way we've also had
12 discussions with American College of Radiology
13 and other entities to ensure that we are
14 addressing the major needs of this - in
15 addressing the evidence presented.

16 The measure just to be sure - this
17 is - one of the - just to clarify how our
18 measure is done, basically this measure has a
19 denominator includes the MRI for lumbar spine
20 studies with a diagnosis of low back pain on
21 the initial claim and the numerator is from
22 the denominator cases for patients that do not

1 have claims-based evidence of a prior
2 conservative therapy, and we have a series of
3 exclusions among them - I'll cite some -
4 there's cancer, trauma, intravenous drug
5 abuse, neurologic impairment, HIV, other
6 immune deficiencies and abscess and there are
7 a number of additional exclusions that we also
8 have provided.

9 So basically that has been an
10 overview of the measure. If there are any
11 questions for the committee.

12 CHAIR CHOU: Thank you, so the
13 lead discussants on this one are Craig, Thiru,
14 and Katherine. Does one of you want to take
15 the lead? Go ahead, Craig.

16 DR. BUTLER: I've been appointed
17 to volunteer. So just without being
18 repetitive just I want to emphasize the level
19 analysis here is the facility, and I have some
20 questions because I seen imaging facilities
21 and care facilities and maybe we can talk
22 about whether that in the context of where

1 health care is moving affects our judgment of
2 this measure entirely.

3 Additionally, it is classified as
4 an efficiency measure, and as we heard
5 earlier, we're going to process this as a
6 process measure, so my job is really to talk
7 a little bit about the evidence and just a few
8 facts and bullet points about evidence.

9 It is not a health outcome
10 obviously. It is based upon a systematic
11 review of about 15 guidelines and the girding
12 underneath those guidelines thee is a total of
13 48 studies, and the summary is provided so
14 that I'm not suggesting everybody walks
15 through this diagram or algorithm as I did,
16 but as I walked through it, it still leaves us
17 with three options to rate as high, moderate,
18 and low.

19 Obviously when we try and make
20 those distinctions we're looking at three
21 things - the quantity, the quality, and the
22 consistency, and I think we can agree that

1 there's plenty of quantity here and the
2 consistency in those studies is pretty high as
3 well.

4 I do have some questions because
5 they do break down the categories in those 48
6 studies which would be the foundation of the
7 quality of the evidence and I see what, 40 of
8 the 48 studies are rated in Category 3 and 4,
9 so it suggests that the overall quality of the
10 evidence is relatively low, and in fact they
11 have zero in Category 1, and so that was my -
12 and, again, you know, everybody makes your own
13 judgment about where you - how you weight that
14 factor, but we get pretty far down the road
15 and we have some choices and I think that's
16 the distinguishing feature.

17 CHAIR CHOU: Thanks, Craig. Thiru
18 or Katherine.

19 DR. ANNASWAMY: I don't have
20 anything to add to that.

21 CHAIR CHOU: Okay, Katherine?

22 DR. GRAY: Nothing to add either.

1 CHAIR CHOU: All right. I'm going
2 to open it up to the rest of the panel. Do
3 you have questions for either the lead
4 discussants or for the developers? John?

5 DR. VENTURA: I guess this is for
6 the lead discussants. One of the comments was
7 there are no harms identified from
8 overutilizing MR to counter or support the
9 benefit of the measure. I would cite what I
10 had referenced to JD. I didn't realize he was
11 doing plain film.

12 Webster's study clearly showed
13 higher costs, five times higher costs, delayed
14 recovery, and higher disability associated
15 with early unindicated MR, so I think it does
16 address that issue.

17 CHAIR CHOU: So the study that
18 John's referring to a study by Barbara Webster
19 which was an observational cohort study. I
20 think it was in a workman's comp kind of
21 setting, and they followed patients out and,
22 you know, they did find these associations

1 after trying to control for confounders, but
2 it was an observational study just so people
3 are aware.

4 Other questions or comments here?
5 So, you know, the evidence for this one, it's
6 not quite as direct actually I don't think as
7 the one for the last measure where we have
8 studies of routine imaging without routine
9 imaging.

10 This is more about, you know,
11 whether people got kind of what are considered
12 to be appropriate therapies before jumping to
13 MRI, and there's no studies that have really
14 looked at that directly. I think that's a
15 fair statement that you can make a lot of
16 assumptions that based on the RCTs that doing
17 a routine MRI doesn't really help patients,
18 and the fact about these MRIs these days is
19 that they're so - the detail is so fine that
20 you pick up stuff in so many patients I mean
21 Kat probably can speak to this some more, but
22 the - you know, if you're over 50, the

1 likelihood that you're not going to have
2 something on your back MRI is pretty low just
3 because that's what happens as people's backs
4 get older, and, you know, we've talked before
5 about kind of all these kind of downstream
6 harms which I think are some of the concerns
7 that people have about MRI including, you
8 know, additional surgeries and things like
9 that which may be unnecessary, so, you know,
10 again I think that some of the evidence to me
11 at least seems a little bit indirect, but I
12 think there certainly is some evidence to
13 support what's in the measure here.

14 Do we have other comments or -
15 yes, Thiru.

16 DR. ANNASWAMY: Yes, I'm glad you
17 brought that up. I agree with the directness
18 of evidence or the lack of it in terms of the
19 conservative care of therapy recommended
20 before getting an MRI.

21 The other issue was also - the
22 measure developer clarified this during the

1 work group call where their intent is to try
2 to reduce the number of MRIs that are ordered
3 at the first visit and not necessarily trying
4 to have them uncomplicated back pains always
5 get therapy before ordering an MRI.

6 So perhaps the measure is stated
7 in a way that doesn't completely capture the
8 primary purpose of the measure so that was
9 part of my thought that I wanted to share.

10 CHAIR CHOU: Okay, so bear that in
11 mind because I think that will come up later
12 again when we talk about - I'm not sure
13 whether that fits into reliability or validity
14 or whatever, but I think it comes up later
15 again.

16 Okay, are there other comments
17 about or questions about the evidence because
18 otherwise I think that we're ready to take a
19 vote on it.

20 All right, let's -

21 MS. PHILLIPS: All right we're
22 voting on Measure 0514 evidence. You have

1 five options, one for high, two for moderate,
2 three for low, four for insufficient evidence
3 with exception, and five is insufficient
4 evidence.

5 You may begin voting now. Okay.
6 We have 21 present, and we are at two for
7 high, 12 for moderate, four for low, two for
8 insufficient evidence with exception, and one
9 for insufficient evidence.

10 CHAIR CHOU: We meet our 60
11 percent threshold for high or moderate, so
12 we're going to move on now, so, Craig, do you
13 want to talk about research gaps and
14 opportunities for improvement?

15 DR. BUTLER: Sure, so we have a
16 performance gap between the tenth and 90
17 percentile, somewhere in the neighborhood of
18 between 14 and 16, 15 percent.

19 There I think strikingly is a lack
20 of significant percentage change between the
21 2007 and 2011 data that you presented, but
22 those small percentages may in fact represent

1 big dollars, so there's two ways to look at
2 that admittedly.

3 Nothing much in the way of patient
4 level disparity data, but they did note what
5 they termed a performance disparity with
6 respect to the rate of the appropriate -
7 according to their criteria MRI in the
8 chiropractic hands versus surgeon hands and
9 with the chiropractic being much lower rate of
10 inappropriateness compared to surgeons, so
11 that - I think again looking across the two
12 years that they give you comparative data I
13 think it's pretty striking at the inability to
14 move the needle very much.

15 CHAIR CHOU: Do you respond to
16 that?

17 DR. BRUETMAN: Yes, we understand
18 and I just want to clarify how - maybe it's
19 just an issue of how the data is collected.

20 We are looking - these are
21 publicly reported measures of how hospitals
22 compare for facilities in outpatient care for

1 hospitals.

2 The way the data is collected, and
3 I know when you look at 2007 and 2011 it looks
4 like a small - and it is a small number, the
5 issue is that these measures are collected
6 with data from two years behind so - because
7 of the way - these are paid claims, so we
8 can't collect in 2011 in 2011. We collect
9 2011 really 2009 data.

10 Public reporting started in 2010,
11 so we're starting to see now the evidence of -
12 or at least we're starting to see the ability
13 of hospitals to react to the public reporting
14 process which we did not have when we reported
15 in 2010 because they could say any change I do
16 will not be reflected until two years from
17 now.

18 So that is why the variation has
19 not moved enough. We hope that it will be
20 moving as you get more information and more
21 years of public reporting and hospitals look
22 at this, and we're also looking at, as I said,

1 the higher end to decrease slightly - start
2 decreasing towards the mean.

3 CHAIR CHOU: Yes, so some of this
4 I think that Craig brought up will come back
5 when we talk about usability and use. I think
6 what we want to try to focus on a little bit
7 is is there a performance gap. Are there
8 people that aren't getting treated
9 appropriately before they get their MRI, and
10 at least according to this data that a
11 substantial proportion of patients are - look
12 like they're going pretty directly to MRI.

13 I have another comment that I
14 think - well it's probably more related to
15 usability and use also, but just I can't get
16 patients PT or chiropractic care if their
17 Medicaid or some of these other, you know,
18 payers, so I think there are some challenges
19 in terms of the usability thing, but again
20 we'll talk about that when we get there.

21 Other comments about the
22 performance?

1 DR. BUTLER: Just a question. I'm
2 just wondering if the level of analysis has
3 anything to do with the failure to see a
4 change in performance. Any consideration in
5 that this level of the facility is at the best
6 level to measure and to really sense changes?

7 DR. BRUETMAN: Can you - what
8 would be - maybe if you can clarify a little
9 bit more to capture that concept.

10 DR. BUTLER: We've looked at other
11 measures there at the level of an individual
12 clinician or a group or plan, and this is a
13 facility and especially how do you define a
14 facility in a three hospital system and how
15 that reports out or five hospital system. I
16 don't - again, some explanation around what -
17 how that's really done and called facility
18 might help answer my question.

19 MS. ANDERSON: So facility has
20 captured the individual outpatient facility
21 level but also reason to capture at the
22 facility level rather than the individual

1 clinician level is you increase the size of
2 your denominator counts. You have a lot more
3 power with the information you're saying.

4 If you're only capturing at the
5 individual clinician level, most of your
6 clinicians won't meet minimum case count
7 requirements.

8 MS. MCKIERNAN: And other point,
9 the reporting program I which this is included
10 is the health hospital outpatient quality
11 reporting program, so we are a bit constrained
12 by the requirements of the project.

13 DR. BRUETMAN: So it's all
14 hospital outpatient, I know hospital
15 outpatient has been getting broader, but it's
16 not at the individual physician, it's at the
17 hospital level reporting, so we capture -
18 really we're looking at the hospital's
19 approach to developing to doing another study.

20 CHAIR CHOU: Any other comments
21 about the performance gap?

22 DR. GRAY: I have one question and

1 that has to do with there was the notion that
2 you would - and I think you just referenced it
3 now that you would bring in the variants if
4 you kept on going.

5 You didn't at least nothing that I
6 could see describe what the outliers were and
7 what - you know, were they things of
8 disparities, you know. What characterizes the
9 outliers and why would you think that they
10 would change?

11 MS. ANDERSON: So our outliers
12 tend to be more rural facilities. They're
13 also ones with smaller bed counts and they
14 tend to be non-teaching facility hospitals, so
15 you do see some disparities based on hospital
16 characteristics.

17 DR. GRAY: You're saying that they
18 are overutilizing the MRS more?

19 DR. BRUETMAN: Yes, there's more
20 use in those facilities, and we - I mean there
21 are multiple hypotheses why this could happen.
22 One of them is that - and this was discussed

1 by expert panel, you know, their concerns.

2 Are we, you know, there are two ways of
3 looking at this.

4 One is, well, are we putting rural
5 facilities at a disadvantage, and on the other
6 hand and that was the majority of the expert
7 panel's thinking, well, it is also true that
8 many times and probably with many of these
9 measures you see much more on the primary care
10 or family physician that might not be using
11 completely appropriately the latest
12 information on guidelines and that might be
13 also part of why you can see the non-teaching
14 hospitals or rural areas versus urban which
15 might be using more frequently and more
16 specialists on this, and I think that probably
17 one of the reasons this measure was selected
18 by the American Academy of Family
19 Practitioners and not maybe other specialists
20 who believe that they have much more an
21 understanding of the details of why you needed
22 or not an MRI.

1 CHAIR CHOU: I think that 31
2 percent is - it's not - I mean it's people
3 that get an MRI without prior - you know,
4 without these other care markers, so people
5 who aren't getting PT and spinal manipulation
6 and stuff, so it's - I'm not sure if it's
7 really a measurable overutilization or it's
8 more measured inappropriate that you're not
9 doing the other stuff before ordering the MRI.

10 DR. BRUETMAN: I understand the
11 question. I think you look at the idea is
12 that you should not immediately do an MRI when
13 a patient comes with low back pain and one of
14 the approaches is really to say, well, there
15 has to be a timeframe which people get some
16 type of therapy or that do it before they get
17 it and they were trying to avoid the doctor
18 just going for the first time and the doctor
19 saying, okay, you have low back pain, get an
20 MRI because they say there's a significant
21 chance that you're going to find something
22 which - because that's - everybody's spine as

1 somebody said, they're all very different and
2 even that was said that that's why some -
3 there was a study and I don't have the exact
4 who did the study, but the American Academy of
5 Family Practitioners say - stated that they
6 looked at older patients, and a study of older
7 patients demonstrated - and these are people
8 without back pain and that 80 percent I think
9 were stating had some abnormality. It doesn't
10 mean that they required something, so that was
11 why they felt that even for older patients
12 there's not - we can't say that you should do
13 it immediately. There's always going to be
14 findings on these patients and probably on
15 other populations as well.

16 CHAIR CHOU: Linda, you had a
17 comment?

18 MS. DAVIS: I have a question
19 actually. The population doesn't have an age
20 - or age range that I can see in the - so is
21 this exclusively Medicare which means 65 plus
22 or are there other populations that could use

1 this or do use this measure now?

2 DR. BRUETMAN: There's two parts
3 to this. One is our population is 100 percent
4 Medicare claims. We use Medicare, and it's
5 for the Medicare program.

6 Now although we look at Medicare
7 and it is - the majority of the people are
8 over 65. It includes non - under 65 as well,
9 and not in this case but in some that we use
10 for emergency departments you see even more
11 used under 65 than in the over 65 because the
12 under 65 are either sicker or are dual
13 eligibles or Medicare and Medicaid eligible,
14 so they use more those departments, but in
15 this case you have the study, the majority is
16 over 65, but we do not restrict the measure to
17 just apply only to the Medicare population.

18 We do not - although people live
19 longer now, but, yes, it does include -
20 fortunately they live longer, but it does not
21 include - we do not restrict the age.

22 Also there's - well, we'll get to

1 that when we get to the numbers.

2 CHAIR CHOU: Thanks. Jason.

3 DR. MATUSZAK: I just wanted to
4 clarify, the performance gap that you guys see
5 and I took a look at some of your information
6 in there between different large groups and
7 small groups, rural areas and some of the
8 other things, family practitioners and
9 internists and things like that, but what I
10 wasn't clear about I guess is is it the
11 performance gap in between, you know, you're
12 talking about the utilization of MRI at the
13 first visit or is it underutilization of
14 specific services prior to getting an MRI?

15 I mean are you measuring the
16 conservative services ordered versus when they
17 get an MRI or is it specifically based on that
18 first?

19 DR. BRUETMAN: We are measuring
20 the use of the MRI and when - and we use the
21 use of conservative treatment as - in addition
22 to exclusions that are included in the

1 measure, we also use that as an - if they had
2 conservative treatment and evidence of this,
3 then it's an appropriate study.

4 We're looking at the use
5 basically. We're not measuring the use of
6 conservative treatment. We're measuring the
7 use of overutilization of MRI.

8 DR. MATUSZAK: So you're measuring
9 the use of the MRI and then you're going to
10 subtract out basically that they've had
11 conservative management.

12 DR. BRUETMAN: I don't know if we
13 have the - we don't have a presentation of the
14 algorithm right? Okay, but basically we -
15 let's see if we have the algorithm, we don't
16 have it in front of us, but we can explain it
17 if we have it in front of us, but basically we
18 take in denominator everybody that gets an MRI
19 and then we start taking the exclusions plus
20 the people that we find evidence of prior
21 conservative treatment.

22 DR. MATUSZAK: So I guess my

1 question is the gap that you see in the - the
2 performance gap measurement that we're talking
3 about is strictly just in the number or the
4 percentage of patients with this diagnosis
5 that get MRIs.

6 MS. ANDERSON: So there's two
7 parts to the performance gap. The first part
8 is, yes, what patients get MRIs and don't, and
9 then the second part is actually with the data
10 that you see in our measure which is you do
11 see a wide range of rate of MRI imaging on our
12 measure, and so you both have a performance
13 gap in the order and then also within the
14 facilities we actually do calculate the scores
15 for.

16 CHAIR CHOU: Zoher.

17 DR. GHOGAWALA: I see how this is
18 structured. Have you had some experience to
19 see what the cost implication here? That is,
20 you know, physical therapy is not inexpensive,
21 and I just am curious. I know you have an
22 option for evaluation and management, 28 days

1 to 60 days, but how is that breaking out in
2 your measure?

3 DR. BRUETMAN: I'll be - you know,
4 we'll clarify that and if CMS is here they can
5 provide you further information. This program
6 is strictly based - it's called pay for
7 reporting program. There's no - CMS does not
8 have the authority to use it as based on any
9 performance at this point or pay for
10 performance or looking at this outcomes of,
11 well, but if you do physical therapy there
12 might be an additional cost. We do not look
13 at the cost implications of an alternative at
14 this point.

15 We know that obviously the overuse
16 of scans do lead to higher costs, but - and
17 they do also lead potentially to
18 overutilization of other services like surgery
19 and other medical expenses as highlighted
20 before, so there are costs but we do not
21 calculate and CMS at this point was not
22 looking to calculate costs on this. It's more

1 on the efficiency of the measure, and measure
2 is defined and I think we used what NQF or ION
3 had defined as do not provide - avoid use of
4 resources that do not provide benefits to
5 patients, and then the RAND which uses also
6 the clinical ways of which the cost outweighs
7 the benefit, and it was looking at really the
8 - in this case the use of MRI not the
9 subsequent cost.

10 CHAIR TEMPLETON: And this is Kim.
11 I just have a question that refers to the
12 exclusions especially since this measure as
13 opposed to the last one does not have an age
14 limit, should we also - or could there be
15 inclusion of or why was there was exclusion of
16 - exclusions such as signs and symptoms of
17 infection such as fever or unexplained weight
18 loss, osteoporosis, chronic use of
19 corticosteroids, all those things especially
20 if this is going to apply to an older
21 population may need to be included because
22 greater there - an exclusion for a history of

1 trauma, but if you have an elderly patient
2 with osteoporosis, they may not have a defined
3 episode of trauma that would lead to a
4 compression fracture or something else that
5 would need to be imaged.

6 DR. BRUETMAN: Can I - if I can -
7 we understand that, and I just want to clarify
8 that we have a number of exclusions followed
9 most of the - I would say one of the major
10 sources is the ACR guidance provided for this.

11 I'm not going to say it's 100
12 percent following, but probably you'll hear
13 that, but we want to clarify that in the - and
14 there's no reason for you to know this, but
15 from the time we presented this we were still
16 working as our angle maintenance process and
17 we presented this in February.

18 We had our expert panel discussion
19 in March, on 14 it was March 10th, so it was
20 like a few days afterwards in which we
21 presented additional exclusions with the -
22 which the expert panel approved which included

1 many of the ones just mentioned - infections
2 and osteoarthritis and we - many others that
3 I'm sure are going to come up in the next few
4 minutes, so those are going to be - CMS is in
5 the process of internally approving this
6 additional sources.

7 CHAIR CHOU: So, I just wanted to
8 keep us focused on performance gap. We'll get
9 back to the specifications and all that
10 validity stuff when we get to those sections,
11 but any other comments about performance gap?

12 So really what we're voting on is
13 there a performance gap that this measure is
14 addressing? Yes, Karen.

15 DR. PACE: Yes, and I just want to
16 emphasize what you said. Obviously, you know,
17 we're interested in improvement when we get to
18 usability like you said, but one of the things
19 to look at here is within a year the
20 difference between like the tenth percentile
21 and the 90th percentile, and you say see that
22 there's differences in performance across

1 these facilities.

2 CHAIR CHOU: Okay. Additional
3 comments about performance gap or shall we go
4 ahead and do a vote? Let's do the vote.

5 MS. PHILLIPS: Okay. We're voting
6 on performance for Measure 0514. Your options
7 are one for high, two for moderate, three for
8 low, four for insufficient. Voting begins
9 now. We are at 22 - okay we have seven for
10 high, 13 for moderate, zero for low, and two
11 for insufficient.

12 CHAIR CHOU: So this passes.
13 Let's move on to the priority. Craig, any
14 opening comments?

15 DR. BUTLER: I think we can agree
16 this is high resource use. Nothing else.

17 CHAIR CHOU: All right. Let's
18 vote on priority.

19 MS. PHILLIPS: All right. Measure
20 0514 on priority. Your options are one for
21 high, two for moderate, three for low, four
22 for insufficient. You can begin voting as

1 soon as the mouse cursor comes back. Here you
2 go. Begin voting now. Okay. We've got 19
3 for high, three for moderate, zero for low,
4 and zero for insufficient.

5 CHAIR CHOU: Again, it passes, so
6 we're going now to reliability, so again,
7 focusing here on the specifications, whether
8 things have been specified clearly and then
9 anything about reliability testing. Did the
10 developers have any comments to make about the
11 reliability testing before we get into this
12 discussion?

13 MS. ANDERSON: So I can provide an
14 overview of the reliability testing we did if
15 that would be helpful.

16 We - similar to the last measure
17 you all heard about conducted a signal to
18 noise analysis, and what we found is that we
19 had a 53.1 percent median value for that
20 analysis, and this is slightly lower than the
21 target value you might want to see for a
22 signal-to-noise analysis, but part of that is

1 reflective of both the way we structure the
2 measure and the intent of what we're trying to
3 achieve, and so when you're trying - the
4 intention of the signal-to-noise analysis is
5 to see how well you can distinguish one
6 facility's performance from another.

7 We're never comparing head to head
8 two facilities against each other. What we're
9 instead trying to say is here's the median
10 value of performance. Is a facility
11 significantly different than this median
12 value, and so when we ran a similar intent
13 analysis but instead to look at how well we
14 can distinguish facilities that are performing
15 statistically significantly differently than
16 the mean we were able to categorize over 50
17 percent of facilities having performance that
18 was statistically significantly different from
19 the median, and so I think that's a better
20 measure of reliability given the intention of
21 this measure.

22 CHAIR CHOU: Craig, any comments

1 here?

2 DR. BUTLER: This point, one of my
3 other lead discussants now to take the floor.

4 CHAIR CHOU: Great, Thiru.

5 DR. ANNASWAMY: Yes, we traded, so
6 with the reliability testing, there were not
7 too many concerns. Most of the concerns under
8 reliability actually applies to validity. The
9 one concern expressed in the work group call
10 was - well, concerns about addition of the new
11 denominator exclusions, and there's no data
12 but what the current data would look like if
13 you use this as part of the analysis and that
14 could impact changes in reliability over time
15 because the criteria changed, so I guess it
16 remains to be seen because you alluded to a
17 lag period between when the claims are
18 submitted to analysis to when you change some
19 of the denominators so this is probably
20 referring to that, but outside of that, there
21 were no major concerns expressed.

22 So I think the consensus among the

1 work group and the lead discussants with
2 reliability was at least moderate.

3 CHAIR CHOU: Katherine, anything
4 or, Craig, go ahead.

5 DR. BUTLER: I did have a question
6 about the denominator exclusion regarding
7 prior surgery. Obviously it reached enough of
8 a threshold that they made an exclusion. I
9 was just wondering what was magical about the
10 90-day timeframe.

11 DR. BRUETMAN: Yes, I expected
12 that and we heard this and this was a
13 discussion with our expert panel and probably
14 there's going to be potential differences in
15 this and I'll leave to the expert clinicians
16 to decide.

17 The way this was reviewed, the
18 expert panel did not consider any prior
19 surgery, and I know that's different than the
20 ACR as an automatic exclusion. Their view was
21 that what they were looking at was a prior
22 surgery and within the 90 days as one could be

1 an arbitrary number is is there any issues
2 related to that surgery that occurred, and
3 they're putting the 90 days to see well maybe
4 there was a problem and we want to go back to
5 see there, and they want to put a timeframe so
6 it's not, you know, we put a year would be
7 completely maybe unrelated. That's why the
8 prior surgery and the 90 days was based on
9 follow up to a recent surgery that had
10 occurred.

11 DR. BUTLER: That Number 5
12 guideline to get there it was just a - what
13 you use for all of your validity and
14 reliability as a condition of low back pain,
15 and so when you exclude surgeries of 90 days,
16 my point is I don't think someone who's had
17 surgery in say 91 days after can be called
18 just low back pain, and, you know, even a year
19 or two after, probably is not uncomplicated
20 low back pain, and I kind of speak to the
21 issue as a multiple back surgery patient, so
22 none of it's uncomplicated.

1 DR. BRUETMAN: I understand - and
2 I know and I understand the concern and we're
3 open to bringing this up again to the expert
4 panel and to CMS.

5 We did look at the number of
6 surgeries and it wasn't -- there is a number
7 of surgeries, but it wasn't affected that much
8 the measure.

9 MS. MCKIERNAN: So that's
10 approximately 11 percent of the cases were
11 associated with surgery within the 90 days
12 prior to the - and the other point that I
13 wanted bring up is I think that - so Charlie's
14 explanation about the reason for having going
15 back for surgery was to look for something
16 related directly to the surgery.

17 I think that you're speaking to a
18 different reason to exclude surgery. As
19 Charlie mentioned, I think that it's valid and
20 it's something that we can discuss.

21 DR. BUTLER: Just to understand
22 you that of the claims that you looked at, 11

1 percent have had surgery within 90 days and
2 they were excluded. Is that -

3 MS. MCKIERNAN: Apologies. I was
4 thinking of a different exclusion. One
5 percent.

6 CHAIR CHOU: Okay. Thanks, so
7 keep that stuff in mind because I think that -
8 again, a lot of that will get the validity
9 stuff. I want to see if there's any final
10 thoughts about reliability, so again, whether
11 the specifications are clear and whether their
12 measurements are reliable. I want to focus on
13 here before getting into the validity stuff.
14 Oh, go ahead, Kim.

15 CHAIR TEMPLETON: Sorry. I forgot
16 to lower my hand. I'm okay.

17 CHAIR CHOU: Okay. I think it's
18 time for a vote then, so we're voting on
19 reliability.

20 MS. PHILLIPS: Okay. Reliability
21 for Measure 0514. You have four options. One
22 for high, two for moderate, three for low, and

1 four for insufficient. You may begin voting
2 now.

3 We are at 21 holding there for a
4 couple of seconds so if you can all vote
5 again. There we go. Thank you.

6 We have one for high, 19 for
7 moderate, one for low, and one for
8 insufficient.

9 CHAIR CHOU: Okay, so that passes
10 the reliability test. Excuse me. Now we're
11 going to move to validity, and I think some
12 issues have already been brought up with the
13 exclusions, the surgery exclusion in
14 particular. Do the lead discussants want to
15 make some more comments here?

16 DR. ANNASWAMY: So the validity of
17 the measure was the biggest point of concern.
18 The purpose of the measure, the intent, is to
19 look at uncomplicated low back pain and figure
20 out how many of them got an MRI as kind of a
21 trigger-happy clinician at first visit or as
22 early as possible without trying conservative

1 care, so the issues with numerator and the
2 denominator.

3 The denominator is you're calling
4 uncomplicated back pain, but the diagnostic
5 code is essentially claims based on ICD 9
6 coding. Perhaps things would be a little
7 clearer for ICD 10 but with ICD 9 you didn't
8 include just the diagnosis of uncomplicated
9 low back pain or 724.2 or 724.5, but a slew of
10 degenerative codes are also included, so all
11 the degenerative disease, spondylosis,
12 sprains, strains, radiculopathy, they're all
13 included in the denominator which makes the
14 measure in my view and the work group's view
15 very low validity.

16 In the numerator, you're looking
17 at people who had antecedent conservative
18 therapy.

19 All the literature that talks
20 about sufficient trial of conservative care
21 but here you're looking at physical therapy,
22 chiropractic adjustments, and E&M code. I've

1 never quite - I can't quite say it unless I
2 read it. Greater than 28 days but less than
3 60 days before the MRI. I think it means to
4 say between 28 and 60 days before the MRI. I
5 understand that better than greater than 28
6 and less than 60, but be that as it may, I
7 don't think it quite captures the intent
8 because you may have a variety of different
9 conservative options used by clinician that
10 are very appropriate and stated in the
11 literature as being very appropriate which
12 does not include these three things, and the
13 measure does not capture those.

14 For example, education, avoidance
15 of activities that might have strained it in
16 the acute back pain, modifications of the work
17 place for example, things of that nature are
18 not captured here.

19 If an evaluation was done three
20 months before but there was a delay in getting
21 an MRI or perhaps a follow up was scheduled
22 and at that follow up visit an MRI was ordered

1 because sufficient time has elapsed, treatment
2 has been instituted, patient is not getting
3 better, so in the Medicare population an MRI
4 was ordered at that point, and that will be
5 counted against it because this is a trigger-
6 happy clinician ordering an MRI at the visit.
7 Ninety days ago the first visit was not
8 included in the claim because of the time
9 window, and there are scenario after scenario
10 that I could think of that was brought up in
11 the world group call that just makes this
12 measure extremely problematic in terms of its
13 specifications, its inclusion, exclusions, and
14 all of the above.

15 CHAIR CHOU: Thanks. Other
16 comments? Katherine? Craig?

17 DR. GRAY: Yes, I have one. I
18 think the one that we got into the most lively
19 comments had to do with - well first of all,
20 if you look at all the information that you
21 provide for the evidence, you have all these
22 overlapping guidelines, and I think in itself

1 is very confusing for anybody to know what do
2 they really follow, but what really took the
3 cake was when we got into Guideline Number 5
4 which you actually pull out and list in a
5 separate thing as being important, one of the
6 variables in it for Variant 2 is age greater
7 than 70, and the group would just - freaked
8 out at that and because it's a Medicare
9 population and so we went back and re-read it,
10 and it says one or more of the following, so
11 just being over 70 means that the ordering
12 doctor would be legitimate in ordering an MRI.

13 Now what's that do with the whole
14 purpose of the measure, you know. That was
15 what really caused us the greatest concern.

16 CHAIR CHOU: Do the developers
17 want to respond?

18 DR. BRUETMAN: Yes, as we said, we
19 had mentioned, we - the way we look at that
20 there's overlapping measures and not all
21 address the same issues and I wouldn't say the
22 conflict some, but there are minor

1 differences.

2 We follow significantly the ACR
3 guideline and when we looked at the age, and
4 I think it was brought up even the discussions
5 as we saw on the transcript and we heard last
6 time, the expert panel thought that it was not
7 inappropriate - it was not an appropriate
8 exclusion that a person over 70 is
9 automatically should be excluded.

10 In their perspective it's not a
11 sufficient reason to say that you're 70 to not
12 have it and this is might be a disagreement
13 with ACR's guideline.

14 I think it was presented even by -
15 I think, yes, because I'll say Zoher, I think
16 he mentioned that he wouldn't - as an
17 orthopedic surgeon he would not - he does not
18 believe that's an appropriate exclusion. I
19 think, and I don't want to mistake, but I
20 think it was part of the saying that we would
21 never have a surgery - we would not
22 immediately scan somebody just because they're

1 over 70. The expert panel felt the same way,
2 and I think as we said our development is
3 based both on evidence from guidelines as well
4 as experts that come to the discussion and
5 that's why that specific area was not included
6 as a direct exclusion in our measure.

7 MS. ANDERSON: And just to add to
8 that, we also did review the evidence table
9 behind that ACR guideline, and only two of the
10 studies included in the evidence table
11 discussed age at all as a factor when
12 considering the appropriateness of an imaging
13 study for MRI of the low back, and both of
14 those studies only noted that you were likely
15 to have - or a higher likelihood of abnormal
16 findings, but they didn't correlate that with
17 a need to do this, so even though as you get
18 older you expect to find more abnormalities in
19 the back. It's not actually the MRI might be
20 necessary based on the evidence we saw in the
21 evidence table.

22 DR. GRAY: And I've looked at that

1 evidence table, and it's over 50, so I spent
2 some time actually finding the over 70, and I
3 think that what I found when I looked it up is
4 that it's not in isolation but that guideline,
5 the information that is being laid out as the
6 validation for the measure does not have that
7 subtle - all the information that the
8 literature actually shows, so there's a real
9 conflict in terms of what - you know, what
10 you're actually trying to - I mean we - you
11 and your expert panel may know, but how are
12 people out there using this measure and being
13 judged by it, what does it all mean to them if
14 they actually are mixed up enough to have
15 picked Guideline Number 5, Variant 2, to be
16 their thinking?

17 CHAIR CHOU: Other comments from
18 the panel? JD.

19 DR. DANIELS: Yes, I guess I'm
20 stuck on a horse fetish today. This is like
21 the Wizard of Oz. It's kind of like a horse
22 with a different color. You know, different

1 people come into the doctor for different
2 reasons, and dependent on their age and what
3 happened to them, we look at it differently,
4 so if a real young person comes in the office
5 and they just didn't fall off a swing set or
6 something or having back pain, most of the day
7 you kind of go along with it, but every once
8 in a while your antennas go up and you go,
9 wow, I got to kind of pay attention, and then
10 you get to kind of the middle aged people who
11 kind of like don't need to see you unless
12 they've got one of these big burning red
13 flags, but when you kind of look at the
14 elderly group when you get over like 50 it
15 doesn't count any more, you know, like 50 is
16 the new 30, so, you know, when they're up
17 around the elderly, you know, there's some
18 simple things like they fell when they were
19 coming out of church, and there you can do an
20 x-ray and see if they've got a compression
21 fracture or something, but more sinister stuff
22 comes on to bring those, so most likely what's

1 going to happen, and I'm just talking
2 practical, is an older person comes into the
3 office or having pain and you talk to them.
4 This seems okay, or, you know, they actually
5 examine them and take their chart. Well
6 they've got shingles - oh, boy. Sometimes
7 that happens. People don't look, but the
8 bottom line on it is that if a period of time
9 goes by and they've got those, they're a lot
10 higher risk now. That, I don't know if you
11 can find that in - you know, teasing it out,
12 but in general, the MRI would be one of the
13 few times because the way I sort of look at an
14 MRI as a primary care doc is not to make a
15 diagnosis because they're going to give me 50
16 diagnoses to choose from when I order the MRI.
17 You go A, B, C, D, E and kind of tell the
18 patient a nice story. What I really look at
19 is for two reasons.

20 One is to make sure that I'm not
21 telling the person, hey, you're going to be
22 fine almost no matter what you do, okay, and

1 the other one is you need surgery or you need
2 - and, you know, very few times I have to call
3 someone and say, hey, can you get him worked
4 in, so that's kind of how it's clinically.

5 CHAIR CHOU: Thiru.

6 DR. ANNASWAMY: I just - I had
7 more things to say, but I didn't want to hog
8 the mic, so Round Two.

9 So in the guidelines that you have
10 so elaborately summarized contradicts your
11 measure directly. I'll just read out some
12 underlined points here.

13 A specific clinical diagnosis of
14 suspected lumbar disc herniation or sciatica,
15 radiographs are not indicated unless patient
16 is aged greater than 50 or has progressive
17 neurological deficit, so that itself, the
18 guideline states that in several of the
19 instances that you're trying to capture, it
20 might be appropriate to get an MRI.

21 Another one, Guideline 2, for
22 patients with back pain, clinicians should

1 consider the use of medications with proven
2 benefits in conjunction with back care
3 information and self-care, so that counts as
4 appropriate conservative care before getting
5 an MRI and that's not captured in your
6 numerator.

7 Guideline 7, MRI is not
8 recommended for acute radicular pain syndromes
9 in the first six weeks unless they are severe
10 and not trending towards improvement and both
11 the patient and surgeon are willing to
12 consider prompt surgical treatment assuming
13 the MRI confirms ongoing root compression.

14 So in this case, six weeks, if
15 they're severe and there is a plan for
16 surgery, it's appropriate according to this
17 guideline to get an MRI.

18 MRI at three to four weeks may be
19 reasonable if you're planning an epidural
20 steroid injection with is also accepted as
21 appropriate conservative therapy. It's
22 evidence Level B, a moderate recommendation.

1 Guideline Number 10, spinal cord
2 infarction or degenerative conditions,
3 degenerative disc disease or its sequelae in
4 the lumbar, thoracic, and cervical spine are
5 indications for MRI.

6 For radicular pain without
7 weakness by greater than - at greater than or
8 three weeks, if there is no improvement
9 obtained in MRI Level 2B evidence or
10 diagnostic obtained in EMG.

11 If pathology is proven on an MRI,
12 consider evaluation by specialist or surgical
13 eval, so it's just on and on and on about how
14 it may be so many instances that are not
15 captured in this measure where obtaining an
16 MRI is appropriate and also it's instances
17 that are not captured here where obtaining an
18 MRI is not appropriate that are not excluded -
19 I mean that are excluded.

20 CHAIR CHOU: I want to go the
21 developer the chance to respond and then come
22 back to Jason.

1 DR. BRUETMAN: Obviously there is
2 difference evidence and different guidelines
3 that state, and we try to make the best case
4 of understanding. That's why we bring some
5 experts.

6 One of the things and I understand
7 some of the denominator codes, there is a
8 number of exclusions that eventually these
9 patients are excluded from the analysis, and
10 as I said, there's some additional exclusions
11 that were not initially involved and are now
12 currently in the measure or will be in the
13 measure, but we had a lot of the number of
14 these would-be - although they're included in
15 the initial code, but then when that diagnosis
16 is there, they will not be included so it will
17 not be telling any provider that you're doing
18 the wrong thing because they would eventually
19 be excluded, so that addresses many of the
20 issues.

21 The second is, yes, it is a
22 claims-based measure, and, you know, one of

1 the challenges we have with claims-based
2 measures you're not going to get all the
3 information, but that would probably then
4 leave matters to be almost, as I said, the
5 trigger-happy doctor to justify and could
6 almost justify any study because there is a
7 way to almost justify any study, so that's why
8 also the measure does not have a benchmark and
9 the goal is not to have zero.

10 If you look at the rate, it's not
11 a zero, so we understand that many cases are
12 going to be, you know, well, but you don't
13 have in the claims all the exact symptoms that
14 you can capture and that's why, you know, we
15 are not telling people, you know, oh, you're
16 at 30 percent, it's really bad performance.
17 You're at 22, you're bad performance.

18 There are - that is that I think
19 was discussed previously, there's no
20 expectation to get a zero on these measures,
21 and as we call it, we try to work in giving
22 I'll call the benefit of the doubt of why and

1 that - there's long discussion on how E&M - I
2 know it's not very clearly captured. At least
3 I know there have been a number of questions
4 regarding our E&M approach and ability to
5 capture that as - the claim for that as a
6 conservative treatment, but obviously if a
7 patient - we try to use proxies as, you know,
8 they did not because our goal is to avoid a
9 person going the first time to the doctor and
10 getting the MRI immediately, and if they took
11 60 days - and one could say, well, what
12 happened if they waited 60 days to get the
13 MRI, yes, we will say they were included but
14 if you have 100 percent of your patients that
15 have that reason, I think there's another
16 problem. That's why I think, you know, we're
17 trying to play with getting people to
18 acknowledge that there's an overuse as was
19 agreed by the whole committee. There is a
20 significant utilization capture as much as
21 possible of the claims data, give I'll call
22 leeway to the doctors to understand that

1 there's not going to be perfectly black and
2 white cases because medicine is not a black or
3 white science, and also to understand that,
4 you know, your facility is not going to be if
5 you want to call it punished or seen as a bad
6 provider because you have a number of these
7 cases.

8 Now when you have that 60 percent
9 of your patients that come through your
10 facility get an MRI for low back pain, you
11 have to question yourself and that's what
12 we're trying and CMS is trying to work on is
13 trying to say how can we do the best way
14 possible within the limitations of a claims-
15 based measure and the hospital community and
16 the medical community in general has reacted
17 very positive to the measure. There's not
18 been in many other measures I can tell you
19 there's not been positive reactions as you are
20 probably all well aware, and in this case we
21 have not had any comments saying, well, we're
22 not being captured. There's a mistake.

1 Everybody has their unique cases.

2 You know, I have a lot of this
3 type of population or that type, and that
4 happens all the time and we understand that.
5 That's why you explain to them we're not
6 paying for performance. We don't expect it to
7 be zero, and there's no established benchmark.

8 We are working on people being at
9 a rate which is called the average rate and
10 try to get people when they're very high to
11 see - recognize that their facility is very
12 high on that to question themselves, are we
13 doing something that is not appropriate that
14 we need to work with our physicians to ensure
15 that, you know, if I'm in a rural facility and
16 maybe don't have access because we don't want
17 to make a measure and nothing against - I mean
18 - John Hopkins and we have people from John
19 Hopkins in our panel.

20 I don't want to make a measure
21 that address Johns Hopkins because it's like
22 that's not what we're looking for. We're

1 looking to see if there is a facility that is
2 saying, wow, why am at 60 percent and others
3 are at 30? What is going on? I'll have to
4 talk to my physicians to see are we just
5 trigger - trigger to get or other cases, and
6 every hospital we provide every single data
7 point to every hospital so they can see
8 because it's 100 percent of paid claims so I
9 mean this is 100 percent of reality assuming
10 that what was claimed - we'll assume that case
11 and everything that was paid and claimed is
12 reality, but, you know, we're not going to get
13 into that discussion, but we are assuming that
14 the facilities did perform the study. We
15 provide every single patient and every
16 facility has a time to come back to us and
17 say, look, we reviewed this, and there's
18 something wrong, and we go to that case and
19 clarify that.

20 I have to say for this measure I
21 don't want to say we've never had a concern,
22 but it's not been a problem. Recently there

1 was a change in the way for multiple reasons,
2 different way of calculating. There was a
3 problem with the measures, and hospitals
4 immediately called us saying we didn't meet
5 the minimum case count. Our cases are not
6 right. What is going on, so we had to explain
7 there was a change in not our system, another
8 systems, and that was clarified and fixed, but
9 - so hospitals are aware of - they look at
10 this and again, I think the goal is to not
11 have perfection but to get in this case
12 facilities to react to say what am I doing
13 differently, what can I learn, what should I
14 be doing to be more aware that why am I
15 having, and I have to say, not this case where
16 we facilities with 100 percent cases.

17 CHAIR CHOU: I want to have some
18 of the panel members give their input, so,
19 Jason, and then John.

20 DR. MATUSZAK: Well, I think your
21 point is well taken that we want to raise
22 awareness around the issue. I think that we

1 all accept that - that is part of the problem
2 is making sure that people are aware, but I do
3 think that Thiru did a wonderful job of
4 pointing out just how conflicting your
5 guidelines are and how physicians might be
6 dinged for performance or facilities might be
7 dinged for the physicians' performance even
8 when they're following Medicare's own
9 guidelines about it.

10 I also would just, you know, just
11 in case by some chance this goes through I
12 would also ask that you guys if you're looking
13 at conservative manage tests, this stuff
14 really be very inclusive. You don't have
15 osteopathic manipulation, but you have
16 chiropractic manipulation. Why?

17 You don't have athletic training
18 services even though them doing a home
19 exercise program could be just as effective as
20 physical therapy in some of these things. You
21 don't include that. You don't include
22 anything about nutritional services, and you

1 know that dietary interventions can make a big
2 difference in low back pain, so, you know, I
3 would just encourage you to take a look at
4 being much more inclusive as to the
5 conservative measures that you would deem as
6 being part of your qualifying things, but
7 certainly I think you did a fantastic job of
8 pointing out just some of the flaws and the
9 validity here.

10 CHAIR CHOU: John.

11 DR. VENTURA: My question is
12 actually along the same lines, but it's
13 actually more for Thiru.

14 I could be reading this wrong, so
15 please help me if I'm just off base here. The
16 intent is that in essence you're not ordering
17 an MR in the first 28 days in the absence of
18 an exclusion, so if there are no exclusions,
19 they don't want you ordering within the first
20 28 days. Am I reading that correctly?

21 DR. ANNASWAMY: The measure
22 developer probably can clarify, but, yes, the

1 idea is that if you had an E&M claim which
2 means a visit, a clinic visit, less than a
3 month before you got the MRI that most likely
4 means that the MRI was ordered at that first
5 visit for the back pain which you don't want
6 to have, but if you waited - if the MRI was 60
7 days after the clinic visit, it's likely that
8 there was a good set of conservative care that
9 happened in between. That's the assumption.

10 DR. VENTURA: I also get the
11 impression though that if an E&M code is
12 submitted after 28 days -

13 DR. ANNASWAMY: So it's E&M should
14 be looking back from the MRI date, so that's
15 how you do it. Looking back from the MRI
16 date, you go back 60 days - no, wait. No,
17 looking forward from the clinic visit.

18 DR. BRUETMAN: It's backwards.
19 You're right.

20 DR. ANNASWAMY: So from the clinic
21 visit, your MRI should be not before the first
22 month, and it shouldn't be - it should be

1 between that first month and second month.

2 That's basically it.

3 DR. BRUETMAN: And just to
4 clarify. I know it can look confusing why we
5 didn't say between this and that. It's just
6 the way the program has to be done. You have
7 to look at the way you put it's more than
8 this, less than that, and that's why it was
9 not in the perfect English wording, but that's
10 how it's programmed.

11 What you said, it's very clearly
12 not easily interpretable.

13 CHAIR CHOU: I want to ask one
14 clarifying question and then I'm going to kind
15 of summarize where we're at because we need to
16 come to some resolution here, but I'm actually
17 - now that I look at this Item Number 3, it's
18 actually confusing to me, so in terms of the
19 description, so we're saying if they got PT in
20 the 60 days prior, it's okay. If they got
21 chiropractic evaluation and manipulation, it's
22 okay. I don't understand what this third one

1 is saying that if they were evaluated sometime
2 between 28 and 60 days whether they got PT or
3 anything else, it's okay also.

4 DR. VENTURA: Yes, that was my
5 question actually that I thought that
6 encompassed a lot of the concerns that Thiru
7 had that, you know, that they could have had
8 education during that period. They could have
9 gotten nutrition. They could have had
10 anything else.

11 CHAIR CHOU: Well they could have
12 had just had come in to see the doctor and
13 that would be considered that they got
14 conservative care.

15 DR. BRUETMAN: The proxy is that
16 the first part is pretty clear. You know, you
17 had physical therapy in the 60 days.
18 Obviously we can determine there's been some
19 conservative treatment. The same with the
20 second one.

21 The third one is so you - it goes
22 to this issue, well, we don't want you on the

1 first visit to do it, so there's a time lapse
2 that is between the last E&M and an assumption
3 that it wasn't done immediately because there
4 was some type of conservative treatment or
5 some treatment, education, done by a physician
6 that is not a chiropractor or a physical
7 therapist, and unfortunately there is - for
8 those who work with claims, there is never -
9 you know, the claims, the way they're put in
10 place, they will not put certain codes where
11 they'll say we are doing or giving them this
12 type of therapy or doing that. It's not
13 capturing the claims, so we - to avoid - and
14 this is a very broad approach, to avoid giving
15 doctors that might be doing this or saying if
16 you identify and E&M claim that has been more
17 than 20 days were related and that's when it
18 was ordered, were related that something
19 occurred that was conservative before just
20 providing.

21 It is true that if somebody gets
22 in Day 60 their order and goes 60 days later,

1 yes, that would be we're excluding a
2 physician, let's say in this case, although
3 we're not measuring physicians that shouldn't
4 have been excluded, but that's why it's not
5 going to be zero.

6 CHAIR CHOU: All right, so if
7 you're seen in the doctor's office one to two
8 months before the MRI, that's your proxy for
9 getting conservative care. Okay. All right,
10 so I just want to summarize where we're at,
11 and then we'll take a couple of final remarks
12 and then I think we need to come to some
13 resolution here, so I'm hearing some concerns
14 about how the denominator is being defined, in
15 particular about the exclusions and that there
16 are some discrepancies between guidelines and
17 I think it's not clear to everyone how the
18 developers kind of reconcile those
19 discrepancies or decided how to apply them.

20 Then I'm also hearing concerns
21 about the numerators, both in terms of I guess
22 the specific, you know, interventions that are

1 discussed as well as whether this other one to
2 two month thing is an appropriate proxy.

3 Other final - a couple of final
4 comments if there are some, and then we can
5 maybe come to some resolution here. Craig.

6 DR. BUTLER: Maybe just one final
7 comment. I see this is as a measure that
8 become increasingly less valid especially when
9 you consider the evolving models of care and
10 you've kind of constrained it to three
11 different ways to basically document
12 conservative care, and I submit that you might
13 have an app, you might have a video you refer
14 a patient to that gives them a new care model
15 to initiate conservative therapy which means
16 that this becomes again less and less valid
17 over time.

18 CHAIR CHOU: Yes, I was actually
19 thinking about telemedicine for like people
20 who are in rural communities who may not have
21 access to PT or something. Telemedicine is
22 probably something that's going to be widely

1 used in the future whether you can - how
2 people are going to bill for that and all that
3 other stuff is a question, but any other final
4 comments? Yes, Thiru.

5 DR. ANNASWAMY: I'm not sure how
6 many clinicians use the neurological
7 impairment exclusion code in their coding.
8 I've practiced spine care for 15 years. I've
9 never once used it, and I've seen a lot of
10 neurological impairment.

11 I would use radiculopathy or
12 sciatica which are inclusions not exclusions
13 here, so I just wanted a clarification on that
14 neurological impairment exclusion.

15 CHAIR CHOU: Okay. I think we
16 need to come to a vote here, so let's put it
17 up for a vote for the validity criterion.

18 MS. PHILLIPS: Okay. We're voting
19 on validity for Measure 0514. You have four
20 options - one, high; two, moderate; three,
21 low; four insufficient. Voting begins now.

22 We are at 22, and we have zero

1 high, four moderate, 15 low, and three
2 insufficient.

3 CHAIR CHOU: All right, so this
4 doesn't pass the validity test. I think we
5 want to maybe provide some feedback and then -

6 MS. PHILLIPS: Do we have
7 additional feedback.

8 CHAIR CHOU: Yes, so I mean,
9 Thiru, did you want to say something here?

10 DR. ANNASWAMY: Yes, I think the
11 intent that this is a very important priority
12 and that you want to prevent the trigger-happy
13 clinician from getting too many MRIs too
14 quickly for uncomplicated back pain is
15 extremely valid, and that bore out in the way
16 we rated the evidence and the priority and the
17 performance gap.

18 The issue is how the measure is
19 structured, so I believe there is room for
20 refining the measure so that you adequately
21 capture that intent.

22 CHAIR CHOU: Craig.

1 DR. BUTLER: I would also point
2 out when we are trying to do this thing using
3 the guidelines for evaluating validity, the
4 first question is are the measure
5 specification consistent with the evidence
6 provided in support of the measure, and I
7 would submit that some of your evidence was
8 inconsistent and some of the evidence wasn't
9 presented witness the technical expert panel
10 input on some of those ages and things like
11 that that we didn't always have access to in
12 the materials that we got a chance to review.

13 DR. GRAY: And I would suggest
14 that the validity issues that we discussed and
15 were raised may very well be the reason you're
16 seeing no change over time.

17 CHAIR CHOU: Yes, so, again, I
18 think everyone - the panel generally felt this
19 is important and that there is evidence to
20 support the overall aim.

21 I would bring up another issue
22 which is that it seems to me that there are

1 two - I mean one problem we have is that not
2 enough people are doing appropriate therapies
3 for low back pain, that people are jumping to
4 opioids, unnecessary surgery, etcetera,
5 etcetera, and it's kind of addressed here but
6 not really.

7 I mean I think that's almost a
8 separate issue. I mean I think kind of
9 confuses the picture here, and I wonder if
10 there's some way to try to separate out the
11 appropriateness of MRI separately from whether
12 they're receiving appropriate conservative
13 care. It may be the only way you can do it,
14 but it's just something worth thinking about.

15 The other suggestion I would have
16 is just to stick to one or two guidelines. I
17 mean you're not going to be able to reconcile
18 12 guidelines. It's just - you've got to -
19 because the methods that people use and the
20 standards that they rate the evidence with and
21 all this other stuff are completely different,
22 and I would say that the ACR appropriateness

1 criteria are completely different from like a
2 clinical guideline in terms of how they're
3 meant to be used and interpreted and so to try
4 to develop a measure that's based on all these
5 disparate things, I think it's going to be
6 tough, and so I think if there's a way that
7 you're able to come to some - evaluate the
8 guidelines and come to some, you know,
9 agreement about which ones you think, you
10 know, are the best developed or whatever, I
11 think that would help kind of clarify some
12 things, so, Thiru.

13 DR. ANNASWAMY: I agree with you
14 about the ACR. I think ACR, a lot of the
15 sentiments expressed here are try to get the
16 patient in the middle of this.

17 ACR - not ACR, AUC, Appropriate
18 Use Criteria, sorry, is focused on the
19 modality as a focus, so you're trying to
20 figure out for the modality in my hand, for
21 the hammer in my hand, what should be the
22 nail? How should it look like?

1 On the other hand you want to
2 focus on the nail and you try to figure out
3 what's the best hammer to use, so that would
4 be - so you shouldn't - I would actually
5 extend what Roger said and not use AUCs at all
6 in determining this kind of measure. Patient
7 focus should be the priority.

8 CHAIR CHOU: Any additional
9 comments? All right, I think we're done with
10 the measures. Thank you.

11 MS. STREETER: Just take a quick
12 break to see if we have any members from the
13 public that would like to make a comment on
14 the phone.

15 OPERATOR: At this time if you
16 have a comment, please press Star One, and
17 there are no comments.

18 MS. STREETER: Thank you. So
19 thank you all for joining us for our in-person
20 meeting.

21 Just so you know, next steps as I
22 mentioned yesterday, staff will be preparing

1 a draft report that summarizes your
2 recommendations from today.

3 We'll be posting that report for
4 public comment in a 30-day public comment
5 period in June, then we'll be reconvening in
6 July, I believe it's July 31st, to discuss the
7 comments received.

8 MS. FRANKLIN: And I just wanted
9 to ask if folks are interested in going around
10 the table quickly to talk about gaps in the
11 portfolio.

12 CHAIR CHOU: I'll just mention I
13 think management of chronic pain should fit
14 under the musculoskeletal thing, and I think
15 opioids are one of the major issues, public
16 health issues, right now. Gaps that people
17 think that there should be measures to
18 address?

19 CHAIR TEMPLETON: This is Kim.
20 Getting back to some of the imaging
21 modalities, perhaps use of MRI in management
22 of chronic knee pain.

1 CHAIR CHOU: Thanks, Kim. Yes,
2 Sean.

3 DR. BRYAN: One of the things we
4 see very commonly in primary care sports
5 medicine is tendinopathy, and it might be nice
6 to have a measure on that.

7 CHAIR CHOU: Management and
8 treatment, so evaluation management, okay.
9 Yes, Linda.

10 MS. DAVIS: Common procedures
11 outcomes from knee replacements, hip
12 replacements, and spinal fusions.

13 CHAIR CHOU: Okay. Thanks. Other
14 thoughts? Yes, Zoher.

15 DR. GHOGAWALA: I think the
16 overutilization efforts or the efforts to
17 create measures to address overutilization
18 didn't do as well as we might have liked, but
19 I think that there's a real role for more
20 measures that look at some of the very costly
21 overutilization procedures including in our
22 field lumbar spinal fusion surgery with the

1 effort of not necessarily limiting but
2 clarifying for patients and for providers when
3 these kinds of expensive treatments are
4 appropriate.

5 CHAIR CHOU: Yes, I think for the
6 developers we wanted to be clear that we are
7 interested in measures that address
8 overutilization, that's is just challenging to
9 develop them, but we'd like to see them again
10 or see more of them. JD.

11 DR. DANIELS: Yes, integration of
12 different disciplines in the management of
13 musculoskeletal problems, I mean it's exactly
14 what we're talking about today with the back
15 and that.

16 I mean I don't think that's -
17 everything is siloed, you know.

18 CHAIR CHOU: Thanks. All right

19 CHAIR TEMPLETON: This is Kim. I
20 guess maybe one more is evaluation or
21 secondary fracture prevention, the evaluation
22 of bill of health after the initial fracture.

1 CHAIR CHOU: Thanks, Kim. All
2 right I sense people are flagging and ready to
3 go out jump out the door, so are we ready to.-

4 MS. FRANKLIN: Yes, you can also
5 feel free to email staff with your additional
6 suggestions, and we'll be in contact with you.
7 We still have to - we're not - I don't think
8 we have any - yes. At this time we don't
9 anticipate that, but let's leave the dates
10 open in case we have some issues to
11 reconsider. We will as soon as possible. As
12 soon as possible.

13 CHAIR CHOU: All right. Thanks,
14 everybody.

15 (Whereupon, the above-entitled
16 matter was concluded at 2:34 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Musculoskeletal Measures Standing
Committee

Before: NQF

Date: 05-08-2014

Place: Washington, D.C.

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