

THE NATIONAL QUALITY FORUM

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PATIENT OUTCOMES STEERING COMMITTEE

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MEETING

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Tuesday, October 20, 2009

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The meeting convened at 9:00 a.m. in
Salon D in the Marriott Metro Center, 775 12th
Street, N.W., Washington, D.C., Joyce Dubow

and Lee Fleisher, Co-Chairs, presiding

MEMBERS PRESENT:

JOYCE DUBOW, MUP, Co-Chair
LEE FLEISHER, MD, CO-Chair*
RUBEN AMARASINGHAM, MD, MBA
LAWRENCE BECKER*

E. PATCHEN DELLINGER, MD*
ANNE DEUTSCH, PhD, RN
BRIAN FILLIPO, MD, MMM, FACP
LINDA GERBIG, RN, MSPH
EDWARD F. GIBBONS, MD
LINDA GROAH, RN, MSN, CNOR, FAAN
PATRICIA HAUGEN

DAVID HERMAN, MD*
DAVID S.P. HOPKINS, MS, PhD
DIANNE JEWELL, PT, DPT, PhD
DAVID A. JOHNSON, MD, FACP, FACG, FASGE*
IVER JUSTER, MD
BURKE KEALEY, MD, FHM
PAULINE McNULTY, PhD

MEMBERS PRESENT (Continued):

VANITA PINDOLIA, PharmD, BCPS*

AMY K. ROSEN, PhD*

BARBARA J. TURNER, MD, MSED, MA, FACP*

BARBARA YAWN, MD, Msc, MPH, FAAFP

STAFF PRESENT:

HELEN BURSTIN

SARAH CALLAHAN

JENSEN CHIU

ALEXIS FORMAN

MELISSA MARINELARENA

EMMA NOCHOMOVITZ

KAREN PACE

REVA WINKLER

BONNIE ZELL

MEMBERS NOT PRESENT:

SHELDON GREENFIELD, M.D.

*Via Telephone

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

2 (9:02 a.m.)

3 CO-CHAIR DUBOW: Good morning

4 again. Hope you all had a nice evening last
5 night.

6 Day two, we probably will arrange
7 our agenda just a little bit in order to be
8 able to break early, depending on how our
9 conversation goes.

10 We're going to talk about the
11 measure evaluation criteria. And again, we
12 have Karen Pace to walk us through some of
13 that material. Helen will join us later.

14 We also have Linda Gerbig, who
15 joins us, so, Linda, we'd like to welcome you
16 and give you an opportunity to just share with
17 us who you are. Go ahead.

18 MS. GERBIG: Thanks. I'm glad to
19 have finally arrived and to not be on the
20 telephone today. That's an absolutely
21 miserable experience.

22 I'm an RN by trade, a nurse by

1 trade, and I'm the vice president of
2 performance improvement for Texas Health
3 Resources, and we are a 14-hospital system
4 across North, Central and Western Texas, not-
5 for-profit, faith-based organization.

6 MS. GERBIG: Great. Well,
7 welcome.

8 Pat, you had a really truncated
9 opportunity yesterday. Maybe you'd like to
10 re-introduce yourself, too.

11 MS. HAUGEN: Okay. I'm Pat
12 Haugen. I'm an inflammatory breast cancer
13 survivor, 12 years, and I do volunteer work
14 with the National Breast Cancer Coalition.

15 My business career was with IBM,
16 so I have some experience with quality not
17 specific to health care measures, but have
18 been on one NQF panel for physician-level
19 oncology measures. And then our organization
20 has done some work to train advocates in some
21 of the specifics on measures relative to
22 cancer, and breast cancer, specifically.

1 Thanks.

2 CO-CHAIR DUBOW: Thanks very much.

3 Okay. If there are no other

4 issues at hand, let's get started.

5 DR. WINKLER: Okay. I just wanted

6 to make a couple comments, and thank you all

7 for your discussions yesterday.

8 I spent some time kind of

9 reviewing and figuring out what it was we

10 talked about. Lots of food for thought. And

11 I would like to encourage all of you who keep

12 coming up and whispering in my ear and showing

13 me some of the things that you're doing and

14 ideas and thoughts.

15 Keep the cards and letters coming,

16 because some great ideas have really

17 stimulated my thinking on terms of how to

18 organize some of this stuff. So, I really do

19 value and need your input. That's how the

20 steering committee can work very effectively

21 in shaping the way this project goes forward.

22 So, thank you very, very much.

1 Just as a follow-up, we had a lot
2 of talk about principles and definitions
3 yesterday, but I don't think we kind of came
4 to any conclusions, and so one of the things
5 we will be doing is, from all the discussion,
6 the notes, the recordings, all of it, is
7 drafting what we think you said or think you
8 wanted to say or tried to say, or something,
9 and then send it back out for you to then, you
10 know, work with it and see if you can come to
11 do the wordsmithing, be sure the meanings are
12 correct so that we can kind of capture all the
13 good thinking that was there.

14 Though I still think it's still in
15 rough form, I think we've got the kernels from
16 which we can get some good final product.

17 Okay. This morning's conversation
18 is about some of the nuts and bolts of NQF
19 work. For the part of the project where we're
20 going to be evaluating candidate measures for
21 endorsement, it's really critical that the
22 steering committee understands the whole

1 process of evaluation and NQF's evaluation
2 criteria.

3 As I mentioned briefly yesterday,
4 the whole process and the whole criteria over
5 NQF's lifespan has evolved, it's matured, it's
6 become more rigorous, and it's become more
7 focused with some very specific reasons for
8 that.

9 And we are trying to reach a
10 higher level of performance, recognizing that
11 performance measures are tools, that can drive
12 performance through a variety of mechanisms.
13 And so, we want to keep pushing it, raise the
14 bar higher, pushing harder.

15 So, as I mentioned yesterday, the
16 evaluation criteria were revised a year ago in
17 an attempt to meet these sort of higher
18 expectations.

19 And a lot of our processes are
20 also evolving. We're trying to move into a
21 fairly exclusively electronic world. For
22 those of you who have worked with this before,

1 you realize that a lot of trees were
2 sacrificed in our behalf, and so we're trying
3 to, you know, keep everything electronic.

4 In doing so, a couple of things
5 around the evaluation and the measure
6 submission process are now as automated and,
7 hopefully, are going to become more and more
8 so as we go forward.

9 But probably one of the most
10 significant changes for us was, this summer we
11 were able to institute an electronic measure
12 submission form.

13 Previously it was a fill-in-the-
14 blank Word document that, you know, then we
15 had paper. Lucky us. And it's a fairly
16 voluminous amount of information to manage.

17 Now that we've got it in
18 electronic form, we can then reformat it and
19 change it and give it back to you in any old
20 way we want.

21 So, this has been a change. All
22 changes do not necessarily go totally

1 smoothly, and they are not without their own
2 individual issues.

3 My friend Karen, who will talk a
4 lot more about the evaluation criteria has
5 been very much involved in working out the
6 bugs, working with the contractors, kind of
7 make this process work, because it's still in
8 evolution, and trying to make it work for
9 today, when they keep saying, "Well, in six
10 months we'll be able to do this."

11 It's like "Great! But what are we
12 doing today?" So, Karen is our how-are-we-
13 going-to-do-it-today kind of person.

14 So, the measures do come to us now
15 in an electronic submission format. For those
16 of you who have contacts with measure
17 submitters or are, you know, potentially
18 someone who will submit measures, the
19 information on measure submission is available
20 on the website, and you can, from our project
21 page, because we have an open call for
22 measures right now, go to the measures

1 submission form.

2 Go to the Call for Measures
3 section, open it up, submit measures. There's
4 a button. You actually need to have
5 registered for the website in order to submit
6 because then whoever is submitting has their
7 profile.

8 Dashboard. That's what we call
9 it. Dashboard. The wrong word, to follow
10 what happened to that submission.

11 So, if you're a measure submitter,
12 there's a reason to be registered and all that
13 kind of stuff. So, things are happening in
14 that realm.

15 So, luckily now, as opposed to a
16 bunch of Word documents, we now have
17 spreadsheets with a whole bunch of stuff in
18 them. So, that information is now available
19 to us electronically.

20 Thanks, again, to Karen's good
21 work, the output that we're going to be giving
22 you is something we've given you an example

1 of, and we're going to talk about today,
2 because we asked the questions in ways that we
3 hope work for the measure submitter.

4 But for the evaluation, we want to
5 use that information, aligned with the measure
6 evaluation criteria, so we reshuffle it, and
7 put it in a different format, something that
8 was almost impossible because it was so
9 cumbersome in a paper world.

10 So, again, Karen has worked with
11 that. So, we want to go through that with
12 you.

13 Part of the evaluation process,
14 though, does have a lot of up-front work, and
15 so staff has work to do. The steering
16 committee has parts of it, the TAP have parts
17 of it, and we're kind of building an
18 evaluation process that gets more robust over
19 time.

20 So, this sort of outlines the
21 process. The staff, our staff will be
22 evaluating whether the conditions for

1 consideration are met, prepare and distribute
2 things. So, we're the paper-pushers, if you
3 will, the electronic paper-pushers. Thank you
4 very much.

5 And this steering committee will
6 be primarily reviewing the cross-cutting
7 measures. There isn't a TAP for the cross-
8 cutting measures, all right, so you won't have
9 that step.

10 The TAPs are going to evaluate the
11 subcriteria, and if that's a confusing term,
12 hang in there, we'll show you what we mean for
13 the condition-specific measures appropriate to
14 the different areas.

15 Then, the full steering committee
16 will evaluate and vote on the threshold
17 criterion, which is importance to measure and
18 report, and we're going to talk about that.

19 And for measures that pass that
20 criteria, then we evaluate the remaining three
21 major criteria.

22 The full steering committee, then,

1 votes on those recommendations regarding
2 whether to recommend to the membership the
3 measures go forward for endorsement.

4 So, that's sort of the outline of
5 the process, but we want to take you through
6 the evaluation criteria, because our
7 experience is such that sometimes it's hard
8 for steering committee members to grasp what
9 we're meaning, why we've got the criteria the
10 way we do.

11 And this is an opportunity to kind
12 of go through it in detail with you and you
13 can ask questions and we can all try and get
14 onto the same page.

15 As both Joyce and David will tell
16 you, the more the steering committee can work
17 within this construct, the cleaner things come
18 down the rest of the steps, and we don't have
19 to do a lot of "Send it back," or "What in the
20 world were they thinking?" or "Why did they
21 did they do that?"

22 And it facilitates the

1 communication if we're all working off the
2 same sort of rules of the road, if you will.

3 So, the evaluation criteria that
4 we use is standardized. There are four main
5 criteria. The first one is importance to
6 measure and report, and we very specifically
7 have stated it that way. In the old world it
8 was importance.

9 But important has so many meanings
10 to so many different people. We are all about
11 these performance measures being important to
12 drive quality improvement. That's what we're
13 here for. All right. There are so many very
14 important things out there, but not all
15 measures that are developed have the
16 characteristics and the capability of doing
17 good things as a result of implementing them.

18 So, it's an important threshold
19 criteria. We're going to talk more about the
20 details.

21 Scientific acceptability of the
22 measure, itself, as opposed to the science of

1 the topic that is being addressed. It's not
2 just are beta blockers good in patients with
3 coronary artery disease, is this measure, the
4 way it's specified, you know, precisely
5 specified, reliable, valid and all the other
6 good things necessary. So, we are really in
7 that category, looking at the measure.

8 Usability, it's the "So, what?"
9 question. Okay. Somebody does it, collects
10 the data, has the data, can they use it? Can
11 they use it? Do they understand what it
12 means? Is it useful for a wide variety of
13 things, particularly for public reporting?

14 And then feasibility. Can it be
15 done? Is it even possible? Great idea, but
16 can it be put into production such that it can
17 be used in a widespread way.

18 So, we're going to talk about the
19 subcriteria that helped feed into those,
20 because again, so many of the questions that
21 come back during comment period, that you may
22 get asked back by the CSAC or even potentially

1 the Board of Directors, generally you're
2 embedded in one of these somewhere and without
3 appropriate consideration of them, you end up
4 kind of wishing you'd spent a little more time
5 thinking about it.

6 So, I'm going to ask my friend
7 Karen to jump in at any time. Karen was the
8 staff person who worked with the subcommittee
9 of the CSAC to revise the criteria last year.
10 So, she spent endless hours of these
11 conversations of how the criteria should be
12 characterized to try and reach the goals that
13 we've set for what the endorsed measures
14 should do.

15 So, importance to measure and
16 report, this is looking at the specific focus
17 of what is measured, and it needs to be
18 important enough to expend the resources to
19 collect data, analyze the data and report the
20 data.

21 All right. So we're talking about
22 a balance. There are lots of very important

1 things, and that's why we try not to use the
2 term "important," because, you know, that's a
3 value system, and what's important to you is
4 important, but we're talking about the
5 importance of this measure in measurement
6 reporting within the NQF world.

7 And so, it's a balance, because
8 measurement is not free. It's costly. So, we
9 need a bang for our buck, and so that's the
10 importance to measurement report. So, not
11 that it's important in its own right, but that
12 the measure, the actual measure, has
13 importance.

14 And this is one area that was
15 really worked on very significantly in the
16 revisions. There are three. One is
17 relationship to an NQF priority, and if it's
18 one of the NQF priority or the priority
19 partnership's goals, aces, and we actually
20 have a special section on the form, and then
21 we'll check it and tell you, flag it and say,
22 "Hey, this one of them," or, because not

1 everything falls under all those priorities,
2 a high-impact aspect of health care.

3 Now, impact can be a large number
4 of things, number of people, dollars spent,
5 severity of illness, you know, those sorts of
6 things.

7 So, impact, again, is in the eye
8 of the beholder, but it is important that it
9 has some oomph behind it in some way, shape or
10 form.

11 Importance, and you may think this
12 is a little bit inconsistent, because so many
13 people say why isn't this in the science, but
14 the evidence to support the measure focus.
15 Okay. If their process measures were looking
16 for the relationship to outcome, what is
17 there, what is the evidence, how good is the
18 evidence, what is the evidence that says doing
19 this will get you what you want.

20 And so good ideas might be very
21 important, but without the evidence behind
22 them that really gives us a strong tie to good

1 patient outcomes, you know, maybe not so good.

2 In this particular case, we kind
3 of jump this one because all of our measures
4 should be outcome measures. And so, outcome
5 measures sort of in and of themselves, reach
6 that higher level of criteria of being outcome
7 measures.

8 However, at the same time, perhaps
9 not all outcomes, which will be your realm to
10 determine, are the most important things
11 going.

12 Opportunity for improvement.
13 Again, some people will short-cut this to say
14 the gap in care, but it's not just that. The
15 question is, at the end of the day: do you
16 envision that if this measure is put into
17 play, and measurement we do know changes
18 behavior, that we will see improvements in
19 overall health care, in overall outcomes.

20 So, the opportunities for
21 improvement may be current lower performance,
22 but it could also be variation. So, maybe

1 you've got some folks doing really well, and
2 their mortality rates or their complication
3 rates or their intermediate outcomes are just
4 stellar, but there are a whole bunch of folks
5 that aren't doing so hot.

6 So, you know, we've got this
7 variation. We want everybody to experience
8 good care. We want to raise all the boats.
9 So, the opportunity for improvement in
10 variation in care is also an important aspect.

11 Also, the opportunity for
12 improvement, as Helen alluded to, may be a
13 combination of the impact. You get a lot of
14 people, even if you're only going to move it
15 a little bit, you're going to move a little
16 bit over a lot of people, and that may
17 ultimately have a significant improvement.

18 So, part of the challenge to the
19 steering committee is weighing these in
20 determining if it's important to measure and
21 report and move it on further through the
22 process.

1 The key aspect of all of this is,
2 if you decide it's important, why? On what
3 basis, so we can say it's because it's this,
4 it's because it's this, it's because it's
5 this.

6 Conversely, if you say it's not
7 important, then it's not important because it
8 doesn't meet these criteria.

9 This is the way we communicate to
10 all the stakeholders out there, because, as
11 you know, in a multi-stakeholder world, there
12 are folks who are tied to certain things, and
13 some measurements are going to be very
14 important to them, but perhaps not in a
15 greater world.

16 So, we need to be able to explain
17 the decisions and not just say, well, I just
18 thought so. That one's hard to justify and
19 hard to move forward.

20 Yes. Karen, jump in.

21 DR. PACE: Just a couple other
22 things to building on what Reva's already

1 mentioned, and that is with the NPP, you know,
2 we really are looking for the specific goal,
3 but as Reva said, if it doesn't address an NPP
4 goal, that doesn't mean the measure is out.
5 You know, there's all kinds of way to look at
6 high-impact. So, that's not a reason.

7 The national priority partners.

8 DR. WINKLER: That we talked
9 about.

10 DR. PACE: Thank you.

11 PARTICIPANT: Six priorities we
12 mentioned.

13 DR. PACE: Right. And there are
14 some specific goals attached to each of those
15 priority areas. So, that's what staff will be
16 looking for and provide that information to
17 you.

18 The other thing is that all of the
19 things that Reva talked about, about, you
20 know, the opportunity for improvement and the
21 evidence, we really are asking the measure
22 submitters to provide some data.

1 So, rather than just saying
2 there's variability in performance, if there's
3 any studies that have been done in the
4 literature, even if it's from some pilot work
5 that they did, we're trying to ask people to
6 provide some context for saying that it's a
7 performance gap so that you have something to
8 look at.

9 And, as Reva mentioned about the
10 evidence, we have gone back and forth of where
11 we situate that, so it's interesting, but the
12 idea is that, and some of our earlier
13 documents talked about leverage, and Reva was
14 talking a lot about, you know, are we
15 measuring things that are really going to move
16 us forward in improving health care.

17 And so, this idea of leverages, if
18 you're doing things that have really been
19 proven to improve outcomes, that's what's
20 going to, you know, warrant measurement so
21 that we continue to make some improvement in
22 those areas.

1 And because it's a threshold
2 criterion now, we thought it best to be
3 included in that importance criterion.

4 DR. WINKLER: Yes, that's what I
5 was going to say. Just to reiterate, the
6 must-pass, and it kind of stops things right
7 there. So, just to reemphasize.

8 Okay. Now, questions.

9 DR. JEWELL: So, I think one of
10 the interesting things about the evidence
11 piece that you just discussed, is that many of
12 the outcome measures, at least in our world,
13 were designed, as we talked about yesterday,
14 at the patient level, and really were not
15 designed with quality improvement in mind.

16 DR. WINKLER: Right.

17 DR. JEWELL: So, the availability
18 of evidence, I think, is going to be pretty
19 variable, depending on which outcome measures
20 we're talking about. And I would venture to
21 guess, probably pretty scarce initially, just
22 because they weren't designed as provider-

1 level measures in the first place.

2 DR. PACE: And as Reva said, you
3 know, for all of our other types of measures,
4 we're looking for evidence of association with
5 the outcome. So, when we're starting with the
6 outcome, it's the question: What would the
7 evidence be?

8 We have asked in this round of
9 measure submissions for submitters, if they
10 have knowledge of studies that have shown that
11 that outcome can be improved. It's not an
12 absolute requirement because the way we look
13 at outcomes for quality improvement is the
14 variability that Reva was talking about.

15 If there are some providers that
16 are doing really well, it shows that you
17 can't, you know. And if it's a proper
18 measure, risk-adjusted, it shows that you can
19 achieve higher levels, but it is helpful and
20 strengthen things if there have been studies
21 done that show that improvements can be made
22 in that area.

1 So, we ask for that, but it's not
2 like something that would necessarily stop a
3 good outcome measure from going forward.

4 DR. WINKLER: Yes. This is really
5 the difference between evaluating process
6 versus outcome measures, one significant thing
7 is where it's a very critical part of
8 evaluating a process measure, how do you
9 determine the link to outcomes on an outcome
10 measure? I mean, you know, it sort of negates
11 itself, if you will.

12 Are there any other questions,
13 because this actually is the criterion that
14 steering committees wrestle with the hardest,
15 because they want to keep that "important"
16 concept, you know, tightly bound. Well, this
17 is really, really important. Yes. Okay.
18 Good.

19 But that difference is sometimes
20 difficult, and we appreciate that, but that's
21 why we're trying to get you indoctrinated, if
22 you will, into kind of thinking of importance

1 the way NQF thinks of importance.

2 DR. YAWN: Well, I think that's
3 one of the potential advantages of having sort
4 of multi-perspectives, because you guys are
5 very tied in to rehab. I have to tell you
6 that most of my patients never go to rehab.
7 They don't need to go to rehab.

8 So, I'm going to have a very
9 different perspective. When you tell me, "Oh,
10 this is the most important thing in the
11 world," I say, "Yes, it is for the eight
12 percent of patients that do it, but it's not
13 too important for the 92 percent that don't
14 need it."

15 So, I think that will be one thing
16 that's helpful, and I look forward to lots of
17 people sort of pulling my chain back and
18 saying, "No, no, you're not looking broadly
19 enough."

20 DR. GIBBONS: Would you say that,
21 then, in this context, every measure has to be
22 an outcome measure and a process measure has

1 to be associated with an outcome measure?

2 DR. PACE: That's what we would
3 prefer.

4 DR. GIBBONS: Right.

5 DR. PACE: But we know in reality
6 there are thousands of health care processes
7 that haven't been studied with the evidence
8 that we're talking about, but the ideal is if
9 it's something, you know, important enough to
10 drive changes and improvements in patient
11 outcomes, that there's some evidence behind
12 it.

13 DR. WINKLER: I'm going to take it
14 one step further, because not only do these
15 measures have the potential to drive
16 improvement, they are used for accountability.

17 And if you're holding people
18 accountable in any variety of ways, you really
19 want something that's based on some pretty
20 strong evidence as opposed to, well, it seems
21 like a good idea, you know.

22 And that is one of the reasons we

1 want to keep the threshold fairly high, is the
2 impact on ultimate uses for accountability.

3 CO-CHAIR DUBOW: But in terms of
4 linking it, you know, having a known
5 relationship to an outcome, I think it's fair
6 to say that among all of the measures in the
7 NQF portfolio, there is quite a degree of
8 variation.

9 And the point is that, you know,
10 we're trying to raise the bar, as we said
11 yesterday. So, as we keep raising the bar, I
12 think the likelihood of seeing more measures
13 that have that known relationship to
14 proliferate and see the other ones go by the
15 board.

16 DR. WINKLER: And a lot of it is a
17 relative thing. We will often see a lot of
18 measures based on, say, guidelines, but the
19 level of evidence is Level C consensus.
20 There's no science behind it.

21 So, you know, is that evidence or
22 is it not evidence, you know? And so, it

1 isn't as black-and-white, and there are
2 gradations, but luckily for the outcomes
3 project that is less of a concern for us.

4 But you can see why it becomes a
5 real significant issue for the steering
6 committees.

7 MS. GERBIG: Yes, and another
8 issue that I just raised is, without evidence
9 from the user's point of view, the user of
10 these measures.

11 We spend all of our time storming
12 and arguing about the validity of the measure,
13 and quite frankly, we never get on to
14 improvement because we can delay it by arguing
15 it.

16 And I think one of the reasons
17 also, as users, we tend to sort of glom onto
18 a process measure, as you can measure them and
19 report on them quickly. So you can do
20 something very quickly.

21 But I am not aware of an outcome
22 measure that you can get with any sort of real

1 time data that's actionable, so then you storm
2 into the issue of, well, this data was two
3 years old, or more than a year old, so I fixed
4 that, and I don't have to pay any attention to
5 it, only to wait another year to see that it
6 was never fixed, and you're back into the same
7 position again.

8 So, I think that's something we're
9 going to have to deal with on the outcome
10 measure issues, along with the evidence.

11 DR. HOPKINS: It seems to me, if
12 we do our job here, we will have defined the
13 outcomes and identified the measures of
14 outcome that are what we want process measures
15 to be linked to. No?

16 But this is the outcome steering
17 committee.

18 DR. WINKLER: Okay.

19 DR. JUSTER: I had one question of
20 Linda. Maybe I didn't understand where you
21 were going with that it can take a year or two
22 to get the outcome. It certainly would be if

1 you were looking at, for example,
2 hospitalization rates for something you
3 wouldn't want to track changes in that every
4 week, necessarily.

5 But would some outcome measures
6 such as presenteeism, possibly some kinds of
7 functional status, and then the intermediate
8 outcomes, of course, like blood pressure or
9 something, naturally you would track.

10 I'm looking at the other side of
11 importance, the accountability that you were
12 talking about in terms of driving the outcomes
13 improvement system directly from the outcomes
14 measurement system.

15 If I was building a tool inside of
16 a, you know, an office, I mean, a facility, I
17 might want to have the outcomes measurement
18 system directly feed into the outcomes
19 improvement system.

20 MS. GERBIG: And, you know, we
21 have the opportunity, maybe, to begin to think
22 about outcomes in a different manner than we

1 have historically considered them.

2 For instance, all-cause mortality
3 or all-cause readmission on hospital
4 comparers, what we typically think of as an
5 in-patient outcome measure now, but does it
6 need to be.

7 I don't know. Are there outcome
8 measures that we could measure much more real
9 time than we do and we have sort of taken the
10 easy way out in the way that we do it now.

11 So, I would agree that there could
12 be some possibilities that we've just not
13 looked at in the past.

14 DR. WINKLER: Yes. Linda, one of
15 the conversations the committee had yesterday
16 was on the types of outcome measures and I
17 don't want to scroll all the way back through
18 that slide, but there were any number and the
19 group added a few more.

20 Certainly mortality, certainly
21 complication rates, certainly service
22 utilization, like readmission, however, there

1 were other things such as the intermediate
2 outcomes, things like functional status,
3 things like patient-reported outcomes around
4 symptoms, or how are you feeling.

5 So, we were discussing that wide
6 spectrum. So, I think to the degree that
7 there might be measures in existence out
8 there, we would certainly want to be able to
9 look at it from that perspective.

10 DR. JOHNSON: Rita, this is Dave
11 Johnson. Can I add one thing just to extend
12 the discussion about -- about accountability
13 and how some measures may be helpful, even
14 though they're not really outcomes measures,
15 they are process measures.

16 The example is one thing that
17 we've been working on is trying to standardize
18 a benchmark for colonoscopy reports, and we
19 worked with CDC and their quality assurance
20 program to come up with a document that says
21 this is a standard that, for example, when a
22 colonoscopy is done, people should do photo

1 documentation of the cecum and the ileocecal
2 valve.

3 That's a process measure, but it
4 makes people think when you start to put that
5 in a report that, you know, you documented it.
6 It makes it also recoverable, discoverable and
7 also allows for analyses in quality programs
8 when you go back and you do snapshot analyses
9 of did they do what they said.

10 And that's a measure that I could
11 see as being a standard, just to make people
12 more accountable and part of the report
13 process would be kind of a quality improvement
14 in and of itself, just holding people
15 accountable, and also allowing for
16 retrospective reviews of these as you start to
17 move into, you know, into a process of
18 evaluating quality report cards.

19 DR. WINKLER: Thank you.

20 DR. PACE: Just one comment about
21 real time information on outcome measures, and
22 it's true, if you're talking about risk-

1 adjusted rates that you can compare to other
2 hospitals or physicians, et cetera.

3 But there's really nothing that
4 would prevent an organization from monitoring
5 their outcomes real time. So, I mean, you
6 know, an extreme example is mortality.

7 You can look at each case as it
8 occurs and do an investigation of any issues.
9 If we're talking about function, you could set
10 up some systems where you're monitoring their
11 achievement, and intervene before the
12 patient's discharged if they are not making
13 progress.

14 So, I think, you know, it is
15 definitely something that providers need to
16 get used to in terms of how they use outcome
17 measures versus process measures, but there
18 are ways to start thinking about how you
19 monitor that real time, and realizing that
20 you're not going to have that risk-adjusted
21 comparison, but if you're comparing yourself
22 to your prior performance, kind of in the

1 continuous quality improvement vein, you know,
2 most organizations don't have dramatic changes
3 in their own case mix from year to year.

4 So, risk-adjustment, if you're
5 just comparing your own performance within
6 your institution isn't as big an issue as when
7 you start doing external.

8 DR. JEWELL: So, I need to ask a
9 clarifying question. Because the call is
10 specifically for outcomes measures, we're not
11 anticipating, are we, that people will have
12 submitted process measures that are linked to
13 outcomes?

14 DR. WINKLER: No, not as
15 submissions, but one of the things we are
16 going to be doing is going back into that
17 database and pulling out the measures in the
18 topic areas, diabetes.

19 DR. JEWELL: Right.

20 DR. WINKLER: You know, we've got
21 probably a dozen, 15 measures.

22 And so, one of the things we're

1 going to do is pull those out to look at the
2 process measures, go back and look at the
3 evidence and say, for each of these processes,
4 what's the outcome it's related to, the total
5 list of outcomes, it's just another way of
6 asking what are outcomes for this particular
7 topic area.

8 So, there are different ways of
9 looking at it. But that was just one approach
10 I was thinking of to help tie all these things
11 together.

12 DR. JEWELL: No, and that makes
13 sense to me. The conversation, at times, it
14 sounded like what you just described, and at
15 other times it sounded like perhaps process
16 measures that were linked to outcomes would
17 come in as original submissions, and I just
18 wanted to be clear in my head which.

19 CO-CHAIR DUBOW: The issue of
20 intermediate outcomes. Do you not expect any
21 intermediate outcomes?

22 DR. WINKLER: No, we do.

1 CO-CHAIR DUBOW: Well, isn't that
2 what you're talking about?

3 DR. WINKLER: Yes.

4 (Off-mic comment.)

5 DR. WINKLER: Well, not
6 necessarily.

7 CO-CHAIR DUBOW: Well, it could be
8 a process measure that has a link.

9 DR. WINKLER: Microphone.

10 DR. GIBBONS: I think there could
11 be distinctions. I mean, I think for purposes
12 of our work, it would be important to be very
13 specific about the scope.

14 DR. WINKLER: Yes.

15 DR. GIBBONS: And I think there
16 are process measures that are not intermediate
17 outcomes.

18 DR. WINKLER: Right.

19 DR. GIBBONS: There are process
20 measures that could be intermediate outcomes,
21 and then there's outcome measures.

22 DR. WINKLER: Yes. At this point

1 we have kept it as broad as we discussed
2 yesterday, and intermediate outcomes,
3 certainly, as well as functional outcomes,
4 patient-reported outcomes, those all were on
5 the original list and you all kept them on the
6 list.

7 CO-CHAIR DUBOW: Right.

8 DR. WINKLER: And said, "Keep
9 them." And so, and even embellished some of
10 them. So, we are casting at that line, but a
11 true process measure, was this thing done, was
12 this process of care, was this test done.

13 The classic process measures are
14 not something we're asking for or expecting to
15 entertain in this particular project.

16 CO-CHAIR DUBOW: Okay.

17 DR. WINKLER: Process measures.
18 Classic process measures.

19 DR. AMARASINGHAM: Okay. So we
20 are not going to be taking them into account?

21 CO-CHAIR DUBOW: But we are going
22 to look at intermediate, like blood pressure

1 control?

2 DR. WINKLER: Yes.

3 DR. AMARASINGHAM: Right.

4 CO-CHAIR DUBOW: Okay.

5 DR. AMARASINGHAM: Which is a true
6 outcome measure.

7 CO-CHAIR DUBOW: True outcome
8 measure, right.

9 DR. WINKLER: Did I hear somebody
10 on the telephone just now?

11 DR. JOHNSON: Yes. Dave Johnson
12 again.

13 DR. WINKLER: Oh, okay.

14 DR. JOHNSON: Would it be, maybe,
15 again, more reasonable to have a little bit of
16 leeway to each of the TAPs to decide really
17 where they think the biggest contributions
18 could be, for example, the discussions we had
19 a little bit yesterday about colonoscopy.

20 We're going to have a large gap in
21 time until we really have appropriate outcome
22 measures, and we don't even have good process

1 measures in defining quality and
2 standardization of reporting and things that
3 we, by consensus, the national societies would
4 agree, and we do have consensus documents that
5 would support that.

6 So, the are not Level 1-A
7 evidence, but if you really want to make a
8 difference in quality, some of the short steps
9 would be process for standardization of
10 reporting, and that's really something that is
11 not at all out there right now.

12 We talked about things like, you
13 know, withdrawal time and adenoma detection
14 rate, and those, again, are somewhat
15 intermediate outcomes to prevention of colon
16 cancer or reduction of colon cancer mortality,
17 which might take ten to twenty years to show.

18 So, that's what I'm just seeing
19 potentially more of an issue in ability for GI
20 measures to make a really meaningful
21 difference in overall quality in a shorter
22 time. We might have to have a little bit of

1 leeway on some of these being process
2 measures.

3 DR. WINKLER: Well, as we've also
4 discussed, there are areas among the
5 conditions that this project is hoping to
6 address where we realized there just aren't
7 outcome measures yet.

8 And so, we can't work with
9 something that doesn't exist. However,
10 starting to do some serious thinking about
11 what would be appropriate outcome measures, so
12 that we can encourage measure developers to
13 take them on and so that the next time we try
14 and do this in a year or two, we won't come up
15 empty.

16 Just as an aside, NQF, this is not
17 the only work NQF is doing. We have any
18 number of ongoing projects that address all
19 sorts of things, and so the opportunity to
20 consider other process measures exists
21 currently and in the future.

22 So, we're trying to keep the scope

1 such to address the issues around outcome
2 measures that so many of the stakeholders
3 have, you know, been clamoring for.

4 And so, that's why this project
5 has the kind of boundaries on it that it does,
6 but realize there are a lot of things
7 happening at NQF. So, it's not an either/or,
8 it's just what are you going to look at as
9 opposed to what is NQF going to look at.

10 CO-CHAIR DUBOW: So, the
11 opportunity, for example, as Dave is
12 suggesting for the TAP to suggest to some
13 other steering committee or to the NQF staff
14 that process measures are needed in that
15 particular area and may be appropriate, but if
16 it were straight process measure, as we just
17 discussed it, would probably be out of scope
18 for this particular steering committee.

19 DR. WINKLER: But there are others
20 we could probably --

21 CO-CHAIR DUBOW: But it could be
22 referred to some other committee.

1 DR. WINKLER: Correct.

2 DR. KEALEY: So, will the TAP
3 chairs going to be updated on what other work
4 is going on in their area?

5 DR. WINKLER: Sure. To the degree
6 you can manage that amount of information,
7 we'll be more than happy to share it with you.

8 DR. KEALEY: Yes. I mean, it
9 sounds like his impression is that he's
10 working on the latest update of GI measures,
11 where it sounds like you're saying he needs to
12 come up with outcomes and somebody else is
13 working on the latest.

14 DR. WINKLER: Yes.

15 CO-CHAIR DUBOW: I think the staff
16 attends all of these meetings and they know
17 how to triage this stuff to go to the
18 appropriate places, so it's not as though
19 every chair has to know everything because the
20 staff provides --

21 DR. WINKLER: That's our job.

22 CO-CHAIR DUBOW: Right. That's

1 what we've been kind of, and the rest of the
2 staff are there for. So, I don't think we're
3 going to lose any opportunity. But, you know,
4 there's a triaging function that will happen.
5 Okay.

6 DR. WINKLER: All right. Second
7 of the major criterion I think is something
8 that is, again, another thorny one.
9 Scientific acceptability of the measure
10 properties.

11 And we say that very explicitly
12 because we don't want to go back into the
13 evidence. That's not what we're talking
14 about. So, sometimes, again, a bit confusing
15 in the conversations that we have, but we're
16 looking at the actual measure itself, so it's
17 not, you know, the concept of beta blockers
18 after MI, it's this beta blocker after MI
19 measure and the way it's specified and has
20 been used, and what do we know about it as a
21 measure.

22 So, the subcriterion, and we'll go

1 into details and the precision of the
2 specifications, is there ambiguity, are there
3 definitions, could it be interpreted in a
4 variety of ways in different places. That
5 really doesn't help the standardization of
6 comparability of the results. So, precision
7 specifications.

8 The reliability, validity and
9 discrimination of the measure. Does it work
10 as a measure, is it going to tell us the
11 things we want to know. We are hoping to get
12 information about performance. Can it do it?
13 Is it designed well enough to do that?

14 Clearly, what we hope is that
15 during measure development there has been
16 testing of these characteristics to find out,
17 is the data that's obtained reliable, does the
18 measure actually measure what you want it to
19 measure, is it valid, and does it, at the end
20 of the day, give you results that allow you to
21 make comparisons.

22 I mean, that's the whole name of

1 the game here. And this information is not as
2 easy to come by.

3 The measurement world has sort of
4 been ramped up in response to a lot of urgency
5 in the market place, and so wanting the
6 measures and getting the measures out, this
7 step has kind of been truncated or at times
8 sort of temporized, if you will.

9 And so, while I don't want to
10 spend a lot of time on it, we have made
11 provisions for measures that aren't fully
12 tested to the degree we'd like them to, and
13 giving them a time-limited endorsement, for
14 only two years.

15 But again, you know, that's an
16 uncomfortable place to be, measures that
17 haven't been tested are difficult, and I think
18 we do want to see the degree of what we know
19 about this measure, how does it behave, as we
20 do this.

21 Question, Mike.

22 DR. AMARASINGHAM: Just because

1 I'm new to this process, what degree of
2 validation do we usually require, like, and do
3 we specify the method of validation?

4 So, for example, can split-sample
5 validation on a single population be
6 sufficient? Do we need to have separate
7 samples? Do we need to sample it on entirely
8 different populations with different
9 socioeconomic characteristics?

10 DR. PACE: Good questions. For
11 validity, and I think you're talking about the
12 risk model development, the split-sample --
13 sorry. Are you talking about validity, in
14 general?

15 DR. AMARASINGHAM: Validity, in
16 general.

17 DR. PACE: Okay.

18 DR. AMARASINGHAM: But, obviously
19 --

20 DR. PACE: I think Reva may have
21 mentioned this at the beginning, and I'll
22 emphasize it now because this is an area where

1 it really comes into play, and that is that
2 our evaluation criteria are guidance that we
3 don't have, especially in this area, we don't
4 have, like, strict rules like you have to do
5 inter-rater reliability or you have to do
6 criterion validity, and we don't have
7 thresholds, so that we don't have something
8 that says, you know, for reliability, your
9 CAHPS statistic needs to be, you know, .4 or
10 higher in other -- so, what we ask the measure
11 stewards to provide information on what
12 analysis they did and what those results were
13 for, you know, our committee, our TAPs and
14 committees to take a look at.

15 So, and, you know, we often get
16 that question, and it's hard to just give one
17 answer, because sometimes what testing you do
18 -- or most times, and it depends on what type
19 of measure it is, what the data are that
20 you're using, and so it would be impossible,
21 at least at this stage of our game, to, you
22 know, tell everybody now, if you have this

1 measure we expect this type of testing.

2 So, for validity, and the other
3 thing I just want to mention about validity,
4 and both reliability and validity.

5 So, having precise measure
6 specifications is the foundation for having a
7 reliable measure. And what we mean by
8 reliability is repeatable, reproducible
9 results.

10 So, if you have those good
11 specifications, that's the first step to
12 moving towards reliability. And the evidence
13 we talked about under importance is that
14 foundation for validity, I think outcome
15 measures have inherent validity, because it's
16 the reason that people seek health care, and
17 the goal of health care.

18 But, having said that, what we're
19 actually talking about with validity is, can
20 you make valid conclusions about quality of
21 care from that measure.

22 So, it's a little bit trickier in

1 terms of validity, and that's one of the
2 reasons that we often don't get information on
3 validity, but quality is kind of an abstract
4 construct.

5 So, it's not like the validity
6 that, when you take someone's blood pressure
7 you are actually getting their blood pressure.
8 We know, you know, the quality measure of what
9 percentage of patients achieve a certain level
10 of blood pressure is measuring blood pressure
11 are the percentage of patients, but what we're
12 interested in is: does that measure
13 discriminate quality of care.

14 So, we do make provision, and we
15 recognize that validity is one of the more
16 difficult aspects of testing, and we do say
17 that if face validity is the only validity
18 that is provided, it should be systematically
19 assessed.

20 So, we would prefer that measure
21 developers, if they are going to rely on face
22 validity, to provide more information about

1 how that was determined; did they do some kind
2 of voting, some kind of rating among their
3 committee members?

4 Some of you may be familiar with
5 the RAND method of rating validity of
6 measures. So, having said that, you know, the
7 reality is we often don't get good validity
8 information, and that's why we have this
9 variety of stakeholders together to identify
10 whether there are issues with whether that's
11 a valid measure of quality or not, but this is
12 an area where NQF is, you know, continuing to
13 try to implement and encourage good
14 measurement principles but, you know, you
15 won't always have that information.

16 CO-CHAIR DUBOW: Dianne.

17 DR. JEWELL: So, in my mind
18 there's a distinction, at least I thought I
19 heard you say, that there are really two
20 levels of validity. One is the validity of
21 the measure itself which is, I think, what
22 initially you were talking about.

1 And I would say that in the realm
2 of principles, I would encourage us strongly
3 to ask measure developers to submit evidence
4 of validity of the measure for its intended
5 purpose, because we ran into that problem two
6 years ago with a set of measures that only had
7 reliability data to support.

8 The second piece of validity,
9 which is, is it valid as a quality metric.
10 Again, I think we're not going to get much
11 evidence, because that's not what they were
12 designed to do originally.

13 So, not that we shouldn't ask for
14 it, but I think that's where we're not going
15 to find -- where we're really going to
16 struggle for them to submit evidence because
17 they didn't create these things as provider
18 metrics.

19 DR. PACE: So actually, for
20 reliability and validity, there's kind of two
21 levels, at the data level and then at the
22 aggregate measure, quality measure level.

1 And so, you know, so sometimes you
2 have for a -- you know, if you're talking
3 about a scale, you might have internal
4 consistency reliability for that scale. In
5 terms of the reliability of the ultimate
6 aggregated measure, maybe not.

7 There may be some analysis of, you
8 know, what portion of the variation is random
9 versus systematic, et cetera, and that gets
10 very complicated and we have all kinds of
11 experiences with our measure stewards.

12 So, it will depend on, you know,
13 what type of measure, what the data are but I
14 think, you know, we need to think of these as
15 building blocks, and so we may not be at the
16 level of the most sophisticated testing, but
17 we'll encourage everyone to be looking at, you
18 know, first is it on a sound foundation.

19 Because, if those first two
20 foundations aren't there, the chances are
21 you're not going to get to a measure that
22 would test out properly.

1 But, you know, it's something
2 that, you know, you all will have to work
3 through because it's challenging.

4 DR. AMARASINGHAM: Just a quick
5 follow-up. I mean, the conundrum that I see,
6 and I'll propose a potential way of looking at
7 it is that, you know, on one hand we don't
8 have enough measures.

9 And so if we keep waiting for a
10 certain level of evidence for standards, we're
11 not going to ever have any measures. It's
12 going to take a long time.

13 On the other hand, I'm concerned,
14 as someone on the ground taking care of these
15 patients, that among my colleagues, there's
16 always this concern that these half-vetted
17 measures come out that ultimately, after five
18 years you find out aren't very important, or
19 aren't validated appropriately.

20 And so I wonder whether there's
21 some middle ground of a level of confidence in
22 the measure that, you know, if a measure had

1 not only face validity, but criterion
2 validity, discriminant validity, convergent
3 validity, concurrent validity and has been
4 tested in multiple different populations on
5 both national and local data sets, that's an
6 incredible measure.

7 DR. WINKLER: Yes. Have you seen
8 one? Do you know of any?

9 DR. AMARASINGHAM: Well, I mean,
10 for example, you know, I thought that the
11 hospital readmission is on the way to becoming
12 a very good measure. I think it has some
13 serious flaws in certain areas, but among
14 measures, that measure was very well done,
15 done in a Connecticut sample, done in a
16 national sample.

17 They did c-statistics. They did,
18 you know, large technical papers on it. A
19 measure that just has face validity would have
20 extreme concern to me, especially if the NQF
21 measures are tied to accountability and pay
22 for performance, and the average person can't

1 distinguish which measure should be used for
2 which, and if it comes out of NQF sanction and
3 potentially is in widespread practice, what
4 you have the potential of doing is saying the
5 people that are deciding this really don't
6 know what they're doing and I can't
7 distinguish between the most important
8 measures as a person on the ground.

9 And so, I think the NQF, if it
10 hasn't been considered already, needs to think
11 about something like the US Task Force for
12 Preventive Services or others that kind of
13 have grades of evidence and levels, because,
14 you know, I think there are certain measures
15 that are phenomenal.

16 At the same time, you don't want
17 all measures to go through that process,
18 because it's going to take ten years, how you
19 get practice with the measure and so forth.

20 And because I think these very
21 careful levels of validity need to be
22 demonstrated for each measure, and if we don't

1 have it, but we believe a measure is on its
2 way, if we intuitively believe that a measure
3 could be very useful, you know, then we should
4 present it as a certain level of confidence
5 and, you know, I mean, because I think there
6 are important measures, but I just don't think
7 we're going to have that level of evidence.

8 DR. PACE: You know, it's an
9 interesting point and it has been brought up.
10 You know, right now NQF's process is endorse
11 or not endorse, or time-limited endorsement
12 for measures that are not tested.

13 We do ask, you know, the reviewers
14 to rate each of the criteria or subcriteria,
15 but pretty much on a scale of kind of
16 completely met, partially met, minimally, or
17 not at all, in helping you come to a
18 conclusion about recommending or not
19 recommending.

20 But it's certainly an area that we
21 need to be thinking about in terms of whether
22 we want to institute some kind of grade to the

1 endorsement, is what you're saying, you know,
2 and it's something that we would need to
3 discuss with our CSAC and ultimately with the
4 Board to institute something like that.

5 But, you know, certainly,
6 throughout this process, you know, to
7 certainly think about that and, you know, that
8 can help us, you know, sort out how something
9 like that would be operationalized.

10 At this point what the Steering
11 Committee has the option of doing, and Helen
12 can chime in here, is you know, as I said,
13 it's either recommend or not recommend, but
14 the report can identify any specific guidance
15 that the Steering Committee wants to at least
16 make known in terms of your decisions.

17 The reality is that we don't have
18 control over, you know, how measures are
19 implemented, but I think that's certainly
20 something we should continue to think about.

21 Helen.

22 DR. BURSTIN: I apologize for

1 being late. I was on a safe practices
2 steering committee and we were discussing the
3 grading of evidence. That's just the story of
4 my life.

5 So, this is an important issue.
6 It's not going to go away. Clearly, we need
7 to kind of reconcile this. Whether we would
8 actually grade the measures, per se, or
9 actually have a more formal assessment of the
10 grading of the evidence underlying the
11 measures, that's more transparent and easily
12 reconciled to something I think we need to do
13 a better job of.

14 The US Preventive Services Task
15 Force which I oversaw at AHRQ for five years
16 doesn't always fit many of these kinds of
17 measures that grading evidences. It is really
18 two grades, which I think people often forget
19 as well, is actually the grade which is the
20 overall recommendation of, you know, an A
21 recommendation, the benefits significantly
22 exceed the risks, all the way to a D, don't do

1 it, risks exceed benefits.

2 But there's actually a second
3 grading system of the quality of the evidence.
4 I think that's kind of what we keep hearing as
5 a recurring theme, is it's less about the
6 overall recommendation, A, B, C, D, E -- A, B,
7 C, D, I -- no E, but instead the
8 recommendations are on the grading of the
9 evidence as being a more crucial input we need
10 to be more thoughtful about how we grade. It
11 keeps coming up.

12 DR. PACE: But I think what he was
13 talking about was specifically how confident
14 we were in the measure.

15 DR. AMARASINGHAM: The only point
16 I would say is that I've been impressed with
17 the way CMS has done some of its measures in
18 that there's sort of a pilot period of two
19 years where everybody's getting use to the
20 measure and actually quite a bit is learned
21 about the measure, but if that sort of semi-
22 sanction hadn't come from CMS, no one would

1 have tested it.

2 So the question is: Would there
3 be a group of measures that NQF says doesn't
4 meet our set of gold standard level of
5 evidence, but that we would encourage regions
6 to experiment with accepting, and I bet that
7 might take hold, because there are places that
8 would like to experiment.

9 DR. BURSTIN: And the only thing
10 I'll add is, I mean, that was somewhat of the
11 thinking of the idea behind having a
12 designation for time-limited endorsement.

13 And I think you could certainly
14 say the CMS measures that have come to us are
15 very well tested. They have been extensively
16 tested. Well, what they don't necessarily
17 have, which as CMS enables, is a field test.

18 DR. AMARASINGHAM: Right.

19 DR. BURSTIN: Where hospitals and
20 others have a chance to see the results and
21 reflect on them, and that's a question of, as
22 we sort of get a better sense of the

1 performance of some of those measures that got
2 time-limited endorsement, we may reevaluate
3 what field-testing really means in terms of
4 how this all fits together.

5 CO-CHAIR DUBOW: Iver, did you
6 want to say something?

7 DR. JUSTER: Yes. I was actually
8 going to ask whether this time-limited
9 endorsement was stamped clearly somewhere so
10 that whether it's report cards, P4P, whatever,
11 that people wouldn't think that these measures
12 should -- P4P or public reporting, at least
13 not on the same list as the ones that were
14 endorsed with higher validity.

15 My second question was whether in
16 the portfolio you have examples that could
17 easily be shared with this group of what would
18 be considered -- they did a really good job of
19 validating this measure.

20 They did an okay enough job
21 considering the kind of measure this is, and
22 the other one, well, the other ones, I guess

1 would be the two-year ones, be pretty clear
2 which ones those were, so that we can stand on
3 their shoulders, basically.

4 DR. WINKLER: Yes. Excellent
5 suggestion. There's absolutely no reason we
6 can't pull those out of the database. Karen's
7 done so much work on outcome she could
8 probably come off the top of her head and come
9 up with a couple.

10 And it would be -- yes -- no, but
11 the good, the bad and ugly, I mean, we can do
12 it all. So, we'd be more than happy to share
13 that with as examples. Just try not to get
14 them confused with the work that's being asked
15 of you to act on. They are strictly a
16 reference sort of thing. We'll do something
17 to make them look not actionable.

18 DR. JUSTER: Okay. Yes, the
19 question of validity, you know, if you're
20 thinking, I have a new test, I have a new
21 imaging test that's a lot safer than a
22 pulmonary angiogram, but I already know that

1 I already have an idea of what the gold
2 standard is, so I assume that's a hundred
3 percent accurate, and now I have this new test
4 and I'm going to compare it to the gold
5 standard.

6 Well, we don't really have that a
7 lot here, so we have other ways to get at
8 validity, I think.

9 DR. WINKLER: Your question about
10 is are they stamped time-limited. NQF stamps
11 them on the things we have control over. Once
12 they get out into the field where we don't
13 have control over things, it's kind of a jump
14 ball.

15 Some people are fairly good at it
16 and some are not. So, you know, that's sort
17 of our influence only extends so far.

18 DR. AMARASINGHAM: That's where
19 the recommendation would be so valuable.

20 DR. WINKLER: Yes.

21 DR. AMARASINGHAM: Because if I
22 was a person in the field using this and I

1 said NQF says this is so good it could be used
2 to determine your reimbursement, that to me is
3 a level of evidence that's a little bit
4 different than we have some early experience
5 with this measure, and you could use it for
6 quality improvement at your institution.

7 I mean, I think it would be
8 valuable, particularly for us as we're making
9 decisions to be able to have a kind of
10 framework like that.

11 CO-CHAIR DUBOW: But it should be
12 clear, NQF does not get deeply involved in the
13 implementation of measures. So, to Iver's
14 point about whether, you know, we say this is
15 okay for pay for performance, what happens
16 with these measures post-endorsement is not
17 within the purview of NQF.

18 So, I understand your point. If
19 we had that kind of designation, people would
20 understand that it had exemplary properties
21 and would be suitable for something of that
22 sort.

1 DR. AMARASINGHAM: Because I'll
2 say, as a committee member, I just decided at
3 the last point, as a committee member that,
4 you know, if it was my level sort of a
5 methodologist, my level of standards, a lot of
6 measures I would say no for NQF.

7 That's why I'm wondering whether
8 there could be something beyond an all-or-
9 nothing standard, and I think different people
10 in the room would have different standards.
11 But I would say, as a strict methodologist, I
12 would not approve most of the measures.

13 DR. WINKLER: Yes. You've kind of
14 hit the crux of NQF, if you will, in those
15 last two statements, because one, it's a
16 multistakeholder organization, and so the
17 levels vary everybody, and that's what this
18 is, is a negotiation.

19 Your suggestions about levels and
20 how measures are used is not a new one. We've
21 heard this many times in many different
22 venues. Again, that would be very hard to do.

1 And it's not that we haven't thought about it,
2 we just haven't figured out to do it
3 particularly, that suits our multistakeholder
4 kind of approach to things.

5 So, at this point it's not that we
6 haven't considered it. We certainly have, but
7 at this point it just isn't working, it
8 doesn't seem to suit the current construct of
9 the way the NQF is organized.

10 But we keep thinking about it.

11 CO-CHAIR DUBOW: Pauline.

12 DR. McNULTY: Yes. Just when it
13 comes to listening to this debate, but when it
14 comes to the patient-reported outcome
15 measures, I think I've mentioned this already,
16 there is a draft guidance from the FDA out
17 there which is considered a best practices on
18 the development of patient-reported outcomes
19 measures and testing them in terms of
20 reliability and validity.

21 So, I think you really should look
22 at that, and I'll send you the link for that.

1 But, you know, one thing that, you know, just
2 keeps popping into my mind as I'm listening to
3 the discussion around validity, I was at a
4 meeting a couple of weeks ago and I heard
5 somebody who used to be at the FDA talking
6 about validity and reliability, and the
7 comment that he made really just stuck with me
8 which is that, you know, you can have great
9 reliability, interrater reliability on some
10 kind of measure, I mean, it's mostly scales
11 that I would be dealing with, and you could
12 say it's a reliable measure. However, maybe
13 the validity isn't there because the thing
14 that people have been asked to rate is that
15 the moon is made of green cheese.

16 So, you know, that's not valid,
17 yet you can get great interrater reliability
18 if you got everybody in the same room to agree
19 on it. But you still don't have a valid
20 measure.

21 So, it's kind of a perfect thing
22 to keep in mind about this debate that we've

1 just had around validity.

2 DR. PACE: Right. And that's an
3 excellent point. Reliability is necessary,
4 but not sufficient to prove validity, and so
5 you can have something that's absolutely
6 reliable on giving you the wrong information.
7 Right.

8 DR. HOPKINS: So this conversation
9 reminds me of so many we had at the CSAC and
10 elsewhere and every steering committee. It's
11 good.

12 But, I keep thinking that our
13 focus here is a little bit different from what
14 it's been in these other NQF committees,
15 because we're talking about outcomes, so I
16 don't think our job is to figure out if this
17 process is linked to some outcome. If
18 anything, it's the other way around.

19 We're supposed to be focusing on
20 the outcomes, and as I look at the list here,
21 it seems to me like we need to think a little
22 bit more about how to apply that list which

1 was really constructed more for the process
2 measures to straight outcomes.

3 How do I judge validity, 30-day
4 mortality following X? I mean, I understand
5 all the complexities of how you adjust for
6 risk and all that. That's a separate item.

7 DR. AMARASINGHAM: Well, I think
8 for that one, I think the big question would
9 be the risk adjustment. But the other --
10 right.

11 DR. PACE: Right. And so, with an
12 outcome measure, risk adjustment affects
13 validity, and so we may not need a separate
14 test of validity, but we do need the risk
15 adjustment or the issues that threaten the
16 validity of the measure.

17 Exclusions can threaten the
18 validity of a measure of quality. So, you're
19 right that, you know, we may need to look at
20 these different, but the concept of validity
21 is what we expect for testing may be
22 different, depending on the type of measure.

1 DR. JEWELL: Well, and also the
2 issue of validity for the self-report measures
3 is absolutely relevant to outcomes, you know,
4 when you're looking at what pay -- I mean,
5 that gets to the point you just made.

6 If I'm looking at disability or
7 looking at function and I'm doing that by way
8 of a patient self-report questionnaire, the
9 issues of validity are absolutely something we
10 would wrestle with.

11 DR. PACE: Right.

12 DR. BURSTIN: Just one other
13 comment is that I think that in general while
14 we have had time-limited measures without
15 testing that are mainly process measures,
16 outcomes tend to take on a higher level, and
17 it's almost like it's sort of inconceivable
18 that a nontested measure would likely come
19 forward to this committee for an outcome.

20 So, I think that probably won't be
21 an issue.

22 CO-CHAIR DUBOW: But we won't have

1 time-limited?

2 DR. BURSTIN: I suspect we will
3 not. I think it's very difficult to really
4 ensure validity of an outcome without having
5 any testing of any kind.

6 DR. JUSTER: Yes, and I would
7 agree with that, that certainly process
8 measures, I could imagine somebody saying,
9 well, did you have an ACE inhibitor in the
10 last year -- well, I guess that's not a
11 terrible measure, but it's a process measure,
12 but it doesn't discriminate very well against
13 people who will have a good outcome because
14 they took their ACE inhibitor every day, than
15 those who filled it once.

16 But even for outcome measures, one
17 might consider, for example. And I think it's
18 on here, this discrimination thing, so suppose
19 you have the SF-1 we were talking about
20 yesterday. How are you feeling, and it's a
21 five-point scale, that might not discriminate
22 quality of care very well in the sense of you

1 have to move so much to move to the next point
2 on a five-point scale of a one-question item,
3 that no matter how valid the measure is, it
4 doesn't discriminate quality of care very
5 well.

6 There might not be very many
7 interventions that could move a population by
8 a whole scale point. Is that what you're
9 getting here with discriminating quality of
10 care? Nice measure, great outcome, but it
11 just doesn't discriminate quality of care very
12 well.

13 DR. PACE: Well, again, we're
14 talking about measures at the aggregate level
15 of the provider, so what we would want to see
16 is provider-level scores, whether it's a
17 hospital, a physician, a home health agency,
18 where there's some discrimination of quality.

19 So, you know, that's the whole
20 point of these measures, is to identify where
21 improvement is needed for quality improvement,
22 or to identify providers that you'd want to

1 seek care from.

2 And so, if you have a measure that
3 ends up where there's no distinction among the
4 scores, we're doing a lot of measuring with no
5 next step to happen from it, so that's what
6 we're trying to get at.

7 DR. JUSTER: Sort of like the old
8 satisfaction surveys where almost everybody
9 was either satisfied or very satisfied, it
10 doesn't discriminate much. In this case I'm
11 thinking that the scale might, no matter how
12 valid it is, having a provider move their
13 entire practice by one scale point on a five-
14 point scale would be herculean.

15 CO-CHAIR DUBOW: I just want to
16 point out to those people in the audience who
17 want to say something, we'll have a public
18 comment period about five minutes before our
19 break at 10:30.

20 Okay. Reva, we haven't gotten to
21 exclusions yet.

22 DR. WINKLER: Thank you.

1 Exclusions are in red because this is a topic
2 that has been pulled out specifically because
3 we've had to struggle with it over the years
4 with the issues around exclusions.

5 A couple of things. Issues
6 increase the complexity of measurement burden.
7 You have to collect more data, and the more
8 exclusions, the more data.

9 Often, the exclusionary things are
10 hard to identify so that they're not
11 necessarily in maybe more readily available
12 data streams.

13 They often create a barrier to
14 measure harmonization, and of this beta
15 blocker measure and that beta blocker measure,
16 one excludes this and another one excludes
17 three things or not the same or three
18 different things, so that the measures can't
19 work well together as a group.

20 So that we really want to see
21 evidence that the exclusions that are part of
22 the measure are important parts of the

1 measure. They actually contribute something,
2 that it would be distorted without those
3 specifications.

4 Also, if patient preference is a
5 consideration, the numerator or the
6 denominator exclusions, it should be specified
7 so that the effect of the patient preference
8 on the measure is transparent.

9 And the classic one we had to deal
10 with, and Karen can take you through this one,
11 is flu vaccination rates and patient refusal
12 of flu vaccination.

13 How do you accommodate for flu
14 vaccination? Do you get rid of them in the
15 denominator or do you include them in the
16 numerator as a separate category. That way
17 you know what happened to everybody. So, you
18 know, there are a variety of ways of doing it.

19 And, Karen, did you want to talk
20 about that particular --

21 DR. PACE: Yes, I think, yes.

22 That was a perfect example, because there was

1 some concern about just removing patients that
2 refused from the denominator because then that
3 information just goes away, and you could have
4 providers with identical scores, but one had
5 50 percent of their patients refusing, and
6 another one, you know, with the same score
7 with all of their patients included.

8 So, the approach we took in that
9 project, which was a big harmonization
10 project, was to make that a numerator category
11 so it would at least be transparent, so that
12 we would have the actual rate of immunization,
13 but that that could be reported, as well.

14 I think probably these come up,
15 the exclusions tend to be more of an issue
16 with some of the process measures, but having
17 said that, if you remember back, our
18 conversation yesterday, that one way of having
19 an outcome measure that maybe doesn't have a
20 sophisticated risk adjustment or even
21 stratification model is to have a narrow
22 homogeneous patient population.

1 So, then exclusions will play a
2 vital part of that measure and, you know, need
3 to be carefully looked at by view in terms of,
4 you know, what we're accomplishing with that
5 kind of measure.

6 So, it is something that we want
7 to pay attention to.

8 DR. WINKLER: Right. The devil's
9 in the details.

10 DR. HOPKINS: I just have one
11 piece on that inclusion for patient
12 preference. There's also a feeling among some
13 of us, and I think some evidence to support
14 it, that some clinicians are actually more
15 effective in getting patients to do what is
16 good for them.

17 And we didn't want to lose that in
18 the measurement of quality.

19 DR. WINKLER: The area of
20 scientific acceptability, you know, is
21 sometimes fairly thorny, fairly scientific and
22 fairly beyond what I understand. I'm very

1 happy Karen's a good friend and colleague.

2 And so, I just want to remind
3 everybody around the table that if you got
4 lost in that conversation and it got a little
5 too down in the details for you, remember that
6 the evaluation of these measures is a team
7 effort, and there is a very deliberate reason
8 we have different areas of expertise around
9 the table.

10 And I think you'll find that, as
11 we go through the measure evaluation criteria,
12 your particular expertise you bring to the
13 table will feed into different elements of it.

14 And so for those of you who are
15 methodologists, really enjoy the reliability
16 and validity discussion. But for those of you
17 who are more in the audience kind of realm and
18 we're going to talk about usability.

19 Is it useful to you, does it give
20 you something you want to know, let's move on.
21 So, it is deliberate, and that's why it's
22 going to take all of us to come to a

1 reasonable conclusion on how to recommend the
2 measure go forward.

3 Usability. What we'd like to see
4 is evidence that the measurement results are
5 meaningful and understandable to the intended
6 audience. It's like, you know, you can create
7 all sorts of information, but does it mean
8 anything to anybody, is it actionable, is it
9 useful, does it respond to the needs of the
10 audiences for information.

11 And this is where particularly the
12 various stakeholders have a real significant
13 role to play is, is it going to be useful for
14 the consumers in terms of information about
15 health care.

16 Is it useful to purchasers to
17 understand the value of the health care
18 they're purchasing? Is it useful to health
19 care organizations and institutions to
20 understand and be able to improve the quality
21 of care they provide? Is it useful to
22 professionals to understand the performance

1 that they're providing?

2 So, if data is just data unless
3 it's useful. And so, we really want to avoid
4 the, you know, just data, and is it useful for
5 a wide variety of audiences.

6 This is why one of the criteria is
7 that the measure is useful by the evaluation
8 criteria, by the intended purpose of the
9 measure developer when they submit it, is that
10 it is not just for internal quality
11 improvement, not just, you know, for fixing
12 things in your own house, but that it is
13 suitable for public reporting and useful for
14 a wide variety of audiences.

15 In addition to usability in trying
16 to enhance that and to make it as easy as
17 possible for measures to be used by
18 purchasers, reporting systems, providers
19 systems, whomever out there, is that the
20 measures are harmonized.

21 So that we've got four or five
22 different diabetes measures from different

1 places, but diabetes is defined differently in
2 all the denominators. Oh, you know, that does
3 not help anyone.

4 If we can get the common
5 definition of diabetes, then all those
6 measures can work together to provide a much
7 more robust picture of the performance of
8 what's going on, but even though they came
9 from a variety of places.

10 So, harmonization is becoming a
11 real critical issue for usability because if
12 it's not harmonized with the measures you're
13 already doing, you're probably not going to
14 adopt it.

15 However, if it is, and you can
16 easily fit it into your portfolio because,
17 hey, we're already collecting data on all
18 those diabetics, we'll just, you know, pick
19 one more numerator data point. Fine, we can
20 do it.

21 So, usefulness, if things are just
22 so out of step with everything else that's

1 going on, it's just going to be that much
2 harder, the barriers are greater to get them
3 implemented.

4 So, usability again. This is
5 where your stakeholder perspectives becomes
6 very, very important, because useful to you in
7 the world you come from and bring that
8 representation to that committee.

9 Because I'll tell you, when we go
10 to comment, this is an area that we hear about
11 lots. I don't know what in the world I'm ever
12 going to do with this measure, you know, from
13 a variety of the stakeholders.

14 So, this is really an important
15 area for you, and it sometimes doesn't get the
16 attention it needs, so I really like to
17 emphasize it, and don't be shy about bringing
18 your concerns forward about utility of these
19 measures.

20 Questions on that particular
21 criterion?

22 DR. DEUTSCH: Just, can you give

1 us an example of a measure that was not for
2 public reporting, but just quality
3 improvement? You obviously have a reason why
4 you put that there, and I'm just struggling
5 with an idea that might be appropriate for us.

6 DR. WINKLER: You want to use.

7 DR. PACE: I was just going to say
8 that in the earlier years of NQF, we had some
9 measures come through that were developed
10 primarily for quality improvement, and were
11 endorsed for quality improvement, and since
12 then, you know, through policy, and now more
13 explicitly in our evaluation criteria, we say
14 that the measure should be intended for both
15 purposes, both public reporting and quality
16 improvement.

17 And we probably can drop that kind
18 of highlight, but this was, you know, a very
19 explicit, wanted to call it out as something
20 that we were emphasizing.

21 DR. BURSTIN: Just to add to that,
22 I think that part of our thinking is also that

1 there are so many measures out there, even
2 beyond the hundreds we've already endorsed
3 that are really very appropriate for internal
4 QI, but you would not want to publicly report
5 those measures necessarily if they don't, in
6 fact, achieve the same level of quality of the
7 measure itself, that we would want for a
8 public-reported measure.

9 So, the measure that's useful for
10 QI is great, but we also want to make sure
11 it's also appropriate for public reporting.

12 CO-CHAIR DUBOW: This has been a
13 subject of ongoing discussion and debate.
14 Ongoing meaning over a lot of years. So, the
15 fact that it's here just was trying to put it
16 to rest to clarify purpose, it has to be dual.

17 MS. GERBIG: Just an actual
18 example of something like that might be, to
19 prevent central line bloodstream infections,
20 you could measure the five step process that
21 prevents it, but many of us measure the number
22 of days or the number of years without a CLPC

1 in our organization.

2 Now, that's not a publicly-
3 recognized number. It would be a doozy of a
4 number to try to ever report publicly, but
5 that's sort of an outcome measure.

6 And just from a user's point of
7 view, that's why I'm so interested in the work
8 of this group because we have all of these
9 process measures, but they don't answer the
10 question, so what.

11 And the outcome measure answers
12 the question, so what. And so, in a perfect
13 world you'd have process measures, but always
14 an outcome measure that is the overarching
15 measure and allow perhaps providers some
16 wiggle room to implement the process measures
17 with keeping your focus always on the outcome.

18 DR. WINKLER: Linda David just
19 whispered in my ear. She gets it.

20 MS. GERBIG: I live it.

21 DR. WINKLER: So, anyway, any
22 other questions or comments on usability? It

1 is an important criteria, but sometimes we
2 always get lost in the discussion around the
3 science and the validity and, you know, that
4 goes on for hours, and the usability often
5 gets short shrift.

6 So, don't let it, because it will
7 ultimately -- it's the endgame, if you will.
8 If it isn't usable it can be as valid as it
9 wants to be.

10 Feasibility. Again, often a topic
11 that engenders a great deal of discussion, and
12 feasibility, again, there's a wide variety of
13 what's feasible out there in the world. I'll
14 just give you an example of something that
15 I've lived with, Alexis and I have lived with
16 for the last year, and that's our project in
17 clinically enriched administrative data.

18 In looking at the measures that
19 came across in that project, we had 206
20 measures submitted, so you know, sometimes a
21 few measures is a relief, flooding is not
22 always appropriate.

1 We looked at the measures and they
2 have a wide variety of characteristics, and
3 you know, we basically were able to categorize
4 the measures into a couple of different
5 levels.

6 And one is a level that has just a
7 single, like, traditional claims data stream,
8 basic, pretty much anybody can do it. All
9 right.

10 So, on the level of feasibility,
11 real high. The problem was that measures are
12 not real robust and they tend to have the
13 criticisms that many people have with the
14 straight claims measures.

15 Second level were measures that
16 pulled together two different claim streams.
17 It's like medical visit claims, pharmacy
18 claims, lab claims, whatever, but requires
19 methodological complexities, you needed to
20 have some people who could do this stuff and
21 combine the different data elements together.

22 But again, fairly straightforward.

1 A lot of people can do it. Not everybody, but
2 still a lot of people can do it. So, while
3 this one is high feasibility as level one,
4 it's still a reasonable level of feasibility
5 to do.

6 We get to the third level which is
7 really what a lot of people think clinically
8 enriched means, and that is, to one or more
9 claims streams of data you add electronic
10 clinical data. The most classic example is
11 laboratory values. Okay. Not just did it --
12 was it done, but what was it.

13 And we have a small number of
14 those sorts of measures in the portfolio.
15 Those measures, very robust, measures
16 everybody loves to see, but the feasibility
17 suddenly drops because you just don't have
18 lots and lots of organizations that are able
19 to do it.

20 But yet, hopefully in the future,
21 more and more organizations will develop the
22 capability to manage data in that fashion such

1 that feasibility can be improved.

2 And the Steering Committee took
3 the stance, of very deliberately choosing to
4 have some measures in level three and some in
5 level two, hoping to sort of point the way,
6 encourage more measurement complexity and more
7 measurement rigor.

8 So, feasibility can become a
9 really cornerstone of a project such as it was
10 in that last one. And so, your expertise
11 coming from whatever realm and world you live
12 in, understanding is this a measure I'll be
13 able to take home and do, can this be done at
14 my house, without undue burden. How much
15 burden will it encounter?

16 And so, that becomes a factor as
17 you mix in and understand all these criteria.
18 There are no thresholds, there are no
19 absolutes, but it's a factor because it really
20 makes a difference how far this measure can be
21 used and will be used going forward.

22 So, feasibility becomes a really

1 important part of the assessment. Corollary
2 to that is realizing the work that we and a
3 lot of people are doing to transition us to an
4 electronic world, and the feasibility has, you
5 know, the ability to maybe translate some of
6 these data elements and make this ready for
7 moving into the EHR world, again, is another
8 aspect of feasibility that we want to see.

9 You know, the classic old chart-
10 based measures, you've got to pull paper
11 records and read pieces of paper and abstract
12 it onto a form. I mean, those are probably
13 the least feasible and most expensive to
14 measure, kind of measures known.

15 There's a whole gradation of
16 feasibility. So, an assessment on the
17 feasibility of the measure, who can do it, how
18 much will it cost them to do it, and I don't
19 mean just in terms of dollars, manpower, time,
20 resources that might be otherwise used
21 somewhere else, to do that.

22 So, certainly with an emphasis on

1 electronic collection, if they're still
2 relying on some sort of hand collection, you
3 know, what's their plan for losing that,
4 because it's just not going to make it very
5 feasible going forward.

6 So, Karen, did you want to say
7 anything about feasibility?

8 Helen? Like I say, it's the world
9 I've lived in for the last year.

10 Joyce, David, feasibility,
11 anything to say?

12 DR. HOPKINS: You said it well.

13 DR. WINKLER: Okay. Alrighty.

14 So, what we want to do is give you an example
15 and we sent one to you in your bundled set of
16 things. I don't know. Which one did we send
17 them?

18 DR. PACE: Yes, I just want to
19 mention, you know, we sent you this early
20 example just to give you some idea of what
21 you'll be seeing, but please keep in mind that
22 this particular example, the measure steward

1 had informed us, and we knew this in advance,
2 that they were still completing some of their
3 analysis so this is going to be updated, so
4 this is not the final information.

5 But we just wanted you to see an
6 example of some of the information that you'll
7 be getting. And we'll also be working with
8 all of the measure stewards if we want
9 information moved to a different section.

10 So, this is just a brief look at
11 the types of information you may be seeing,
12 but keep in mind this is not the final, this
13 measure is going to --

14 CO-CHAIR DUBOW: Just before we go
15 to the example, it is 10:30, and I did mention
16 that we would allow for public comment,
17 because I assume that you still want to make
18 a comment?

19 MR. HARDER: Yes, I do.

20 CO-CHAIR DUBOW: Thank you.

21 And, Operator, if there is anybody
22 on the phone who wants to make a public

1 comment, could you open the phones and ask,
2 please, we have one comment here in the
3 audience.

4 OPERATOR: All lines are now open.

5 MR. HARDER: Great. Can you hear
6 me? I wanted to go back to the risk
7 adjustment models and just highlight that.
8 Please be aware that sometimes there's going
9 to be two risk adjustment models for the
10 readmission measures and think about this.

11 It's going to be based upon
12 planned procedures, which are done for the
13 sickest patients, and I wanted to emphasize
14 that publicly reporting both of those is going
15 to be a concern in our case because we think
16 people don't understand the rationale behind
17 the plan procedures.

18 One thought is that we're doing it
19 for the money, you know, because you get
20 double amount of the money, but also you've
21 got to realize that these are the sickest
22 patients and that this is in the best interest

1 of the patient because they can't handle the
2 contrast or they can't handle some of the
3 stresses of the procedure.

4 So, I just wanted to bring that up
5 in that discussion about scientific
6 acceptability and validity. Thank you.

7 CO-CHAIR DUBOW: Thank you.

8 Operator, is there anybody on the
9 line who would like to make a public comment?

10 OPERATOR: All lines are open.

11 CO-CHAIR DUBOW: Okay. Thank you.

12 DR. PACE: Are we going to take a
13 break?

14 CO-CHAIR DUBOW: Well, I was just
15 going to ask. Does everybody want to take a
16 break? Yes. Okay. We're going to break for
17 15 minutes, and then we'll come back and have
18 the example presented.

19 (Whereupon, the above-entitled
20 matter went off the record at 10:28 a.m. and
21 resumed at 10:51 a.m.)

22 DR. DEUTSCH: I just wanted to

1 kind of wrap up on the previous conversation,
2 if we're getting started. Just a couple of
3 questions.

4 I guess one thing is, Dianne and I
5 were just kind of talking break about the
6 issue of, you want to harmonize, we want to
7 have measures that work across diagnoses, but
8 we also want validity.

9 So, something like readmissions,
10 certainly what would be preventable as
11 readmission might be different by different
12 diagnoses. So, would we expect to see one
13 measure that had just risk adjustment or
14 different exclusion criteria or is that --

15 DR. PACE: Well, I'll just make a
16 comment, and then others can chime in. We
17 have quite a few readmission measures. The
18 ones we currently have endorsed are primarily
19 all-cause readmission.

20 One of the issues about the
21 preventable readmissions is getting into
22 agreement about what's preventable, and the

1 methods that have been used to date to try to
2 classify those.

3 And so, you know, if we do get
4 measures of preventable readmissions it would
5 have to be specific for a particular condition
6 in order to go through that process of
7 identifying what would or would not be
8 preventable.

9 DR. DEUTSCH: Okay.

10 DR. HOPKINS: Okay. So, here's
11 another example that I've been thinking of.
12 So one of the focus areas is cancer. Almost
13 every cancer researcher uses as a fundamental
14 measure of outcome disease-free survival, you
15 know, for X years.

16 Are we going to have to go through
17 a process of approving 20 of those or however
18 many subcategories there are within cancer or
19 is there some way we can arrive at a measure
20 which is disease-free survival after five
21 years for cancer patients?

22 And, how will that play out,

1 because I'm trying to track the flow. You
2 know, the call for measures. Who owns that
3 disease-free survival measure? That's the
4 first problem. If we don't come out of here
5 endorsing a measure like that for cancer care,
6 it really blows my mind, but I don't know how
7 you're going to get it.

8 DR. WINKLER: David, I think that
9 has been one of the measures that has been
10 used sort of on both within the research
11 realm, the clinical realm and the public
12 health realm, and all of the, you know, the
13 cancer world and registries as sort of a data
14 point. But I'm not sure it's ever been really
15 thought of and portrayed as a quality measure.
16 It's information. It's an outcome,
17 absolutely, but from a quality measure
18 perspective.

19 So, I think it's an interesting
20 challenge because certainly I'm not hearing it
21 and I have yet to see anything submitted like
22 that, and I'm not really sure I expect to.

1 What do you think, Helen?

2 DR. BURSTIN: I actually had a
3 conversation with Jane Weeks, who's at Dana-
4 Farber, probably one of the guru's in outcomes
5 research and cancer specifically saying that.

6 So, what are the outcomes out
7 there, and her response back was that that's
8 actually a really difficult measure to track
9 because there are so many complicated issues
10 around this issue of the different kinds of
11 diagnoses and things like that.

12 I have to share it with the group.
13 It was a very thoughtful response. And,
14 again, this is the kind of thing where,
15 hopefully, I mean, we have a really strong
16 chair in Lee Newcomer who really understands
17 this issue well.

18 So, you should talk to Lee in
19 advance, or see if you have specific concerns.
20 But those measures currently are not used for
21 public reporting.

22 CO-CHAIR DUBOW: And don't forget,

1 there has to be a measure that comes to us to
2 evaluate.

3 DR. HOPKINS: That's what I'm
4 worried about. That's exactly what I'm
5 worried about.

6 CO-CHAIR DUBOW: So, you know,
7 that measure that you like so much may not
8 exist.

9 DR. HOPKINS: Well, it exists
10 throughout the research community.

11 CO-CHAIR DUBOW: Well, is it a
12 numerator, denominator kind of measure?

13 DR. WINKLER: Yes, it is.

14 DR. HOPKINS: I think so. I mean,
15 it's very straightforward.

16 CO-CHAIR DUBOW: Well, then bring
17 it on.

18 DR. HOPKINS: I have to find
19 somebody who owns it, that's the problem.

20 CO-CHAIR DUBOW: Well, there you
21 go. After you finish your --

22 DR. HOPKINS: But I'm thinking of

1 the patient, right. What does the patient
2 want to know. That's fundamental.

3 DR. PACE: But, I mean, my concept
4 would be that you would need something
5 diagnosis-specific, because those disease-free
6 survival rates are very different, depending
7 on the type of cancer, and if you're going to
8 try to make some assessment of whether your
9 center, you know, is treating appropriately --
10 anyway, there's a lot of questions that you
11 raise.

12 DR. YAWN: One of the ways to
13 think about that is quality of life, but you
14 have to be very careful of what you put in the
15 denominator and how do you assess someone's
16 quality of life if they are not alive?

17 And so, there's all kinds of
18 fascinating ways to look at that, and some of
19 the cancer survivor papers, they do try to
20 address some of that, and assign a zero
21 quality of life if you're not alive.

22 CO-CHAIR DUBOW: Okay. So, let's

1 get back to - yes, it will certainly be
2 continued.

3 DR. DEUTSCH: Sorry, one other
4 quick comment. I'm not sure where this fits
5 in in terms of the criteria, but just kind of
6 potential unintended consequences might fit
7 under importance.

8 I kind of heard, you know, benefit
9 and just as an example, falls. I mean, you
10 already have items related to falls, and my
11 concern would be if you're encouraging and
12 falls are not good, but you might encourage
13 that the patient would stay in the bed and
14 become debilitated, or not get all the care
15 that they needed and not get up and around.

16 If the staff are so worried about
17 falls, discharge to community is something we
18 measure in rehab, but is the person really
19 ready to go home. And so we don't want to
20 encourage people to discharge somebody home.

21 DR. BURSTIN: Just one follow-up
22 point to that, and I see lots of heads

1 nodding. I mean, one of the things that's
2 under, I believe it's feasibility, is
3 unintended consequences.

4 So, it's a really important
5 consideration, this issue of, you know, the
6 catheters versus falls versus taking out the
7 catheters. I mean, there are just trade-offs
8 in so many of these things, and the last thing
9 we want to do is have unintended consequences
10 because of measurement. So, we really look to
11 you for that thoughtful commentary. Is your
12 head nodding? As a hospitalist this is
13 reality for you.

14 CO-CHAIR DUBOW: All right. We're
15 going to now go to just sort of take a high
16 walk through the evaluation sheet for the AMI
17 mortality, just to give you a sense. It's not
18 completely filled in. We did receive a copy
19 of this, and Reva and Karen are going to --

20 DR. WINKLER: One thing just to
21 wrap up our earlier discussion, in your
22 materials that was sent to you, here is a copy

1 in hard copy of the measure evaluation
2 criteria laid out in all of its glorious
3 detail. And so, for things I may have not
4 gone into appropriate detail on or whatever,
5 here it is all laid out with the subcriteria,
6 each one, if you notice, importance to measure
7 and report. You know, there's criteria,
8 whatever it is, I can't even read. Yes,
9 where's my eye outcome test. It's 1-A, 1-B,
10 1-C and so through all the various criterion.

11 So, there it is in detail for you
12 as a reference. And this is an important
13 document for you to keep at hand as we go
14 through the measure evaluation process. So,
15 I just wanted to point that out to you. You
16 don't have to rely on remembering what I said,
17 or even understanding what I said, if I didn't
18 say it well.

19 Now, we're bringing up a version
20 that you have this measure submission form as
21 an example in your packet, but it is a PDF
22 form, and what we've got is an example of what

1 you're actually going to receive and this is,
2 again, Karen's work.

3 What we've done is place the
4 information that got submitted. We've
5 reformatted into a measure evaluation tool
6 form with the information. So, the blue
7 information that's in this form is what the
8 measure submitter, the measure developer gave
9 us. They entered it into the appropriate
10 question. It gets dumped in here.

11 One of the things we're noticing
12 is people are putting their answers to the
13 wrong questions in the wrong spot. That's
14 always fun, and incomplete, not answering
15 things. So, this is an example of things that
16 aren't completely filled out, but it can give
17 you a sense of that.

18 And Karen is going to walk you
19 through it because there are some
20 characteristics of it that she put in this
21 tool that we want you to be aware of so that
22 you can use it optimally.

1 DR. PACE: Right. And as I
2 mentioned, we knew in advance that this
3 particular measure wasn't fully complete. The
4 measure steward had notified us of that, and
5 they're ready to submit the rest of the
6 information. So, we'll be getting you the
7 final information when that's available.

8 So, as Reva said, we're importing
9 the information that is submitted online into
10 this form and this form has embedded in it the
11 evaluation criteria.

12 So, I'll point out a couple of
13 things. There are some areas for NQF staff
14 use so that we'll make sure that certain, you
15 know, the numbers are in there, the NQF staff
16 will be checking that the conditions are met
17 before this measure even gets to the TAPs or
18 steering committee.

19 And so there's some color coding
20 in here in terms of the gray-shaded areas or
21 NQF staff. The yellow-shaded areas will be
22 for the TAP work group review and the pink-

1 shaded area is for steering committee. And
2 the reason for that is, as Reva mentioned
3 earlier today, what we're going to be asking
4 the TAPs to do is to evaluate each of the
5 subcriteria and provide their advice back to
6 the steering committee in terms of how well
7 they think the measure met those subcriteria.

8 They will not be evaluating
9 overall that big criterion like importance or
10 scientific acceptability. Their assessments
11 will be provided to the steering committee who
12 will make those bigger evaluation comments.
13 But I'll get to that in a minute. So, here
14 you'll see that if the conditions haven't been
15 met, the staff will make some notes back to
16 the steward and send it back.

17 If the staff have any particular
18 notes to the reviewers, they'll put them in
19 here. If there are any particular questions
20 or issues they want you to be particularly
21 aware of. There's a place for the staff
22 reviewer name, the TAP, and the steering

1 committee names.

2 Our intent is to try to build this
3 as we go along so that we eventually will have
4 all the information, kind of the summary
5 information from the TAP and from the steering
6 committee, not each individual reviewer's
7 information.

8 Okay. So, in each section, there
9 is a link back to the evaluation criteria, so
10 if you're looking at this on your computer and
11 you have internet access, if you want to go
12 back to the criteria, this will be a link back
13 to the web page for that. But also embedded
14 within here are using the comment function of
15 Word, and if you move your cursor over -- why
16 is it not staying up? Let me go to another
17 one and see if it will -- it was doing it
18 before.

19 Yes. But anyway, the actual
20 criteria language are embedded in there, and -
21 - I don't know why, it was doing it before, so
22 we -- yes, we've had all kinds of gremlins

1 with computer technology.

2 The other thing is, you know, with
3 your own system, if you prefer to have those
4 comments in balloons along the side, if that's
5 easier for you, that's a possibility as well.

6 But let me see if I can get back -
7 -

8 DR. WINKLER: What we're trying to
9 do is make everything in one place so you
10 don't have to be flipping pages and going back
11 looking for documents. We're trying to embed
12 all the information so you don't get lost like
13 I tend to do.

14 But, in terms of the rating scale
15 that we'll be using, again, the TAPs will be
16 using it for the subcriteria and the steering
17 committee for the overall criteria is kind of
18 a four point scale. C means completely met,
19 unquestionably demonstrated to meet the
20 criterion. Partially, P, partially, M
21 minimally, and N, not at all, or incorrectly
22 addressed. So sometimes you'll see stuff

1 filled in, but it may not really be responsive
2 to the criteria or the question.

3 And then there are some areas that
4 are NA not applicable, for example, justifying
5 exclusions if there are none. Then, that
6 would be, you know, a valid response, not
7 applicable for that particular measure. So,
8 where not applicable is truly not applicable,
9 that would be an option. Okay.

10 DR. McNULTY: Karen, can I just
11 ask a question. The piece under measure
12 descriptive information is the National
13 Priority Partners Priority Area. Is this
14 filled out by the measure developer?

15 DR. PACE: The priority area is
16 filled out by the measure developer, because
17 that's just a categorization and those are
18 just those six broad areas. But if you go
19 down in importance there's a section where the
20 staff will fill in the specific goals.

21 DR. McNULTY: Okay.

22 DR. PACE: So, right here, for NQF

1 staff use, they will be filling in -- they'll
2 be checking to see if the measure addresses
3 one of the specific goals and if so, they'll
4 be putting it in here so that you'll have that
5 information when you get the form.

6 DR. McNULTY: Okay. And then in
7 that same section earlier where the developer
8 fills it in, consumer care, need, getting
9 better, is that terminology that you use or
10 the developer just --

11 DR. PACE: That terminology is
12 from consumer language and it's terminology
13 that --

14 CO-CHAIR DUBOW: It was part of
15 the framework that was used to present
16 information to consumers, and so they -- I
17 can't remember, was staying healthy --

18 DR. PACE: Yes.

19 CO-CHAIR DUBOW: Getting healthy.

20 DR. PACE: Staying better.

21 CO-CHAIR DUBOW: You know, living
22 with illness.

1 DR. PACE: Right.

2 CO-CHAIR DUBOW: There were four,
3 weren't there four?

4 DR. BURSTIN: End of life.

5 CO-CHAIR DUBOW: End of life.

6 DR. PACE: Right. And I should
7 also mention that most of the things in here
8 are things that NQF asked in our last round of
9 measure submission, but since that time, Reva
10 led a project for data fields collaboration
11 with a group of measure developers. And so
12 we've come to try to reach some agreement on
13 the types of information, and that was one
14 that one of the other groups was, I think,
15 AHRQ - was using to categorize the measures in
16 the National Quality Measures Clearing House.

17 So, in our effort to be
18 consistent, we've included that. So, some of
19 the information, most of it, is things is that
20 we would have been asking for, anyway, but
21 there have been some changes and there will
22 probably be still a few more tweaks to make

1 sure that we're fully in alignment with that
2 data fields collaboration. But I think, for
3 the most part, for this initial round of the
4 online submission, we're pretty close to that.

5 DR. WINKLER: Just, I'll mention
6 to you that the collaborators in that group,
7 so that we all kind of look at a measure the
8 same way, included CMS, included NCQA,
9 included the Joint Commission, included the
10 PCPI. So, hopefully, you're going to start
11 seeing a standardized way of presenting
12 measures from all of these organizations so,
13 you know, it just isn't disjointed when we are
14 looking at presentations of measures.

15 DR. PACE: For those of you who
16 have this on your computer, are you able to
17 cursor over and see the comment? Okay.

18 So, we're having some problem with
19 this particular -- yes.

20 DR. JEWELL: At least some of
21 these, it's linked to the internet. That's
22 why we don't have internet.

1 DR. PACE: Well, the links are
2 linked to the internet, but the comments are
3 just part of the Word document. So, you don't
4 have to be hooked to the internet to get the
5 comments.

6 DR. WINKLER: No, but that's only
7 for the Word version rather than the PDF.

8 DR. PACE: You were sent the PDF
9 version. A couple of you have the Word
10 version. When you get the official ones we
11 want you to work with, they will be the Word
12 version with all this functionality in it.
13 Okay. We don't want you to work on the one
14 you've got, because it's not complete yet.

15 If you find that that's not
16 working on your computer, as I said, you can
17 display the comments in another format, so
18 I'll just do this, since we're having trouble
19 with the functionality.

20 So, here you'll see. So, for
21 high-impact, it gives the exact language from
22 the measure evaluation criteria that Reva

1 pointed out to you earlier. And, you know,
2 data demonstrating performance gap, that will
3 actually give you some of the examples from
4 the footnotes in the evaluation criteria. So,
5 if you have a question about what you're
6 looking for, that's where you'll find it. We
7 tried to embed most everything that relate to
8 that criteria within the document. So, if
9 you're doing this on your computer, it will
10 be, you know, either cursor over it or do it
11 this way. If you're printing them out, you
12 may choose to print them out this way, though
13 they will be fairly lengthy by the time, you
14 know, all the information is input in here.

15 Okay. Is there anything in
16 particular that you wanted to look at?

17 DR. WINKLER: No. I just want
18 everybody to be aware how to use the tools
19 that we're going to be using, and even more
20 granular nuts and bolts. The measures that
21 will go to the TAPs, each one of them will get
22 a copy, but ultimately their collective

1 conclusions, if you will, will be determined
2 such that it's one version.

3 The TAP final version, if you
4 will, comes to the steering committee, sort of
5 the same thing, you all get to see that. You
6 all can figure out, you know, discuss how
7 you're going to collectively -- you'll each
8 get your own copy and you can draft your own
9 responses and all that stuff, but ultimately
10 there will be one version.

11 So, you can see us building it,
12 you know, the TAP fills in their section, the
13 steering committee fills in their section, the
14 staff has filled in their section, and at the
15 end of the day this is what's going to get
16 posted as the final evaluation. This is so
17 that it becomes a cumulative, single document.
18 So, again, we're trying to avoid the flipping
19 pages thing and going between multiple
20 documents so that it tells the story in an
21 ongoing fashion.

22 We get a lot of feedback, again,

1 trying to quantify to the degree possible the
2 evaluation. It is difficult. We've certainly
3 looked at a variety of ways of doing it, but
4 the evaluation criteria are what they are, and
5 the evaluation grading scale is meant to try
6 and capture some of the -- it's just not a
7 perfect situation. So, I would guess that a
8 measure that has a whole bunch of C's in it,
9 all complete, you know, is probably going to,
10 you know, do better than a measure that has a
11 whole bunch of -- what are they, N's? None's.

12 And there are no absolutes in all
13 of this. But that's how we're going to carry
14 this through with you, so we want you to be
15 really familiar with these documents and
16 understand all the things that they can do for
17 you. And, we're also very open to any
18 suggestions you have since you're the first
19 steering committee that's actually going to be
20 working with them. So, help us make it
21 better.

22 DR. BURSTIN: I'll just add, this

1 is a little unusual of a project as well, in
2 that we don't often have the TAP chairs
3 oftentimes come and present to the steering
4 committee. We've made you guys members of the
5 steering committee quite intentionally. First
6 of all, we get consistency across all the
7 conditions, and secondly, you get to come and
8 bring that sort of collective voice of the
9 evaluations done.

10 We'll obviously have the data on
11 the evaluations done within the technical
12 panels, but I think we're hoping it will give
13 more consistency for us across the various
14 technical panels.

15 DR. PACE: And we're also trying
16 to, in this process, delineate TAP role and
17 steering committee role, and so we really want
18 the TAPs to focus on the specifics of the
19 subcriteria, and you see that, you know,
20 certainly to rate those, and then to have some
21 kind of summary about what are the strengths
22 and weaknesses based on the review of those

1 subcriteria that then will get fed to the
2 steering committee in terms of their
3 deliberations about whether importance is met,
4 whether scientific acceptability is met, et
5 cetera.

6 CO-CHAIR DUBOW: So, I have a
7 question about actually the specific process
8 that we should expect, when the next time we
9 meet we will be reviewing measures because
10 they will have gone through at least some of
11 the TAP -- all of them. Okay.

12 So, do you still assign measures
13 to a primary and secondary reviewer in the
14 steering committee? Can you describe a little
15 bit of what the process will be?

16 DR. WINKLER: Well, how we do
17 that, how we handle is very much dependent on
18 the volume of measures. When we're dealing
19 with large numbers of measures, like 200, yes,
20 we break it down. When we're dealing with,
21 for instance, the steering committee, and I'm
22 envisioning, to date, all I see in terms of

1 cross-cutting measures is four.

2 Okay. You know, we can think
3 about, you know, do we need to break those
4 down, or can everybody, you know, take a look
5 at four. If it were 20, certainly, we would
6 break it down into primary and secondary.

7 It's just a matter of how we divvy up the work
8 and make it reasonable. At this point does
9 anybody see that that's an overwhelming burden
10 that we need to break it up?

11 Okay. Good. Ten? Yes. Okay. I
12 mean, that's where I start seeing some, so I'm
13 just saying, you know, I don't expect it, I'm
14 just saying --

15 CO-CHAIR DUBOW: People still have
16 to be familiar with the content of the
17 measures.

18 DR. WINKLER: Absolutely.

19 CO-CHAIR DUBOW: You know, you
20 can't not --

21 DR. WINKLER: Right.

22 CO-CHAIR DUBOW: You know, even if

1 we get a lot, you know, even if it's a high
2 volume, we still have to vote as a steering
3 committee, so you can't not know what the
4 measures and their properties are.

5 DR. WINKLER: Right. Exactly.

6 CO-CHAIR DUBOW: You're not, you
7 know --

8 DR. WINKLER: One of the things I
9 think, because, for the cross-cutting measures
10 you don't have a TAP who's going to do some
11 preliminary groundwork and kind of point out
12 the big issues to say, here, look, this may be
13 a land mine. I think that it would be useful
14 -- talk to Joyce about this, is scheduling a
15 conference call for the committee and it will
16 probably be February, you know, January,
17 February, to have a preliminary discussion.

18 You'll get the measures. You'll
19 have the information. You know what the
20 criteria is. You'll all have a chance to
21 look, and we'll have a talk. Not necessarily
22 decision making, but let's talk about it.

1 Where do you see them? How do you see the
2 evaluation criteria? What are the questions?
3 Because you may have questions that you need
4 more information for. Fine, give us a chance
5 to go get it.

6 The measure developers are part of
7 that conversation. You can ask them
8 questions, and that may change. Hearing
9 somebody else's conversation may help how you
10 see things differently.

11 So, it will be an opportunity for
12 you to work as a work group, if you will,
13 large, to do your initial review before you
14 have to make your decision, and I think that
15 might help you, so you'll act as your own TAP,
16 if you will, so your TAP will meet by call
17 before you come to the final meeting to
18 discuss the cross-cutting. And that might
19 make it just a little bit easier.

20 The decision making meetings tend
21 to be fairly intense meetings, so you do have
22 to kind of be geared up and ready to work.

1 And so, we're still uncertain for the number
2 of measures, but even still, we're going to
3 have to do the evaluation. We've got 50 and
4 we know of at least, you know, six more, so we
5 could be talking 25, 30 measures, and we will
6 be talking about complex measures like
7 outcomes. That's a loadful. That's a lot of
8 measures. So for the discussion, and we'll
9 have two days to do it in.

10 So, you know, getting familiar
11 with the measures, becoming familiar, thinking
12 about them before you come to the meeting,
13 ready to kind of do the final discussions and
14 decision making, it just makes those days go
15 a little bit easier.

16 They are never easy, but --

17 CO-CHAIR DUBOW: And before we
18 adjourn today, Alexis is going to tell us
19 about polling us for our dates, because we
20 need to get it on the calendar. Ideally, the
21 entire committee will be here for that spring
22 meeting, whenever it is.

1 DR. WINKLER: Yes.

2 CO-CHAIR DUBOW: Because it's

3 really, really hard to do it by telephone.

4 So, I hope that everybody will be able to do

5 it, and we will poll for the best dates for

6 the majority.

7 Barbara.

8 DR. YAWN: One of the things that

9 I think might help out sort of a primer, and

10 I don't think that you planned it in your

11 other discussions today, is risk adjustment

12 101. Risk adjustment is going to be so

13 crucial in these outcome measures, and I just

14 looked down this one and the risk adjustment

15 here is all patient refined DRGs, age and

16 gender.

17 Well, what does that mean, and how

18 useful is that and what does it take into

19 account, whether it's strengths, whether it's

20 weaknesses, what are the most common risk

21 adjustment mechanisms? And I know there's 15,

22 you know, you can sort of look over the 15 and

1 say, okay, here are the three most common risk
2 adjustment methodologies used because they
3 aren't all created equal, and I think it is
4 just real important for everyone to
5 understand.

6 DR. WINKLER: All right. Would
7 you recommend a conference call just with that
8 as the focus of it?

9 DR. YAWN: That would be what I
10 would recommend, a webinar, a conference call.

11 DR. WINKLER: Webinar.

12 DR. YAWN: Yes, I think webinar is
13 much better because then we could have some
14 slides up there in front of us.

15 CO-CHAIR DUBOW: It would be
16 stored, wouldn't it.

17 DR. WINKLER: Yes, that's not a
18 bad thing, yes.

19 CO-CHAIR DUBOW: So if they
20 couldn't make it they could have it.

21 DR. WINKLER: And then it would be
22 stored.

1 CO-CHAIR DUBOW: Actually, it
2 would probably have utility for more than just
3 this committee.

4 DR. YAWN: Yes, because, you know,
5 I'm going to want to share that with my TAP,
6 and whether we try a conference call with just
7 the steering committee and then ask the TAP
8 representatives, say, could I have, you know,
9 whoever gave it support me in giving it or,
10 you know, see one, do one, teach one, or
11 whatever we do.

12 DR. BURSTIN: I just want to also
13 point out that it's really important, the
14 actual measure evaluation forms, themselves,
15 the measure submission forms themselves have
16 a lot of citations and evidence. So, you
17 know, we could take a 10,000-foot view of risk
18 adjustment and the important considerations
19 like if doctors should present on admission or
20 as close to admission as possible.

21 But you're still going to get into
22 very condition-specific nuances, for example,

1 AMI has been, actually interesting, fairly
2 well-validated using these kind of data,
3 whereas you wouldn't necessarily think that
4 for other conditions. So, again, the devil's
5 in the details for some of this but I agree,
6 we should give you some high level of review.

7 DR. YAWN: Some people have
8 probably never really spent much time thinking
9 about risk adjustment. Process measures tend
10 to have a little bit less with risk adjustment
11 than some of the --

12 DR. BURSTIN: All of you who were
13 chosen have thought about risk adjustment as
14 well as the TAP.

15 DR. YAWN: No, the steering
16 committee, some of the TAP people that are
17 consumers, for example, may not have thought
18 as much.

19 CO-CHAIR DUBOW: Are there any
20 other questions, comments, observations about
21 the measure evaluation form or the process it
22 undergo, because we have one more item to

1 address before we adjourn for lunch, and then
2 for the day.

3 DR. PACE: Joyce, can I make one--

4 CO-CHAIR DUBOW: Please.

5 DR. PACE: I just want to make one
6 other comment, and I think Reva's mentioned
7 this throughout, but as you see here in this
8 pink area, the steering committee makes, on
9 importance, for example, that's the threshold
10 criterion, and was it met, yes or no for that
11 particular one. But we do ask for you to
12 think about the rationale. So as Reva was
13 saying earlier, why yes or why no, and we are
14 really continuing to push on our reviewers to
15 ground decisions in the criteria.

16 So, just encourage you to continue
17 to work with us on doing that and we know this
18 is a process and a learning process for all of
19 us as we continue to evolve our processes and
20 criteria, but try to keep that in mind.

21 MS. GROAH: On the citations, does
22 staff go back and validate those or look at

1 those or should we be concerned about that?

2 DR. WINKLER: Actually, I'm hoping
3 that that's something the TAPs will be able to
4 help us out with because, hopefully that's
5 where they've got the expertise. Hopefully,
6 they know that better than us. I don't think
7 we can go back and do all of them at a staff
8 level, but at the TAP level we can certainly
9 say, you know, are these the right ones, is
10 something missing? I think that's the
11 clinical expertise of the TAP members, I think
12 that's one of the important ways of using
13 them.

14 CO-CHAIR DUBOW: Okay. So,
15 there's one more item, and that is to discuss
16 the gaps, and a way of thinking about
17 addressing the gaps.

18 DR. WINKLER: I'm not trying to
19 belabor this, but you all have been coming to
20 me with some outstanding ideas, and I just
21 want to be sure I can capture them to the best
22 way possible in terms of approaching the

1 second goal of the project, which is
2 identifying the gaps in the outcome measures.

3 My thinking along that, sorry if
4 it's not in projection form, my thinking along
5 that is a lot of people like grids. David's
6 been sitting here, you know, doing this.

7 Has anybody else written one of
8 these? Okay. If you do, would you share it
9 with me?

10 What David has done is, he has
11 across the top row are the condition areas,
12 and down the side are the types. And that was
13 why I kind of laboriously took you through
14 those types to be sure what was in was out,
15 embellish them, make them the best they can
16 be, because I wanted to do this. And then,
17 what he envisions is that we put in the
18 measures, the outcome measures that we've
19 already endorsed into little boxes,

20 DR. HOPKINS: They are the ones
21 that are on the table -

22 DR. WINKLER: Right. And the

1 candidates. We can do that, too. And I had
2 sort of thought of that from a, you know, each
3 TAP has got it's own page as opposed to a
4 single one, but whatever, to help identify
5 where those gaps are. Another thing is
6 Pauline brought up a slide that I guess
7 originated with the FDA and patient-reported
8 outcomes where she was looking at data
9 sources, but not in a traditional way, but for
10 instance, where would the data for the
11 information come from. One was the patient.
12 It says patient information or caregiver. The
13 two I think are very similar, they are
14 external to the health care system.

15 Another would be the clinician,
16 whoever, health care person, provider,
17 representative, observation, and then
18 objective things like the blood pressure, the
19 lab result, something hard and fast nobody's
20 observing or interpreting, as types of data,
21 in terms of where you would get this.

22 And you know, I was very intrigued

1 with it because I can see, as we were talking
2 about functioning, you may have measures of
3 function from the patient's perception, and
4 you may have measures of function from the
5 clinician's observation assessment. And those
6 may both be very useful. Maybe not in all of
7 these conditions, maybe some, maybe not. What
8 are we doing?

9 Yes, unfortunately, how do we
10 share it with everybody? At lunch, come look
11 at Pauline's thing.

12 But clinician-reported
13 physiological, which is more objective. The
14 caregiver reported or the patient reported and
15 I think the two, it's a proxy report for kids
16 or other folks who need the proxies.

17 But I just loved seeing this, and
18 it just kind of chinks something. So, those
19 are the sort of things that you guys are just
20 an incredible resource for.

21 So, David's got his grid.
22 Pauline's got her slide. Barbara, yesterday,

1 talked a little bit about, you know, breaking
2 down function, the role function, occupational
3 function. You know, I'm going to try to embed
4 all of this. I also want to use the -- so
5 it's a care framework to help us thinking
6 about over time, outcomes over time, because
7 addressing Linda's issue, you know.

8 So, the big, final end point
9 that's down the road some ways, all important,
10 but in a measurement world, sometimes very
11 challenging. What are the more short-term
12 outcomes? How do we think about the different
13 processes as a patient goes through an episode
14 of care, you know, yes, hospitalization may
15 be, you know, for an AMI, but there's the
16 post-acute, and then there's the secondary
17 prevention, and then there's all the impact of
18 that disease.

19 Those that are on a, you know, I'm
20 going to do okay trajectory, versus those that
21 are on a not doing so well trajectory, what
22 are the outcomes of the care that person is

1 experiencing that you'd want to have
2 information about. So, these are the kinds of
3 characteristics of ways of framing the
4 question of where are the gaps in outcome
5 measurement that we want to identify to
6 address the second goal of the project.

7 So, my question to you all is:

8 What other good ideas have you got brewing
9 there, because I know they're out there.

10 You're starting to kind of share them, but I
11 want to try and take advantage of the fact
12 that we're here together today.

13 If there's anything out there
14 brewing, just as Pauline did and David, I
15 mean, you didn't share it, I took it. But
16 anything else then, as well as if, on your
17 travels in the next couple of days, as you
18 sort of mull over and think about the
19 conversations we've been having, for the last
20 two days, thoughts on how we might portray
21 this, to be able to do the analysis of where
22 are the gaps in the outcome measures, what

1 outcome measures would really be useful to a
2 wide variety of audiences that would help this
3 whole process?

4 How do we fill those gaps, what do
5 they look like, because I think for different
6 topics and different conditions they're going
7 to be different. Certain topics are going to
8 lend themselves to certain types of outcomes
9 more than others. And that may be, you know,
10 some of the acute and chronic, some of the,
11 you know, natural history of the disease, the
12 expectations, what we know about the efficacy
13 of treatment, all sorts of things.

14 So, any way to help characterize
15 it at this point is a good idea. We're trying
16 to figure out the best way to move this one
17 forward. And so, this is sort of another
18 assignment, if you will, for goal two of the
19 project, is if you've got any additional ways
20 of thinking about it that you'd like to slice
21 and dice this, please share them.

22 Your first assignment, of course,

1 on goal one was, are there any measures out
2 there, do you know any measures out there, and
3 get them to us, as well as beginning to orient
4 yourself around the measure evaluation
5 criteria as we go forward. So, I'm kind of
6 open. At this point we've pretty much reached
7 the end of our agenda. Lunch should be ready.
8 Yes. And so, I want to open it to any
9 questions that you may have. Let's give this
10 a final opportunity to talk about the things
11 we've talked about and ask questions.

12 DR. HOPKINS: So, goal one is to
13 hustle and get measures submitted. Is there
14 any chance that you guys can push the deadline
15 on that? It's like two weeks from now, or one
16 week. And, you know, this is the first
17 opportunity I've had to really think more
18 about the gaps and the great opportunity we
19 have.

20 DR. WINKLER: Yes.

21 DR. HOPKINS: To fill some of
22 those gaps. But I'm really going to be hard-

1 pressed to see how we can identify the source
2 and get them to fill out the form and all that
3 by October 31st.

4 DR. WINKLER: No. At this point
5 that's an open call for -- it was just part of
6 it. But in terms of getting the measures
7 like, you know, the desperation aspect of it,
8 we'll take them. We'll figure it out.

9 DR. HOPKINS: Okay.

10 DR. WINKLER: Okay. Just let us
11 know, we'll work with you. It's not a
12 problem. Don't consider that a limiting
13 factor. We'll deal with it.

14 Now, it will be very hard if you
15 come up with them in April. Okay.

16 DR. HOPKINS: A month or two.

17 DR. WINKLER: Yes. If we really
18 would like to see things, you know, no later
19 than the end of November.

20 DR. HOPKINS: All right.

21 DR. WINKLER: I mean, we can
22 probably still put things in in November.

1 Beyond that, it's going to get a little bit
2 tough on some of the topic areas.

3 DR. BURSTIN: Well, some of that
4 depends on the dates of the TAP.

5 DR. WINKLER: Right.

6 DR. BURSTIN: That we're
7 conceiving to be in December, so we need to
8 leave them sufficient time to review the
9 measures and not just dump it on them right
10 before the meeting.

11 DR. WINKLER: Right. Exactly.
12 Right. And that's why I'm saying.

13 DR. KEALEY: So I just need a
14 little clarity about the previously NQF-
15 endorsed outcomes measures that you sent us.
16 What exactly is the relationship between those
17 and these new measures we're getting? Are we
18 evaluating those as well or it's just --

19 DR. WINKLER: No. Those provide
20 the context of what you're doing because the
21 work you're doing is to add to that portfolio.
22 One of the things we're likely to do with

1 David's grid is make a grid and populate it
2 with those, find out where we do have measures
3 in italics or pink or some other color.

4 We'll put in the candidates, see
5 how it fills out the grid, and then we'll look
6 at the empty spots. So it's an ongoing
7 building of a portfolio of outcome measures.

8 It would be very important for you
9 to not look at the candidate measures without
10 the context because if you saw the one AMI
11 mortality, we've been through AMI mortality
12 before.

13 There are endorsed measures around
14 AMI mortality. It would not be appropriate
15 for you to evaluate that without considering
16 what's already endorsed, you know, and looking
17 at the big picture, if you will, because our
18 goal isn't to just keep endorsing multiple
19 versions of the same measure, but how do these
20 all fit, does this bring something new to the
21 table, does it -- is it better, you know, is
22 it a better mouse trap, is it -- and so you

1 need the context of what other measures are
2 out there to build this out.

3 So that's what it's for. It's the
4 context.

5 CO-CHAIR DUBOW: And don't forget,
6 otherwise, the measures, the endorsed measures
7 are routinely -- they are maintained, and they
8 are reviewed every three years unless there's
9 a reason to do it more frequently.

10 So that process happens, but if
11 there's a measure coming in anew that can be
12 compared, we're looking for best in class.

13 DR. KEALEY: Okay. So, yes, so
14 the criteria, the four criteria, you said,
15 have changed in the last year, but because
16 these are renewed every three years, we can
17 assume that even if they predated this
18 reclassification that they are still valid and
19 they are going to be looked at?

20 DR. WINKLER: Yes, and the other
21 issue is, as you are doing your comparison it
22 will be difficult for you not to get into some

1 of the details of them, and if you see issues
2 with some of the currently-endorsed measures,
3 we will collect that feedback and feed it into
4 the maintenance process.

5 So, you know, every opportunity to
6 really understand what are the best measures,
7 we'll try and take advantage of it.

8 DR. BURSTIN: We'll actually try
9 to build in for you the date of the next
10 maintenance so you have a sense of how stale
11 or fresh they are and whether you -- you could
12 really make a pretty significant impact on
13 that maintenance review by giving us input as
14 to the existing measures in addition to the
15 ones that come to you.

16 DR. JEWELL: So specific to that
17 conversation, at least some of the outcome
18 measures that you have in that file were
19 originally endorsed as time-limited to begin
20 with, so their window is shorter. It's two
21 years.

22 DR. WINKLER: Yes, it's happening

1 right now.

2 DR. JEWELL: And part of the time-
3 limitedness or, at least my memory is that a
4 big reason for the time-limitedness was
5 because they really had not been tested for
6 the purpose of quality evaluation, so I think
7 when that information comes back around, these
8 newer criteria that have come into play can be
9 applied at that point in time.

10 DR. WINKLER: Right.

11 DR. JEWELL: Regarding the gaps
12 question, I think it's going to be important
13 for us to be clear about whether we think
14 every type of measure on the grid needs to be
15 filled.

16 DR. WINKLER: Right.

17 DR. JEWELL: And I know you didn't
18 say that, but I think when we're talking
19 amongst our TAPs and others, we don't want to
20 confuse gap with every little block in a grid
21 should be filled with a measure for a
22 condition -- this type of, you know, every

1 type of measure out there in the condition.

2 So I just want to make sure that we agree that
3 that's true.

4 And the third thing I just wanted
5 to bring up was, it seems to me the biggest
6 gap is that there are lots of outcome measures
7 out there already, but they weren't, again,
8 designed with the aggregate in mind. And so
9 really what we're talking, at least in my
10 world and in Anne's world, we are really
11 talking about measures that have potential to
12 be aggregated but just hasn't been thought of
13 that way and so that's really where the gaps,
14 I think, may come for others as well.

15 So it's not that the measures
16 don't exist.

17 DR. WINKLER: Right.

18 DR. JEWELL: It's just that they
19 haven't been thought of in that particular
20 framework.

21 DR. PACE: And I think that's good
22 information to know, whether it's a patient-

1 level measure, but it hasn't been developed
2 into a provider-level quality measure, so that
3 would be useful information because that's a
4 great building block.

5 DR. WINKLER: Right. Exactly.

6 Yes, I think because this is doing the gaps
7 analysis part of it is such an important part
8 of this project, we're going to be able to
9 look at the nuances around that and include
10 that.

11 And absolutely, Dianna, if I
12 didn't emphasize, yes -- not all of those
13 types of measures will be appropriate for all
14 of the types of -- and where it's not
15 appropriate, we'll just say so. You know,
16 it's just not -- you know, not a particularly
17 useful outcome for that particular condition,
18 and that's part of the assessment and part of
19 the analysis.

20 We wouldn't want somebody to go
21 create something that is meaningless. So I
22 definitely agree, and thank you for making it

1 explicit.

2 DR. BURSTIN: And just to add to
3 that, I think, you know, for example, I'm
4 thinking of Gallo, you know, we'll have no
5 wine before it's time, I think there's also
6 sort of a sense that although there's a real
7 sense of urgency here -- I know it's right.

8 Go stand with the drunk under the
9 street lamp was just too much to, you know --
10 all these street lamps down the road here.
11 But too many bad analogies today.

12 But I think that, you know, there
13 are gaps that are going to be identified
14 clearly. Some can be filled in the time
15 course of this project, and some can't.

16 And so I think the idea of saying
17 there are some that really could be created
18 into a quality measure, the idea that that's
19 going to happen in a month or two in a high-
20 quality way is unlikely.

21 So I think it's just as important
22 that we identify what needs to happen, even if

1 it doesn't happen in this current project, as
2 I mentioned, we now have the resources that I
3 think we should be able to go back and say, in
4 a year, let's reopen the outcomes project and
5 bring back in those measures that were
6 identified as gap areas and bring them back
7 in.

8 I know there's a sense of urgency.
9 Let's get this first set done. But I also
10 just don't want people to feel like we have to
11 sort of push so hard that things are coming in
12 that you're just not comfortable with that
13 won't make it through the process.

14 DR. PACE: I'd just like to make
15 one comment about the evaluation criteria. We
16 talked about them being revised last year, but
17 I do want to mention that, in essence, they
18 are the same. I mean, NQF has always had
19 criteria about importance, scientific
20 acceptability, usability, and feasibility,
21 even to the extent of, you know, reliability
22 and validity being under scientific

1 acceptability.

2 So there's more clarification,
3 there's more detail and guidance, but I just
4 want to make sure that we're understanding,
5 it's not like a totally new ball game. I
6 mean, these have always been kind of the
7 expectations, but I think it would be fair to
8 say we're ramping up and trying to expect more
9 of meeting those criteria in more rigorous
10 ways and will continue to make that evolution.

11 CO-CHAIR DUBOW: Any other
12 comments?

13 DR. KEALEY: Yes. I was wondering
14 if you guys could walk me through. I know we
15 talked a little yesterday about, say, the
16 unintended consequences scenario.

17 So we endorse a measure; CMS puts
18 it out and starts using it; unintended
19 consequences happen. From the end user, what
20 do they do, how do they effect change, and
21 kind of what has been the experience with the
22 time line between users starting to have

1 trouble and boom, boom, boom, it goes up the
2 chain and back down the chain, and that
3 measure's gone.

4 DR. BURSTIN: To be honest, it
5 hasn't happened a whole lot so, you know, I'm
6 giving you ns of two or something like that.
7 It's been very, very small.

8 And our experience has been when
9 there actually has been evidence, like the
10 pneumonia example I gave you yesterday, of
11 significant unintended consequences, we had
12 that ad hoc committee impaneled within a
13 couple of weeks of publication. The measure
14 was revised and brought to the board, I think,
15 within a month or two. I mean, it was very
16 rapid, and CMS adopted the new measure.

17 So I think when there's truly
18 evidence, and that's the biggest piece of
19 this, when there's evidence. And the problem
20 is we've had other discussions, for example,
21 about perceptions of unintended consequences,
22 a whole discussion around the 30-day mortality

1 measures and this question of the fact that
2 you couldn't exclude patients who were put
3 onto the hospice benefit beyond day one.

4 And this was a huge issue that
5 came up but, you know, the evidence for the
6 unintended consequences wasn't really there,
7 although I think there was a lot of
8 perceptions of that.

9 So I think that's one of our
10 challenges, and which is why we talked a lot
11 about making that robust feedback loop
12 stronger, but I think the key for us is we
13 need to hear from people when there are
14 measures with unintended consequences, and we
15 just don't hear very much, but I think CMS is
16 responsive.

17 DR. AMARASINGHAM: But I guess, in
18 that scenario there was a peer review
19 publication that needed to occur, right? So
20 that's probably nine months, nine to twelve
21 months.

22 DR. KEALEY: Right. For people to

1 start looking around, noticing issues coming
2 up, critical mass, get together somebody to
3 say, hey, I'm going to study this, publish it,
4 then it comes to NQF.

5 DR. BURSTIN: And it doesn't --
6 and I should clarify that that -- that it
7 doesn't, from our point of view, require a
8 peer reviewed publication. We all know how
9 long that takes.

10 Another example we've got going on
11 right now is there is some debate within the
12 surgical community about hair removal, a
13 measure I spend way too much of my time on in
14 an extraordinary kind of way.

15 But a whole issue of whether it's
16 actually, you know, you're not supposed to
17 shave, you're supposed to use depilatories or
18 other mechanisms, but there's some issue about
19 whether it's actually appropriate for
20 neurosurgery.

21 So we don't require a huge number
22 of, you know, publications to say this is an

1 issue. There's been some concerns from the
2 field, and so we're convening an ad hoc
3 maintenance review committee to look at the
4 evidence as it exists.

5 But, again, we can only do that if
6 we know there's a problem.

7 DR. KEALEY: And so if end users
8 who I doubt fully understand kind of the way
9 these measures go through the system, so if
10 they're reporting back to Medicare or
11 complaining to their local Medicare person,
12 they know to move it to NQF or do they mull on
13 it a while or what's to ensure that the word
14 is getting back here?

15 DR. WINKLER: At this point,
16 absolutely nothing, except it's sort of a
17 random thing, which is why we're trying to get
18 the word out to you all and the people you
19 work with, that bring those to us as well as
20 to CMS.

21 I would have to say there's
22 probably no guarantee that that communication

1 occurs. Sometimes it does, but I think
2 sometimes it doesn't. So if we're talking
3 about measures that we've endorsed, we really
4 want to hear about it, and we're happy to hear
5 about it, you know, sooner rather than later,
6 so that we can keep an eye on what's going on.
7 That would be my best recommendation.

8 DR. PACE: Certainly if we're
9 talking about end users and unintended
10 consequences to providers, professional
11 associations also present an avenue for
12 getting information back to NQF, which is, I
13 would say, how our members typically do it,
14 that they are not as willing to rely on fiscal
15 intermediaries of any kind.

16 CO-CHAIR DUBOW: But the point is
17 that they need to contact NQF so that it's,
18 you know, it's assured that NQF knows about it
19 so that NQF can take steps.

20 I mean, if the issue is to address
21 the endorsement, either to reaffirm it or to
22 withdraw endorsement, NQF has to initiate a

1 process, and so the feedback about how
2 measures are doing is necessary.

3 DR. AMARASINGHAM: I was just
4 going to say, because I think Burke's point is
5 very important, because I think a lot of the
6 clinicians and others may not know the rigor
7 that it's gone through, and then think that it
8 may take a long time.

9 The question is whether NQF should
10 actually, rather than just be a purely
11 reactive process, should have a proactive
12 process about measure surveillance, exactly
13 how well is the measure working, you know,
14 look at quality assurance with respect to the
15 data sets that's coming back for it.

16 Because if it's all in the end
17 user's -- just thinking about how even a
18 hospital is putting an EMR together,
19 clinicians don't report problems that they
20 have with EMRs. I can't imagine they're going
21 to do anything with measures. So just those
22 kind of considerations.

1 DR. BURSTIN: Those are all really
2 important points. For the first time we're
3 actually going to be doing a formal, external
4 assessment of the impact of NQF-endorsed
5 measures to give us a better sense of how do
6 we even begin to -- I mean, I have to be
7 honest. I wouldn't even know how to begin
8 tracking some of this without being reactive,
9 but actually active surveillance of some of
10 these. And so we're hoping that this work
11 that will be done externally will help us sort
12 of think through some of the paths to getting
13 at that.

14 But I agree completely. And I
15 think Dianne's point is well-taken. NQF is an
16 organization of organizations, and so going
17 through your professional organizations or
18 consumer organizations is probably the best
19 mechanism.

20 DR. KEALEY: So does NQF track or
21 do they ask to be notified if somebody's using
22 one of their measures? Do we have a database

1 of who's out there using the recommendations?

2 DR. BURSTIN: No, and this is one
3 of those interesting points as well. We've
4 talked about this a lot as well because we are
5 not the measure developer.

6 We are not the measure steward.
7 So our hope is the measure steward should know
8 that. But, again, we're trying to think
9 about, you know, where is our logical fit in
10 that measure steward, measure user, endorser
11 kind of loop, and advice and thoughts about
12 that are very welcome.

13 CO-CHAIR DUBOW: There is some
14 activity going on at the AQA for the
15 ambulatory measures to make some kind of an
16 assessment about reports that are out there
17 and which measures are being used, but I don't
18 know what the -- it hasn't fielded yet. It's
19 in the, you know, it's in the development
20 stage.

21 And I don't know what will come of
22 it or what the response rate will be, but in

1 the past AQA has done some surveying of the
2 health plans to see which measures they are
3 using.

4 So, you know, there are these
5 pockets of inquiry to find out. But, you
6 know, I mean that was done a while ago. I
7 don't know if that was the point where AQA was
8 actually using only -- now AQA endorse -- uses
9 endorsed NQF measures or supports using NQF
10 measures.

11 So I don't know what the status of
12 that was, but --

13 DR. WINKLER: Yes, and one thing I
14 would just add is, part of the maintenance
15 review is one of the questions, one of the
16 most important questions is, is the measure in
17 use and how is it being used.

18 And the idea of keeping,
19 collecting that in a database that becomes
20 available, that we can use, and then even
21 encouraging people to let us know prior to the
22 maintenance, you know, is something that I

1 think we can certainly consider going forward
2 because I can, you know, perceive the utility
3 of it.

4 But we will have a foundational
5 way of filling initially the database with our
6 maintenance information, and that's what we're
7 starting to collect this year. So, you know,
8 we do have the beginnings of something.

9 Before it was a completely random
10 thing. Who did you talk to, who did you hear
11 from and what did you trip over, as opposed to
12 any systematic way of collecting the
13 information.

14 But I can see that we kind of have
15 the beginnings of something that we could
16 certainly work on and it's a great idea.

17 DR. KEALEY: Yes, I mean, I guess
18 the concern I would have is you've got people
19 out there using these measures. You're
20 updating them using new science and
21 everything, and how do you get the word out to
22 all the people who are actually using them

1 that, oh, that measure we endorsed three years
2 ago is not any good any more and we think this
3 one's better, and right now you have no way of
4 getting that out there.

5 DR. BURSTIN: I guess it would all
6 depend as we improve our online database. I
7 mean, at this point you can at least see
8 what's endorsed or not endorsed. Hopefully,
9 you'll be able to, in fact, track the timing
10 of a measure when it was last endorsed, when
11 it's up for maintenance, did it make it
12 through maintenance.

13 And currently, just so you know,
14 the first set of 40-some-odd measures that are
15 going through our maintenance process are now
16 on the NQF website and posted for public
17 comment. So we're hoping to actually do a
18 more proactive polling of what's people's
19 experience.

20 CO-CHAIR DUBOW: But it does
21 suggest that the implementers need to be
22 knowledgeable about referring to the NQF

1 database, now that it is maintained. You
2 know, now you actually have access to the
3 current information.

4 So it behooves an implementer to
5 look carefully at what, you know, the status
6 of the measure is.

7 Dianne.

8 DR. JEWELL: So I haven't been a
9 participant in the maintenance process. I
10 know that you ask how's it being used. I
11 heard the two questions. Is there a specific
12 question about unintended consequences because
13 I'm thinking like adverse event reporting in
14 research trials, you know, in clinical trials.

15 DR. WINKLER: Essentially, and
16 Helen, help me out here, but what we're asking
17 them to do is take the original submission
18 criteria and ask where it changed. And
19 unintended consequences falls into one of
20 those categories.

21 So those are the kinds of things
22 that we're looking for, what did you learn

1 about the measure's behavior, both good and
2 bad, as well as how it's being used.

3 DR. BURSTIN: The only thing I
4 would add to that as well is we've had some
5 discussions actually as recently as last week
6 with our board about what are the requirements
7 of maintenance in terms of public reporting
8 and use of the measure.

9 So should a measure continue to
10 be, you know, endorsed by NQF if no one is
11 using it. And I think we're still trying to
12 figure out exactly what that means.

13 But if nothing else, I think we
14 are continuing to raise the bar in saying,
15 okay, it's been endorsed for three years. As
16 best as we can tell, no one's used it.

17 And actually, the secondary
18 question is not just is anybody using it, are
19 they using it in public reporting, but if
20 you've used it, does it actually help you
21 improve quality, I mean, the QI piece as well.

22 So this is definitely a work-in-

1 progress. We finally have the resources to
2 really be able to do maintenance in a way that
3 we've never been able to do before.

4 I think, if I had to predict, I
5 think the portfolio would be half the size it
6 is in a couple of years, which I think
7 probably would be right-sizing it to where it
8 should be.

9 DR. YAWN: Do you also have some
10 funding to look at people who currently don't
11 use but do public reporting? And Minnesota is
12 one of the examples I always use because we
13 have a public reporting process.

14 They make up their own measures on
15 a regular basis, and there's also ICSI who
16 takes measures and then redoes them. And so
17 I'm fascinated, and there's probably other
18 states. You ask them why and try to find out.

19 So I'll look forward to that kind
20 of information because I think that's crucial
21 as NQF becomes recognized as the resource of
22 endorsement and why --

1 DR. WINKLER: Just in response,
2 are you talking about Minnesota Community
3 Measurement and ICSI? Actually, we evaluate
4 their measures and, you know, we use --

5 DR. YAWN: Yes, but they use them
6 before you ever have time.

7 DR. WINKLER: Absolutely.

8 DR. YAWN: Believe me. I know
9 because they sort of say, "You've got to
10 finish looking at this today because we're
11 going to start tomorrow." And so --

12 DR. KEALEY: But isn't that what
13 we are asking? We want people to kind of use
14 these and try them and give us good evidence.

15 DR. YAWN: Yes, but they change
16 them every year.

17 DR. KEALEY: I know. I live
18 there. I know.

19 CO-CHAIR DUBOW: Okay. This has
20 been a fruitful discussion, I hope, and if
21 there are no other questions, I think I see a
22 couple of new faces in the audience.

1 If there's any public comment --
2 and also to ask the operator if there's
3 anybody on the phone who has a comment.

4 OPERATOR: All lines are now open.

5 CO-CHAIR DUBOW: Okay. Anybody
6 here?

7 DR. WINKLER: No. Alexis --

8 CO-CHAIR DUBOW: Okay. So we have
9 Alexis to talk about getting our act together.

10 MS. FORMAN: Just quickly, this is
11 a tentative time line. We're still waiting
12 for our approval from Health and Human
13 Services, but we had to come up with some
14 dates, and so we would like to start the TAP
15 meetings for phase one in December.

16 And I will work with the TAP
17 chairs to make sure that they can attend the
18 meeting. So if they aren't available on this
19 particular date, we can always change the
20 date. We just needed something down for them
21 to approve. So it is flexible.

22 (Off-mic comment.)

1 MS. FORMAN: Yes. These are one-
2 day face-to-face meetings, and it will be in
3 D.C.

4 So, phase one, we have, starting
5 in December, the beginning of December, and
6 we've only scheduled two, and I think we're
7 going to change cardiovascular and we're going
8 to move that date to December because we do
9 have a lot of measures under that TAP, and
10 we'll be doing some measure maintenance
11 possibly.

12 So we'll have multiple conference
13 calls, probably, with that TAP. And any of
14 the conference calls that we might need to
15 have after this in-person meeting, we'll send
16 out a survey so we can make sure that everyone
17 could attend that call. So we'll do an
18 availability survey.

19 And for the main steering
20 committee, we want to meet towards the end of
21 April, but, again, this will depend on your
22 schedules, so, again, we'll do an availability

1 survey, and we'll survey the entire steering
2 committee to make sure everyone can attend.

3 So, hopefully, this should get
4 approved within the next one to two weeks, and
5 then you'll be hearing from me, especially the
6 TAP chairs, to finalize the dates of the in-
7 person meeting, and then we'll get the dates
8 for the second steering committee meeting, and
9 any conference calls that we have in between
10 we'll also do a poll so that we can make sure
11 the majority can attend.

12 CO-CHAIR DUBOW: Alexis, can you
13 please let us know when those calls happen,
14 just so people can put it on their calendar as
15 a reference. I think the most critical issue,
16 though, is to get on our calendar the date
17 this next meeting because as I said before,
18 it's really important to try to be here, and
19 it's going to be a two-day meeting, is that
20 correct?

21 MS. FORMAN: Yes.

22 CO-CHAIR DUBOW: Okay. Right.

1 We're going to have a lot of work. So, but
2 we'll have some preliminary stuff. We'll have
3 the opportunity to look at the cross-cutting
4 measures, and we might as well get those dates
5 on the calendar as well, and even this
6 tutorial on risk adjustment that Barbara
7 suggested sounded like a really good idea.

8 So, even though we're not meeting
9 until April in person, we will have multiple
10 opportunities to be thinking about the
11 activities related to this steering committee.

12 MS. HAUGEN: And just to clarify,
13 it's the 28th and 29th? That's what you're
14 targeting, April 28th and 29th?

15 CO-CHAIR DUBOW: No. No, we're
16 going to poll for those dates.

17 MS. FORMAN: Well, wait. It's
18 just tentative. We had to put something down,
19 but we'll poll.

20 (Off-mic comment.)

21 DR. WINKLER: Those are ball park.
22 Consider it ball park.

1 CO-CHAIR DUBOW: You'll be polled
2 for the dates. These are just sort of to
3 provide some --

4 DR. WINKLER: The month is
5 correct.

6 CO-CHAIR DUBOW: The month is
7 correct.

8 MS. FORMAN: Yes. The week, it
9 could be correct. It depends. We're going to
10 work with the TAP chairs, but we had to put
11 something down within a day or two, so we had
12 to give them like a skeleton type of time
13 line.

14 CO-CHAIR DUBOW: We're just going
15 to have to be flexible until we're polled, and
16 then respond as soon as you can so we can firm
17 up these dates and put them on our calendars.

18 MS. FORMAN: The polling will
19 occur once the Department of Health and Human
20 Services approves it. So we have to make sure
21 because we're under contract with them. We
22 have to make sure that they are okay with our

1 time line.

2 CO-CHAIR DUBOW: It's within a
3 week.

4 MS. FORMAN: Yes, it should be
5 within a week or two.

6 CO-CHAIR DUBOW: Yes.

7 MS. FORMAN: Because they've had
8 this time line, so it's just making sure
9 they're okay with it, and I mean, we
10 apologize, but we have to have them approve it
11 before we can schedule dates.

12 CO-CHAIR DUBOW: It's the nature
13 of working with a contract with the
14 government. You know, we just have to be
15 flexible until they say okay, and then we can
16 get into action.

17 DR. YAWN: Alexis, when we poll
18 the TAP committees, I think it's very
19 important that we let them know this committee
20 meeting will begin at 7:30 a.m.

21 The reason for that is, you know
22 what happens, people want to fly in that

1 morning. They get there at ten, and then they
2 want to leave at two.

3 And so I think we have to make it
4 very, very clear that we're going to start
5 really early in the morning, even if we don't,
6 so we can get them there for the full day.

7 CO-CHAIR DUBOW: Ruben, did you
8 have a comment?

9 DR. AMARASINGHAM: Just a quick
10 question about time. So then after our
11 meeting in the spring, is this committee
12 continuing to work through October? So it's
13 for another year after that or just --

14 DR. WINKLER: In reality, the role
15 of the steering committee, the biggest part of
16 your work is through the meeting in April.
17 After that you do have several activities.
18 We'll go out for public comment, and you'll
19 come back to respond to those comments.

20 Then it will go to voting and to
21 CSAC. You may or may not be asked to have any
22 feedback or responses. And then it will

1 ultimately be endorsed so that, pretty much,
2 that will be the end of the steering
3 committee's real work.

4 Occasionally we've had situations
5 where we've come back to you for a question.
6 We said, hey, can we get you guys together on
7 a conference call, and something has come up.
8 But those are very unpredictable and tend to
9 be sort of on an ad hoc basis.

10 So the vast majority of your work
11 will be done by the summer, though there could
12 be an occasional, hey, you know, we want to
13 check in with you on something after that
14 time.

15 MS. FORMAN: And then, again, when
16 we do set up the conference call to review the
17 comments, we will, again, poll you to make
18 sure that you're available.

19 CO-CHAIR DUBOW: Okay. So, you
20 know, the idea of polling obviously is to get
21 as many people on the call as possible, so you
22 know, we need to be flexible, but the NQF

1 staff will accommodate us to the extent that
2 they can.

3 So I think with that --

4 DR. WINKLER: I just want to
5 mention lunch is out in the hall. Please, you
6 know, we bought you lunch, please enjoy it.

7 CO-CHAIR DUBOW: We actually
8 finished early because we were really
9 efficient. I hope that this was a productive
10 meeting and that you have a good sense of what
11 the expectations are of us.

12 We have a lot of work to do
13 between now and April, but the staff has even
14 more work than we have, and don't forget to
15 see if you can find good measures that fit the
16 scope of the project and to think about a
17 framework to add onto David's really neat
18 grid. And I'm sure people will just hang out
19 here for lunch, but I wish everybody who's
20 traveling good trips, safe travel, and I'm
21 sure we'll be in touch soon.

22 DR. BURSTIN: I just want to add

1 my thanks to the steering committee and Joyce
2 and especially to our staff who have worked,
3 obviously, very hard to get all this stuff
4 together.

5 CO-CHAIR DUBOW: I was going to
6 say I wanted to thank the staff, too.

7 DR. BURSTIN: And in particular
8 I'd like to --

9 DR. WINKLER: Don't be strangers.
10 We work for you.

11 DR. BURSTIN: Let's hope there's
12 no hurricane in Cabo San Lucas for Melissa and
13 Alexis's part for next week when they're
14 supposed to be on vacation.

15 (Whereupon, the above-entitled
16 matter was concluded at 11:59 a.m.)

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