

NATIONAL QUALITY FORUM
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GASTROINTESTINAL/GENITOURINARY ENDORSEMENT
MAINTENANCE STEERING COMMITTEE MEETING
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MONDAY
AUGUST 27, 2012

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The Steering Committee met at the
National Quality Forum, 9th Floor Conference
Room, 1030 15th Street, N.W., Washington,
D.C., at 9:00 a.m., Andrew Baskin, MD, and
Christopher Saigal, MD, Co-Chairs, presiding.

PRESENT:

ANDREW BASKIN, MD, Aetna, Co-Chair
CHRISTOPHER SAIGAL, MD, UCLA Medical Center,
Co-Chair
LILIANA BORDEIANOU, MD, Massachusetts General
Hospital

ZAHID BUTT, MD, Medisolv, Inc.
ROBERT ELLIS, Consumers' Checkbook
NANCY FALLER, RN, MSN, PhD, CWOCN, Nursing
for Wellness
ED GILL, MD, Virginia Commonwealth University
Medical Center
JOHANNES KOCH, MD, Virginia Mason Medical

Center
JENIFER LIGHTDALE, MD, MPH, Children's
Hospital Boston
ALAYNE MARKLAND, DO, MSc, University of
Alabama at Birmingham
PAUL MERGUERIAN, MD, MS, Seattle Children's
Hospital

JOHN MORTON, MD, MPH, Stanford University
ANNE PELLETIER-CAMERON, MD, University of
Michigan Hospitals & Health Centers

STUART REYNOLDS, MD, MPH, Vanderbilt

University Medical Center

PHILIP SCHOENFELD, MD, VA Ann Arbor Medical

Center

JUDITH TOBIN, PT, MBA, Centers for Medicare &

Medicaid Services

NQF STAFF:

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ASHLIE WILBON, RN, MPH

EVAN WILLIAMSON, MS, MPH

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

9:01 a.m.

MS. BOSSLEY: Hi. I am Heidi Bossley. I am the Vice President of Performance Measures.

So, I get to welcome all of you here today. We really appreciate you participating.

I know staff have taken you through this, but, again, you are a unique group because you are piloting-out a possible redesign of how we go about our consensus-development process. So, you are going to see quite a bit of active participation from the staff as well as at the end of the session tomorrow, hopefully, you will have some time to evaluate how this experience to date has been. And so, we are very excited to have you here.

I am going to turn it over to Andy and Chris.

CO-CHAIR SAIGAL: Yes, I am Chris

1 Saigal. I am a urologist from UCLA.

2 Andy and I are the Chairs here.

3 Our job is to make sure the trains run on time
4 and you guys get out of here on schedule, and
5 to facilitate an open discussion. A lot of
6 preliminary votes show some differences of
7 opinion. So, it is a systematic process. We
8 will walk through it, and I am sure it will be
9 interesting.

10 CO-CHAIR BASKIN: So, good
11 morning, everybody.

12 My name is Andy Baskin. I am a
13 rookie at this particular Steering-Committee-
14 type event. So, please bear with me. Chris
15 will be the senior director here.

16 (Laughter.)

17 But I have been on NQF's Consensus
18 Standards Approval Committee for the past
19 about year and a quarter. So, that is my big
20 credential here and how I got to this Steering
21 Committee.

22 And just I get the embarrassment

1 out of the way really early, I did forget to
2 pack a belt. Now it's all out and we're fine.
3 And hopefully, today I will find one somewhere
4 in a store to buy.

5 (Laughter.)

6 But, anyway, welcome. I am
7 looking forward to this.

8 MS. WILBON: Actually, I guess
9 Taroon and I should also introduce ourselves.

10 My name is Ashlie Wilbon. I think
11 I have emailed with everyone here, and you
12 have gotten lots of emails from me. So, here
13 is the face behind the emails.

14 Thank you, everyone, for coming.
15 We are really excited to have you all here and
16 get started. By all means, as Heidi
17 mentioned, we are really looking forward to
18 getting your feedback on how things went
19 today, and you will be somewhat guinea pigs.
20 We are trying some new things in several
21 areas.

22 So, thanks and welcome.

1 MR. AMIN: And my name is Taroon
2 Amin.

3 It is a pleasure to see all of you
4 in person, and I am hoping we will have a very
5 successful and productive two days.

6 I don't think I have anything else
7 to add. Maybe just introduce Evan as well,
8 since I stole his seat.

9 (Laughter.)

10 MR. WILLIAMSON: Evan Williamson.
11 I am the Project Analyst. I am sure you have
12 all seen a lot of emails from me. I am happy
13 to be here. I am looking forward to the day.

14 Thank you.

15 MS. WILBON: We are going to have
16 Ann Hammersmith, who is our General Counsel,
17 walk you guys through the introductions and
18 the disclosure-of-interest process. And we
19 will go through that.

20 Thanks, Ann.

21 MS. HAMMERSMITH: Good morning,
22 everyone.

1 As Ashlie said, we are going
2 combine introductions with the disclosure of
3 interest. Probably several months ago, you
4 all received a rather lengthy form from us,
5 and we asked you to fill it out and tell us
6 about yourself and your activities.

7 What we do at the first public
8 meeting of every committee is we go around and
9 do an oral disclosure, just go around the
10 table. We don't expect you to recount your
11 CV. In fact, please don't because we will be
12 here all day. We know that you are experts,
13 and that is why you are on the Committee.

14 What we do ask you to do is to
15 reveal anything to the Committee that you
16 think is pertinent to your service on the
17 Committee and what is before the Committee.
18 We are especially interested in your revealing
19 grants, research funding, and consulting
20 activities if they are relevant to the subject
21 matter before the Committee.

22 I want to remind you of just a few

1 things. You serve as an individual on this
2 Committee, not as a representative of an
3 organization, including your employer or any
4 organization that may have nominated you to
5 serve on the Committee. Often, I hear
6 Committee members innocently say, "I am Suzie
7 Smith, and I am here representing the American
8 Society of" fill in the blank. Actually, you
9 are not; you are here as an individual subject
10 matter expert.

11 The other thing that I want to
12 remind you of is, because of the unique nature
13 of the work that we do here, you could have
14 something that should be disclosed even where
15 no money passed hands. So, for example, if
16 you served as a volunteer on a committee for
17 a professional society that had something to
18 do with the work before the Committee, that
19 would be something that we would look for you
20 to disclose. Just because you disclose
21 doesn't mean you have a conflict. The idea is
22 to be open and transparent.

1 So, with that, I am going to ask
2 you to go around the room, introduce
3 yourselves, tell us who you are with, and then
4 let us know if you have anything to disclose.

5 So, would the sashless Dr. Baskin
6 like to start?

7 (Laughter.)

8 CO-CHAIR BASKIN: So, my name is
9 Andy Baskin. My place of employment is Aetna.

10 In terms of disclosures, the only
11 thing I need to say is one is I am on NCQA's
12 Committee for Performance Measurement, but
13 that is not a conflict with any of this work
14 we are doing, but just so people know.

15 And the other thing is that I
16 noticed that one of the measure developers is
17 ActiveHealth, which is a subsidiary of Aetna.
18 I had nothing to do with those measures being
19 developed nor wasn't even aware of them until
20 they were submitted here. So, I don't see
21 that as a conflict. So, I am hoping that I
22 could still vote in that situation. Okay.

1 Thank you.

2 Other than that, nothing to
3 disclose.

4 CO-CHAIR SAIGAL: Okay. So, Chris
5 Saigal. I sit on two AUA committees. One is
6 a Quality Improvement Patient Safety
7 Committee, and the other is the data like
8 Registry Committee.

9 Research-wise, I lead an NIH-
10 funded project to look at quality, costs, and
11 access in urology, and incontinence is one of
12 the topics that we do research on.

13 MEMBER FALLER: I am Nancy Faller.
14 I am an ET nurse clinical specialist from
15 Massachusetts. I am in private practice doing
16 consulting at this point. I am on the board
17 of one journal that covers ostomies, wounds,
18 tubes, continence, et cetera.

19 MEMBER BORDEIANOU: I am Liliana
20 Bordeianou. I am a surgeon at Mass General
21 Hospital. I am a colorectal surgeon. I
22 served as a consultant on AMS. I do think

1 they make slings and meshes. My consulting
2 had nothing to do with that, but here it is.

3 Also, I ran into somebody in the
4 airport who is going to give a presentation
5 here who turns out to be working at my
6 hospital. She is a urogynecologist who I know
7 very well.

8 MEMBER REYNOLDS: I am Stu
9 Reynolds. I am a urologist from Vanderbilt in
10 Nashville, and I don't have any disclosures.

11 MEMBER MARKLAND: Hi. I am Alayne
12 Markland, and I am a geriatrician from the
13 University of Alabama at Birmingham. I am
14 also associated with the Birmingham VA and
15 have a dual appointment at point.

16 I don't have any disclosures
17 directly related. However, I do research in
18 urinary incontinence and lower urinary tract
19 symptoms, and receive funding both from NIH
20 and the VA.

21 MEMBER ELLIS: I am Robert Ellis.
22 I am the Director of Operations and Online

1 Information Resources for the Center for the
2 Study of Services and Consumers' CHECKBOOK.

3 I don't have any conflicts to disclose.

4 MEMBER TOBIN: Good morning.

5 Judy Tobin. I am a Technical
6 Advisor for the Centers for Medicare and
7 Medicaid Services. I am here in a non-voting
8 capacity, evaluating the two-stage process.

9 MEMBER MORTON: I am John Morton
10 from Stanford University. I am the Section
11 Chief for Minimally-Invasive Surgery and a
12 Director of Quality for the hospital. I chair
13 the Surgical Champions' Forum for the American
14 College of Surgeons.

15 MEMBER BUTT: I am Zahid Butt.

16 MEMBER MORTON: No disclosures.

17 MEMBER TOBIN: Sorry.

18 I am Zahid Butt. I wear a couple
19 of different hats. I am a member of
20 gastroenterology group in Maryland, a 15-
21 person gastroenterology group. I also am CEO
22 and CMO of Medisolv, which, amongst other

1 things, implements quality measures that are
2 NQF-endorsed and other quality measures. I do
3 not have any conflicts.

4 MEMBER GILL: I am Ed Gill. I am
5 a urogynecologist at VC Medical Center,
6 Richmond, and I have no disclosures.

7 MEMBER KOCH: Hi. Johannes Koch.
8 I am a gastroenterologist from Virginia Mason
9 in Seattle. And I don't think it is a
10 conflict, but I do serve on the AGA Political
11 Action Committee.

12 MEMBER MERGUERIAN: I am Paul
13 Merguerian. I am the Chief of Pediatric
14 Urology at Seattle Children's Hospital. I am
15 also interested in continuous process
16 improvement and chair the Quality and Safety
17 Committee of the operating room at Seattle
18 Children's.

19 I have nothing to disclose except
20 I am an Associate Director of the Journal of
21 Urology and, also, an Associate Director of a
22 textbook on pediatric urology.

1 MEMBER LIGHTDALE: Good morning.

2 I am Jenifer Lightdale. I am a
3 pediatric gastroenterologist at Boston
4 Children's Hospital, and I don't think I have
5 any disclosures. But I obviously do a lot of
6 society work. I think the biggest thing is I
7 am on the Standards of Practice Committee for
8 the ASGE, which does write guidelines about
9 colonoscopy and abnormal detection rate, et
10 cetera. I am also involved in various
11 journals, but I don't think that will really
12 matter.

13 The other thing that you guys had
14 pointed out is I occasionally do formula
15 reviews, whether an infant should get a
16 specialized formula for a Fallon Community
17 Healthcare plan, and it pays very little.

18 (Laughter.)

19 MEMBER PELLETIER-CAMERON: Anne
20 Pelletier-Cameron. I am a urologist at the
21 University of Michigan.

22 No disclosures other than someone

1 who is presenting a measure today happens to
2 be one of my partners that I work with, but I
3 didn't know this until he tried to sign out
4 his patients to me when I was coming here.

5 (Laughter.)

6 MS. HAMMERSMITH: Okay. Are there
7 any Committee members on the phone? No?
8 Okay.

9 All right. Thank you for those
10 disclosures.

11 Do you have any questions of me or
12 anything you would like to discuss with each
13 other based on the disclosures this morning?

14 (No response.)

15 Okay. Thank you. Have a good
16 meeting.

17 MS. WILBON: So, we do have one
18 other staff member here, a very important one,
19 who we failed to introduce, Karen Pace. I
20 will let her introduce herself. She is
21 sitting over here.

22 DR. PACE: I am Karen Pace, one of

1 the Senior Directors at NQF. I work with all
2 our Task Forces and CSAC on our major
3 evaluation criteria. So, I am interested to
4 see how things go today.

5 MR. AMIN: Quick, Ashlie? Again,
6 just noting that this is the first time we are
7 launching a two-stage process. One of the
8 components of this two-stage process was a
9 technical review period in which we asked
10 measure developers, prior to submitting
11 concepts that you will be evaluating -- Karen
12 Pace and Alexis Forman were leading that
13 effort prior to the measures coming to you,
14 the concepts coming to you. So, at various
15 points, Karen will offer some additional
16 insights based on the technical review process
17 that these concepts underwent.

18 MS. WILBON: Just a note for
19 myself and for you guys, too, and we have a
20 transcript that is produced after the meeting.
21 So, we can remind each other; we can help each
22 other through the day to use your microphones.

1 That is how we kind of keep track and record
2 the conversation that went on. So, if you see
3 that I am talking and my light is not on,
4 please let me know, and we will do the same
5 for you.

6 So, a few logistical things that
7 we will point, where the restrooms are, and
8 for those of you who have not logged in yet to
9 the internet, the wireless access log-in and
10 password are on the screen, and we have some
11 bullet sheets we can pass around as well, but
12 I think everyone is in.

13 So, the restrooms, if you walk out
14 of this conference room and walk towards
15 the -- I don't even know, actually. Through
16 the glass doors, and then make a right, yes.
17 Okay.

18 So, Taroon and I are going to
19 start out with a brief introduction with some
20 overview slides. We are actually going to
21 walk you guys through the evaluation of the
22 first few concepts. Because this is a new

1 process, we kind of wanted to make sure that
2 everyone is clear on how to apply the
3 criteria, the things you should be thinking
4 about as you are applying the criteria to make
5 sure that everyone is on the same page. So,
6 we will go ahead and get started with that.

7 MR. AMIN: And I also will just
8 take a moment to say that we also recognize
9 that many of the Committee members are new to
10 NQF and also new to this process. So, we
11 encourage you at any point, if there are any
12 questions or any clarifying comments, please
13 stop us because the process of evaluating each
14 of the concepts will repeat itself over and
15 over, over the course of today and tomorrow.
16 So, any clarifying questions that you have,
17 please ask them.

18 As Andy pointed out during one of
19 our calls, it is helpful that you are a newer
20 group because this is a new process. So, we
21 are all kind of learning together in the
22 spirit of continuous process improvement.

1 This is one of our tests to see if this
2 process actually works or how it works, I
3 should say.

4 So, with that, I will turn it back
5 to Ashlie and maybe we can get started with
6 the preliminary slides.

7 MS. WILBON: So, we are just going
8 to do a few introductory slides here to get
9 everyone on the same page here this morning.
10 Some of these you may have seen; some of them
11 will be a little bit different. But, again,
12 it has been a while since we had our
13 orientation. And so, we will just go through
14 it again for the sake of clarity.

15 So, the purpose of these slides --
16 we have already done the disclosures -- we
17 will do a quick project overview and scope of
18 the project. We will, again, kind of do a
19 quick overview of what the two-stage process,
20 what we are proposing it will actually be and
21 where we are in this process so far.

22 We will talk a little bit through

1 the actually meeting process. So, the steps
2 will go through to evaluate the concepts and
3 the order that we will go through the
4 criteria.

5 And then, Taroon is going to go
6 through and actually walk you through the
7 first concept and each of the important
8 subcriteria.

9 So, we have done that already.
10 Those are the Steering Committee members.

11 So, NQF is a private, not-for-
12 profit, voluntary consensus-standard-setting
13 organization, public and private partnership,
14 multi-stakeholder board of directors. We have
15 eight stakeholder Councils, of which we try to
16 get representation on each of the committees,
17 so that we do have that multi-stakeholder
18 perspective. We don't always get all of those
19 on the committees, just because the content
20 areas tend to be -- we try to, obviously, seat
21 people who are experts in the content area.
22 But those are our eight member Councils.

1 So, our mission, essentially, is
2 to build consensus, endorse national consensus
3 standards, which is the process that you guys
4 are involved here in with the Steering
5 Committee, and to promote the attainment of
6 national goals through education and outreach.

7 So, NQF endorsement essentially
8 allows a place for standards to get endorsed.
9 So, there is a standardized body of measures
10 for people to reach, or for organizations and
11 providers to have as a toolbox to assess
12 quality and, also, to allow kind of equal
13 comparisons across different entities, and
14 that they are all using the same types of
15 standards.

16 The fact that our process is very
17 regimented -- we have very standardized,
18 specific criteria for importance, scientific
19 acceptability, usability, and feasibility --
20 it has become a standard in the way that
21 people like to use measures that have been
22 through this process because they know that

1 they have been well-vetted.

2 So, a quick project overview here.
3 Again, it is a two-stage process. This first
4 stage is focused on the concepts. What the
5 concept is is essentially the numerator, the
6 denominator, and the details associated with
7 each of those; the exclusions. We did ask for
8 some information if they had some preliminary
9 codes or what have you. We also asked for
10 some information about if they had an idea
11 about how they might want to risk-adjust, if
12 it would be risk-adjusted. And we have a
13 slide with some of the other specific
14 components, but it is only a part, the
15 beginning stages of an actual measure that
16 would be specified further.

17 And so, the purpose of this
18 process is to review those components against
19 the importance criteria and the additional
20 information they submitted for evidence,
21 impact, and opportunity. And then, hopefully,
22 at the end of this process, we will have some

1 approved concepts that will move on into stage
2 two, in which the developers will submit the
3 remaining information associated with those
4 concepts. So, the actual specific codes, the
5 algorithm associated with how the measure
6 would be implemented, and so forth.

7 So, here is the project scope.
8 This was kind of the list of conditions that
9 we put out when we did the call for measures.
10 Obviously, we didn't get measures in all of
11 those condition areas, but wanted to just
12 quickly point out, we do have a couple of
13 pediatric docs on the Committee, of which we
14 didn't actually get any measures specified
15 specifically for the pediatric population.
16 But because we tried to have endorsed measures
17 that are cross-cutting, that cover various
18 populations that are the broadest populations,
19 you know, there may be some opportunity for
20 you guys to provide input on whether or not
21 this would actually apply to a pediatric
22 population.

1 At the concept stage, it is
2 actually really good input, where you can kind
3 of provide some guidance to the developers on
4 how to expand their population for the
5 measure. So, I think that is a really unique
6 kind of good aspect of the way we have divided
7 this process up.

8 So, again, we are looking for
9 cross-seeing inclusive or broad populations,
10 so adults, pediatric, elderly, and the
11 vulnerable populations, and for chronic-care-
12 and care-coordination-focused measures.

13 We ended up getting 20 concepts,
14 10 GI and 10 GU. I will also point out that
15 this Committee is divided. We initially
16 started with a smaller group of GI measures
17 that needed to go through maintenance and a
18 small group of GU measures that needed to go
19 through maintenance. So, we kind of, I guess,
20 somewhat artificially put you guys together.
21 The conditions aren't necessarily completed
22 related. So, we are about half and half with

1 expertise and some people who bring a little
2 bit of both. We realize, obviously, that
3 everyone won't have specific expertise in
4 every topic area, but do expect to provide
5 your kind of medical knowledge and expertise
6 to participate in the discussion and provide
7 your vote.

8 So, we are about half divided. Of
9 those that were submitted, about six of those
10 twenty were actually maintenance measures.
11 So, these are going to be concepts of measures
12 that have been endorsed before, but they are
13 going through the maintenance process, but
14 they will still be evaluated as concepts for
15 this stage of the process.

16 We received concept from eight
17 developer organizations, which are listed
18 here. Many of those are actually in the room
19 today. So, they will probably have questions
20 and you might have questions for them, and you
21 can address them at the Committee's
22 discretion, if you have questions throughout

1 the day.

2 So, this is a list of the GU
3 concepts. I won't linger on this. You guys
4 all have several handouts in your folder which
5 I will go through shortly that have this, and
6 you also should have them electronically as
7 well. So, just a formality there.

8 And these are the GI concepts.
9 And that is it.

10 I will just pause briefly. Before
11 I hand it over to Taroon, I will just walk you
12 through briefly what was in your folder. So,
13 some of these we emailed electronically, and
14 you may have them also on your thumb drive, if
15 you downloaded some of the documents on there.

16 Obviously, we have an agenda in
17 the front. The next handout, I believe,
18 behind that is the staff review comments as
19 well as the member comments that were
20 reviewed.

21 So, part of the new process, one
22 of the steps that we implemented as part of

1 the new process was an early member comment
2 period. Normally, in our process we have the
3 public and the members comment together after
4 the Steering Committee meeting, in which they
5 comment kind of on the Committee's
6 deliberations and the votes, and so forth.
7 But what we have done is kind of added an
8 upfront member comment period where the
9 members actually get to comment on the
10 specifications early in the process and
11 provide input to the Committee for them to
12 discuss, actually, at the in-person meeting.

13 So, in those tables, you will see,
14 for each concept, you will see a row at the
15 bottom which will describe what the member
16 comment is. So, we just ask that you look at
17 that and consider that in your deliberations
18 along with the staff comments.

19 Behind that should be the
20 preliminary evaluations, which are compiled
21 from everyone on the Committee that submitted
22 evaluations. So, everyone that went into

1 Survey Monkey and went through that evaluation
2 process, we have taken all of those results
3 out and compiled them by measure into these
4 tables. So, for those of you that are primary
5 reviewers, you can refer to this table to help
6 you kind of give a summary of what the votes
7 were as you are going through your measures
8 and presenting them to the group.

9 Behind that, I believe -- mine are
10 somewhat out of order -- but I believe was a
11 meeting quick guide, which walks you through
12 the steps that we will kind of go through for
13 the meeting to actually evaluate the concepts.
14 It starts with the developer introduction, the
15 lead discussant, and so forth.

16 And so, the Co-Chairs and staff
17 will kind of help make sure that we are going
18 through that process, but it will kind of help
19 you, too, to kind of know what is coming up
20 next and what that particular part of the
21 process is actually about.

22 Behind that, you have a few

1 different tables, one of which is review
2 assignments by concept. So, this is the same
3 table that was in the memo that we sent out a
4 few weeks ago telling you which concepts you
5 were assigned to. We actually added a table
6 behind that that is by individual. So, rather
7 than you trying to find your name for each
8 concept, we actually have your name and then,
9 associated with that, each of the concepts
10 that you were assigned to review along with
11 which you were assigned as a lead reviewer in
12 bold.

13 We will go through some of these
14 in more detail. But we also have a table of
15 existing endorsed measures. That table will
16 come into play when we talk about
17 harmonization and which of these concepts that
18 got approved were actually similar and how
19 they might need to be harmonized.

20 The last document in your folder
21 should be a table which we will have you guys,
22 two tables which we will have you guys refer

1 to, in order to help evaluate the evidence
2 associated with each of these concepts that
3 were submitted.

4 So, that was just a quick
5 overview. We will direct you to the handouts
6 as we think you might need them throughout the
7 day or throughout the process. So, just kind
8 of a quick orientation of what is in there.
9 We realize it is a lot of paper, but we wanted
10 to make sure that everyone had at their
11 fingertips anything they might need throughout
12 the day.

13 So, any questions? Did I miss
14 anything?

15 MR. AMIN: No. It was very
16 exhaustive.

17 MS. WILBON: Okay.

18 MR. AMIN: Thank you.

19 MS. WILBON: Exhausting or
20 exhaustive? Okay.

21 (Laughter.)

22 MR. AMIN: It's good. It's good.

1 Okay. So, I will go through a
2 little bit more of a detailed discussion of
3 the two-stage process. The two-stage process
4 follows the same process steps as the
5 consensus-development process. So, there was
6 a call for nominations, which meant all of you
7 have gone through. We have identified gaps in
8 the nominations process in which I reached out
9 to many of you in this room. And again, I
10 sincerely appreciate those that responded in
11 a very short timeline with all that
12 information. It seems like a number of people
13 around this table fit into that category. So,
14 I sincerely appreciate that because we were
15 able to really have the content expertise that
16 we need to really evaluate the measures in
17 front of us.

18 We had an open call for standards,
19 for candidate standards, that are in front of
20 you. This was an open call for any developer
21 that was developing measures in this clinical
22 area.

1 We will review the candidate
2 standards, which is where we are right now.
3 And staff will take all the recommendations
4 that you present and develop a draft report,
5 which will go out for public and member
6 comments. And there will be a public and
7 member comment period where anybody from the
8 public can provide input on the measures that
9 are in front of you and your recommendations.

10 And then, there won't be voting at
11 the concept period. And then, you will have
12 the CSAC. There is an overarching body that
13 ensures that we follow the CDP process, which
14 is the CSAC which Andy is part of. The CSAC
15 will review the recommendations, and they will
16 go to the Board. And then, we will move into
17 stage two.

18 Moving on to slide 15, I want to
19 make sure that we are clear on what we are
20 trying to achieve here. So, this is a
21 consensus-development process. We felt that
22 it is important to make sure that we are all

1 on the same page in what we mean by consensus.
2 So, this means general agreement and not
3 necessarily unanimity. All comments that are
4 submitted by public and members are fully
5 considered, and that each of the comments that
6 is submitted by public and members are fully
7 discussed and considered by the Committee.

8 So, what you will expect to
9 receive as we go into public and member
10 comment period is a commenting table, which
11 includes all the comments that were received.
12 And staff will provide a draft response to the
13 Committee based on the Committee
14 deliberations. But you will be expected to
15 review those comments and provide any
16 additional feedback that you feel is
17 appropriate. And body members, the Committee,
18 will have an opportunity to change their votes
19 if they feel it is needed after the comment
20 period.

21 So, that is what we are trying to
22 achieve over the course of this effort and

1 when we go into the public and member
2 commenting period.

3 So, on the next slide you will see
4 an overview of the two-stage process here.
5 So, what we are looking at in stage one is the
6 measure concept and then the fully-specified
7 measure that will move into endorsement. And
8 concepts will be approved.

9 So, what we are trying to achieve
10 in this two-stage process is really ensuring
11 that the measurement community does not invest
12 significant amount of resources to fully
13 develop measures and test measures before
14 there has been an opportunity to provide early
15 input on the concept; i.e., are you measuring
16 something that is important to measure? Is it
17 important for us to move the needle in terms
18 of quality improvement? Or it is simply a
19 measure that we would expect to be a standard
20 for all clinical practice?

21 And there are many quality
22 measures that are important for quality

1 improvement, but they don't rise to the
2 standard of being a national consensus
3 standard for moving forward for all
4 accountability functions.

5 So, that is what we are trying to
6 achieve here. We are trialing this. And
7 essentially, that is why you will be reviewing
8 all the concepts against the importance
9 criteria.

10 Yes?

11 MEMBER BUTT: So, Taroon, the
12 second bullet in stage one where it says, "The
13 concept numerator/denominator exclusion
14 taxonomy," how deep do we get into those or
15 the way the measure is constructed? In other
16 words, do we sort of get into the details of
17 how the measure is constructed rather than
18 focus more on sort of is there evidence and is
19 there a gap, and those types of things?

20 MR. AMIN: We don't want to get
21 too far into the details on how it is
22 constructed. I mean, if you look at the

1 numerator and the denominator and the way that
2 it is designed doesn't make sense to you, this
3 would be the time to discuss it. But as far
4 as the details in the sense of code tables, I
5 think that would be -- again, we are going to
6 have to find a balance here because we are
7 testing this. To a certain extent, you need
8 to have the details in order to assess whether
9 it is important to measure. But we also don't
10 want to get too far into the details in terms
11 of how they have constructed.

12 Is that a fair capture, Karen and
13 Ashlie?

14 DR. PACE: Yes, I think that is
15 true. We are trying to find the line here.
16 But, obviously, definitions are very important
17 to even understanding the concept that is
18 intended.

19 So, we will be kind of seeing how
20 this goes and also getting your feedback on
21 it. But I think, obviously, we need to
22 understand what they are intending to measure

1 and if that makes sense based on the impact,
2 opportunity for improvement, and the evidence
3 that is presented.

4 MR. AMIN: Yes, we are hoping that
5 by focusing on the importance criteria, the
6 three subcriteria components, that that will
7 help drive the nature of the discussion.
8 Again, the level of specificity, I think that
9 is a little bit of a test. We may ask you
10 that same question at the end of tomorrow,
11 whether you had enough information to assess
12 the concept.

13 Any other questions or comments?

14 Okay. So, I will just walk
15 through this, again, at a really high level.
16 Moving on to the next slide, you will see that
17 the stage-one process, there was a technical
18 process that was upfront in which we asked
19 measure developers to submit at least one
20 concept to the technical review period, which
21 Karen, to my right, our lead methodologist,
22 led.

1 At that point, we asked them to
2 submit 30 days prior to the submission
3 deadline and we provided them feedback prior
4 to submitting the measures. There was a
5 concept submission. We are at the Steering
6 Committee evaluation. As I described, the
7 draft report will go out for public comment,
8 and there will be an adjudication of those
9 public comments, and then moving on to the
10 CSAC and Board.

11 Moving to the next slide, an
12 overall timeline of where we are. The call
13 for measures was at 6/4, and we expect that
14 this information will go -- we are at the in-
15 person meeting -- will go to public and member
16 comment on September 14th. And it will go to
17 CSAC for review on November 11th and board
18 approval soon thereafter.

19 And then, we will move into stage
20 two. For the concepts that are approved in
21 this process, they will move to stage two.

22 Again, at a very detailed level,

1 we talked about the numerator and denominator
2 statements.

3 And I will just move over to slide
4 20. Sorry, Evan.

5 So, what we are looking at in
6 terms of stage two is that the measures that
7 you recommend to move forward in stage two,
8 the fully-specified measure, will also go
9 through a technical review process, which will
10 be 30 days prior to submission deadline. And
11 I will also note here that between stage one
12 and stage two the Committee will have an
13 opportunity to provide a checklist of
14 components that they would like to see prior
15 to the measure coming back for stage two. So,
16 at the end of each measure evaluation, we will
17 ask the Committee if there is anything that
18 they would like the measure developers to
19 consider prior to seeing these measures again
20 in the stage-two process.

21 The stage-two process will be
22 mirroring, essentially, what you see here,

1 with the only exception that, once you go
2 through the Steering Committee review, it will
3 also go to a draft report, public comment, but
4 there will actually be a member voting
5 process. The CSAC and Board will actually
6 endorse the measure for use in public
7 accountability and quality improvement
8 functions.

9 So, moving on to the next slide,
10 the timeline for this, we will expect that the
11 required technical assistance process will be
12 completed by December 3rd, and the measure
13 submission deadline will be December 19th.
14 And we will meet again in February, early
15 February, to review the second stage of the
16 measures that were moved forward.

17 It will also go through, as I
18 described, the public and member comment
19 period, an actual vote. And we expect that
20 this project will end around this time next
21 year.

22 What will be evaluated in stage

1 two? Measures with full specifications and
2 testing results. Testing results will include
3 results on validity and reliability testing,
4 and the remaining three criteria, which will
5 be the scientific acceptability, the usability
6 and use of the measure, and the feasibility of
7 the measure as planned to be implemented.

8 Some key points to keep in mind on
9 the two-stage process is that all maintenance
10 measures, in addition to new concepts, will be
11 required to go through stage-one and stage-two
12 reviews if they make it through stage one.
13 The evaluation does not change. We expect
14 that all measures that are endorsed by NQF
15 will still pass all the criteria. And
16 developers will have 18 months to bring back
17 full specification and testing results on
18 reliability and validity. And if they don't
19 by that point in time, they will be required
20 to go through stage-one review again. The
21 principle behind this is to ensure that the
22 evidence is still valid for the measure as it

1 goes through stage one.

2 So, just at a high level, the way
3 that we have currently constructed this is
4 that you will go straight from stage one into
5 stage two, as you think about the timeline.
6 However, developers don't necessarily have to
7 move straight from stage one to stage two.
8 They could take a concept and then take 18
9 months to build it out and then bring it back
10 for review at that point in time.

11 Does that make sense? It sounds
12 good. Okay.

13 So, essentially, this is a pilot.
14 Again, I just want to reiterate that. This is
15 an iterative and first step to our process
16 that was a result of a lean Six Sigma process
17 improvement effort that we underwent at NQF to
18 try to align the efforts of measure
19 development and measure endorsement.

20 So that we heard from our
21 stakeholders that they did not want to
22 continue to invest resources in testing

1 measures when they were not going to pass the
2 importance criteria. So, this is an effort to
3 try to be responsible to that concern and to
4 make sure that we are focusing on the most
5 high-impact areas of healthcare improvement.

6 So, again, what we are testing
7 here -- and we will look for feedback from you
8 all at the end of day two -- is some feedback
9 around the effectiveness of the technical
10 review process and the revised measure
11 submission form, the scalability -- that is
12 what we are looking for in general from our
13 internal process -- and, also, looking at the
14 overall cycle time. Sorry. This is not areas
15 that we are looking for feedback from you.
16 This is how we are testing the effectiveness
17 of this process in general.

18 In stage two, we will also be
19 looking at the overall cycle time and the
20 effectiveness in terms of the staging of the
21 evaluation. So, what we will also be looking
22 for is how many measures actually made it from

1 stage one to stage two and what were the
2 reasons for not making it.

3 CO-CHAIR SAIGAL: Taroon, if the
4 measure developers in this round don't submit
5 into stage two for the February meeting, is
6 there a mechanism for that, if they take
7 longer to sort of test and develop the data
8 around the measure? Is there another venue
9 for them to resubmit the measure within 18
10 months.

11 MR. AMIN: So, the plan is that we
12 would have something for them to submit into
13 within 18 months. We are working on moving
14 into standing committees in the future, and
15 that would be the goal. The exact project and
16 the exact time period is a little bit up in
17 the air.

18 But if there is anything else you
19 want to add, Heidi, on that, in particular,
20 feel free.

21 MS. BOSSLEY: No.

22 MR. AMIN: Okay. All right.

1 By the way, I don't know if we had
2 the opportunity -- Heidi, did you have the
3 opportunity to introduce yourself?

4 MS. BOSSLEY: I did.

5 MR. AMIN: Oh, you did? All
6 right. There we go. Excellent.

7 (Laughter.)

8 And Helen Burstin also joined us.
9 Apologies that there was not enough room at
10 the table, but she is in the back.

11 Anyhow, next steps: as far as
12 where we go from the stage-two process, just
13 make sure you have these dates listed for
14 yourself to ensure that we are good for stage
15 two in 2013.

16 But the orientation will be in
17 early January. The Committee evaluation, the
18 training webinars, which you all participated
19 in, will be January 22nd and 24th. And the
20 in-person meeting will be in early February,
21 with a conference call to discuss the public
22 and member comments.

1 So, I will turn it back to Ashlie
2 to discuss the meeting process for today.

3 MS. WILBON: Some of this I have
4 already been over. So, I am not going to take
5 a lot of time. I think everyone is probably
6 anxious to get to the meat of this meeting,
7 which is actually evaluating the concepts.
8 So, just make sure you have all the resources
9 you need to be able to do that.

10 We have already been through some
11 of your handouts. If you find you are missing
12 anything, just let us know. We will get it
13 for you.

14 Again, what we are going to do for
15 the meeting format is we will start with a
16 developer introduction. The way the agenda is
17 set up is most of the concepts are grouped by
18 developer, in addition to kind of topic area.
19 So, we will have a developer come to the
20 microphone, give a really introduction, two to
21 three minutes, about what they have presented,
22 if there are any unique attributes of their

1 concept that they want you to consider or any
2 additional information.

3 And then, we will have the lead
4 discussant kind of start and introduce the
5 concept, go through and highlight some of the
6 things that came out of the preliminary
7 evaluations, and then open it up to the group
8 for discussion from there.

9 After that, actually, the
10 discussion of the Committee will actually
11 align with each of the subcriteria within the
12 importance criterion. We will start with
13 impact, which is the criteria 1(a). We will
14 have you guys vote. We will move on to
15 evidence. We will have you vote. Then, we
16 will move on to performance gap and have you
17 vote.

18 In between those, both Chris and
19 Andy are going to try to summarize the
20 Committee's discussion, so that we are clear
21 as a group and the staff, so that we can
22 translate the Committee's kind of feel or, you

1 know, judgment or evaluation of each concept,
2 so that it is reflective of what the actual
3 votes were.

4 So, if you find during the summary
5 that it is not quite reflective of what you
6 heard, please, by all means, let us know and
7 we will make sure that we have captured all of
8 that.

9 Following that, we will actually
10 have you submit a vote on your overall
11 recommendation for whether or not you think
12 this concept should move forward to stage two.
13 So, we will have each of the votes on the
14 subcriteria within importance, but, then, we
15 are asking you to kind of, taking all of that
16 into consideration, whether or not you think
17 it should move forward to stage two. Again,
18 we will have the summary of discussion.

19 There are several periods in the
20 agenda that we will have periods for the
21 public and the members to comment. We do have
22 several members of the public and the

1 developers in the audience. So, that will be
2 an opportunity for them to pose questions to
3 the Committee or just make general comments
4 for those in the room.

5 At the end of the discussion of
6 each topic area, so at the end of our
7 discussion today of all the GU concepts, we
8 will have a broad discussion for those
9 concepts that actually are approved on whether
10 or not there are any issues around
11 harmonization that need to be discussed. And
12 we will walk you guys through that when we get
13 to it a little bit more.

14 And then, the same for day two,
15 when we have the discussion on the group of GI
16 concepts, we will have a discussion at the end
17 of that, that group of concepts, on whether or
18 not there is any harmonization that needs to
19 occur within those.

20 Sure.

21 MEMBER MORTON: I had a question a
22 question about harmonization. So, if we see

1 a couple of measures just on the agenda that
2 look pretty close together, we approve the
3 items individually and then come back to them?

4 MS. WILBON: Right. So, if they
5 make it through the -- which is why we have
6 harmonization at the end, because we only
7 really discuss harmonization for those that
8 are actually approved. So, we do evaluate
9 each one individually and then we kind of come
10 back and look at the group of those that were
11 approved and see what might need to be done.
12 Yes, absolutely.

13 So, the next slide, I will just
14 talk a little bit about the role of the lead
15 discussant. I think we have said this many
16 times, and there were several things that were
17 sent out. But, essentially, we are just
18 asking you to introduce the concept for the
19 group, summarize what was submitted in the
20 preliminary evaluations and anything
21 additional you would like to add that you
22 think the group should consider, and,

1 obviously, emphasizing any areas of concern
2 that either you were troubled with or had
3 difficulty discerning, or whatever, so that
4 the whole Committee can comment on those
5 things.

6 So, the electronic voting.
7 Everyone should have a little remote thingy
8 that they will be using to vote with. I
9 think, with the exception of Judy who is non-
10 voting, everyone should have one. If you
11 don't, let me know. I think I have given
12 everyone one.

13 At the time of the voting for each
14 subcriteria, we will have slides up that will
15 give you instructions. Actually, I think the
16 next slide is an example. Yes.

17 So, it will be a slide that looks
18 very similar to this. It will tell you what
19 your voting options are. You will just hit
20 the corresponding number on your remote and
21 point it towards this thingy.

22 (Laughter.)

1 This is the electronic reception
2 for how you vote.

3 So, it is anonymous. We won't
4 really know who voted how necessarily. But
5 that is how we will do voting.

6 And then, once all the votes will
7 show up on the screen, we will read them
8 aloud, so that everyone knows what they are.
9 And then, we will move on to the next.

10 Do you want to just go back to
11 that one slide?

12 Okay. Oh, go ahead.

13 MR. WILLIAMSON: Yes, just a
14 clarification on this slide. You don't need
15 to hit "Send". If you just press the number,
16 1 for yes, 2 for no, or 1 for high -- it will
17 show on the slide -- it will record it on
18 there.

19 And you don't need to worry about
20 duplicative votes. You can keep pressing it
21 and it will only record it once. Sometimes we
22 find that we are like one vote short and we

1 ask everybody to press it again. Just make
2 sure you are pointing at, I believe it is
3 called a "dongle".

4 (Laughter.)

5 MS. WILBON: Oh, okay.

6 MR. WILLIAMSON: That is the
7 technical term for it.

8 MS. WILBON: "Dongle" and "thingy"
9 sound very similar.

10 (Laughter.)

11 MR. WILLIAMSON: So, just point
12 there, press the button, and you don't need to
13 hit "Send". It will record your vote.

14 MS. WILBON: So, the last slide, I
15 believe the timer is set for 60 seconds.

16 MR. WILLIAMSON: Yes.

17 MS. WILBON: So, we will kind of
18 let you know before we are going to hit
19 "Start". So, kind of have an idea of how you
20 are going to vote. You have a minute.
21 Hopefully, by the time we have a discussion,
22 everyone will know how they want to vote. And

1 then, again, we will display the results on
2 the slide and read them aloud.

3 So, that is the meeting process
4 itself. Does anyone have any questions or
5 anything about that?

6 (No response.)

7 Okay. I am going to hand it over
8 to Taroon, and we are actually going to --

9 MR. AMIN: Get started.

10 MS. WILBON: -- get started, yes.

11 MR. AMIN: Does anybody have any
12 questions before we get started? I know
13 everybody is very excited to get started.

14 (No response.)

15 So, the way that we will do this
16 is, for the first two to three concepts,
17 staff, myself in particular, will help to lead
18 the discussion, so that everybody gets the
19 hang of how this is supposed to work and we
20 don't put too much pressure on the lead
21 discussant right from the beginning.

22 So, what I will do at a high level

1 is introduce each of the subcriteria, and then
2 we will ask for the lead discussant to provide
3 their input, as Ashlie described. We will ask
4 for some discussion around the preliminary
5 evaluation and, also, to address the member
6 comments, if they are relevant to the measure,
7 in particular. And then, open it up to
8 general discussion for those that were also
9 reviewing the measure, and then to move
10 forward on voting.

11 I would also keep in mind, in
12 order for us to stay on schedule, we have
13 about 20 minutes a measure over the course of
14 the two days. So, while we want to have
15 robust conversation, let's try to keep the
16 comments and we will kind of rely on the Co-
17 Chairs to make sure that we move along in that
18 fashion, not to put any pressure, but that is
19 kind of the pace that we are thinking about.

20 (Laughter.)

21 We have great staff support.

22 So, we will start with, we will

1 ask the measure developer, NCQA, to give a
2 brief, two-to-three-minute introduction to
3 both of their measures that will be considered
4 in the first time spot. And again, this will
5 be the nature of how we will ask the measure
6 developers to give a brief introduction to all
7 their measures that are going to be considered
8 in their block of time.

9 So, we will ask NCQA to give a
10 brief, two-to-three minute introduction,
11 again, in the spirit of making sure that the
12 time is two to three minutes. And that will
13 be for Measure 0030 and Measure 0098.

14 Please.

15 DR. GIOVANNETTI: My name is Erin
16 Giovannetti. I am with NCQA. I will let my
17 colleagues introduce themselves.

18 MS. ALAYON: Hi. I'm Dawn Alayon
19 from NCQA

20 MS. BARTON: I am Mary Barton from
21 NCQA.

22 DR. GIOVANNETTI: Our measure is,

1 the first one I am presenting, is management
2 of urinary incontinence. It is a patient-
3 reported measure that has two parts. The
4 first is a question which asks, for people who
5 have self-report symptoms of urinary
6 incontinence, have they discussed it with
7 their provider. The intent of this first rate
8 is to get at whether or not healthcare
9 providers are discussing urinary incontinence
10 with their patients.

11 The second question is, have you
12 received treatment for your urinary
13 incontinence? The intent here is that people
14 who have urinary incontinence should receive
15 some sort of treatment for that.

16 This is a measure which we feel is
17 very important. It is up for maintenance.
18 So, this has been a longstanding measure in
19 our Health Outcomes Survey. It addresses what
20 I think is a very important quality gap, which
21 a lot of individuals, especially older
22 individuals, which this measures targets,

1 individuals 65 years and older have urinary
2 incontinence but do not receive treatment for
3 it, either because they think it is a natural
4 part of aging or for other reasons around
5 embarrassment. This is a significant quality
6 gap that we see that needs to be addressed.

7 The measure is based off of
8 guidelines and evidence behind those
9 guidelines suggesting that individuals with
10 urinary incontinence should be screened for
11 urinary incontinence and that they should
12 receive treatment.

13 The question itself, if you look
14 at the wording, is not prescriptive in what
15 type of treatments, although we included all
16 the guidelines in there for the
17 recommendations for various types of
18 treatment. But the question itself just says
19 you should receive some type of treatment and
20 lists some examples, but leaves it open.

21 And so, with that, I will be happy
22 to answer questions, and maybe I can sit and

1 be by my notes to answer those.

2 MR. AMIN: What I will do at this
3 point is walk through the criteria, just to
4 make sure that we are all kind of
5 understanding what we are looking at
6 individually.

7 So, just as an overall, we will do
8 an introduction of the criteria, and then,
9 again, we will turn it over to the lead
10 discussant to have a discussion. And then, we
11 will go through each of the individual
12 criteria. What I will do is I will introduce
13 the criteria, the individual subcriteria, and
14 then vote.

15 Again, this will only be for the
16 first two concepts, and then I will kind of
17 turn it over to Andy and Chris to take a
18 little bit more of a lead here. This is just
19 something that we are trying to see how this
20 works.

21 So, what you are looking at for
22 these two measures or for these two concepts

1 is to the extent that the measure focuses
2 evidence base, important to make significant
3 gains to healthcare quality and improving
4 health outcomes for specific high-impact
5 aspects of healthcare. That will be evaluated
6 through high impact, the evidence that
7 supports the measure focus, and gaps in
8 performance.

9 Specifically, when we are looking
10 at impact, we are looking to assess whether
11 the concept addresses a specific national
12 healthcare goal of priority or the data
13 submitted that demonstrates the high-impact
14 aspect of care. What you should specifically
15 be looking for is the number of people and the
16 percentage affected or dollar amounts, the
17 specific relationship to the target
18 population, and the category of impact
19 selected.

20 And you will rate this in terms of
21 high, moderate, low, and insufficient. The
22 rating scale, on the next slide, high,

1 actually, what the definition for high is that
2 it is based on the information submitted.

3 There is a high confidence there is certainty
4 that this criterion has been met. Moderate is
5 that it is moderate confidence, and low is
6 that there is low confidence. Insufficient is
7 that there is insufficient information
8 submitted to evaluate whether this criteria is
9 met. In particular, blank, incomplete, not
10 relevant, or responsive to the particular
11 question at hand.

12 So, before we move to discussion,
13 to the lead discussant, I will turn it over to
14 Nancy to have the lead discussion
15 conversation.

16 I would like to note for the
17 group, first is that you should evaluate the
18 information presented to you through the
19 submission form. So, you are actually just
20 evaluating the information in front of you.
21 That will become very important as we talk
22 about the evidence component.

1 The second is that Measure 0098 is
2 actually being combined. There were three
3 measures that were currently endorsed.
4 Measure 0098 was the assessment of UI measure.
5 Measure 0099 was the characterization of UI,
6 and Measure 0100 was the plan of care UI,
7 which have been combined in this measure that
8 is in front of you. So, we will leave it
9 there.

10 I will also make a note that we
11 have a procedure here. The measure developer
12 should really only speak when spoken to by the
13 Committee. If there are questions that you
14 would like to ask, that is fine, but we want
15 to limit the back-and-forth.

16 The second thing I will just note
17 is that I asked the developer to give an
18 introduction to both measures, and that will
19 be the format that we will be using. If there
20 is additional conversation you would like to
21 have about 0098 --

22 CO-CHAIR BASKIN: I think what

1 happened is when she did the introduction, she
2 only introduced No. 0030 instead of 0098. So,
3 I realize you asked for both, but this time
4 around maybe we could get you to talk about
5 0098 as well.

6 MR. AMIN: Sure. That is your
7 discretion.

8 CO-CHAIR BASKIN: Because it just
9 didn't happen.

10 MR. AMIN: That is your
11 discretion.

12 CO-CHAIR BASKIN: That just didn't
13 happen, but in the future we will be a little
14 clearer in our communication.

15 MR. AMIN: Sure.

16 CO-CHAIR BASKIN: So, yes, go
17 ahead.

18 DR. GIOVANNETTI: I apologize. It
19 is a lot of instructions flowing around. We
20 are all trying to do the best we can in a new
21 structure. So, I apologize for interrupting.
22 I wanted to make sure things were clear.

1 Measure 0098 is a measure that is
2 a provider-level measure. It is a measure
3 that does combine three rates. This is for
4 older women, women age 65 and older who are
5 seen in the ambulatory care setting.

6 This has three rates in it. One
7 is to screen for urinary incontinence those
8 individuals who are then have a diagnosis of
9 urinary incontinence to ensure that they had
10 both characterization and a plan-of-care
11 documented in their medical record.

12 So, I will leave it at that.

13 MR. AMIN: Okay. So, we will
14 start with the lead discussant conversation.

15 MEMBER FALLER: This isn't fair;
16 since I am the first one, I don't know what I
17 am supposed to do.

18 But just from a practical
19 perspective and a patient perspective, in
20 reading it, I had two concerns. One, were
21 they asking the patient whether the MD had
22 initiated that discussion or whether they, as

1 the patient, had initiated that discussion,
2 because I think that is really significant in
3 terms of historically what we know about
4 patients discussing incontinence with
5 providers.

6 And the second concern that I had
7 was the word "treatment". Even though they
8 are given different treatments in what they
9 are being asked, are they being asked, were
10 you treated or were these discussed with you?
11 Because those are very different. Sometimes
12 the provider may give them the options of
13 biofeedback, or what have you, and the patient
14 may choose not to do any of them because they
15 don't particularly like any of them. Or they
16 may have only been suggested surgery, and they
17 don't want surgery.

18 CO-CHAIR SAIGAL: Nancy, could I
19 ask? So, I think it is good for the group if
20 you could categorize your comments in terms of
21 like the different things we are voting on, to
22 help us understand what sort of portions you

1 are concerned about. So, there is importance
2 to report it and the evidence behind that. I
3 guess those are importance to measure and
4 report which we are talking about right now.

5 MEMBER FALLER: I guess mine was
6 even before that in terms of, what are we
7 asking? I mean, I have no problem with the
8 issues and the importance of them, the impact
9 that they will have because of the numbers of
10 people who are incontinent. But I have a
11 concern with what we are going to be asking
12 the people. So, I am not sure which one of
13 those that falls under.

14 CO-CHAIR SAIGAL: I mean, we have
15 to evaluate the measure as submitted. So,
16 basically, if what you are saying is that, as
17 submitted, you think that these are
18 insufficiently defined to be important, then
19 I guess that is how we would think of it. Is
20 that what you were trying to say or?

21 DR. PACE: I think in the measure
22 submission form, under the details, there is

1 a specific question that is on the survey.
2 And so, for example, the discussing urinary
3 incontinence question is, "Have you talked to
4 your current doctor or other health provider
5 about your leakage problem?" So, that is the
6 exact language of the question that is being
7 asked on the survey. And then, the other one
8 is there as well.

9 But I think, getting back to the
10 point that was just made, if we can talk about
11 impact of urinary incontinence in terms of
12 whether that general area is a high-impact
13 area, and then we can move on to the evidence
14 about this specific focus. But let's, first,
15 just talk about the impact of that general
16 area of condition, urinary incontinence.

17 CO-CHAIR BASKIN: So, I see people
18 starting to raise their hands. So, we found
19 it very helpful in the past, because it is
20 hard to keep your hand up, if you will just
21 put your card up, we will know that you want
22 to speak, and then we will get you speaking.

1 Okay? But I think your hand up first. So, it
2 would just make it easier.

3 MEMBER MORTON: Either raise it or
4 just throw it out, right, one or the other?

5 (Laughter.)

6 The question I had is it might be
7 useful just to have the criteria up, and that
8 will help formulate some of the responses that
9 we are all looking at.

10 DR. PACE: I would like to say
11 that high impact is more than just number of
12 persons and percentage affected. I mean,
13 those are key ones that are generally brought
14 up, the number of people affected, the
15 resource involved. It could be, also, the
16 consequence of poor quality could be of high
17 impact. And sometimes even with a small
18 volume of patients, it could be an extremely
19 high impact area, the consequence of poor
20 quality. So, I think just kind of keep in
21 mind it is looking at it in context to the
22 particular condition.

1 MEMBER MERGUERIAN: I am just
2 wondering if another question should not be
3 added. Even though it is in the summary of
4 the evidence for high impact where you
5 basically say that it affects their well-
6 being, but there is really no question on
7 quality of life and how bothersome that
8 incontinence is to that woman. So, I think
9 adding a quality-of-life question there or a
10 bothersome index into that question, that
11 survey would be important.

12 MEMBER BUTT: I think there is a
13 question that says big problem or a small
14 problem.

15 MEMBER MERGUERIAN: So, that is in
16 0098?

17 MEMBER BUTT: No, 0030.

18 CO-CHAIR BASKIN: Yes, it is not
19 just a yes-or-no question, apparently. It is
20 a none, little, some, or a lot kind of
21 question.

22 Oh, I'm sorry, I should have my

1 microphone on.

2 I mean, it is rather obvious to me
3 that this is a common problem. It affects a
4 lot of people and a great percentage of the
5 target population, which is over 65 women.
6 Any concerns about that?

7 MEMBER BORDEIANOU: There is a big
8 study in JAMA, I believe, and I can't remember
9 the reference right now, that documented the
10 rate of urinary incontinence in women at
11 various ages. I think the rate of
12 incontinence in women is over 25 percent by
13 age 65. I said it is a common problem in
14 women over 65 that has been very well-
15 documented, and I can't remember the reference
16 off the top of my head, but it has been
17 published in JAMA several years ago.

18 CO-CHAIR BASKIN: So, any concerns
19 here at all about the first impact 1(a)?

20 (No response.)

21 Then, let's move on to the next
22 one.

1 CO-CHAIR SAIGAL: Yes, I would
2 agree. That's fine. I agree. Go ahead.

3 CO-CHAIR BASKIN: Then, the next
4 question we were to answer --

5 MR. AMIN: First, we vote.

6 CO-CHAIR BASKIN: Oh, we vote on
7 1(a) first?

8 MR. AMIN: Yes.

9 CO-CHAIR BASKIN: Okay.

10 MR. WILLIAMSON: So, we will now
11 vote on the importance to measure and report
12 for high impact. You may begin voting now.

13 (Vote taken.)

14 We have one not voting, right?

15 Fourteen? Okay. All right.

16 And the results, we have 14 high,
17 zero moderate, zero low, and zero
18 insufficient.

19 MR. AMIN: Okay. So, thank you
20 for that.

21 So, high impact, you know,
22 generally, there isn't as much probably

1 discussion. Maybe I should have prefaced that
2 by saying there is probably not much debate
3 there.

4 So, moving on to the next criteria
5 that we will evaluate, the first is -- I will
6 just wait for Evan to transition the slide.

7 What you are going to be looking
8 at here is assess the evidence that supports
9 the measure. If it is a health outcome, we
10 are only looking at a rationale. And again,
11 you want to look at the evidence based on the
12 information that is submitted.

13 Looking at the preliminary
14 reviews, I noticed that there were a number of
15 comments that the Committee members made about
16 the evidence that exists, but not necessarily
17 the evidence that was submitted. Again, I am
18 not referring to this measure in particular;
19 I am just referring broadly, that there was
20 evidence that exists but not submitted in the
21 measure. You need to evaluate the measure
22 that is submitted in front of you and the

1 information that is submitted in front of you.

2 And I will give you some caveats
3 as we go through. I will also say that this
4 is the subcriteria that will probably require
5 the most discussion and the most clarification
6 upfront. So, I just want to make sure
7 everybody is aware.

8 So, what we are looking for is for
9 the measure developers to summarize the body
10 of the evidence. That would be through three
11 different options. If the measure is based on
12 the guidelines, to look to see the evidence
13 that supports the guidelines under evaluation.
14 The second is a summary of the evidence
15 through a systematic review or, third, that
16 the developer does a review of the evidence
17 themselves.

18 There is a question?

19 MEMBER LIGHTDALE: I have a
20 question. I have a question about what you
21 mean by evidence. Is it evidence that the
22 problem exists or is it evidence that

1 treatment would make a difference, or whatever
2 is being proposed as you numerator would make
3 a difference?

4 CO-CHAIR BASKIN: Right. It is
5 evidence that whatever process or whatever is
6 being measured would make a difference.

7 MEMBER LIGHTDALE: Okay.

8 MR. AMIN: And again, I think that
9 was another point that I wanted to bring up,
10 in that that seemed to have come up also in
11 the preliminary evaluations. That is
12 information that supports the performance gap
13 question around the problem exists, but really
14 what we are looking for is that this measure
15 focus actually improves patient outcomes. And
16 that is particularly the type of evidence that
17 we are looking for.

18 CO-CHAIR SAIGAL: And so,
19 basically, we are looking for evidence that
20 measuring this would reduce incontinence in
21 women. That is the idea.

22 Go ahead.

1 MEMBER BUTT: Yes, I have a
2 question. A measure like this, where it seems
3 to be it is submitted as a process measure,
4 but incontinence itself is an outcome, isn't
5 it? And it is a combination process and
6 outcome. So, the treatment part is the
7 process, and the incontinence itself is the
8 outcome. So, it is more we focus on the
9 treatment? Because it is a two-part measure,
10 right?

11 CO-CHAIR SAIGAL: The resolution
12 of incontinence will be the outcome.

13 MEMBER BUTT: Okay.

14 MEMBER MORTON: Well, the process
15 is asking about it, isn't it? The process is
16 asking about it?

17 DR. PACE: This is actually two
18 processes. One is whether the person
19 answering this survey has had a discussion
20 with their care provider, and the second part
21 is about whether they received treatment.

22 MEMBER BUTT: Okay. Got it.

1 DR. PACE: So, you are right that
2 a measure of actual incontinence before and
3 after would be an outcome measure, and that is
4 what we are asking for. It is what the
5 evidence about these particular processes in
6 terms of achieving that outcome of resolution?

7 The other thing that I will just
8 mention about this to kind of consider -- and
9 it is a distinction between this one and the
10 next measure -- is this is actually from the
11 patient's perspective in terms of, did they
12 actually have a discussion; did they receive
13 treatment? And this would be an experience
14 with care, and people would think of this as
15 the patient being the authoritative source of
16 whether they actually had a discussion and
17 actually received treatment.

18 MEMBER ELLIS: Hopefully, I am not
19 being too redundant, but just to clarify this.
20 It struck me that the first part of this
21 measure seemed much more focused on patient
22 engagement, which I think it is easier to kind

1 of wrap our brains around its importance
2 because we have addressed the importance of
3 patient engagement in a lot of other measures.

4 And then, you have this kind of
5 dividing line and you have the outcome piece.
6 I am wondering how the evidence evaluation
7 plays in those two component parts.

8 CO-CHAIR SAIGAL: Well, my
9 understanding of this is that there was an NQF
10 Evidence Committee that emphasized the
11 importance of process/outcomes links in these
12 measures. We can measure a lot of processes
13 of care that may not affect what patients care
14 about. So, they would like us to evaluate
15 whether we, based on the evidence submitted,
16 can find a link there. I think for many of
17 these measures it is very hard to find a
18 specific study that shows that process/outcome
19 link.

20 There is an exception that we have
21 and the option to use if we feel that the
22 evidence isn't there, but that the benefits

1 outweigh the harms of proceeding with it. But
2 it is supposed to be an exception and not a
3 routine thing that we do to override a lack of
4 evidence behind any one specific measure. So,
5 the bar is pretty high, I would say.

6 MR. AMIN: So, before I move on --
7 and maybe, Karen, also you want to jump in
8 here -- but for each of the components, when
9 we have multiple components, there needs to be
10 evidence supporting each piece. So, that is
11 really the way you want to think about this.
12 Again, not necessarily just related to these
13 measures broadly.

14 And let me just, if I can, go
15 through the rest of this related to evidence,
16 just to make sure everybody understands the
17 options in front of them. So, what you are
18 looking for is, when you are looking at that
19 body of evidence, you are looking to evaluate
20 the quantity, quality, and the consistency of
21 the evidence that supports the measure focus.
22 We would expect that, for consistency, it is

1 rated moderate or high, and that the quality
2 and quantity is rated moderate or high.

3 So, just moving on to the next
4 slide, again, what we are looking for in terms
5 of quantity, the total number of studies, not
6 just the articles or papers.

7 For quality, the certainty of the
8 evidence -- or sorry -- the certainty or
9 confidence in the point estimates.

10 And the consistency is we are
11 looking for the stability and the magnitude
12 and direction of the clinically- and
13 practically-meaningful benefits and harms to
14 the patients.

15 So, I will go through each of
16 these individually in terms of how you vote.

17 Quantity, so moving on to the next
18 slide, you will see that we are looking for
19 high. There are five or more studies. Two to
20 four is moderate, and one would be low.

21 Insufficient is that the information that was
22 presented to you, there is no empirical

1 evidence or that the selected studies are from
2 a larger body of evidence.

3 MEMBER BUTT: Taroon, in this
4 context, do you consider a guideline a study?

5 MR. AMIN: No.

6 MEMBER BUTT: That is a paper?

7 MR. AMIN: It is not either. The
8 guideline needs to demonstrate, needs to
9 catalog the quality, quantity, and consistency
10 of the evidence that supports the guideline
11 itself. And we will go into a little bit more
12 on that because I think that will be the
13 nature of the discussion broadly, again, not
14 particular to these measures, but just
15 broadly.

16 Karen?

17 DR. PACE: There's more slides.

18 MR. AMIN: Yes, there's more
19 slides.

20 DR. PACE: Okay.

21 MR. AMIN: Oh, yes.

22 DR. PACE: Why don't you finish?

1 MR. AMIN: Okay. All right. So,
2 for quality, we are looking for high quality;
3 we are looking for randomized controlled
4 trials with direct evidence specific to the
5 measure focus. We are not looking for just
6 information related to the condition broadly.
7 We are looking for really what the measure is
8 specifically focused on measuring.

9 Adequate size for precision in the
10 point estimates, moderate is non-RCTs with the
11 control for the confounders, and low looks at
12 RCTs with serious biases. And again,
13 insufficient is that there is no empirical
14 evidence.

15 And third, and probably most
16 significantly, looking at consistency, which
17 is often lacking in the information presented
18 in the guidelines broadly, but that is
19 tangential, is that for high, you are looking
20 for estimates that there is clinically- and
21 practically-meaningful benefits in the
22 evidence base that is actually presented, and

1 similar magnitude across the studies.

2 And moderate would be that there's
3 estimates of benefits and harms, but they may
4 differ in terms of magnitude. And low is that
5 there is estimates of benefits and harms, but
6 they differ in terms of magnitude and benefit,
7 and there's wide confidence intervals.

8 CO-CHAIR SAIGAL: So, Taroon, we
9 are being asked to evaluate the impact of
10 this, but also its relationship to outcomes.
11 So, those are two types of evaluations because
12 there is, generally speaking, a lot more
13 evidence of the impact of the problem on
14 people than there is about process outcome.
15 So, how should we define that or decide on
16 that in terms of doing this rating?

17 MR. AMIN: I think, again, we are
18 looking for this particular subcriterion --
19 and again, Karen, if you want to add anything
20 here -- we are looking at, in particular, for
21 this subcriteria the evidence that supports
22 the measure focus.

1 So, impact is 1(a), which we are
2 looking for information that supports the
3 impact of the measure focus. But here what we
4 are looking at is really the evidence that
5 supports the measure focus in relation to the
6 outcome, not a cataloguing of the nature of
7 the problem that exists.

8 DR. PACE: Right. So, I think
9 your vote already showed that all of you
10 thought that this was a high-impact area. So,
11 now we are moving on to, what is the evidence
12 for these processes in terms of relationship
13 to the outcomes. And then, the third
14 component that we will eventually get to is
15 performance gap.

16 So, just to get back to
17 guidelines, some are just based on expert
18 opinion, some guideline recommendations and
19 the evidence task where it is really focused
20 on empirical evidence, but we do have an
21 exception if it is really deemed necessary by
22 the Steering Committee that it still warrants

1 having a performance measure.

2 And I don't know if you were going
3 to talk about those two things.

4 MR. AMIN: Yes, I am going to go
5 over it. Yes, I will go into it.

6 DR. PACE: But, the Evidence Task
7 Force did make a specific distinction between
8 guideline and evidence. As you all know, not
9 all guidelines are created equal in terms of
10 the processes that are used. So, that is
11 where the Evidence Task Force really asked for
12 a description of the summary of that evidence
13 review, so that we could really be transparent
14 about the evidence.

15 CO-CHAIR SAIGAL: Okay. So, for
16 this group, we have evidence in this measure
17 about importance, but nothing was submitted
18 specifically about the treatment and outcome
19 relationship. But the urologists in the room
20 at least -- and some of the gynecologists --
21 are aware of evidence that suggests that
22 treatment of incontinence is effective. So,

1 we could basically talk about that in this
2 meeting or we could have the developer to
3 include those data when they go to phase 2,
4 studies showing that, you know, Kegels or
5 surgery are effective in treating
6 incontinence.

7 MR. AMIN: I think we will
8 actually probably do both. And so, I will
9 talk about the options for the evidence in a
10 second. Chris, that was a great summary, and
11 I might need you to do that again as we
12 actually go through this.

13 But let me just finish this real
14 quick, and then we will open up to questions
15 because I want to make sure everybody is on
16 the same page.

17 So, Evan, if you can go to the
18 next slide?

19 What you are ultimately going to
20 actually rate is the last column here, which
21 is whether it passes this criterion on
22 evidence. And we talked about the fact that

1 you will have a discussion around the
2 quantity, quality, and the consistency of what
3 is presented in front of you. And again, the
4 only way that this criterion really passes, as
5 you can see really, that if it is moderate or
6 high across quality, quantity, consistency.

7 Now, just moving on to the next
8 slide, what we will ask you to do is vote on
9 the information that is presented in front of
10 you. So, if you do not believe that the
11 information presented in front of you
12 adequately captures, gives you the actual
13 information related to quantity, quality,
14 consistency for you to adequately rate it, we
15 ask you to first make that very transparent.

16 Again, one of the key
17 considerations from the Evidence Task Force
18 which was, again, a consensus-based group that
19 asked how we should be endorsing national
20 consensus standards, was that you need to make
21 it very transparent when there is not evidence
22 that is supporting the measure focus in what

1 is submitted in the evaluation, in the measure
2 submission form.

3 So, you will first rate, and you
4 will have three options. The first is that
5 the evidence, the body of evidence, meets our
6 guidance on quality, quantity, consistency.
7 The second is that the evidence does not meet
8 the guidance for quality, quantity,
9 consistency, including that there is no
10 empirical evidence that exists. And if there
11 is no evidence that exists at all to support
12 the measure focus, you have the option of
13 invoking an exception that there is
14 exceptional and compelling reason that the
15 measure should be considered forward;
16 specifically, that the benefits outweigh the
17 harms.

18 And we will ask that, once you
19 actually vote -- so, you will vote no, and
20 then we will ask for the Committee to invoke
21 an exception. And there will need to be a
22 rationale that supports that exception. So,

1 specifically describing the body of evidence
2 that supports this measure focus that may not
3 have been submitted as part of the measure
4 evaluation.

5 The last option you have is that
6 there is insufficient information that was
7 submitted to rate quantity, quality, and
8 consistency in terms of that there is
9 information that exists, but the measure
10 developer did not provide it. And there, we
11 will ask whether there is general agreement
12 that the quality, quantity, and consistency of
13 the body of evidence would meet the NQF
14 criteria. And then, we would ask for a
15 discussion and rationale.

16 So, if the information doesn't
17 exist at all, that would be No. 2. And if the
18 information exists, but was not submitted as
19 part of the measure submission, that would be
20 No. 3. Is that clear?

21 And then, as you vote no, there
22 will be an option for you to have a secondary

1 vote to continue to move the concept forward,
2 with the caveat being that the information
3 that was presented would not meet the guidance
4 for the NQF -- would not meet the NQF criteria
5 as submitted. Is that clear?

6 MEMBER BUTT: The four different
7 methods of grading that are given as examples,
8 are those the only ones? Or, for example, if
9 there is a grading system that is quoted that
10 is not listed here, how do you sort of tackle
11 that?

12 DR. PACE: That is a good
13 question. That really gets at the heart of
14 the Evidence Task Force recommendations that
15 we ask for a summary of the quantity, quality,
16 and consistency of the body of evidence,
17 because across guidelines they use so many
18 different grading and rating systems, that
19 there is no way to do a crosswalk among those.

20 You know, you can see guidelines
21 where grade A means it is a strong consensus
22 opinion versus other guidelines where grade A

1 means there are multiple RCTs. And so, that
2 was really part, you know, very clear as the
3 Evidence Task Force looked at current
4 practices and guideline development and, also,
5 at the same time our Evidence Task Force was
6 working. The IOM actually had two projects
7 going on related to this same issue, one in
8 systematic reviews and one on developing
9 guidelines.

10 And so, in order to be
11 transparent, the Evidence Task Force said we
12 really need to have at least some summary
13 information about the quantity, quality, and
14 consistency of that body of evidence because
15 we don't really know what those processes were
16 and what those gradings -- you know, it is
17 hard to equate those grading systems across
18 guideline developers.

19 But I will say that one of the
20 things that the developers come up against is
21 about the status of guideline development,
22 that guideline developers maybe have not been

1 very transparent around their systematic
2 reviews or making their evidence tables
3 available.

4 So, this is an area, again, where
5 there is a lot of variation and, hopefully,
6 evolution to higher standards. That is why we
7 have you, as experts, around the table, to
8 also provide guidance in this area.

9 We really do expect the measure
10 developers to understand the evidence on which
11 they are proposing National Performance
12 Standards. But, again, there are some
13 limitations of what is available.

14 So, sometimes if it is not real
15 evident with the guideline, perhaps the
16 guideline is based on a systematic review
17 where that information would be available. Or
18 there may be something through the Cochrane
19 Collaboration or AHRQ or some other reference.
20 But, again, that is where you all may have
21 more information about that.

22 MEMBER BUTT: So, I am still not

1 sure if I understand. Should we sort of
2 accept the way it is presented, that (a) means
3 good scientific evidence was reviewed, even
4 though it is not a specific methodology that
5 we are familiar with? Or do we combine that
6 with our sort of other information and
7 knowledge and say, yes, it sounds like it is
8 okay?

9 DR. PACE: So, I don't know, if
10 you look at the measure submission, the
11 attachment about the evidence, we ask about
12 the guideline and the grade. And the section
13 where we really ask for them to summarize the
14 quantity, quality, and consistency starts at
15 1(c)(8) or that section on findings from the
16 systematic review.

17 And so, if the information has
18 been provided there that you can use that
19 information and the findings from the
20 systematic review beginning with item 1(c)(8),
21 then you can just apply the rating scale. If
22 that hasn't been provided in a way that you

1 can actually provide the rating scale, then we
2 would say that you really have insufficient
3 information on which to apply the rating scale
4 and you would vote it that way.

5 But, then, the next question is,
6 are you aware of the evidence that would meet
7 these criteria or whether you think it is
8 really an exceptional situation that we really
9 need a performance measure in this area.

10 So, I will stop there.

11 CO-CHAIR SAIGAL: Okay. So,
12 should we vote?

13 Oh, one more?

14 MEMBER REYNOLDS: I just want to
15 make sure because I know that this is the
16 first one, and we are just trying to get our
17 hands on it. I think you are giving a good
18 overall, but you are trying hard not to push
19 us a little bit and point out specifics.

20 So, I just want make sure on this
21 one that people do see the specifics, that if
22 you look at the form that you can get off the

1 website and on the pilot submission form, I
2 think the measure developers have done a
3 pretty good job of giving evidence and
4 summary. And so, they have identified two
5 guidelines that speak to both of these, the
6 two components of this measure. And so, they
7 give the specific results of the guidelines
8 with the grade of the recommendation, and then
9 information on the levels of evidence.

10 So, I would point to Section
11 1(c)(4).4, and they specifically say that, in
12 terms of the first part, "Health professionals
13 should be vigilant and adopt a proactive
14 approach in consultations with patients who
15 are greatest risk." They gave that a
16 recommendation grade of B. And the levels of
17 evidence to form that recommendation are 2-
18 plus and 3.

19 Well, then, they go on to the next
20 section to describe what those recommendations
21 are. A grade D is a body of evidence
22 including -- you will be able to read it for

1 yourself. But, essentially, they are saying
2 that the guidelines show it is the summary of
3 the evidence on it and it is based on high-
4 quality, systematic reviews of case control or
5 cohort studies.

6 But, then, the second part, which
7 is that we know that there is evidence that
8 treatment of incontinence is strong -- and
9 Chris has pointed to the point that you made
10 -- that also is there in both guidelines. And
11 certainly, the ACOG guideline gives those
12 treatments a grade recommendation of A, which
13 is based on good and consistent results.

14 And so, I would argue that, for
15 the summary data submitted here, that there is
16 enough information here that I think you could
17 probably formulate a pretty good vote on what
18 there is, but I don't think we have really
19 pointed that out yet. We have been talking
20 more about general aspects, but looking at
21 this specific one.

22 MEMBER MERGUERIAN: I just wanted

1 to make a clarification. So, the first
2 concept is for males and females. So, it is
3 all people above age 65, and the second
4 concept is just women, right?

5 CO-CHAIR SAIGAL: Okay. So, now
6 shall we vote?

7 MR. AMIN: I think as we presented
8 all of the information to the group, I think
9 we still want to have the discussion on what
10 is in front of you. I mean, if you feel
11 comfortable that there has been sufficient
12 discussion, it is a question, I think, out.
13 We still haven't had a discussion from the
14 lead discussant. If you feel comfortable that
15 you can vote at this point, it seems like
16 additional discussion would probably still be
17 needed on what is in front of you, on the
18 quality, quantity, consistency.

19 CO-CHAIR SAIGAL: So, Nancy, I'm
20 sorry.

21 Stu, so you were a reviewer for
22 this, right?

1 MEMBER REYNOLDS: I was not
2 technically.

3 CO-CHAIR SAIGAL: You were not?

4 MEMBER REYNOLDS: No.

5 CO-CHAIR SAIGAL: Who else was?
6 Anne, were you one?

7 MEMBER PELLETIER-CAMERON: No.

8 CO-CHAIR SAIGAL: No? Okay. I
9 was I think.

10 So, you want to go through the
11 whole formal process again? We already voted
12 on importance.

13 MR. AMIN: We did importance. Now
14 you have evidence.

15 DR. PACE: So, we did impact.
16 This is all part of importance.

17 MR. AMIN: Right. Sorry. We did
18 impact. Now we are doing evidence. Now we
19 are doing evidence. And so, the goal here
20 would be to have a discussion around -- I
21 introduced what the quantity, quality,
22 consistency of what you should be looking at.

1 There should be a discussion around what is in
2 front of you. I think Stuart did a nice job
3 of beginning the conversation around what is
4 in front of you.

5 If there is general agreement that
6 it meets the quality, quantity, consistency,
7 that would be fine; we could move forward.
8 But, again, in the spirit of having this be
9 the sample of what we want this discussion to
10 be going forward, some additional discussion
11 around whether we think that that has been met
12 and, if not, there are additional options for
13 how you can move forward in terms of general
14 agreement that, even if it is not presented,
15 that you could move forward. But, anyway,
16 that doesn't seem to be the case here. But
17 some discussion seems necessary.

18 MEMBER PELLETIER-CAMERON: I just
19 have a quick comment, just to reiterate what
20 Nancy said. She was discussing just her
21 concerns about the numerator at the very top.
22 I mean, the numerator, there are two

1 questions, whether you discussed incontinence
2 with your provider, and there is no mention of
3 who brought it up, which is fine, coming from
4 a urologist perspective.

5 And the second one, whether you
6 received treatment or not. And I agree with
7 Nancy that you can be offered treatment
8 options, but it is up to the patient to decide
9 whether they want treatment. So, they may
10 have been given their options and opted not to
11 be treated. But, in a general perspective, I
12 don't think that is poor quality, to have not
13 received treatment, but to have discussed it
14 is good care. But you don't have to elect to
15 be treated. So, that is just a general
16 comment about the numerator.

17 MEMBER MORTON: I have a comment.
18 I like one part of the measure, in that it is
19 pretty open-ended in terms of the treatment
20 options. It is not shoe-holed into surgery or
21 Kegels or, frankly, even weight loss is
22 something that could be used as a treatment

1 option. So, I like that aspect of the
2 measure, that it is pretty open-ended in terms
3 of treatment.

4 And it seems pretty
5 straightforward. The question is whether or
6 not patients had some sort of discussion
7 around their incontinence.

8 CO-CHAIR SAIGAL: Yes, I agree
9 with all of the comments that were made, but
10 evidence is good that -- they talk about the
11 ACOG guidelines and the other guidelines in
12 here that are from SIGN, that there are
13 recommendations of high levels to treat
14 incontinence with these various interventions.
15 So, that seems to be a good link, in my head.

16 Yes?

17 MEMBER LIGHTDALE: This is just
18 more of a comment. I guess part of the guinea
19 pig thing here is you have got some people who
20 really know nothing about urinary
21 incontinence, a good thing. So, I am actually
22 learning like literally reading the document.

1 I guess I would just go on having
2 to really pick through now to sort out, okay,
3 SIGN used these levels of evidence. They
4 talked about 1-plus-plus as high-quality meta-
5 analyses systematic reviews of RCTs. I don't
6 know if that is two RCTs or ten RCTs. Then,
7 I was trying to translate into your metrics.

8 So, actually, I would say that it
9 is actually important for the developer to go
10 back and really give me five good randomized
11 controlled trials that I could, then, point
12 to. And I don't want it for me necessarily,
13 but if this is in a toolbox for an
14 organization to use, that they would be able
15 to go to those randomized controlled trials.
16 I think that is important for those of us who
17 are new to the field.

18 DR. PACE: Yes, and I would just
19 say that we really do ask the developers to
20 rely on systematic -- you know, doing a
21 systematic review of the evidence is another
22 whole area of expertise. And so, to ask the

1 developer to do a primary systematic review is
2 probably not going to be the best systematic
3 review. However, if they want to do a
4 performance measure and there has been no
5 systematic review, that may be where they are
6 starting.

7 So, that is why we asked them to
8 cite the evidence that they are providing, and
9 in this case they are using two guidelines
10 that did systematic reviews. But we are
11 asking you to apply the criteria based on what
12 they present in 1(c)(8) through the end of the
13 document in terms of the quantity, quality,
14 and consistency.

15 And the other thing I will just
16 mention about the Evidence Task Force and that
17 rating scale is that it is not just RCTs.
18 There are other types of evidence that can
19 certainly be considered.

20 One other thing, when you are
21 looking at the evidence, is whether the
22 evidence presented is on point with what the

1 measure is measuring. And so, there are a lot
2 of treatments that have good evidence behind
3 them. But this, again, is the nature of the
4 patient experience point of view, is that it
5 is just being asked any treatment. So, there
6 is really no kind of whether they are getting
7 the right treatment. That is not part of this
8 particular measure.

9 MEMBER LIGHTDALE: Sorry, I just
10 feel like I need to clarify. So, there are
11 two guidelines cited here. That is basically
12 the evidence. I don't know either society or
13 how to evaluate whether that is -- and I have
14 been involved in guideline development to the
15 point that I know that some guidelines are
16 well-done and some aren't. Often, it depends
17 on what is the evidence out there.

18 So, is that enough to cite two
19 guidelines? I am actually looking at 1(c)(8).
20 Or do you want now --

21 CO-CHAIR BASKIN: I think where we
22 stand on here is that, yes, they cited two

1 guidelines. In this particular case, these
2 are guidelines that are evidence-based
3 guidelines rather than consensus-based
4 guidelines. I think we have to rely on the
5 folks here or the urology community to tell us
6 whether these are evidence-based guidelines
7 that are the kind of quality that we would
8 expect. I am not, but I suspect they are. I
9 mean, I am not a urologist, but I suspect that
10 these are well-done evidence-based guidelines
11 and have great background.

12 We are just going to have to ask
13 our colleagues to make that decision for us,
14 and we will live with it, because that is all
15 we have presented to us. That is what we have
16 our expertise for. So, a urologist to comment
17 would be helpful.

18 CO-CHAIR SAIGAL: And they break
19 out a number of studies in each of these
20 guidelines. So, that may be helpful. And
21 then, in quality and the consistency, they
22 also kind of enumerate different studies as

1 well that are in there.

2 MEMBER MARKLAND: I would just
3 like to add that the guidelines presented, one
4 is European. So, it may not always apply here
5 in the U.S. The other one is U.S.-based.

6 But there are quality measures and
7 studies, randomized controlled trials, that
8 have been done looking at quality measures in
9 primary care settings. And I think that is
10 where we know the treatment and the guidelines
11 for treatment, but to ask these questions and
12 to see in a primary care setting if asking
13 about urinary incontinence helps improve
14 outcomes, I think that is a very important
15 aspect of this.

16 There has been a randomized
17 controlled trial looking at the improvement in
18 people receiving treatments for urinary
19 incontinence just by asking and discussing.
20 And so, I think there is evidence outside of
21 treatment guidelines to suggest improvements
22 in processes of care.

1 CO-CHAIR BASKIN: Let's take these
2 last comments and --

3 MEMBER REYNOLDS: I am actually
4 going to withdraw my comment because it has
5 been answered already.

6 CO-CHAIR BASKIN: Zahid?

7 MEMBER BUTT: Yes, I'm sorry we
8 are taking more time, but I think we are sort
9 of giving feedback in the general sense also.

10 So, I think I sort of come back to
11 that all comment about guidelines. I think
12 Nancy just mentioned that -- you know, I
13 looked at some of the other ones that I
14 reviewed primarily, and there is sort of the
15 common theme that, when a guideline is quoted,
16 and especially if we are not going to treat
17 that as a study and it just says, "Was a
18 systematic review done by the guidelines
19 developer?", it is yes and no. It seems like
20 perhaps there should be another requirement or
21 at least a recommendation for the developer to
22 actually provide the number of studies that

1 were done as part of that systematic review of
2 the guideline, which is kind of what she was
3 saying.

4 DR. PACE: Right, and that is what
5 -- and, you know, we will also get some more
6 feedback on the flow of the form -- but the
7 idea is and the instruction is that, if that
8 systematic review is done, to give a summary
9 of the quantity, quality, and consistency in
10 that section, the last section of the form.

11 MEMBER BUTT: Okay.

12 DR. PACE: So, you are exactly
13 right, that is what the intention is.

14 CO-CHAIR SAIGAL: Okay. Johannes?

15 MEMBER KOCH: So, I think we could
16 spend a lot of time, all day, arguing between
17 high and moderate. And really, what would be
18 helpful, especially as a GI person, is for
19 somebody to say this does not meet a moderate
20 or high. So, if I vote moderate and it is
21 really high, no relevance. But if somebody
22 could give guidance as to, does this not meet

1 moderate or high, then we can have a relevant
2 discussion. If it is going to meet moderate
3 or high, say it is moderate or high, and then
4 we can after hours discuss over a beer whether
5 it is high or moderate or not.

6 (Laughter.)

7 CO-CHAIR SAIGAL: Great point.
8 Okay. With that, in the spirit of that, can
9 we move to a vote then?

10 Any last questions about what we
11 are going to do in terms of voting?

12 (No response.)

13 We are pretty good about that?

14 MR. WILLIAMSON: We will now vote
15 on the evidence. This is a yes/no.

16 DR. PACE: No, there are the three
17 options, yes -- and we are not going to
18 quibble over the high, moderate, low at this
19 stage. So, 1 is, yes, it meets the criteria
20 for quantity, quality, consistency. And then,
21 there are two options. No. 2 is, no, it
22 clearly does not meet it, including it is not

1 even based empirical evidence. And then, the
2 third one is simply, no, because there is not
3 sufficient information for you to even know.
4 And then, we have different options based on
5 those.

6 CO-CHAIR SAIGAL: Okay. Can we
7 hit the buttons now?

8 MR. WILLIAMSON: One second. You
9 can begin voting now.

10 (Vote taken.)

11 All right. And we have 15 yes; 2,
12 no, evidence does not meet guidance, and zero,
13 no, insufficient information submitted to
14 rate.

15 CO-CHAIR SAIGAL: Two people voted
16 no?

17 MR. WILLIAMSON: No. Sorry. Oh,
18 it is zero. Sorry.

19 MR. AMIN: Okay. The first time
20 around it is going to take a little bit just
21 to get us there.

22 So, the last one is, the last

1 subcriteria under importance to measure is --
2 Evan will get us there -- it is the
3 opportunity for improvement and the
4 performance gap. It is slide 53.

5 So, what we are looking for here
6 is the data demonstrates considerable
7 variation or less-than-optimal performance
8 across providers and/or population groups.
9 The distribution of performance scores, the
10 number and representativeness of the entities
11 included in the measure performance data, data
12 on disparities, the size of the population at
13 risk. And then, we will use a high, moderate,
14 low, or insufficient rating scale.

15 And I will turn it back to the
16 group for discussion and then vote.

17 CO-CHAIR BASKIN: So, comments
18 regarding gaps in performance?

19 CO-CHAIR SAIGAL: Nancy, any
20 comments about that?

21 They have a good section in here
22 about the gaps in performance. Where is it?

1 Section 1(b)(2).

2 MEMBER PELLETIER-CAMERON: Yes,
3 1(b)(2) and 1(b)(3).

4 CO-CHAIR SAIGAL: Page 4.

5 MEMBER PELLETIER-CAMERON: Yes.

6 There is raw data and there is also several
7 citations that are all pretty unanimous in
8 their impression of the gap that exists.

9 CO-CHAIR SAIGAL: Yes. And they
10 have health plan data in here as well. So, I
11 would say it is pretty convincing.

12 Any other comments?

13 MEMBER MORTON: I would say that
14 it looks like there is a lot of data to
15 support that people don't have this question
16 posed to them very often, for a variety of
17 reasons. It is a sensitive subject. So, it
18 seems like that there is a lot of support that
19 this is not discussed commonly.

20 CO-CHAIR SAIGAL: Right. Yes.

21 Okay. Good.

22 Anyone else? You wanted to make a

1 comment? Oh, no?

2 Okay. Any other last comments
3 before we vote?

4 (No response.)

5 Okay.

6 MR. WILLIAMSON: We will now vote
7 on the performance gap. There are four
8 options: 1 is high; 2 is moderate; 3 is low,
9 and 4 is insufficient.

10 You may begin. Once the clock
11 shows -- sorry -- with the mouse, it takes a
12 while to show up. You may begin voting now.

13 (Vote taken.)

14 And we have 13 high, 2 moderate,
15 zero low, and zero insufficient.

16 CO-CHAIR SAIGAL: Okay. That's
17 it. That is the process to move to the next
18 one.

19 MR. AMIN: Well, we will do an
20 overall vote on the whole concept, and then
21 that will be the tenor of the conversation
22 going forward.

1 CO-CHAIR SAIGAL: Okay. Do we
2 have to hear discussion about this part, too?
3 Or do we just move to --

4 MR. AMIN: Basically, what you are
5 doing here is that you are going to just
6 recommend approval of this concept, which will
7 then go to the CSAC.

8 CO-CHAIR SAIGAL: Okay.

9 MR. AMIN: There is some question.

10 MEMBER FALLER: Isn't it at this
11 point that we make the recommendation that
12 they should add the data that she was talking
13 about that includes the fact that discussing
14 incontinence with your provider improves --

15 MR. AMIN: So, this would be a
16 good time to be the checklist, what you would
17 want to see before you would let this measure
18 come forward in stage two. So, if there is
19 additional -- if the measure of submission is
20 missing components that you would want to see
21 before to complete the importance criteria,
22 this would be the time to do that, or if you

1 have any other considerations before stage
2 two. So, as explicit as you can, just so that
3 that information goes back to the developers.

4 MEMBER MARKLAND: There is a
5 reference in this that does reference that
6 work. It is not explicitly stated as
7 evidence, but they do reference the work, the
8 earlier work, from this group that looked at
9 quality indicators and vulnerable elderly.

10 CO-CHAIR SAIGAL: So, you are
11 satisfied with that? Okay. Great.

12 Do you want to do any summary
13 before you vote or shall I do a summary?

14 MR. AMIN: If you --

15 MEMBER GILL: Excuse me. I would
16 also be concerned about that one word where it
17 says, "received treatment" versus "offered
18 treatment". I think that would make it a
19 better measure, given what everybody has said
20 about offering versus -- because the patient
21 can refuse the treatment or not decide on it.

22 DR. PACE: You might want to ask

1 the developers to comment on that because this
2 is part of the Health Outcomes Survey. So, I
3 don't know how much flexibility. Is that
4 okay, to ask them to --

5 CO-CHAIR BASKIN: Any comment at
6 all regarding the wording of the question?

7 DR. GIOVANNETTI: Yes. That is a
8 concern that we have heard before, and we are
9 working, actually, on modifications to this
10 measure. However, the timing of that work
11 didn't sync up with this Committee.

12 So, the measure that you are
13 presented with is the measure as it is
14 currently in the Health Outcomes Survey. We
15 hope in about a year, after we finalize all of
16 our testing on the new measure, we will have
17 an improved measure that will get around some
18 of this issue around the received treatment
19 versus did you discuss different treatment
20 options.

21 However, as we have this measure
22 as it is now, it is in the Health Outcomes

1 Survey. We can't just go in and change it,
2 based off of the recommendations of this
3 Committee. You know, we can't change it
4 tomorrow.

5 So, I believe the option in front
6 of you is to look at this measure as it is
7 now. If you still think the concept is worthy
8 of endorsement, we will move forward to stage
9 two. If this is a straw that breaks the
10 camel's back on this measure, then that is
11 your own kind of prerogative. I can only tell
12 you that we are working on improving this
13 measure.

14 MR. AMIN: So, in terms of a
15 summary, Chris, I think it would be helpful
16 not necessarily for you at this point, because
17 it seems like the general consensus for the
18 group was that it meets all three subcriteria
19 fairly well.

20 CO-CHAIR SAIGAL: Okay.

21 MR. AMIN: And I think that has
22 been fairly well-stated.

1 CO-CHAIR SAIGAL: Time to vote.

2 MR. WILLIAMSON: We will now vote
3 on the overall recommendation. This has two
4 options, yes and no.

5 And you may begin voting now.

6 (Vote taken.)

7 And we have unanimous approval, 15
8 yes and zero no.

9 MR. AMIN: Okay. Evan, if we
10 could switch back to slide 35?

11 MR. WILLIAMSON: Thirty-five?

12 MR. AMIN: Yes. Okay.

13 So, I assume that there will
14 likely not -- and you guys in the group can
15 tell me if we need to not -- we will go
16 through it very quickly now in terms of what
17 you are looking at. But, again, we will start
18 with the importance-to-measure criteria.

19 Now this will be, again, the
20 nature of how this conversation will go. So,
21 you got a general sense of what -- we will be
22 looking at high impact, then the evidence that

1 supports the measure focus, and then the gap.

2 So, the first one is looking at
3 high impact to assess whether the measure
4 focus is evidence-based.

5 CO-CHAIR SAIGAL: For Measure
6 0098, and Dr. Baskin here is going to be the
7 lead discussant for that

8 MR. AMIN: Yes. So, we are
9 looking at high impact.

10 CO-CHAIR BASKIN: All right. So,
11 Measure 0098, very similar in that we are
12 measuring something very much like the last
13 measure, except that this is an administrative
14 measure of providers and really has to do with
15 documentation in the record and actually
16 submission of claims information that the
17 documentation is in the record, which makes it
18 a little bit different.

19 But in terms of the importance, it
20 is the same issue of stress incontinence and
21 the information given in terms of the impact
22 is literally identical to the last measure.

1 So, I am going to just spit it out, that it
2 seems like this is a high impact based on the
3 same, exact item that we just reviewed.

4 And looking for any comments
5 around the room regarding the impact.

6 (No response.)

7 Okay. So, I think that is pretty
8 clear. I think that we could really progress
9 and just move on to voting regarding impact,
10 since it is so straightforward. So, why don't
11 we get the voting machinery up and running?

12 MR. WILLIAMSON: We will now vote
13 on high impact. There are four options:
14 high, moderate, low, or insufficient.

15 You will begin voting now.

16 (Vote taken.)

17 One person is out.

18 CO-CHAIR BASKIN: One person
19 hasn't. So, press again, if you haven't.

20 There we go. Okay.

21 MR. WILLIAMSON: There we go.

22 CO-CHAIR BASKIN: And let's see,

1 and away you go. I don't even get an envelope
2 to open, but there it is. That is the
3 equivalent of an envelope in today's world.

4 (Laughter.)

5 MR. WILLIAMSON: We have 15 high,
6 zero moderate, zero low, and zero
7 insufficient.

8 CO-CHAIR BASKIN: Okay. And the
9 next one is the --

10 MR. AMIN: So, the next one is
11 that we are going to be looking at evidence.

12 Evan, if you could go to slide 46?

13 And so, basically, you are going
14 to look at the quantity, quality, and
15 consistency of the evidence that is presented
16 in front of you. Ideally, if you can go
17 through each of those --

18 CO-CHAIR BASKIN: Which one was
19 first? Help me out there.

20 MR. AMIN: Oh, the quantity.

21 CO-CHAIR BASKIN: Quantity? Okay.
22 So, just to lead this discussion, once again,

1 this so parallels the prior one. I mean, the
2 evidence is the same evidence, okay, in terms
3 of the quantity of evidence. And once again,
4 it is those two large meta-analyses that we
5 accepted last time around.

6 So, is there any concern about
7 those, the body of evidence in terms of
8 quantity for this particular measure that we
9 would want to speak about? Anybody want to
10 bring that up?

11 Go ahead.

12 MEMBER BORDEIANOU: We are looking
13 at the evidence that urinary incontinence
14 needs to be treated. And there is a lot of
15 evidence on that. But does documenting your
16 medical record, when you have a 15-minute
17 visit as a PCP and you have discussed
18 hypertension, and so on and so forth, really
19 impact how well a patient is treated for
20 incontinence? And should we be measuring the
21 PCPs on that?

22 CO-CHAIR BASKIN: Yes, so the

1 concern here is kind of similar to the last
2 one in that there is evidence that the
3 treatments work. There is a large body of
4 evidence to that. There is evidence that
5 there is under discussion of this particular
6 problem. But the question is whether
7 improving on this measure actually improves
8 outcomes. That is the leap of faith that we
9 are making here, and the leap of faith we made
10 on the last one, too.

11 I don't know. That was my comment
12 in the pre-discussion, was, you know, where is
13 the evidence linking the measure itself to a
14 better outcome? And I don't know that that
15 exists. But if someone has a comment on that,
16 then go ahead.

17 Chris?

18 CO-CHAIR SAIGAL: I could ask our
19 colleague -- I don't have your name of me.
20 I'm sorry, what was your name again?

21 MEMBER MARKLAND: Alayne.

22 CO-CHAIR SAIGAL: Alayne, you had

1 some data about a rural implementation of
2 this?

3 MEMBER MARKLAND: Well, it is
4 broader quality care for older adult data
5 where urinary incontinence is one of the
6 measures of improving care for all older
7 vulnerable adults.

8 And in that, though, they do use
9 some administrative data, which this is very
10 different from the last measure, that it is
11 all based on administrative data, which we
12 know tends to underestimate rates of
13 discussion. Especially, I am questioning some
14 of these CPT codes to actually measure the
15 assessment of versus an ICD-9 code, which
16 would be the only character here.

17 I think it is still important to
18 assess how often these are being coded in a
19 primary care setting to determine, does it,
20 therefore, link to treatment. So, I think
21 there are two, the patient and the provider
22 level. This gets more at that provider level,

1 in my opinion, which is a part of the other
2 study I mentioned.

3 CO-CHAIR SAIGAL: In the other
4 study you mentioned, the assessment in the
5 primary care setting was linked to treatment,
6 is that right?

7 MEMBER MARKLAND: Uh-hum.

8 CO-CHAIR SAIGAL: So, there is
9 some data about that, then?

10 MEMBER MARKLAND: Uh-hum.

11 CO-CHAIR BASKIN: Other comments?

12 (No response.)

13 Then, we should move on to a vote
14 regarding the -- wait. Do we do the quantity
15 of evidence?

16 MR. AMIN: You do the overall -- I
17 mean, so you are going to discuss quantity,
18 quality, and consistency.

19 CO-CHAIR BASKIN: Oh, all at one
20 time?

21 MR. AMIN: And then, you vote all
22 at one time on the body of the evidence,

1 whether it meets all three of those.

2 CO-CHAIR BASKIN: And then, any
3 other comments? Because, I mean, that is the
4 one glaring issue here, is the relationship of
5 the measure itself to improving outcomes. I
6 think we were pretty clear last time that the
7 evidence shows that there is an issue, and it
8 is not discussed, and that the treatments are
9 valuable. So, that is the one leap of faith
10 I think we are making based on some evidence
11 that wasn't submitted.

12 And any reason why we shouldn't go
13 to a vote?

14 (No response.)

15 I guess not. Let's go to a vote
16 then.

17 MR. WILLIAMSON: We will now vote
18 on the evidence. There are three options:
19 yes; no, the evidence does not meet the
20 guidance for quality, quantity, consistency,
21 or, no, insufficient information was
22 submitted.

1 You may begin voting now.

2 (Vote taken.)

3 And we have 13 yes; zero, no, that
4 the evidence does not meet the guidance, and
5 2, that insufficient information was submitted
6 to rate.

7 CO-CHAIR BASKIN: Just so that we
8 are all clear, anybody want to make a comment
9 other than what was already suggested as to
10 why the evidence may be insufficient? Is
11 there some other reason it was thought to be
12 insufficient, just so we can document that?
13 Or was it simply the link between the measure
14 and the outcomes, which is, I think, something
15 we have already discussed wasn't there?

16 (No response.)

17 Okay. No one has to make comment.
18 I just wanted to make sure there was nothing
19 that was missed in the conversation that we
20 should have documented.

21 MR. AMIN: And now we go to
22 performance gap.

1 CO-CHAIR BASKIN: So, performance
2 gap, they did give us information here in
3 1(b)-(c), and this is from the PQRS, of which
4 this measure is a part of PQRS.

5 The issue here, I think, is rather
6 obvious, in that the percentage of providers,
7 eligible providers, who actually report is so
8 low that the performance gap is based on a
9 very, very small sampling of providers. And
10 the performance gap seems to vary from year to
11 year rather significantly, but probably
12 because of the low volume of providers, there
13 is probably a lot of randomness here.

14 I think, though, that some of the
15 evidence review and some of that evidence does
16 actually speak to a performance gap other than
17 this PQRS information. So, my personal
18 feeling is there is a significant performance
19 gap here based on that evidence, the body of
20 evidence that was submitted, as opposed to
21 just the PQRS data. I think the PQRS is just
22 rather insufficient to make any conclusion on,

1 but that is my personal opinion/review. But
2 I am opening the floor to any other comments
3 regarding the performance gap.

4 MEMBER BUTT: So, the PQRS data,
5 could you interpret by just saying that there
6 is not enough overall compliance?

7 CO-CHAIR BASKIN: Well, the way I
8 see it is the compliance rates, you can see
9 they vary anywhere from the high 50s to 90-
10 some percent, and from year-to-year it changes
11 considerably. But, if you see, it is based on
12 such a small number of physicians --

13 MEMBER BUTT: I mean, is that the
14 interpretation, that there is overall less
15 compliance or overall less reporting?

16 CO-CHAIR BASKIN: Well, I think it
17 is both. So, if you felt that this was a
18 reasonable sample of physicians, then you
19 would say the compliance rates vary in the
20 high 50s to 80s. I think that is a
21 reasonable-enough performance gap, and I
22 suspect it is much higher than that because

1 this is a selected population who voluntarily
2 submitted this information. They didn't have
3 to report on this particular measure. I am
4 pretty certain that folks who don't do so well
5 probably didn't voluntarily report.

6 So, I personally don't think the
7 PQRS data is very helpful for me in terms of
8 the evidence of a performance gap. To me, it
9 is all in the literature that backed up the
10 evidence reviews, is really where the
11 performance gap is demonstrated.

12 MR. WILLIAMSON: We will now vote
13 on the performance gap. There are four
14 options: high, moderate, low, or
15 insufficient.

16 And you may begin voting when the
17 mouse shows up. There it is.

18 (Vote taken.)

19 CO-CHAIR BASKIN: I feel like we
20 are on Jeopardy here, and everyone is trying
21 to be the first to click.

22 (Laughter.)

1 MR. WILLIAMSON: And we have 7
2 high, 8 moderate, zero low, and zero
3 insufficient.

4 CO-CHAIR BASKIN: Okay. So, to
5 summarize that, I think it was pretty clear,
6 the importance of the issue. That has been
7 well-demonstrated. And I think we have
8 clearly showed that there is some evidence,
9 strong evidence, that there is adequate
10 treatment and that there is certainly adequate
11 evidence submitted.

12 The question only became the
13 evidence regarding the actual measurement
14 process itself and how that actually relates
15 to the outcomes, as to whether actually the
16 measure will improve outcomes in and of
17 itself. I think that gap exists, and it is
18 may exist in the literature. There seems to
19 be only a little bit of information out there.

20 The issue with the -- what is the
21 last thing we just voted on?

22 CO-CHAIR SAIGAL: The performance

1 gap.

2 CO-CHAIR BASKIN: Oh, the
3 performance gap, understandably, many of us
4 thought moderate versus high was probably
5 based on the idea that PQRS data is rather
6 insufficient, and I think that was pretty
7 clear to us. But, overall, I think that
8 moderate, high, everyone considered that, that
9 there is enough of a performance gap here to
10 support this particular measure.

11 So, I think we can go ahead and
12 take a vote on this measure.

13 MR. WILLIAMSON: We will now vote
14 on the overall recommendation. There are two
15 options, yes and no.

16 And you may begin voting now.

17 (Vote taken.)

18 And we have 14 yes and 1 no.

19 MEMBER BUTT: Could I make a
20 suggestion at this point for the developers,
21 like we did before for the previous one?

22 CO-CHAIR BASKIN: Yes. Yes,

1 please do. In fact, I was going to ask that.

2 MEMBER BUTT: Oh, I'm sorry.

3 CO-CHAIR BASKIN: But, even before
4 that, I was going to ask if anybody wanted to
5 -- and this is purely voluntary, once again --
6 but if anybody wanted to give the dissenting
7 opinion, we would be welcome to do that for
8 the documentation, but there is no obligation
9 to do that.

10 MEMBER BUTT: I was just going to
11 say that we would like to encourage them to
12 look at an e-measure specification for this
13 measure because it looks for the plan of care
14 in the numerator, which is currently defined
15 through CPT II, which is sort of an
16 administrative, by definition, claims type of
17 plan-of-care definition.

18 So, I don't know if they have
19 plans to try to specify that more, so that EHR
20 data could be used to get at the numerator.

21 CO-CHAIR BASKIN: Well, I do
22 think, in general, almost all measures at some

1 time will go through the e-measures process
2 over time. I think all new measures, don't
3 they have to go as well?

4 DR. PACE: Well, I will let Heidi
5 speak.

6 MS. BOSSLEY: We have not yet
7 instituted a requirement that -- most
8 measures, not all measures, can, of course, be
9 translated into EHR data. But we don't have
10 that requirement yet, in part, because the
11 tools that the developers would need to get it
12 into the standardized format and a few other
13 things is probably not quite ready for them.

14 So, the hope is that over time we
15 would see measures move forward, and exactly
16 this type of measure you see in front of you
17 would be perfect for translating into an
18 e-measure. And so, that would be the hope.
19 But there is no requirement yet.

20 CO-CHAIR BASKIN: I have one
21 comment for the developers. It is similar to,
22 basically, the other one, but I don't think

1 the hurdle is quite as high on this one as it
2 is on the survey and changing it, in that
3 there really should be an option for member
4 choice of no treatment, if there isn't
5 already. I don't believe there is.

6 I don't think that would be -- it
7 is unclear to me on the plan of care that the
8 plan of care includes the conclusion
9 "discussed with member; member chose no
10 treatment as the plan of care," but that
11 should be an option available. So, just a
12 suggestion to take back to consider, please.

13 Any other comments on this before
14 we close out on this measure?

15 (No response.)

16 Okay. Well, we went a little over
17 to get this done from our break, but we will
18 still get a break. So, how long of a break
19 will we take? Still take 15 minutes or not?
20 All right, we will take a 10-minute break.

21 About 11:15, we will resume.

22 Thank you.

1 (Whereupon, the foregoing matter
2 went off the record at 11:04 a.m. and went
3 back on the record at 11:17 a.m.)

4 CO-CHAIR BASKIN: Folks, we are
5 convening again.

6 Just one brief comment. We did it
7 a little bit on this first time around for
8 these first two measures, but I understand
9 that everyone has concerns, when they read
10 these measures, about the construct of the
11 measure, the ability to measure; is it really
12 measuring what we think it is going to measure
13 and really have the same outcome?

14 So, we need to understand that in
15 this process the validity/reliability of the
16 measure, the ability to measure what it is
17 supposed to measure really comes up in stage
18 two. But it is not unreasonable at some point
19 to make a suggestion or a comment after the
20 voting is completed.

21 So, in other words, we complete
22 the voting on the part we are talking about,

1 the importance. But, then, after that, I
2 mean, if anybody has a comment that they would
3 like to send back with the developer or into
4 the record of concerns that, gee whiz, if you
5 don't really think about this between now and
6 stage two, you may have trouble with validity
7 and reliability, I think some comments are
8 reasonable.

9 What I don't want are those
10 comments to be part of our discussion and vote
11 because we don't want to get into those weeds
12 in this stage one of the process. So, for
13 instance, when we made a comment about, you
14 know, a change in the Healthy Outcomes Survey,
15 or a potential change in that, as a
16 suggestion, that is a reasonable thing to do
17 after we are done with the voting. Let's
18 limit that, though, not a lot of time spent on
19 it. But, as we get into some of the newer
20 measures, those suggestions are insights may
21 be helpful to the developers. So, when they
22 come back, they will actually have a valid and

1 reliable measure.

2 CO-CHAIR SAIGAL: Great. So,
3 maybe we can start off with the next measure
4 set from the AUA. Can the AUA presenter
5 please give us two or three minutes of
6 background?

7 MS. WILBON: Excuse me. I'm
8 sorry, if you could just give an overview of
9 all of your measures, instead of a one-by-one
10 approach, that would be helpful for all.

11 MR. CLEMENS: I am happy to do all
12 five. That was my plan.

13 MS. WILBON: All five, actually,
14 yes. Go ahead.

15 MR. CLEMENS: So, I am Quentin
16 Clemens. I am a urologist at the University
17 of Michigan. I am here on behalf of the AUA
18 to discuss the five measures that we have
19 brought to your attention today.

20 This measure set was developed
21 under the auspices of the AMA Physician
22 Consortium for Performance Improvement Work

1 Group which was jointly chaired by the AUA as
2 well as the American College of Obstetrics and
3 Gynecology. It included members from family
4 medicine, geriatrics, and nursing.

5 This is a measure set that we have
6 planned to submit to the PCPI shortly for
7 their comment and potential revision. With
8 this process here at the NQF coming up, we put
9 that on hold to bring it here first.

10 The focus is on the surgical
11 treatment of stress incontinence. We know
12 that there are between 100 and 200 thousand of
13 these surgeries done every year in the U.S.
14 So, it is an important thing and a major
15 component of the practice of urologists and
16 urogynecologists.

17 We have five measures. The first
18 has to do with a complete evaluation of
19 patients. The denominator for all of these is
20 women who had stress incontinence surgery.

21 And the important thing with
22 measure 1 is certain components, such as a

1 physical exam, assessing a post-void residual.
2 We know that these surgeries often make it
3 harder for the bladder to empty afterwards,
4 and it is important to assess that, as well as
5 objectively showing that the patient has
6 stress incontinence.

7 Anecdotally, at least many of us
8 see patients who have failed surgery and it is
9 pretty clear they didn't have stress
10 incontinence all along. So, to be able to
11 really show that we felt was important. These
12 are all based on evidence-based guidelines
13 from the AUA, I should mention.

14 Then, we have two counseling
15 measures. One is making sure that the
16 patients who have had surgery were counseled
17 about other options, such as behavior therapy
18 and medical therapies.

19 The other counseling measure has
20 to do with patients who have had mesh placed
21 for stress incontinence, to make sure that
22 they were counseled about that. And in

1 particular, there are three components to the
2 counseling: letting them know that erosion
3 can occur, that pain can occur, and the mesh
4 is permanent.

5 Measure 4, then, has to do with
6 performing cystoscopy at the time that the
7 surgery is done. We know that these mesh
8 slings, or any type of sling, actually, can be
9 placed into the bladder. If that is
10 recognized interoperably, it can just be
11 repositioned without any problem to the
12 patient. But if the cystoscopy is not
13 performed and there is some foreign material
14 in the bladder, then that can cause major
15 morbidity for the patient postoperatively.
16 So, using cystoscopy during the surgery is the
17 fourth measure.

18 And finally, we have a followup
19 measure, measure 5, indicating that patients
20 who were characterized postoperatively with
21 many of the things we recommended
22 preoperatively, such as a pelvic exam, post-

1 void residual analysis, and, of course,
2 assessment of their symptoms.

3 This was indicated to be within 12
4 months followup. It is a reflected, a
5 significant discussion among the Work Group
6 about differences in practice patterns, where
7 some may at the short-term simply do a
8 telephone call and then ask the patients to
9 come back at a longer followup. And others in
10 the group, based on practice patterns, would
11 have patients come in earlier in person and
12 then have them call later if there were a
13 problem. So, that was the reason for the 12-
14 month time period for measure 5.

15 And with that, I will turn it back
16 to you.

17 CO-CHAIR SAIGAL: Thanks, Quentin.

18 Okay. Paul, could you lead us
19 through Measure 2049, starting with importance
20 to measure and report, high impact?

21 MEMBER MERGUERIAN: Measure 2049,
22 basically, deals with the preoperative

1 assessment of patients with urinary
2 incontinence. Basically, their denominator
3 includes history and physical, testing
4 performed, and, also, evaluation performed.

5 The AUA has come up with some
6 guidelines which I have reviewed. And you can
7 actually look at the AUA site. There are
8 basically four chapters there. One of the
9 chapters deals with evaluations of patients
10 with urinary incontinence, with references.

11 CO-CHAIR SAIGAL: So, in terms of
12 the impact of the measure that we are talking
13 about, which is complete workup of stress
14 incontinence, this is a big problem, you would
15 say, that people aren't doing this, based on
16 the evidence that they have presented?

17 MEMBER MERGUERIAN: So, the
18 evidence that they presented was that it is a
19 significant problem. Millions of women are
20 affected. The impact of SIU treatment in the
21 United States exceeds \$13 billion per year,
22 and around 30 percent of women describe their

1 measures are being bothersome.

2 CO-CHAIR SAIGAL: Okay. Any other
3 comments?

4 MEMBER MERGUERIAN: It is high
5 impact.

6 CO-CHAIR SAIGAL: Incontinence is
7 a high-impact problem?

8 MEMBER MERGUERIAN: The
9 incontinence is the high-impact problem. The
10 fact that the management, I mean, there is
11 really not a lot talking about individuals
12 paying themselves for care costs related to
13 urinary incontinence, and that is a huge
14 impact on the cost to the individual, but also
15 on the cost to the healthcare system.

16 CO-CHAIR SAIGAL: And there is
17 data in there about the lack of performance of
18 the complete physical exam and the --

19 MEMBER MERGUERIAN: There is data
20 in there that suggests -- I mean, again, the
21 numbers are pretty small -- but there does
22 suggest that there is quite a gap, where

1 around 66 percent of those surveyed -- and
2 this is not just from the urological
3 literature, but also from gynecological
4 literature. I mean, the gap is around 66 --
5 there is compliance with around 60 to 80
6 percent.

7 MR. AMIN: Chris, could I just
8 make one quick suggestion?

9 CO-CHAIR SAIGAL: Yes.

10 MR. AMIN: Again, ideally, we
11 would just do high impact, and then the
12 evidence, and then the performance gap. It
13 just keeps the conversation a little cleaner.

14 CO-CHAIR SAIGAL: Okay.

15 MR. AMIN: So, if everybody is
16 okay with high impact, just feel free to move
17 on, if that is where everybody feels, but try
18 to keep the conversation that way, so that it
19 keeps it a little more structured.

20 CO-CHAIR SAIGAL: Okay. So, then,
21 any other comments about the impact concern?

22 (No response.)

1 Okay. So, shall we vote?

2 MR. WILLIAMSON: We will now vote
3 on high impact. There are four options:
4 high, moderate, low, or insufficient.

5 And you can begin now.

6 (Vote taken.)

7 And we have 13 high, 2 moderate,
8 zero low, and zero insufficient.

9 CO-CHAIR SAIGAL: Okay. And now,
10 we will talk about the quality of evidence.

11 MEMBER MERGUERIAN: I guess the
12 AUA guidelines, basically, they did the meta-
13 analysis. They reviewed over 7,000 articles
14 and came up with 150 articles that they based
15 their guidelines on. So, there is quite a bit
16 of evidence relating to the evaluation of
17 these patients initially.

18 I think the eventual impact, it
19 could be also a reduction in healthcare cost
20 where, overall, in the long-term you may
21 reduce costs of surgical treatment if the
22 incontinence is actually characterized prior

1 to surgery.

2 CO-CHAIR SAIGAL: Any other
3 questions or concerns about the evidence?

4 (No response.)

5 MR. AMIN: So, again, I just would
6 like to have the Committee keep in mind that
7 you should rate the information that is
8 presented in front of you in terms of the
9 quality, quantity, and consistency, which is
10 provided in 1(c)(8), 1(c)(9), 1(c)(10), and
11 1(c)(11). And maybe I will leave it there.

12 MEMBER MORTON: It seems like this
13 is kind of an appropriateness question more
14 than anything else and making sure you are
15 operating on the right patient, the right
16 indications.

17 From what I could see in the data,
18 it was just surveys, like how often people
19 were doing it. I don't know if there is more
20 enlightenment around appropriateness, if there
21 have been any studies around that.

22 CO-CHAIR SAIGAL: Well, we have

1 two incontinence specialists I am aware of at
2 least in the room from urology. I don't know.
3 Do you guys have any comments about other data
4 about this topic?

5 MEMBER PELLETIER-CAMERON: I am
6 aware there is more data that is not even
7 referenced here about surgical -- it is a
8 randomized controlled trial that was published
9 on the results of two different incontinence
10 surgeries in women. The group that had the
11 worst outcomes in terms of care were the
12 people who they never actually demonstrated
13 their incontinence. So, if you couldn't prove
14 they had incontinence, those people did badly.
15 No kidding, yes.

16 MEMBER MERGUERIAN: And the other
17 thing, if you look at the guidelines and
18 actually go to their website, they actually
19 have a table with all the different treatments
20 that are provided and, then, also, the success
21 rate of these with CIs.

22 CO-CHAIR SAIGAL: So, it sounds

1 like specifically about the idea of whether
2 doing these interventions improves the
3 outcome, there is some evidence that may not
4 be cited in this document, the summary? Okay.

5 Any other comments before we vote
6 then?

7 MEMBER BUTT: So, are we voting
8 for the evidence presented and then --

9 CO-CHAIR SAIGAL: Yes, there are
10 three options. Either you vote that the
11 evidence meets the guidance there or it does
12 not, or it is insufficient -- there is data,
13 but it is not submitted, basically.

14 MEMBER MERGUERIAN: That is for
15 the first concept, which is a complete workup.

16 CO-CHAIR SAIGAL: Right, for 2049.

17 DR. PACE: Right. So, this
18 particular measure is doing the workup. I
19 know the comment was made about 7,000 studies.
20 I doubt that the 7,000 studies were about
21 doing the workup. That is what we have asked
22 for each guideline. You know, this is based

1 on a guideline recommendation. I think it is
2 primarily -- you know, whether that is
3 evidence-based or expert opinion, but we ask
4 for a summary of the quantity, quality, and
5 consistency of the body of evidence for that
6 particular guideline, not in general for a
7 whole clinical practice guideline document
8 that may have multiple recommendations. So,
9 the evidence for this particular
10 recommendation.

11 CO-CHAIR SAIGAL: Go ahead, Stu.

12 MEMBER REYNOLDS: Well, to echo,
13 though, specifically, if you look at the
14 evidence that is submitted, there, admittedly,
15 is probably not that great evidence that
16 shows, specifically looking at this, whether
17 you had an assessment that changes the
18 outcome. There is certainly strong
19 consistency across these guidelines and, then,
20 other ones about the appropriateness of what
21 needs to be done before you do surgery.

22 Certainly, anecdotally, from a

1 personal experience, I see a lot of patients
2 who come in who have complications. And you
3 ask them, and they have never had a physical
4 exam before they had surgery, which is a bit
5 egregious, but there is no data to support
6 that, and that is just anecdotal.

7 I guess I would support the
8 consistency of it. But, specifically, the AUA
9 guideline is the standard, which is based
10 primarily on consensus as opposed to strong
11 data. I don't know that -- they don't clearly
12 demonstrate how many, in terms of quantity of
13 the studies that are here, but I think the
14 consistency certainly is highly strong across
15 all the guidelines and the references that
16 they give.

17 CO-CHAIR SAIGAL: So, to summarize
18 what you said, basically, in terms of
19 consistency, what data are out there suggest
20 that it is an important thing to do, but there
21 are not many studies that are out there. The
22 guidelines are based on consensus to a large

1 degree. And there is at least one study that
2 we are aware of that is not submitted here
3 that does point in the same direction. Is
4 that fair?

5 MEMBER PELLETIER-CAMERON: There
6 is never going to be a randomized controlled
7 trial about whether working up your patient
8 before you do surgery or not impacts their
9 outcome because of the ethics involved of
10 doing surgery on people without doing a proper
11 workup. So, I don't think the data would ever
12 become available that answers that question.

13 MEMBER MERGUERIAN: Yes, and they
14 state that in their link, that it is basically
15 based on consensus statements. Those
16 recommendations for evaluation are based on
17 consensus.

18 CO-CHAIR SAIGAL: Yes.

19 MR. AMIN: So, Chris, can I
20 provide some process guidance here?

21 CO-CHAIR SAIGAL: Sure.

22 MR. AMIN: So, what you would want

1 to do in this case, I mean, really, my
2 understanding of the summary statement of the
3 Committee is that the information presented
4 here would not meet the NQF criteria for
5 quality, quantity, and consistency. But once
6 you vote to, if you vote to, I should say, you
7 will have the option of saying that there is
8 information out there that would meet this
9 criteria, if I am hearing the Committee
10 correctly.

11 CO-CHAIR SAIGAL: Is the one that
12 you would use for that purpose?

13 So, to be clear, if you say three,
14 that there is in the document not enough
15 evidence, but there is evidence that exists
16 that could be put into the document, if you
17 said three? Or you could say one, and,
18 basically, you feel that consensus statements
19 are enough. That would be an exception,
20 though, right?

21 DR. PACE: Right. Consensus
22 statements are not what we need to consider

1 meeting our evidence criterion. So, that
2 would be No. 2. It doesn't meet our criteria,
3 but you could consider it as an exception to
4 the evidence criterion.

5 CO-CHAIR SAIGAL: For example, if
6 we got a vote where everyone said two, we
7 could then see if there was room for an
8 exception because of the special nature of
9 these kinds of measures. Okay.

10 So, with that, are we ready to
11 vote? Okay.

12 Question?

13 MEMBER SCHOENFELD: So, I may have
14 missed this, but I was going to ask, could the
15 lead discussant -- or is this not the way you
16 want to do the process? -- actually give their
17 recommendation about how they would vote on
18 this particular issue?

19 CO-CHAIR SAIGAL: I think that is
20 a great idea.

21 MEMBER MERGUERIAN: I think I
22 would vote for two, that it is basically a

1 consensus and there is no evidence that it
2 does not meet the guidelines or the guidance
3 for quantity, quality, and consistency.

4 CO-CHAIR SAIGAL: Okay. And as I
5 said, I would probably vote three because
6 there is some data out there that we could
7 introduce, it sounded like to me. So, that is
8 what I would say.

9 Stu?

10 MEMBER REYNOLDS: True, but, then,
11 I guess my question is this option that we
12 have to throw out the exception and then push
13 it forward even with insufficient data, but,
14 clearly, the benefit outweighs the harms and
15 all that kind of stuff. Where does that come
16 out? And can we have a preliminary thought
17 that, if we all voted three, that it was
18 insufficient, but we thought it was important
19 enough we would also have a vote on that? Or,
20 from a procedural standpoint, I guess, where
21 do we look at that?

22 DR. PACE: Yes, yes.

1 CO-CHAIR SAIGAL: Go ahead.

2 DR. PACE: Yes, if you vote it
3 down on either two or three, you can bring up
4 -- you know, if someone wants to say, yes, but
5 evidence does exist, we have a way for you to
6 vote on that to discuss it and vote it, or if
7 you say, even though it is consensus opinion
8 and not evidence, we think it is important,
9 then there is a way for you to vote on that to
10 move it forward.

11 So, the whole point of this vote
12 is one of the key principles of the Evidence
13 Task Force was to be very transparent about
14 the evidence that does or does not exist. And
15 then, you, as the Steering Committee and the
16 experts, can either say, you know, it calls
17 for an exception to having empirical evidence
18 or there is additional evidence that exists
19 that wasn't represented.

20 But we just want it to be very
21 clear to all the constituents who will then be
22 also reviewing your work and your

1 recommendations to understand on what basis
2 you moved it forward.

3 CO-CHAIR SAIGAL: Thanks.

4 Okay. So, with that, let's vote.

5 MR. WILLIAMSON: We will now vote
6 on the evidence. You have three options. The
7 first is yes; the second is, no, that the
8 evidence does not meet the guidance for
9 quality, quantity, consistency, and three is,
10 no, that insufficient information was
11 submitted to rate.

12 You may begin voting now.

13 (Vote taken.)

14 And we have zero yes; 4 for, no,
15 that the evidence does not meet the guidance,
16 and 3, no -- sorry -- 11 for, no, insufficient
17 information was submitted to rate.

18 CO-CHAIR SAIGAL: So, process-
19 wise, then, what do we do now?

20 MR. AMIN: Okay. So, because now
21 you are at three, you will describe again,
22 just for the record, so that we are

1 understanding, the evidence that does exist.
2 And then, you will vote on whether there is
3 general agreement within the group that the
4 quantity, quality, and consistency of the
5 evidence, based on the evidence that is
6 discussed that does exist out there, that it
7 would meet the quality, quantity, and
8 consistency of the NQF criteria.

9 CO-CHAIR SAIGAL: Okay. So, we
10 heard from Anne that there was at least one
11 study that showed that women who had an
12 incomplete workup as defined by the measure
13 had worse outcomes?

14 MEMBER PELLETIER-CAMERON: So, not
15 even an incomplete workup. This is a subset
16 analysis of patients where they couldn't
17 actually demonstrate their incontinence, fared
18 poorly after surgery.

19 So, it is one more piece of work,
20 but it is not a randomized controlled trial
21 concerning this.

22 CO-CHAIR SAIGAL: Okay.

1 MEMBER PELLETIER-CAMERON: I think
2 I more mentioned it just for completeness'
3 sake.

4 CO-CHAIR SAIGAL: Okay. So, then,
5 it sounds to me like maybe we will have to
6 consider this as an exception then. I mean,
7 the issue in front of us is whether there will
8 ever be data developed to look at whether
9 these interventions before surgery are going
10 to be impactful in terms of their outcome.
11 And probably my feeling is that no one is
12 going to fund that kind of trial. As Anne
13 mentioned, it is probably not ethical.

14 So, we have to decide if it is
15 important enough from a population health
16 point of view that these interventions get
17 done, which are based on what experts in the
18 surgical field tend to think that should get
19 done to override the lack of evidence
20 supporting their opinion.

21 Any comments about that?

22 CO-CHAIR BASKIN: So, in my

1 opinion, it is not only that it will never be
2 done, but it doesn't even need to be done,
3 frankly. I think at some point as physicians
4 we can be honest and sit there and say, hey,
5 you know, an appropriate assessment prior to
6 surgery is kind of like mom and apple pie
7 here. It is one of the basic tenets of
8 medicine in itself. So, to me, I don't think
9 that assessment should ever -- I mean, I don't
10 think that particular study should ever be
11 done. I don't think it is really a question
12 that we have to have. I think we can accept
13 this as basic scientific way of performing
14 medicine.

15 MEMBER MERGUERIAN: I agree. I
16 think it is the standard of care. It is
17 pretty much what you do when you evaluate a
18 patient that comes into your urology clinic.
19 I mean, to get an analysis, you take a
20 history.

21 MEMBER MORTON: I agree. I mean,
22 this is very similar to like doing these

1 applications without having a pH probe ahead
2 of time. You have to have the appropriate
3 indications.

4 And I agree with Andy that no
5 trial is necessary for this. We didn't have
6 randomized trials for parachutes, either. So,
7 we figured that would work. So, this makes
8 pretty good sense.

9 CO-CHAIR SAIGAL: Okay. So, then,
10 Karen?

11 MEMBER PELLETIER-CAMERON: And
12 from a clinician's point of view, what they
13 are talking about doing as a complete
14 evaluation is not rocket science. They are
15 talking about a history, a physical exam, just
16 demonstrating that they have incontinence. We
17 are not talking about complicated, expensive
18 testing. We are talking about a simple office
19 evaluation and making sure they don't have a
20 urine infection, and that is about it. So, it
21 is pretty straightforward.

22 DR. PACE: So, one of the things

1 -- and I know this is a relatively-new area
2 for you or for us to do performance measures
3 -- but one of the things that also comes up in
4 terms of where NQF is moving with performance
5 measures and our guidance is that this kind of
6 standard of care, does it rise to the level of
7 needing a national performance measure?

8 So, we have had this shift in our
9 overall portfolio. It is that assessment
10 measures that are at the very beginning of a
11 long line of steps that had to happen to have
12 an effective outcome is why not measure things
13 that are closer, more proximal to the desired
14 outcomes.

15 And you may say that this is such
16 a new area or people are doing so poorly with
17 just doing basic assessments that you all
18 consider standard of care, that we need a
19 performance measure. But some of the other
20 things that I have heard you say was about
21 appropriateness.

22 So, for example, would a measure

1 of the patients who actually received surgery,
2 and did they have the appropriate
3 indications -- and I don't know if that is
4 even something to consider at this point. But
5 it is something, as you look at these
6 measures, remember, we are talking about a
7 national performance measure, and the things
8 that are most likely to improve patient
9 outcomes and improve the quality of care. So,
10 you need to think about that, but also in the
11 context of where this field is in terms of
12 where performance measures are needed.

13 CO-CHAIR SAIGAL: So, in that
14 light, Paul, can you make a comment on the
15 performance gap in terms of whether that --
16 what we are talking about here, basically, is
17 like whether it is a big enough problem. It
18 gets back to that.

19 DR. PACE: Actually, probably that
20 is the next criterion. And the question here
21 is whether this is an exceptional circumstance
22 that you want to go on and evaluate that

1 performance gap. Because if it doesn't meet
2 the performance gap, it won't meet the
3 criteria anyway.

4 CO-CHAIR SAIGAL: Right.

5 MEMBER SCHOENFELD: Just a quick
6 comment? Because it almost sounded to me like
7 it is almost premature to answer this question
8 until we hear about the performance gap
9 because wouldn't a significant performance gap
10 be the reason to answer yes to this question?
11 Maybe I am missing that.

12 DR. PACE: That is a good point.

13 CO-CHAIR SAIGAL: Well, I think we
14 talked about it to start with. But,
15 basically, what you were saying was, is this
16 an extreme enough problem? Like maybe we
17 could revisit how big of a problem it is
18 because we are basically saying we are not
19 going to need any evidence that you would
20 qualify as evidence to measure it. I mean,
21 maybe we could reconsider the magnitude of it.

22 DR. PACE: So, I think this is

1 question is, do you want to move on, continue
2 to keep considering this, even though it is a
3 consensus-based guideline recommendation and
4 it is kind of the first step in a long line of
5 things that happen? But this is just kind of
6 a preliminary, yes, we think it is important
7 and we want to move on to the next criterion.

8 But I will defer to you. If you
9 want to have that discussion about the
10 opportunity for improvement, I think that is
11 perfectly fine as well.

12 CO-CHAIR SAIGAL: Okay. So, does
13 anyone have any comments about the -- go
14 ahead.

15 MEMBER BUTT: I think it will get
16 trapped in the next one, if it makes it
17 through here. So, it would be fine to go
18 ahead.

19 CO-CHAIR SAIGAL: Agreed, but the
20 whole point is to avoid having them go down a
21 path of developing something that we don't
22 think is important.

1 MEMBER BUTT: No, I mean, the gap,
2 it will be caught in 1(b).

3 CO-CHAIR SAIGAL: Oh, I see what
4 you are saying. Okay.

5 Okay. So, then, I guess maybe we
6 could just move to the exception vote then.
7 Okay. Is there a special thing we can put up
8 there for that? All right. So, let's vote on
9 whether this meets the qualifications to be
10 important enough to be an exception to the
11 evidence rules.

12 MR. WILLIAMSON: We will now vote
13 on the exception. And the question is, is
14 there an exceptional and compelling reason
15 that the measure should be considered further?
16 We have two options, yes and no.

17 And you may begin voting now.

18 Shall we do a hand vote? And
19 then, I will look at this in the break. It
20 was working before, but it is not working now.
21 We will get that fixed, but we will just do a
22 hand vote.

1 MS. BOSSLEY: So, this will be
2 good practice for tomorrow because you lose
3 the options of doing electronic voting. The
4 other Committee will be using it.

5 So, we are going to have you do a
6 hand vote. I'm sorry.

7 (Laughter.)

8 Just when you got really good at
9 it, yes.

10 MR. AMIN: All those voting yes?

11 (Show of hands.)

12 Those no?

13 (No response.)

14 DR. PACE: So, the next one is ht
15 performance gap.

16 MR. AMIN: Let me just say that
17 the vote on that was 15-to-0, just so we have
18 it in the record.

19 Okay. So, performance gap, you
20 are looking at the data demonstrating
21 considerable variation or overall less-than-
22 optimal performance.

1 CO-CHAIR SAIGAL: Okay. Paul, I
2 think you are going to take us through
3 performance gap next.

4 MR. AMIN: Paul, can you use your
5 microphone, please.

6 MEMBER MERGUERIAN: There are
7 several articles that they cite. They are
8 basically articles from the UK, the U.S.,
9 Australia, New Zealand, and Canada, that show
10 that there is variability in evaluating
11 patients with stress urinary incontinence.
12 There are some studies from the UK that show
13 that there was a compliance of 10 percent,
14 that they actually performed continence
15 surgery without proper evaluation. There are
16 some other areas where it is as high as 72, in
17 some places where it is as high as 80 percent.
18 But there is quite a bit of variability in the
19 articles that they presented as far as
20 evaluating those patients.

21 There are 2006 NICE guidelines
22 that pretty much talked about, looked at

1 responders, and there is really no agreement
2 among responders that some of these tests are
3 actually necessary.

4 CO-CHAIR SAIGAL: So, how would
5 you characterize this for us in terms of
6 performance gap?

7 MEMBER MERGUERIAN: That there is
8 a performance gap. There is quite a bit of
9 variation in the way people evaluate these
10 patients.

11 CO-CHAIR SAIGAL: And that the
12 European studies are probably applicable for
13 the U.S. setting, you would think, in terms of
14 how that --

15 MEMBER MERGUERIAN: I would think
16 so. They cited the Dutch study that pretty
17 much looked at primary care providers, but
18 most of the other studies were urologists and
19 gynecologists.

20 CO-CHAIR SAIGAL: Any comments
21 from the Committee?

22 Liliana, go ahead.

1 MEMBER BORDEIANOU: Just reading
2 through this, there are a couple of things
3 that are quoted as performance gaps. One, did
4 the patient answer a questionnaire? Two, did
5 the patient get urodynamics testing?

6 But what we don't know is which
7 one of these specific measures really matter.
8 Is it necessary to do urodynamic testing or is
9 it enough to determine leakage on a physical
10 exam?

11 So, I am not convinced that the
12 papers that are quoted are addressing these
13 five things need to be documented in each
14 exam, going back to the fact that there is no
15 data because some of this has become standard
16 of care without accumulating.

17 So, is the role of NQF to say this
18 is standard of care and we want this done,
19 because it is? Or do we ask the societies to
20 go back and dig up material that they will
21 never be able to get anymore because there is
22 some variability?

1 CO-CHAIR SAIGAL: It is a good
2 summary of the problem, I think.

3 Zahid?

4 MEMBER BUTT: And this may, again,
5 be one of the broader questions as well as
6 pertaining to this measure in terms of when a
7 gap is sort of trying to get at the practice
8 of medicine. How relevant do international
9 studies become in that context, when you are
10 trying to do a gap analysis?

11 Because one can sort of relate to
12 those in a more sort of non-practice type of
13 setting where it is patient sort of
14 symptomatology, et cetera. But I think in
15 terms of where it is trying to get at a
16 procedure or a practice, in that context, it
17 seems like at least a couple of the studies
18 that I can see appear to be U.S.-based
19 studies, and the gap seems to be more not in
20 sort of general H&P, but those urological
21 studies that are specific to measuring the
22 stress incontinence.

1 So, I don't know whether this is
2 the --

3 CO-CHAIR SAIGAL: Yes, thank you
4 for your comments.

5 MEMBER BUTT: -- level of what we
6 are looking for, but at least there are two of
7 them that point to fairly low rates of those
8 assessments.

9 CO-CHAIR SAIGAL: So, I could
10 summarize, basically, Paul feels that there is
11 enough evidence from international studies to
12 indicate there would be a problem in the U.S.
13 And I think Liliana made the point that a lot
14 of the studies specifically look at elements
15 that are not part of the measure in terms of
16 performance gap, but that she recognizes that
17 they may never have those kind of data. And
18 Zahid mentions that the transportability of
19 those observations into the U.S. setting not
20 be there.

21 MEMBER BUTT: There may be a
22 couple of U.S. studies that do point towards

1 a gap.

2 CO-CHAIR SAIGAL: Yes. Okay.

3 MEMBER MERGUERIAN: I think one of
4 the other things that was not mentioned -- and
5 maybe it should be mentioned -- in this, which
6 is when you actually look at the AUA
7 guidelines, they give examples of things, for
8 example, if you have a patient that has high
9 post-void residual and has stress urinary
10 incontinence, you might decide a different
11 type of treatment for that patient, a
12 different type of surgery.

13 And so, those are things that
14 basically maybe should be included in that
15 concept, also. That may guide the urologist
16 to manage this patient differently.

17 CO-CHAIR SAIGAL: Okay. All
18 right. I mean, I think we have some other
19 comments about this. We should probably vote
20 about the demonstration of the performance
21 gap.

22 Ready to vote?

1 MR. WILLIAMSON: You will now vote
2 on the performance gap. There are four
3 options: high, moderate, low, or
4 insufficient.

5 And you may begin voting now.

6 (Vote taken.)

7 And we have zero high, 13
8 moderate, 2 low, and zero insufficient.

9 CO-CHAIR SAIGAL: Okay. The final
10 issue is really approval of the concept. And
11 just to summarize, we have decided or the
12 group has talked about that this is an
13 important concept to measure. The evidence
14 supporting the specific measure set was
15 insufficient to meet NQF standards, but we
16 felt that the overall problem was a big enough
17 deal that we would go ahead and make an
18 exception. In terms of the definition of the
19 gap, there is moderate evidence that the gap
20 existed. And now, we are going to see if you
21 want to approve the concept overall for the
22 measure to proceed, with the exception that we

1 noted.

2 Okay? Any comments?

3 (No response.)

4 Okay. Let's vote.

5 MR. WILLIAMSON: You will now vote
6 on --

7 CO-CHAIR BASKIN: It is more of a
8 question because I think I am understanding
9 what some folks here who are urologists -- and
10 I am not; as an internist, I am not sure I
11 have the answer here.

12 So, I guess what I am trying to
13 understand is, yes, I see there is a gap, that
14 these things aren't being done. What I am
15 trying to get is the link here. Does this
16 evidence include the information that, had you
17 done this preoperative assessment, you would
18 have had a better diagnosis and performed the
19 better or the right type of surgery? I am
20 having trouble with that link.

21 If you did this urodynamic
22 testing, does that lead to a better outcome,

1 a better surgery, the right kind of surgery,
2 or something? Or are we asking people to do
3 an assessment that I have no proof is of
4 value?

5 MEMBER PELLETIER-CAMERON: There
6 is data to show that, if you were doing stress
7 incontinence surgery on people who have, for
8 example, urge incontinence, which is not
9 stress incontinence, they do very badly
10 because they had the wrong kind of
11 incontinence.

12 And stress incontinence surgery
13 is, I mean, as a general rule, well-paying and
14 easy to do, and urge incontinence is more
15 difficult to treat. So, I mean, in clinical
16 practice I see people all the time who have
17 clear urge incontinence who were treated
18 surgically inappropriately.

19 And there is data to support that,
20 if you really have stress incontinence, that
21 surgery will work. But there is a big
22 difference between the two types of

1 incontinence, and determining the difference
2 between the two does involve a workup, does
3 involve a history, a physical, and some
4 testing. You can't just guess.

5 I think there is a big gap that
6 may not be reported in the literature, but it
7 is present in clinical practice, that people
8 are putting slings in people who shouldn't
9 have them done.

10 CO-CHAIR SAIGAL: So, I think
11 that, basically, the issue Anne mentioned
12 before is that they are not -- this measure is
13 not recommending a lot of testing be done. I
14 mean, there is a lot of question about
15 urodynamics and other elements of care. It is
16 a pretty basic toolkit that is being required.
17 It is a judgment call about how basic "basic"
18 is, but I think it is pretty basic in terms of
19 our field.

20 MEMBER REYNOLDS: I would echo
21 that. I mean, you specifically said
22 urodynamics, which is not what is at issue

1 here. That is a separate level of intensity
2 and workup. And there is some recent
3 randomized controlled trial looking at that,
4 but that is not what is included in here,
5 exactly as Chris said.

6 So, this is very basic stuff. If
7 any of you have not been to the urologist's
8 office, you get all these when you walk in the
9 door almost every time, in theory, but maybe
10 not in practice.

11 CO-CHAIR BASKIN: So, help me
12 understand urodynamics just for a second.
13 What would be an objective demonstration of
14 stress incontinence that is not a urodynamic
15 test? Help me here.

16 MEMBER PELLETIER-CAMERON: Have
17 them lay down and cough.

18 CO-CHAIR BASKIN: That is
19 objective?

20 MEMBER PELLETIER-CAMERON: Yes.
21 You put a speculum in. You say, "Cough." And
22 then, if urine squirts out of the urethra,

1 that is objective demonstration of --

2 CO-CHAIR SAIGAL: That is better
3 than urodynamics probably.

4 MEMBER PELLETIER-CAMERON: --
5 incontinence, yes.

6 CO-CHAIR SAIGAL: Okay. So, then,
7 I think we can vote on the overall approval of
8 the concept, yes or no.

9 MR. WILLIAMSON: You will now vote
10 on the overall approval of the concept. There
11 are two options, yes and no.

12 You may begin voting now.

13 (Vote taken.)

14 And we have 15 yes and zero no.

15 CO-CHAIR SAIGAL: Great.

16 MR. AMIN: Chris, can I just jump
17 in here real quick for a second?

18 CO-CHAIR SAIGAL: Yes.

19 MR. AMIN: Sorry. I know we are a
20 little behind schedule, and I appreciate the
21 fact that you are on top of it.

22 One of the components of feedback

1 that we got from the first few measures that
2 I just want to kind of push back to you guys
3 is that this is the opportunity now, now that
4 stage one has ended and you are going forward
5 as stage two, to review also any concerns that
6 you have about the way the measure is
7 constructed.

8 While the validity of the measure
9 will be evaluated in stage two, if there are
10 concerns, in essence, of the way the
11 numerators are defined or other concerns that
12 you had, this would also be a place to
13 describe those concerns before the measure is
14 fully specified and you evaluate it in stage
15 two.

16 So, an example of that would be,
17 if you were looking at, for example, a prior
18 measure that was looking at five different
19 components or a couple of different
20 components, if you agreed that some components
21 were important and others weren't, or if you
22 wanted to expand the numerator, this would be

1 the place to provide that feedback.

2 DR. PACE: Another place where you
3 may want to look at is the exclusions, whether
4 the people being excluded, or potentially
5 being excluded from the measure are
6 appropriate, you know, or if you want to make
7 any suggestions or comments about that.

8 CO-CHAIR SAIGAL: Okay. Any such
9 comments for the developer?

10 CO-CHAIR BASKIN: Yes. And this
11 is actually a comment that I hate to have to
12 repeat several times today, and it wasn't
13 about exclusions because I have written down
14 for comments about many of these measures this
15 whole idea of excluding people, medical
16 reasons for not performing a workup. And I
17 have a little trouble with this, in that if
18 you have medical reasons for not performing
19 this basic workup, and, yet, you are okay to
20 have surgery done, I am having issues with
21 that.

22 The other issue I have is this

1 whole thing with cognitive impairment. If
2 somebody is cognitively-impaired, then there
3 is a medical guardian who is making the
4 decision. I don't understand why that person,
5 this discussion, why this workup still
6 wouldn't have to happen. I mean, there is
7 informed consent by this other person, but I
8 still don't understand why the workup doesn't
9 happen when there is cognitive impairment.
10 Your history may be taken by the medical
11 guardian, but it still obtained.

12 It just seems to me that this just
13 opens a door that shouldn't be opened. I
14 mean, the 1 or 2 percent of the people for
15 which it is absolutely impossible to ever do
16 this, I guess is one thing, but I just don't
17 see it happening. And I think these are just
18 exclusions that become shady and subjective
19 and just shouldn't be allowed. They weaken
20 the measure.

21 CO-CHAIR SAIGAL: So, the
22 developers could take home the idea that they

1 would have to have a better justification for
2 those exclusions.

3 Okay. So, can we move on? We
4 have three more of these to do in 30 minutes.

5 So, C2050, Alayne, could you lead
6 us? This is the counseling-on-treatment
7 options and importance to measure and for high
8 impact.

9 MEMBER MARKLAND: I am going to do
10 a brief overview, and then state my findings
11 in this review.

12 Briefly, this is the percentage of
13 female patients who are having stress urinary
14 incontinence and surgery, that a documentation
15 that treatment options were discussed. These
16 treatment options are twofold. Treatment
17 options include non-surgical therapies, both
18 behavioral, which is defined here, and other
19 surgical treatments.

20 And then, the second part of this
21 is expectations for treatment. What are the
22 rates of potential cure or potential problems

1 with the complications of having surgery?

2 And so, it is the twofold measure.

3 The numerator statement is as such. The
4 denominator is excluding female patients who
5 had stress surgery without concomitant surgery
6 for pelvic organ prolapse. So, these are just
7 women presenting with one type of surgical
8 intervention.

9 And then, the same denominator
10 exclusions, in addition, are the medical
11 reasons for not counseling patients, including
12 the cognitive impairment with the statement as
13 just said, and those patients who might be
14 uncomfortable with the responsibility of
15 making choices regarding their care.

16 So, with this, the timeframe is a
17 12-month period. So, the discussion, I guess,
18 on options is specified as 12 months. They do
19 list the types of surgeries here -- I am not
20 going to read those out -- and the types of
21 different behavioral or non-surgical
22 treatments, including non-pharmacologic

1 measures, and the actual rate in the
2 literature in terms of cure rates that they
3 are stating here for each of those surgical
4 measures that they are trying to look at what
5 kind of treatment options were discussed.

6 The level of analysis is both
7 administrative claims and paper medical
8 records. Really, the level of analysis is at
9 the clinician or the individual level in terms
10 of these discussions.

11 And the impact is that really
12 large amounts of surgeries, as we have already
13 heard, are being done for stress urinary
14 incontinence. This is a really fairly easy
15 procedure with little time for
16 hospitalization, if at all, commonly being
17 done. Stress incontinence is a broadly-
18 accepted problem among older females as well
19 as younger females.

20 These surgeries can be very
21 effective at improving outcomes. However,
22 oftentimes, they state the evidence that

1 really people don't counsel about other types
2 of treatments in the broad sense, maybe not in
3 specialty groups, but maybe more providers in
4 different areas.

5 And sometimes women come to have
6 surgery without having all other treatments
7 informed of them. We don't have data saying
8 what that number is per se, but it is fairly
9 common. And the authors do cite here that 97
10 percent of the women who have surgery really
11 expect this to have been the cure, and that is
12 often not the case. The cure rates are more
13 in, what they report here is 69 to 82 percent
14 with some variability.

15 CO-CHAIR SAIGAL: So, then, in
16 terms of the impact, this is counseling people
17 appropriately for a high-volume surgery is a
18 high-impact measure, is that right? Okay.

19 Anyone else on the Committee have
20 any comments about that?

21 (No response.)

22 Okay. So, can we move on to the

1 impact part of this then?

2 MR. WILLIAMSON: Okay. We will
3 now vote on the impact. There are four
4 options: high, moderate, low, or
5 insufficient.

6 You may begin voting now.

7 (Vote taken.)

8 CO-CHAIR SAIGAL: Okay.

9 MR. WILLIAMSON: And we have 12
10 high, 3 moderate, zero low, and zero
11 insufficient.

12 CO-CHAIR SAIGAL: Great. Okay.
13 So, then, maybe talk about the evidence
14 supporting their measure?

15 MEMBER MARKLAND: The evidence
16 cited with this guideline includes statements
17 or guidelines from European societies as well
18 as U.S. societies. And basically, they list
19 options here, that non-surgical treatments can
20 be very effective and are often grade A types
21 of evidence for treatment for this problem and
22 should be considered in the treatment line.

1 Let's see, basically, patients
2 should be given all these options in a
3 clinical setting prior to proceeding straight
4 to surgery. And I think that is what this
5 measure is trying to establish. But what we
6 don't know is really what are the rates of
7 this discussion happening.

8 CO-CHAIR SAIGAL: So, to summarize
9 what you said, basically, there is evidence,
10 they provided evidence that incontinence is an
11 important problem, but this specific measure
12 about appropriate counseling, there is not a
13 direct -- there is no evidence that counseling
14 someone completely will improve their
15 outcomes. It maybe isn't a study we can
16 really do again conceptually. It is more this
17 may fall under an issue that we have -- it is
18 a consensus that you should counsel patients
19 appropriately.

20 And so, any of the other reviewers
21 who read this document have anything to say
22 about the evidence, or other Committee

1 members?

2 (No response.)

3 Okay. So, I think we are going to
4 have to make a vote then. I have feeling this
5 is, again, we already said it is important.
6 The evidence that suggests that it is
7 important in terms of the outcomes, that we
8 have a gestalt that it is important, doesn't
9 really rise to the level of an NQF situations
10 of acceptability.

11 So, we have the options of saying,
12 yes, we believe it does; no, we believe it
13 does not definitely, or that it does not, but
14 we have a feeling that this is important
15 enough as a problem that we should make an
16 exception.

17 I mean, we are going to have this
18 discussion several times today. So, I will
19 tell you what the NQF staff told me, that we
20 are not supposed to be doing this routinely,
21 but only in situations in which we feel that
22 the problem is important enough. So, it is up

1 to us to decide.

2 MR. AMIN: Chris, can I just
3 clarify, because I think we will be going down
4 this road a number of times? I just want to
5 clarify, No. 2 is where you would be invoking
6 the exception, where there is no empirical
7 evidence here. It is okay. I just want to
8 make sure that we are clear. From the tenor
9 of the conversation, that seems to be where
10 you are going.

11 And No. 3 would be that the
12 information exists, but that information that
13 exists actually would meet the quality,
14 quantity, consistency requirement, but it just
15 wasn't presented by the developer. And the
16 group would have a discussion around what that
17 evidence entails.

18 CO-CHAIR SAIGAL: Great. Okay.
19 Thanks for that clarification.

20 Liliana?

21 MEMBER BORDEIANOU: Sorry, I am
22 waiting for the green light to go on.

1 But, then, okay, the clinician in
2 me says, so let's say I am taking care of a
3 patient like that and I document that I have
4 discussed the risks of a surgical procedure
5 and I have discussed all the other options,
6 but the patient decided to proceed with
7 surgery. Does that make me a quality surgeon,
8 just because I documented that in one
9 sentence? Or do we really want to look at how
10 much care was provided to these patients
11 before they actually proceeded to surgery, in
12 which case I don't think that this measurement
13 would measure it.

14 CO-CHAIR SAIGAL: You say "how
15 much care". What do you mean by that?

16 MEMBER BORDEIANOU: In the medical
17 record in general, not from the documented
18 note from this particular provider, but the
19 physical therapist that might have taken care
20 of this patient, the nurse practitioners, the
21 primary care physicians. The medical record
22 of a patient is larger than the encounter with

1 a surgeon.

2 So, if the surgeon says, "This
3 patient came to me and they already had
4 biofeedback, and I am offering them
5 surgery" --

6 CO-CHAIR SAIGAL: So, you are
7 suggesting that it would be more convincing if
8 they took into account what other providers
9 the patient had seen?

10 MEMBER BORDEIANOU: I think that
11 it is easy to cheat the system and say in
12 every note that you dictate automatically, "I
13 have provided counseling," et cetera, et
14 cetera, "and the patient still wants surgery."

15 CO-CHAIR SAIGAL: I see. So, that
16 is a good question for, I think, the validity,
17 and so on, of the measure. But I think,
18 first, we decide whether if in a perfect world
19 it was valid, would it be a good measure?

20 And then, when they come back in
21 stage two, they can tell us when they actually
22 tested these things out whether it was valid.

1 As you point out, you can easily game the
2 system.

3 So, let's put that aside for right
4 now and imagine it was valid, I think is the
5 idea. Is that right?

6 DR. PACE: Right, but I think your
7 question kind of also relates to evidence. I
8 mean, because, again, is there evidence that
9 counseling or providing this list of options
10 is the right thing? Or are you saying it
11 should be that they have actually tried some
12 of these lower-level or lower-invasive -- I
13 think that is maybe what you are asking at
14 this stage, is: where is the evidence? Where
15 would the evidence be most appropriate?

16 CO-CHAIR SAIGAL: Right. So,
17 there is no evidence that they have presented
18 that provides this link. But, as we talked
19 about last time in the last measure, it is
20 pretty standard of care to fully counsel
21 patients. So, will we ever develop evidence
22 around that or should we?

1 CO-CHAIR BASKIN: Actually, I
2 don't think this evidence was presented here.
3 But I think there is a body of evidence out
4 there that, in general, not related to this
5 particular surgery, that when you provide
6 members with, when you provide patients with
7 treatment options, that people do change their
8 treatment. There is a whole body of evidence
9 about preference-sensitive surgeries and
10 things like that.

11 So, that I don't know that there
12 is any need to have that evidence specific to
13 this particular surgery and for every surgery
14 that is contemplated out there, but I think
15 there is a great body of evidence that
16 decision-support information for patients is
17 a good thing in making an informed decision,
18 and it does change treatment choices.

19 CO-CHAIR SAIGAL: In that regard,
20 I think if you look at the data on shared
21 decisionmaking, that for sure providing people
22 with all their options does impact their

1 decisionmaking in general. So, if we were to
2 accept those kind of data which aren't done in
3 incontinence, but are done in BPH or CABG
4 surgery, and so on, if those data are
5 acceptable to the Committee, then we could
6 vote a three, that there is data about
7 decisionmaking that exists that would be
8 convincing enough that it would work in
9 incontinence surgery, but it wasn't presented
10 in the document. So, that is another option
11 we have.

12 MEMBER PELLETIER-CAMERON: Yes,
13 and, I mean, there is evidence presented in
14 this document, evidence about the success of
15 each of these interventions. I mean, there is
16 good data on the success of pelvic floor
17 physical therapy, good evidence on weight
18 loss, good evidence on all the surgeries. So,
19 there is evidence that each of the suggestions
20 that you can discuss are effective.

21 CO-CHAIR SAIGAL: Okay. Okay.
22 So, then, to summarize where we are at, we are

1 going to take a vote on evidence here
2 supporting this measure. This is not direct
3 evidence about the specific measure and
4 outcome that matters to patients that is
5 presented by the developer. This is
6 definitely a standard of care that we all
7 probably, as physicians, feel is important to
8 do. So, we have that option of, if we don't
9 feel evidence is there, we can make an
10 override.

11 And then, I think there is also an
12 argument that there is a large body of data
13 about shared decisionmaking that says, when
14 you fully counsel patients about any treatment
15 choice, that you tend to get more appropriate
16 treatment choices and you impact the patterns
17 of care.

18 So, our choices are one, two, or
19 three. Let's vote.

20 MR. WILLIAMSON: We will now on
21 the evidence.

22 You may begin voting now.

1 (Vote taken.)

2 And we have 3, yes, that the body
3 of evidence meets the guidance. We have 3,
4 no, the evidence does not meet the guidance,
5 and we have 9 that, no, insufficient
6 information was submitted to rate.

7 DR. PACE: So, the next question
8 is, if we go with this question, if people
9 want to address, to specifically vote that,
10 yes, a body of evidence does exist, just to
11 have that on the record that everyone agrees.

12 CO-CHAIR SAIGAL: Okay. So, for
13 the plurality of us who voted for three, we,
14 I guess, believe that there is evidence out
15 there, a large body of evidence about shared
16 decisionmaking. So, do you want to affirm
17 that as guidance from the Committee to the
18 developer? Or, if you don't believe that that
19 is relevant, which it may not be, then you can
20 vote no.

21 Zahid?

22 MEMBER BUTT: When we say there is

1 a body of evidence that exists, do we need to
2 also provide the reference?

3 CO-CHAIR SAIGAL: No.

4 MEMBER BUTT: Or is it just simply
5 to acknowledge that it exists?

6 CO-CHAIR SAIGAL: Yes.

7 MEMBER BUTT: Okay.

8 CO-CHAIR SAIGAL: Yes, it is
9 specifically, you know, the Foundation for
10 Informed Medical Decisionmaking has many
11 studies on this. Al Mulley is one of the
12 authors, Mike Barry.

13 Okay. Anything else?

14 (No response.)

15 We should vote. Let's vote.

16 MR. WILLIAMSON: This will be a
17 hand vote, and I believe these slides are not
18 working. So, we will now vote if there is
19 general agreement that the quantity, quality,
20 consistency of the body of evidence meets the
21 NQF guidance.

22 So, please raise your hand to

1 indicate yes.

2 (Show of hands.)

3 And raise your hand to indicate

4 no.

5 (No response.)

6 It is unanimous. We have 15 yes,

7 zero no.

8 CO-CHAIR SAIGAL: Okay. Then,

9 Alayne, the last comment is on performance

10 gap.

11 MEMBER MARKLAND: The last comment

12 being I do think there are some people who may

13 do a part of this, but not all. Specifically,

14 the counseling on the procedure itself, maybe

15 not always about other treatments. So, I

16 think there could be a performance gap that

17 could be measured here in this measure.

18 CO-CHAIR SAIGAL: Okay. And they

19 list some data about that under 1(b)(3). Did

20 you have any comments about that body of data?

21 MEMBER MARKLAND: Yes, I think

22 some of this data, though, that they list here

1 isn't as applicable to a U.S. population. We
2 don't often cover pads and discussion of pads,
3 although the VA does, but in the U.S.

4 And so, I think this discussion
5 could be improved on in the data that they
6 list here. But what they do list here is what
7 patients' expectations are. And I think that
8 does factor into this equation, that often
9 patients really have high expectations for
10 surgery and may not realize other treatments
11 may be also helpful.

12 CO-CHAIR SAIGAL: Okay. Any other
13 comments about the performance gap?

14 (No response.)

15 Okay. So, it looks to me like
16 there is some evidence, some observational
17 data that there are patterns-of-care
18 variations that sound totally believable to
19 me. And I do believe I am sure that not all
20 doctors provide all the appropriate counseling
21 for patients before they do surgery.

22 So, let's vote. Okay. Let's

1 vote.

2 MR. WILLIAMSON: We will now vote
3 on the performance gap. There are four
4 options: high, moderate, low, or
5 insufficient.

6 And you will begin now.

7 (Vote taken.)

8 And we have 3 high, 11 moderate, 1
9 low, and zero insufficient.

10 CO-CHAIR SAIGAL: Our final
11 overall vote now -- do you have questions?
12 Okay. So, to summarize this concept, which is
13 basically looking at appropriate treatment
14 counseling prior to surgery for stress
15 incontinence, we felt that it was an important
16 thing to tackle in terms of the number of
17 surgeries that get done and the variety of
18 options women face.

19 We felt that the evidence
20 surrounding the measure was generally indirect
21 and provided from things like literature that
22 this would be a good thing to do.

1 And in terms of the performance
2 gap, there is probably moderate evidence that
3 there is a gap, but we believe that it is
4 sufficient to move forward with it.

5 And then, we can vote about
6 whether we want to approve this concept
7 overall to provide to stage two.

8 MR. WILLIAMSON: We will now vote
9 on the overall recommendation of this concept.

10 You may begin voting now.

11 (Vote taken.)

12 And we have 15 yes and zero no.

13 CO-CHAIR SAIGAL: Great.

14 Okay. So, then, we have two more
15 to do

16 MEMBER FALLER: I was just going
17 to echo your comment on the last one about the
18 exclusion of informing people who had
19 cognitive deficits that somebody would be
20 involved in the decisionmaking. And just to
21 do the surgery without counseling somebody
22 doesn't --

1 CO-CHAIR BASKIN: And even in
2 addition, this has an additional one about
3 people who have patient reasons for not
4 counseling and this whole thing about
5 uncomfortable. I can't buy that one, and I
6 don't think it will get bought on the next
7 level of review someplace.

8 I also, though, have a question
9 about why -- and once again, my urology
10 friends may be able to answer this for me, and
11 it wouldn't go any further than this
12 suggestion -- this whole thing about continent
13 and prolapse. I don't understand. If they
14 are also getting urinary incontinence surgery
15 as a part of their surgery, why would you
16 exclude those people? The whole idea of
17 treatment options and counseling people still
18 exists. I don't think there is any specific
19 reason why you have to have a pure denominator
20 group of homogenous people who are getting
21 strictly urinary incontinence surgery without
22 prolapse surgery at the same time. Why this

1 measure wouldn't apply to all those folks at
2 the same time?

3 CO-CHAIR SAIGAL: Go ahead, Stu,
4 please.

5 MEMBER REYNOLDS: Well, it is
6 certainly a complicating issue. Those
7 treatments, while they may be concurrent in
8 some people, are very different and have their
9 own logistics, including risks/benefits, and
10 whatnot.

11 And even going back to the last
12 one, the work up there is also a little bit
13 different in the assessment of the degree of
14 prolapse. And so, the conditions can exist in
15 the same individual. That individual could
16 choose to have one or both of those things
17 repaired, but they are also very different.
18 And so, I feel pretty comfortable that they
19 split this out, because it is a subset
20 population, that someone who has prolapse is
21 sort of a different ball game in terms of how
22 you are going to counsel them, the workup you

1 are going to do, and all that kind of stuff.

2 CO-CHAIR BASKIN: But the measure
3 has nothing to do with workup. The measure is
4 simply that you have counseled them on
5 treatment options. So, those folks still have
6 treatment options and still require
7 counseling. Even though they may require
8 additional surgery and additional testing,
9 that is really not what the measure is
10 measuring. It is measuring whether you
11 provided treatment options and discussed them.

12 MEMBER REYNOLDS: That is a fair
13 enough comment. I was lumping, also, the last
14 one in as well. And you sort of had brought
15 up that with many of these ones. But,
16 certainly, the argument may be less strong
17 with this specific measure --

18 CO-CHAIR BASKIN: Yes.

19 MEMBER REYNOLDS: -- than the
20 assessment one, which would be different.

21 CO-CHAIR SAIGAL: I think, Stu,
22 basically, with prolapse, I mean, you can have

1 other treatment options as part of your
2 recommending them. And so, maybe you wouldn't
3 just say you are a good candidate for Kegels
4 if you have got bad prolapse. So, it may be
5 a different cohort to counsel. So, they
6 wanted to make this a homogenous enough of a
7 group that the treatment options that they
8 were counseling about were appropriate for
9 this group.

10 But in terms of the other
11 exclusions, I agree with you. I think that
12 the developers should reconsider the other
13 denominator exclusions and the rationale for
14 them, because I agree with you on that.

15 Zahid, do you have a question?

16 MEMBER BUTT: Yes, just another
17 comment. I made a comment earlier about
18 encouraging developers to do e-measures, but
19 I also want to make a comment -- and this may
20 be sort of for all the measures -- the data
21 source here is specified only as claims data
22 and paper records, but it should also include

1 EHR data because, even though someone is
2 answering the CPT question, they could use an
3 EHR to look at the information. This one,
4 just for completeness' sake, limits to only
5 paper record.

6 CO-CHAIR SAIGAL: Okay.

7 CO-CHAIR BASKIN: And one last
8 comment. So, if this does remain as-is with
9 just strictly urinary incontinence patients,
10 then I can't imagine why this and the prior
11 measure wouldn't be combined as one measure.
12 Every patient needs assessment. Every patient
13 needs treatment options. And essentially, it
14 just calls out for a composite measure that
15 says you have done both of these things. Any
16 less than both of these things doesn't make
17 any sense.

18 CO-CHAIR SAIGAL: Okay. Any other
19 comments from developers?

20 (No response.)

21 No? Okay.

22 So, then, the next one is 2051,

1 patients counseled about risks associated with
2 the use of mesh in sling surgery.

3 And Dr. Ellis is going to do that.

4 MEMBER ELLIS: So, remember
5 everything you just heard about the last
6 measure because a lot of it just transfers
7 over as we keep subsetting this group down.

8 (Laughter.)

9 So, now we are talking about the
10 patients counseled about risks associated with
11 use of mesh in sling surgery prior to surgery.
12 The author presents reasonable evidence that
13 a majority of that growth in SUI surgery we
14 are seeing is being driven with mesh use.

15 The impact to that group, if we
16 kind of skip up to a little bit of the
17 evidence part, there is a lot of European
18 evidence cited here showing a lot of adverse
19 outcomes and complication rates and the like
20 with mesh.

21 There is less reference to it on
22 the American side. There is reference to an

1 FDA alert. There is some reference to the
2 construct of that, I use the word "counsel"
3 because that is the measure word, although in
4 the European citations it is almost always
5 "warn, warn, warn," not "counsel, counsel,
6 counsel". So, you have to kind of make a
7 distinction in how those two words are used.

8 But, essentially, the population
9 at risk here I think has been defined by these
10 kind of previous measures. That kind of
11 defines the impact group, if we want to start
12 there.

13 CO-CHAIR SAIGAL: Okay. So, the
14 impact here is a very common surgery. This
15 material being used has been documented to
16 have a specific risk that is different from
17 other materials used to suspend the urethra.
18 This is a high enough impact problem that it
19 should be measured at the national level.
20 That is the question before us.

21 Any comments about that?

22 MEMBER ELLIS: I will say, for

1 guidance for some of you, in the preliminary
2 evaluation it was kind of split on high and
3 medium from the original reviewers.

4 CO-CHAIR SAIGAL: Yes. Okay.

5 Want to vote?

6 MR. WILLIAMSON: We will now vote
7 on the impact. You have four options: high,
8 moderate, low, or insufficient.

9 And you may begin voting now.

10 (Vote taken.)

11 And we have 9 high, 3 moderate, 2
12 low, and 1 insufficient.

13 CO-CHAIR SAIGAL: Okay. So, we
14 can move on to the level of evidence
15 supporting the measure.

16 MEMBER ELLIS: Again, the
17 citations, a lot of citations specifically
18 about outcomes using mesh, a lot of the stuff
19 out of European studies, a lot of RCTs cited
20 out of Europe, very little out of America.

21 And in neither case were these
22 studies about counsel. It was all about

1 outcomes related to use of mesh. So, we have
2 to kind of take that same leap of behavioral
3 change relative to being engaged and informed
4 as to the risks associated with it based on
5 the results of those outcome trials as opposed
6 to the outcomes of counsel.

7 There was more than enough
8 evidence on the European side, I think,
9 submitted to support the notion that these
10 risks are increased with this material, less
11 so, although we do have an alert from the FDA
12 on the American side.

13 CO-CHAIR SAIGAL: Right. So,
14 mainly, it is observational data supporting
15 it. There is a reasonable quantity, according
16 to NQF standards, of European and American
17 studies.

18 I personally think that the FDA
19 action is significant in terms of its
20 relevance for the U.S. population.

21 Any others? John?

22 MEMBER MORTON: I was just going

1 to ask, for someone who is not super-familiar
2 with the slings, what was the source of
3 concern from the FDA? Was it erosion, sort of
4 inappropriate use, putting them in patients
5 who didn't need the mesh?

6 CO-CHAIR SAIGAL: It was mainly
7 erosions.

8 Okay. So, if no one has any other
9 comments on evidence, we can vote that it
10 meets guidance, doesn't meet guidance, or
11 there is data we are aware of that has not
12 been presented.

13 CO-CHAIR BASKIN: Sorry. I am not
14 quick enough raising my hand here.

15 This is unlike the previous
16 measures in that where there is a discussion
17 of different options. This is somebody has
18 got a planned surgery, and have they explained
19 the risks of the surgery or have not explained
20 the risks of the surgery. I don't understand
21 how any of the evidence here is anything about
22 whether explaining risks to people of a

1 surgery that has already been selected, as
2 opposed to making a choice of here's two
3 different ones, a medical treatment versus a
4 surgical treatment. That is a very different
5 thing.

6 This is a check-the-box measure
7 that just says, "Check the box that you gave
8 somebody informed consent," which I am
9 presuming is required. I don't even see this
10 as a measure, let alone that there is evidence
11 to support what we are measuring here. I
12 mean, I don't understand. Are we saying that
13 people are going to not have the surgery
14 because they weren't explained risks before
15 and now they are going to be explained risks,
16 and the people are going to change their mind
17 about having the surgery? I don't see any
18 evidence that is pointing to that.

19 CO-CHAIR SAIGAL: John, go ahead.

20 MEMBER MORTON: Well, I think the
21 one thing that makes it fairly unique -- I
22 agree with you, this falls under informed

1 consent. You go over risks, benefits, go
2 through that equation; the benefits should
3 outweigh the risks.

4 But I think what makes it unique
5 is this issue from the FDA that makes it a
6 fairly unique problem. Rather than waiting
7 until a lot of data comes out, if there is
8 this FDA ruling, there needs to be a specific
9 recommendation around it. That is my
10 impression.

11 CO-CHAIR SAIGAL: I think you are
12 making a good point. This is similar to the
13 last one, though, in that there is not a
14 direct -- I mean, I think it is important to
15 mention mesh because it would stop a patient
16 from having mesh if they mention they want to
17 use it, if they told them all about it.

18 But the idea that you would
19 counsel them and then they would have less
20 mesh erosion, there is no direct evidence
21 about that. So, in that sense, it doesn't
22 meet the NQF evidence guideline.

1 I think it might meet the
2 guideline if we consider the other evidence on
3 shared decisionmaking, like we did the last
4 time; that when you fully inform patients,
5 they can take information and make different
6 decisions.

7 MEMBER ELLIS: I think the problem
8 there with that, of course, is that both the
9 numerator and the denominator are people who
10 had mesh sling surgery, not an indicator that
11 we had a change in choice, right, to a
12 different type of surgical intervention.

13 So, I think that is what muddies
14 the water in terms of the informed consent
15 part of this, unless we make a leap that
16 informed consent truly affected the outcome of
17 that mesh surgery. And I think that is not a
18 leap we are willing to take.

19 CO-CHAIR SAIGAL: So, that would
20 argue maybe to change the denominator to
21 include all patients that are being counseled
22 for surgery that have a mesh -- Jenifer?

1 MEMBER LIGHTDALE: It is informed
2 consent versus shared decisionmaking. I mean,
3 it is difficult to call it shared
4 decisionmaking if the moment of discussing
5 risks is happening at the time of the
6 procedure. I think that is very different.
7 So, I think you have a --

8 CO-CHAIR SAIGAL: Well, it is
9 before the procedure, I would think, yes.

10 MEMBER LIGHTDALE: Right, right,
11 but immediately before a patient is NPO,
12 prepared themselves psychologically to undergo
13 a procedure. It is a very different
14 experience. Counseling them at that moment
15 about an FDA warning is very different from --

16 CO-CHAIR SAIGAL: Is that what it
17 says, right before the surgery?

18 MEMBER ELLIS: It just says
19 before.

20 MEMBER LIGHTDALE: No. Well, it
21 just says before. I mean, talking before, it
22 could be at that moment of informed consent,

1 right?

2 CO-CHAIR SAIGAL: So, you are
3 saying that, to make it of high impact, it
4 would be done not in the preop holding area,
5 obviously, which I think makes good sense,
6 right?

7 MEMBER MERGUERIAN: May I maybe
8 suggest another concept? Maybe for the AUA to
9 actually have an informed consent written up
10 with all the pros and cons of these types of
11 surgeries. And then, the question would be,
12 was that actually given to the patient, yes or
13 no?

14 CO-CHAIR SAIGAL: Okay. So, then,
15 in terms of the evidence, we have evidence
16 that there is a problem with mesh in this
17 country. We have the measure that says, if
18 you tell people about mesh, that is a good
19 thing to do because it will decrease, the
20 implication is that it would decrease mesh
21 complications, I guess is the idea. No? I
22 mean, that is how I guess we could measure it.

1 That is a patient impact.

2 MEMBER ELLIS: It seems like the
3 only way you would get there the way this
4 measure is presented.

5 CO-CHAIR SAIGAL: Yes. Right.
6 That is a stumbling block conceptually.
7 Because what you are saying is, potentially,
8 the only way to avoid mesh complications is
9 not to use mesh, and then you could drive
10 utilization to zero. That is the idea that I
11 am reading from this measure.

12 Yes, Ed?

13 MEMBER GILL: We are supposed to
14 be, as far as I understand it, evaluating it
15 based on the measure as it is written. And we
16 are sort of trying to read into all of these
17 things and put our own spin on it. But, I
18 mean, basically, all they are measuring is was
19 the patient counseled appropriately that had
20 the surgery. And everything else is sort of
21 secondary to that, I think. I mean, we are
22 really just trying to evaluate whether people

1 are being counseled appropriately for their
2 procedure.

3 MEMBER ELLIS: Yes, I think that
4 is a big leap, is the appropriate part. There
5 is a lot of variation, if you look through
6 their evidence, on what one might assume is
7 appropriate.

8 CO-CHAIR SAIGAL: And the evidence
9 the NQF is asking us to look at is evidence
10 that links it to an outcome that matters to
11 patients. So, the outcome that matters to
12 patients in this setting would be, it could be
13 either I didn't have a complication from mesh
14 or I had a complication, but I was aware there
15 was a risk. One of those two things is the
16 outcome, I guess.

17 Stu, you had a comment?

18 MEMBER REYNOLDS: I was going to
19 say one other outcome could be whether they
20 chose to have the operation or not.

21 CO-CHAIR SAIGAL: Right.

22 MEMBER REYNOLDS: I don't know if

1 you said that or not, but --

2 CO-CHAIR BASKIN: But not in this
3 measure because the measure is only, as Robert
4 says, it is only those patients who had the
5 surgery.

6 MEMBER REYNOLDS: So, my second
7 comment is it is tempting to look at this one
8 in the framework with the other ones that are
9 all sort of part of this. I guess a question
10 I would pose to everyone is, do you kind of go
11 forth with it and say, well, maybe at the end
12 we will kind of condense into one on
13 counseling and discussion, or do we take it as
14 it is, a standalone and say, is it good enough
15 to go through? And I don't know the --

16 MR. AMIN: Chris, let me jump in
17 here --

18 CO-CHAIR SAIGAL: Go ahead.

19 MR. AMIN: -- on some procedural
20 options that you have. So, what we talked
21 about doing is having a harmonization
22 discussion. Essentially, what that

1 harmonization discussion will entail is
2 precisely that. While you want precisely
3 that, you may make some recommendations about,
4 first, if there are components that seek to
5 measure the same care process and should be
6 combined or that there is some logical
7 harmonization related to the population being
8 measured.

9 So, what you should do right now
10 is evaluate this individual measure as it is
11 constructed. If you feel that you want to,
12 then, use this measure and recommend that this
13 measure should be combined with others in the
14 future, in the future conversation we have
15 later this afternoon, that would be
16 appropriate at that time.

17 So, I guess that your procedural
18 options, I guess.

19 CO-CHAIR SAIGAL: Zahid?

20 MEMBER BUTT: Just one more
21 comment, that this might be the type of
22 measure where experience abroad might be

1 relevant because it is really a complication
2 of something that is put in. One would assume
3 that it is put in correctly by different
4 people, as opposed to more practice patterns
5 and what you do in certain situations. Here
6 something has been done, and it erodes
7 through.

8 CO-CHAIR SAIGAL: Yes.

9 MEMBER BUTT: And if it is eroding
10 through in Australia, it might be relevant in
11 the U.S.

12 CO-CHAIR SAIGAL: I agree with
13 that. But I think the issue before us is
14 really, I think we all agree that the evidence
15 is strong that there is a problem in this
16 country. The problem is how the NQF wants us
17 to measure this evidence supported in a
18 measure. Does it support the measure as
19 written, which basically looking at people
20 that have mesh surgery and have never been
21 counseled around the risks of mesh.

22 So, I am just not clear what the

1 outcome is. The outcome, I guess, implied is
2 that you are aware of the risks of mesh and
3 you had surgery. That is just the outcome.

4 MEMBER BUTT: I think it really
5 just has to be what was mentioned earlier,
6 that somebody might choose not to get it done.

7 CO-CHAIR BASKIN: That is not the
8 measure, though.

9 CO-CHAIR SAIGAL: Yes.

10 CO-CHAIR BASKIN: This is not
11 counseling about treatment options. There is
12 no option here. You have had the surgery. It
13 is a lookback to see whether somebody told you
14 you could have had a risk. This is not
15 measuring whether you changed your mind.

16 MEMBER BUTT: But if, let's say,
17 that if you counseled your patients regarding
18 the three specific things that are in the
19 measure numerator, erosion, exclusion, pain,
20 permanence, and you counseled it in 100
21 prospects that you were contemplating surgery
22 on versus only 10 percent, I would imagine

1 that the ones --

2 CO-CHAIR SAIGAL: But the
3 denominator is people who have had mesh. You
4 only identify people who have had the surgery.
5 The people that didn't have the surgery are
6 not captured.

7 MEMBER BUTT: I understand. I
8 understand. But it still gets to the
9 provider's practice pattern, whether they
10 counsel 100 percent of the ones they did or
11 only 10 percent. And I would imagine that, if
12 they did that as part of their engagement with
13 the patient, that the one that only mentions
14 this 10 percent of the time will probably
15 have more people willing to go through it
16 than the ones who tell this complication to
17 100 percent of their people that --

18 CO-CHAIR SAIGAL: So, the evidence
19 is even more tenuous. That may be true.

20 MEMBER BUTT: I am just saying
21 that --

22 CO-CHAIR SAIGAL: Yes.

1 MEMBER BUTT: -- is kind of the
2 only sort of --

3 CO-CHAIR SAIGAL: Link.

4 MEMBER BUTT: -- way you can link
5 this as to where there may be a difference in
6 outcome.

7 CO-CHAIR SAIGAL: Right. Yes.

8 All right.

9 MEMBER PELLETIER-CAMERON: Just
10 for my own clarification, so right now we are
11 kind of at the stage where we can either
12 accept or reject this measure. But, from the
13 discussion, I hear a lot of people agree that
14 this is important, but that it almost seems
15 like it needs to be harmonized with the
16 previous one where seems to fit in much more
17 appropriately.

18 So, I can tell you what I think is
19 I think it should be harmonized with the
20 previously one because your denominator and
21 numerator now make sense. And what direction
22 do we go in to have that happen?

1 MR. AMIN: So, then, you would
2 move this measure forward. And then, we will
3 have a discussion at, I think it is at three
4 o'clock, where that would be the
5 recommendation that you put forward.

6 CO-CHAIR SAIGAL: You could not
7 move it forward and still recommend it to be
8 harmonized into a measure later. It doesn't
9 have to move forward to make a recommendation
10 of harmonization.

11 MS. WILBON: So, the other option
12 is you don't have to move the measure forward,
13 but we could add a note, like we have been
14 doing for every measure, your recommendations
15 to the developer, that we will be giving each
16 developer a checklist to say the Committee
17 wants to see you do A, B, C, and D before it
18 comes back to stage two. That would be an
19 addition that we would make to one of the
20 prior measures, to say we want you to add this
21 to the numerator before you bring it back to
22 stage two. That is your other option.

1 CO-CHAIR SAIGAL: Okay.

2 MEMBER MORTON: Harmonization does
3 not require prior approval of the measure? Do
4 we have to approve this measure, so it can be
5 harmonized later?

6 CO-CHAIR BASKIN: No, no, they
7 would have to bring it back as a measure or
8 bring it back as a harmonized measure or
9 something like that.

10 MS. WILBON: Right. When it came
11 back to stage two, we are still working this
12 out, but there would be a period where we kind
13 of review what you recommended, what they
14 brought back, does it match. Does the
15 evidence kind of match what they actually
16 brought back? So, that is what we are
17 thinking.

18 MEMBER ELLIS: I just want to make
19 one last comment on Zahid's comments about
20 using it kind of in its current form as an
21 evaluator of physician performance, for
22 example. Even though there is very little

1 reference to that concept in this measure, it
2 also struck me as troublesome, if we tried to
3 take it down that path, and it being,
4 basically, an administrative measure. You
5 know, check the box. "Yes, I did," right? I
6 mean, relatively easy thing to do with no
7 construct of what is quality counsel, what
8 were the options that were required. So, I
9 think that is a dangerous way to take it as
10 well in its current form.

11 CO-CHAIR SAIGAL: Okay. So, I
12 think we should probably move to a vote on
13 this. It sounds like there are a lot of
14 conceptual problems some of us have with this
15 measure. The denominator is only people that
16 have had mesh surgery, which limits its
17 potential usefulness as a measure.

18 There is a recognition that there
19 is evidence that the mesh is bad, but the
20 evidence that this measure will impact things
21 that matter to patients is limited from the
22 NQF standard in that it not even meet the

1 issues we raised previously on shared
2 decisionmaking because of the denominator
3 issue.

4 So, we can vote on this. We can
5 turn it down and ask that it be harmonized.
6 We can vote it up and ask that it be
7 harmonized. There are both options for us.
8 Okay?

9 Let's vote.

10 MS. WILBON: So, can I just make a
11 point of process? This vote is still on
12 whether the evidence submitted before you
13 meets the criteria. So, I know there has been
14 a lot of discussion about whether or not the
15 concept should move forward, but we are kind
16 of still back to the foundational information
17 that was submitted on whether or not what they
18 submitted supports the measure focus and based
19 on that.

20 CO-CHAIR SAIGAL: Okay.

21 MR. WILLIAMSON: We will now vote
22 on the evidence.

1 You may begin voting now.

2 (Vote taken.)

3 We have 5, yes, that the body of
4 evidence meets the guidance. We have 7, no,
5 that the evidence does not meet the guidance.
6 And we have 3, no, that there is insufficient
7 information submitted to rate the evidence.

8 CO-CHAIR SAIGAL: So, for those
9 who voted three, are there any specific
10 studies that you are aware of that you -- that
11 is the implication there, I think, is that
12 there are other data out there to support the
13 measure focus that wasn't submitted here.

14 Anyone who wants to comment about
15 that? Is that the idea that you had about
16 that? Any ideas?

17 (No response.)

18 No? Okay.

19 So, can we proceed?

20 MR. AMIN: Here, well, you are
21 going to have to have a discussion around --
22 voting two would essentially bring us back to

1 where we have been, which is invoking the
2 exception.

3 CO-CHAIR SAIGAL: Okay.

4 MR. AMIN: So, your discussion
5 around invoking the exception -- actually,
6 Evan, can you move to the next slide on the
7 exception.

8 CO-CHAIR SAIGAL: Okay. So, now
9 we have got to vote as to whether, although
10 the majority of people felt or a lot of people
11 felt that the measure did not meet the
12 evidence criteria of the NQF, is this a big
13 enough problem? And do we think that there is
14 a fundamental relationship between the measure
15 and the outcome that matters to patients, that
16 we would vote to make an exception here and
17 let the measure move forward? So, let's vote
18 on that.

19 Is the voting open?

20 MR. WILLIAMSON: No, I didn't open
21 it.

22 CO-CHAIR SAIGAL: Okay.

1 MR. WILLIAMSON: This will be a
2 hand vote again. This will be a hand vote.

3 So, first, raise your hand for
4 yes.

5 (Show of hands.)

6 All right, so we have 3 yes, 4.

7 All right.

8 And for no?

9 (Show of hands.)

10 MR. AMIN: That was 4 yes, 11 no.

11 Okay. So, the measure does not go forward,
12 and we can move on to the next measure.

13 CO-CHAIR SAIGAL: Okay. The next
14 measure is C2052, reduction of complications
15 through the use of cystoscopy during surgery
16 for incontinence.

17 Dr. Gill?

18 MEMBER GILL: So, we have talked
19 about this a lot. It has been well-presented.

20 Stress incontinence is a common
21 problem. The procedure is very common. And
22 so, there is certainly a high impact here, in

1 my opinion.

2 And cystoscopy has been
3 recommended by -- three major guidelines
4 recommend this measure.

5 I guess we will go in order here,
6 though. You just want --

7 CO-CHAIR SAIGAL: The importance.

8 MEMBER GILL: -- impact and
9 importance.

10 So, yes, I mean, I am not going to
11 go through it all again, but it is very
12 important, I would say.

13 CO-CHAIR SAIGAL: Okay. So, and
14 then it comes to the panel about importance.
15 Again, this is a high-volume surgery.
16 Cystoscopy is used to decrease complications
17 for it. Is that important as a measure
18 nationally? That is the question.

19 So, we should vote.

20 MR. WILLIAMSON: We will now vote
21 on the impact. There are four options: high,
22 moderate, low, or insufficient. You may begin

1 voting now.

2 (Vote taken.)

3 And we have 13 high, 2 moderate,
4 zero low, and zero insufficient.

5 CO-CHAIR SAIGAL: Okay. So, now
6 the evidence surrounding this measure.

7 MEMBER PELLETIER-CAMERON: So, the
8 evidence is mostly the three recommendations
9 from the European Urology, AUA, and ACOG, who
10 have all recommended doing it. It is all
11 expert opinion and consensus. They didn't
12 really present a lot of or any evidence other
13 than those guidelines.

14 CO-CHAIR SAIGAL: So, there is
15 expert opinion. Isn't there some
16 observational data they mention in this, about
17 this?

18 MEMBER GILL: Right. I'm sorry,
19 yes. Yes, yes, yes. This one, there is
20 actually a fair amount --

21 CO-CHAIR SAIGAL: Right.

22 MEMBER GILL: -- of observational

1 data. There are some randomized controlled
2 trials as well.

3 I was thinking of the other one.
4 I'm sorry. There is actually quite a bit of
5 information supporting this.

6 CO-CHAIR SAIGAL: It sounds like
7 it is an area of controversy to some degree,
8 but that there is at least observational data
9 and there is some CEAs that have been done on
10 this topic.

11 I don't know, Stu or Anne, if you
12 have any comments about that or you are aware
13 of --

14 MEMBER BUTT: You are talking
15 about 052?

16 CO-CHAIR SAIGAL: 2052, using
17 cystoscopy to reduce complications of stress
18 incontinence.

19 MEMBER BUTT: Yes. I'm sorry.

20 MEMBER REYNOLDS: What I would say
21 is that, the way that the form is filled out
22 is that there is very little data actually in

1 the data part, and most of it is back under
2 the impact and the gap, which I think does
3 reinforce or suggest that there is some
4 evidence there, but it is poorly filled out.

5 CO-CHAIR SAIGAL: Uh-hum. Okay.

6 MEMBER GILL: Really, to go back
7 to what I said initially, the only evidence
8 they presented were those three guidelines in
9 the evidence section.

10 CO-CHAIR SAIGAL: Right. So, I
11 think there is a summary under 1(8)(3). They
12 talk about a study by Beckett in the use of
13 cystoscopy and what they found there in terms
14 of complications. There is a TVT study.
15 Those are both observational studies.

16 What else is in here? So, there
17 is at least two observational data and then
18 there are guidelines.

19 MEMBER REYNOLDS: In Section
20 1(b)(2), there are some very specific on
21 interoperative cystoscopy and injuries.

22 CO-CHAIR SAIGAL: 1(b)(2)?

1 MEMBER REYNOLDS: That is under
2 the gap.

3 CO-CHAIR SAIGAL: Right. The gap?
4 Again, this is this TVT study and a study by
5 Gill.

6 So, without cystoscopy, talking
7 about Gill, only 12 percent of injuries to the
8 lower tract were found at the time of surgery.
9 So, there are at least three observational
10 studies that they cite that show that there is
11 a benefit to patients for doing cystoscopy.
12 Cystoscopy is a two-minute, low-risk
13 procedure, and that is where we are at in
14 terms of evidence. And guidelines, of course,
15 consensus.

16 MEMBER MORTON: I would like to
17 hear from the urologists, you know, the
18 utility for this. It sounds like, for us in
19 GI surgery, we connect two pieces of bowel.
20 We do a leak test. This is essentially what
21 you are doing with the cystoscopy, make sure
22 there is not a leak. For us, for leak test,

1 there is some variation. Some people do them;
2 some people don't.

3 Is there a general consensus this
4 is important to do?

5 CO-CHAIR SAIGAL: Stu?

6 MEMBER REYNOLDS: It is analogous,
7 but, I mean, you are not looking for leak.
8 Usually, what you are looking for is actual
9 injury or perforation into the bladder. So,
10 for example, when you do these procedures, one
11 of the risks, that you could directly
12 penetrate into the bladder, into the urethra.
13 And so, you are looking to see.

14 And one of the great benefits is
15 that, whatever it acknowledges, if you looked
16 in and you saw that, you would just pull it
17 out, and then you can replace it safely. And
18 then, there is virtually no sequelae to the
19 patient. Whereas, if you did not look and you
20 left that piece of synthetic mesh in the
21 bladder, that is major sequelae. So, it is
22 certainly low-risk, high-yield in that sense.

1 MEMBER MORTON: This is really
2 primarily stones or repeated infections?

3 MEMBER GILL: Yes. It can be
4 stones. It can be repeat surgery required.

5 CO-CHAIR SAIGAL: Blocked ureter.

6 MEMBER GILL: It can be acquired
7 infection, ureter damage, right. It is a big
8 deal. It can be a very big deal.

9 MEMBER PELLETIER-CAMERON: And
10 some of the controversy that surrounds this is
11 that the retropubic approach, when you go
12 around the pubic bone, you are going right
13 next to the bladder. I mean, you are this far
14 from the bladder.

15 There is also a transobturator
16 approach where you go through the thigh and
17 approach the vagina from that direction, where
18 you are much further away from the bladder.
19 And that method was devised to minimize the
20 risk to the bladder. I think that is a little
21 bit more where the controversy arises. I
22 don't think anyone would do a retropubic

1 approach where they are doing a cysto, but the
2 obturator approach people would theoretically
3 do this without doing a cystoscopy, although
4 the rate of injury to the bladder is still
5 there, it is not zero ever.

6 MEMBER REYNOLDS: There is a
7 little bit of politics, historic politics,
8 that goes into this. And so, some of these
9 types of procedures which are lumped in
10 together were specifically designed ideally so
11 that you wouldn't have to do a cystoscopy
12 because there was thought that people who may
13 be able to do the procedure were or are not
14 qualified to do cystoscopy or not.

15 I think that a lot of that maybe
16 has gone away, and most people would agree
17 that cystoscopy is -- or is that not a fair
18 statement, that most people would agree that
19 cystoscopy is worthwhile or not?

20 CO-CHAIR SAIGAL: Jenifer, you had
21 a comment?

22 MEMBER LIGHTDALE: Yes, that was

1 my question. What would keep you from doing
2 this look? It sounds like politics maybe or
3 scope availability. I mean, I don't know.
4 Time? I mean, what else?

5 MEMBER REYNOLDS: Some of it is
6 training. I mean, I think that, originally,
7 when these were coming around, there was
8 concern that, for example -- and maybe you all
9 can speak more to this -- that maybe some
10 gynecologists weren't trained or credentialed
11 to do the cystoscopy, but they may be
12 credentialed to do the sling. And that is a
13 little bit before my time. And so, I don't
14 want to talk too much about it.

15 MEMBER GILL: No, I think you are
16 right. I think, historically, there were
17 those issues. I think that is mostly
18 historical now. I think we can distinguish
19 between diagnostic cystoscopy that I think
20 everybody that is doing these surgeries should
21 be able to do at the time versus more
22 operative or higher or advanced cystoscopy

1 that may be a different animal. But I think
2 everybody that is doing these slings now
3 should be able to do cystoscopy.

4 CO-CHAIR SAIGAL: Zahid, did you
5 have a comment?

6 MEMBER BUTT: Yes. It looks to me
7 that what is in 1(b) should be really in 1(c),
8 and there is not much in 1(b) for the gap,
9 which I guess we will get to next.

10 CO-CHAIR SAIGAL: Okay. Andy?

11 CO-CHAIR BASKIN: So, once again,
12 the non-surgeon here, I am very troubled by
13 what is in 1(b)(2) here, this one-line
14 statement that says, "It is largely
15 acknowledged that cystoscopy improves the
16 safety, but multiple studies have stated that
17 cystoscopy is not necessary and it is
18 economical to avoid performing the technique."
19 And it cites three studies, and you look down
20 and see the three things. Of course, I
21 haven't read those three articles.

22 So, by advancing this particular

1 measure, we are advancing the concept that
2 this is standard of care in this type of
3 surgery. I am a little puzzled. Is this
4 really standard of care in this type of
5 surgery or is this a controversial subject for
6 which there are people that say, no, it is not
7 necessary; it is not appropriate; you can pick
8 and choose; it is not economical; it is not
9 whatever? And therefore, I have trouble. We
10 are not creating standard of care here. That
11 is not our job.

12 MEMBER PELLETIER-CAMERON: There
13 might be studies that conclude that the rate
14 of interoperative injury is low, and then
15 maybe they take that result and say, well,
16 then you don't need to do it.

17 But I think, general consensus,
18 all the practice guidelines and people who do
19 this surgery routinely, I don't think anyone
20 would disagree that it should be done. The
21 rate of injury might be low, but the
22 consequences of a missed injury are very high.

1 So, I think that might be the only difference;
2 the rate might be low.

3 CO-CHAIR SAIGAL: It is a cost-
4 effectiveness argument that is being made.
5 Like per injury, you avoid your spending a lot
6 of money on cystoscopy. Those three articles
7 I think are talking about those kinds of
8 issues.

9 CO-CHAIR BASKIN: But that is a
10 reasonable thing. I mean, there are a lot of
11 surgeries and a lot of GI guys can say the
12 same thing. I mean, you know, to what extent
13 do you have to check when checking and doing
14 something extra takes more time, more money,
15 more everything, and the yield is very, very
16 low? Once again, is that standard of care or
17 is it not standard of care?

18 I am still not so sure that
19 consensus standards should say that, geez, it
20 seems like a really good thing to do because
21 we are going to find injury and it is not that
22 harmful to do, so everyone should do it. I

1 don't know that that is evidence that says
2 this is the standard, and that somebody would
3 be, you know, it would essentially be
4 malpractice not to perform this procedure.

5 CO-CHAIR SAIGAL: Well, I don't
6 now how much we consider economic
7 considerations in these measures. I mean, I
8 am not sure what the answer is to that. I
9 mean, I have never done it before.

10 MR. AMIN: Well, in terms of the
11 high impact, that is certainly where we will
12 look at the evidence. I mean, if the result
13 of this poor practice results in high cost,
14 then that is certainly something that should
15 be considered in high impact.

16 But just keep in mind, you know,
17 as we walk through this, we talked about
18 impact. Where we are right now is still
19 evidence. And reviewing what is in the
20 evidence component and not necessarily going
21 to what is in the gap component is really the
22 way you want to walk through this.

1 MEMBER REYNOLDS: Well, I was
2 going to say that, essentially, what you have
3 to weigh is that there are three of the
4 guidelines which are pretty unanimous in their
5 recommendation that interoperative cystoscopy
6 be performed. I would argue that that, then,
7 becomes the standard of care versus those
8 other three articles that you point up which
9 say it may not be as -- they are in different
10 parts of the document. So, it is hard to know
11 how to interpret that. Certainly, in the
12 evidence part of the document, they point to
13 the consensus guidelines which are those three
14 guidelines which would suggest that cystoscopy
15 would be considered routine or at least more
16 standard of care.

17 CO-CHAIR SAIGAL: John?

18 MEMBER MORTON: I think anytime
19 you are entering into another procedure like
20 a cystoscopy, you get asked the same question,
21 you know, risk/benefit. So, for us, if we are
22 looking for a leak, we can introduce a

1 gastroscopes, and we might go right through the
2 anastomosis. It sounds like that is not the
3 case here.

4 Is there some sort of negative to
5 doing the cystoscopy? Could you injure
6 something?

7 CO-CHAIR SAIGAL: There is a 1
8 percent chance of a bladder infection. That
9 is basically the issue.

10 MEMBER MORTON: And I guess my
11 other question would be in regards to the
12 cost. Since you are doing another primary
13 procedure, isn't this kind of bundled in? And
14 so, the incremental cost is actually not
15 substantial? I don't know.

16 CO-CHAIR SAIGAL: I would think
17 that it is bundled. It is bundled. So, it
18 isn't really a --

19 CO-CHAIR BASKIN: Bundled in in
20 terms of a separate reimbursement doesn't mean
21 it costs less. The cost of doing the
22 procedure for the facility, taking the scope

1 out, cleaning the scope, the nurse, the time,
2 and all that kind of stuff, is still there,
3 whether it gets separately reimbursed or
4 bundled in. So, there is a cost to doing
5 anything that takes out another instrument and
6 uses it and takes the time to do it.

7 CO-CHAIR SAIGAL: Johannes?

8 MEMBER KOCH: Yes, and just the
9 point, again, it is about the evidence here.
10 We are not grading whether the standard of
11 care is a good idea. We are saying that there
12 is evidence. And it doesn't appear that
13 anybody is making the argument that there is
14 evidence that says you should do this. There
15 is consensus, but there is no evidence.

16 CO-CHAIR BASKIN: There is
17 evidence in the document. There is
18 observational data that it --

19 MEMBER KOCH: Observational?

20 CO-CHAIR BASKIN: Yes.

21 MEMBER BUTT: Right. It is just
22 not presented in the evidence section. And

1 so, that is why people may not have seen it.

2 CO-CHAIR BASKIN: Okay.

3 MEMBER MERGUERIAN: They actually
4 cite one article about the cost. They cited
5 a 2005 article that they said the cost of
6 complications doubles. It doubles your cost.
7 So, performing a simple cystoscopy may
8 actually reduce that overall long-term cost of
9 complications.

10 MEMBER MORTON: I guess one more
11 comment. We have ways of grading the
12 evidence. We saw that slide you presented
13 earlier, you know, randomized trials, more
14 than five studies. I mean, based on that, do
15 we have it?

16 MR. AMIN: Well, keep in mind
17 that, when you are looking at guidelines that
18 are based on consensus, that would not meet
19 the criteria for quality, quantity, and
20 consistency. I think, again, we want to try
21 to keep this as systematic as we walk through
22 this as possible.

1 It sounds like you need to vote on
2 the evidence component. If you seek to,
3 again, invoke the exception, there needs to be
4 a discussion on how the benefits outweigh the
5 harms here.

6 But, in the way that it has been
7 discussed, this would not meet the NQF
8 criteria in terms of quality, quantity, and
9 consistency, based on guidelines that are
10 predominantly based on --

11 CO-CHAIR SAIGAL: But wait a
12 minute. Because, right here, you say that two
13 to four studies is moderate.

14 MR. AMIN: Two to four, and
15 then --

16 CO-CHAIR SAIGAL: So, there are at
17 least three studies that are cited here about
18 they are observational that show that there
19 are various documentations of injuries without
20 cystoscopy and with cystoscopy, I think.

21 MR. AMIN: So, that is the
22 quantity. And again, I am not here to make a

1 decision for you. If you feel like that meets
2 the criteria, that is fine. The quantity, you
3 have the five studies.

4 Evan, if you can move to the next
5 slide on the quality, looking at direct
6 evidence of the specific measure focus and
7 adequate size and the precision of the
8 measure. And again, this is information that
9 they should present to you in the evidence
10 component. Moderate is not in RCTs with
11 controls for the confounders, and low -- you
12 can read it for yourself.

13 But, then, the important thing,
14 also, is here in terms of consistency, in
15 looking that you have clear clinically and
16 practical, meaningful benefits and harms in
17 terms of the direction and magnitude of the
18 benefit. So, it is a high bar. There is a
19 clear high bar here.

20 CO-CHAIR SAIGAL: Sure. So, in my
21 reading of it -- and maybe I am wrong --
22 basically, in terms of the quality of the

1 data, it is low, and the number of studies is
2 moderate, and the consistency I think is
3 consistent.

4 I mean, the issue that Andy raises
5 is important about resource utilization, but
6 that is not a question as to whether the
7 direction of the benefit is positive or
8 negative. It is a question of whether it is
9 worth the money.

10 I think it is hard for us to say.
11 I mean, I don't know if we are that kind of a
12 panel to say that there is some financial
13 criteria that the intervention has to pass for
14 us to approve it. I mean, because they are
15 not saying that the study said that this
16 wasn't worth doing because it doesn't find
17 problems. They are just saying that the cost
18 associated with finding those problems is
19 high. So, that is a different dimension of
20 evaluating this. I just don't know at what
21 point we are supposed to do that. I think we
22 shouldn't, frankly.

1 MR. AMIN: Not in this evidence.

2 I mean, the resource use component would come
3 in under high impact. That's it.

4 CO-CHAIR SAIGAL: But it is high
5 impact in terms of the -- it is a value
6 question. That is what Andy is raising, is a
7 value. It is the impact over how much it
8 costs to get there, which is different even
9 from high impact, I think.

10 MR. AMIN: Right. Well, then, it
11 doesn't feel like it has the space right now.
12 I don't know that the cost-effectiveness
13 question --

14 CO-CHAIR SAIGAL: Yes.

15 MR. AMIN: It is an important
16 question, but I don't know where you fit it.

17 CO-CHAIR SAIGAL: Yes.

18 Andy, what do you think about
19 that?

20 CO-CHAIR BASKIN: I mean, part of
21 me says that I don't really want to take into
22 account cost-effectiveness. I am just not so

1 sure that I am just talking cost-effectiveness
2 here. I am talking about making, based on
3 evidence that doesn't tell me that this is
4 absolute standard of care -- that I am
5 measuring something that a reasonable
6 urologist or gynecologist may turn around and
7 say, in this case, it is not appropriate. And
8 I don't know there is enough evidence that
9 tells me that every time this is the
10 appropriate thing to do.

11 So, it is not just about the extra
12 cost and time. I mean, I am even going to set
13 that aside. That wouldn't be the reason for
14 me to say no on this one. I have just not
15 been convinced from this that there are three
16 sets of consensus standards that are not
17 necessarily totally evidence-based that say
18 this is the only way to do it; I mean, this is
19 the care, and we are going to measure whether
20 people are actually doing it or not. I just
21 don't -- I haven't made that link.

22 CO-CHAIR SAIGAL: Zahid?

1 MEMBER BUTT: Yes, I guess this
2 sort of comes back to that original question
3 about where do you put guidelines in because
4 most practicing physicians, when their
5 specialty gives them a guideline, they treat
6 that as standard of care, however they got to
7 that guideline. And so, that might be a very
8 important question, perhaps not for this
9 discussion, but a future discussion, because
10 that is considered, for all practical
11 purposes, the standard of care.

12 CO-CHAIR SAIGAL: Yes.

13 Anyone else have any comments?

14 (No response.)

15 All right. So, Stu? No? Okay.

16 So, I mean, maybe I am going to
17 try to summarize this very complicated
18 discussion. So, this is what I think I heard
19 from the group.

20 In terms of the evidence
21 supporting this measure, that there is low
22 quality of evidence, some observational data

1 that is not well-controlled that indicates
2 that cystoscopy has a benefit. And there is
3 also a consensus from guidelines that it is a
4 good thing to do. And the consensus statement
5 stuff, we don't meet the NQF quality criteria.

6 There is a moderate quantity of
7 evidence, and I think the direction of the
8 evidence is in a positive direction for
9 cystoscopy.

10 We had a side discussion about
11 whether it is worth the cost because there
12 were data that the developers cited that some
13 people thought it wasn't cost-effective. But,
14 at this point, we are not going to include
15 cost-effectiveness in our decision.

16 And some of us noted that the
17 evidence was presented in the document in a
18 variety of places where it could be better
19 organized.

20 So, I think, based on that, we
21 should vote as to whether we feel that the
22 evidence meets the guidance for support,

1 whether it does not meet the guidance for
2 support, or whether there is other data
3 available that we are aware of that would
4 support the data that wasn't presented here.
5 Okay.

6 MR. WILLIAMSON: We will now vote
7 on the evidence.

8 You may begin voting now.

9 (Vote taken.)

10 CO-CHAIR SAIGAL: Okay. So, in
11 this case it did not meet the evidence basis.
12 So, we have got to vote as to whether this is
13 an important enough measure that we would go
14 around the NQF standards for data to proceed.
15 And that would be on the basis that we think
16 this is just the gestalt or the reading of the
17 measure, it sounds like a good thing to do,
18 and it is important enough to patients that we
19 would say we don't need the evidence to move
20 forward with it.

21 Any comments about that before we
22 vote?

1 Stu?

2 MEMBER REYNOLDS: So, I would
3 argue that, even though the data is not
4 presented, that it is considered the standard
5 of care to do cystoscopy at the time you do
6 sling, and that certainly the risks of doing
7 that and potentially the cost are far
8 outweighed by the risk of not doing it. So,
9 the benefits are far outweighed by the risk of
10 not doing it.

11 CO-CHAIR SAIGAL: Thank you.

12 Personally, I agree. I think if
13 my mom was having the surgery, for sure I
14 would want her to have a cystoscopy. It is a
15 low-risk thing to do, and it definitely
16 catches things that are serious. So, my bias
17 is that it is important, but the evidence is
18 not super-strong.

19 Okay. So, should we vote?

20 MR. WILLIAMSON: Yes, we will now
21 vote on the potential exception to empirical
22 evidence. Again, this will be a hand vote.

1 For yes, please raise your hand.

2 (Show of hands.)

3 And for no?

4 (Show of hands.)

5 Okay. So, we have 13 yes and 2

6 no.

7 CO-CHAIR SAIGAL: Okay. So, then,
8 the last part is the gap.

9 MEMBER GILL: So, in the gap data,
10 they don't really present a gap, that people
11 are doing it or not doing it. They just
12 presented several articles that have suggested
13 it may not be necessary. So, it is a little
14 difficult to see the data on the gap
15 performance to me, although it is implied that
16 there might be one.

17 CO-CHAIR SAIGAL: Okay. So, it
18 is, I guess, inconsistently presented in the
19 document. I think my reading of the studies
20 about whether cystoscopy is beneficial or not,
21 some people are not doing it. So, that is
22 just logical, I guess. But they do have the

1 observational data that like a third of people
2 use routine cystoscopy. So, I think it is
3 probably, my reading, there is a gap.

4 Any other comments?

5 (No response.)

6 Okay. So, let's vote as to
7 whether there is a documented gap in the
8 performance of this measure.

9 MR. WILLIAMSON: We will now vote
10 on the performance gap. There are four
11 options.

12 You may begin now.

13 (Vote taken.)

14 And we have 2 high, 7 moderate, 4
15 low, and 2 insufficient.

16 CO-CHAIR SAIGAL: Okay. Then, the
17 next vote will be on whether the concept
18 should be approved. So, to summarize it, it
19 is looking at cystoscopy after the surgery.
20 We think it is important to measure. We felt
21 that the evidence supporting the measure was
22 insufficient according to NQF standards, but

1 we felt that the problem was a big enough
2 problem for the public that it was worth it to
3 circumvent the NQF standard.

4 And we felt there was a gap.
5 Generally speaking, the gap wasn't documented
6 at a high level but at a moderate level.

7 And now, we can say if we think we
8 should approve this and move forward to stage
9 two.

10 MR. WILLIAMSON: We will now vote
11 on the overall recommendation. This is a
12 yes/no vote.

13 You may begin now.

14 (Vote taken.)

15 We have 11 yes and 4 no.

16 CO-CHAIR SAIGAL: Okay. That was
17 the last -- are there any comments for the
18 developers?

19 MEMBER PELLETIER-CAMERON: Just in
20 their exclusions, in this one specifically,
21 they state that concomitant prolapse surgery
22 is an exclusion, but I don't see why that

1 would make you an exclusion, because what we
2 are hoping to measure is that if there is an
3 injury from your stress incontinence surgery,
4 and I don't see how prolapse surgery factors
5 in it.

6 I know it does in decisionmaking
7 and treatment plans, but I don't see how
8 having a prolapse surgery would make the use
9 of cystoscopy any different. So, I disagree
10 with that as an exclusion.

11 CO-CHAIR SAIGAL: Okay. So, the
12 developers should just note that, once again,
13 the exclusions in the document are being
14 questioned.

15 Zahid?

16 MEMBER BUTT: I think it would be
17 good to provide evidence for the gap because
18 I think that is a gap.

19 (Laughter.)

20 CO-CHAIR SAIGAL: Okay.

21 MEMBER BUTT: And I voted no, to
22 be consistent because I voted no on the gap

1 question.

2 CO-CHAIR SAIGAL: Okay. Got it.

3 So, the document could be attended to,
4 reorganized, and gap information could be
5 strengthened.

6 Liliana?

7 MEMBER BORDEIANOU: So, the
8 question I have is whether we should specify
9 which of the two approaches. One is much more
10 standard of care than the second one.

11 CO-CHAIR SAIGAL: For prolapse?

12 MEMBER BORDEIANOU: All right.
13 So, do I have to wait for the green light to
14 go on?

15 CO-CHAIR SAIGAL: No.

16 MEMBER BORDEIANOU: So, the only
17 question I had is whether or not we should
18 have a specification about which approach is
19 being used, because it sounds like cystoscopy
20 is much more important in one versus the
21 other.

22 CO-CHAIR SAIGAL: Okay.

1 MEMBER BORDEIANOU: And that might
2 be the issue about the gap and where it is
3 standard of care and where it is not.

4 CO-CHAIR SAIGAL: Okay. So, a
5 suggestion that the measure be divided
6 specifically by procedure for the developer to
7 consider as a plus or minus.

8 Ed?

9 MEMBER GILL: And then, also, for
10 the developer, going forward -- this would be
11 for stage two -- in terms of feasibility and
12 usability, I don't put myself out there as a
13 coding expert, but we talked about this a
14 little bit before. I am not sure you are
15 going to capture all the cystoscopies that
16 were done if you use CPT codes because it may
17 be bundled and not show up that it was done at
18 all. You may not be able to measure it using
19 your criteria.

20 CO-CHAIR SAIGAL: Okay. So, a
21 caution on feasibility.

22 Okay. So, with that, then, there

1 is a member and public comment period. And
2 so, I would invite anyone monitoring us --

3 MS. WILBON: Let's start with
4 people in the room. If you have any comments
5 or would like to address the Committee, please
6 queue at the microphone. And then, if there
7 is no one in the room, then we will go to the
8 phone.

9 (No response.)

10 It looks like no one in the room.

11 Operator, Arnika, if there is
12 anyone on the phone who would like to make a
13 comment, could you please give them
14 instructions on how to address the Committee?

15 THE OPERATOR: At this time, in
16 order to ask a question, press *, then the
17 number 1 on your telephone keypad. We will
18 pause for just a moment to compile the Q&A
19 roster.

20 (Pause.)

21 Again, to ask a question, press *,
22 then the number 1 on your telephone keypad.

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(No response.)

CO-CHAIR SAIGAL: Okay. So,
hearing no comments, maybe we can have lunch.
And so, 12:45 is lunch, is a 15-minute break
for lunch. So, we have a working lunch?

(Whereupon, the foregoing matter
went off the record for lunch at 1:16 p.m. and
went back on the record at 1:36 p.m.)

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

2 1:36 p.m.

3 CO-CHAIR SAIGAL: Do we have the
4 AUGS representative here? Great.

5 Okay. So, our next set of
6 measures --

7 MR. AMIN: Chris, I think we still
8 have one more AUA one.

9 CO-CHAIR SAIGAL: Oh, I'm sorry.
10 That is an AUA measure.

11 MR. AMIN: 2054.

12 CO-CHAIR SAIGAL: Sorry about
13 that. I'm sorry. We will call you up in a
14 minute. Okay? We jumped the gun.

15 So, Stu, C2054, assessment of
16 treatment within one year of SUI surgery.

17 MEMBER REYNOLDS: You were just
18 hoping that we had finished with all the
19 stress incontinence ones.

20 (Laughter.)

21 So, this is Measure No. 2054,
22 which is entitled, "The assessment of

1 treatment within one year of stress urinary
2 incontinence surgery".

3 It is very similar to the ones
4 that we have been discussing. Here, the
5 numerator is the number of female patients who
6 have had stress incontinence surgery and then
7 received four components of their
8 postoperative assessment within a year of
9 their surgery: characterization of
10 incontinence, physical examination, post-void
11 residual analysis, and urinalysis urinary
12 culture. This is very similar to the ones
13 that we had discussed previously in the preop
14 assessment.

15 The denominator statement is those
16 who underwent stress incontinence, and there
17 are, again, very similar exclusions to the
18 ones that we had addressed before.

19 Again, this is a process concept.
20 I think it is important because, in terms of
21 the outcome, it is, again, not entirely clear
22 to me what the overall outcome is or exactly

1 how the process relates to that, but we will
2 probably discuss that a little bit more as we
3 go forth.

4 I would draw your attention, there
5 were a number of comments made by the
6 technical staff regarding this one, as well as
7 comment from the members. And then, there
8 were some previous ratings and comments. They
9 are on some of those forms. I won't read them
10 for you.

11 But I guess I would say that our
12 first task is to look at the impact. And
13 again, similar to the previous ones, there are
14 a number of studies that are included that
15 suggest that stress incontinence is common
16 and, thus, has a great impact on not only
17 U.S., but also worldwide populations, although
18 the evidence does not specifically relate to
19 the measure, but mostly to the idea of stress
20 incontinence, and that stress incontinence
21 surgeries are commonly done.

22 CO-CHAIR SAIGAL: So, Stu, besides

1 the evidence, just we are going to be voting
2 on the impact, I suppose.

3 MEMBER REYNOLDS: Yes.

4 CO-CHAIR SAIGAL: So, could you
5 just summarize, is this an important national
6 health goal? Does not have a lot of people
7 that are affected by it? A lot of resources
8 that are used to treat it?

9 MEMBER REYNOLDS: Yes to all the
10 above questions.

11 CO-CHAIR SAIGAL: Okay.

12 MEMBER REYNOLDS: And they give
13 specific details which are, again, the same
14 ones that have been on the other ones. But
15 anywhere from 4 to 30 percent of the female
16 population, direct costs of over \$13 billion
17 back in 1995, and it has, presumably,
18 increased since then. So, yes, I would say at
19 least certainly moderate to high impact --

20 CO-CHAIR SAIGAL: Okay.

21 MEMBER REYNOLDS: -- would be my
22 recommendation.

1 CO-CHAIR SAIGAL: Andy?

2 CO-CHAIR BASKIN: Well, I would
3 argue that this measure, the impacts already
4 occurred before this measure. I mean, the
5 costs are all gone. I mean, that has all been
6 done. Now we are measuring whether you should
7 be doing something a year later. I am not so
8 sure what the high impact is of people who
9 have already had surgery. That impact is not
10 part of this, you know, a year later getting
11 an assessment. I don't necessarily read that
12 as being high impact.

13 CO-CHAIR SAIGAL: I think if you
14 look at the way it says here, "a specific
15 national health goal or priority," so I think
16 measuring outcomes of care is a health
17 priority for us. Would you agree? And
18 certainly, treatment efficacy is part of that.
19 So, in my mind at least, having attention to
20 outcomes is a health priority.

21 DR. PACE: Except this measure is
22 not about outcomes. It is about another

1 process of assessment.

2 CO-CHAIR BASKIN: All right. What
3 is about the characterization of incontinence,
4 a history, of physical, a post-void analysis,
5 that is truly a measure of outcome? I mean,
6 this is the real outcome, is patient
7 satisfaction, patient functional status. I
8 mean, you know, stuff that is beyond what they
9 are asking here.

10 CO-CHAIR SAIGAL: Well, they are
11 characterizing incontinence in this measure
12 postoperatively. I mean, that is the medical
13 outcome of the measuring.

14 DR. PACE: Right. So, for us to
15 consider this an outcome measure, it would be
16 something like percent of women who have the
17 surgery who have their incontinence resolved.
18 That would be the outcome measure.

19 So, this is really about the
20 process of doing an assessment. One of the
21 rationales given was so that you can have some
22 outcome data, but that is not an outcome

1 performance measure. It is still just the
2 process.

3 CO-CHAIR SAIGAL: Okay. So, to be
4 clear, this is still a process-of-care measure
5 that relates to a potential outcome-of-care
6 measure which would be measuring the success
7 of the surgery. So, in my view -- and anyone
8 who wants to, please jump in -- the way that
9 it meets high impact is because it is a
10 process that allows us to measure outcome,
11 which is a health goal and priority for the
12 country, in my view.

13 But Andy and Karen feel that it is
14 not necessarily a process that matters because
15 the surgery has already happened, and that we
16 are not doing something to actually say, was
17 the surgery success or not?

18 Andy, am I getting you right?

19 CO-CHAIR BASKIN: No, I agree. I
20 think an assessment a year later is a good
21 idea, but if the assessment is truly a measure
22 of success, not a measure of documentation

1 that you ask the question.

2 CO-CHAIR SAIGAL: As written, it
3 is a process measure. You don't have to say
4 whether the person was continent or not.

5 Okay. And are there other
6 comments about the impact or the nature of
7 this kind of -- Judith?

8 MEMBER TOBIN: Because I am trying
9 to evaluate the process of evaluating these
10 measures, isn't part of evaluating a process
11 measure its proximity to the outcome? So,
12 then, the issue that Andy spoke to earlier
13 would be important if you don't think that
14 proximity, you know, if it is too far away
15 from the outcome to have any kind of an
16 impact. That was something, as I went through
17 these, I was thinking about as well.

18 CO-CHAIR SAIGAL: I think that
19 Andy was talking about the surgery already
20 happened. I think what you are talking about
21 is it is a process-of-care measure that is, I
22 think it is proximate to measuring an outcome.

1 I mean, it is within a year. If you ask a
2 person, "Are you still incontinent," and they
3 say yes, you can then make the link and say,
4 well, you are going to record that in the
5 database and have an outcome. So, I think
6 that is a pretty proximate measure.

7 But what Andy was talking about
8 is, is it worth it to measure a process-of-
9 care measure after the surgery is done? I
10 think that is the distinction that we have to
11 decide on, where we lie.

12 Okay. Yes, Paul?

13 MEMBER MERGUERIAN: If you look at
14 the numerators, they are pretty much the same
15 measures that they had in 2049, which is a
16 preoperative assessment, except for one
17 measure, basically. So, it is really looking
18 at the characterization of the incontinence.
19 If they are incontinent, it is a focused
20 physical, post-void residuals, and urinalysis.

21 CO-CHAIR SAIGAL: Yes, right. And
22 what is your conclusion from that?

1 MEMBER MERGUERIAN: Well, it
2 should be part of the examination. The
3 question is if we link that to an outcome. I
4 mean, I have a hard time trying to figure out
5 those process measures without linking it to
6 an outcome, because we have got to link
7 process with outcome. And what is the outcome
8 that they are looking it? Is it really
9 success of surgery?

10 CO-CHAIR SAIGAL: Yes, that is a
11 good question. That is basically the idea.
12 Is this process-of-care measure important to
13 measure because the implication is you would
14 learn if the person was incontinent or not
15 after surgery. So, if you believe that that
16 is a reasonable thing to do as a measure, then
17 you vote this as high impact. If you think it
18 is not important enough to do that, you should
19 measure directly the outcome, then you can
20 vote a different way.

21 MS. WILBON: I just wanted to
22 point out that there is a question on the form

1 that asks the developer to demonstrate where
2 they feel like this measure falls in that
3 stream, that value stream. It is 1(c)(3).
4 So, if you are trying to figure out which
5 outcome they felt like they were measuring to
6 be proximal to, it will give you an idea of
7 what their value stream was for mapping the
8 process/outcome linkage.

9 CO-CHAIR SAIGAL: Uh-hum. Okay.
10 Yes?

11 MEMBER BORDEIANOU: What I thought
12 I heard is that the measure also looks at
13 complications of surgery. So, measuring the
14 post-void residual shows you whether or not
15 the sling is too tight. And so, it is a
16 process of quantifying complications.

17 CO-CHAIR SAIGAL: It is a process
18 that you would need to do to get an outcome
19 like a complication rate.

20 She is saying that PVR, measuring
21 the post-void residual, if you have a high
22 post-void residual, then the person is in

1 retention, and that is possibly as a result of
2 the surgery causing the sling to be too tight.
3 So, again, it is a process that measures a
4 potential outcome.

5 Robert?

6 MEMBER ELLIS: Since this is being
7 measured using administrative data and paper
8 records, is there a specific identifier for
9 this type of followup that would identify
10 specifically what we are trying to measure
11 here?

12 CO-CHAIR SAIGAL: Well, I am not
13 sure that we are supposed to get into
14 feasibility of it.

15 MEMBER ELLIS: Okay. I'm sorry.

16 CO-CHAIR SAIGAL: But I think
17 that, just in general, some of these things
18 are capturable by CPT codes, yes, PVRs,
19 physical exams, urinalysis and culture.
20 Obviously, the characterization of
21 incontinence is not. It is from a CPT II
22 code.

1 DR. PACE: In general, the CPT II
2 codes are the physician saying that they did
3 these four or five. So, it would be giving a
4 code that says I did this post-surgery
5 assessment, is generally the way they are
6 structured.

7 But, in this case, again, this is
8 a concept. So, we don't have that detail yet
9 of what the CPT II code would actually be.

10 CO-CHAIR SAIGAL: Okay. Can we
11 vote then whether this is high impact? Can we
12 vote as to whether this is high impact or not?

13 MR. WILLIAMSON: We will now vote
14 on the impact. There are four options: high,
15 moderate, low, or insufficient.

16 You may begin voting now.

17 (Vote taken.)

18 I think that is every single one.

19 Zahid is out of the room. Okay.

20 And we have 2 high, 7 moderate, 4
21 low, and 1 insufficient.

22 CO-CHAIR SAIGAL: Okay. So, then,

1 I think it proceeds. So, now you talk about
2 the evidence underlying the measure.

3 MEMBER REYNOLDS: So, in the
4 portion of the document in which there is and
5 should be evidence, there is essentially no
6 evidence listed. That would be in the pilot
7 submission form under Sections 1(c).4 all the
8 way to 1(c).13.

9 I don't have a great opportunity
10 to explain this. There is some data discussed
11 in other sections. This is a problem we have
12 run into before.

13 I am not aware specifically of
14 data that suggests, if you do or do not check,
15 it would affect the outcome of the measure.
16 I think that is either difficult to measure or
17 maybe hasn't well been done. Certainly, the
18 AUA guidelines, which have been previously
19 referenced and are referenced, recommend for
20 efficacy studies that you should have at least
21 12 months followup data for that. But I am
22 not sure there is any other data that suggests

1 there is a specific --

2 CO-CHAIR SAIGAL: Okay. So, this
3 is one of the situations, I think, unless
4 there is other data that people are aware of
5 that is relevant here, where this is
6 essentially a consensus statement from experts
7 that you should measure or you should ask
8 patients about how they are doing after
9 surgery and examine them. So, I think
10 probably we would be in the situation we had
11 in the past in this vote.

12 Are there any other studies people
13 are aware of that are relevant regarding
14 physical exam after surgery?

15 (No response.)

16 Okay. Then, I would suggest we
17 move to a vote on the evidence, whether, yes,
18 it does meet the NQF criteria; 2, it does not,
19 or 3, there is evidence around us that we are
20 aware of that they are not aware of.

21 MR. WILLIAMSON: We will now vote
22 on the evidence.

1 You may begin voting now.

2 (Vote taken.)

3 CO-CHAIR SAIGAL: Okay. So, it
4 doesn't meet the NQF criteria.

5 MR. WILLIAMSON: Just for the
6 record, we have 13, no, that the evidence does
7 not meet the guidance for the quality,
8 quantity, consistency, and 1, no, that there
9 is insufficient information submitted.

10 CO-CHAIR SAIGAL: Okay. The
11 person who voted insufficient, is that because
12 you are aware of other data? Or was that just
13 a misfire? Or don't want to admit it?

14 (Laughter.)

15 Okay. So, then, in terms of the
16 next vote, it has got to be as to whether we
17 think that, if a person has had surgery, that
18 quantifying their incontinence after surgery
19 and doing a physical exam is important enough
20 and has enough face validity that we would
21 skip evidence to support it.

22 And again, we are not talking

1 about getting an outcome recorded, but just
2 doing a process to collect data. That is what
3 we are measuring. So, that is the question
4 for the group.

5 Any comments about that? Yes?

6 MEMBER BORDEIANOU: I would say
7 that, if we are reporting the data, we would
8 want to report much more data about an outcome
9 with surgery than just that, complications, et
10 cetera.

11 CO-CHAIR SAIGAL: So, you
12 conceptually could have more data?

13 MEMBER BORDEIANOU: Incontinence.
14 Yes, more.

15 CO-CHAIR SAIGAL: Okay.

16 MEMBER BORDEIANOU: I don't think
17 it is sufficient.

18 CO-CHAIR SAIGAL: Stu?

19 MEMBER REYNOLDS: I have a little
20 bit of issue in sort of how they are defining
21 the timing of it. And I don't know if that
22 comes up now or at another time. I mean, it

1 is within 12 months. Admittedly, I think it
2 is hard to know what the correct timing would
3 be, but there is a big range between one day
4 and 12 months, if you are looking at outcomes.
5 And so, I think there is a flaw here in terms
6 of the timing of that. I don't know what the
7 right answer is, but I see that as an issue.

8 CO-CHAIR SAIGAL: Okay. So, I
9 think these two comments have to do with our
10 general sense of how important this measure
11 is. If it was a great measure without a lot
12 of concerns, maybe we skip over the fact that
13 there is no evidence to support its
14 implementation. But if there are concerns
15 about the measure itself in terms of how it is
16 constructed or the value of the data it
17 provides, that is something we have to
18 consider as well.

19 Any other comments about this
20 measure?

21 (No response.)

22 I will say that my take on it is

1 that it is important to measure. I think that
2 it would be nice to link it to some harder
3 recording of what the result was about the
4 patient was incontinent or not incontinent in
5 the chart. But that is just my view.

6 All right. So, we should vote.
7 So, this is a hand vote?

8 MR. WILLIAMSON: I think it is
9 fixed now.

10 CO-CHAIR SAIGAL: Oh, good. Okay.

11 MR. WILLIAMSON: We will try this,
12 and if it doesn't work, then we will do a hand
13 vote.

14 But we will now vote on the
15 exception to the evidence.

16 You may begin voting now.

17 (Vote taken.)

18 We stand at 14, yes. If everybody
19 wants to point at the receiver again? There
20 we go.

21 And we have 4 yes and 10 no.

22 CO-CHAIR SAIGAL: Okay. Then, it

1 does not pass the exception measure. So,
2 then, it doesn't proceed. Okay.

3 And then, are there comments for
4 the developers that we ought to give them?

5 So, I could summarize what I have
6 heard. Mainly, the concern was that just
7 having a process-of-care measure at this point
8 in the evaluation was a little weak, and that
9 having an outcome measure would be better;
10 that to look at outcomes, maybe there are more
11 data points that you would want to collect
12 specifically from patients in terms of
13 infections, or whatever it might be, and that
14 the window of assessment could be better
15 defined. It is a little broad from day one to
16 day 365.

17 Anything else? Comments for the
18 developer?

19 (No response.)

20 Okay. Good.

21 Then, the next one -- yes?

22 MEMBER SCHOENFELD: Evan, could

1 you go back one slide? Right. No. Right
2 there.

3 I just wanted to reaffirm
4 something that I think I heard from Karen and
5 Taroon before, even though I got here a little
6 bit late. We have already come to this kind
7 of a vote a few times. And I just wanted to
8 make sure I understood.

9 Voting yes to this kind of
10 question should truly be unusual and uncommon.
11 Is that the overarching philosophy about this?
12 I mean, I am a gastroenterologist, not a GU
13 specialist. I am not trying to step on
14 anybody's toes. But I just want to make sure
15 I am reaffirming what I heard was the
16 philosophy with respect to this situation.

17 MR. AMIN: We will tag-team here.

18 I think, clearly, yes, it should
19 be an exception and there should be a
20 compelling reason why you should vote yes.

21 And there have been discussions
22 earlier today in which there have been, in the

1 sense that a randomized controlled trial or
2 any other experiment would be clinically
3 unethical or that the benefits clearly
4 outweigh the harms in terms of the benefit to
5 the patient.

6 So, really, this is intended to be
7 an exception. I mean, the challenge with
8 invoking this frequently is that you can make
9 an argument that a measure that is really
10 distal to an outcome would not have evidence
11 as well. But what we are really trying to do
12 is get measures that are closer or more
13 proximal to outcomes.

14 So, when you invoke this, it
15 becomes very unclear to those external on
16 which one it is. Is it just so distal that it
17 won't have evidence or that there isn't
18 evidence because of some exceptional reason,
19 but the benefits greatly outweigh the harms.

20 And so, there needs to be an
21 explanation, a clear rationale from the
22 Committee that, when you are invoking this,

1 why, very clearly why, and what the benefit to
2 the patient is. And there should be a high
3 bar for why you let measures go forward under
4 this exception.

5 But, Karen, if there is
6 anything --

7 MEMBER SCHOENFELD: When I heard
8 you say that, it just kind of reminded me to
9 expand on what John said. I mean, yes, we
10 don't need a randomized controlled trial about
11 the efficacy of parachutes when you jump out
12 of a plane. On the other hand, I am not sure
13 we need a quality indicator to say, yes, you
14 should wear a parachute when you jump out of
15 a plane.

16 DR. PACE: And I think that is the
17 crux of it. First of all, I will keep
18 emphasizing our criteria do not require
19 randomized controlled trials. We recognize
20 all types of evidence. But I think the real
21 issue is trying to, as Judy mentioned, our
22 guidance is to really focus National

1 Performance Standards on those things that are
2 most proximal to the desired outcome.
3 Because, as you know, once you assess
4 something, somebody has to actually interpret
5 that assessment. They have to identify
6 potential treatment alternatives. They have
7 to discuss those. The right treatment has to
8 be applied before you really get to the
9 outcome.

10 And so, measuring something way
11 down here does not in any way assure that we
12 are going to get to the outcomes. And so, the
13 push from NQF is for National Performance
14 Standards to measure those things that are
15 most proximal. It doesn't in any way say that
16 assessment isn't important; it is critical.
17 You all have to do it in everything that you
18 do. But we are trying to get at those things
19 that are most important in terms of National
20 Performance Standards. Because, as you can
21 all imagine, there are thousands of things
22 that you do that could be measured if we start

1 talking about all the different assessments
2 that all the different patients could have.
3 And that is really the emphasis.

4 CO-CHAIR SAIGAL: Okay. So, then,
5 that is that for that measure.

6 Okay. The next one, Stu, it is
7 yours still, C2037.

8 MR. AMIN: But you want the --

9 CO-CHAIR SAIGAL: Oh, yes, yes,
10 yes.

11 AUGS, could you please come up and
12 introduce your measures?

13 MR. AMIN: This is for the set of
14 measures. I just want to make that clear.

15 CO-CHAIR SAIGAL: The next three
16 measures, two or three minutes of your time,
17 please. Thanks.

18 MS. PULLIAM: My name is Samantha
19 Pulliam. I am from Massachusetts General
20 Hospital, and I am here to present the next
21 three measures for the American Urogynecologic
22 Society.

1 The first measure is evaluating
2 the percentage of female patients with a
3 characterization of the degree or prolapse in
4 each vaginal compartment using a validated,
5 objective measurement system. And we would
6 like that to happen within 12 months of
7 surgery.

8 Annually, there are over 200,000
9 surgeries to repair pelvic organ prolapse, and
10 there is a great diversity of surgeries
11 addressing a variety of problems within the
12 pelvis. Failure to fully evaluate prolapse
13 causes inadequate or incorrect surgical
14 repair, resulting in increased patient
15 morbidity, failure of the surgeries, and
16 reoperation rates that are increased, and
17 often resulting in unneeded expense.

18 The POP-Q, which stands for Pelvic
19 Organ Prolapse Quantitative System, and then
20 the Baden/Walker, which is the antecedent to
21 that, are validated, objective ways to
22 evaluate all areas of prolapse in the vagina.

1 These measurement systems are taught in
2 residency. But only 43 to 78 percent of
3 people who could use these tools do so.

4 The evaluation systems are
5 endorsed by the American Urogynecologic
6 Society, the International Urogynecologic
7 Association, the International Continence
8 Society, and the NIH. We believe that
9 universal use optimizes communication and
10 treatment for these women.

11 The POP-Q system, for example, is
12 an evaluation using nine points within the
13 pelvis to quantify the anterior vaginal wall,
14 the posterior vaginal wall, and the top of the
15 vagina and the uterus.

16 This is a high-impact measure in
17 that evaluates properly over 200,000 women who
18 are going to undergo surgery. There is a gap
19 in that maybe up to 50 percent of specialists
20 don't use this. And this is a validated tool
21 that is recommended by multiple societies.

22 The second measure looks at

1 suspension of the top of the vagina during
2 surgery for pelvic organ prolapse. To perform
3 a hysterectomy alone on a patient who has
4 pelvic organ prolapse is to leave the apex of
5 the vagina unsuspended and does not repair the
6 problem.

7 Over 78,000 hysterectomies are
8 performed each year for pelvic organ prolapse,
9 and perhaps only 53 percent of patients have
10 vaginal apical suspensions at the time of this
11 hysterectomy. This means that there is an
12 increased risk of repeat surgery; 7.4 percent
13 of those with hysterectomy alone as compared
14 to 2 percent who have a complete prolapse
15 repair require repeat surgery.

16 This is an American College of
17 Obstetrics and Gynecology guideline. It is
18 interesting in that there are multiple
19 systematic reviews looking at which type of
20 apical suspension is appropriate. And perhaps
21 most impressive for its absence, hysterectomy
22 alone is not a type of suspension for the

1 vagina apex. It would be unethical, we think,
2 to perform a randomized trial evaluating the
3 absence of an apical repair to address
4 prolapse.

5 Again, a high-impact evaluation.
6 The gap is present and has been demonstrated,
7 and the evidence has been evaluated in
8 multiple systematic reviews.

9 The final measure is looking at
10 patients who undergo cystoscopy at the time of
11 surgery for correction of anterior or apical
12 vaginal prolapse. Damage to the ureters and
13 the bladder at the time of prolapse repair
14 surgery can occur at a rate of 5.1 percent.
15 In many studies, only as few as 12 percent of
16 ureteral and 35 percent of bladder injuries
17 are detected without cystoscopy. And we know
18 that unrecognized damage is dangerous and
19 expensive and may result in hospital
20 readmissions, repeat surgeries, and even renal
21 demise.

22 Routine cystoscopy identifies 99.4

1 percent of bladder of ureteral injuries, and
2 is cost-effective for an injury rate of 1.5 to
3 2 percent. This is a guideline that is
4 endorsed by the American College of Obstetric
5 and Gynecology. This is a procedure for which
6 ACGME residency programs in both obstetrics
7 and gynecology provide training. In most
8 operating rooms, cystoscopy equipment is
9 readily available.

10 So, again, this is a high-impact
11 procedure. There is a defined gap of people
12 who fail to perform this procedure, and there
13 are systematic reviews that contain strong
14 evidence supporting routine cystoscopy for
15 procedures repairing prolapse.

16 CO-CHAIR BASKIN: Thank you.

17 Stuart? Oh, okay. So, Stuart,
18 you are the lead discussant here?

19 MEMBER REYNOLDS: Yes.

20 So, this is specific to the first
21 concept, which is No. C2037, objective
22 characterization of pelvic organ prolapse

1 prior to surgery. We had a good overview
2 there.

3 I would point out that the
4 numerator for this concept is the number of
5 patients whose pelvic organ prolapse exam was
6 documenting using a validated tool as
7 described, either the POP-Q or the
8 Baden/Walker, within 12 months prior to
9 surgery for pelvic organ prolapse. And then,
10 the denominator is all the patients or women
11 who have undergone pelvic organ prolapse
12 surgery.

13 Again, this is a process concept.
14 There is a component of the relationship
15 between this process to an outcome measure,
16 and it is suggested that proper documentation
17 of the degree of prolapse will likely increase
18 the chance of the appropriate procedure and,
19 thus, reduce the risk of recurrent prolapse
20 later.

21 I guess getting to the meat of
22 what we are here to discuss is the impact.

1 Pelvic organ prolapse is a common condition.
2 There are a lot of surgeries that are being
3 performed in the U.S. for it. There is some
4 increased impact or awareness because of
5 ongoing issues brought on by the FDA over the
6 last couple of years regarding the common
7 materials used for these types of repairs,
8 specifically the synthetic mesh that we have
9 been talking about before, but plays a bigger
10 role in the pelvic organ prolapse.

11 And so, the impact, for example,
12 of getting the diagnosis correct maybe is even
13 more important here because the negative
14 aspects also can be so high. And so, I guess
15 looking at the evidence for high impact, well,
16 I guess we could open that up for discussion,
17 but it looks like there is probably something
18 in terms of moderate, in terms of how much
19 prolapse plays a role.

20 It is not clear from the evidence,
21 the summary of the evidence for high impact
22 exactly what the role of the POP-Q or the

1 Baden/Walker assessment is in that, but that
2 is, I presume, a presumptive relationship.

3 CO-CHAIR SAIGAL: So, thank you.

4 Any comments here? I mean, it
5 sounds like there are two parts of this. One
6 is that this characterization occur. And two
7 is, should it occur with one of these
8 objective tools? I don't know whether people
9 want to speak either one of those. I am not
10 an expert here, other than, once again, this
11 is one of those did you take a history; did
12 you characterize it happening. I can't speak
13 to the value of these tools versus an
14 alternative. So, if someone could, that would
15 be very helpful for me.

16 MEMBER REYNOLDS: Well, I would
17 say that they are the most common methods or
18 most common validated methods to assess that.
19 So, generally accepted, the POP-Q is the most
20 common and the Baden/Walker. So, it is the
21 grading system that you would use for a
22 prolapse.

1 MEMBER BORDEIANOU: This really
2 gets to the crux of who needs surgery and who
3 doesn't, because there are lots of women with
4 prolapse that don't necessarily need surgery
5 as the first step. By quantifying prolapse
6 introitus, either with a Baden/Walker or with
7 a POP-Q, you stratify that better.

8 CO-CHAIR BASKIN: Yes, but, once
9 again, we get into the chicken-and-the-egg
10 thing because this measure is a measure of
11 those that have had surgery, not as the
12 measure of whether someone should have surgery
13 or not. So, it is similar to the other issue
14 we had. It is having occurred prior to
15 surgery, but the denominator is only people
16 who have had surgery. So, the construct may
17 not be getting the best value for this.

18 MEMBER REYNOLDS: It is a
19 different measure if it is all women with
20 prolapse, and then you could discuss their
21 treatment options. But you're right, this is
22 specific for surgery.

1 MEMBER GILL: So, I think one of
2 the differences with this measure and the
3 other one that we were discussing is this one
4 has clearly been shown -- and I know we are
5 not on gap and everything -- but it has been
6 clearly shown to make a difference. If you
7 don't do this preoperatively, get the right
8 diagnosis, then your outcome is going to
9 suffer. So, I mean, I think this is different
10 than the other one because there actually is
11 evidence to support this.

12 CO-CHAIR BASKIN: Is it the right
13 diagnosis or the severity of the diagnosis
14 that this tool is doing? I am really asking
15 that. Because if you think someone has
16 prolapse, I am not sure how that diagnosis is
17 made. And the tool is really to assess the
18 degree of prolapse that would help you, then,
19 choose? Is that what happens here?

20 MEMBER GILL: Well, I think there
21 are a couple of things here. There is grading
22 it and recognizing. I think that is part of

1 the measure, is that, if it is not measured,
2 it may not be recognized and, therefore, it
3 wouldn't be treated.

4 MEMBER REYNOLDS: Both grade and
5 anatomical defect. So, if you asked a woman
6 if she has a bulge, it is very difficult to
7 delineate what that is that is prolapsing in.
8 If you just looked without doing a more
9 standardized exam, you would just see
10 something bulging out, but, again, you may not
11 know if that is anterior defect, an apical
12 defect, or a posterior defect, which is how
13 they describe how you can divide the vagina
14 into compartments. And all three of those
15 different anatomic defects, which may present
16 the same way, have different treatment
17 options. So, knowing exactly what you have
18 would determine the type of, for example,
19 surgery that you would perform.

20 CO-CHAIR BASKIN: Any other
21 comments?

22 (No response.)

1 Then, I think we will go ahead to
2 vote on this one.

3 It sounds like this is one where
4 the actual assessment could make a difference
5 in the choice of treatment. I think that is,
6 to me, where the quality part comes up, but I
7 guess we are not up to that part yet, to the
8 evidence part. So, this is just the impact
9 part. So, I'm sorry, I jumped ahead.

10 (Laughter.)

11 MR. WILLIAMSON: We will now vote
12 on the impact. There are four options: high,
13 moderate, low, or insufficient.

14 And you may begin voting now.

15 (Vote taken.)

16 And we have 9 high, 5 moderate,
17 zero low, and zero insufficient.

18 CO-CHAIR BASKIN: Okay. Thank
19 you.

20 And then, we will move on to the
21 quantity and quality of the evidence.

22 Stuart, did you want to make

1 another comment regarding that?

2 MEMBER REYNOLDS: So, in terms of
3 the evidence, there is quite a bit of evidence
4 that is listed for us to review, many of which
5 are of pretty high quality. The issue I have
6 with the evidence is that I am not sure it
7 specifically addresses the measure as it is
8 described. So that, specifically, the
9 evidence that is presented is about the study,
10 the diagnostic procedure itself. So, how good
11 is, for example, the POP-Q at detecting the
12 grade and anatomical effects?

13 And then, there are a lot of
14 studies looking at correlation between
15 observers and whether it is repeatable. And
16 all that is high-quality evidence, and good
17 data suggests that the test is reproducible
18 and that seems to measure what it does.

19 I don't see that there is any
20 evidence here suggesting that, again, by
21 assessing that, you are going to change the
22 downstream outcomes. This is the issue that

1 we have been running into all day. But there
2 is a lot of data here, but, again, I am not
3 quite sure it is exactly applicable to the
4 measure.

5 CO-CHAIR BASKIN: So, it sounds
6 like the data is validation of the tool?

7 MEMBER REYNOLDS: Correct.

8 CO-CHAIR BASKIN: Okay.

9 CO-CHAIR SAIGAL: But not
10 validation of an outcome in matters of
11 patients.

12 MEMBER REYNOLDS: Yes, I agree.

13 CO-CHAIR SAIGAL: Just a similar
14 issue.

15 MEMBER REYNOLDS: We are in the
16 same boat.

17 CO-CHAIR SAIGAL: Yes.

18 CO-CHAIR BASKIN: We will do this
19 vote first, and then, depending on the results
20 of this, we have an optional vote that comes
21 up next.

22 So, I think we are ready to vote

1 on this one. I think the statements have been
2 made that the evidence really is not here for
3 the actual outcome, but just that the tool
4 does what it is supposed to do, measures what
5 it is supposed to measure. So, vote with your
6 heart -- and the facts.

7 (Laughter.)

8 MEMBER BORDEIANOU: What is the
9 outcome?

10 CO-CHAIR BASKIN: I guess the
11 issue is, does doing this have any effect on
12 the type of surgery or lack of surgery or what
13 kind of surgery is performed, which I think
14 was really what the goal is, is that you are
15 going to get a better outcome because you have
16 done the right surgery.

17 They talk about reoperations is
18 the issue here. And I don't see that the
19 evidence does anything for that.

20 MEMBER BORDEIANOU: That is just
21 saying doing a good physical exam, when
22 calling it a POP-Q or Baden/Walker, and using

1 a language to describe your exam. I mean, do
2 we need data to document the physical exam?

3 It is like the discussion we had
4 about urinary incontinence. It goes back to
5 the same thing. There might not be a study,
6 but it is intuitive that doing a good physical
7 exam before doing a surgery and planning a
8 surgery appropriately would improve outcomes.

9 CO-CHAIR SAIGAL: Yes, I mean, the
10 idea is that you are believing that doing the
11 systematized exam will have an impact that is
12 beneficial for the patient, which I think
13 sounds obvious, as you are saying. But there
14 is no evidence that they have presented to
15 support it. So, we are in that situation of
16 just believing the expert consensus, that if
17 you do this, they will get better care.

18 CO-CHAIR BASKIN: So, that would
19 be the next vote, if we get that --

20 MEMBER MORTON: I was just going
21 to mention having an H&P as part of the record
22 is a CMS requirement. So, this goes a bit

1 beyond just an H&P.

2 CO-CHAIR BASKIN: So, let's vote
3 on this part of it, which is clearly the
4 evidence that is submitted and is it evidence
5 for the health outcome or not. And that is
6 what this vote is about. So, that is going to
7 be a 1, 2, or a 3? Is that it? Can you put
8 that back up there for us? And let's bring
9 this to a vote. I think we all know what 3 is
10 at this point in time, too.

11 But I don't think anyone has
12 submitted any evidence to say that it is out
13 there, that wasn't reported to us. So, I
14 don't think that is a great option for us.

15 MR. WILLIAMSON: We will now vote
16 on the evidence.

17 You may begin voting now.

18 (Vote taken.)

19 CO-CHAIR BASKIN: Okay, that is
20 pretty clear.

21 MR. WILLIAMSON: We have 1 yes;
22 12, no, that the evidence does not meet the

1 guidance, and 1 that, no, it was insufficient
2 information submitted.

3 CO-CHAIR BASKIN: So, now we have
4 the branching question comes out, that only if
5 we say no here can we get this question. I
6 think that is what we all really wanted.

7 And that is whether there is a
8 compelling exception here. I am going to ask
9 people if they want to speak to this. I
10 understand we have made an argument before
11 about this, but I think people ought to
12 realize, though, that there is an opportunity
13 to have a better measure that actually does
14 measure outcomes, as opposed to whether you
15 just use the tool or not. And no one has
16 taken the opportunity to create that measure.
17 But is this the low-bar measure that we should
18 accept or is this the measure that is the
19 better measure that could have been --

20 CO-CHAIR SAIGAL: So, what you are
21 saying is that you would prefer an outcome
22 measure of appropriateness of the surgery?

1 CO-CHAIR BASKIN: Well, that would
2 seem more proximal to what we wanted, yes.

3 MEMBER PELLETIER-CAMERON: And
4 pelvic organ prolapse is a little bit more
5 complicated than that. Just because you have
6 a prolapse doesn't mean it needs to be
7 repaired. The POP-Q does not evaluate
8 "bother". I mean, for most people who do this
9 surgery, it really doesn't matter to me what
10 their POP-Q score is. I mean, that does
11 matter to me and I evaluate it, but what makes
12 me decide whether or not to do surgery is the
13 "bother". I do a POP-Q on every patient that
14 I operate on because I think that it is a
15 great measurement tool, but I don't think you
16 could use the POP-Q to decide whether or not
17 surgery was appropriate.

18 CO-CHAIR BASKIN: And that is not
19 what the measure is.

20 MEMBER PELLETIER-CAMERON: Right.

21 CO-CHAIR BASKIN: It is these
22 people have had surgery. That is why they are

1 in the denominator of the measure.

2 So, my point is, why not measure
3 whether they had the appropriate surgery as
4 opposed to whether they just had surgery?
5 Isn't that what the tool is supposed to help
6 decide, is what is the appropriate surgery?

7 MEMBER FALLER: To go back to what
8 Anne said, it is not just did they have the
9 appropriate surgery based on their POP-Q, or
10 whatever you are using, but did they get the
11 solution that they wanted? I mean, they were
12 bothered by it. Are they no longer bothered
13 by it? It is like you were incontinent; are
14 you no longer incontinent? You were bothered
15 by it; are you no longer bothered?

16 MEMBER GILL: So, the other thing
17 that this tool is useful for is communicating
18 between physicians, evaluating further
19 studies. So, it is not just a patient outcome
20 and question for that individual patient, but
21 sort of on a more global scale, to see if
22 these surgeries are going to be appropriate.

1 I am not sure how this fits in
2 here, but it is certainly an important thing
3 to do on a larger scale. It is a measure of
4 quality to see if that was done or not and to
5 be able to evaluate things more globally later
6 on. So, again, I am not sure how it fits in,
7 but that is one of the main ways we use this.

8 DR. PACE: Because I know that is
9 part of the rationale that was laid out, is
10 that the reason for this is to have data for
11 something later, you need to evaluate that in
12 terms of we endorse performance measures for
13 accountability based on things that really
14 should be done. So, we don't endorse measures
15 for research, is what I am saying. You know,
16 it is really for accountability applications
17 and performance improvement. And obviously,
18 there are linkages there.

19 MEMBER BORDEIANOU: I only wanted
20 to say that, also, the "bother" can be a wrong
21 thing to measure as well because there are a
22 lot of patients with pelvic organ prolapse

1 that have a lot of other psychiatric issues
2 and emotional issues and associated issues.
3 You need some quantifying measurement of the
4 disease, whether it exists or it doesn't,
5 whether there is a component of constipation
6 that is going on here as opposed to prolapse,
7 et cetera.

8 CO-CHAIR BASKIN: Okay. Well, if
9 there are no more comments then, I don't know
10 that I can summarize that as pushing us in one
11 direction or the other here.

12 It is not the most proximal
13 outcome. But the question is, is it valuable
14 to measure this and is there a compelling
15 reason to think that this will improve
16 outcomes, in and of itself?

17 So, let's bring that to a vote.

18 MR. WILLIAMSON: All right. We
19 will now vote on the exception to empirical
20 evidence. The question posed is, is there an
21 exceptional and compelling reason that the
22 measure should be considered further?

1 And begin voting now.

2 (Vote taken.)

3 We are missing two, if everybody
4 wants to point at the receiver again and vote.
5 There we go.

6 And we have 3 yes and 11 no.

7 CO-CHAIR BASKIN: All right.

8 Then, I guess we move on.

9 CO-CHAIR SAIGAL: Any comments for
10 the developers?

11 CO-CHAIR BASKIN: Oh, yes. I'm
12 sorry. Please. Anyone want to make comments
13 to the developers, I mean other than the
14 obvious, what we have already stated in that
15 there is a more proximal outcome here which
16 may be a more meaningful measure?

17 (No response.)

18 No other comments? Thank you.

19 Then, we will move on.

20 CO-CHAIR SAIGAL: So, the next one
21 is C2038, performing vaginal apical suspension
22 at the time of hysterectomy to address

1 prolapse.

2 And Dr. Gill has that for us.

3 MEMBER GILL: So, the crux of
4 matter here is patients that have uterovaginal
5 pelvic organ prolapse that are undergoing
6 surgery for it. They are broken down into two
7 main categories, the women who just had
8 hysterectomy as the treatment and women who
9 had hysterectomy plus a specific additional
10 procedure to support the apex.

11 It is an incredibly-common
12 procedure, you know, 100 to 200 thousand done
13 for prolapse a year. It is very costly. It
14 affects a lot of people.

15 And we will eventually get to the
16 evidence and the gap, but there is a lot of
17 room for improvement here. I guess we will
18 just talk, again, about impacts.

19 I think it is very high-impact. A
20 lot of people, a lot of cases, a lot of
21 surgery, and it is very expensive if we get it
22 wrong.

1 CO-CHAIR SAIGAL: Okay. So, any
2 other comments about the impact here? It
3 sounds like it is a pretty important -- it is
4 a very common women's health issue, and doing
5 the right surgery is important to women.

6 So, can we vote on impact?

7 MR. WILLIAMSON: We will now vote
8 on impact.

9 You may begin voting now.

10 (Vote taken.)

11 We have 13 high, 1 moderate, zero
12 low, and zero insufficient.

13 CO-CHAIR SAIGAL: Okay. So, it
14 passes that criteria.

15 So, Dr. Gill, could you tell us
16 about the evidence that supports the measure?

17 MEMBER GILL: So, this actually
18 has a lot of good evidence, including
19 guidelines I will talk about first. ACOG
20 recommends it. In addition to that, there are
21 published systematic reviews, including
22 randomized controlled trials. In addition,

1 there are five new reviews that have come out,
2 all supporting this measure. So, to cut to
3 the chase, there is a lot of evidence this
4 one, actually.

5 CO-CHAIR SAIGAL: And the quality
6 of the evidence, it is randomized and some
7 observational?

8 MEMBER GILL: It would be
9 categorized, I would think, moderate to high.

10 CO-CHAIR SAIGAL: Moderate to
11 high? And a high amount of data --

12 MEMBER GILL: Uh-hum.

13 CO-CHAIR SAIGAL: -- all pointing
14 the same way?

15 MEMBER GILL: I think so.

16 CO-CHAIR SAIGAL: And that is
17 looking at the actual process. The outcome
18 being -- was it failure of the repair?

19 MEMBER GILL: It is, for example,
20 as was mentioned earlier, if just the
21 hysterectomy is done, 7 percent of patients
22 need a reoperation. If you do it with a

1 specific colpopexy procedure, only 2 percent
2 need reoperation.

3 CO-CHAIR SAIGAL: Okay. So, that
4 is failure. There is a direct link to an
5 outcome that we care about?

6 MEMBER GILL: Right. Correct.

7 CO-CHAIR SAIGAL: Good. That
8 makes it easy.

9 (Laughter.)

10 MEMBER GILL: Right.

11 CO-CHAIR SAIGAL: So, let's take a
12 vote, then, on the evidence.

13 MR. WILLIAMSON: We will now vote
14 on the evidence.

15 You may begin voting now.

16 (Vote taken.)

17 And we have 14 yes.

18 CO-CHAIR SAIGAL: Awesome.

19 Okay, the next one is the gap.

20 MEMBER GILL: So, fortunately, we
21 actually do have information on the gap as
22 well that identifies a large gap. Based on

1 these recommendations, these guidelines, in
2 some series, only 35 percent of surgeons are
3 following the recommendations currently. So,
4 there is a tremendous amount of room for
5 improvement.

6 CO-CHAIR SAIGAL: Great. So,
7 strong observational data from the California
8 Hospital Survey about the gap and some other
9 articles as well.

10 Any other comments about the gap?

11 CO-CHAIR BASKIN: A question about
12 the gap.

13 CO-CHAIR SAIGAL: Okay.

14 CO-CHAIR BASKIN: So, is it
15 because this is a newer guideline or a newer
16 standard to do this, that it hasn't been
17 widely adopted? Is that the reason? I mean,
18 I can't understand why something that so
19 clearly should be done isn't done all the
20 time. I just don't understand it. Is it just
21 something that, obviously, hasn't made its way
22 through the community yet?

1 MEMBER GILL: Yes, yes. You know,
2 I think it is a work-in-progress. Twenty or
3 30 years ago, hysterectomy was pretty much the
4 accepted standard treatment for it. But, as
5 more information has been garnered, it has
6 changed. So, I think it has just been slow to
7 be adopted, but it is clearly evidence-based.

8 MEMBER PELLETIER-CAMERON: And it
9 is harder to do.

10 MEMBER GILL: That's true.

11 MEMBER PELLETIER-CAMERON: There
12 is more skill involved. Doing a hysterectomy
13 or doing a hysterectomy plus a proper apical
14 suspension, it is just harder to do for the
15 surgeons.

16 MEMBER BORDEIANOU: Does that mean
17 that converts all the surgery to
18 transabdominal versus -- no? Okay.

19 CO-CHAIR SAIGAL: Can do it
20 robotically, in fact.

21 So, anyway, I think that we can
22 vote then on evidence about the importance of

1 the gap.

2 MR. WILLIAMSON: We will now vote
3 on the performance gap. And there are four
4 options: high, moderate, low, or
5 insufficient.

6 You may begin voting now.

7 (Vote taken.)

8 We have 12 high, 1 moderate, zero
9 low, and 1 insufficient.

10 CO-CHAIR SAIGAL: Okay. Great.

11 So, then, the general vote about approval of
12 the concept.

13 To summarize, this is a process-
14 of-care measure about a very important women's
15 health problem. There is high-quality
16 evidence or moderate-quality evidence that
17 links it to an important outcome that patients
18 care about, which is reoperation or treatment
19 failure. And there is evidence that there is
20 a significant gap in performance.

21 So, let's vote.

22 MR. WILLIAMSON: We will now vote

1 on the overall approval of the concept. This
2 is a yes/no question.

3 You may begin voting now.

4 (Vote taken.)

5 And we have 14 yes and zero no.

6 CO-CHAIR SAIGAL: Okay. Any
7 comments for the developer?

8 (No response.)

9 I congratulate you for a strong
10 measure.

11 And then, the last one is C2063,
12 and that is appropriate use of cystoscopy in
13 pelvic prolapse repair, probably similar to
14 the one we saw before.

15 Anne, could you talk about the
16 importance to measure on that one?

17 MEMBER PELLETIER-CAMERON: So,
18 similar to the previous discussion where we
19 had whether or not you should do a cystoscopy
20 at the same time as another surgery, whereas,
21 here we are talking about doing a cystoscopy
22 at the time of a prolapse repair. They are

1 specifically discussing cystoscopy at the time
2 of an anterior or an apical suspension. And
3 that is because, if you are just doing a
4 posterior repair, there is very little risk of
5 bladder injury. So, they are really focusing
6 on the procedures that do carry a high risk of
7 bladder and ureter injury.

8 To contrast that with the sling
9 that we were discussing, there is really not
10 a risk of ureter injury. But with any of
11 these, especially the apex and the cystocele
12 repairs, there is a risk of ureter injury.

13 So, their numerator is they are
14 looking at the number of patients who have a
15 cystoscopy at the same time as their apical or
16 anterior repair, and the denominator is the
17 number of patients who are having the repair.
18 And they are not excluding anybody. They are
19 not excluding sling patients. They are just
20 saying, if you are having one of these
21 repairs, you should have a cystoscopy done.

22 And this is a process. They are

1 identifying these two procedures by CPT codes.

2 I guess the importance of this is
3 pretty clearly stated. There are several
4 studies. I think I counted eight or nine
5 studies, some observational, but all had
6 fairly substantial numbers of patients stating
7 that there is a real risk of injuring the
8 bladder and the ureter during these
9 procedures. And obviously, if you injure a
10 ureter and you don't recognize it, someone
11 could lose their kidney. And the same goes
12 with the bladder; if you injure a bladder, you
13 could end up with a fistula or other problems.
14 So, I think the high impact of this problem
15 was very clearly stated in the literature.

16 CO-CHAIR SAIGAL: Okay. So, in
17 terms of any other comments about the
18 importance to measure this, its impact on the
19 population health, as a general concept?

20 (No response.)

21 Okay. So, let's vote on that
22 then.

1 MR. WILLIAMSON: We will now vote
2 on the impact. You have four options: high,
3 moderate, low, or insufficient.

4 Begin voting now.

5 (Vote taken.)

6 And we have 8 high, 6 moderate,
7 zero low, and zero insufficient.

8 CO-CHAIR SAIGAL: Great.

9 So, Anne, could you discuss the
10 evidence?

11 MEMBER PELLETIER-CAMERON: So,
12 there is quite a bit of evidence in both
13 gynecologic surgery and bladder and ureter
14 injury. However, most of the data does look
15 at hysterectomy data, either laproscopic or
16 open hysterectomy data.

17 There are several references here.
18 Some of them look at benign gynecologic
19 surgery, but many of them do use hysterectomy
20 data. And so, they are extrapolating from
21 that data which, having participated in these
22 surgeries, is not a big leap, so say that you

1 are working in the same area. You are
2 operating on the same structures, just in a
3 slightly different way. But the risk isn't
4 there, but I think that is the bit of a gap in
5 the data here, that is not a whole lot of data
6 on -- or I would say there is a moderate
7 amount of data on -- the risk of prolapse
8 surgery injury, but there is a high amount of
9 data if you are looking at the hysterectomy
10 data combined with it.

11 CO-CHAIR SAIGAL: So, the quality
12 of the data is moderate, because there is no
13 randomized data? It is just observational?

14 MEMBER PELLETIER-CAMERON: There
15 is some randomized data --

16 CO-CHAIR SAIGAL: Oh, there is?
17 Okay.

18 MEMBER PELLETIER-CAMERON: --
19 specifically looking at hysterectomy. The
20 randomized data is not whether or not to do a
21 cystoscopy, but it is there is randomized data
22 of hysterectomy surgeries where the

1 complication rate was noted. So, there is no
2 randomized controlled trial that we did a
3 cystoscopy or not --

4 CO-CHAIR SAIGAL: Right.

5 MEMBER PELLETIER-CAMERON: --
6 because that would be unethical.

7 CO-CHAIR SAIGAL: But for the
8 purposes of the measure, though, there is no
9 randomized data specifically about
10 cystoscopy --

11 MEMBER PELLETIER-CAMERON: No.

12 CO-CHAIR SAIGAL: -- use, or no?

13 MEMBER PELLETIER-CAMERON: No.

14 CO-CHAIR SAIGAL: So, it is mainly
15 observational. So, moderate quality, but it
16 sounds like there is a lot of evidence or a
17 high amount of evidence, and the direction is
18 all the same.

19 Anne, you have your concern about
20 value. And they have a paragraph in here
21 about how cost-effectiveness of a cystoscopy
22 shows that it is cost savings above a certain

1 threshold of ureteral injury, and it is
2 actually universally cost-effective. These
3 are the data in this area. So, there is some
4 that maybe mitigates some of the concern you
5 might have had about this setting at least.

6 Any other comments about the
7 evidence?

8 (No response.)

9 Okay. So, then, let's vote. So,
10 there is moderate-ish level of quality and a
11 lot of data in that direction.

12 MR. WILLIAMSON: We will now vote
13 on the evidence.

14 You may begin voting now.

15 (Vote taken.)

16 Okay. So, we have 12 yes and 2,
17 no, that the evidence does not meet the
18 guidance.

19 CO-CHAIR SAIGAL: Okay. And then,
20 Anne, the last part is the gap on this
21 measure.

22 MEMBER PELLETIER-CAMERON: So,

1 there are three studies cited referencing the
2 gap. And I did read the description of each
3 of these. A lot of these are survey studies,
4 survey of residents in practice. And one is
5 discussing how many residents get
6 credentialed.

7 So, the data provided doesn't
8 really provide a lot of hard evidence about
9 whether or not people are doing the
10 cystoscopies or not in practice. There is a
11 survey study.

12 CO-CHAIR SAIGAL: There is one
13 survey study, basically, about the use of
14 cystoscopy, and it just sort of residents, you
15 said?

16 MEMBER PELLETIER-CAMERON: Uh-hum.

17 CO-CHAIR SAIGAL: Okay. So, there
18 is no hard evidence that this is not being
19 done, but I guess my thought -- and I don't
20 know if anyone else wants to comment about
21 this -- that if there is controversy about it,
22 some people aren't doing it, that is very

1 indirect line of reasoning. I don't know what
2 your gynecologist colleagues have to say about
3 that gap issue.

4 MEMBER GILL: Yes, I would agree
5 that the data aren't strong, but our opinion
6 or impression or expert consensus would be
7 that there is a large gap and this bears
8 moving forward with it.

9 CO-CHAIR SAIGAL: Stu?

10 MEMBER REYNOLDS: Well, the way I
11 interpreted their data here, though, too, is
12 that they were suggesting that there is a big
13 gap between the specialties of urogynecology
14 and female urology almost universally use
15 interoperative cystoscopy, and then maybe the
16 general urologists who they quote as having
17 the much lower number, which suggests, again,
18 that there may really be a big gap in
19 practice.

20 CO-CHAIR SAIGAL: Okay. Okay.

21 All right.

22 MEMBER PELLETIER-CAMERON: And I

1 think the data is not strong, but what data is
2 there is clearly identifying a gap.

3 CO-CHAIR SAIGAL: Okay. So, then,
4 we will all make our decision about how
5 convincing that is.

6 MR. WILLIAMSON: We will now vote
7 on the performance gap.

8 Begin voting now.

9 (Vote taken.)

10 We have 1 high, 10 moderate, 3
11 low, and zero insufficient.

12 CO-CHAIR SAIGAL: Okay. And then,
13 the last, concept approval. Again, we have
14 seen something like this before. It is
15 looking at an intervention to reduce the
16 morbidity of a surgery. It is very common
17 surgery, and the morbidity is serious if it
18 occurs.

19 The evidence supporting this is
20 somewhat better than we saw in the previous
21 measure, and the performance gap documentation
22 is moderate at best. But the experts in the

1 room felt that there is a performance gap,
2 based on their consensus and how they read the
3 evidence.

4 So, we can vote to approve or not
5 approve.

6 MR. WILLIAMSON: We will now vote
7 on the overall recommendation of the concept.

8 Begin voting now.

9 (Vote taken.)

10 CO-CHAIR SAIGAL: Okay. So, it is
11 approved.

12 MR. WILLIAMSON: Yes, we have 14
13 yes and zero no.

14 CO-CHAIR SAIGAL: Okay. Any
15 comments for the developers to go home with?

16 MEMBER PELLETIER-CAMERON: I just
17 had a comment about the use of CPT codes to
18 identify the cystoscopy. I am not a coding
19 expert, but I thought that was bundled with an
20 anterior repair. So, that was my comment.

21 MEMBER GILL: Right, I agree with
22 the same problem. But when I have checked on

1 it, it seems to depend on what procedures were
2 done or not. If a sling is included, it seems
3 to be bundled. If it is just a prolapse
4 repair, it may not be. I think we just have
5 to get that straight about the coding, how we
6 are going to identify the numbers.

7 CO-CHAIR SAIGAL: Some feasibility
8 questions for the developer to think about.
9 Okay.

10 So, then, now we open this up to
11 NQF member comment about our last wave of
12 concepts for GU.

13 (No response.)

14 Okay. Do you want to ask the
15 operator?

16 MS. WILBON: Is there anyone in
17 the room who has questions or would like to
18 address the Committee on anything, any of the
19 GU concepts? We are kind of wrapping up.

20 (No response.)

21 No one? Okay.

22 So, we will go to the phone.

1 CO-CHAIR SAIGAL: Okay. So, then,
2 Operator, if you could let anyone listening in
3 make a comment?

4 THE OPERATOR: Yes. If you have a
5 question or a comment, please press *1.

6 (No response.)

7 CO-CHAIR SAIGAL: Okay. Well,
8 then, we get an extra three minutes of break.
9 So, let's come back at 3:15.

10 MR. AMIN: Well, no, let's come
11 back at three o'clock.

12 (Laughter.)

13 MS. WILBON: We are back on
14 schedule.

15 MR. AMIN: We are 15 minutes ahead
16 of schedule.

17 CO-CHAIR SAIGAL: Oh, really?

18 MR. AMIN: So, let's come back at
19 three o'clock.

20 CO-CHAIR SAIGAL: All right.
21 These guys are pretty tough.

22 (Laughter.)

1 So, three o'clock.

2 (Whereupon, the foregoing matter
3 went off the record at 2:42 p.m. and went back
4 on the record at 3:03 p.m.)

5 MR. AMIN: Okay. Just as
6 everybody is searching and finding what they
7 need to get started, I will also say that not
8 everything will probably be on the comparison
9 table that you need to get started.

10 But, essentially, what we want to
11 do -- and again, this is part of the pilot
12 process here. I mean, we normally always have
13 a conversation around harmonization, but,
14 typically, this happens after a fully-
15 specified measure has been endorsed across all
16 four criteria.

17 You have an opportunity here for a
18 measure that looks at the same measure focus
19 and/or the same target population to address
20 harmonization upfront. So, this gives you an
21 opportunity to look across the measures that
22 you evaluated this morning and this afternoon

1 to look at how well they work together as a
2 set to understand the various care processes
3 that we are trying to measure.

4 So, essentially, the nature of the
5 discussion that we want to trigger for right
6 now is to look across the various measures
7 that you approved as concepts and think about
8 which measures could be harmonized across each
9 other, meaning that when we say "harmonize,"
10 meaning that the denominator populations are
11 similar, or if there are other considerations
12 for how exclusions are handled, and basically
13 making sure that the measures are giving
14 similar signals based on the target
15 population.

16 I think, also, as we had a number
17 of concepts that were submitted here, to have
18 a discussion around whether or not you felt
19 that measures should be, more or less,
20 combined in order to get a better signal of
21 the overall care process, which seemed to be,
22 again, the tenor of the conversation that we

1 were having earlier today around a measure
2 that went down and a recommendation that that
3 be paired with a concept -- I'm sorry --
4 combined with a concept that was approved to
5 go forward. This is all new language for us
6 or me, us collectively.

7 So, anyway, what we have put
8 together here is lists of related concepts
9 that are intended to start the conversation
10 around which components and which measures you
11 would like to, first, think that they are
12 logically paired together, paired in the sense
13 that they are trying to measure the same care
14 process for the same population, and then have
15 a discussion of whether they could be combined
16 or whether they need to be harmonized in terms
17 of the way that they are constructed.

18 So, with that, I will turn it over
19 to Chris and Andy.

20 CO-CHAIR SAIGAL: Okay. So, then,
21 in regards to this, one of the things you
22 should keep in mind, because basically we are

1 charged with giving these developers feedback
2 about what they are spending their dollars on.
3 We don't want them to waste their money.

4 I think we were having a sidebar
5 earlier about the fact that in the past some
6 payers, not Medicare but private payers, have
7 looked askance at measures that were
8 standalone process measures that didn't have
9 any teeth, and they felt they weren't worth
10 using.

11 I think one way to make a set of
12 process measures more useful to everybody is
13 to combine them, if they are a spectrum of
14 services that could be considered to be, you
15 know, synergistic. So, as we talk about
16 harmonization, we should consider them both
17 across developers, so we don't have five
18 measures that are looking at the same thing,
19 but also within any one measure set if we can
20 have multi-part measures, I think that
21 probably makes sense for everyone at the end
22 of the road, in my view at least.

1 DR. PACE: Just one thing to
2 consider, because you have seen some multi-
3 part measures where it is essentially
4 standalone measures just combined into one
5 form, but one thing to really consider is, if
6 it is something that a patient should receive
7 both things, assessment and counseling, then
8 the question is measuring all those patients
9 who did receive both things, rather than
10 looking at them separately. So, I think it is
11 looking at it, also, that way, if there are
12 processes that every patient should receive.

13 CO-CHAIR SAIGAL: Right. A good
14 process of care can really be as long as you
15 want it to be.

16 All right. So, with that, we will
17 talk about the ones that are on the board
18 here. Am I the one walking us through it? Or
19 how does that work?

20 MS. WILBON: However you guys are
21 comfortable. We can help, if you want.

22 CO-CHAIR SAIGAL: Okay. Well,

1 maybe I will start and then I will open it up.

2 Okay?

3 So, then, there were four measures
4 that were thematically-related, related to
5 incontinence. And NCQA has a measure that
6 asks about whether the patient says they were
7 asked about incontinence, whether the patient
8 reports a treatment plan, and, also, one that
9 looks at the actual system-level or provider-
10 level; was one provided to the patient in
11 terms of a treatment plan.

12 And the AUA has a workup measure
13 that says, was the workup appropriate for this
14 patient before they got surgery, and then one
15 that is basically about counseling them about
16 treatment options.

17 So, some of those are
18 conceptually-related across these four
19 measures.

20 Just to start us off, I think that
21 the counseling and the treatment plan
22 characterization are sort of conceptually-

1 related, in my mind. I don't know what people
2 think about it in terms of the differences
3 that are captured, specifically talking about
4 treatment option counseling versus a care plan
5 or basically harmonized.

6 CO-CHAIR BASKIN: Well, let's be
7 careful with terms here. So, harmonization,
8 if you are talking about C2049 and 2050, that
9 is not harmonization, we are not talking
10 about. We are talking about combining them
11 either into a composite measure or to a
12 combination measure.

13 Harmonization is when you are
14 going to maintain two separate measures, but
15 you want the populations to match. One is age
16 50 to 75 and the other one 65 to 75. And the
17 answer is, could they be the same populations?
18 Does that make some sense?

19 So, I agree with you, though, 2049
20 and 2050 are both two components of care that
21 should occur on every patient. And is it
22 acceptable, or even meaningful, to measure

1 each component separately when, in fact, the
2 ultimate outcome is that both components
3 occurred? Now that is combining into a
4 composite --

5 CO-CHAIR SAIGAL: That is how I
6 meant.

7 CO-CHAIR BASKIN: Okay. So,
8 harmonization on those two --

9 CO-CHAIR SAIGAL: I meant
10 harmonization on 0030 and 2050.

11 CO-CHAIR BASKIN: Okay. Then, we
12 agree, because I was going to talk about
13 harmonization for those two.

14 CO-CHAIR SAIGAL: Right.

15 CO-CHAIR BASKIN: So, if you want
16 to do those first --

17 CO-CHAIR SAIGAL: So, I mean, and
18 this may or may not be a good idea. It is
19 just on the table.

20 CO-CHAIR BASKIN: Yes.

21 CO-CHAIR SAIGAL: So, the idea is
22 basically that you have one of these things

1 that says that you should counsel a woman who
2 is going to have surgery and explain all the
3 treatment options to her. The other says, if
4 you ask this patient, does she say she has a
5 treatment plan? So, those are related ideas.
6 They may not be worth combining. But if you
7 are one individual, you will be measured in
8 several different ways if we have these two
9 things measured.

10 So, Stu?

11 MEMBER REYNOLDS: Well, the way
12 that these things are written, they are asking
13 (a) two different populations about two
14 specific conditions. So, the NCQA is men and
15 women, and they are asking about anytime of
16 incontinence, not just stress incontinence.
17 And obviously, the AUA one that we talked
18 about is women, and then those with stress
19 incontinence and those with surgery. So, I
20 don't know how well those -- conceptually,
21 yes, but I don't know how well they really
22 overlap.

1 CO-CHAIR SAIGAL: Okay. Good.

2 MEMBER BORDEIANOU: I think,
3 expanding on this point, that NCQA really is
4 raising awareness about the disease amongst
5 PCPs. It seems like that is the point of the
6 measure, to discuss the problem, inform
7 patients of their options, perhaps send them
8 to see experts or specialists, et cetera;
9 whereas, the other one is about appropriate
10 discussion once you see a specialist.

11 CO-CHAIR SAIGAL: Okay. Good
12 point.

13 MEMBER TOBIN: Just a question. I
14 can appreciate the value of
15 harmonizing/combining like concepts, but can
16 you even get to the point of saying, yes,
17 combine these if potentially they might have
18 completely different data sources, if you are
19 collecting these measures in completely
20 different ways? So, that is just a question
21 I would pose.

22 MS. WILBON: Actually, if you

1 scroll down the table, there are some more
2 rows on the table where we do actually have
3 side-by-sides of the data sources, the level
4 of analysis, because you are right, Judy, that
5 should be part of the consideration on whether
6 or not they are using similar data sources and
7 the level of analysis on whether or not that
8 might have any implications for them further
9 specifying the measure.

10 CO-CHAIR SAIGAL: Right. One is a
11 survey instrument, and one is CPT II code-
12 related. So, to harmonize them, either the
13 survey would have to be changed or they would
14 have to use CPT II codes in the survey, which
15 wouldn't work.

16 MEMBER TOBIN: I mean, I can't
17 speak for the other measure developers, but
18 that may be significant for why they submitted
19 a separate measure, if they feel like a
20 different data source needs to be used.

21 CO-CHAIR SAIGAL: Good point.

22 Andy, do you have comments about

1 those two? You are interested in those?

2 CO-CHAIR BASKIN: Well, you know,
3 I mean, I see why the difference. I mean,
4 this whole thing about the Health Outcomes
5 Survey measure being one group of patients,
6 like females, and yet it is unclear whether
7 there is enough of a male problem that it
8 makes sense to have males, when overwhelmingly
9 the female issue of incontinence is probably
10 much more so than men, and the root causes
11 being entirely different.

12 MEMBER BORDEIANOU: You just
13 stepped into a big puddle.

14 (Laughter.)

15 CO-CHAIR BASKIN: But I see
16 reasons not to harmonize these measures, I
17 guess is the point here. I mean, you know, a
18 member survey is really looking for whole
19 different information about your relationship
20 with your doctor and bringing it up and being
21 able to talk about things. And the other one,
22 the NCQA measure for the PQRS measure is

1 really measuring a provider and whether they
2 are doing what is appropriate, not just in
3 seeking out the diagnosis, but once the
4 diagnosis is there.

5 I see good reasons for them to be
6 separate and that they complement each other.
7 They find out different things about the
8 issue. And then, you would respond to that
9 with a different kind of quality improvement
10 activity, depending on which one of these
11 measures showed what. You know what I mean?
12 You wouldn't actually go in the same
13 direction.

14 CO-CHAIR SAIGAL: Fair enough.

15 CO-CHAIR BASKIN: So, I think it
16 is reasonable.

17 CO-CHAIR SAIGAL: Okay.

18 CO-CHAIR BASKIN: What I do worry
19 about is why they start at age 65. This is
20 just not a problem before the age of 65? I
21 understand that Medicare is probably the
22 impetus behind this, but is there room for

1 expanding these measures to the larger age
2 groups?

3 CO-CHAIR SAIGAL: Alayne, you have
4 a comment about the prevalence?

5 MEMBER MARKLAND: Quickly, yes,
6 two comments. The ratio is usually 2-to-1,
7 women-to-men. So, men definitely have less;
8 it is not inconsequential, and that rate could
9 be as high as 40 percent versus 20 percent,
10 depending on an increase in age. And so, I
11 think it is very relevant to include men in
12 these surveys.

13 And the second part would be
14 expanding the age a little bit, I think. You
15 know, especially in women the types and
16 treatments may change depending on age as
17 well, the same as men, depending on what type
18 and age, other comorbidities. So, those are
19 valid points.

20 CO-CHAIR SAIGAL: Okay. Thank
21 you.

22 So, then, it sounds, from my

1 understanding of what the group is saying,
2 that probably these two measures should not be
3 harmonized, for reasons that they are
4 different data sources. There is a different
5 intent and different patient populations. So,
6 leave that alone.

7 Are there any other measures up
8 here, of these four, that people think should
9 be harmonized? I think the merging thing
10 between the two AUA measures, which is not
11 harmonization -- but what is it called again,
12 collapsing? Combining?

13 (Laughter.)

14 So, that is one thing on the
15 table. And then, is there anything else that
16 people think, of these four, let's say, that
17 people feel should be brought together, any of
18 the measures that we have reviewed?

19 I think maybe the mesh measure
20 could be combined with the AUA measures as
21 well that we voted down. It has got, I think,
22 enough going for it. Just maybe it was

1 constructed in a way that we didn't like. So,
2 maybe the importance of that could be brought
3 into the treatment counseling.

4 MS. WILBON: I just have a
5 question for Alayne. In terms of expanding
6 the age group, do you have a recommendation on
7 what that age span would be?

8 MEMBER MARKLAND: Yes, it is a
9 good question. I don't know; the survey
10 itself may be limited to 65 and older. Maybe
11 that is why. I don't know enough about that
12 survey itself.

13 But I would say I don't have an
14 age cutoff, but menopause is a big factor for
15 urinary symptoms in women. And so, to include
16 a perimenopausal population or a postpartum
17 would also be a very important piece.

18 CO-CHAIR SAIGAL: Okay.

19 CO-CHAIR BASKIN: They were
20 pointing out that NCQA is in the room. We all
21 understand the HOS was, obviously, for the
22 Medicare population. So, that is why it is 65

1 and older. And then, the PQRS was developed
2 for Medicare or was it -- but I guess the
3 point is, is there some consideration, though,
4 of bringing that down into the commercial
5 population in terms of age? Or is that just
6 no one has asked or there doesn't seem to be
7 a calling for that?

8 MS. WILBON: Can you use the
9 microphone, please?

10 DR. GIOVANNETTI: The Health
11 Outcomes Survey is Medicare. It does include
12 people under the age of 65, but they are in
13 the disabled Medicare population, and so not
14 exactly the population you were talking about.
15 And we didn't think it was entirely -- there
16 wasn't enough evidence to suggest that they
17 should all be included in this measure.

18 The PQRS measure was developed
19 originally with AMA, as part of their
20 Geriatrics Work Group. And so, we were
21 focusing on specifically geriatric syndromes.
22 And I believe the argument there for its being

1 65-plus was that this was the most prevalent
2 in that population and, therefore, the
3 measurement burden was worthwhile in that
4 population, because it is a screening for all
5 people who come into the ambulatory care
6 setting.

7 So, that is why the ages were set
8 that way. But we are happy to explore, at
9 least on the PQRS side, expanding that age.

10 CO-CHAIR SAIGAL: Great. Thank
11 you.

12 Okay. So, then, I am hearing no
13 other suggestions for harmonization or
14 combining that we haven't already discussed.
15 Is that true?

16 CO-CHAIR BASKIN: The only
17 question is the characterization of how much
18 incontinence somebody has, because the PQRS
19 measure, I forget, it is either you say -- the
20 PQRS is, I think, you either have incontinence
21 or you don't have incontinence. And the
22 Healthy Outcome Survey I think has none, a

1 little bit, or a lot of it. And the question
2 is, is there some way that we could really be
3 measuring the same gradations in both of these
4 measures.

5 DR. GIOVANNETTI: So, the reason
6 that the two are different is because in
7 cognitive testing of the question "Do you have
8 urinary incontinence," what we found was that
9 a lot of individuals who did have symptoms of
10 urinary incontinence did not respond "yes" to
11 that question because they didn't feel that it
12 was a problem.

13 And so, the revision of the
14 question to -- I'm sorry -- no, it was the
15 revision of the question was to try to pull in
16 more people for whom urinary incontinence was
17 maybe not a big problem in their life, but we
18 really wanted to get at that population.

19 So, the reason that the two are
20 slightly different versus a diagnosis of
21 urinary incontinence versus this kind of small
22 or big is because we were trying to get the

1 maximum sample we possibly could of people who
2 have symptoms of urinary incontinence. And
3 so, it just had to be slightly different in
4 the way we word it to patients than how we
5 would code it in the charts.

6 CO-CHAIR BASKIN: But, since then,
7 hasn't NCQA discussed the idea that people
8 with just a little bit of a problem really
9 aren't the same, really are not being treated
10 the same now anymore, and the measure has been
11 changed, I think? Or is it that an
12 accompanying measure, the accompanying NCQA
13 measure has been changed so much, so that the
14 people only with a significant problem, is
15 there further measurement of the provider?

16 DR. GIOVANNETTI: We discussed
17 that change, but decided not to follow through
18 on that because of the sample size issue. So,
19 as the measure stands now, all individuals are
20 included who report that it is either a small
21 or a big problem.

22 CO-CHAIR BASKIN: It does sound

1 like there is some reasonableness to
2 discussing, you know, how you can align the
3 provider measure and the member measure maybe
4 a little bit better since there seems to be
5 this confusion now as to what --

6 DR. GIOVANNETTI: Well, so the
7 provider level is based off of a diagnosis of
8 urinary incontinence, because our only data
9 source is the ICD-9 codes. And the patient-
10 reported measure, we don't want to exclude it
11 to people diagnosed with urinary incontinence
12 because that implies that they have already
13 had a diagnosis; they have discussed it with
14 their provider. So, we are really also trying
15 to get at that additional population that
16 doesn't have a diagnosis yet.

17 But I agree. I mean, we can work
18 on that, and there will be changes to this
19 measure.

20 CO-CHAIR BASKIN: Thanks.

21 CO-CHAIR SAIGAL: Thank you.

22 Liliana?

1 MEMBER BORDEIANOU: I want to say
2 that the only ones that are harmonizing are
3 2052 and 2063, which are both looking at the
4 use of cystoscopy and procedures for pelvic
5 organ prolapse.

6 CO-CHAIR SAIGAL: Great idea. We
7 will work it out. Those are two we are going
8 to talk about as well.

9 So, at this point, I was wondering
10 if we could talk about collapsing the two,
11 2049 and 2050, and the mesh measure. In my
12 view at least, the denominators and numerators
13 are similar. The intent of the measures is
14 similar. The populations are similar. And I
15 think that it will be a more durable and
16 credible measure over time if they are
17 combined.

18 I don't know if other people have
19 different opinions.

20 CO-CHAIR SAIGAL: Aren't the mesh
21 patients already included in the denominator
22 for 2050?

1 CO-CHAIR SAIGAL: Well, there is
2 no specific numerator saying, "Was a person
3 counseled about mesh." They counsel about the
4 treatment options, including Kegels and
5 everything else. But I think if they added a
6 statement about surgery, including the risks
7 of mesh, that would --

8 CO-CHAIR BASKIN: So, a subset of
9 those that said, if the surgery is actually
10 going to be mesh, would have an additional
11 requirement that the others don't have, the
12 risk assessment?

13 MS. WILBON: So, we just brought
14 up the denominators; 2049 and 2050 are the two
15 of the far right columns, and the denominators
16 are essentially the same right now.

17 CO-CHAIR SAIGAL: Right. And it
18 would keep you away from the issue that we had
19 about only the denominator for the mesh, for
20 people that had mesh surgery. So, I think it
21 would make it a more useful measure in terms
22 of looking at its impact. So, that is what I

1 would think makes sense.

2 Does anybody else have -- yes, go
3 ahead.

4 MEMBER PELLETIER-CAMERON: No, and
5 I agree with you. I mean, just thinking about
6 this clinically, if someone has incontinence
7 and you talk to them about their options, and
8 they say, "Hey, I want to go for Kegels," I am
9 not going to have a big discussion about mesh
10 with them because they have decided to go for
11 Kegels. I don't think the mesh factors into
12 that decision. So, I agree that the
13 denominator of people who actually undergo
14 mesh surgery should have the mesh discussion,
15 but not necessarily everybody.

16 DR. PACE: But are you saying that
17 they would first elect mesh and then have that
18 discussion? Or wouldn't that be part of the
19 discussion of the treatment options and the
20 pros and cons of treatment options?

21 MEMBER PELLETIER-CAMERON: I guess
22 maybe if they were discussing surgical

1 options. Because if someone comes in and you
2 say, "You can lose weight. You can go for
3 pelvic pharmaceutical therapy, or surgery,"
4 and they elect to go for physical therapy, it
5 doesn't seem reasonable to go into a lengthy
6 discussion about the risk of surgery with
7 those patients. I don't think that is fair,
8 like that is necessarily measuring quality,
9 because you go over risks of something that
10 they aren't interested in having.

11 CO-CHAIR SAIGAL: Uh-hum.

12 Jenifer?

13 MEMBER LIGHTDALE: I think you
14 could write this generically. So, basically,
15 whatever treatment option you are going to go
16 with, you make sure that all benefits and
17 risks are known, including potentially risk of
18 failure for your Kegels. So, I mean, I think
19 you go ahead and say, whatever your treatment
20 option is, you have disclosed everything.

21 CO-CHAIR SAIGAL: Probably to make
22 it feasible, it would have to have like

1 specific points you are looking for. So, I
2 don't know how overspecified we are going to
3 get wit this. But I think mesh is its own
4 special case in this field. And so, I thought
5 that it was an important-enough thing -- it is
6 measure that didn't quite make it, but I think
7 if you changed the language of the numerator
8 so that it is including biofeedback, Kegels,
9 and surgical options, and then put in
10 parentheses that, if surgical options are
11 considered, mesh risks need to be covered.
12 Make that a parenthetical there. That is what
13 I would think.

14 MEMBER LIGHTDALE: Are medications
15 options here? Yes. So, I mean, also,
16 benefits/risks of the medications need to be
17 discussed. I mean, there is lots of -- and I
18 am sure there are some black-box warnings with
19 some of the --

20 MEMBER PELLETIER-CAMERON: But
21 there is no medical therapy for stress
22 incontinence.

1 MEMBER LIGHTDALE: There isn't?

2 MEMBER PELLETIER-CAMERON: No.

3 MEMBER LIGHTDALE: Okay.

4 MEMBER MARKLAND: It is not FDA-
5 approved.

6 CO-CHAIR SAIGAL: Okay. So, then,
7 how do we proceed after we have this
8 discussion? What happens next?

9 MS. WILBON: So, if you guys have
10 settled on -- I am not sure if I heard an
11 actual settlement on what, if there is an
12 actual recommendation.

13 CO-CHAIR SAIGAL: Do we vote?

14 MS. WILBON: So, this would have
15 to be part of the --

16 CO-CHAIR SAIGAL: Well, whatever
17 you guys think is the way to go.

18 MR. AMIN: So, I guess just
19 summarize it. Yes, just a summary, if you
20 want. Let's do that. We are trying things.

21 CO-CHAIR SAIGAL: All right. So,
22 I will summarize our discussion, and if anyone

1 thinks I said it wrong, please correct me.

2 So, we said that we didn't feel
3 like harmonization across the two measures,
4 0030 and 2050, made sense because they were
5 different data sources and different intents.

6 We thought that collapsing
7 Measures 2049, 2050, and the mesh one that
8 didn't go forward, 2051, made sense because
9 the populations were similar, and the intent
10 was to ensure a high-quality process of care
11 that resulted in fewer inappropriate surgeries
12 and failed surgeries, and that that would make
13 the measure have more value to a variety of
14 stakeholders. So, we recommend that that
15 would be a good thing to do for those
16 measures.

17 And then, the last two we want to
18 talk about were these cystoscopic -- I'm a
19 urologist (laughter) -- cystoscopy for pelvic
20 prolapse and cystoscopy for patients having
21 incontinence surgery.

22 So, there isn't a slide for that,

1 I don't think.

2 MEMBER TOBIN: So, can I ask a
3 clarification question? How can you combine
4 a measure that didn't go forward with measures
5 that did? I mean, wouldn't that be excluded,
6 or no?

7 CO-CHAIR SAIGAL: We already asked
8 about that before we said no, and we were told
9 that we could.

10 MEMBER TOBIN: Okay.

11 CO-CHAIR BASKIN: Yes, the measure
12 didn't go forward as is. What we are
13 basically suggesting as a group is that there
14 are aspects of that measure that you can still
15 get the value of that measure in a different
16 way by saying that, when you counsel people
17 about treatment options, if the treatment
18 option you are landing on is potentially mesh,
19 that you additionally have the responsibility
20 to explain about the risks of the mesh. So,
21 you can still get the value of it and not have
22 that separate measure that has other issues.

1 MR. AMIN: Chris, what would be an
2 easier way to do this is just go ahead and
3 vote on what you have already discussed, and
4 then we can do the other two. Just make sure
5 there is general agreement, and then we will
6 move on.

7 CO-CHAIR SAIGAL: Okay.

8 MR. AMIN: Just a hand vote, a
9 quick hand vote.

10 CO-CHAIR SAIGAL: So, regarding
11 the summary I just made, if everyone thinks
12 that is reasonable, raise your hand.

13 (Show of hands.)

14 And if you think it is
15 unreasonable, feel free to raise your hand.
16 My feelings won't be hurt.

17 (Laughter.)

18 Okay.

19 The last two we are going to talk
20 about potentially combining were the ones
21 about cystoscopy. Aliana, you brought that
22 up. So, maybe you could talk about it a

1 little bit?

2 MEMBER BORDEIANOU: Well, it seems
3 like the exclusion criteria by the urologists,
4 when we discussed it the first, was pelvic
5 organ prolapse. And then, you know, the
6 second proposal was to include pelvic organ
7 prolapse on the anterior repair. So, why not
8 say all urinary incontinence surgery plus
9 anterior repairs should have cystoscopy, if we
10 are going to go that way?

11 CO-CHAIR SAIGAL: Are there
12 comments about that? It sounds convincing to
13 me.

14 MEMBER PELLETIER-CAMERON: I mean,
15 they happen concomitantly so frequently. I
16 don't know the actual numbers, but the rate of
17 a sling surgery with an anterior or apical
18 suspension is very, very high. So, why split
19 hairs over who is in which group?

20 CO-CHAIR SAIGAL: You may a point
21 when you were reviewing it that, basically,
22 why would you not do it if you were doing

1 prolapse surgery at the same time, if you are
2 doing a sling. So, it makes sense.

3 If there are no other comments,
4 then I will summarize that discussion, that we
5 felt that harmonization of 2052 and 2063,
6 which are measures looking at use of
7 cystoscopy after surgery for stress
8 incontinence and cystoscopy after surgery for
9 pelvic prolapse repair, could be combined
10 because they have a similar patient population
11 and the risks and benefits -- the benefits of
12 the measure/intent are the same, that is, to
13 reduce complications of the surgery. And that
14 is basically it.

15 MS. WILBON: I would just add a
16 point of information, that they both have --
17 because we did have the side-by-side tables
18 with all the specifications, just a quick
19 overview. The levels of analysis are
20 generally the same. The 2052, which was for
21 cystoscopy during SUI, only specified an
22 individual clinician level of analysis. And

1 then, 2063 for cystoscopy during prolapse
2 repair, you specified clinician-group-level
3 analysis and the individual clinician. So,
4 very similar level of analysis. And they had
5 the same data sources, administrative claims
6 and paper records.

7 CO-CHAIR SAIGAL: Yes. Let's
8 vote.

9 (Show of hands.)

10 Okay. Are there any other
11 concepts that people feel -- I'm sorry, any
12 dissenting, any no?

13 Okay. Thanks for bringing that
14 up.

15 Any other people have ideas about
16 merging, combining?

17 (No response.)

18 Okay. And I would like to make
19 one last comment I think that may be relevant.
20 I don't know where this goes on the agenda,
21 but just for the developers to think about the
22 use of CPT II codes and their future in this

1 whole measurement paradigm and think about
2 ways to specify measures not using those codes
3 conceptually because they may not have a lot
4 of legs in terms of long-term use.

5 MEMBER BUTT: Could I add to that
6 comment that this sort of, again, goes back to
7 the burden on providers of pulling these CPT
8 II codes? I mean, they are such a difficult
9 thing to do because it is not a simple yes or
10 no. You have to go dig into the chart, often
11 retrospectively, and find out whether the
12 three conditions were met to code it as such.

13 So, to the extent that things are
14 moving in the e-measures world and the EHR
15 world, I think these developers really need to
16 stay in sync with that and retool these
17 measures so that much of this data should be
18 available from the EHRs.

19 CO-CHAIR SAIGAL: Okay. So, we
20 have ActiveHealth.

21 Thank you.

22 Do we have somebody from

1 ActiveHealth Management here? Hi. Could you
2 introduce your two measures and give us two or
3 three minutes of time?

4 DR. WU: I am George Wu from
5 ActiveHealth Management, and this is Dr. Bani
6 Vir.

7 The first one is GERD patients
8 with alarm symptoms doing an upper GI study or
9 endoscopy. For GERD and alarm symptoms, we
10 are mainly looking at two things, either
11 unintentional weight loss or dysphagia.

12 As we all know, in the U.S. about
13 10 to 30 percent of the population has GERD,
14 and it is increasing because of multiple
15 different factors, like stress, obesity -- as
16 we all say, obesity is killing us every single
17 day -- and multiple other factors.

18 The measure is actually aimed to
19 identify, early identification of
20 complications of GERD; namely, lower
21 esophageal cancers. About 20 years ago, most
22 of the esophageal cancers were squamous cell

1 in the mid to upper thoracic esophagus. But,
2 nowadays, 1 to 50 percent are in the distal,
3 and GERD plays a major role in that.

4 Secondly are strictures.

5 Third is to identify whether PPIs
6 are helpful in treating GERDs.

7 And fourth is for biopsy
8 opportunities and, as we all know,
9 eosinophilic esophagitis is on the rise right
10 now, and it is part of the differential.

11 So, that is our first measure.

12 Our second measure is on chronic
13 liver disease patients and hepatitis A
14 vaccination. We look for patients with
15 chronic hepatitis B and chronic hepatitis C,
16 and see if they ever had the hepatitis A
17 vaccination being done.

18 Since the introduction of hep A
19 vaccine in 1995, in the United States we see
20 a significant decrease since then. The cases
21 are actually not that much when you look at
22 it. There were only about 2,000 or so

1 reported cases in 2009. But the underreported
2 cases and the non-reported or the asymptomatic
3 cases could go up to about 20 to 22 thousand
4 in 2009. And especially now, with the CDC's
5 recommendation of screening everybody born
6 between 1945 and 1965, the estimated number of
7 undetected or underreported hepatitis C cases
8 reach about 800,000. So, that is a huge
9 opportunity right there.

10 So, that is our measure. Any
11 questions?

12 CO-CHAIR SAIGAL: Okay. John?

13 MEMBER MORTON: One question about
14 the first measure. How you identify people
15 with alarm symptoms?

16 DR. WU: So, we use multiple ways.
17 No. 1 is we use claims data, ICD-9s. No. 2 is
18 from our PHR. So, we have a 4-million-user
19 personal health record that actually enters
20 patient symptoms in it, and we actually
21 specify specifically unintentional weight loss
22 and/or dysphagia.

1 And the third part is through our
2 disease management program, where we also have
3 about 3 or 4 million members. Through that,
4 we obtain this information as well. So, it is
5 a combination of administrative claims data
6 and, also, survey-type data.

7 DR. VIR: And just to add to that,
8 wherever it is available, we do take in data
9 from the Health Information Exchange.

10 CO-CHAIR SAIGAL: May I have a
11 question of NQF staff? So, it sounds like
12 there are some proprietary data sources that
13 they are using to measure this measure. If
14 this is a national measure and you don't have
15 access to their various data sources, how
16 would that play out in terms of its being
17 adopted?

18 DR. PACE: So, I think that is a
19 good question. I guess one of the questions
20 is, do you have those data sources on all the
21 patients or do some patients have one data
22 source and other patients may have two data

1 sources and other patients three? But we will
2 get back to that in just a second.

3 So, NQF endorses measures that
4 should be standardized, so that anyone could
5 implement them. This will also come down to
6 feasibility when you actually get to the
7 actual measure, and you may want to comment on
8 it.

9 But if the specifications are
10 precise enough that anyone could implement if
11 they had EHRs, PHRs, and disease management
12 programs, as long as those data elements are
13 specified so that anyone else could implement
14 them, it could still be NQF-endorsed.

15 Heidi?

16 MS. BOSSLEY: I think another good
17 example that we often see is measures that are
18 produced out of a registry, such as FTS or
19 others. Again, the measures are specified
20 precisely, so that anyone else could take that
21 information and implement it. But the data
22 that you see before you comes from that

1 registry. I think it is very similar to what
2 you are seeing here.

3 DR. PACE: So, in this case, I
4 think you need to think about the
5 standardization and what happens. Ultimately,
6 when the measure comes in, is it specified so
7 that you know the specifications for all of
8 those different data sources?

9 CO-CHAIR SAIGAL: Now we will do
10 the phase 2 thing. So, really, let's look at
11 the concept and the quality.

12 Johannes?

13 MEMBER KOCH: To that end,
14 dysphagia is, obviously, not a patient report.
15 That is an interpretation of the patient. So,
16 that is a physician taking a good history.
17 And weight loss, my guess is you are asking
18 the patient report, although there would be
19 EHR documentation of actual weight loss.
20 Which is it? Is it the actual documented
21 weight loss or the patient report of weight
22 loss, which they may or may not do at any

1 particular time?

2 DR. WU: It is actually a
3 combination of both. There are ICD-9 codes
4 for weight loss per se. Again, this is
5 actually out of more personal practice. Most
6 people probably, if you see someone have
7 intentional weight loss, you would not
8 document weight loss as an ICD-9 code. So,
9 that is how we capture the weight loss from
10 the diagnosis portion, but also from the
11 personal health record portion we have
12 unintentional weight loss per se.

13 Did that answer your question or
14 no?

15 MEMBER KOCH: Well, not quite,
16 because in those 4 million people, 200 of
17 them, you know, 100 patients are not getting
18 an upper endoscopy. My guess is from personal
19 experience that there is probably thousands of
20 patients who are getting an upper endoscopy.
21 And the whole question that you are raising
22 is, who is getting the appropriate endoscopy

1 and what knowledge does a physician have, or
2 should have physician have, at the time that
3 they are deciding do you get one and do you
4 get one? Does the patient have symptoms,
5 right, and how are those documented, right?

6 DR. WU: That is true.

7 MEMBER KOCH: So, we are doing
8 lots and lots of endoscopies. There is only
9 a teeny-weeny fraction of patients that you
10 have identified that may not be getting one in
11 some timely fashion, based on data that we
12 know isn't recorded well, which is physicians
13 documenting patient symptoms or patients
14 telling physicians their symptoms, or whether
15 they actually have true weight loss or not.

16 CO-CHAIR SAIGAL: So, we can have
17 a discussion with ourselves and carry this on

18 John, are you going to introduce
19 the measure for us in terms of the importance?

20 MEMBER MORTON: Yes. I think
21 everybody is heard a little bit about the
22 measure. The idea is to take a look

1 specifically at patients who have reflux with
2 alarm symptoms. Reflux is the most common GI
3 complaint. If you read the Gallup Poll, it is
4 probably two out of three Americans have it.
5 So, it is anywhere from 150 million, maybe
6 even 180 million. There are about 15,000
7 esophageal cancer cases diagnoses annually.
8 The gentleman is right; there was an increase
9 in the types of esophageal cancers.

10 The main risks, though, appear to
11 be in the obese and in the male gender
12 populations. I was wondering why those
13 weren't included.

14 If you look at the citation about
15 alarm symptoms, it is down to essentially two
16 studies. One is a case series, and the other
17 one is from Scandinavia. The idea is to try
18 to identify these people sooner rather than
19 later, before there is disease progression.

20 The numerator, as you heard
21 already, is people had an upper
22 gastrointestinal study, not specified if it is

1 EGD or upper GI swallow; the denominator those
2 who are 18 or older with GERD who have these
3 alarm symptoms. I think Johannes has just
4 pointed out, how do we determine who has these
5 symptoms? If they are by documentation by
6 physician, it may not be apparent. I can say
7 that, around weight loss or weight gain, that
8 is generally poorly-documented.

9 I think that is enough about
10 probably the importance, unless people have
11 questions about it.

12 CO-CHAIR SAIGAL: I have a
13 question as a urologist.

14 MEMBER MORTON: Yes?

15 CO-CHAIR SAIGAL: What you are
16 saying is that it is a very small number of
17 people out of the prevalent population who
18 develop this problem that would need to be
19 identified. So, does that mean that it is
20 like a worthwhile thing in your mind or not
21 worthwhile?

22 MEMBER MORTON: In my mind, it is

1 a pretty small yield here, a really, really
2 small yield. If you examine everybody who has
3 got reflux, that is a huge population. If you
4 narrow it down to these alarm symptoms, it
5 becomes a smaller population. But I think
6 that is the problem, is figuring out who these
7 alarm symptoms are.

8 For the gastroenterologist, the
9 only thing I have found in looking at the
10 data, where there were only two studies about
11 the alarm symptoms, so I don't know how super-
12 specific those are. I know from my practice,
13 male gender is a big one. Being obese is a
14 big one. And so, I would have included those
15 if you are trying to really capture who have
16 got emerging esophageal cancer.

17 CO-CHAIR BASKIN: So, are you
18 saying that the evidence would support the
19 idea that, if you have GERD and you are either
20 male or obese, that it would be appropriate to
21 do an upper gastrointestinal study? And by
22 the way, they do say that it could be a barium

1 study or an endoscopy.

2 MEMBER MORTON: My only point,
3 Andy, is to include that in addition to those
4 alarm symptoms.

5 CO-CHAIR BASKIN: Yes, but I guess
6 that is my point. The measure here is to
7 measure a population, by the way, not an
8 individual provider, but a population, to see
9 whether a population with GERD and alarm
10 symptoms, are they getting an upper GI study
11 of some sort or another?

12 So, what is that population? If
13 that population is getting bigger by calling
14 them male and obese, then that population is
15 huge. So, that is what I am trying to figure
16 out.

17 And even if it is only a small
18 percent with just a couple of symptoms that we
19 were talking about, 2 percent of 150 million
20 people is a big impact problem. So, I am
21 trying to understand what is the real
22 population --

1 MEMBER MORTON: I don't think that
2 is exactly -- oh, go ahead, Johannes.

3 MEMBER KOCH: I think the
4 population we are looking at are people who
5 actually have cancer, right? So, it is
6 15,000, roughly, or less. We are looking at
7 the number of people who did not have an
8 endoscopy with alarm features, having had a
9 history of reflux. This is a teensy-weensy
10 group, right?

11 MEMBER MORTON: Uh-hum.

12 MEMBER KOCH: It is patients with
13 cancer.

14 CO-CHAIR BASKIN: This is just
15 people with alarm symptoms, did they get an
16 upper gastrointestinal study?

17 MEMBER KOCH: Right, but that is a
18 guideline recommendation. What we are arguing
19 with in GI is that we are doing an endoscopy
20 on everybody, anybody with GERD. So, what we
21 are trying to do is restrict that to people
22 who have had longstanding GERD, 10 years or

1 more, people who have risk factors of obesity,
2 alcohol, cigarettes, and everybody with alarm
3 features, by the guidelines, should be getting
4 an endoscopy.

5 So, we are just saying people who
6 have alarm features should be getting an
7 endoscopy. I mean, I don't know that that is
8 that big of a group. We don't have an
9 identified -- out of 4 million, they have
10 identified 100 patients in their group, which
11 is of questionable administrative data, right,
12 because who codes for dysphagia when you are
13 doing an upper endoscopy? Maybe you do or
14 maybe you don't. Who codes for weight loss?
15 That may or may not be documented, right?
16 Everybody is coding for an EGD for GERD. That
17 is part of what we do.

18 MEMBER MORTON: Just a couple of
19 more points, and these are some of the staff
20 notes that came up in reviewing.

21 One is that the numerator states
22 it includes patients with at least one gastric

1 or esophageal cancer diagnosis; the
2 denominator excludes patients with documented
3 gastrointestinal malignancy. Is this
4 construction appropriate?

5 There was a member comment from
6 America's Health Insurance Plans that it
7 cannot be collected easily, given
8 administrative data; however, it is a good
9 registry measure.

10 When people reviewed it before
11 this came up, it was pretty split, 3-to-3, in
12 terms of importance.

13 MEMBER SCHOENFELD: I just want to
14 clarify, we are saying whether or not this is
15 a high impact. I mean, that is a little bit
16 different than performance gap. I mean, high
17 impact, should people who have alarm signs get
18 an upper endoscopy? If that is the way we
19 need to answer this question -- I mean, do we
20 have a high impact from doing an upper
21 endoscopy on people who have GERD plus alarm
22 symptoms? It goes beyond just esophageal

1 cancer. They may have a stricture, et cetera.

2 So, is that an impactful thing to
3 do? Okay? Sure, we are going to get to the
4 performance gap. I don't think the
5 performance gap is going to be very big, but
6 we will come to that discussion a little bit
7 later on. But is it something that should be
8 done? Is it going to have a big impact on
9 those people who do have weight loss or
10 dysphagia or anemia, iron-deficiency anemia,
11 who also have GERD?

12 CO-CHAIR SAIGAL: Phil, I think
13 the issue is, though, not that it is impactful
14 for the individual patient, but then, on a
15 population basis, are you moving the dial in
16 the health of the population of a city? So,
17 if it is 10 people in the city, then maybe it
18 is not high impact. It depends.

19 MEMBER SCHOENFELD: But I think --
20 I mean, maybe I missed this in terms of the
21 discussion -- but an important minority, a
22 substantial minority of people with GERD

1 develop alarm symptoms that aren't going to be
2 treated appropriately unless you do an
3 endoscopy because it is for more than just
4 cancer.

5 Now I think a little bit further
6 we are going to find that looks like virtually
7 everybody who has documented alarm features
8 actually does get their upper endoscopy, that
9 there might not be much of a performance gap
10 we have to address.

11 CO-CHAIR SAIGAL: Jenifer?

12 MEMBER LIGHTDALE: I was just
13 going to ask, though, I think I could see this
14 being more useful for getting at primary care
15 physicians who are seeing patients and
16 treating patients with GERD and are missing
17 the fact that they have alarm symptoms and
18 aren't referring them. So, it is more about
19 referral.

20 CO-CHAIR SAIGAL: It could be high
21 impact for that? Okay.

22 MEMBER LIGHTDALE: Yes.

1 CO-CHAIR SAIGAL: Zahid?

2 MEMBER BUTT: So, I think that if
3 we define the high impact as large groups of
4 people, then the missing piece in this is the
5 one that you mentioned, which is chronic GERD,
6 because that has the biggest impact on a large
7 number of people, because that is one
8 screening criteria for Barrett's and bad
9 things with chronic reflux.

10 So, this sort of narrows the
11 denominator substantially because a smaller
12 percentage of them present with alarm
13 symptoms. But if you take that group, it has
14 a very high impact, in my opinion, because you
15 will have a very high percentage of them with
16 something bad there.

17 But, again, it sort of goes back
18 to several issues with the construct of this
19 measure, which we can discuss later on,
20 because, by definition, many of these people
21 who will get the test will be esophageal
22 cancer, and then you exclude them, because the

1 exclusion is GI malignancy. It doesn't
2 specify a specific malignancy. So, in a
3 sense, you are sort of excluding your own
4 numerator by diagnosing them.

5 CO-CHAIR SAIGAL: Is the exclusion
6 a known malignancy? I mean, if you make a
7 diagnosis, you are still excluded?

8 MEMBER MORTON: I am pretty sure
9 it is a known.

10 MEMBER BUTT: It doesn't specify
11 when it would be excluded, right?

12 MEMBER MORTON: I am pretty sure
13 it is known.

14 CO-CHAIR SAIGAL: Yes.

15 MEMBER BUTT: Okay. So, it should
16 be previous, prior to this, right?

17 CO-CHAIR SAIGAL: Right. Yes.

18 MEMBER BUTT: But that is not
19 specified.

20 CO-CHAIR SAIGAL: Right.

21 MEMBER BUTT: But, anyway, the
22 other thing is that this doesn't really have

1 upper endoscopy as the numerator. It has
2 gastric motility studies. All sorts of things
3 are in here as the upper GI tests. So, if you
4 have any upper GI test, you are in the
5 numerator. I don't know what the relevance of
6 that is.

7 CO-CHAIR SAIGAL: A lower impact,
8 in your mind?

9 MEMBER BUTT: I think yes. So, I
10 mean, in terms of the relevance, if someone
11 has a motility gastric emptying study, how is
12 it relevant to a dysphagia patient in GERD?

13 CO-CHAIR SAIGAL: Comments about
14 that from our GI specialists? No?

15 MEMBER BUTT: But, you know, that
16 is kind of where I -- so, what I was going to
17 say was that is where we had that earlier
18 discussion, that those are issues with the
19 construct of the measure, but not sort of the
20 importance. I mean, the issue is important,
21 but how it is constructed is some of the
22 problems.

1 MEMBER SCHOENFELD: Right. I
2 think that will go to the evidence part, yes.
3 I mean, to paraphrase what you said, there is
4 no good data that esophageal motility studies
5 are going to be --

6 MEMBER BUTT: Well, there is
7 gastric motility.

8 MEMBER SCHOENFELD: -- gastric
9 motility studies are going to be real helpful
10 in somebody with dysphagia and GERD.

11 CO-CHAIR SAIGAL: Okay. Liliana?

12 MEMBER BORDEIANOU: I only wanted
13 to point out that, for some reason, Barrett's
14 is an exclusion criteria, which I found
15 confusing since Barrett's is a precursor.

16 CO-CHAIR SAIGAL: It is a known
17 pathology before, my understanding is, if you
18 know there is Barrett's, then they are
19 excluded from the study.

20 MEMBER SCHOENFELD: They have
21 already been evaluated.

22 CO-CHAIR SAIGAL: Jenifer?

1 MEMBER LIGHTDALE: One more
2 comment, which is maybe to also to be pro for
3 impact. I guess giving more impact would be
4 to actually notice that you don't actually
5 need to exclude patients 18 years and younger.
6 Actually, the same rule applies; if you have
7 GERD and alarm symptoms, you are going to do
8 an endoscopy.

9 CO-CHAIR SAIGAL: Great point. We
10 want to bring these aspects of these measures,
11 if we can.

12 Okay. John, go ahead.

13 CO-CHAIR SAIGAL: I was just going
14 to say the first part of this is just, is this
15 important or not? That is our first
16 determination. And it comes down to: what is
17 the level of importance? Does it affect a lot
18 of people? If it doesn't affect a lot of
19 people, does it affect a population that is
20 clearly at risk that needs special attention?

21 I think you could argue that it is
22 the latter, that this is not a huge

1 population, but we are seeing data to show
2 that that group is increasing, people that get
3 esophageal cancer. So, I think based on the
4 second criteria, a vulnerable population with
5 potential for increase probably meets that
6 criteria.

7 CO-CHAIR SAIGAL: Okay. Well-
8 said. So, then, maybe we can move to a vote.

9 I will just summarize real quick
10 the discussion. The comments were that this
11 is probably a small number of people. So, it
12 would be low impact from a population health
13 point of view. However, of the people that
14 this measure would affect, the severity and
15 consequences are high. So, some individuals
16 feel that that makes it high impact.

17 And there are certainly questions
18 about it is defined and whether it would be
19 made better through different specifications.
20 We have to vote on the measure as it is
21 written now. So, if you think that the way
22 the measure is specified makes it unlikely to

1 impact the health of that small group of
2 people in whom it is intended to help, that
3 would be a problem. And the age limitations
4 that we mentioned are also of consideration,
5 whether it could be a more impactful or a way
6 to increase its impact.

7 So, with that introduction, then
8 why don't we vote on the impactfulness of this
9 measure?

10 MR. WILLIAMSON: We will now vote
11 on the impact. And there are four options:
12 high, moderate, low, or insufficient.

13 And you may begin voting now.

14 (Vote taken.)

15 CO-CHAIR SAIGAL: Let's all vote
16 again. There we go. Okay.

17 MR. WILLIAMSON: And we have 2
18 high, 7 moderate, 5 low, and 1 insufficient.

19 CO-CHAIR SAIGAL: Okay. So, then,
20 we can move on, John, to the evidence that
21 supports the measure.

22 MEMBER MORTON: So, this gets to

1 the evidence supporting the measure. What is
2 cited right now for evidence, that the alarm
3 systems -- the alarm systems? (laughter) --
4 the alarm symptoms will help indicate if there
5 is going to be a problem down the road.

6 I know there must be more out
7 there, but I just go with what was cited. And
8 we had essentially one case series and we also
9 had one other study out of the Scandinavian
10 journal. So, that was two studies, and I
11 would give them moderate strength in terms of
12 support. I have a feeling there must be more
13 than that, but that is what I was able to see
14 from the evidence.

15 And then, I guess we are going to
16 discuss the gap in performance after the
17 evidence discussion.

18 CO-CHAIR SAIGAL: Anyway, Zahid,
19 could you turn off your microphone if you are
20 not using it?

21 MEMBER BUTT: Oh, I'm sorry.

22 CO-CHAIR SAIGAL: Thanks.

1 So, are there other studies/data
2 that people are aware of that have not been
3 brought up specifically to this topic?

4 MEMBER MORTON: I did forget to
5 mention the AGA did have a technical review.
6 So, that is three.

7 CO-CHAIR SAIGAL: Okay. So, three
8 studies, and the quality was moderate?

9 MEMBER MORTON: I would call it
10 moderate at best.

11 CO-CHAIR SAIGAL: Moderate at
12 best?

13 MEMBER MORTON: Yes.

14 CO-CHAIR SAIGAL: Okay. Moderate
15 at best, moderate level of evidence, and the
16 direction was correct.

17 John, it is a USPSTF
18 recommendation?

19 MEMBER MORTON: I mean, that is
20 what 1(c)6.3 says. It is not one I read very
21 often. So, I can't help you with that.

22 CO-CHAIR SAIGAL: 1(c)6.3?

1 CO-CHAIR BASKIN: It says USPSTF
2 is a grade B.

3 MEMBER MORTON: The grade here is
4 intermediate strength recommendation.

5 CO-CHAIR BASKIN: I mean, my point
6 is, if it is USPSTF, then there is a whole
7 body of evidence to support the USPSTF making
8 that recommendation that we may or may not be
9 seeing in this document. That is an evidence-
10 based recommendation that they make at grade
11 B. So, it makes me think that there is
12 evidence that perhaps has not been presented,
13 but it does exist. That body is pretty
14 conservative in their recommendations.

15 CO-CHAIR SAIGAL: Phil?

16 MEMBER SCHOENFELD: This isn't
17 really my area of expertise within GI, but
18 having said that, there is a lot more out
19 there on scoping people who have GERD and
20 alarm symptoms like dysphagia than what is
21 listed in here.

22 CO-CHAIR SAIGAL: Thank you.

1 Okay. So, there may be data that
2 is out there that we are not seeing.
3 Obviously, if the USPSTF has a B grade, there
4 is a lot of data. The developer put that on
5 here in terms of the grade. And in the
6 document, there is at least a moderate level
7 of evidence to support the quality and
8 quantity supporting the measure.

9 So, unless there are other
10 comments, we can vote about that.

11 (No response.)

12 Let's vote.

13 MR. WILLIAMSON: We will now vote
14 on the evidence. Again, there are three
15 options.

16 You may begin voting now.

17 (Vote taken.)

18 One more. There you go.

19 We have 7 yes; 2, no, that the
20 evidence does not meet the guidance, and 6
21 that insufficient information was submitted to
22 rate.

1 CO-CHAIR SAIGAL: So, for the
2 people who voted no, can anyone please voice
3 your opinion about what the concern was?

4 MEMBER MERGUERIAN: The evidence
5 seems to be existing, but they did not provide
6 it to us.

7 CO-CHAIR SAIGAL: The evidence in
8 the document was not convincing to you? Okay.

9 Phil?

10 MEMBER SCHOENFELD: And I think
11 there is an important thing to differentiate
12 here, which is, is there a lot more data out
13 there that they could have included? Yes.
14 Everybody has to make a judgment on their own
15 whether or not that actually rises to the
16 level of saying that what they did cite is
17 inadequate to support the need to do this.
18 And I think that is an important thing just to
19 remind people about.

20 CO-CHAIR SAIGAL: Sure. Three,
21 you are not supposed to use three just because
22 there is more they could put in there. If it

1 is convincing enough on its own, you can say
2 yes, and then, later, tell them to put more
3 data in at the end. So, I don't know. I
4 mean, it was a squeaker, but --

5 MR. WILLIAMSON: It is no.

6 CO-CHAIR SAIGAL: Oh, is it no? I
7 thought it was yes.

8 MR. WILLIAMSON: It was 7 yes and
9 8 no --

10 CO-CHAIR SAIGAL: All right.

11 MR. WILLIAMSON: -- split
12 between --

13 CO-CHAIR BASKIN: Doesn't that
14 mean that there may be other information
15 available?

16 CO-CHAIR SAIGAL: Well, let me ask
17 the group again, just to be clear, does anyone
18 think they would change their vote, based on
19 the discussion we just had? Or was there some
20 miscommunication about the meaning of vote?
21 Or are we good on our votes?

22 Can you raise your hand if you

1 think you are good with your vote?

2 (Show of hands.)

3 Yes.

4 MS. WILBON: So, maybe we should
5 clarify, too, because I am not sure that it
6 was clear. So, option 2 is the evidence that
7 they submitted is insufficient and you don't
8 think that there is anything else out there
9 that they could have found; it just doesn't
10 exist. Option 3 means the information they
11 submitted is insufficient, but there is
12 potentially other data out there that they
13 could have submitted, but what is in the form
14 does not meet the criteria. So, there is some
15 differentiation. Two means it doesn't exist.
16 Three means it exists, but they didn't find
17 it.

18 DR. PACE: I was just going to say
19 that, either way, it is a no.

20 MS. WILBON: Yes.

21 DR. PACE: And then, you can
22 decide on what the next step is.

1 CO-CHAIR SAIGAL: Yes.

2 DR. PACE: You know, to talk about
3 the evidence that does exist or --

4 CO-CHAIR SAIGAL: My only concern
5 was that we are talking about all the other
6 data that is out there, and people might have
7 shorthanded it and said, well, yes, there is
8 other data out there and pressed 3. I may be
9 wrong about that.

10 Maybe we could just do this: if
11 you think that maybe that we should do it
12 again because of miscommunication, raise your
13 hand.

14 (Show of hands.)

15 Two, three, four, five.

16 So, most people are happy with
17 their votes then. Okay. So, we will leave
18 it.

19 MEMBER SCHOENFELD: If I
20 understood what John said, he did say for the
21 quantity of evidence it was moderate and for
22 the quality of evidence it was moderate.

1 CO-CHAIR SAIGAL: Right.

2 MEMBER MORTON: John will speak
3 for John here.

4 (Laughter.)

5 MEMBER SCHOENFELD: Yes. Because
6 if I didn't understand, that is fine.

7 MEMBER MORTON: Well, to be clear,
8 if I were grading this, you know, like a
9 Cochrane-type deal, this would be poor. You
10 know, we are talking about a case series that
11 is not Level 1 evidence. Okay? That is
12 probably Level 3 at best. And then, we are
13 dealing with a recommendation from a society.
14 Even as August as AGA, it is still a societal
15 recommendation.

16 And the second one was the best.
17 The third study was out of Scandinavia, three
18 years, a single-site study, though. It wasn't
19 randomized. So, that is why I would put it
20 moderate at best. And we had three studies,
21 mind you. So, that is where I would put it.

22 CO-CHAIR SAIGAL: Okay. Paul?

1 MEMBER MERGUERIAN: One of the
2 things regarding the Quality B evidence, I
3 think it says recommends this service. But
4 when you look at the numerator, there are like
5 five or six different studies that are in the
6 numerator, and they did not provide evidence
7 for each one of these studies. So, I am not
8 sure what the service means. Is that the
9 endoscopy? Is that upper GI motility series?
10 Is that an upper GI series? I don't have that
11 data.

12 CO-CHAIR SAIGAL: You are
13 referring to 1(b), you said?

14 MEMBER MORTON: I think he is
15 referring to the US Preventive Health --

16 MEMBER MERGUERIAN: Yes, but,
17 then, when you look at the numerator, there
18 are multiple studies, but I see no evidence,
19 there is no evidence to suggest that each one
20 of these tests -- they are pretty much
21 grouping them all together rather than taking
22 just one test and providing evidence for each

1 one of these tests specifically.

2 DR. PACE: So, it is unclear
3 whether there is -- I mean, they give a U.S.
4 Preventive Services Task Force grade, but I
5 don't see the citation for the U.S. Preventive
6 Services Task Force recommendation. Or am I
7 missing it? So, does anyone see a specific
8 U.S. Preventive Services Task Force citation?

9 MEMBER MORTON: I am sorry, I
10 didn't look that up specifically. I went by
11 that it was in the report. So, I assumed that
12 was correct.

13 DR. PACE: Right. I understand.
14 So, maybe we can ask the
15 developer, is there actually a U.S. Preventive
16 Services Task Force recommendation?

17 DR. WU: So, they used the USPSTF
18 grading. And when you look at the technical
19 review that you pulled up in the PDF over
20 there, page 1397 --

21 DR. PACE: Okay. So, this is the
22 AGA, and they are using the --

1 DR. WU: This is the technical
2 review.

3 DR. PACE: -- terminology that
4 U.S. Preventive Services Task Force uses?

5 DR. WU: The grading system of the
6 USPSTF grading system.

7 DR. PACE: Okay. Okay.

8 CO-CHAIR SAIGAL: That's
9 different. That's different. That is
10 unclear, then. That's different. You are
11 using their grading system, and you are
12 calling the grade fair. Okay.

13 So, there have been a few post-
14 vote discussion items. I would probably feel
15 better if we voted again, just to be on the
16 safe side. So, is that okay?

17 All right, let's vote one more
18 time.

19 Any more questions?

20 (No response.)

21 We're good? Okay.

22 CO-CHAIR BASKIN: But I still have

1 a comment. So, if that is the grading system
2 used by the -- is this the ASG that used this
3 grading system?

4 MEMBER SCHOENFELD: AGA.

5 CO-CHAIR BASKIN: Oh, the AGA?

6 So, I am presuming, then, the AGA has an
7 evidence-based guideline. I mean, you can't
8 have a grading system of grade B if it is not
9 evidence-based. So, once again, there is
10 theoretically an evidence base out there that
11 convinced the AGA to make this recommendation.
12 I mean, you know, they either did or they
13 didn't. I haven't read what studies they
14 cited, but I am going to give credit to the
15 AGA that it is an evidence-based guideline,
16 which makes me think it exists.

17 CO-CHAIR SAIGAL: Okay. So, that
18 is food for thought for the hopper for the
19 vote.

20 Let's vote.

21 MR. WILLIAMSON: We will now
22 revote on the evidence. Again, there are

1 three options. The first, yes, the body of
2 evidence meets the guidance. The second, no,
3 the evidence does not meet the guidance. And
4 three, that insufficient information was
5 submitted.

6 So, you may begin now.

7 (Re-vote taken.)

8 Did anybody leave the room?

9 All right. It just counted wrong.

10 Yes.

11 CO-CHAIR SAIGAL: Okay. So,
12 then --

13 MR. WILLIAMSON: Yes. So, after
14 re-vote, we have 4 yes; 1, no, that the
15 evidence does not meet the guidance, and 10
16 insufficient information submitted.

17 CO-CHAIR SAIGAL: So, the
18 reliability of our voting process needs to be
19 worked on.

20 (Laughter.)

21 But we are basically needing to
22 vote now about whether -- I am just kidding --

1 about whether, despite the fact that there is
2 not a level of evidence to support the measure
3 from an NQF guidance standpoint, we think the
4 measure is important enough to do an override
5 and have it go forward.

6 MR. AMIN: Actually, Chris, I know
7 it is the last hour here.

8 CO-CHAIR SAIGAL: Yes.

9 MR. AMIN: So, because you voted
10 3, essentially, you are saying that there is
11 an evidence base that exists that was not
12 provided by the developer. So, the question
13 here is actually slightly different. It would
14 not be the exception where there isn't an
15 evidence base. What you are asking here is
16 whether there is a general agreement by the
17 experts in the room that the evidence that
18 does exist that John and others described
19 would meet the quantity, quality, consistency.
20 So that there is the evidence that exists, but
21 it was just not presented, which is slightly
22 different than the exception that the group

1 has been invoking in the past.

2 CO-CHAIR SAIGAL: So, I don't know
3 that we have had an explicit discussion of all
4 the evidence exists, but people think there is
5 a lot of it.

6 So, would anyone who is familiar
7 with it like to give us a comment?

8 (Laughter.)

9 MEMBER SCHOENFELD: If you go back
10 to the AGA's technical review on page 1037-38
11 -- okay, I will speak loudly. No, no, go back
12 up to 1038. Okay.

13 If you read the wording on that
14 meta-analysis -- maybe you would like to,
15 Chris, if you can see that far? Okay.

16 The wording there, it says, from
17 where it says, "A recent meta-analysis
18 addressed the specific issue of the utility of
19 alarm signs and symptoms in diagnosing upper
20 gastrointestinal malignancy based on 15
21 published prospective evaluations encompassing
22 46,161 patients, 8,669 with one or more alarm

1 feature, and 150 subsequently found to have
2 gastric or esophageal cancer on endoscopy.
3 Although those investigators concluded that
4 alarm features perform poorly as a diagnostic
5 test, they reported the overall pooled
6 sensitivity and specificity to be 67 percent
7 and 66 percent, respectively."

8 So, I guess I would just say there
9 that there is a meta-analysis not cited here
10 that says that relying on alarm features to
11 tell you that a patient might need to be
12 screened for cancer is not good. But when you
13 screen everybody with alarm features, you at
14 least do pick up a fair number of cancers.

15 Everybody can choose how they want
16 to interpret that statement, but it looks like
17 there are a lot of prospective studies that
18 are out there that were not cited.

19 CO-CHAIR SAIGAL: That is really
20 helpful. Thanks, Phil.

21 And those numbers are similar to
22 like mammography and PSA testing and those

1 kinds of things.

2 MEMBER MORTON: Just one small
3 clarification. There is no mention of this in
4 the United States Preventive Task Force. It
5 is just the grading.

6 CO-CHAIR SAIGAL: Okay. So, we
7 are all good?

8 Any other comments about the data
9 that are out there?

10 (No response.)

11 Let's vote about whether we think
12 there is high-quality data out there that
13 hasn't been cited yet.

14 MR. WILLIAMSON: We will now vote
15 on the evidence, the insufficient information
16 provided on the quantity, quality, and
17 consistency. And so, the question is, there
18 is general agreement that the quantity,
19 quality, and consistency of the body of
20 evidence meet the NQF guidance. So, this is
21 a yes/no question.

22 And you may begin voting now.

1 (Vote taken.)

2 And we have 10 yes and 5 no.

3 CO-CHAIR SAIGAL: Okay. So, that
4 goes back to the developer. The measure
5 stops.

6 MR. AMIN: No.

7 CO-CHAIR SAIGAL: We continue? It
8 continues?

9 MR. AMIN: Yes.

10 CO-CHAIR SAIGAL: Okay. Good.
11 Okay. Good. Great. Fantastic.

12 (Laughter.)

13 John, performance gap?

14 MEMBER MORTON: The performance
15 gap, I think this is the big question that we
16 all kind of have. We don't doubt that there
17 is not a lot of evidence to support that there
18 are people at risk. The question is, how
19 often are people who are at risk not getting
20 some sort of diagnostic, whether it be an
21 upper GI series or it be an EGD?

22 They do cite one study where they

1 believe there is a performance gap of about 33
2 percent. It is a bit intuitive. They look at
3 a general population and then decide who is at
4 risk for GERD and who has these potential
5 alarm symptoms, and then they see the mismatch
6 between the two.

7 By that criteria, there is about a
8 33 percent performance gap, according to them.
9 It is a population of about 4 million people
10 that they did this in, and it was
11 administrative data. But that is the only --
12 there are no population-based studies.

13 CO-CHAIR SAIGAL: Any other
14 comments on performance gap?

15 (No response.)

16 We have seen this kind of thing
17 before today with -- Johannes?

18 MEMBER KOCH: Yes, I was going to
19 say that I thought the comment earlier about
20 whether this really applies more to primary
21 care or to gastroenterology is really key. If
22 you have a patient in primary care who has

1 reflux symptoms and you don't ask them about
2 dysphagia and weight loss, that is an error,
3 right? I mean, that is something that we
4 would want to measure.

5 This I don't think quite gets at
6 that. And so, I am loathe to just recommend
7 that people do a good history and physical on
8 patients that they see. That seems a little
9 bit mundane for the quality metrics we are
10 trying to achieve.

11 CO-CHAIR SAIGAL: So, you think a
12 performance gap exists at the primary care
13 level, not the specialist level?

14 MEMBER KOCH: Right. I mean, I
15 think in specialty it is the opposite because
16 there is lots of data to suggest that we do
17 endoscopies on anybody who has reflux,
18 independent of how long they have it, and
19 there is overutilization of that.

20 This really is a question, is
21 there underutilization? And there may be
22 under-referral to GI. I don't think there is

1 an underutilization per se. And it is a
2 slightly different question, I think.

3 CO-CHAIR SAIGAL: Karen, in terms
4 that this is a population measure, so try to
5 obviate that? Is that what you are saying?

6 DR. PACE: Right. You know, the
7 question of general versus specialist -- and
8 maybe we want to hear from the developer why
9 they are suggesting this measure is a
10 population-level measure versus at a health
11 plan or clinician level.

12 DR. WU: To Johannes' comment,
13 from a specialist standpoint, there is zero
14 gap, probably zero gap. But when you have
15 about a thousand primary care physicians out
16 there, I mean a thousand patients per primary
17 care physician out there, you might not
18 remember whether you did the endoscopy or not.
19 You may not remember who had the dysphagia or
20 not. You may not know what the data is coming
21 from, whether someone has the dysphagia, was
22 admitted into the hospital, and you didn't get

1 that data.

2 So, this is a way to kind of
3 identify that population that you just forgot
4 about, and mainly geared toward the primary
5 care physician than the specialist.

6 DR. PACE: Who will use this
7 measure, if it a population, to identify those
8 patients?

9 DR. WU: Primary care physicians.

10 DR. PACE: But it is not a
11 primary-care-physician-level measure. You are
12 saying you measure this at a population level,
13 and your example is having 3 million records,
14 or whatever.

15 CO-CHAIR BASKIN: I think the
16 issue here is using this as a population
17 measure, you are not measuring the performance
18 of an individual physician; you are measuring
19 the performance of a system of care. So, that
20 could be at the level of an ACO-type
21 organization where they are responsible for
22 50,000 patients, and the answer is that not

1 all your patients who have alarm symptoms and
2 GERD are getting endoscopies. And then, you
3 would do whatever you do to identify where
4 your issues are. That would be, I think, how
5 this measure is used.

6 And you may find your issue is not
7 with your gastroenterologist. You may find in
8 investigation that your issue is your primary
9 care doctors. But that is your quality
10 improvement activity.

11 All this does is identify that you
12 have a problem that you are not capturing all
13 these cases in a population level. That is
14 what the measure is meant to do.

15 DR. PACE: But I guess I am
16 curious because I made a purposeful choice of
17 not checking like health plan or system. And
18 so, I just want to clarify what your intent
19 is.

20 DR. VIR: I just want to bring up
21 a point that we had been asked to check off at
22 what level the measure was tested and

1 specified; whereas, in the past we certainly
2 had this measure marked off. Because this is
3 an endorsed measure by the NQF, we had this
4 marked off at the level of the provider and
5 the health plan and various other levels.

6 But we were asked to only identify
7 the measure for the level at which it had been
8 tested this time around. And this measure has
9 been tested at the population level. It can
10 certainly be used at the provider level.

11 DR. PACE: Well, that is the
12 question. I mean, NQF is really trying to be
13 very specific because, especially when you go
14 down in levels of analysis and with the
15 numbers you have seen, to do a provider-level
16 performance measure, the numbers may be too
17 small to actually have reliable -- so, that is
18 why, you know, that is definitely what we are
19 looking for, is that we endorse measures that
20 have been specified and tested, you know,
21 tested at the level for which they are
22 specified.

1 So, you are right. Thank you.

2 DR. VIR: Just one other thing.

3 This measure is often used by large
4 organizations, like Accountable Care
5 Organizations. So, they are, as someone
6 brought up the point earlier, they are being
7 looked at across the entire organization, and
8 the organization is able to identify certain
9 providers who have maybe more patients with
10 those issues than others. But it is used for
11 larger organizations.

12 CO-CHAIR SAIGAL: Thank you.

13 John?

14 MEMBER MORTON: Just one comment
15 about the population-based. I think you would
16 have to have a pretty big Accountable Care
17 Organization to make this meaningful and
18 impactful.

19 If I could just read what was
20 exactly in there, "2.46 million lives are
21 included in the sample population,
22 representing cross-sectional nationwide sample

1 from our client population. The test of any
2 sort was performed in 260 of 392 eligible
3 patients."

4 So, you can get an idea of scale.
5 You are talking about 240, 260 patients out of
6 a 2.5 million population. I am not sure
7 exactly how you would implement that on a
8 population basis.

9 CO-CHAIR SAIGAL: Okay. So, yes,
10 go ahead, Jenifer.

11 MEMBER LIGHTDALE: I just have two
12 things. If you were going to look at this at
13 the gastroenterologist level -- and I will try
14 to articulate both -- first off, I think
15 gastroenterologists are at risk of
16 interpreting iron-deficiency anemia which can
17 present and, also, with fecal occult blood as
18 only in the colonoscopy, and they forget to do
19 the upper endoscopy. They forget to ask about
20 the GERD. So, that issue is there, and to
21 really remember that they need to be thinking
22 about upper.

1 And again, I am a pediatric
2 gastroenterologist, but we sort of routinely,
3 if we are going to sedate our kids, we are
4 going to do both, but I know my adult
5 colleagues are not in that same mindset. So,
6 that could play out. There could be some gap
7 that hasn't been identified. I don't know if
8 there is data or I don't know of the data
9 myself.

10 The other thing, though, I wanted
11 to put on the table is the issue of
12 overutilization because I think that is real.
13 And then, you are going to have a problem not
14 just with negative outliers, or you might not
15 have the negative outliers in
16 gastroenterologists, but you may have positive
17 outliers. I don't know how NQF feels, but, as
18 a gastroenterologist, I start to worry about
19 metrics out there that now are being used
20 against me. So, now I can't get approval to
21 do the procedure that I need to do.

22 CO-CHAIR SAIGAL: So, then, if I

1 can sort of summarize, our discussion is about
2 performance gaps specifically. There is, I
3 guess, moderate evidence of a performance gap.
4 There is one big study that John has talked
5 about where there was a small number of
6 people, although there was, whatever, two-
7 thirds of them getting the procedure. So,
8 there is a gap, but it is a relatively-small
9 number of people in that gap.

10 We had a discussion about many
11 other things related to feasibility,
12 implementation, and measurement level which
13 probably are more related to the stage two of
14 this measure.

15 But in front of us is a question:
16 is the document as is showing us there is
17 enough of a performance gap for this measure
18 as specified to move it forward?

19 So, let's vote on that.

20 MR. WILLIAMSON: We will now vote
21 on the performance gap.

22 Please begin voting now.

1 (Vote taken.)

2 One more. There we go.

3 CO-CHAIR SAIGAL: Okay.

4 MR. WILLIAMSON: Zero high, 2
5 moderate, 13 low, and zero insufficient.

6 CO-CHAIR SAIGAL: Okay. So, that
7 is not so great.

8 So, then, the next question is
9 about whether we should approve it. No? We
10 stop here? Okay.

11 MS. BOSSLEY: So, this is always
12 fun.

13 (Laughter.)

14 Because we haven't dealt with this
15 yet in concepts, but this is a maintenance
16 measure. So, there is an opportunity to move
17 a measure into what we call reserve status if
18 it meets all of the other criteria with the
19 exception of the gap.

20 I don't know that we have thought
21 it through on how this works with the concept,
22 but I think --

1 CO-CHAIR SAIGAL: Let me comment.
2 The idea is basically that this measure, it is
3 a good job of moving the dial for quality, but
4 there is no room for improvement anymore.

5 MS. BOSSLEY: Exactly.

6 CO-CHAIR SAIGAL: But I am not
7 sure that is what we are saying.

8 MS. BOSSLEY: And that's fine.
9 So, that is why we are raising it as a
10 question.

11 CO-CHAIR SAIGAL: Because we are
12 reviewing this as a first-time measure. I
13 didn't realize it was a maintenance measure.

14 MS. BOSSLEY: Right.

15 CO-CHAIR SAIGAL: And so,
16 apparently, someone else has thought that the
17 evidence was great and that the performance
18 gap was terrific. So, we didn't see that. I
19 am not sure why that is.

20 No one gave us information about
21 how the implementation of this measure changed
22 the performance gap from when it was first

1 introduced. So, it is very hard to make that
2 decision.

3 MS. BOSSLEY: Well, and to be
4 honest, I don't know that you could make a
5 full decision and a recommendation on reserve
6 status until this measure moved into stage
7 two.

8 CO-CHAIR SAIGAL: Good.

9 (Laughter.)

10 MS. BOSSLEY: So, actually, I
11 think what it could be is I actually think you
12 should probably, at a minimum, do a vote on
13 whether you think --

14 MR. AMIN: Could we vote on
15 importance overall first?

16 MS. BOSSLEY: Yes. So, I am
17 thinking you should vote to approve or not.

18 CO-CHAIR SAIGAL: Yes.

19 MS. BOSSLEY: And then, this is
20 one that we know, if you approve it, it may
21 move forward. And at the time in stage two,
22 you may determine you would like it for

1 reserve status.

2 CO-CHAIR SAIGAL: How can you move
3 it forward if you said it wasn't important
4 there is a gap?

5 MR. AMIN: Well, hold on. Well,
6 let's vote here first. There is criteria for
7 whether it meets the criteria for reserve
8 status, right?

9 MS. BOSSLEY: Right.

10 MR. AMIN: And so, they need to
11 vote on that as well. Because I think what we
12 are hearing is --

13 CO-CHAIR SAIGAL: There is no data
14 about whether high performance is even an
15 actual improvement. That has not been
16 presented to us; I don't think it is in the
17 document.

18 MEMBER MORTON: I didn't present
19 anything about implementation because there
20 was nothing in there.

21 MS. BOSSLEY: This is where,
22 typically, if the measure was being reviewed

1 in the current process, you would have all of
2 that information in front of you. You don't
3 today because we are only looking at the
4 concept.

5 DR. PACE: They do have the
6 performance on the measure.

7 MS. BOSSLEY: Right. As it stands
8 now, yes.

9 CO-CHAIR SAIGAL: We are going to
10 change from prior. So, I don't know. If this
11 is a maintenance measure, what I would suggest
12 is that we are not looking at is -- there was
13 an NQF panel about like measure maintenance,
14 and they specifically looked at what has
15 happened to the population since this measure
16 has come into play. That is maybe a better
17 place for this. Don't you think?

18 MS. BOSSLEY: Well, you are that
19 group for GI/GU for maintenance.

20 CO-CHAIR SAIGAL: For maintenance?

21 MS. BOSSLEY: For maintenance,
22 yes.

1 CO-CHAIR SAIGAL: Yes.

2 (Laughter.)

3 MS. BOSSLEY: So, sorry, but you
4 are.

5 CO-CHAIR SAIGAL: Is there
6 anything else that we are?

7 (Laughter.)

8 MS. BOSSLEY: We will find out
9 throughout the next two days.

10 CO-CHAIR BASKIN: So, if I may --

11 MS. BOSSLEY: Go for it.

12 CO-CHAIR BASKIN: -- you know, at
13 this point it seems that, since this measure
14 had been deemed important in the past, it had
15 been deemed as having a performance gap in the
16 past, we have agreed that it is important up
17 to the performance gap today, and the only way
18 we can assess the performance gap, and whether
19 it has made any difference, is to get to phase
20 2.

21 Then, I've got to tell you, it
22 makes sense to send the measure to phase 2

1 since it is already in place. It is not like
2 we are endorsing a measure that is not being
3 used. It is being used. And all we are
4 saying is we would like to give it the
5 opportunity to go through the feasibility,
6 reliability, validity that it must go through
7 after three years. And it can only be done if
8 we move it on to the next level.

9 So, my suggestion to those on this
10 Committee is that, based on what I have seen
11 today, and if it is only performance gap that
12 is our issue, that can only be assessed by
13 going to the next level and giving the
14 developers an opportunity to submit the
15 information that we will need.

16 MS. BOSSLEY: Right. And so, what
17 we would do is bring this forward to you in
18 stage two with a note that it didn't pass the
19 gap now as a maintenance measure.

20 And I think the other thing we can
21 talk through is what information may be of
22 value for them to bring back in stage two that

1 might actually look at perhaps the difference
2 in the performance over the last few years.
3 And you can, then, provide your assessment on
4 whether or not it should continue on for
5 reserve status or if you should recommend that
6 endorsement be removed or if it stays as an
7 endorsed measure.

8 CO-CHAIR SAIGAL: Okay. Jenifer,
9 is that up for you for a reason? Okay.

10 So, why don't we do a vote, then,
11 on whether we think it should be the reserve
12 status? So, given what we just talked about
13 in terms of its maintenance measurement
14 history, and we don't know anything about how
15 it has changed since it had a debut versus
16 now, can we put it on reserve for
17 reconsideration pending more data about
18 performance data?

19 So, let's vote on that idea, yes
20 or no.

21 MR. WILLIAMSON: We will now vote
22 on reserve status. This is a yes-or-no

1 question.

2 Please begin voting now.

3 (Vote taken.)

4 DR. PACE: This just means that
5 you will continue to evaluate the rest of the
6 criteria. It doesn't mean that you are making
7 any --

8 CO-CHAIR SAIGAL: Two more. Okay.

9 MR. WILLIAMSON: Fourteen yes and
10 1 no.

11 CO-CHAIR SAIGAL: Is there
12 anything else we have to do?

13 (No response.)

14 Okay, next measure.

15 MR. AMIN: Wait. I think, Chris,
16 before we get there -- sorry -- it sounds like
17 from the discussion here that there is a
18 significant amount of feedback that the group
19 wants to get related to the way this measure
20 is constructed. I think it would be very
21 helpful and good use of the time of the
22 Committee to provide that feedback, so you can

1 review that when it comes into stage two.

2 CO-CHAIR SAIGAL: Fair enough.

3 Okay.

4 So, I think I could summarize the
5 group's comments, and please jump in.

6 So, the issue No. 1 was, within
7 the evidence basis for the measure, there are
8 existing studies that are supporting the
9 measure that weren't included in the document.

10 No. 2, in the performance gap
11 issue, we felt there was a small performance
12 gap, given the absolute magnitude of the
13 differences. And we have no information about
14 what has changed in terms of any population
15 health management measurement before the
16 introduction of this measure and today.

17 So, those are some important
18 things to consider in terms of helping the
19 Committee understand the width of the
20 performance gap for these people. Is that
21 fair?

22 Zahid?

1 MEMBER BUTT: Yes, Chris, just to
2 add one more thing is to specify the test and
3 the numerator more precisely.

4 CO-CHAIR SAIGAL: Thank you for
5 reminding me. So, also, the numerator may be
6 looking at procedures that have no impact on
7 the outcome of interested patients.

8 Anyone else have any? Paul?

9 MEMBER MERGUERIAN: Could there be
10 risk stratification, because you talked about
11 the obesity and males? So, is that a measure
12 that should be looked at also?

13 CO-CHAIR SAIGAL: So, specifying
14 the numerator more specifically to make it
15 more impactful, finding the cases where it
16 should make more of a difference.

17 Okay. The last measure, which is
18 0635, chronic liver disease, hep A
19 vaccination.

20 And, Zahid, can you discuss the
21 importance?

22 MEMBER BUTT: Okay. Sure. Thank

1 you.

2 This is hepatitis A vaccination in
3 patients with chronic liver disease. The
4 measure description is that it is a percentage
5 of adult patients with chronic liver disease
6 who have received hepatitis A vaccine.

7 The numerator in this case,
8 actually, the denominator is patients age 18
9 or older who are diagnosed with chronic liver
10 disease, and the numerator is those with
11 chronic liver disease who have received
12 hepatitis A vaccine or who have been tested
13 for immunity in the past. So, this is one of
14 those construct issues that we will probably
15 come back to later on.

16 But, in terms of the evidence, in
17 terms of the impact first, they present some
18 studies that have been done which show that
19 both chronic liver disease is quite prevalent
20 and common, and the patients with chronic
21 liver disease who develop hepatitis A often
22 are associated with higher rates of fulminant

1 hepatitis and mortality.

2 There are several studies that are
3 cited to support this impact and contention.
4 So, I would say that it is moderate to high
5 impact from that standpoint.

6 CO-CHAIR SAIGAL: Anyone else have
7 comments about hepatitis A vaccination in this
8 population and its impact on the population's
9 health?

10 (No response.)

11 Okay. So, then, it sounds like we
12 can have a vote on this concept's impact
13 level, that he feels that it is moderate
14 impact on the population to get them
15 vaccinated to reduce the risk of fulminant
16 hepatic failure.

17 Yes?

18 MEMBER BUTT: And mortality.

19 CO-CHAIR SAIGAL: Mortality.

20 MEMBER BUTT: Higher mortality.

21 CO-CHAIR SAIGAL: More mortality.

22 Okay. Shall we vote?

1 MS. BOSSLEY: Voting starts now.

2 (Vote taken.)

3 MR. WILLIAMSON: We have 7 high
4 and 8 moderate.

5 CO-CHAIR SAIGAL: Okay, Zahid,
6 quality of evidence.

7 MEMBER BUTT: Okay. All right.
8 So, now to the evidence that was presented, it
9 is mainly the three guidelines that they have
10 presented, one from CDC and there are two
11 AASLD, the liver folks with their practice
12 guidelines. Those two guidelines, one is
13 specific to hepatitis B and one is specific to
14 hepatitis C, the AASLD guidelines. So, they
15 are a subset of the chronic liver disease
16 population.

17 The two AASLD guidelines were
18 systematically reviewed. The hepatitis B has
19 a two-three multiple time series, dramatic,
20 uncontrolled experiments and referral.

21 CO-CHAIR SAIGAL: What is
22 dramatic --

1 MEMBER BUTT: Yes, it sounds
2 pretty dramatic, doesn't it?

3 (Laughter.)

4 And the hepatitis C one has a
5 Class Level 2A, Level C. Weight-of-evidence
6 opinion is in favor of usefulness, efficacy,
7 and the evidence is only consensus, opinion of
8 experts, case studies, and standard of care.
9 So, it sort of comes back to that same
10 guideline issue.

11 The third one is really by the
12 CDC. Since they are the government, they did
13 not grade it. So, they make the rules.

14 (Laughter.)

15 So, all three are pretty
16 consistent in the recommendation that it
17 should be done.

18 CO-CHAIR SAIGAL: Okay. So, it
19 sounds like it is mainly, then, expert opinion
20 and some observational series supporting a
21 guideline recommendation. Is that right?

22 MEMBER BUTT: And some dramatic

1 something.

2 CO-CHAIR SAIGAL: The dramatic,
3 uncontrolled --

4 MEMBER BUTT: Yes, dramatic,
5 uncontrolled experiments.

6 CO-CHAIR SAIGAL: All right. So,
7 then, that would be like, I guess, low to
8 moderate quality.

9 MEMBER BUTT: Moderate probably.

10 CO-CHAIR SAIGAL: There are
11 several studies, though, so probably --

12 MEMBER BUTT: Yes, so there are
13 lots of studies. Again, the AASLD have been
14 graded. So, they at least qualify for a
15 moderate on this. But consistency is high.

16 CO-CHAIR SAIGAL: The direction --

17 MEMBER BUTT: All the guidelines
18 are unequivocal about it being done.

19 CO-CHAIR SAIGAL: Okay. Great.

20 Any other comments or data people
21 are aware of that is related to this in terms
22 of hep A vaccination?

1 CO-CHAIR BASKIN: Anyone more
2 familiar than I with the CDC process about
3 evidence base? I mean, honestly, it is not
4 something that I have read up on lately, but,
5 historically, the CDC doesn't make
6 recommendations lightly without some pretty
7 strong evidence. But I am not aware of what
8 their process is.

9 MEMBER BUTT: Yes. So, again, I
10 am going by what is presented in the
11 submission. Whether the CDC has a lot of
12 information, I didn't go in and check. But,
13 over here, it is mentioned that there is no
14 systematic review through the CDC guideline.

15 CO-CHAIR SAIGAL: Okay. All
16 right. Then, I guess we could vote on this.

17 So, let's vote.

18 MR. WILLIAMSON: We will now vote
19 on the evidence.

20 Begin voting now.

21 (Vote taken.)

22 And we have 13 yes; 1, no, that

1 the evidence does not meet the guidance, and
2 1, that insufficient information was
3 submitted.

4 CO-CHAIR SAIGAL: Great. Okay.

5 And now, we talk about the gap.

6 MEMBER BUTT: So, in the gap, they
7 do present a couple of studies that show that
8 the implementation rate remains low. One is
9 a NHANES study which showed that patients with
10 chronic liver disease increased from 13.3
11 percent to 23 percent over a 10-year period.
12 Similarly, there is a VA study quoted that has
13 a 20.7 percent vaccination rate. So, there
14 does appear to be a gap, and there is some
15 additional registry information that supports
16 that gap concept. They did, again, a sample
17 on their own database and found that there was
18 a 64 percent gap in their population when they
19 used the criteria that they have in this
20 measure.

21 CO-CHAIR SAIGAL: Okay. Any
22 comments about this performance gap?

1 (No response.)

2 All right. Then, I think it is
3 time to vote.

4 MR. WILLIAMSON: We will now vote
5 on the performance gap.

6 Please begin.

7 (Vote taken.)

8 I think that was a record.

9 (Laughter.)

10 We have 11 high, 3 moderate, 1
11 low, and zero insufficient.

12 CO-CHAIR SAIGAL: Terrific.

13 So, then, the last one is --

14 MR. AMIN: Chris, can I just get
15 some clarification on that last vote? So, my
16 understanding was that there was a general
17 discussion around the fact that there was not
18 -- maybe I am misunderstanding because I just
19 did step in, and I was out of the room for a
20 second -- but that there was not a sufficient
21 gap demonstrated by the material that was
22 presented.

1 There was information that was
2 described about a 64-percent gap off the
3 patients that were in the sample of 2.4
4 million, of the 5900 that were identified.
5 So, is that the basis of the fact that it was
6 a high performance --

7 MEMBER BUTT: No, there were other
8 studies.

9 MR. AMIN: Okay.

10 MEMBER BUTT: There are two other
11 studies that show similar low percentages.

12 MR. AMIN: Okay. Thank you.

13 CO-CHAIR SAIGAL: So, we are good?

14 MR. AMIN: Yes.

15 CO-CHAIR SAIGAL: All right. So,
16 then, this one, basically, is approval of the
17 concept. So, this is, we thought, a moderate-
18 to-high-impact measure on patients who have C,
19 given this vaccination reduces their risk of
20 fulminant hepatic failure and death.

21 The evidence surrounding it was of
22 moderate grade from different guidelines which

1 are based on several different types of
2 studies. And we felt the gap was significant,
3 20 percent performance levels, something like
4 that.

5 And so now, we can decide if we
6 want to approve the concept in total. So,
7 let's vote.

8 MEMBER BUTT: So, it is not just
9 hepatitis C. It is all chronic liver disease,
10 inclusively.

11 CO-CHAIR SAIGAL: Right. Thanks
12 for that correction. All chronic liver
13 disease.

14 MR. WILLIAMSON: We will now vote
15 on the overall recommendation of the concept.

16 Please begin.

17 (Vote taken.)

18 We have 15 yes and zero no.

19 MEMBER BUTT: So, Chris, this is
20 now back to sort of the construct issue. In
21 the numerator they define not just people who
22 get hepatitis A vaccination, but those who

1 have been tested for hepatitis A antibodies.
2 So, not necessarily the result of it, but any
3 test that was done. So, that is sort of
4 inconsistent with the title of this, which
5 says they have received it. So, they make a
6 leap from there that, if you were tested, then
7 someone had the intention to treat you if you
8 were negative for the hepatitis A antibody.

9 CO-CHAIR SAIGAL: Yes. Right.
10 And so, do you think that is not a valid way
11 to do that?

12 MEMBER BUTT: I think that I am
13 not sure how you could say that, if you were
14 tested, that that is a priori evidence that
15 you either were immune or received it, if you
16 were not immune.

17 CO-CHAIR SAIGAL: So, would you
18 like data that looks at the chart, those LOINC
19 codes, and looks at their concordance, and
20 maybe there is a sample of chart extractions
21 between positivity on those antibody tests and
22 inappropriate use of the vaccine, to say that

1 that assumption is --

2 MEMBER BUTT: Maybe they, then,
3 should, you know -- well, I just have
4 difficulty in saying that, if a test was done,
5 that is evidence that the patient either was
6 immune or received the vaccination, because
7 those are the two conclusions they draw from
8 a test being done for antibodies.

9 CO-CHAIR SAIGAL: Right.

10 MEMBER BUTT: So, I am not sure.

11 CO-CHAIR BASKIN: So, I mean, this
12 would be an issue of validity.

13 MEMBER BUTT: Yes, yes.

14 CO-CHAIR BASKIN: Is it really
15 measuring what it is supposed to measure?

16 MEMBER BUTT: So, I bring it up
17 for them to address it when they bring it back
18 in stage two.

19 CO-CHAIR BASKIN: Yes. So, the
20 whole issue would be, for those who were
21 tested and were not shown to be immune, were
22 those patients vaccinated?

1 MEMBER BUTT: No. Right, right.

2 CO-CHAIR BASKIN: Right.

3 MEMBER BUTT: So, this basically
4 just makes the assumption that, if you were
5 tested for hepatitis A antibody, they assume
6 in this measure that you either received it --
7 you either were positive for the antibody or
8 you actually received it.

9 CO-CHAIR BASKIN: Right. So,
10 those who didn't have an adequate
11 immunization, right --

12 MEMBER BUTT: So, I am not sure if
13 you can make that assumption.

14 CO-CHAIR BASKIN: So, that would
15 be interesting information --

16 MEMBER BUTT: Something that they
17 would have to --

18 CO-CHAIR BASKIN: -- if a sample
19 could be obtained to see --

20 MEMBER BUTT: Right. They would
21 have to somehow prove that that is the case.

22 CO-CHAIR BASKIN: -- what is the

1 outcome, right.

2 MEMBER BUTT: Yes.

3 CO-CHAIR BASKIN: Right, right.

4 CO-CHAIR SAIGAL: Any other
5 comments for the developers of this measure?

6 (No response.)

7 Okay. Then, any NQF member
8 comments about this last set of activities we
9 have engaged in?

10 MS. WILBON: In the room, is there
11 anyone who has any comments or questions for
12 the Committee?

13 (No response.)

14 CO-CHAIR SAIGAL: Apparently not.

15 Okay. Then, Operator, are there
16 any public comments?

17 THE OPERATOR: If you would like
18 to make a comment, please press *1 on the
19 telephone keypad.

20 CO-CHAIR SAIGAL: I am just amazed
21 that she is listening.

22 (Laughter.)

1 (No response.)

2 THE OPERATOR: And there are no
3 comments at this time.

4 CO-CHAIR SAIGAL: Thanks.

5 Good. Okay. So, I think that
6 wraps up for today.

7 I want to thank everybody for
8 their attention. It is a long a process. I
9 think we have made some progress in getting
10 our rhythm going. So, thank you very much.

11 And thanks to the NQF staff for
12 keeping us on track.

13 (Whereupon, at 4:47 p.m., the
14 meeting was adjourned for the day, to
15 reconvene the following day, Tuesday, August
16 28, 2012.)

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This is to certify that the foregoing transcript

In the matter of: Gastrointestinal Endorsement

Before: NQF

Date: 08-27-12

Place: Washington, DC

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