

NATIONAL QUALITY FORUM  
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GASTROINTESTINAL/GENITOURINARY ENDORSEMENT  
MAINTENANCE STEERING COMMITTEE MEETING  
+ + + + +  
TUESDAY  
AUGUST 28, 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 8:30 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

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EVAN WILLIAMSON, MS, MPH

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

2 (8:30 a.m.)

3 CO-CHAIR BASKIN: Good morning.

4 We're going to start on time. I think within  
5 one minute is on time. I hope everybody had  
6 a restful night. We should have an exciting  
7 morning. I guess we just got a hint of the GI  
8 measures at the end of the day yesterday, but  
9 today will be GI day.

10 I don't have too much to say about  
11 a recap for yesterday, other than it was a  
12 learning experience. I think we started to  
13 find our place in terms of what we consider  
14 evidence submitted, evidence implied, evidence  
15 probably-out-there, and I'm proud to say we  
16 didn't use the exception rule very often,  
17 right? I think we stayed within --

18 (Laughter.)

19 CO-CHAIR BASKIN: There's a fear  
20 that we jump into that too often by everybody,  
21 and I'm glad we didn't.

22 There's been a request that we

1 change the order of reviewing the measures, so  
2 when we do the first measures, the C2056 we're  
3 going to do at the end of the 8:45 session, so  
4 we're going to do 658 and 659. I think they  
5 will be easier to start with, and it will help  
6 us when we get to C2056 if we've gone through  
7 those first.

8 Do you have anything in particular  
9 you want to say, Chris, this morning?

10 CO-CHAIR SAIGAL: No. Let's just  
11 get it started.

12 CO-CHAIR BASKIN: All right. Then  
13 we're going to start with 658. And Johannes,  
14 you're up -- whoops. See that? I already  
15 made a mistake. Developer, the developer. So  
16 is the representative for the AMA-PCPI here?  
17 And that's both of the 0658 and the 0659, so  
18 if you could just spend three minutes or so  
19 talking about both measures, not just one,  
20 introducing them? Thank you.

21 (Interruption from phone.)

22 DR. PARK: Good morning. I'm

1 Walter Park, a gastroenterologist representing  
2 the American Society for Gastrointestinal  
3 Endoscopy. I'm here with Maged Rizk, who is  
4 here representing the American College of  
5 Gastroenterology. Joel Brill, representing  
6 the American Gastroenterological Association,  
7 is on the telephone. And together, our three  
8 societies represent virtually all practicing  
9 gastroenterologists in the United States.

10 On behalf of the PCPI, the three  
11 GI societies just mentioned, and a  
12 multi-stakeholder workgroup, I would like to  
13 briefly introduce two measures for your  
14 consideration: 0658 and 0659. Both address  
15 the appropriate timing of follow-up  
16 colonoscopy. 0658 addresses the appropriate  
17 follow-up intervals for colonoscopy in  
18 average-risk patients with a normal  
19 examination, and 0659 addresses colonoscopy  
20 intervals for patients with a history of  
21 adenomatous polyps.

22 The intent of both measures is to

1 avoid inappropriate use or overuse of  
2 colonoscopy. These measures were developed in  
3 2008. The multi-stakeholder workgroup was  
4 chaired by Doctors John Allen and Douglas  
5 Faigel. I believe Dr. Faigel is with us via  
6 telephone today, as well.

7           These measures received  
8 time-limited NQF endorsement in 2011. Testing  
9 data was submitted earlier this year for 0658,  
10 and testing data for 0659 will begin later  
11 this year.

12           Regarding the importance of these  
13 measures, colorectal cancer is the third most  
14 common cancer and the second leading cause of  
15 cancer death in the United States. The vast  
16 majority of colorectal cancers arise from  
17 adenomatous colon polyps. The progression  
18 from polyp to cancer occurs over an estimated  
19 five to ten years in average-risk populations.  
20 Finding and removing polyps during this window  
21 interrupts malignant transformation and  
22 reduces the incidence of, and mortality from,



1 colorectal cancer.

2           There are numerous studies to  
3 support these measures, beginning with the  
4 landmark National Polyp Study published in  
5 1993, that demonstrated that patients who  
6 underwent colonoscopy and had polyps removed  
7 developed colorectal cancer up to 90 percent  
8 less than untreated historical controls.  
9 Colonoscopy is considered to be the most  
10 effective screening option for colorectal  
11 cancer. This procedure directly visualizes  
12 the entire extent of the colon and rectum, and  
13 permits immediate polypectomy and removal of  
14 macroscopically abnormal tissue.

15           The timing of follow-up  
16 colonoscopies should be tailored to the  
17 number, size, and pathologic findings of  
18 adenomatous polyps removed. For average-risk  
19 patients with a normal exam, colonoscopy is  
20 recommended approximately every 10 years in  
21 all current guidelines. Current guidelines  
22 recommend that patients with one to two small

1 tubular adenomas, defined as less than one  
2 centimeter, with only low-grade dysplasia,  
3 should undergo follow-up colonoscopy no  
4 earlier than five years. Patients with  
5 advanced adenomatous lesions, or greater than  
6 three adenomas, should have a repeat  
7 colonoscopy in three years. A shorter  
8 interval of follow-up is recommended in those  
9 patients with numerous adenomatous polyps, and  
10 in patients with large cecal adenomatous  
11 lesions where complete removal is uncertain.

12           These guidelines assume a complete  
13 examination, a high-quality bowel preparation,  
14 and complete removal of all visualized polyps.  
15 When these assumptions are not met, it is  
16 appropriate to reschedule colonoscopy within  
17 one to two months to ensure a high-quality  
18 examination.

19           After a normal surveillance  
20 colonoscopy, repeat examinations should be  
21 done at five year intervals. Performing  
22 colonoscopy too often not only increases

1 patients' exposures to procedural harm, but  
2 also drains limited resources that could be  
3 more effectively used to adequately screen  
4 those in need.

5 The evidence for these measures  
6 has recently been revisited and updated by the  
7 U.S. Multi-Society Task Force on Colorectal  
8 Cancer. Released electronically this past  
9 July, they found that the growing evidence  
10 continues to support these measures.

11 Despite strong evidence for these  
12 measures, a performance gap exists, providing  
13 an opportunity for improvement. In a 2006  
14 study of over 1,200 colonoscopy reports,  
15 recommendations were consistent with the  
16 current guidelines in only 37 percent of  
17 cases. Further, the adjusted mean number of  
18 years in which repeat colonoscopy was  
19 recommended was 7.8 years following a normal  
20 colonoscopy.

21 Four different surveys have  
22 indicated that post-polypectomy surveillance

1 colonoscopy in the United States is frequently  
2 performed at intervals than those that are  
3 recommended in guidelines.

4 In closing, we want to thank the  
5 Steering Committee for considering continued  
6 endorsement of these important questions, and  
7 are available for questions and  
8 clarifications. Thank you.

9 CO-CHAIR BASKIN: Thank you very  
10 much. Does anybody have a particular question  
11 to the presenter before we proceed with our  
12 review? Zahid, go ahead.

13 MEMBER BUTT: The submission  
14 states that it will be a stage two with  
15 electronic specification available. When will  
16 that be? It's 0658, there's mention in the  
17 submission that there will be a stage two, an  
18 electronic specification will be available in  
19 stage two.

20 MS. AST: Just as we stated, it  
21 will be ready for the measure submissions when  
22 they're due. I believe that might be

1 December.

2 MEMBER BUTT: Okay. Thank you.

3 MEMBER BORDEIANOU: As far as the  
4 issue of impact --

5 CO-CHAIR BASKIN: Well, we haven't  
6 presented the case yet. So just if there was  
7 a question for the developer, that was that  
8 part there.

9 Johannes, then, let's go ahead.  
10 We'll go with impact first.

11 MEMBER KOCH: All right. So this  
12 is a process and overuse measure. I think  
13 that it was quite clearly stated that this has  
14 potential large impact, given the number of  
15 colonoscopies currently being done for  
16 screening in the United States, as well as  
17 colon cancer being a very prominent and common  
18 condition. So I think that the rationale for  
19 this being a high impact is pretty well  
20 stated, in my opinion.

21 CO-CHAIR BASKIN: Any comments or  
22 questions from anybody regarding that?

1                   MEMBER SCHOENFELD: I would only  
2                   add that the ABIM and Consumer Reports have  
3                   come out with their "Choose Wisely" campaign.  
4                   Many of you may have seen the big displays in  
5                   the malls about this, about overused medical  
6                   procedures that patients should question their  
7                   physicians about when ordered. And screening  
8                   colonoscopy done sooner than 10 years, and  
9                   surveillance colonoscopy for polyps done  
10                  sooner than three to five years are actually  
11                  the two big GI ones.

12                  So there's a lot of literature  
13                  about it, but it's also becoming a bigger  
14                  public health issue in terms of publicity.

15                  CO-CHAIR BASKIN: I think this is  
16                  probably not terribly controversial, so we  
17                  could probably vote on the impact quickly  
18                  here. Oh, we're not using voting buttons  
19                  today. That's right. Because our ID guys  
20                  usurped them.

21                  (Laughter.)

22                  CO-CHAIR BASKIN: Okay. So I

1 guess we're going to vote. You'll be able to  
2 raise your hand. I'm going to ask for a 1, a  
3 2, a 3, or a 4, right? Because we have four  
4 options here. So think for a second about  
5 which one you're going to do, because once I  
6 get past one to two, it's too late to go back  
7 to one, okay?

8 (Laughter.)

9 CO-CHAIR BASKIN: Now, I know this  
10 is difficult. All right. So we're going to  
11 have a count for each one. One is high, so  
12 who's voting for high impact? And who's  
13 counting?

14 (Show of hands.)

15 MR. AMIN: It's unanimous. 15  
16 high.

17 CO-CHAIR BASKIN: Well, then,  
18 there should be no twos, threes, or fours.  
19 Just to make sure, no twos, threes or fours?  
20 We only have 15, right?

21 (No response.)

22 CO-CHAIR BASKIN: Okay.

1 MR. AMIN: That's 15 high.

2 CO-CHAIR BASKIN: Yes, that was 15  
3 high. Yes. All right. Then we'll move on to  
4 the evidence base. Johannes, if you want to  
5 go ahead again?

6 MEMBER KOCH: So there's a large  
7 body of evidence that's cited. Unfortunately,  
8 as in so many other cases, the developers  
9 don't actually grade the evidence. I think  
10 that there's an overwhelming body of evidence.  
11 None of it is high quality, no randomized  
12 clinical control trials, but a large number of  
13 series, started with the National Polyp Study  
14 that was cited.

15 So there's a large quantity. The  
16 quality is moderate, and it's all very  
17 consistent, both supporting the use of  
18 colonoscopy as well as the fact that there  
19 needs to be proper intervals associated with  
20 that.

21 CO-CHAIR SAIGAL: A question,  
22 Johannes. Is there evidence that 10 years is



1 not overuse?

2 MEMBER KOCH: No. Again, the  
3 evidence is that 10 years is -- there's  
4 nothing that suggests that 15 or 20 years  
5 might not be better or just as good. So 10  
6 years is kind of the lowest bar.

7 CO-CHAIR SAIGAL: Is there an  
8 expert consensus, then, that 10 years is the  
9 number?

10 MEMBER KOCH: Well, I think that  
11 there's some evidence from the National Polyp  
12 Study that when you look at patients, the  
13 interval -- the timing of colonoscopy, the  
14 protective effect of it diminishes over time.  
15 So I think it's more than just consensus, but  
16 I don't think it's locked in time, and I don't  
17 think it's been studied beyond 10 years.

18 MEMBER SCHOENFELD: I would note,  
19 there is evidence from prospective  
20 cross-sectional studies that five years is too  
21 soon. There's not evidence from prospective  
22 cross-sectional studies that 10 years is the

1 right time, say versus 15 years.

2 Having said that, the available  
3 natural history data, which does date back to  
4 the 1960s, where you did serial barium enemas  
5 to assess the growth of polyps, because it was  
6 a choice of either doing a surgical resection  
7 or leaving it in place, shows that the average  
8 time for an approximately one centimeter polyp  
9 to develop into a cancer is between five and  
10 10 years. So that's part of the expert  
11 opinion that led to that choice.

12 CO-CHAIR SAIGAL: So that's in the  
13 document?

14 MEMBER SCHOENFELD: That's  
15 certainly in the guidelines that are cited.

16 CO-CHAIR BASKIN: Any other  
17 comments regarding the evidence?

18 (No response.)

19 CO-CHAIR BASKIN: Then I think  
20 we're ready to go to a vote for this evidence.  
21 You're saying that there's a significant body  
22 of evidence, some limitations on the upper

1 limit of study, but there's some reasonable  
2 science behind that number of 10 years.

3 DR. PACE: I just want to point  
4 out to everybody that this is a measure, not  
5 measuring the interval, but measuring that a  
6 recommendation was made. So, just so you  
7 know.

8 CO-CHAIR BASKIN: That's a later  
9 comment I have. But as is.

10 Okay. Well, our choices here are  
11 one, two and three. So one is yes, a body --  
12 so again, think ahead. Two: the evidence does  
13 not meet it. Three: that it was insufficient  
14 in terms of what was presented.

15 I think you've made it clear,  
16 though, there was significant evidence  
17 presented, so the question is whether it's  
18 good or bad, I guess. But everyone has an  
19 option for three. So, let's go.

20 Option 1. Yes, the body of  
21 evidence meets the guidance.

22 (Show of hands.)

1 CO-CHAIR BASKIN: Fifteen. Okay,  
2 so there are no twos and threes, then. All  
3 right. That's straightforward. Let's move on  
4 to performance gap.

5 MEMBER KOCH: So again, I think  
6 that it was well-stated, and it's  
7 well-documented in the literature as well,  
8 that the performance gap here is that there's  
9 overuse, that people are doing colonoscopy too  
10 frequently, and that the guidelines that are  
11 outlined both here and in the literature  
12 aren't being adequately followed, so that as  
13 a performance measure of overuse, I think this  
14 is a very worthwhile first step.

15 MEMBER BORDEIANOU: I know we're  
16 saying that it's a performance measure of  
17 overuse, but really the denominator here is  
18 this "at least 10 years follow-up." So if you  
19 recommended a one month follow up, it would  
20 still count as check. So the measure doesn't  
21 really measure overuse.

22 MEMBER KOCH: It's measuring

1 whether or not you correctly recommended a 10  
2 year interval for somebody who's low-risk. So  
3 if you say two years for somebody who is  
4 low-risk, you would not meet the quality  
5 measure. If you say 10 years, you --

6 MEMBER BORDEIANOU: That's not  
7 what it says here. Recommended follow up of  
8 at least 10 years.

9 CO-CHAIR BASKIN: Of at least 10  
10 years.

11 MEMBER BORDEIANOU: So it could be  
12 a one month follow up.

13 CO-CHAIR BASKIN: No, no. "At  
14 least 10 years" means 10 years or greater.

15 MEMBER BORDEIANOU: All right.  
16 That's why English is my second language.  
17 Thank you.

18 CO-CHAIR BASKIN: So anything less  
19 than 10 years would be a non-hit in the  
20 numerator.

21 MEMBER BORDEIANOU: I'll shut up.

22 CO-CHAIR BASKIN: No, it's good to

1 ask. Any other comment regarding the  
2 performance gap? So you're saying there's  
3 reasonable evidence here of a significant  
4 performance gap, and I think that's pretty  
5 obvious.

6 Well, then, I think this is pretty  
7 straightforward as well for performance gap.  
8 So once again we have four choices. Vote one  
9 for high. Raise your hands, please.

10 (Show of hands.)

11 CO-CHAIR BASKIN: Okay, and that's  
12 unanimous, so we'll move on from that. I  
13 think then we have one more vote to take,  
14 right? Recommending or not. And this is  
15 going to go down to the wire, I know it.

16 (Laughter.)

17 CO-CHAIR BASKIN: Any discussion  
18 prior to this vote? Does anyone want to put  
19 forth any particular position?

20 (No response.)

21 CO-CHAIR BASKIN: Didn't think so.  
22 Okay. So one, raise your hand for yes.

1 (Show of hands.)

2 CO-CHAIR BASKIN: Okay. Then the  
3 recommendation unanimously was for approval of  
4 the concept. At this point, though, there may  
5 be some comments for the developers before  
6 this moves forward to Stage 2. Any  
7 recommendations or thoughts?

8 I have one particular one that I'd  
9 like to bring up, and that is the possibility  
10 that the measure is actually backwards, and  
11 that we should be looking at colonoscopies  
12 that were performed, and look back to see if  
13 it was a normal surveillance colonoscopy, was  
14 it 10 years or more since the prior  
15 colonoscopy?

16 And the reason I say that is  
17 because this is -- just as Karen mentioned,  
18 this is a recommendation of an interval of 10  
19 years. And in fact, if you measured it the  
20 other way, we'd be measuring the actual  
21 outcome. You know, was it performed 10 years  
22 or later? Not what was recommended. In 10

1 years, we don't know when people are going to  
2 get their actual colonoscopies. So to me,  
3 it's the difference between telling somebody  
4 to do something and actually having it done.

5 Plus, I think it would avoid a lot  
6 of the situations where when you do a  
7 colonoscopy, you're recommending at the time  
8 surveillance in 10 years, should the biopsies  
9 be all normal, or whatever. Because there's  
10 a lot of biopsies taken that may be a  
11 hyperplastic but not an adenomatous polyp, and  
12 therefore wouldn't change the screening  
13 interval.

14 And since that information is not  
15 known at the time, oftentimes, of dictating  
16 the report of the colonoscopy and recommending  
17 10 years -- and in fact you may or may not be  
18 making the right recommendation -- if you  
19 reverse the measure, you will always know  
20 whether the surveillance was truly an  
21 average-risk surveillance at the time the next  
22 colonoscopy was done.



1                   So that's one thought of a way to  
2                   consider doing it. Phil?

3                   MEMBER SCHOENFELD: I would agree  
4                   that actually both need to be performance  
5                   measures. And although there are logistical  
6                   issues with determining how to develop a  
7                   performance measure when polyps are biopsied,  
8                   what more recent data has demonstrated is  
9                   that, even when a colonoscopy is normal, that  
10                  if the quality of the bowel cleansing is not  
11                  optimal, that up to 40 percent of the time the  
12                  colonoscopist, at the time of writing the  
13                  report, even though it's a normal colonoscopy,  
14                  will say five years or three years to repeat  
15                  it, because they're worried they might have  
16                  missed something.

17                  And this is a discussion for  
18                  another day, but I would just note that both  
19                  need to be performance measures, because, as  
20                  a primary care physician in a managed care  
21                  organization, if the GI doc says "Well, you  
22                  need to repeat this in five years," and the

1 patient somehow manages to stay in the same  
2 managed care organization for five years,  
3 primary care doc's going to send him back at  
4 that time.

5 In addition, if it's been  
6 documented as normal colonoscopy, absolutely,  
7 you want to be able to document, when you  
8 repeat that screening colonoscopy, that you  
9 can document that yes, you're doing it  
10 appropriately, and in fact now for the next  
11 measure, which is colon polyp surveillance,  
12 that's exactly what's being recommended.

13 MEMBER KOCH: So I think that the  
14 biggest limitation is that we don't have data  
15 from patients previously. I mean, patients  
16 change health plans so many times that knowing  
17 what their colonoscopy was five or 10 years  
18 ago is frequently a very difficult process.  
19 Just as a point, though, if you say that the  
20 bowel prep was inadequate, you can do it in  
21 less than 10, as long as you have a rationale.

22 Now, I think it should -- my

1 recommendation would be that the number of  
2 times that you are recommending something  
3 outside -- you know, if you write "bad bowel  
4 prep" in every single patient, you will have  
5 met quality guidelines, you'll just have done  
6 lots of bad colonoscopies. So I think the  
7 number of times that this exception is used  
8 actually should be monitored, right? So the  
9 rate at which you're going out of guideline is  
10 a quality measure as well. Just because you  
11 state that you repeated it in five years and  
12 have a rationale for it --

13 MEMBER SCHOENFELD: That's coming  
14 up in the third one.

15 MEMBER MORTON: The only thing I'd  
16 say about utility of the bowel prep is, it's  
17 not always physician-directed. And if you  
18 have different populations, you may have to  
19 make different sort of accounting for who's  
20 going to be bowel prepped or not.

21 MEMBER MARKLAND: I'd just like  
22 to, as a geriatrician, there's a growing body

1 of evidence about maybe there's an upper age  
2 -- not age alone, but criteria for maybe not  
3 doing a colonoscopy in 10 years, and if the  
4 developers could somehow consider some of that  
5 growing body of evidence as to who may be a  
6 good candidate in terms of -- maybe not life  
7 expectancy, but multi-morbidity, I think that  
8 would be an important piece of a measure like  
9 this.

10 MEMBER LIGHTDALE: The only thing  
11 I'd add is, beyond the bowel prep, there are  
12 other reasons you might also not be following  
13 the guideline -- I like your point, by the way  
14 -- including inflammatory bowel disease.  
15 Those patients need colonoscopy more often.

16 CO-CHAIR BASKIN: They do talk  
17 about exceptions, exclusions, for above  
18 average risk. It may be helpful to define a  
19 little more clearly what above average risk  
20 may be, other than -- obviously, inadequate  
21 prep is not above average risk. But I could  
22 see that being an easy way out to do them more

1 frequently. There's a lot of people who  
2 consider above average risk, and what is truly  
3 above average risk. That's another story.  
4 Okay.

5 Oh, Zahid?

6 MEMBER BUTT: I think the  
7 exception thing is referenced here in the  
8 denominator section. They do say that you  
9 should calculate the exceptions as a separate  
10 calculation, to track what people are doing.

11 CO-CHAIR BASKIN: The issue there  
12 is whether they're excluded from the  
13 denominator or whether they're in the  
14 denominator, but you separately calculate the  
15 exception in the numerator. I think NQF has  
16 been -- at least at the CSAC level -- has been  
17 more saying "include them in the denominator,  
18 but you can count them as a separate category,  
19 exception, in the numerator."

20 MEMBER BUTT: Yes. There's this  
21 whole discussion about the difference between  
22 exclusion and exception, exclusion being

1 excluded from the denominator and exception  
2 being that you get credit for it, it stays in  
3 the denominator somehow. I think that's kind  
4 of how it is coming out to be.

5 CO-CHAIR BASKIN: Yes. Well, that  
6 we can go through, maybe at the next stage.  
7 But there's different ways to consider how  
8 they count.

9 Any other comments for the  
10 developers before we move on to the next one?

11 (No response.)

12 CO-CHAIR BASKIN: Okay. Thank  
13 you. The next one, Philip, 0659?

14 MEMBER SCHOENFELD: So, 0659  
15 refers to the issue that Andy actually  
16 mentioned before, which is to say at the time  
17 an endoscopist is performing a colonoscopy for  
18 colon polyp surveillance -- so, repeating the  
19 colonoscopy in someone who's had adenomas  
20 identified in the past -- that at that time,  
21 they be able to document that they are not  
22 overusing colonoscopy by showing that it's

1       been at least three or more years since their  
2       last colonoscopy.

3               So the specific measure is the  
4       percentage of patients over 18 receiving a  
5       surveillance colonoscopy with a history of a  
6       prior colon polyp who had a follow-up interval  
7       of three or more years since their last  
8       colonoscopy, with the numerator being the  
9       percentage of patients who had that three or  
10      more year interval, the denominator being all  
11      patients undergoing surveillance colonoscopy,  
12      recognizing that there are some exceptions,  
13      multiple listed.

14             For example, if a person all of a  
15      sudden had gross hematochezia in that  
16      interval, you'd repeat a colonoscopy, although  
17      it wouldn't specifically be for surveillance.  
18      If a patient had more than 10 adenomas, we  
19      normally go back in one year, because of that  
20      number.

21             This is a maintenance indication  
22      from the AMA-PCPI. And in terms of impact,

1 again, similar to what we already discussed  
2 for screening colonoscopy. This is considered  
3 one of the most overused GI procedures, which  
4 is a poor use of health care resources and  
5 exposes patients to additional risks. The  
6 fact that it's overused is documented in  
7 multiple endoscopic database studies, as well  
8 as survey studies of physicians, asking them  
9 what their actual practice is.

10 So, I'll stop there for impact.

11 CO-CHAIR BASKIN: Comments  
12 regarding impact?

13 (No response.)

14 CO-CHAIR BASKIN: No surprise.

15 Then I think we'll go ahead and vote on  
16 impact. So, again: one, two, three or four.  
17 So one is high impact. Raise your hands,  
18 please?

19 (Show of hands.)

20 CO-CHAIR BASKIN: I think we got a  
21 unanimous out of that. Okay. Then we'll move  
22 on from impact. 15 voted high.



1 The evidence base?

2 MEMBER SCHOENFELD: Okay. With  
3 respect to evidence, there are multiple  
4 randomized controlled trials that have been  
5 looked at, both in pooled patient-level  
6 analyses, as well as in meta-analyses that  
7 demonstrate that performing surveillance  
8 colonoscopies sooner than three years in  
9 patients with one or more large adenomas, and  
10 sooner than five years in patients with more  
11 than one or two small adenomas, does not  
12 increase your yield for precancerous adenomas,  
13 in effect that those are appropriate  
14 intervals.

15 So I would say that the quality of  
16 evidence is actually high in terms of coming  
17 from randomized controlled trials of high  
18 quality, demonstrating that these are  
19 appropriate intervals, and they are  
20 consistent, and there are more than four.  
21 With respect to the fact that there is  
22 overuse, that again comes from database

1 studies, as well as survey studies of  
2 physicians.

3 So they are consistent, and there  
4 are more than four. The quality would be  
5 moderate, in that they're not randomized,  
6 controlled trials.

7 CO-CHAIR BASKIN: Comments  
8 regarding the evidence?

9 DR. PACE: I just have a question,  
10 because that's -- what you're reporting seems  
11 to be different than what was in their forms.  
12 Are you reporting what you know, or what --

13 MEMBER SCHOENFELD: With respect  
14 to the survey studies, that's actually  
15 material that they did not -- well, actually,  
16 they did to some extent. If you actually look  
17 at the guidelines, those specific studies I  
18 commented are subsumed within their  
19 guidelines.

20 DR. PACE: Right. But the meta  
21 analysis you talked about, they didn't provide  
22 any results. What was the meta analysis on?

1                   MEMBER SCHOENFELD: The meta  
2 analysis looked at randomized controlled  
3 trials, comparing three year versus five year  
4 intervals for patients with one or more  
5 adenomas versus more than three adenomas, to  
6 determine whether three years versus five  
7 years versus shorter intervals was the  
8 appropriate interval to repeat the  
9 colonoscopy. They actually cited the pool of  
10 patient level analysis by Martinez et al.  
11 specifically.

12                   But again, the meta analyses are  
13 subsumed within the actual guidelines.

14                   CO-CHAIR BASKIN: Other --

15                   DR. PACE: Can I just make one  
16 clarification? So, just as we had all these  
17 discussions yesterday, what we're asking the  
18 developers to do is to summarize the quantity,  
19 quality and consistency. And as we talked  
20 about, that's definitely an issue with a lot  
21 of the guidelines, of actually being able to  
22 access that information.

1                   For example, on the meta analysis,  
2                   having some actual information about what the  
3                   outcome was that was being studied, and what  
4                   the effect size was, is kind of what we're  
5                   looking for, but understand the difficulties  
6                   with the current guidelines.

7                   CO-CHAIR BASKIN: Other comments  
8                   regarding the evidence?

9                   (No response.)

10                  CO-CHAIR BASKIN: Okay. It sounds  
11                  like a little bit of a mixed bag. Some of the  
12                  evidence was directly submitted, and some of  
13                  it is behind the guidelines. And while we  
14                  would certainly prefer that be submitted, at  
15                  least in this case we have some inkling of  
16                  what's behind those guidelines.

17                  MEMBER SCHOENFELD: I think I  
18                  would just say, if -- and maybe this is part  
19                  of an issue of guidance from NQF to the  
20                  developer about just how long you want the  
21                  packet to be. With respect to this topic,  
22                  probably they could have gone into more

1 detail, it just would have -- at least within  
2 this specific field, considering the volume of  
3 evidence, it would have ended up, as they gave  
4 you a couple of paragraphs on multiple studies  
5 -- would have been longer. But that may be  
6 appropriate feedback for the next stage, to  
7 include the meta analyses.

8 DR. PACE: Right. And just to be  
9 clear, we're not asking them to summarize  
10 every study. It really is in terms of the  
11 body of evidence, which can include multiple  
12 studies and multiple meta analyses, but not to  
13 -- we don't really want a summary of each  
14 individual study, because that's not a summary  
15 of the body of evidence.

16 So I realize that it's difficult,  
17 yes.

18 CO-CHAIR BASKIN: Zahid?

19 MEMBER BUTT: Yes. I think the  
20 ideal thing would be to have the guideline,  
21 and then whatever studies were used to support  
22 the guideline, just listed with whatever links

1 -- like, some of them have provided links to  
2 the studies, if they are available, or at  
3 least an abstract that you can link back to.  
4 So just a listing of those guidelines behind  
5 it, because the guideline itself does not  
6 often include the listing of the studies that  
7 were used to support the guideline.

8 CO-CHAIR BASKIN: Other comments?

9 (No response.)

10 CO-CHAIR BASKIN: So your vote  
11 here is a one, two, or three. One is you're  
12 basically saying that enough was submitted and  
13 you're comfortable enough that it is there,  
14 that's a yes. Obviously two means no, the  
15 evidence doesn't meet the guidance. Three is  
16 the possibility that it's insufficient, but  
17 that it does exist somewhere. That's why  
18 we're voting.

19 So, all those voting number one?

20 (Show of hands.)

21 CO-CHAIR BASKIN: And those voting  
22 number two?

1 (Show of hands.)

2 CO-CHAIR BASKIN: That's zero.

3 And those voting number three?

4 (Show of hands.)

5 CO-CHAIR BASKIN: And we have one  
6 vote for number three. If I may ask, though,  
7 insufficiently submitted, I certainly  
8 understand that vote. Do you feel that body  
9 of evidence does exist, though?

10 MEMBER SCHOENFELD: Yes.

11 CO-CHAIR BASKIN: Okay. A little  
12 more comfort knowing that. Then we'll move on  
13 to the next part, which I guess is performance  
14 gap, if my memory serves me well. Philip?

15 MEMBER SCHOENFELD: So performance  
16 gap for this measure has been difficult to  
17 quantify as outlined here, as this goes, I  
18 think, more to what might be done in Stage 2,  
19 meaning development of better electronic  
20 health records, development of better  
21 reporting in databases, and better use of  
22 ICD-9 codes will allow, for this specific

1       measure, a better assessment of the  
2       performance gap. Meaning at the time you  
3       perform your colonoscopy, how well are you  
4       documenting that and reporting that yes, it's  
5       been three or more years since the last  
6       colonoscopy?

7                       So this may be an issue that Karen  
8       can provide some further feedback about, but  
9       again, in terms of database studies  
10      demonstrating that patients who are undergoing  
11      colonoscopies for colon polyp surveillance are  
12      getting colonoscopies sooner than three years,  
13      there's certainly been multiple studies that  
14      have demonstrated that. So I guess I'll pause  
15      there and ask Karen if she has any other  
16      comments specifically.

17                      DR. PACE: Well, one of the  
18      things, because this is a measure undergoing  
19      maintenance endorsement review, we ask for  
20      performance on the measure as specified. And  
21      they've reported that the performance rates on  
22      this measure, though it's not given by



1 physician group, I don't believe -- well,  
2 maybe it is.

3 But they say that at the 10th  
4 percentile, it's 93.4 percent, and at the 25th  
5 percentile it's 100 percent. So this is a  
6 measure that really has very high performance  
7 rates as it's specified. So the question is,  
8 if studies show that there's a performance  
9 gap, then this measure is probably not  
10 measuring that. So that's part of the issue  
11 with an endorsement maintenance, whether the  
12 measure as specified is actually indicating  
13 that there's a performance gap, or room for  
14 improvement.

15 MEMBER SCHOENFELD: And that's why  
16 I wanted to turn it over to you, because I'm  
17 not really sure how the measurement is being  
18 done, because other published data indicates  
19 that there's a much bigger performance gap.  
20 And this goes back to at least the way I  
21 interpreted their application, talking about  
22 how better utilization of electronic health

1 records would actually facilitate better  
2 quantification of what the performance gap is.  
3 That's what it seemed to me, but I'm still a  
4 novice at looking at these applications, so  
5 you might be able to better discuss that issue  
6 with relation to performance gaps. Because I  
7 did note that it didn't look like the  
8 performance gap was that great, based on what  
9 they put in here.

10 MEMBER KOCH: So I think that one  
11 of the limitations is that currently much of  
12 the data is being gathered through  
13 self-selected registries. So the AGA and the  
14 ACG have registries to which people  
15 voluntarily upload data, to try to become  
16 quality leaders in their field.

17 So obviously, only the people that  
18 are going to meet that bar -- you know, you're  
19 not going to voluntarily allow your records to  
20 be reviewed if you know that you're not  
21 meeting the quality metrics. So I think that  
22 the difficulty here is that there's a huge

1 selection bias for what's currently available.  
2 Now, applying this as a quality standard  
3 outside of self-reporting, obviously, would  
4 show much different data, I think.

5 DR. PACE: Right, but that's not  
6 the measure that this is. This is a measure  
7 that's self-reported, and these data are from  
8 the PQRS program, which is how the measure's  
9 been implemented. So that's the issue, is  
10 that if you all think that there are  
11 substantial performance gaps, then this  
12 measure is not doing that. And what is the  
13 reason for that?

14 CO-CHAIR BASKIN: John? I'm  
15 sorry.

16 MEMBER SCHOENFELD: I think the  
17 issue is, having been involved in this, the  
18 vast majority of GI docs do not report this to  
19 PQRS at this time, and that's why initially,  
20 in the next two years, PQRS is trying the  
21 carrot first. You're going to get a slight  
22 increase in your Medicare reimbursement if you

1 begin to report this. And then in 2015, then  
2 the stick comes in, and you actually start  
3 getting decreases in your Medicare payment if  
4 you don't report this.

5 So again, going back to what  
6 Johannes said, we still have quite a ways to  
7 go to improve the number of endoscopists who  
8 are actually reporting this. So I'll go ahead  
9 and stop there.

10 MEMBER MORTON: And just for Phil,  
11 do you think there's more data out there than  
12 what's presented here by the developer in  
13 regards to the performance gap?

14 MEMBER SCHOENFELD: There are  
15 certainly multiple database studies that --  
16 these are Medicare database studies that  
17 demonstrate that patients who have a colon  
18 polyp found are getting their repeat  
19 colonoscopy at one or two years. That appears  
20 to be overuse based on the review of the  
21 Medicare database.

22 MEMBER BUTT: And I think that the

1 PQRs program is being aligned with the EHR  
2 incentive program, and there is currently a  
3 pilot underway. And the alignment between the  
4 EHR incentive program and the PQRs, actually,  
5 on the ambulatory side, is further along than  
6 on the inpatient side. So this probably is  
7 going to happen relatively quickly, in terms  
8 of being able to generate this measure from  
9 EHRs.

10 MEMBER MERGUERIAN: There may be  
11 also a selection bias, because if PQRs takes  
12 patients 65 and older, and does not include  
13 younger patients, they cite three articles  
14 above that that basically say that there  
15 probably is a performance gap, up to a 36  
16 percent compliance rate.

17 CO-CHAIR BASKIN: Any other  
18 comments regarding the performance gap?

19 (No response.)

20 CO-CHAIR BASKIN: So it seems as  
21 if the performance gap is low, at least from  
22 the PQRs data, but we've heard comments that

1 that's not necessarily representative of the  
2 gastroenterology population out there. And  
3 that makes some sense, and there seems to be  
4 some data that's less crystal clear, less  
5 superb on the level of quality of data, that  
6 there is a gap, but it's unclear exactly how  
7 much it is.

8 So I guess we have to determine --  
9 Oh, I'm sorry. Phil, did you want to make one  
10 more comment before we vote?

11 MEMBER SCHOENFELD: I think part  
12 of my question to Karen was this, though.  
13 When I read it, it seemed like what was going  
14 to happen in Stage 2 of the process is exactly  
15 what Zahid was referring to, that in Stage 2  
16 of the process the developers wanted to work  
17 out better how to make this measure be  
18 correlated better with EHR reporting, so that  
19 that way you would get a more precise  
20 measurement of this issue.

21 DR. PACE: I guess we can ask the  
22 developer. I mean, basically our criteria are

1 whether there's a performance gap. And when  
2 you have this situation of actual performance  
3 on the measure being quite different than you  
4 as experts saying is the reality, then the  
5 question is, is this actually the right  
6 measure to be put forward as a quality  
7 performance measure.

8 But could we ask the developer to  
9 indicate whether they're submitting  
10 eSpecifications, or if they're going to be  
11 submitting the CPT II specifications?

12 MS. AST: As indicated earlier, we  
13 will be submitting eSpecifications.

14 CO-CHAIR BASKIN: Any other  
15 comments before we take this to a vote?

16 (No response.)

17 CO-CHAIR BASKIN: Okay. So, once  
18 again, we have four choices. How many are  
19 voting one, that there's a high performance  
20 gap?

21 (Show of hands.)

22 CO-CHAIR BASKIN: How many are

1 voting two, a moderate performance gap?

2 (Show of hands.)

3 CO-CHAIR BASKIN: And then how  
4 many are voting three, low?

5 (Show of hands.)

6 CO-CHAIR BASKIN: None. And how  
7 many votes for insufficient evidence, four?

8 (Show of hands.)

9 CO-CHAIR BASKIN: One. Did we add  
10 up to 15 votes? Yes. So could you?

11 MR. WILLIAMSON: We have four  
12 high, 10 moderate, zero low, and one  
13 insufficient.

14 CO-CHAIR BASKIN: So we've gone  
15 through that threshold, so let's go to the  
16 next part, recommending the approval of the  
17 concept. Is there any additional discussion  
18 before we have this vote?

19 (No response.)

20 CO-CHAIR BASKIN: Okay. Those  
21 voting yes, raise their hands?

22 (Show of hands.)



1 MR. WILLIAMSON: We have 15 yes  
2 and zero no.

3 CO-CHAIR BASKIN: And the measure  
4 moves on. Any comments for the developers, to  
5 help them before this goes to the next stage?

6 (No response.)

7 CO-CHAIR BASKIN: No comments?  
8 Okay, thank you.

9 MEMBER BUTT: I have a --

10 CO-CHAIR BASKIN: Oh, Zahid,  
11 please.

12 MEMBER BUTT: I assume that the  
13 measure will be able to make a distinction  
14 between whether the recommendation should be  
15 three years or five years? Because right now,  
16 it says "at least three years," but one of the  
17 studies they cite was looking more at the five  
18 year number, because of the definition of what  
19 it should have been.

20 In other words, will it be aligned  
21 with what the recommendation should be in  
22 terms of the interval?

1 CO-CHAIR BASKIN: The measure is  
2 as it is. It's just measuring three or more  
3 years. So both those cases are being lumped  
4 into "greater than three years."

5 MEMBER BUTT: Right.

6 CO-CHAIR BASKIN: It would require  
7 a change in the measure to distinguish between  
8 three and five.

9 MEMBER BUTT: They should look  
10 into whether another subset of this should be  
11 the five years as well.

12 CO-CHAIR BASKIN: Thank you for  
13 those comments. Additional comments for the  
14 developers?

15 (No response.)

16 CO-CHAIR BASKIN: Okay. Then  
17 thank you all. We'll move on to the next  
18 measure. So we're going to go back to C2056.  
19 Gail, are you still on the phone?

20 DR. AMUNDSON: I am here, Andy.

21 CO-CHAIR BASKIN: Oh, great.

22 Gail, you have approximately three minutes or

1 less. Not three to five, I think we've  
2 decided this one measure is three, right?

3 (Laughter.)

4 CO-CHAIR BASKIN: If in three  
5 minutes, you could just give us a few words  
6 about this measure before we do the review?  
7 This is the Colonoscopy Quality Index.

8 DR. AMUNDSON: Yes. This is the  
9 Colonoscopy Quality Index --

10 CO-CHAIR BASKIN: Gail, a little  
11 closer to the phone if you can? We're having  
12 a little difficulty hearing you.

13 DR. AMUNDSON: Okay. Is that  
14 better?

15 CO-CHAIR BASKIN: Be quiet and  
16 listen closely.

17 DR. AMUNDSON: Okay. Can you hear  
18 me well now, Andy?

19 CO-CHAIR BASKIN: That's good  
20 enough. Thank you.

21 DR. AMUNDSON: Okay. Colonoscopy  
22 Quality Index is a composite all-or-none

1 measure, and I have been listening to the  
2 discussion on these previous measures, and so  
3 I think I will be able to short-circuit my  
4 comments just a little bit.

5 But the premise of the measure is  
6 that a high-quality screening or surveillance  
7 colonoscopy is one that is performed on a  
8 patient that needs the test. It is a  
9 procedure that's performed in a thorough  
10 manner. It is one that is performed without  
11 harming the patient.

12 And so the elements that are  
13 included in this measure are whether or not  
14 the patient actually needed the procedure they  
15 are having today. I would contrast that with  
16 existing measures that look at follow-up  
17 recommendations exclusively. So in this  
18 measure, if a patient is having a procedure at  
19 too short an interval, there will be a fail on  
20 the composite measure, with the detail  
21 providing that the failure was related to the  
22 fact that the patient was being screened or

1 surveilled too soon, or too early.

2           The other items that are -- the  
3 other distinction I would make is that this  
4 denominator combines patients who are  
5 undergoing both screening and surveillance, so  
6 it is a large denominator. It is intended to  
7 minimize small number sizes. We have data on  
8 individual endoscopists. We've been reporting  
9 this measure publicly since 2010 and have  
10 baseline data going back to 2008.

11           The process items are important  
12 because they factor into determining  
13 appropriateness. For example, the previous  
14 conversation, if the patient's prep is  
15 inadequate, it is inappropriate to wait 10  
16 years to repeat that procedure.

17           So the process items are an  
18 assessment of a standardized ASA assessment of  
19 medical risk, standardized assessment of the  
20 bowel preparation, a complete examination to  
21 the cecum, with documentation,  
22 photo-documentation of that, that if the

1 patient had a polyp that was removed, all of  
2 the necessary information -- there are five  
3 elements -- are completed when that polyp is  
4 sent to pathology.

5           The withdrawal time is recorded.  
6 The patient does not suffer serious  
7 complications of either perforation, death,  
8 admission to hospital, or bleeding requiring  
9 transfusion, and the patient was told to come  
10 back in an interval that is appropriate based  
11 on their pathology findings. So that last  
12 item will have precisely the same  
13 characteristics as the first one, although the  
14 last item, the indications for future, is  
15 future-looking.

16           The measure is -- I think our  
17 documents that we submitted are quite thorough  
18 in terms of the evidence for each of these  
19 items. It's grounded on the guidelines, the  
20 guidelines being those that are themselves  
21 evidence-based.

22           Other comments I would make would

1 be that the -- in our experience, based on the  
2 performance of this measure, the largest gaps  
3 are in appropriate indication at baseline. In  
4 aggregate in our data set, we had one in five  
5 patients being screened too soon. There was  
6 an occasional patient at baseline in the  
7 follow-up item that was being told to come  
8 back at too long an interval, but that was  
9 really a rarity by comparison by being told to  
10 come back too early.

11 So the first item and the last  
12 item were significant performance gaps in the  
13 range of 1 in 5, and the other item that had  
14 a significant performance gap was the  
15 completeness of the information that the  
16 pathologist got related to the polyp. That  
17 was a gap about 1 out of 4 times.

18 There's quite a bit of variability  
19 in performance across physicians. At baseline  
20 on the composite score, meaning that  
21 everything was meeting standards, the range  
22 was zero to 80, so there was -- the lowest

1 performer met everything in none of his  
2 patients, and the highest one met everything  
3 in 80 percent of their patients.

4 What we have seen over time is  
5 that, because of the structure and the  
6 precision of the measure, the history-taking  
7 and documentation has improved substantially,  
8 practice patterns have changed, and the gaps  
9 on everything have narrowed.

10 I believe you have with you  
11 presentation material on this, and there's  
12 trend data that's quarterly over the past  
13 two-year cycle, as well as individual  
14 proceduralist performance information.

15 What else would I say? I would  
16 say that we have a lot of field experience  
17 with this measure, and our experience is that  
18 the current electronic medical records are  
19 weak in the area of family and personal  
20 history, and so calculating appropriateness,  
21 both front-end and back-end, are more  
22 challenging than they should be. And so to do



1 eSpecifications at this point, the GI records  
2 are really not up to it. Neither are the  
3 registries.

4 CO-CHAIR BASKIN: Gail?

5 DR. AMUNDSON: Yes?

6 CO-CHAIR BASKIN: Any last  
7 statement? I realize it's a complex measure,  
8 but we try and keep the comments short,  
9 please.

10 DR. AMUNDSON: I thought I was  
11 being pretty brief.

12 CO-CHAIR BASKIN: You were doing  
13 great, but we're getting a little over.

14 DR. AMUNDSON: Okay. And then the  
15 other item on the electronic record is that  
16 the nursing and the physician components don't  
17 link. So we've been working on that.

18 And I think I will stop there and  
19 open it up to your questions and comments.

20 CO-CHAIR BASKIN: Any particular  
21 question for Gail, before we start to proceed  
22 and talk about how we're going to do this?

1 Zahid, do you have a question?

2 MEMBER BUTT: Yes. I have a  
3 question. In the data that you have  
4 submitted, you have shown stratified data, but  
5 you have chosen not to stratify the measure.  
6 Any particular reason?

7 DR. AMUNDSON: Not to stratify the  
8 measure?

9 MEMBER BUTT: Yes.

10 DR. AMUNDSON: Meaning?

11 MEMBER BUTT: Meaning to break out  
12 the rates for each individual element, like  
13 you show in your results.

14 DR. AMUNDSON: Well, we do have  
15 the rates for each individual element.

16 MEMBER BUTT: Wouldn't that fall  
17 under sort of stratification?

18 DR. AMUNDSON: All of the results  
19 are reported online, and they are reported by  
20 individual physicians. And so it is -- one of  
21 the screenshots in the presentation should  
22 demonstrate the drop-down list that shows that

1 all of the rates are also reported by  
2 individual element.

3 So the composite is available, but  
4 all of the elements are available for analysis  
5 as well.

6 MEMBER BUTT: Okay. Thank you.

7 CO-CHAIR BASKIN: Now, before we  
8 review this measure, this is a little bit  
9 different than the measures we have been  
10 reviewing, so I think maybe Taroon would like  
11 to make some comments. This is a composite  
12 measure, obviously, that has nine different  
13 measures within it, and does require a  
14 different level of analysis than just at the  
15 composite level.

16 Taroon, do you want to make some  
17 comments?

18 MR. AMIN: I'll actually turn it  
19 over to Karen, just to give us a brief  
20 introduction, a little bit on how we should be  
21 thinking about evaluating a composite in  
22 reference to each of the individual

1 components.

2 DR. PACE: So I just wanted to  
3 kind of orient you that NQF has done some work  
4 in the past on composite measure evaluation  
5 framework, and actually this fall we'll be  
6 revisiting that. But I just wanted to mention  
7 that we consider a composite a measure that  
8 combines multiple components, either  
9 individual measures or, as you can see here,  
10 multiple components, that result in a single  
11 score.

12 So, that is our definition of a  
13 composite. However, one of the considerations  
14 that we have, which kind of gets discussed  
15 later on, is the ability to decompose the  
16 composite, to look at the individual elements.  
17 So the fact that this is constructed as a  
18 single score, to result in a single score,  
19 that's our very definition of a composite.

20 There are definitely different  
21 types of composites. As Gail mentioned, this  
22 is an all-or-none, meaning that this

1 information is aggregated at the patient  
2 level. So it's looking at each patient,  
3 whether all components were met. There are  
4 other types of composites where you're  
5 actually using individual performance measure  
6 scores and aggregating them in some way, but  
7 this is an all-or-none.

8           And there has been a drive at NQF  
9 for calling for more composite measures, for  
10 a couple reasons. One is that it's considered  
11 a higher bar, these types of all-or-none. For  
12 example, your discussion yesterday about a  
13 measure of a patient being assessed, and then  
14 a separate measure for a patient being  
15 counseled. Well, it doesn't make a lot of  
16 sense that a patient isn't assessed and  
17 counseled.

18           And so these all-or-none  
19 composites are trying to get at that element,  
20 and also there's some thinking and analysis  
21 that shows that you get a stronger, more  
22 reliable, quality signal when you have more

1 data that goes into a performance measure.

2 But having said that, you need  
3 first of all to look at the overall composite,  
4 but you also need to be looking at the  
5 components, and whether those make sense in  
6 terms of the criteria that you're looking at  
7 in this aspect of importance to measure and  
8 report.

9 So again, the impact, performance  
10 gap and evidence. And we did ask the  
11 developers to -- we'll have to think about  
12 this in the future, but we did ask them to try  
13 to address the evidence in separate forms. So  
14 I know that created more paper, but to try to  
15 break those out for your review.

16 So I'll stop there and see if you  
17 have any questions about composites in  
18 general.

19 MEMBER BUTT: So in terms of a  
20 composite score, if you will, my sort of  
21 understanding of that was exactly the way you  
22 were describing, that you would score

1 individual components with perhaps even  
2 different weighting, depending on how  
3 important it was to the overall score. With  
4 this --

5 CO-CHAIR BASKIN: That's not  
6 necessary. That's in the eyes of whoever's  
7 doing the scoring.

8 MEMBER BUTT: I understand.

9 CO-CHAIR BASKIN: It doesn't have  
10 to work that way.

11 MEMBER BUTT: I'm saying that  
12 this, to me, looks more like a percentage of  
13 patients that received quote unquote "perfect  
14 scores," perfect care, if you will. So is the  
15 term scoring accurate in this context, would  
16 be my first question. Because I understand  
17 scoring to be somewhat different.

18 CO-CHAIR BASKIN: Scoring can be  
19 multiple methodologies.

20 MEMBER BUTT: So for instance,  
21 what this conveys -- it weights everything  
22 equally, right? So for instance, someone

1       could have a 90 percent score, and out of 100  
2       colonoscopies they could have had 10  
3       perforations, and the other person with a 90  
4       percent score, the only 10 cases that could  
5       have fallen out were that they didn't take a  
6       picture of the cecum. They'd all be looked at  
7       in the public the same, according to this  
8       methodologies.

9                   CO-CHAIR BASKIN: And there's pros  
10       and cons to different methodologies of  
11       scoring. But as this one is presented --

12                   MEMBER BUTT: It is presented as  
13       it is.

14                   CO-CHAIR BASKIN: It is presented  
15       as all or none. You either --

16                   MEMBER BUTT: So it is accurate to  
17       call this a score.

18                   CO-CHAIR BASKIN: Yes, it is.

19                   MEMBER BUTT: Okay. That was my  
20       question.

21                   DR. AMUNDSON: But the description  
22       of this being "perfect care" is accurate.



1 CO-CHAIR BASKIN: John, I think  
2 you were up first.

3 MEMBER MORTON: My only question  
4 is to Karen. I know there's been more  
5 emphasis in NQF about these composite  
6 measures. Can you guide us, are there other  
7 measures that have been approved, just out of  
8 curiosity, what those were like?

9 DR. PACE: We have some composites  
10 that are all-or-none. So, for example,  
11 optimal diabetes care, or optimal  
12 cardiovascular care, that has not this many  
13 components but multiple components, maybe five  
14 or six.

15 And then we have some composites  
16 -- I guess the ones that come first to mind  
17 are the AHRQ composites. They'll have a  
18 mortality composite based on procedures. But  
19 in that case, their composites are taking the  
20 individual mortality scores and combining them  
21 in some way. And I can't tell you offhand,  
22 but it could be an average of those various

1 mortality scores, it could be a weighted  
2 average.

3           So there's a variety of ways, and  
4 that's one of the things that we'll be  
5 addressing in our project coming up this fall,  
6 is looking at those different types of  
7 composites more closely, and what implications  
8 there are for those. But we have multiple  
9 examples.

10           CO-CHAIR BASKIN: Judith?

11           MEMBER TOBIN: So composites can  
12 be challenging, and I would maybe just ask the  
13 group -- I'm looking at this composite in  
14 number six, "All essential polyp information  
15 recorded." And if the group is supposed to  
16 evaluate each component of that, is that  
17 adequate? Or is that standardized enough that  
18 everyone feels they'd come to the same  
19 conclusion?

20           CO-CHAIR BASKIN: Well, that's  
21 going to be part of our discussion as -- I  
22 think the way we'll work through this is

1 probably a component at a time.

2 MEMBER TOBIN: Okay.

3 CO-CHAIR BASKIN: Because we may  
4 come to the conclusion that overall this is  
5 fine, or we may come to the conclusion that  
6 six of the components meet our criteria and  
7 three of them don't meet our criteria, and I  
8 think that's probably going to be the simplest  
9 way to work through this.

10 MEMBER TOBIN: Okay.

11 CO-CHAIR BASKIN: Are there  
12 comments about the procedure on this and  
13 composites in general?

14 Go ahead, Jenifer.

15 MEMBER LIGHTDALE: Just a  
16 question, and you may have mentioned it. So  
17 this is a process metric, the way that they're  
18 describing it. But it looks to me like it  
19 combines a process and an outcome.

20 DR. PACE: Right. Unfortunately,  
21 we didn't have a category for them to select  
22 something differently. But it is a mostly

1 process, but there is one component that's an  
2 outcome.

3 And actually, we do have another  
4 example of a composite that includes process  
5 and outcome, and that's the STS cardiovascular  
6 surgery composite measure. But I think that's  
7 a question that we're going to address in the  
8 future, is "When should you combine process  
9 and outcomes?" But we don't have any reason  
10 not to at this point.

11 And I'll just mention one other  
12 thing. And again, I know this will be hard,  
13 just as we've had some difficulty with the  
14 more single concept measures, which is that  
15 the next stage is where we would see some  
16 analysis related to these components as well.  
17 I mean, obviously you've seen the performance  
18 that they've reported on the various  
19 components, so that's useful as well.

20 CO-CHAIR BASKIN: Let's try and go  
21 in some order. So I think Philip, you had a  
22 comment next?

1                   MEMBER SCHOENFELD: I was just  
2 going to suggest that I think there's a good  
3 chance a lot of these issues might be  
4 addressed once we begin to review each step.

5                   CO-CHAIR BASKIN: Yes, that's why  
6 I'm trying to keep this to just -- because  
7 this is a different way to evaluate, so that  
8 we understand what we're evaluating and how  
9 we're going to do it, but not get into any of  
10 the details of the measure. But if there's  
11 still a question about that, please, Zahid.

12                   MEMBER BUTT: Sure. I just have,  
13 again, one procedural/informational question.  
14 So according to -- definitionally, is there a  
15 definition for an index, if you will, or does  
16 it qualify for that definition?

17                   DR. PACE: And that's part of the  
18 confusion out there, is that composites are  
19 referred to in multiple ways. And sometimes  
20 index is often used to refer to a composite.  
21 And as I said, our definition is a measure  
22 that has multiple components that end up in a

1 single score.

2 MEMBER BUTT: Right. So this type  
3 of composite could qualify as an index.

4 DR. PACE: Yes.

5 CO-CHAIR BASKIN: Yes, but index  
6 is a term used outside of NQF, in terms of --  
7 you can call it what you want.

8 MEMBER BUTT: I was just asking if  
9 there was a specific definition that they had  
10 in that context.

11 CO-CHAIR BASKIN: Jenifer, did you  
12 still have a comment, or was that just up?  
13 Okay. Any other comment before we start the  
14 review process? I'm sorry, go ahead.

15 MEMBER BORDEIANOU: I just wanted  
16 to say that this comment about what's an index  
17 and what's a score is important. Because we  
18 think in general of indexes as scores,  
19 validative measures where one thing is not  
20 measured twice and weighted twice. And in  
21 this score, there is cecal photo and complete  
22 examination. Those are two of the same thing,

1 really.

2           So it is important, as we look at  
3 that, not only to look at it individually, but  
4 also, in the end, as a whole, so that some  
5 things are not double-counted and some things  
6 are under-counted.

7           CO-CHAIR BASKIN: Yes, we can  
8 certainly review that when we review the  
9 measures and make comments. But at the end,  
10 you may also make a comment to the developer  
11 that you think the name is not appropriate for  
12 what it is, or it is appropriate for what it  
13 is.

14           But I think that's where the term  
15 index will come in. It's really not our  
16 review in terms of the parts of the measure  
17 and the composite of the measure. But if you  
18 think the name is inappropriate, it doesn't  
19 reflect the actual measure, then that's --  
20 we're all welcome to make those comments.

21           So with that, I think we're going  
22 to get started. This will be -- well, we have

1 some time. Fasten your seatbelts.

2 (Laughter.)

3 CO-CHAIR BASKIN: And who won this  
4 one? Phil. I hope you've done your homework.  
5 So I can only think that the way to do this is  
6 to try and break it down into individual  
7 components one at a time, and then at some  
8 point talk about how the components interact  
9 with each other, and whether they're  
10 appropriate to interact with each other, and  
11 then, in a sense, talk about it as a composite  
12 for a yea or nay. But I think we really need  
13 to do a yea or nay and vote each individual  
14 component.

15 MEMBER SCHOENFELD: I guess I  
16 would actually suggest that, with respect to  
17 impact, that it can be done -- we can discuss  
18 whether or not the impact of a composite score  
19 or composite index, depending on terminology,  
20 for high quality colonoscopy for colon cancer  
21 screening and colon polyp surveillance can be  
22 done without reviewing individual measures.



1 Then, when we go to the evidence to see if the  
2 specific measures included in this specific  
3 composite index, actually, we have evidence to  
4 show that that represents a high quality  
5 colonoscopy, that we would have to go through  
6 step by step. But it's up to you.

7 CO-CHAIR BASKIN: I agree  
8 somewhat, but I think what we may find is that  
9 it's possible that individual measures within  
10 the composite may not individually have any  
11 documented impact, high impact, which would  
12 make that particular portion of the measure --

13 DR. PACE: But I think what you're  
14 referring to is more along the evidence line.  
15 I think with impact, we're really talking  
16 about measuring colonoscopy quality in  
17 patients at risk for colon cancer, and so I  
18 think it really --

19 CO-CHAIR BASKIN: Good point. I  
20 probably am mixing it up.

21 DR. PACE: I know, it's hard.

22 CO-CHAIR BASKIN: So I think that

1 that's fair, and unless somebody has an  
2 objection to that, I think we'll discuss the  
3 impact of the composite in general, and the  
4 issue in general.

5 CO-CHAIR SAIGAL: That's great.  
6 Is this a competing measure? I mean, a  
7 renewal measure or a new measure.

8 CO-CHAIR BASKIN: New.

9 CO-CHAIR SAIGAL: Okay, thanks.

10 CO-CHAIR BASKIN: With that,  
11 Philip, impact of this particular composite?

12 MEMBER SCHOENFELD: Okay. With  
13 respect to impact, obviously colonoscopy for  
14 colon cancer screening and for colon polyp  
15 surveillance is performed in tens of thousands  
16 of people each year.

17 And that there is a growing body  
18 of data that demonstrates that missed or  
19 interval cancers do occur, meaning by  
20 definition that a patient is diagnosed with a  
21 colon cancer sooner than repeat colonoscopy  
22 would be done based on guidelines. For

1 example, somebody gets diagnosed for colon  
2 cancer within two years of when they had a  
3 normal screening colonoscopy.

4 And database studies have  
5 demonstrated that different criteria, such as  
6 not reaching the cecum, doing a complete exam  
7 in that way, are associated with an increased  
8 likelihood of having interval or missed  
9 cancers. I would note, this is not  
10 specifically part of this application.

11 So with respect to the idea that  
12 this is a national health goal, to do good  
13 colorectal cancer screening with colonoscopy,  
14 and that it's done in a huge group of people  
15 each year, with significant resource use, and  
16 that, to summarize, the overall goal of this  
17 composite index is to allow the consumer or  
18 the payer to say, as a yes or no question,  
19 does this endoscopist do a high-quality  
20 colonoscopy, my comment would be "Yes, that  
21 seems to be a high-impact goal."

22 And in fact, among the

1 professional GI organizations, there is a big  
2 effort to determine criteria to define  
3 high-quality colonoscopy for colon cancer  
4 screening.

5 CO-CHAIR BASKIN: Comments?  
6 Johannes?

7 MEMBER KOCH: So I think that the  
8 real outcome that we want to identify is that  
9 people don't miss cancers, right? The  
10 surrogate marker is that we don't miss polyps.  
11 Neither of those two are really -- your  
12 adenoma detection rate and your missed cancer  
13 rate are not part of this composite. So yes,  
14 I think measuring quality colonoscopy and  
15 identifying good colonoscopists versus not is  
16 really, really important, and there's a high  
17 impact of that. I'm not sure that this  
18 measure actually incorporates the two most  
19 important things, which are missed cancers and  
20 adenoma detection rate.

21 CO-CHAIR BASKIN: John?

22 DR. AMUNDSON: Can I comment on

1 that?

2 CO-CHAIR BASKIN: Actually not,  
3 Gail. I'm sorry. It's not the usual process.  
4 But if we have a specific question for you, if  
5 you're on the line, we'll certainly ask it.

6 MEMBER MORTON: My question is  
7 mainly about impact. Is there about 500,000  
8 colonoscopies done a year? It's an extremely  
9 common procedure.

10 MEMBER SCHOENFELD: The difficulty  
11 -- and I was reviewing this again last night  
12 -- sometimes it's a little bit tough to piece  
13 out the proportion that are done for colon  
14 cancer screening and colon polyp surveillance.  
15 Even though you would think, based on  
16 reporting, it shouldn't be that tough to do,  
17 but it's actually a little bit tough to get  
18 the right estimate.

19 CO-CHAIR BASKIN: Other comments  
20 regarding impact? You know, I think  
21 Johannes's point is a good one, but I think  
22 there's different parts of this measure. So

1       yes, some parts of the measure are having  
2       performed a complete colonoscopy under good  
3       circumstances, like good prep and all that,  
4       and that doesn't get at a lot of the things  
5       that you're talking about for quality, but  
6       there are parts of this that have to do with  
7       appropriate surveillance time, similar to some  
8       of these same issues with the previous ones.

9                 So I think there are certainly  
10       parts of this that I would say are the  
11       impactful ones that we've been discussing over  
12       the past hour or so. Parts of it may or may  
13       not be. But I think, overall, because parts  
14       of it are, my feeling is that this is high  
15       impact.

16                MEMBER KOCH: Just as a  
17       clarification, so the question is, is it high  
18       impact to have a composite measure of quality,  
19       or is it this composite measure of quality?

20                DR. PACE: Remember, because this  
21       isn't different than yesterday or the other  
22       measures, you're talking about whether the

1 area of colonoscopy for cancer screening is a  
2 high-impact area. You'll be getting at the  
3 specifics when you look at the evidence for  
4 what's included.

5 But just as you all talked about,  
6 having a measure of assessment isn't going to  
7 be as impactful as if you had a measure of  
8 actually treating something. It's in the same  
9 realm as that, right? Right now we're just  
10 talking about the broad area, that this should  
11 have a performance measure.

12 CO-CHAIR BASKIN: Right, we're  
13 getting into the next part of the discussion  
14 too early. So Zahid first, and then Robert?

15 MEMBER BUTT: And again, this  
16 might be a next-section comment, but I was  
17 just reading the summary of evidence of  
18 high-impact, and all it refers to is underuse  
19 or overuse of colonoscopy, although they do  
20 cite several studies, so I didn't obviously --  
21 what's your take on that?

22 MEMBER SCHOENFELD: That's why I

1 mentioned, I think, at one point during my  
2 brief discussion there, that it actually  
3 wasn't part of the application. Colonoscopy  
4 is done very frequently for colon cancer  
5 screening and colon polyp surveillance.  
6 Reducing colorectal cancer, which is the  
7 second most common cancer in the United  
8 States, justifies the fact -- this is a major  
9 national health goal, just reading off the  
10 definition of national goals and priorities.  
11 It's high impact because a lot of resources  
12 are used, and in terms of consequences, if  
13 you're not performing a high-quality  
14 colonoscopy, people get interval colon  
15 cancers.

16           So again, just to reinforce what  
17 Karen said, I'm not commenting about the  
18 specific components of this colonoscopy  
19 quality index. I'm merely talking about, is  
20 there a rationale to say "A colonoscopy  
21 quality index that allows you to tell if  
22 somebody's doing a high-quality colonoscopy to



1 minimize or prevent colon cancer," is that  
2 potentially a high-impact quality indicator?  
3 And my interpretation is yes.

4 CO-CHAIR BASKIN: Thank you. And  
5 Robert?

6 MEMBER ELLIS: I think it's  
7 important, as kind of the consumer guy on this  
8 group, to point out that these composite  
9 measures, at the consumer level, are your best  
10 shot at getting something even looked at.  
11 It's very difficult to get consumers engaged  
12 in looking at these scores, indexes, however  
13 you want to characterize them.

14 Composites are your best shot.  
15 There's a lot of literature. Our own studies  
16 of the stuff we deliver, composites are  
17 usually easier for them to wrap their brains  
18 around. They usually answer simple questions.  
19 They're interested in "Did things get done the  
20 right way, and did all the things that are  
21 supposed to get done, get done?" That they  
22 can understand. So I think these composites

1 are really important to really speak to  
2 consumers.

3 CO-CHAIR BASKIN: Okay. So,  
4 certainly an impact on the consumers. I think  
5 we've spoken enough about this that I think we  
6 can come to a vote on impact. Once again,  
7 it's going to be a hand vote. We have a 1,  
8 2, 3 or 4, so those voting 1, high impact?

9 (Show of hands.)

10 CO-CHAIR BASKIN: Looks unanimous.  
11 So that's 15 high impact, and obviously zero  
12 for the other categories.

13 Okay. So now it gets difficult,  
14 right? Philip, I'm hoping that you organized  
15 your thoughts one portion of the measure at a  
16 time, but let's go that way.

17 And I really do think, for the  
18 ease of -- I mean, otherwise, we're going to  
19 get off on tangents like crazy. If we really  
20 try and stick to each component, because there  
21 will be an opportunity at the end for us to  
22 talk about the components and how they

1 interact with each other, but if we talk about  
2 it with each component before we've talked  
3 about the other component, I think we're going  
4 to drive ourselves crazy.

5 So let's try and -- just because  
6 we voted yea or nay for nine components  
7 doesn't mean yea or nay for the composite, and  
8 there will be plenty of opportunity to discuss  
9 what should, may or may not, fall out, and  
10 what works with what, and what interacts with  
11 what in the right way to get where we want to  
12 be. So let's try and minimize this, leave  
13 this to just the component itself, when we're  
14 talking about it. Thank you.

15 MEMBER SCHOENFELD: I may be  
16 foolishly hopeful that this will be easier  
17 than you anticipate, Andy.

18 I'll start my comments by  
19 re-emphasizing what Mr. Ellis said. Having a  
20 composite index to allow -- that is a yes or  
21 no endpoint, to say that an endoscopist has  
22 performed a high-quality colonoscopy, is a

1 crucially important quality indicator, that we  
2 want consumers and payers to be able to say  
3 "Does an endoscopist perform a high-quality  
4 colonoscopy 90 percent of the time," and let  
5 the consumer have that, and then for the  
6 payers, also be able to look at these  
7 different subcomponents.

8           And I really commend Quality Quest  
9 for Health of Illinois for putting forth this  
10 packet. Having said that, the components of  
11 this quality index, in my opinion, do not have  
12 the evidence support to justify multiple  
13 components of this quality index. So in other  
14 words -- and I'll go through each indication  
15 very briefly, and then we can begin, if you'd  
16 like, to do the vote on each indication. To  
17 quote an old phrase, it's just not ready for  
18 prime time yet.

19           So having said that, let me begin  
20 to go through each one very briefly.  
21 Certainly the first thing is that they say  
22 that you should document an appropriate

1       indication for colonoscopy. We had similar  
2       discussions about this yesterday. I mean,  
3       this is a procedure. Maybe not quite like  
4       putting somebody to sleep to do a surgery for  
5       stress urinary incontinence, but good medical  
6       practice is, of course you have to write down  
7       an indication. And so I'll just keep that one  
8       brief.

9                    You also have to do a standardized  
10       medical risk assessment and document that  
11       prior to doing a procedure. And that actually  
12       is part of the PCPI measure set that's already  
13       been put forward as of 2008.

14                   The next thing, though -- so, this  
15       is where we begin. Those two, to me, are  
16       almost pro forma. But having said that, the  
17       next one becomes a little bit more difficult,  
18       or the next point about standardized medical  
19       risk becomes a little bit more difficult.

20                   As part of your standardized  
21       medical risk assessment, you do a cardiac risk  
22       assessment. The problem is that in many

1 practices right now, anesthesiologists do your  
2 cardiac risk assessment, because actually  
3 nurse anesthetists and anesthesiologists  
4 actually provide the anesthesia. So the  
5 medical risk assessment isn't really done  
6 purely by the endoscopists. It's done by two  
7 people.

8 So, how do you actually  
9 operationalize that part of your assessment?  
10 I'm sure that Quality Quest for Health Care,  
11 within their system in Illinois, has a  
12 mechanism for doing that. Whether or not that  
13 could be implemented nationally, I think, may  
14 be a different issue.

15 The really big issues, though,  
16 come once we start talking about assessment of  
17 bowel preparation, standardized assessment of  
18 bowel preparation, complete examination, cecal  
19 photo taken, all polyp information recorded,  
20 withdrawal time recorded.

21 What they're trying to get at is,  
22 does an endoscopist actually get all the way

1 around to the cecum, state that all the stool  
2 has been cleansed out, or most of the stool  
3 has been cleansed out, so that they can  
4 adequately identify polyps, document how many  
5 polyps they found, and also document how long  
6 they spent pulling the scope out?

7           Ultimately, those are trying to  
8 get at the issue of whether or not you're  
9 doing a colonoscopy that's going to minimize  
10 or prevent somebody from getting colon cancer  
11 in the future. The problem is the way they  
12 have the evidence here, that documenting these  
13 factors is going to lead to the outcome we're  
14 hoping to get, which is people aren't going to  
15 get colon cancers in the next couple of years  
16 after your colonoscopy. The way they're  
17 outlined here is not going to achieve that  
18 outcome. So let me begin to specifically go  
19 through this.

20           Should a composite index in the  
21 future assess bowel preparation? Absolutely.  
22 If somebody routinely -- this was already

1 mentioned by Johannes -- documents that they  
2 get a bad bowel prep, and thus justifies --  
3 because that would be a preparation for  
4 repeating the colonoscopy again a month later,  
5 or within a year -- that's actually an  
6 indicator that, within their practice, they're  
7 not doing a good job of colonoscopy. You  
8 know, three quarters or more of your patients  
9 should really have an excellent bowel prep,  
10 and if virtually all your patients have a poor  
11 bowel prep, then you're not doing your  
12 practice properly. So that part, I go along  
13 with.

14 Complete examination means you get  
15 all the way to the cecum, and they try to  
16 subsume that with the idea of taking a  
17 photograph of the cecum. There's not  
18 necessarily great evidence to say that that  
19 definitely support the idea you get to the  
20 cecum, but we generally accept that as a  
21 standard of practice, that if you get to the  
22 cecum and take a photo of it, that proves --



1 or certainly the appendiceal orifice, as well  
2 as the ileocecal valve -- that that proves  
3 that you got there.

4 So again, I can go along with that  
5 part. But the ultimate thing, besides getting  
6 all the way to the cecum, that Johannes  
7 mentioned, is that then we want to show that  
8 you're adequately identifying adenomas.

9 Now, what they talk about here to  
10 show that you have an adequate adenoma  
11 detection rate is how long you spent pulling  
12 the scope out, and describing the size and  
13 shape and location of any polyps that you  
14 found.

15 That does not tell you whether or  
16 not you're finding adenomas. Withdrawal time,  
17 how long you spent pulling it out, impacts  
18 adenoma detection rate. If I actually  
19 quantify how often somebody finds adenomas --  
20 and the current guidelines recommend that it  
21 be found in at least 15 percent of women and  
22 25 percent of men -- if my withdrawal time is

1 4 or 5 minutes, and my adenoma detection rate  
2 is 5 percent, well, okay. That's something I  
3 can identify to work on.

4 But lots of people have withdrawal  
5 times of 10 minutes -- and by the way, the  
6 cutoff is felt to be seven minutes. Lots of  
7 people have withdrawal times of 10 minutes,  
8 and they still only find adenomas in six or  
9 seven percent of people.

10 CO-CHAIR SAIGAL: Phil, can I ask  
11 a question real quick?

12 MEMBER SCHOENFELD: Sure.

13 CO-CHAIR SAIGAL: This is really  
14 helpful. Can you let us know what level of  
15 evidence is supporting what you're saying? Is  
16 it consensus, is it in the document? That  
17 would be really helpful to understand.

18 MEMBER SCHOENFELD: Okay. So just  
19 to then briefly go back, for appropriate  
20 indication for colonoscopy, documenting that,  
21 I would say that is consensus opinion.

22 For standardized medical risk

1 assessment, meaning that prior to performing  
2 a procedure you do an appropriate  
3 cardiac/pulmonary risk assessment, that's  
4 standard of care consensus opinion, and I  
5 would merely point out that documenting that  
6 is problematic to the extent that two  
7 different providers are doing that assessment.

8 With respect to assessment of  
9 bowel preparation, we actually have multiple  
10 endoscopic database studies and randomized  
11 controlled trials that demonstrate that the  
12 quality of your bowel preparation impacts your  
13 adenoma detection rate.

14 So in other words, if I get an  
15 excellent bowel prep compared to what we call  
16 a fair bowel prep, meaning it's not so  
17 horrible I have to immediately repeat it, but  
18 I'm only visualizing about 80 percent of the  
19 mucosa instead of 100 percent, that when I  
20 have an excellent bowel prep, my adenoma  
21 detection rate increases by two- to  
22 three-fold.

1 CO-CHAIR BASKIN: Is that evidence  
2 submitted?

3 MEMBER SCHOENFELD: No, that's not  
4 part of their application.

5 CO-CHAIR BASKIN: Okay.

6 MEMBER SCHOENFELD: I'm expanding  
7 here on what I know to be the data. So you  
8 have RCT data on that, as well as database  
9 data to show that quality of bowel preparation  
10 is associated in the database data with higher  
11 adenoma detection rates.

12 With respect to complete  
13 examination, we have database data to  
14 demonstrate that. Failure to reach the cecum  
15 is associated with a higher risk of having  
16 interval cancers.

17 CO-CHAIR SAIGAL: Is that in the  
18 document?

19 MEMBER SCHOENFELD: No, that's  
20 what I know to be the case. So that's why we  
21 feel it's important as a quality indicator to  
22 be able to document that you reached the

1       cecum.

2                       Having all essential polyp  
3       information recorded, having your withdrawal  
4       time recorded. Again, the idea there is, does  
5       that equate to finding adenomas? For  
6       withdrawal time, we have endoscopic database  
7       studies that demonstrate that, if your  
8       withdrawal time is greater than seven minutes,  
9       your adenoma detection rate is higher than if  
10      your withdrawal time is less than seven  
11      minutes.

12                      However, what we also know from  
13      endoscopic database studies is that plenty of  
14      individuals who have withdrawal times of  
15      greater than seven minutes are still poor  
16      performers in terms of adenoma detection rate.  
17      Recording withdrawal time is helpful, because  
18      if somebody's a poor performer and they have  
19      a very low withdrawal time that's something to  
20      work on. But it doesn't encompass the bottom  
21      line, which is we need to know if people find  
22      adenomas.

1                   And by the way, on that one, we  
2                   again have good endoscopic database data to  
3                   show people with higher adenoma detection  
4                   rates have fewer interval cancers. People  
5                   with lower adenoma detection rates, they're  
6                   more likely to have patients who have interval  
7                   cancers. So the key there would actually be  
8                   to record an adenoma detection rate.

9                   CO-CHAIR BASKIN: But if you're  
10                  recording all essential information about  
11                  polyps being found --

12                  MEMBER SCHOENFELD: But you're  
13                  not. The key piece of information that's not  
14                  included -- here you're saying you describe  
15                  the size of the polyp, the shape of the polyp,  
16                  the location of the polyp, and how you removed  
17                  it. What's not there is the actual histology  
18                  of the polyp.

19                  CO-CHAIR BASKIN: Which you don't  
20                  know at the time of the colonoscopy.

21                  MEMBER SCHOENFELD: Which you  
22                  don't know at the time of the colonoscopy. So

1 that an appropriate quality indicator for  
2 adenoma detection rate is going to require  
3 people to be able to document in their  
4 database, in their registry, the results of  
5 the histology of the polyps they removed.

6 Free of serious complication, this  
7 would be consensus, standard of practice, that  
8 you document whether or not you perforated the  
9 colon at the time you did the colonoscopy. I  
10 would simply note that, in a normal screening  
11 colonoscopy, the likelihood of getting a  
12 perforation, based on meta-analysis, is 1 in  
13 3,000 or less.

14 What's really the key with  
15 documenting complication is being able to  
16 follow the patient out for 14 to 30 days. The  
17 vast majority of complications, bleeding after  
18 you've taken out a polyp, they occur 24 hours  
19 or more after the person's had the  
20 colonoscopy.

21 So my point about that is, and  
22 this is consensus, documenting whether or not

1 you've had a serious complication at the time  
2 of the colonoscopy is definitely important to  
3 do, but it's not actually getting at a true  
4 measurement of complications, which would  
5 require having follow-up with the patient in  
6 14 to 30 days.

7 CO-CHAIR BASKIN: And would you  
8 also say to that, similar to what you've said  
9 about appropriate indications, standard  
10 assessment, that any procedure that is  
11 performed, if you know of a complication at  
12 the time of procedure, it's standard to  
13 document that?

14 MEMBER SCHOENFELD: And so that  
15 part is definitely consensus, that it's  
16 standard of care to report it at the time of  
17 the procedure. My point about this would be  
18 that having a complication at the time of the  
19 actual colonoscopy is exceedingly rare, and  
20 complications from colonoscopy, the vast  
21 majority occur in the 14 days after the  
22 colonoscopy has been performed.



1                   Again, just to provide one  
2                   example, if I take off a big polyp, it's rare  
3                   that it bleeds significantly right at the time  
4                   of the colonoscopy that I can't control. Most  
5                   of the time, it doesn't bleed at all. But if  
6                   I'm going to get a post-polypectomy bleed that  
7                   leads to hospitalization, that usually occurs  
8                   3 to 14 days after the colonoscopy. You can't  
9                   document that based on this kind of a quality  
10                  indicator.

11                  CO-CHAIR SAIGAL: So a few things  
12                  are being discussed here. It sounds like, in  
13                  general, most of these don't meet the NQF  
14                  standard for evidence. A lot of consensus  
15                  stuff.

16                  MEMBER SCHOENFELD: Correct.

17                  CO-CHAIR SAIGAL: For the ones  
18                  where there is evidence that you're aware of,  
19                  it's not in the document. Like, for example,  
20                  database or observational studies about  
21                  withdrawal time, even though they have  
22                  withdrawal time recorded, not even the cutoffs

1 that you mentioned.

2           You also brought up issues that go  
3 to Johannes's point about importance, really.  
4 Because it sounds like what you're saying is  
5 that, unless you know the histology of the  
6 lesions being removed, you can't make an  
7 inference about the quality of the  
8 colonoscopy. So that has to do more with the  
9 importance of the measure, which we already  
10 voted on, but it's sort of in that ballpark,  
11 still.

12           And then you also -- in terms of  
13 importance, you won't be able to measure  
14 complications at the same sitting, basically.  
15 So that also goes to importance, I think,  
16 because you're saying there's not enough of an  
17 opportunity to measure outcomes important to  
18 patients.

19           So, I don't know if that was clear  
20 to the group when we voted on importance, but  
21 those are two things that --

22           DR. PACE: You voted on impact.

1 CO-CHAIR SAIGAL: Impact, right.

2 DR. PACE: All of this is related  
3 to importance. All three of these.

4 CO-CHAIR SAIGAL: I'm sorry, I  
5 meant impact. But those are impact. So  
6 basically, what you're saying is, if you don't  
7 have the histology and if you don't have the  
8 ability to follow up for 30 days, that this  
9 might be a low-impact measure, is what you  
10 both are advising?

11 MEMBER SCHOENFELD: Well, I think  
12 I would say that, in terms of the evidence,  
13 evidence that documenting serious complication  
14 at the time of colonoscopy demonstrates that  
15 somebody has a high-quality colonoscopy has a  
16 very low impact.

17 Again, the general theme that we  
18 voted on: is it really important to have a  
19 colonoscopy quality indicator, a composite?  
20 Absolutely high-impact. When we look at the  
21 specific components here, is there good  
22 evidence to say that documenting serious

1 complications at the time of colonoscopy is a  
2 good representation of complication rates from  
3 colonoscopy?

4 What I'm saying is that the  
5 evidence doesn't support that. You do need to  
6 document it at the time of the procedure, but  
7 again, perforation, 1 in 3,000? That doesn't  
8 really get at measuring frequency of  
9 complications from colonoscopy.

10 CO-CHAIR SAIGAL: My understanding  
11 of voting on impact, then, was that we vote on  
12 the impact of the measure that's in front of  
13 us, not the idea.

14 DR. PACE: Let me. Impact is  
15 about the general area, as Phil's just been  
16 saying, of having a quality measure about  
17 colonoscopy quality. And what we're getting  
18 at through the other criteria of performance  
19 gap and evidence is whether there's evidence  
20 to support that particular component, what's  
21 being measured, or there's a performance gap.  
22 And those three things together combined to

1 designate our importance to measure and report  
2 category.

3 CO-CHAIR SAIGAL: Okay. Thank  
4 you.

5 DR. PACE: So impact is much more  
6 general.

7 CO-CHAIR SAIGAL: All right.  
8 Thanks.

9 MEMBER SCHOENFELD: Karen may  
10 comment on this more. I think the confusing  
11 part is, this is the first composite index  
12 we're looking at, as opposed to previous ones  
13 we have looked at that just look at one  
14 specific question, where there's much better  
15 correlation between impact and the evidence  
16 associated with that.

17 CO-CHAIR BASKIN: I know there are  
18 other comments, but you only had one more  
19 component to talk about before the comments,  
20 so maybe if you can make that, and then the  
21 others can start to comment? Because you got  
22 that far, I hate to break it up.

1                   MEMBER SCHOENFELD:  Appropriate  
2           follow-up recommendation is something that CMS  
3           has already included in PQRS.  That's  
4           definitely very appropriate, and we already  
5           talked about appropriate follow-up  
6           recommendations, actually, within the last two  
7           indicators.

8                   The reason I went through all  
9           these is that, in summary, it appears to me,  
10          my recommendation as the lead discussant is  
11          that when we get to the question for evidence,  
12          about whether or not the evidence supports  
13          this specific colonoscopy quality index, when  
14          you look at all these factors, the answer's  
15          going to be no.  So that's why I kind of did  
16          it in this way.

17                   Having said that, I mean,  
18          everybody's going to vote the way they want to  
19          vote, make comments the way they want to vote.  
20          But I think having a long discussion about  
21          each individual one, in my opinion, may not be  
22          necessary.

1                   So I'll go ahead and stop there.  
2                   I've talked enough here.

3                   CO-CHAIR BASKIN:   So there were a  
4                   couple comments about that overall assessment.  
5                   And thank you, Philip, for going through that  
6                   in a stepwise fashion.   But John, you had  
7                   wanted to make a comment first.

8                   MEMBER MORTON:   I guess my only  
9                   comment is, procedurally, how we're going to  
10                  go about this.   Are we going to be all or none  
11                  in this measure, or are we going to look at  
12                  them step by step?   Because there's a lot to  
13                  kind of go through here.

14                  CO-CHAIR BASKIN:   I do think, at  
15                  the end of the day, we have to do all or none  
16                  in terms of a final decision as to whether to  
17                  move this forward.   But I do think, in terms  
18                  of feedback to this developer, there may be  
19                  feedback about individual components which  
20                  could strengthen this measure to come back at  
21                  another time if the entire measure fails,  
22                  which obviously is still going to be up for

1 vote, but there's obviously some concerns  
2 about many of the components. So I do think  
3 we're going to have to get into the individual  
4 components and give some feedback to that.

5 Zahid, you wanted to make a  
6 comment?

7 DR. AMUNDSON: Andy, this is Gail.  
8 I need to make some corrections to the -- I  
9 just feel there's a need to make some  
10 corrections.

11 CO-CHAIR BASKIN: Gail, I was  
12 going to allow us to ask you some questions,  
13 but that would be helpful. If you just keep  
14 them brief, a few comments would be helpful to  
15 us. Thank you.

16 DR. AMUNDSON: Right. So the  
17 complications, it's not documenting  
18 complication or lack thereof. It's the  
19 patient -- the procedure fails quality if  
20 there is a serious complication within 24  
21 hours. And we have the data on that, and it's  
22 not 1 in 3,000. It is low, but it's not a 1



1 in 3,000.

2 I would say the recording the  
3 time, the element is not a specification of  
4 what the time should be. It's rather that the  
5 procedure records the time. And most of the  
6 state of the art procedures these days have an  
7 electronic timestamp, because the GI community  
8 has agreed that that's important.

9 The ASA is the American Society of  
10 Anesthesiologists, and some of those shouldn't  
11 be getting screened.

12 The information on the polyp is so  
13 the pathologist has the information they need  
14 to make an accurate pathology interpretation.  
15 The challenge is that the pathologist doesn't  
16 know whether it was a complete or a partial  
17 polyp removal. This is a very big and  
18 important issue. And I'd say to suggest that  
19 there's not evidence to support each one of  
20 these is not accurate.

21 CO-CHAIR BASKIN: Okay. Thank  
22 you, Gail.

1 DR. AMUNDSON: One other comment  
2 is the adenoma detection rate is not  
3 appropriate to be -- and the pathology is in  
4 this measure because that's how the follow-up  
5 indications -- so the pathology is known  
6 before this measure is completed. We do have  
7 adenoma detection rates, but those are rates  
8 across 100 patients. They're not for any one  
9 individual patient, you know? That just  
10 doesn't work that way. You can't have a  
11 population rate at an individual level. This  
12 is an individual, person-level, did this  
13 patient get a high-quality procedure, yes or  
14 no?

15 CO-CHAIR BASKIN: I appreciate  
16 that. So it's really not a measure of a  
17 population of folks to see whether an  
18 endoscopist is -- well, I guess you put it --

19 DR. AMUNDSON: It is both, Andy, a  
20 population and an individual. But an adenoma  
21 detection rate is not an individual,  
22 person-level measure.

1 CO-CHAIR BASKIN: All right.

2 Zahid, you wanted to make a comment? Thank  
3 you, Gail.

4 MEMBER BUTT: Yes, I think Gail  
5 made a couple of those points that I was going  
6 to make, but I think in general my comment is  
7 that, really, the intent of this measure is to  
8 understand whether a quality colonoscopy was  
9 done or not. We already said in the impact  
10 that it is important for a quality colonoscopy  
11 to be done for all the various reasons, but  
12 the question here is, do these components  
13 represent a quality colonoscopy, and is there  
14 evidence that is presented to support that?  
15 So I think, really, that's what we need to  
16 focus on.

17 And in terms of the evidence  
18 itself, it was somewhat difficult the way it's  
19 sort of presented. And as I said, maybe it's  
20 an issue of not that there isn't evidence, but  
21 that it isn't -- at least when I read it, it's  
22 sort of the same thing is repeated over and

1 over again, just those two or three studies,  
2 and the guidelines are repeated over and over  
3 again, not specifically referencing each  
4 section, although each section is broken down.  
5 It doesn't really address each section, that  
6 this is the evidence for this section.

7           And I think from our sort of  
8 collective experience we can say that pretty  
9 much all of these things are fairly standard  
10 type of quality things that are measured when  
11 you're just trying to understand whether a  
12 quality colonoscopy was done or not. So I  
13 think we should probably really focus on that  
14 aspect, as to whether there is evidence  
15 presented for each one of those. And for the  
16 ones where there isn't evidence presented, is  
17 there other evidence out there?

18           And we'll sort of get into that,  
19 again, tricky issue of, how do you deal with  
20 it when a few of them might be a 3, and three  
21 might be a 1, or maybe one might be a 1 and  
22 four are a 2, and so that sort of is a

1 challenge that we'd have to address.

2 But I think really the focus --  
3 the point I was trying to make is that the  
4 focus should be whether these represent, in  
5 aggregate, a quality colonoscopy. So whether  
6 it's adenoma versus hyperplasia doesn't  
7 matter, really, in that context.

8 CO-CHAIR BASKIN: Johannes?

9 MEMBER KOCH: I think that adenoma  
10 detection rate is really a crucial metric  
11 here. And part of what's happened is, in the  
12 GI field over the last 10 years, we started by  
13 looking for surrogate markers for adenoma  
14 detection rate, and have all really agreed --  
15 and the data, large population-based studies  
16 have proven that adenoma detection rate is the  
17 single most relevant predictor of patient  
18 outcomes.

19 So we looked at withdrawal times  
20 and adequate polyp preps, and all the other  
21 reasons to do a colonoscopy or to look for  
22 quality, and they are surrogate markers of

1 adenoma detection rate. So we have the best  
2 marker, which is "What percent of patients do  
3 you find an adenoma on?" Beyond that, we know  
4 that "What percent of patients do you find an  
5 advanced adenoma on?" These are all known  
6 metrics within 72 hours of having a  
7 colonoscopy done, so beyond two weeks you can  
8 find out whether or not the procedure  
9 identified a high-risk lesion or not.

10           And really, what we're trying to  
11 do is find out if you're a good driver.  
12 Having a car accident is missing cancer.  
13 Getting speeding is you have an adenoma  
14 detection rate that's too low. And we're  
15 using metrics like "Do you rotate your tires?"  
16 and "Do you have a clean car?" to decide  
17 whether you're a good driver. We have the  
18 metrics, which is "How many cancers do you  
19 miss?" and "What's your adenoma detection  
20 rate?"

21           And really, for a patient, do I  
22 care whether they said they took 10 minutes to

1 withdraw on my colonoscopy? I could say that.  
2 I could say your bowel prep was great. But I  
3 want to know, on the last 100 patients, did  
4 you actually find the same number of polyps?

5 And there's great variability.

6 Advanced adenomas are the single most  
7 important, because those are the ones that, in  
8 the next five years, if you missed them, are  
9 going to be cancer. And that rate should be  
10 up to 10 percent, and there are people who  
11 have an advanced adenoma rate less than 1  
12 percent.

13 Those are the pertinent findings.  
14 Yes, we know that if you don't get to the  
15 cecum you miss colon cancers. You miss them.  
16 So that's an important metric. However, that  
17 falls within the range of your entire  
18 procedure.

19 So I think that there's really  
20 good data to say that you should do an  
21 appropriate indication. There's really good  
22 data that if you do colonoscopy too soon,

1 you're not doing good colonoscopy. Similarly,  
2 if you recommend a colonoscopy too early,  
3 that's inappropriate. Those two are the  
4 measures that we've already addressed. I  
5 think for the rest of them, the data is for  
6 adenoma detection rate, not in any of these  
7 other metrics, to suggest that they, in fact,  
8 impact any patient outcome.

9 CO-CHAIR BASKIN: All right.

10 Jenifer?

11 MEMBER LIGHTDALE: I mean, I agree  
12 with both of you, and I also really am taken  
13 with this concept that patients respond to  
14 composite metrics. This is clearly intended  
15 to be a patient-level metric, and I like your  
16 analogy to driving a car, and what makes a  
17 good driver.

18 I would worry that the standard of  
19 evidence that we need to hold this metric to  
20 is that what is being presented as the  
21 components of this metric are actually -- the  
22 evidence would be that that means it's a



1 high-quality colonoscopy for that patient.

2           And so getting back to this  
3 withdrawal time question -- really, the  
4 question here with withdrawal time is, is it  
5 a surrogate for adenoma detection rate? And  
6 the answer is no. I mean, the evidence will  
7 not -- well, it's a predictor. It's a  
8 predictor. But is it actually -- that's your  
9 entire point, Phil, right? Is that a very  
10 slow withdrawal does not mean you have a high  
11 adenoma detection rate. So I think that would  
12 be critical here.

13           CO-CHAIR BASKIN: Robert?

14           MEMBER ELLIS: Let me take the car  
15 analogy a little bit further. Maybe you can  
16 help me, because I'm wandering off a little  
17 towards the end. If we use the car analogy,  
18 there's like 38 steps in doing a valve job on  
19 a car, and there's a lot of shortcuts in those  
20 38 steps. If you do all 38 steps, there's a  
21 pretty good chance you've done a good valve  
22 job.

1 I can then take those rings, valve  
2 seals, put them under an electron microscope,  
3 and make additional diagnoses about the  
4 problems with the car. And from that, I may  
5 end up actually providing the engine some  
6 benefit, right? Because I've found that it  
7 has probably a blown master gasket, or  
8 something like that.

9 That doesn't deflect from the fact  
10 that the mechanic did a good valve job, right?  
11 And I'm wondering where this measure's kind of  
12 endgame is, and the relative detection of  
13 adenomas, although obviously related to a very  
14 important outcome, is it the defining point of  
15 "Did you do the procedure in a quality way?"  
16 And I don't quite know where that line falls.

17 CO-CHAIR BASKIN: Karen wanted to  
18 make a comment before we moved in between.

19 DR. PACE: I am sorry, I have to  
20 leave for a brief conference call. But I just  
21 wanted to make a couple points for your  
22 consideration. And one is that the adenoma

1 detection rate is not the measure before us.  
2 It's about -- and if that's truly the better  
3 way to measure quality of colonoscopy, you  
4 need to think about the measures that you  
5 approved or recommended to move forward, which  
6 were simply recommending a 10-year return  
7 versus -- I mean, so you need to think about  
8 this and balance in terms of what's most  
9 important in terms of getting out a quality  
10 index.

11 So I'm not saying that all of  
12 these components are absolute, but you need to  
13 think about this measure as it's being  
14 presented, and a different measure might be  
15 preferable, but you need to talk about this  
16 measure in terms of what it's doing and, as  
17 you did yesterday and this morning, even if  
18 the evidence -- you can make exceptions for  
19 expert opinion for different components as you  
20 did for other, single measures.

21 So I just wanted to mention that  
22 as well.

1 CO-CHAIR BASKIN: All right. So,  
2 I partially lost track of when these signs  
3 went up, but I do know that Ed's came up  
4 first, before the others, and I do know that  
5 Philip's came up last. And I'll try to get  
6 the middle ones right. So Ed, go ahead.

7 MEMBER GILL: Thanks. This is  
8 just a quick question. If we're supposed to  
9 be evaluating these measures based on the  
10 evidence submitted, I need some help with this  
11 new process where their evidence equals  
12 logical argument.

13 (Laughter.)

14 MEMBER GILL: And they reference  
15 number two, the parachute hypothesis. So to  
16 me, I don't know what to do with that. That's  
17 not evidence.

18 DR. PACE: Right. So, according  
19 to how you voted yesterday, you either said  
20 "Yes," "No, it doesn't meet the criterion,  
21 there's no empirical evidence," and then you  
22 could invoke the exception, and the third no

1 was "No evidence submitted, but you're aware  
2 of a body of evidence that exists."

3 MEMBER GILL: Right. It seems to  
4 me that's where we are, and the rest of this  
5 is moot, and we just need to rely on our GI  
6 colleagues to help us tell if there is other  
7 evidence that would be helpful here.

8 CO-CHAIR BASKIN: All right. So I  
9 am going to go Johannes and then Zahid.

10 MEMBER KOCH: I think that we all  
11 feel very strongly that a composite index  
12 would be really, really a good thing. So I  
13 think to Karen's point, adenoma detection rate  
14 is the benchmark that should be incorporated.  
15 And if this had included that, the usefulness  
16 of this would be very, very different. I  
17 think there's markers here that are surrogate  
18 markers for that, and we know what it is. We  
19 know what the marker is. So I think that,  
20 just because we approved proper surveillance  
21 intervals doesn't mean that we should approve  
22 this, because it's a composite marker.

1           I think that the question -- and  
2           we're getting mixed up in analogies. The  
3           simple question, I think, is "Does the  
4           consumer care about a physician who misses  
5           cancers and has a very low adenoma detection  
6           rate more than they care about a physician who  
7           says that you had an adequate bowel prep and  
8           says that they saw all the polyps that you  
9           had?"

10           I mean, those are different  
11           weightings of that, and there's no weighting  
12           here. And in terms of evidence, really, for  
13           these affecting outcomes, there's very, very  
14           little evidence for most of these measures.

15           CO-CHAIR BASKIN: And I am going  
16           to break the chain here just for a second,  
17           because I know Gail's on the phone, and I'm  
18           going to make a guess that Gail thought about  
19           adenoma detection rates in creating this  
20           measure. And in fact, obviously, if you put  
21           all the information about polyps, and are just  
22           knowing what the results of those pathology

1 reports are before you give a recommendation  
2 for follow-up, it could have been calculated.  
3 So Gail, is there some reason why that  
4 specific measure is not part of the composite?  
5 Was there a reason for or against that?

6 DR. AMUNDSON: Well, I think you  
7 have to ask yourself, how would you put  
8 adenoma detection in a measure that -- adenoma  
9 detection rate is an important measure, and we  
10 have the data on adenoma detection rate. But  
11 it is a paired measure with this, because this  
12 is about a good valve job.

13 I love that analogy. This is  
14 about a good valve job, and I would really  
15 push back on there not being evidence for  
16 these things. There's evidence for every one  
17 in there. We were asked to do them each  
18 separately, which is why they're repeating.  
19 It wasn't probably our preference, because we  
20 think it makes it much harder to get into the  
21 evidence.

22 But the adenoma detection rate is

1 44 percent in men and 31 percent in women in  
2 this region, and what has happened is that, as  
3 the colonoscopy all-or-none composite drives  
4 up to consistent, high-level reliable  
5 procedures, our adenoma detection rate has  
6 skyrocketed.

7           And that's the reason why the  
8 process reliability is an important measure.  
9 But you can't put an adenoma detection rate  
10 inside a person-level measure. It is not  
11 possible to do it.

12           CO-CHAIR BASKIN: Thank you.

13           DR. AMUNDSON: And I would  
14 disagree with the comment that patients care  
15 about "Are you missing cancer," because  
16 patients don't understand an adenoma detection  
17 rate. We've tried that. They don't get it.  
18 They don't know what 44 percent means, and  
19 they don't know how to compare that to 15  
20 percent.

21           CO-CHAIR BASKIN: Thank you, Gail.

22 And I think part of our problem with this



1 discussion is that we're looking at this  
2 measure differently than the developer  
3 intended it to be. As I see it now, it sounds  
4 like what the measure's really saying is "Did  
5 you do all the parts that are necessary to  
6 make it a high likelihood that you'll get a  
7 better result?"

8 Not what the result is, not  
9 whether you found a lot of polyps or didn't  
10 find a lot, or adenomas, not what the end  
11 outcome is, but "Did you follow all the  
12 processes that are shown to be an essential  
13 part to make it a higher likelihood that the  
14 patient will have gotten the quality  
15 colonoscopy?" And that there would be a  
16 different measure set if you were looking at  
17 the population and saying "What are the health  
18 outcomes of that?"

19 And Gail's pointing out that yes,  
20 there were health outcomes improvement that  
21 were shown, of increasing adenomatous polyp  
22 detection based on the history of this, but

1 that's not what this measure was attempting to  
2 measure. That's in itself a separate measure.  
3 So we're mixing up outcome measures and a  
4 process measure, to say "Did all the elements  
5 of a colonoscopy occur to make it a higher  
6 likelihood that the colonoscopy was a quality  
7 colonoscopy?" The physical act of doing it,  
8 and all the components that you have to do to  
9 make sure that anything you did, you got the  
10 full information from it.

11 You know, did you actually tell  
12 the pathologist what size and what piece of  
13 the polyp is there, so there's a likelihood  
14 that you'll get a quality report back? That's  
15 really what this is saying. At least, that's  
16 how I'm viewing it.

17 I'm sorry to interject. So I  
18 think Zahid, and then Stuart.

19 MEMBER BUTT: So I think, really,  
20 the question that we have before us, it looks  
21 like from all this discussion, is that the  
22 components, 3 which is the bowel prep, 4 which

1 is complete exam, 5 cecal photo taken and 7,  
2 withdrawal time recorded -- the question is,  
3 are these four components -- basically, is the  
4 adenoma detection rate complementary to these,  
5 or these don't matter at all because the  
6 adenoma detection rate really replaces them?

7 So, we have to look at the  
8 evidence, that are these four components,  
9 which really are driving, presumably, the  
10 adenoma detection rate outcome -- is the  
11 evidence such that they are useless, or not  
12 helping the adenoma detection rate? Because  
13 that's really what the crux of this discussion  
14 is. Everybody agrees on the other components.

15 CO-CHAIR BASKIN: Yes, and I think  
16 that's what I was saying as well. In other  
17 words, if you're going to have a good adenoma  
18 detection rate, you have to have done a  
19 high-quality colonoscopy. And did you do a --

20 MEMBER BUTT: Well, what we have  
21 to determine here is, is there evidence that  
22 that's the case? Or is there evidence that

1 that's not the case, actually? Is there  
2 evidence contrary to the fact that if you do  
3 all these things, it doesn't matter to the  
4 adenoma detection rate?

5 CO-CHAIR BASKIN: Stuart, you've  
6 been waiting patiently.

7 MEMBER REYNOLDS: Sort of going  
8 along with that, my issue is I've got a 115  
9 page document and there's almost no data or  
10 evidence in there. And so in an attempt to  
11 try to move things along, we're proposing that  
12 we're going to vote on each one of those  
13 things. And almost without exception, they're  
14 all going to be at best insufficient, if not  
15 nonexistent.

16 And then we're going to be faced  
17 with a vote with "Well, are we going to push  
18 it through anyway based on consensus?" And I  
19 think we should try to move along in that way,  
20 and I would call that we just start voting on  
21 these things. And as they come up, we're  
22 going to be faced with the decision, do people

1       feel strongly enough that they go forward?  
2       Because then we still have to get back to the  
3       composite thing as a whole, and we're really  
4       getting bogged down in these ideas?

5                       CO-CHAIR BASKIN:  I would hope  
6       that the comments could speak to that.  I  
7       think it is a good idea that we start to move  
8       along, because we're starting to rehash here.  
9       But at the same time, if there's a comment  
10      that links to that, please make it.

11                      CO-CHAIR SAIGAL:  Can I just make  
12      one comment about this, and then I'll move us  
13      along?  Stuart is right, basically.  We're  
14      supposed to be recognizing if there's evidence  
15      supporting these measures.  All the document  
16      says is "It's common sense that these work,"  
17      and there's a joke reference for most of them.  
18      And the developer, I think, is not correct in  
19      advocating that there's a lot of evidence in  
20      the document for what they're saying.

21                      The question is -- we'll be voting  
22      it down, I have a feeling, in terms of the

1 evidence being in the document. Will there be  
2 importance to measure as an exception? This  
3 is where I'm concerned, personally, based on  
4 what our colleagues are saying about this  
5 adenoma detection rate.

6 And I think there could be a  
7 patient-level measure that says "Does this  
8 doctor have an adenoma detection rate above a  
9 certain threshold?" A very low bar threshold,  
10 but you could learn from that measure, then,  
11 this is a doctor who does find adenomas, in  
12 general. So you could conceive of it as a  
13 patient-level measure.

14 That's my only comment. I think  
15 we should probably move on unless there's  
16 anything pressing.

17 CO-CHAIR BASKIN: Phil, if you  
18 wanted to say something as the presenter?

19 MEMBER SCHOENFELD: I was going to  
20 reinforce what Stuart said. I would suggest  
21 that we take a vote on the second criteria, on  
22 evidence. And I think it's going to be pretty

1 -- I think, I guess what the outcome will be.  
2 And then if we want to discuss further  
3 feedback to the developer, I think that would  
4 be fine.

5 But I would just reinforce, if I  
6 understood what Stuart said correctly, maybe  
7 it's time to just take a vote on that second  
8 question.

9 MR. AMIN: I will just jump in  
10 here real quick. One thing that I will just  
11 clarify -- and I know we've framed this in  
12 multiple different ways, and Karen said this,  
13 but I just want to make sure I reiterate it.  
14 What we are here to do is evaluate what's in  
15 front of us, and clearly the evidence question  
16 is asking us the quality, quantity and  
17 consistency of the evidence of this process  
18 measure and the components of the process  
19 measure that influence quality outcomes that  
20 are important for patients.

21 And I think that's the frame in  
22 which you have had the conversation, but

1 that's different than having a discussion  
2 around a different measure. So while those  
3 are interconnected, we want to make sure that  
4 what you're looking at right now is the  
5 evidence that supports this measure, that  
6 influences patient outcomes that matter. And  
7 let's keep it there, and not necessarily  
8 around new measures or a measure that this is  
9 not constructed to do.

10 DR. AMUNDSON: And the most  
11 important reference is --

12 CO-CHAIR BASKIN: Gail, no  
13 comments. I'm sorry, you need to shut off.  
14 And shutting off this conversation, I know,  
15 Johannes, you got it in there. So if you can  
16 keep it within 30 seconds, we'd like to get  
17 this to a vote.

18 MEMBER KOCH: Less than 30  
19 seconds. I think the one component here is  
20 that many of these metrics lend themselves to  
21 gamesmanship, so that you can say things about  
22 it, and adenoma or other metrics, hardcore



1 metrics that can't be manipulated, I think  
2 would be more valuable.

3 MS. WILBON: So Andy, can I just  
4 suggest that we go through the list of the  
5 nine components, start with 1, make sure that  
6 the developer knows which? We say the name of  
7 the component?

8 CO-CHAIR BASKIN: I can't agree  
9 with that, only because part of this is  
10 actually surveillance recommendations, for  
11 which we just approved two measures that are  
12 very similar. And to say that the evidence?

13 CO-CHAIR SAIGAL: But that was for  
14 overuse. That was a different impact on the  
15 patient.

16 CO-CHAIR BASKIN: But  
17 nevertheless, it is a component of this. It's  
18 unclear to me whether it's not homogeneous  
19 with it. It doesn't make sense with the rest  
20 of the components, but nevertheless, it is  
21 there. And I don't think it is just whether  
22 a recommendation was made, but it was the

1 appropriate recommendation for follow-up,  
2 which is an outcome for which we've already  
3 said there is evidence.

4 CO-CHAIR SAIGAL: We said that  
5 there was evidence there wasn't harm to wait  
6 longer for the patient. We were avoiding  
7 complications of colonoscopy.

8 MEMBER SCHOENFELD: I've got to go  
9 back to what Taroon said. My impression is,  
10 we're supposed to get to a point where we say  
11 -- this is an all-or-none quality indicator  
12 based on multiple components, where we say  
13 "Yes, evidence supports this all-or-none index  
14 score, that it should be used as a quality  
15 indicator and go through to Stage 2," or "No,  
16 it doesn't."

17 We're not saying that some aspects  
18 of it aren't good. We're saying -- if I  
19 understand what you said correctly, we're  
20 voting on what's presented to us. Does this  
21 all-or-none colonoscopy quality index have the  
22 evidence to say "Yes, this is the right

1 all-or-none quality index?"

2 CO-CHAIR BASKIN: Not whether it's  
3 the right one, because it's the only one. So  
4 it's whether this --

5 MEMBER SCHOENFELD: Right. If  
6 this is the one --

7 CO-CHAIR BASKIN: If this is a  
8 good measure or not a good measure based on  
9 the evidence.

10 MEMBER SCHOENFELD: Yes, I accept  
11 that.

12 CO-CHAIR BASKIN: Okay. Well,  
13 then, I think we'll bring the all-or-none to  
14 a vote regarding the evidence base. At some  
15 point, we could always provide feedback to the  
16 developer about individual components.

17 So let's get the potential votes  
18 of what it is there. The body of evidence  
19 that's presented, that's been submitted, meets  
20 the guidance, or no, the evidence doesn't meet  
21 the guidance, or that it's insufficient, but  
22 perhaps we think there is a body of evidence

1 to support it.

2 There wasn't -- as reported to us  
3 and as we've read, there wasn't a whole lot of  
4 body of evidence about most of these  
5 components, and I think I hadn't heard anyone  
6 say that that body of evidence actually exists  
7 anywhere either. That's what I took from that  
8 voluminous conversation.

9 So I think we'll just go ahead and  
10 vote. It's a 1, 2 or 3. So those voting 1,  
11 yes, the body of evidence submitted meets the  
12 guidance, raise your hands any time now?

13 (No hands.)

14 CO-CHAIR BASKIN: Okay, that's a  
15 zero. 2, the evidence does not meet the  
16 guidance for quality, quantity and  
17 consistency?

18 MS. BOSSLEY: And that it doesn't  
19 exist.

20 CO-CHAIR BASKIN: Yes, and that it  
21 doesn't exist.

22 (Show of hands.)

1 CO-CHAIR BASKIN: Twelve. And  
2 then 3, no, insufficient evidence, but that  
3 that body of evidence may exist.

4 (Show of hands.)

5 CO-CHAIR BASKIN: Three. And  
6 that's 15, so that's fine. So now I think,  
7 then, we go to whether the -- is this the  
8 exception one. I was looking for the word  
9 exception, but I didn't look at the blue part.

10 So now we're trying to determine  
11 whether, despite the fact that the evidence  
12 was not submitted and that we think that it  
13 may not exist, whether there's expert opinion,  
14 or whether this is a standard acceptable and  
15 not a big leap for us to make to say that this  
16 is reasonable. And we'll open that up for a  
17 couple of comments. So, Phil?

18 MEMBER SCHOENFELD: I waited until  
19 this point to bring this up. Okay. The way  
20 this is phrased, "If there is no empirical  
21 evidence, only expert opinion, and expert  
22 opinion was systematically assessed with

1 agreement that the benefits to patients  
2 greatly outweigh the potential harms, is there  
3 an exceptional and compelling reason that the  
4 measure should be considered further?"

5           So now we're saying do we think,  
6 even though there's not evidence, is there  
7 expert opinion that this is so exceptional it  
8 should move forward? So I waited until now to  
9 say this. I've been involved in professional  
10 organizations in GI for a lot of years, and  
11 the three different GI organizations virtually  
12 never agree on anything. But you've got, in  
13 the public comment here, a letter signed by  
14 the presidents of all three organizations all  
15 saying that this colonoscopy quality index  
16 does not meet the criteria to assess the  
17 quality of colonoscopies.

18           So at least with respect to the  
19 three GI organizations that represent  
20 virtually all gastroenterologists in the  
21 world, because the American Gastrological  
22 Association is international, they all say the

1 answer to this question would be no.

2 CO-CHAIR BASKIN: And I'm  
3 presuming we've all read that, but for the  
4 sake of conversation are they a little bit  
5 more specific about why they're saying no?

6 MEMBER SCHOENFELD: They actually  
7 basically say "Assessing bowel prep, yes, and  
8 that's been submitted to CMS. Assessing a  
9 full exam by photographing the cecum, yes.  
10 Using withdrawal time instead of adenoma  
11 detection rate, no. Using serious  
12 complications," which if I understood Gail, is  
13 actually within 24 hours. Well, actually,  
14 you're not really saying "within 24 hours."  
15 You're documenting complications right at the  
16 time of colonoscopy.

17 DR. AMUNDSON: That's not  
18 accurate. That's not --

19 MEMBER SCHOENFELD: No. You're  
20 not an endoscopist, ma'am. That's not the  
21 case.

22 CO-CHAIR BASKIN: Whoa, slow down.

1 So Gail, I'm sorry, but this is not an  
2 interactive conversation. I appreciate that  
3 you're champing at the bit to say something.  
4 How this is actually measured and when the  
5 measure is actually reported as to whether you  
6 submit your data after 24 hours, and you  
7 really do get a 24 hour complication rate,  
8 that's got to do with the feasibility and the  
9 ability to report this.

10 But I don't think this necessarily  
11 says "You completed the colonoscopy. Is there  
12 a complication?" If it measures 24 hours  
13 worth of complications, it measures 24 hours  
14 worth of complications, assuming you're doing  
15 it correctly.

16 MEMBER SCHOENFELD: Okay. And  
17 having said that, I let myself digress.  
18 Having said that, they also say "That's not  
19 the appropriate way to truly measure  
20 complications." So for multiple of these  
21 measures, the societies said "These are not  
22 the right things to measure." And again, our



1 purpose is not to define what is the right  
2 measure at this time, only to comment on these  
3 things. But these were several of the things  
4 that were mentioned in that letter.

5 CO-CHAIR BASKIN: And I think we  
6 should open it up for comments here from the  
7 group, if there's a little bit of discussion  
8 regarding this exception question.

9 CO-CHAIR SAIGAL: Just that the  
10 exception question is supposed to be a true  
11 exception, that we think there's a very  
12 serious, compelling reason. There shouldn't  
13 be any negatives, in my view, that prohibit  
14 us.

15 CO-CHAIR BASKIN: And I think what  
16 I'm essentially hearing, or what I think from  
17 the prior conversation, is that some of these  
18 components could potentially fit into a  
19 quality index, quality score, quality  
20 composite, but as a whole that it doesn't seem  
21 to meet the level that we would want for an  
22 exception, as for this whole composite, but

1 that there's potentially some feedback here  
2 for the developer.

3 Is there any other comment before  
4 we go on to have this vote?

5 (No response.)

6 CO-CHAIR BASKIN: Okay. So 1 is  
7 voting yes, there is an exception, a  
8 compelling reason to move this forward. 2  
9 means no, this will not be an exception, the  
10 evidence criterion has not been met.

11 So, those voting yes, 1, please  
12 raise their hands?

13 (No hands.)

14 CO-CHAIR BASKIN: So that is zero  
15 for yes. So 2, no exception being made?

16 (Show of hands.)

17 CO-CHAIR BASKIN: And that appears  
18 to be unanimous at 15. Okay. So the  
19 exception criterion is not there. Do we even  
20 discuss the gap at this point? We don't need  
21 to go there. And then, of course, the  
22 measure, we can't move forward, so we don't

1 vote for that.

2                   So at this point, I would say any  
3 comments, any feedback for the developer, this  
4 would be a good chance to do so. I think my  
5 comment just a few minutes ago was one for the  
6 developer, that there may be some reason to  
7 believe there's evidence that some of these  
8 components may be very meaningful in a quality  
9 index, and that one potentially could create  
10 one for which all the components would be  
11 acceptable to this group, but that at this  
12 time, this one does not meet that level.

13                   But I would appreciate others to  
14 comment as well. And Zahid, do you want to  
15 make a comment to the developer?

16                   MEMBER BUTT: Yes. I'll just  
17 again state that this type of all-or-none type  
18 of quality index, which weights things that  
19 are on the one extreme serious complications  
20 the same as bowel prep, I think should be  
21 looked at again. Because I think, really,  
22 there is need for an indicator like this, but

1 probably more like a true composite, where  
2 there is some actual scoring, perhaps with  
3 weighted scoring of each component, and  
4 perhaps the components, maybe two or three of  
5 those could be consolidated into a single  
6 component.

7 CO-CHAIR BASKIN: Well, I  
8 appreciate that. I think you're looking down  
9 the line in terms of implementing this and the  
10 impact of the measure itself, not the impact  
11 of the concept. But from the point of  
12 importance, how it would be scored or  
13 methodology is probably not one of the  
14 components that we would vote at this level of  
15 Phase 1. But I appreciate that feedback.

16 MEMBER BUTT: And I fully support  
17 the consumer's desire to have that single  
18 number, that they can say whether this is a  
19 good number or not, that truly represents the  
20 procedure itself.

21 CO-CHAIR BASKIN: Any other  
22 comments that someone wants to have? Anne?

1                   MEMBER PELLETTIER-CAMERON: Just a  
2                   quick comment about the length of this  
3                   document. I just think the rest of these  
4                   measures today that we've measured have been  
5                   documents of reasonable size, and this is a  
6                   115 page document, and most of it is not  
7                   necessarily even focused on the form and  
8                   format. I think it's a little bit difficult  
9                   for members of this panel to go through that  
10                  much volume. I think it speaks poorly of this  
11                  presentation that it's 115 pages, 20 of which  
12                  are a PowerPoint at the end.

13                  CO-CHAIR BASKIN: I understand  
14                  that some information may have been provided  
15                  that was beyond the scope of the Phase 1 part  
16                  of this, which is just the section we were to  
17                  talk about. And yes, I appreciate that the  
18                  PowerPoint provided information regarding  
19                  performance gaps, but it went beyond that to  
20                  some information that just wasn't necessary  
21                  for this committee. I appreciate that  
22                  comment, that we need to filter down this

1 information to make it a little more -- make  
2 all of it pertinent to the decisions that  
3 we're making.

4 MEMBER BORDEIANOU: I just wanted  
5 to say that yes, we don't rate the scoring,  
6 but I think that there is a standardized  
7 scientific way of developing indices that go  
8 through a validation process, and the Delphi  
9 process, and the societies that sent this  
10 lovely three page letter could perhaps unite  
11 and create an index that could then be used.

12 CO-CHAIR BASKIN: Yes. And I'm  
13 not saying scoring is not important. I'm just  
14 saying that it would have been discussed at  
15 the second phase, and not at this phase, in  
16 this context. That's all.

17 MEMBER FALLER: Out of deference  
18 to the consumer and the gastroenterologist, I  
19 think the car analogy's great, but I want to  
20 know whether the brakes are going to fail, and  
21 not whether the valve isn't right.

22 CO-CHAIR BASKIN: Jenifer?

1                   MEMBER LIGHTDALE:  Actually, I'd  
2 follow up on that.  I mean, at the end of the  
3 day, this is intended to be a score that a  
4 patient would use to say that it's okay to go  
5 to this gastroenterologist.  And there,  
6 actually coming back to this question of  
7 process and outcomes being a hybrid, like  
8 here, there's only one outcome in here, and  
9 it's not adequate to really say that you'd be  
10 safe, that the brakes would not have failed,  
11 because the endoscopist would score very  
12 highly on not having immediate complications,  
13 but we don't know what their late complication  
14 rate is.

15                   CO-CHAIR BASKIN:  Yes, and I do  
16 think that was a difficulty, and the fact that  
17 there was a little bit of a mix of process and  
18 outcomes, and that made it a little bit harder  
19 to wrap your hands around this.

20                   MEMBER LIGHTDALE:  And getting  
21 back to the whole ADR question, throwing in  
22 adenoma detection rate would be another

1 outcome, you might start to have a heavier  
2 weight on your outcomes when weighting out  
3 your process. Or make it all process. It's  
4 up to you.

5 CO-CHAIR BASKIN: All right.

6 Well, thank you everybody for comments, and  
7 thank you for a thorough review of that, and  
8 thank you to the developer for presenting  
9 this. I hope you've got some good feedback.  
10 We are beyond our break time, so we're going  
11 to take it now, but I do think we should go  
12 ahead and take at least a 10 minute break.  
13 It's 10:50. If we could reconvene at 11:00,  
14 that would be great. Thank you.

15 (Whereupon, the above-entitled  
16 meeting went off the record at 10:50 a.m., and  
17 was resumed at 11:02 a.m.)

18 CO-CHAIR BASKIN: Let's take our  
19 seats and get started. We have some very  
20 anxious presenters, I'm sure.

21 Okay. We have three more measures  
22 to consider, and these measures -- I guess two



1 of them, the measure stewards are the  
2 developers or the AGA, so I guess we'll ask  
3 the AGA to make three minutes or so of  
4 comments regarding those two measures before  
5 we go into the individual reviews. Do we have  
6 a representative, or someone on the phone? Is  
7 there someone on the phone representing the  
8 AGA to present the two measures, 2059 and  
9 2062?

10 (No response.)

11 CO-CHAIR BASKIN: Is the phone  
12 open? Anyone? They were scheduled for 10:45  
13 and it's 11:04, so they should be there. Was  
14 it supposed to be --

15 MS. ROBIN: Can you hear us?

16 CO-CHAIR BASKIN: Yes. Hi. Could  
17 you say who you are? And I presume you're  
18 representing the AGA.

19 MS. ROBIN: Yes. This is Debbie  
20 Robin for the AGA.

21 CO-CHAIR BASKIN: Oh, hi, Debbie.  
22 It's Andy Baskin. If you would present those

1 two measures, that would be great. Thank you.

2 DR. BRILL: This is Joel Brill.  
3 Yngve will be presenting, and Debbie Robin is  
4 also here. We're all on the phone, and Debbie  
5 and I will mute so we don't hear all the  
6 echoes.

7 CO-CHAIR BASKIN: Okay. And try  
8 and keep it down to about three minutes or so.  
9 Thank you.

10 DR. FALCK-YTTER: Okay. Debbie,  
11 do you want me to present this real quick?

12 MS. ROBIN: Yes, please.

13 DR. FALCK-YTTER: Okay. So thank  
14 you very much for letting us present this.  
15 These are the two measure concepts being  
16 presented today here to the steering committee  
17 for consideration, the NQF C2059 and the  
18 C2062. They address the management of the  
19 bowel patient with inflammatory bowel disease  
20 on long-term corticosteroid therapy.

21 Both measures are basically  
22 intended to raise the provider awareness of

1 the toxic effects of the long-term  
2 corticosteroid use, particular at the greater  
3 dose of 10 milligrams a day, so 10 milligrams  
4 or greater a day, and so that they can take  
5 proactive steps to minimize the dose for those  
6 suffering from the IBD diseases that we are  
7 talking about.

8           So these two measures basically  
9 are preventive care measures, corticosteroid  
10 sparing therapy, and the other measure,  
11 corticosteroid related iatrogenic injury -  
12 bone loss assessment, so it's an assessment  
13 measure. And they are part of the 2012 PQRS  
14 inflammatory bowel disease measure group, and  
15 it's also a proposed PQRS measure for 2013.

16           These measures were developed  
17 during 2010 and 2011 by the AGA, utilizing the  
18 PCPI independent measure development process.  
19 The multi-stakeholder workgroup included  
20 representatives from the Crohn's and Colitis  
21 Foundation of America and the American Society  
22 of Colorectal Surgeons. The workgroup was

1 co-chaired, I believe, by John Allen, from  
2 Minnesota Gastroenterology Group and the  
3 University of Minnesota, and Themis  
4 Dassopoulos, and he's currently at the  
5 Washington University in St. Louis.

6 I'm currently the lead  
7 methodologist for systematic review being  
8 conducted by the AGA on immunomodulators and  
9 biologics for moderate to severe Crohn's  
10 disease. I am Chief of GI here at Cleveland  
11 VA Medical Center. I am at Case Western  
12 Reserve University. If you have any questions  
13 in regard to that systematic review and the  
14 evidence supporting these measure concepts, I  
15 will be happy to go into much more detail.

16 Dr. Brill, as we just heard, is  
17 also on the telephone right now, and he has  
18 also supported this measure group. And Debbie  
19 is also on to tell us about some other details  
20 if necessary.

21 So, just a few words on the  
22 background of this. Approximately 40 percent

1 of patients with inflammatory bowel disease  
2 are treated with corticosteroids. The initial  
3 therapy with steroids is associated with much  
4 poorer prognosis, including inability to taper  
5 off the steroids without experiencing  
6 flare-ups of disease, and disabling symptoms  
7 and surgery. Some of the population-based  
8 studies have shown that steroid dependence  
9 occurs in one third of all the IBD patients  
10 treated.

11 As you all know, major  
12 steroid-related side effects for adult  
13 patients with Crohn's Disease are metabolic  
14 bone disease and infectious complications.  
15 There's a risk of comorbidity, including  
16 sepsis and fractures associated with long-term  
17 high-dose corticosteroid use. Patients with  
18 Crohn's Disease and UC are at an increase risk  
19 of death during the periods of current  
20 corticosteroid use, while treatment with  
21 thiopurines have not been associated with an  
22 increased risk of death.

1                   Increasing the treatment of IBD  
2 patients to steroid-sparing drugs, the use of  
3 dependency on corticosteroids decreases, along  
4 with the risk of comorbidities. The increased  
5 risk of infections is probably attributed to  
6 the disease's severity, also, but concomitant  
7 steroid use probably plays a larger role. The  
8 use of prednisone is a strong independent risk  
9 factor for serious infections and death.

10                   So we use steroid-sparing drugs.  
11 These are immune suppressant biologics that  
12 can provide us alternatives to treating with  
13 corticosteroids alone. I think that's  
14 important. And introduction of those agents  
15 into the IBD treatment regimen provides the  
16 opportunity to minimize those exposures to  
17 corticosteroids and their side effects.  
18 Despite the advantage in the therapy of IBD,  
19 considerable subsets are still kept on  
20 prolonged steroid therapy.

21                   Comprehensive literary review and  
22 analysis showed that, although the majority of

1 patients with active Crohn's Disease respond  
2 rapidly to steroids, about half will be either  
3 steroid-resistant or steroid-dependent in one  
4 year.

5 Osteoporosis in itself is  
6 recognized as a complication from IBD and  
7 steroid therapy, and it contributes to the  
8 increased risk of osteoporosis observed in  
9 IBD. Long-term steroid uses are associated  
10 with an osteoporotic fracture rate of 30 to 50  
11 percent, mostly at the sites of the vertebrae,  
12 hips and pelvis. And to minimize bone loss by  
13 using alternate therapies, alternate steroid  
14 therapy has actually failed to reduce those  
15 fracture rates. So it's really not something  
16 that we can do in practice.

17 In a population-based study from  
18 the U.K., they've cited an unadjusted relative  
19 risk of hip fractures of 1.62 for IBD and 1.49  
20 for UC, and 2 for Crohn's Disease. So about  
21 twice as high, the risk to the general  
22 population.

1                   Wagner et al. performed the survey  
2                   inquiring into the awareness of implementation  
3                   of the IBD or AGA guidelines on osteoporosis  
4                   in IBD patients. Slightly less than half of  
5                   these respondents used these guidelines for  
6                   decision making in the management of IBD  
7                   patients. So physicians who are self-reported  
8                   utilizing these guidelines adhere to those  
9                   recommendations.

10                   There were other studies conducted  
11                   by Wagner and others that have shown disparity  
12                   by rating insurance status in the management  
13                   of IBD, racial and socioeconomic disparities  
14                   have been identified in osteoporosis screening  
15                   and treatment. Details of these studies and  
16                   their findings are included in the submission  
17                   material.

18                   The AGA, which is in the process  
19                   of conducting a systematic review of this  
20                   issue, thanks the National Quality Forum and  
21                   steering committee for the opportunity to  
22                   present these measure concepts and to



1 participate in the redesign of the endorsement  
2 process. Thank you.

3 CO-CHAIR BASKIN: Thank you for  
4 introducing the measures to us, and for  
5 preparing that. Our presenter is Zahid. Go  
6 for it, impact.

7 MEMBER BUTT: Thank you. Yes,  
8 this measure demonstrates that  
9 gastroenterologists do take care of patients,  
10 not just scope them.

11 (Laughter.)

12 MEMBER BUTT: I do have a couple  
13 of questions for the developers, if I may have  
14 your permission to ask a couple of questions.

15 CO-CHAIR BASKIN: Go ahead.

16 MEMBER BUTT: Okay. So my first  
17 question is that, under the denominator  
18 exclusions, you have a statement at the end  
19 that says "We have been able to include a  
20 patient exclusion, for example if the patient  
21 refuses steroid therapy," but you also exclude  
22 patients who are not on steroid therapy.

1 What's the difference between those two?

2 DR. FALCK-YTTER: Debbie, maybe  
3 you want to answer that, because that was  
4 confusing to me too. But that basically means  
5 -- it's a technical issue, right, Debbie?

6 MS. ROBIN: Yes. This has to do  
7 with the way that we have had to struggle with  
8 the coding when this measure was initially  
9 developed in terms of PQRS, and thinking about  
10 administrative coding. We have since had the  
11 ability, and have been exploring use of this  
12 measure through our recognition program, which  
13 is a registry-based program.

14 The point of that comment was  
15 simply to say that we have been able to better  
16 incorporate exclusions and have some  
17 flexibility around the actual denominators and  
18 the exclusions that we did not have when we  
19 originally developed it in PQRS.

20 CO-CHAIR BASKIN: I mean, we can  
21 talk during the comment section at the end of  
22 these comments whether we think the exclusions

1 are appropriate or inappropriate, but I think  
2 we'll get to that after the review.

3 You had another question, though,  
4 Zahid, for them?

5 MEMBER BUTT: Yes. And one quick  
6 question. I just wanted to make sure that the  
7 denominator statement is just people who are  
8 age 18 and have inflammatory bowel disease,  
9 and the denominator does not include "who have  
10 been on steroids." You include that in the  
11 numerator?

12 MS. ROBIN: Yes, we have -- again,  
13 the way it's currently coded, that is -- for  
14 PQRS and administrative purposes, there's a  
15 separate numerator to identify patients who  
16 are not on that level of corticosteroid  
17 treatment. Again, we had hoped to have some  
18 more flexibility there, but we're limited by  
19 the current coding requirements at the time  
20 the measure was developed and went to PQRS.

21 MEMBER BUTT: Okay. Thank you.  
22 So this is a measure that tries to take

1 patients who are on corticosteroids as defined  
2 by the measure: prednisone 10 milligrams or  
3 equivalent -- and there's a little table that  
4 they have for that -- who have been on this  
5 does for 60 or greater consecutive days and  
6 have been prescribed corticosteroid sparing  
7 therapy, as in immunomodulators, such as  
8 imuran or 6-MP, or the biologics, the anti-TNF  
9 agents.

10 The denominator, as mentioned  
11 earlier, are all adult patients with a  
12 diagnosis of inflammatory bowel disease, both  
13 ulcerative colitis and Crohn's Disease. The  
14 data source is electronic clinic data,  
15 registry data, and the level of analysis is at  
16 the individual physician level. I assume that  
17 claims could also qualify as a data source the  
18 way the numerator is being captured, and  
19 certainly the codes for the denominator would  
20 be there, although it's not specifically  
21 mentioned in the submission.

22 So in terms of its impact, there

1 is a significant body of evidence that's  
2 presented that inflammatory bowel disease is  
3 a fairly common disease that is treated by  
4 gastroenterologists, that 40 percent or so in  
5 one study patients with IBD will require  
6 longer-term steroids, and it is sometimes  
7 difficult to get the doses below the dose  
8 that's considered to be a relatively high  
9 chronic steroid does.

10 And certainly, prolonged steroid  
11 exposure, there is data to suggest that it is  
12 associated with several potential  
13 complications and side effects. There is also  
14 a body of evidence that the steroid sparing  
15 agents, when used, do not have the same level  
16 of problems and complications, and are at  
17 least as, if not more, effective than the  
18 chronic use of steroids.

19 So, based on the evidence that's  
20 presented, it appears that this should be a  
21 high-impact condition in my opinion. I'm  
22 certainly interested in seeing what the others

1 think about it.

2 MEMBER MORTON: I definitely  
3 agree, this is high impact. And I think  
4 there's been a lot of mention about some of  
5 the issues around bone necrosis, but one thing  
6 that should be brought up in terms of a  
7 complication is iatrogenic obesity. There are  
8 so many patients who are on steroids who gain  
9 so much weight, and if they end up seeking  
10 therapy, like say bariatric surgery, it's very  
11 complicating. So I think this measure is  
12 very, very important.

13 MEMBER PELLETIER-CAMERON: This is  
14 more of a question than a comment. Not being  
15 a gastroenterologist, why would someone  
16 prescribe steroids to a patient with this body  
17 of evidence? Is it lack of knowledge, or is  
18 it cost to the patient?

19 MEMBER BUTT: I think that,  
20 generally speaking, not everybody who has  
21 inflammatory bowel disease initially will  
22 require long-term steroids. So steroids often

1 can be used on a short-term basis. You can  
2 get the patient off. Many people don't have  
3 a recurrence.

4 So it is an accepted form of  
5 initial therapy. The issue is really the  
6 chronic use of steroids, and it is that subset  
7 of patients that you can't get them below a  
8 certain dose, or can't get them off of it over  
9 a longer period of time. That's where the  
10 complications come in. So it's generally  
11 reasonably safe in the short term, but the  
12 complications are more problematic on a  
13 long-term basis.

14 CO-CHAIR BASKIN: Liliana, go  
15 ahead.

16 MEMBER BORDEIANOU: Just a  
17 comment. Essentially, it's an issue of  
18 maintenance versus induction of remission.  
19 Steroids are used in an acute setting to  
20 induce remission. They're very effective.  
21 But there are other medicines to then maintain  
22 patients in remission with less complication

1 profile, and physicians focus on the acute and  
2 forget about the follow-up. And that's what  
3 this measure is getting at.

4 MEMBER LIGHTDALE: That's exactly  
5 right, so that's key, but the other thing is  
6 this metric is all about chronic use of  
7 corticosteroids, but it doesn't tackle -- and  
8 I did put it in my comments, and I don't know  
9 if this is the right dramatic moment to bring  
10 it out --

11 (Laughter.)

12 MEMBER LIGHTDALE: -- but it  
13 really doesn't actually balance out with --  
14 okay, so you get them off corticosteroids onto  
15 these immunomodulators, biologics. They come  
16 with a whole host of side effects, a whole  
17 host of other issues.

18 And that's the only trick here, is  
19 going to be, how do you do this in a way that  
20 you emphasize the importance of avoiding  
21 inappropriate chronic use of steroids?  
22 Because not everybody responds to the other



1 agents, so that's another reason you can wind  
2 up on chronic steroids. But anyway, how do  
3 you avoid inappropriate use and not actually  
4 push it to the point that somebody says I  
5 could treat you in my urology practice for  
6 your IBD, and start you right away on 6-MP and  
7 mess things up?

8 MEMBER BUTT: I thought your  
9 dramatic statement was going to be "Why is it  
10 just for adults and not pediatric patients as  
11 well?" Because in them, it's an even more  
12 important issue, in some cases.

13 MEMBER LIGHTDALE: Actually, I  
14 think, honestly, we should be exploring a  
15 little bit whether this should be restricted  
16 to over 18. The same issue is going on right  
17 now in pediatrics, and I'm not sure if that's  
18 coming from the Crohn's and Colitis  
19 Foundation, to keep it to greater than 18, if  
20 it's just my adult GI colleagues who are being  
21 respectful of pediatrics. But I would  
22 encourage us to think about that.

1 CO-CHAIR BASKIN: I think we can  
2 just accept that now as a comment to the  
3 developers, so we don't forget it.

4 MEMBER BUTT: I think her comment  
5 actually is addressed in the body of evidence,  
6 later on. Because they do present some  
7 evidence that the anti-TNF in aggregate have  
8 less side effects than steroids, for whatever  
9 that's worth. And I think there is a long  
10 body of evidence for the immunomodulators,  
11 that in that context, where you have to keep  
12 people on very high doses of steroids on a  
13 long-term basis, that the immunomodulator has  
14 less aggregate harm than chronic high-dose  
15 steroids. I think that would be --

16 CO-CHAIR BASKIN: Let's get the  
17 impact part out of the way, because I think  
18 we're getting into the evidence and the  
19 quality of the evidence.

20 So, specifically around impact,  
21 what I've heard so far is that IBD, fairly  
22 common disease. It's certainly a serious

1 disease. The treatment, chronic steroids,  
2 certainly serious. It has significant side  
3 effects. So, impactful in terms of the  
4 severity of the complications involved, and  
5 that there is alternative, less complicating  
6 treatment. There is alternative therapy which  
7 is preferable, to at least reduce the dose of  
8 steroids or eliminate the steroids when  
9 possible, and there's a sizable number of IBD  
10 patients who are in this situation with  
11 chronic steroids, to cause the impact. So --  
12 if it's directly to impact, Robert, then  
13 please, go ahead.

14 MEMBER ELLIS: Just quickly, can  
15 any of you quantify for me what a fairly  
16 common disease means in the U.S.?

17 MEMBER BUTT: I don't know about  
18 the numbers, but it is probably the second  
19 most common condition that GI treat, after  
20 GERD, right? What would you say the total  
21 numbers would be?

22 MEMBER SCHOENFELD: It's at least

1 a -- the U.S. population is 275 million.

2 CO-CHAIR BASKIN: It's three  
3 hundred and something, but you're close.

4 MEMBER SCHOENFELD: So I know the  
5 estimate is 1 out of 300 people have  
6 inflammatory bowel disease, so we're pretty  
7 close to a million on this, then.

8 CO-CHAIR BASKIN: So it's not just  
9 volume, but it's not a rare disease by any  
10 means. But the impact on those that have the  
11 disease is fairly significant, and that's one  
12 way to measure impact as well.

13 MEMBER LIGHTDALE: This is from  
14 the CDC website: "1.4 million persons in the  
15 United States."

16 CO-CHAIR BASKIN: Any other  
17 comments regarding impact, or we'll go to a  
18 vote on impact? Zahid, mic off when you're  
19 not speaking. And Jenifer as well.

20 So let's go to a vote, then.  
21 High, moderate, low, or insufficient. So  
22 high, voting 1 for high?

1 (Show of hands.)

2 CO-CHAIR BASKIN: Okay. So that's  
3 14, and we only have 14, because Chris had to  
4 leave early. So then, obviously, zero for  
5 moderate, zero for low, and zero for  
6 insufficient evidence for impact.

7 So now, let's move on to the  
8 quality of the evidence involved.

9 MEMBER BUTT: So in the evidence,  
10 they do present several studies, and also  
11 refer to guidelines. In one of the AGA  
12 institute guidelines, there is a grading.  
13 Grade A is assigned to where long-term  
14 treatment of corticosteroids is undesirable  
15 and patients with chronic, active  
16 corticosteroid-dependent disease should be  
17 treated with immunomodulators. There's  
18 another reference to a Crohn's Disease and UC  
19 study for immunomodulators that has been  
20 graded as a C.

21 In terms of the risk profile that  
22 was mentioned earlier, there is moderate to

1 high certainty, in the estimate of the quality  
2 of evidence, that the use of immunomodulators  
3 and/or anti-TNF is effective in inducing and  
4 maintaining remission in IBD to the degree  
5 that patients can successfully taper off the  
6 steroids.

7           And then there is also the overall  
8 body of evidence regarding the use of  
9 immunomodulators for steroid-free or  
10 steroid-taper remission, which includes five  
11 randomized controlled trials that looked at  
12 failure to achieve remission, and two  
13 randomized controlled trials that were aimed  
14 at examining disease relapse. The overall  
15 body of these RCTs was moderate, and there was  
16 no significant risk.

17           Same thing with the anti-TNF. The  
18 overall body of evidence for the use of  
19 anti-TNF agents in inducing and maintaining  
20 remission, allowing for successful taper and  
21 steroid-free treatment is moderate to high.  
22 And as was mentioned in terms of the harm,

1       there is evidence to suggest that there is a  
2       balance between benefits versus harm which  
3       favors the use of these agents compared to  
4       long-term steroid use.

5                       So I would say that, on balance,  
6       the body of evidence would be somewhere  
7       between moderate to high.

8                       CO-CHAIR BASKIN:  Comments from  
9       others?  It does seem like there's actually,  
10      for one of the few times, direct evidence of  
11      actual comparisons and some randomized  
12      controlled studies that specifically speak to  
13      the issue, which is unusual for us to have.  
14      But our gastroenterologists may think  
15      otherwise.

16                      MEMBER LIGHTDALE:  I know more  
17      about IBD than I care to admit.  So the only  
18      issue is -- of course, this is thinking about  
19      an entire global body of evidence, and we're  
20      not really talking about effect size, or also  
21      exactly what the outcome was of each of these  
22      trials.  And many of them were kind of

1 short-term, and didn't look at long-term, that  
2 kind of issue. So they're heterogeneous in  
3 that way.

4 MR. AMIN: Andy, the only question  
5 I have for you and the group is, the moderate  
6 to high is across quantity, quality, and  
7 consistency of the evidence that was  
8 presented?

9 MEMBER BUTT: Yes. Consistency is  
10 high, quality would be moderate, and quantity  
11 I would say is high.

12 CO-CHAIR BASKIN: Any comments to  
13 that classification there?

14 (No response.)

15 CO-CHAIR BASKIN: There seems to  
16 be some comfort with that. Any more  
17 discussion before we vote regarding the  
18 evidence?

19 MEMBER BUTT: I think, just to  
20 address Jenifer's comment, the studies are  
21 short because these are relatively new  
22 therapies. So by definition, we don't have



1 long-term data. In the immunomodulator  
2 population, we do have long-term data, but the  
3 biologics are relatively new.

4 CO-CHAIR BASKIN: Yes. I actually  
5 was interested in that some of the data, while  
6 it would seem fairly recent, because it goes  
7 up to 2005-2006, in the world of treatment for  
8 IBD, when these treatments are -- the curve is  
9 pretty steep in terms of the utilization of  
10 these things. Is this even valid today, five  
11 or six years later? I'm not so sure the  
12 performance gap exists the same way as it  
13 does. But we haven't gotten there yet. I  
14 just don't know that the problem is the same  
15 problem anymore.

16 MEMBER LIGHTDALE: To comment to  
17 that, the one drug we've had around for a very  
18 long time is steroids, which is why it's cheap  
19 and there's so much data on it. And frankly,  
20 everybody's starting to look now at the  
21 adverse outcomes, as opposed to "Thankfully,  
22 there was a drug to help with IBD." And so

1 the bottom line is you don't want people  
2 practicing old-school IBD care and leaving  
3 somebody on steroids for a long time.

4 CO-CHAIR BASKIN: So, let's bring  
5 this to a vote. Our options are 1, 2, or 3.  
6 1, yes, the body of evidence meets our  
7 criteria, 2, it does not and it does not  
8 exist, 3, insufficient submitted, but the body  
9 of evidence is out there somewhere.

10 So, those voting 1, please raise  
11 their hands.

12 (Show of hands.)

13 CO-CHAIR BASKIN: And that appears  
14 to be unanimous. Is that a 14 count? Okay,  
15 which obviously means no one's voting 2 and no  
16 one's voting for 3.

17 Okay. Let's move on, then, to the  
18 performance gap.

19 MEMBER BUTT: So in terms of the  
20 performance gap, in the opportunity for  
21 improvement section there is some information  
22 that's provided. There is a study that shows

1 that -- it's a relatively small study, that  
2 does show that there is a performance gap. It  
3 appears that there isn't a lot of studies that  
4 were presented in this proposal that show or  
5 say a performance gap exists based on the  
6 presented information.

7 But I think, in my sort of own  
8 small sample of 15 gastroenterologists in one  
9 practice, I can tell you from experience that  
10 there is a significant variation in the care  
11 that's delivered. And I don't know if that  
12 qualifies for this type of evidence, but I  
13 don't know if there is any additional studies  
14 or data that could be presented that show a  
15 performance gap exists. But my guess is that  
16 it does exist.

17 CO-CHAIR BASKIN: John, you wanted  
18 to comment?

19 MEMBER MORTON: I would say,  
20 having looked at some of these measures  
21 through yesterday and today, I think these  
22 guys did a very good job in documenting the

1 performance gap. I think they were the only  
2 ones who actually addressed disparities, for  
3 that matter. So I think they did an excellent  
4 job in assessing this, and indicating there  
5 was a performance gap.

6 CO-CHAIR BASKIN: It doesn't seem  
7 like there's a volume of evidence regarding  
8 performance. Am I missing something?

9 MEMBER MORTON: I'm going by the  
10 disparities, more than anything else.

11 MEMBER BUTT: There's more data on  
12 the disparities section, yes.

13 CO-CHAIR BASKIN: Jenifer, did you  
14 have a comment, or your thing is just up?  
15 Your card's still up, just because it's still  
16 up. Okay.

17 Any other comments regarding  
18 performance gap?

19 (No response.)

20 CO-CHAIR BASKIN: So I guess what  
21 I'm hearing is that --

22 MEMBER BUTT: It's probably

1 moderate, I would say.

2 CO-CHAIR BASKIN: Yes. One could  
3 say that if there's data in the disparities  
4 section that there's a significant performance  
5 gap -- I mean, that in and of itself may show  
6 moderate to high performance gap, whether it's  
7 in the general population or not.

8 MEMBER MORTON: Well, I think the  
9 performance gap is particularly specific to  
10 racial disparities, because some of these  
11 drugs aren't routinely available to patients  
12 with lower socioeconomic status, because they  
13 are of higher cost, and there's a lot of drug  
14 decision panels about who should get them. So  
15 I think the gap is really prevalent there.

16 CO-CHAIR BASKIN: Unless there's  
17 other comment, then I think we can come to a  
18 vote on performance gap. Once again, four  
19 choices: high, moderate, low and insufficient  
20 evidence.

21 So, let's vote. 1, high. How  
22 many vote for high?

1 (No hands.)

2 CO-CHAIR BASKIN: And actually no  
3 votes for high. So how many voting for 2,  
4 moderate?

5 (Show of hands.)

6 CO-CHAIR BASKIN: And I think we  
7 have 13. Thirteen for moderate. How many  
8 voting for low?

9 (Show of hands.)

10 CO-CHAIR BASKIN: We have one vote  
11 for low. And I presume, then, there's no  
12 votes for insufficient, since that adds up to  
13 14. Okay, so we made it through the  
14 performance gap. Now, I guess, we move on to  
15 recommending this concept.

16 Any particular comments somebody  
17 wants to make regarding this? Okay, Liliana,  
18 you go first, then.

19 MEMBER BORDEIANOU: I'm sorry,  
20 it's the surgeon speaking, but one of the  
21 corticosteroid sparing therapies is a consult  
22 with a surgeon, because that's another

1 treatment in getting people off steroids. So  
2 maybe that could be included under the  
3 exclusions.

4 I'm saying that the list, they're  
5 measuring who was prescribed anti-TNFs,  
6 methotrexate, et cetera. But the other thing  
7 that might have happened is that the patient  
8 was referred to a surgeon for discussion about  
9 surgery, and I don't know if they're capturing  
10 that. I guess that goes more to how it's  
11 being measured than whether or not it should  
12 be approved or not, so we could discuss more  
13 in the second phase.

14 CO-CHAIR BASKIN: Go ahead, John.

15 MEMBER MORTON: I think that's an  
16 excellent point. That's actually one of the  
17 indications to do a total abdominal colectomy.  
18 So it's probably more meant for feedback for  
19 the developer, but I think it's a terrific  
20 point.

21 CO-CHAIR BASKIN: I still have a  
22 struggle with this numerator and denominator.

1 I guess maybe I'm misunderstanding here,  
2 because it seems to me that the denominator is  
3 all patients with IBD, treatment or no  
4 treatment. And the numerator, to get a hit in  
5 the numerator, you have to be on long-term  
6 steroids and be on a sparing agent -- which is  
7 a good thing -- but what about the people who  
8 are on an anti-TNF factor who aren't on  
9 steroids at all? You don't get credit for  
10 that as being a good thing? I guess I don't  
11 understand how this differentiates good and  
12 bad care.

13 MEMBER BUTT: I was saving some of  
14 that commentary for last, but I wasn't sure  
15 where to plug that in. And that was my  
16 original question. Really, for this measure  
17 to be really effective, the denominator should  
18 have been patients who are with IBD and have  
19 been on chronic steroids. And of that  
20 percentage, what percentage were then  
21 prescribed anti-TNF therapy? Because I think  
22 the hole in this measure is that it misses



1 those that are on steroids and were not  
2 prescribed anti-TNF therapy.

3 So in other words, if you look at  
4 your pie of your denominator as all IBD  
5 patients, and you take another circle the  
6 patients who are on steroids, this takes a  
7 slice of that, those that were prescribed  
8 anti-TNF therapy, but then it takes that as a  
9 numerator and assigns it to the IBD as a  
10 denominator, and it kind of loses some of its  
11 fidelity there.

12 CO-CHAIR BASKIN: Jenifer?

13 MEMBER LIGHTDALE: I actually  
14 struggled with this with the next one, as I  
15 was trying to understand it. I think the  
16 reason that they wrote it this way -- and it's  
17 not well-written -- is because of these CPT II  
18 codes that they're using.

19 And so basically what they said  
20 happens, because they're only assigning this  
21 -- and I think this is what the person before  
22 was trying to explain. But because they're

1       only assigning that -- I think, and you guys  
2       can tell me if I'm wrong -- they're only  
3       assigning CPT II codes to somebody who's 18  
4       years or older with a diagnosis of IBD and  
5       who's on steroids, and that's essentially your  
6       denominator. Like, they've sort of  
7       artificially written it in a way that reflects  
8       their coding.

9                       CO-CHAIR BASKIN: If that's the  
10       denominator, then the description should be  
11       that that's the denominator. So maybe we can  
12       ask the developers.

13                      MEMBER LIGHTDALE: Can I follow  
14       myself up with one quick thing?

15                      CO-CHAIR BASKIN: Please.

16                      MEMBER LIGHTDALE: A simpler  
17       question is whether it's simply patients with  
18       IBD who are managed with corticosteroids for  
19       greater than 60 days over all patients with  
20       IBD. I mean, that's all -- never mind the  
21       steroid sparing agent. That's how you get  
22       them off the steroids. You just don't want

1       them on steroids forever, so why not just make  
2       it about being on steroids for greater than 60  
3       days over IBD?

4                   MEMBER BUTT:   Can I make a  
5       comment?   So I think this was the limitation  
6       of -- you're probably correct -- the CPT II.  
7       Because what you'd have to do then, is you'd  
8       have to assign a CPT II code to all of your  
9       denominator cases that have IBD and are on  
10      steroids, and are on steroids greater than 60  
11     days.   So you would have had to assign a lot  
12     more CPT IIs.   So they tried to sort of reduce  
13     the burden, but within that process, I think  
14     it lost some of its value.

15                   CO-CHAIR BASKIN:   Well, I'm going  
16     to ask the developer here to jump in again,  
17     because I'm still confused as to who's in the  
18     denominator and who's counted as a numerator  
19     hit, meaning a positive hit, like you did the  
20     right thing and you get credit for it.

21                   So explain once again the  
22     population of the denominator.   Is it -- it

1 says here just "those over 18 with a diagnosis  
2 of inflammatory bowel disease." Is that the  
3 true denominator, anybody with inflammatory  
4 bowel disease over 18?

5 MEMBER BUTT: I think they said  
6 yes when I asked that question.

7 CO-CHAIR BASKIN: Folks, are you  
8 out there?

9 MS. ROBIN: This is Debbie Robin  
10 again. I will address this as succinctly as  
11 I can. The denominator for purposes of PQRS  
12 is defined by diagnosis and service codes.  
13 There is no combination of those elements  
14 currently available that identifies patients  
15 with IBD who are on chronic corticosteroid  
16 treatment. Therefore, what we had to work  
17 with was to use existing codes that allowed us  
18 to identify all IBD patients.

19 Then, for the various measures or  
20 calculations, we then developed various CPT II  
21 codes. There is a specific code that  
22 identifies patients who are not on long-term

1 corticosteroid therapy. So from a performance  
2 perspective, there's a way to calculate it so  
3 that those patients are taken out of the  
4 equation.

5 To allow people to report this  
6 measure, we had to sort of be able to find a  
7 way to allow them to report it in that manner  
8 with the limitations of the diagnosis codes.  
9 Having said that, in an ideal world with  
10 electronic specifications, which we do plan to  
11 get to in the future, is that yes, we would  
12 create the ability to pull out just those  
13 patients who are currently being treated with  
14 long-term corticosteroid therapies, and that  
15 would be the denominator.

16 CO-CHAIR BASKIN: But essentially  
17 that's what you've done, then. You've just  
18 done it by saying "Take all the inflammatory  
19 bowel disease members. Those with the CPT  
20 code that says they're not on chronic steroids  
21 are excluded, so theoretically what remains is  
22 those that are on chronic steroid therapy. Is

1 that essentially what you've done?

2 MEMBER BUTT: No. I think the way  
3 she explained it is that you have to use two  
4 separate CPT II codes in the numerator. One  
5 would capture the ones that are on chronic  
6 steroids and receive the steroid sparing. The  
7 other would be the ones who are only on  
8 chronic, and you would have to take the two  
9 rates together to come up with the answer to  
10 the single question that we were asking  
11 originally.

12 MS. ROBIN: Yes, that is correct.

13 MEMBER BUTT: But they also say  
14 that, in the electronic specification, the  
15 denominator definition will change.

16 CO-CHAIR BASKIN: Were you going  
17 to say something?

18 MEMBER BUTT: Is that correct?

19 MS. ROBIN: That's correct.

20 DR. BRILL: Yes, that's correct,  
21 Andy.

22 CO-CHAIR BASKIN: When we go to

1 feasibility in the next level we'll see, but  
2 if it says what it's measuring I'm okay with  
3 it. I'm just not so sure it is. But I think  
4 you have found a way to do it, so I'll let it  
5 rest.

6 MEMBER BUTT: Can I make one final  
7 comment, then? Potentially, as long as this  
8 remains a measure and it is not replaced by  
9 the electronic measure, perhaps it should be  
10 a paired measure, where you include the other  
11 one as well?

12 CO-CHAIR BASKIN: Well, let's  
13 first vote on approving this concept to move  
14 along or not, and then any comments to the  
15 developers can make.

16 So, any other discussion before we  
17 come to a vote on this?

18 (No response.)

19 CO-CHAIR BASKIN: Okay. Let's  
20 come to a vote, then. Those saying yes,  
21 recommend approval of the concept?

22 (Show of hands.)

1 CO-CHAIR BASKIN: That appears to  
2 be unanimous. I'm guessing that's 14 people.  
3 So that means zero noes, okay.

4 So, any additional comments for  
5 the developer?

6 MEMBER BUTT: So, that was the  
7 comment that it should, perhaps, be considered  
8 as a paired measure with the other one, with  
9 the second CPT II, as long as this will remain  
10 in circulation.

11 MS. WILBON: Are you talking about  
12 the measure that we're getting ready to  
13 discuss next?

14 MEMBER BUTT: No. What I'm saying  
15 is that there is a CPT II code related to this  
16 that captures the patients who are on chronic  
17 steroids, but have not received anti-TNF  
18 therapy. That percentage calculation, in  
19 combination with this, would give us the  
20 answer of what percentage of patients on  
21 chronic steroids were put on anti-TNF or  
22 immunomodulative therapy.



1 I hope I'm not confusing people.

2 CO-CHAIR BASKIN: So I think the  
3 comment is basically to the extent that the  
4 CPT codes can help in measuring this in a  
5 simpler way, that that would be advantageous  
6 for all.

7 Okay. Any other comments for the  
8 developers before we move on to the next  
9 measure?

10 MR. AMIN: I guess the only  
11 question I have, Andy, is it sounds like there  
12 are some questions here related to the  
13 construction of the measure.

14 CO-CHAIR BASKIN: Right.

15 MR. AMIN: And to the extent that  
16 we can be as specific as possible on what you  
17 would expect to see when this measure comes  
18 back in Stage 2, if there are some changes  
19 related to the construction of the measure,  
20 the more specific we can be there, the better.

21 CO-CHAIR BASKIN: Well, my comment  
22 is simply that when you look at the

1 denominator statement, it says "all patients  
2 with inflammatory bowel disease." And if you  
3 have, in fact, excluded a large group of  
4 patients with inflammatory bowel disease, and  
5 it's a significant exclusion, then the  
6 denominator statement's really not accurate.  
7 It's really not all patients with inflammatory  
8 bowel disease.

9           If there are so many exclusions,  
10 that should be part of the denominator  
11 statement, so it's very clear who is left in  
12 the denominator. That's my only point, is  
13 that when there are exclusions that exclude 2  
14 percent of the patients, they can be  
15 exclusions. But if it's an exclusion that  
16 excludes a large percentage of the  
17 inflammatory bowel disease patients, then it's  
18 part of the denominator statement, to me, in  
19 terms of a reader who's trying to understand  
20 what a measure says.

21           MEMBER BUTT: But what exclusions  
22 are you referring to?

1 CO-CHAIR BASKIN: There's an  
2 exclusion here that says "Because of the use  
3 of clinical data, those that have not received  
4 a dose of corticosteroids greater than or  
5 equal to [...] are excluded from the  
6 denominator." It seems to me that that's a  
7 large patient population. If they're  
8 excluded, they're excluded.

9 MEMBER BUTT: But in the ideal  
10 world, the patients that they are looking for  
11 in the denominator are those that have IBD and  
12 are on chronic steroid therapy. So by  
13 definition, those who are not on chronic  
14 steroid therapy would be excluded.

15 CO-CHAIR BASKIN: Right. And if  
16 that's a large group of people, then that  
17 should be reflected in the description of the  
18 denominator. Don't call the denominator "all  
19 patients with IBD" when 25 percent of the  
20 people with IBD, or 50 percent of them, aren't  
21 included in the denominator. Call it what it  
22 is.

1                   MEMBER BUTT: I see. That's  
2 really what that whole discussion was about --

3                   CO-CHAIR BASKIN: Yes, I  
4 understand

5                   MEMBER BUTT: -- that in the ideal  
6 case, the denominator statement should be  
7 different. It should include "and those who  
8 have been on chronic steroids."

9                   CO-CHAIR BASKIN: Yes. So we're  
10 just saying it in two different ways.

11                   MEMBER BUTT: Right. It is the  
12 constraints that they have, so they have to go  
13 with the CPT II code within the numerator.

14                   CO-CHAIR BASKIN: That's an  
15 implementation issue. The description of the  
16 denominator is not how you got there, it's  
17 what is -- a reasonable person looking at this  
18 is going to look at a numerator and a  
19 denominator, and they should reasonably be  
20 able to tell what we're measuring. And I'm  
21 having trouble telling that from this  
22 description.

1 MEMBER BUTT: Right.

2 CO-CHAIR BASKIN: How they got  
3 there is all in the behind-the-scenes stuff.

4 MEMBER BUTT: Right.

5 CO-CHAIR BASKIN: John, did you  
6 want to make a comment?

7 MEMBER MORTON: I was just going  
8 to say if the question is how many patients  
9 out there are diagnosed who don't get therapy,  
10 I think that's probably a pretty low number.  
11 And I mean, my GI colleagues can comment on  
12 that, but I would think that would be a pretty  
13 low number.

14 CO-CHAIR BASKIN: Yes, but I was  
15 speaking to the exclusion group is the folks  
16 that are theoretically not receiving chronic  
17 steroid therapy. That actually may be a  
18 sizable number. I'm not talking about people  
19 who aren't treated at all. The exclusion is  
20 for people who are not being treated with  
21 chronic steroids. That could be a decent  
22 group of people.

1                   MEMBER BUTT: But I think the key  
2 group that you want to get at is the ones who  
3 are on chronic steroid therapy but did not get  
4 anti-TNF. And this measure construct does not  
5 allow you to do that. The only way to do that  
6 in the current CPT II framework is to assign  
7 the second CPT code, which says that this  
8 patient did not meet this criterion of having  
9 transitioned to it, but out of the IBD  
10 patients, they were on chronic steroid  
11 therapy.

12                   So that's the second CPT, and  
13 that's where my recommendation was, that as  
14 long as this is going to stay, that maybe they  
15 should include the other one as a paired  
16 measure, so that the two of them combined, one  
17 will tell you the percentage of people who  
18 were on chronic steroid therapy but did not  
19 get anti-TNF. This one would tell you the  
20 percentage of IBD patients who were on chronic  
21 steroid therapy and received the anti-TNF.

22                   CO-CHAIR BASKIN: Okay. We need

1 to pull this one to a close, because we've  
2 really fallen behind. So if you've got 15  
3 second comments, you can make them.

4 MEMBER LIGHTDALE: The 15 second  
5 comment is, I guess the only thing I'd be  
6 advising is, first off, generalize it,  
7 simplify it. And really, the goal here is  
8 steroid sparing. I think that has to be key.  
9 And that gets to your surgery discussion, too.  
10 This isn't just driving people to another  
11 drug, this is get them off steroids.

12 CO-CHAIR BASKIN: Right. And  
13 Liliana, 15 seconds or less.

14 MEMBER BORDEIANOU: Right. The  
15 feasibility discussion in the next phase  
16 should include how they propose to measure  
17 patients that refuse treatment. How are they  
18 going to do that?

19 CO-CHAIR BASKIN: Okay. So thank  
20 you, and I guess I'm surprised that took as  
21 long as it took. I wasn't watching the time  
22 as well as I should have, so I apologize.

1                   So let's move on to the next  
2                   measure, which is the bone loss assessment.  
3                   And Jenifer, you're going to present this one?

4                   MEMBER LIGHTDALE: Yes. I'll try  
5                   to avoid redundancy.

6                   So this was, again, a process  
7                   measure, and it does again involve these CPT  
8                   II codes. So the numerator is patients with  
9                   IBD who have received corticosteroids at least  
10                  at a threshold does of ten mgs per day for 60  
11                  consecutive days who have been assessed for  
12                  bone loss -- again, all up there in the  
13                  numerator. And the denominator is all  
14                  patients with IBD. The level of analysis is  
15                  a the clinician level.

16                  And in terms of the high impact,  
17                  the bottom line is both IBD and,  
18                  independently, corticosteroid use are  
19                  associated with osteopenia. And if you put  
20                  the two things together, there's clearly an  
21                  association with the relative risk of hip  
22                  fracture going up in patients who have IBD and



1 are on corticosteroids.

2 And basically for their evidence,  
3 they had two population-based studies. One is  
4 from the U.K., from 2004 --

5 CO-CHAIR BASKIN: Let's just get  
6 to the impact.

7 MEMBER LIGHTDALE: Oh, this is  
8 impact. Sorry.

9 So for their impact, the evidence  
10 that they were citing was two population-based  
11 studies. And again, for me, they were just  
12 older studies, and neither one was in the U.S.  
13 So U.K., 2004, and one in Canada in 2003.

14 CO-CHAIR BASKIN: In terms of the  
15 quality of the studies regarding impact, U.K.  
16 and Canada, that's perhaps acceptable to us.  
17 But did it show a reasonable impact?

18 MEMBER LIGHTDALE: Again, both  
19 studies show that there's an independent risk  
20 of IBD for hip fracture and for corticosteroid  
21 use and hip fracture. And corticosteroid use  
22 plus IBD does increase your relative risk a

1 bit.

2 CO-CHAIR BASKIN: Comments  
3 regarding impact?

4 (No response.)

5 CO-CHAIR BASKIN: Then let's go --  
6 would you have characterized this measure as  
7 high, moderate, or low, in your opinion?

8 MEMBER LIGHTDALE: In my opinion,  
9 it was moderate.

10 CO-CHAIR BASKIN: Then we'll each  
11 vote what's in our hearts.

12 So we're voting now: 1, 2, 3, or  
13 4. 1 is high impact. Raise your hands.

14 (No hands.)

15 CO-CHAIR BASKIN: Zero. 2 is  
16 moderate impact. Raise your hands.

17 (Show of hands.)

18 CO-CHAIR BASKIN: And that appears  
19 to be everyone if I counted correctly. Any  
20 low impacts or insufficients?

21 (No hands.)

22 CO-CHAIR BASKIN: I didn't think

1 so. I thought we had 14 there. Okay, so 14  
2 moderate and no high, low, or insufficient.  
3 So now we're going to the evidence quantity,  
4 quality, and consistency.

5 MEMBER LIGHTDALE: So for this,  
6 basically there were two evidence-based  
7 guidelines that were cited. One was developed  
8 by the AGA in 2006, and then there's also a  
9 guideline that was developed by the American  
10 College of Rheumatology in 2010, and both  
11 spelled out recommendations for prevention,  
12 identification, and treatment of  
13 corticosteroid-related osteoporosis.  
14 Obviously, the AGA one was specifically  
15 looking at inflammatory bowel disease.

16 And basically, the AGA guideline  
17 graded their evidence as an A, suggesting it  
18 was consistent, well-designed. Again,  
19 probably population-based cohort studies with  
20 sufficient power. What was a little  
21 intriguing was the ACR guideline used the  
22 American College of Cardiology grading system,

1 and they gave themselves a C, which is  
2 indicative of consensus, or expert opinion.

3 So the newer guideline, which is  
4 the ACR guideline, is a consensus opinion  
5 statement, although it agrees with the AGA  
6 one.

7 CO-CHAIR BASKIN: Were the AGA  
8 guidelines specific to IBD patients? Because  
9 I think the ACR guideline was not necessarily  
10 specific to IBD patients, but just those who  
11 were on chronic steroid therapy for whatever  
12 reason, presumably a rheumatologic reason, but  
13 nevertheless for whatever reason.

14 MEMBER LIGHTDALE: Full disclosure  
15 is, I read what was here. I did not read the  
16 AGA guideline. But I do know there are other  
17 GI conditions you can treat with long-term  
18 steroids, like chronic pancreatitis. There  
19 are some others. Autoimmune pancreatitis. So  
20 anyway, all by way of saying I think it was  
21 mostly focused on IBD.

22 MEMBER BORDEIANOU: My only

1 question, and I don't know the answer to that,  
2 is we're looking at whether bone loss  
3 assessment, i.e. getting a DEXA scan, changes  
4 outcomes. And I don't see anything here that  
5 suggests that doing the test does anything  
6 other than provides you the information that  
7 you have osteoporosis, which you could infer  
8 if somebody was on steroids for three months.

9 CO-CHAIR BASKIN: So this is one  
10 of those "Is what they're looking for  
11 proximate or distal to what we're really  
12 looking for," which is treatment, or  
13 appropriate treatment based on information.

14 Are there comments?

15 (No response.)

16 CO-CHAIR BASKIN: I don't know  
17 whether that's because this was easier to  
18 measure, and the other would be much more  
19 difficult to measure -- because, frankly, it  
20 probably would be much more difficult to  
21 measure, because it's not just treatment,  
22 there's treatment options, and some of those

1 treatment options are potentially  
2 non-prescription, and some of those treatment  
3 options the patient may have potentially  
4 chosen not to take, for various reasons.

5 I guess it gets a little  
6 complicated. That's not to say it shouldn't  
7 be done.

8 MEMBER LIGHTDALE: I guess my  
9 opinion is probably the ACR was a little bit  
10 more careful about being honest that a lot of  
11 what they were saying is common sense, and  
12 it's consensus as opposed to evidence-based,  
13 and that's why you don't have the studies.

14 MR. AMIN: Just a few follow-up  
15 questions. Particularly on the quality,  
16 quantity, and consistency, just what your  
17 opinion is in terms of what's in here. And  
18 also, just keep in mind that consensus-based  
19 guidelines would not meet the requirement  
20 here, so we could have a discussion around the  
21 exception.

22 CO-CHAIR BASKIN: You or anyone,

1 so let's just say quantity. Is there a  
2 quantity of evidence here, evidence that we  
3 would accept, evidence-based studies, to  
4 support this testing be performed?

5 (No response.)

6 CO-CHAIR BASKIN: And I think he  
7 said, at least, that the AGA is, I believe, an  
8 evidence-based guideline, that there's  
9 certainly a reason to treat these folks, and  
10 one could, of course, infer that you can't  
11 treat if you didn't test them first. But  
12 that's a different level here.

13 Is there some sense that that's a  
14 lot of evidence, or does anybody really know  
15 who's here?

16 MR. AMIN: Well, before we get  
17 there, I guess one of the questions here  
18 procedurally is that the information that they  
19 presented here in the form is very clear in  
20 terms of where you would want to vote. So if  
21 you want to have a discussion after this vote  
22 around what evidence exists, that would be

1 fine, but it seems pretty clear what  
2 information is presented in the form.

3 CO-CHAIR BASKIN: Well, I'm not  
4 sure it's so clear. Because the AGA statement  
5 is theoretically an evidence-based guideline,  
6 as opposed to the ACR which they're admitting  
7 is a consensus-based guideline. So it's not  
8 so clear to me that there's not evidence here  
9 that is acceptable to us. Whether it's low,  
10 moderate or high is, I think, my question.

11 MEMBER LIGHTDALE: Actually, it  
12 was very helpful to have this slide up. So I  
13 think there are two good population-based  
14 studies upon which the AGA guideline really  
15 comes out of, and that would then really  
16 qualify it as moderate for quantity. Low  
17 moderate, but moderate.

18 CO-CHAIR BASKIN: So there is at  
19 least one thought that there is a moderate  
20 amount in terms of quantity. So when we talk  
21 about the quality of the evidence, that  
22 moderate amount of evidence, those two



1 studies, randomly controlled studies?

2 Non-randomly controlled studies? Where would  
3 you fit those into this construct?

4 I mean, if anyone else knows,  
5 please, feel free. I'm not trying to pick on  
6 Jenifer in any way.

7 Stuart?

8 MEMBER REYNOLDS: Well, I think it  
9 seems fairly insufficient. I mean, it's  
10 alluded to in the evidence at the end of the  
11 document, but it's not explicitly stated. And  
12 so I think I would be comfortable saying it's  
13 probably insufficient to evaluate. I mean, it  
14 may be that there's data out there that we're  
15 not presented with. We may choose to move  
16 forward with it even without that data. But  
17 if we can't answer these questions, I would  
18 say insufficient.

19 CO-CHAIR BASKIN: Fair statement.  
20 Thank you. And John?

21 MEMBER MORTON: I agree with  
22 Jenifer and Stu. This seems a lot lighter in

1 terms of evidence than what we've seen in the  
2 other measure.

3 CO-CHAIR BASKIN: Okay. Any other  
4 comments? And obviously, if there's  
5 potentially an insufficient or small amount of  
6 evidence, consistency doesn't really come into  
7 play. It's hard to be consistent when you're  
8 only talking about two potential trials.

9 Okay. So based upon what I'm  
10 hearing here, I think we can come to a vote  
11 regarding the evidence that's submitted here.  
12 Yes, body of evidence meets our criteria. 2,  
13 the evidence doesn't meet the quantity and  
14 quality and we don't think it necessarily  
15 exists. I think that's going to be a little  
16 tricky as to whether that's going to be the  
17 case or number 3, insufficient but we think  
18 the evidence is out there.

19 So, think about that for two  
20 seconds, and then we'll come to a vote, unless  
21 there's any comment that wants to help people  
22 who are on the fence, if they're on the fence

1 between 2 and 3, if anyone wants to make a  
2 comment in support one way or the other.

3 (No response.)

4 CO-CHAIR BASKIN: I'm not so sure  
5 I heard that there is a body of evidence that  
6 I can point to out there that exists.

7 MEMBER LIGHTDALE: What I will be  
8 fair about is, I don't think any of us are  
9 IBD-ologists. Is that correct? So it's  
10 possible.

11 CO-CHAIR BASKIN: All right.  
12 Let's come to our vote, then. A 1 is yes, the  
13 body of evidence meets our guidance. Raise  
14 your hands.

15 (Show of hands.)

16 CO-CHAIR BASKIN: We have one vote  
17 for yes. That's all right. We won't state  
18 who made that vote.

19 2, the evidence does not meet the  
20 guidance, and we're not necessarily aware that  
21 any evidence exists.

22 (Show of hands.)

1 CO-CHAIR BASKIN: I think that's  
2 five votes. And then 3, insufficient evidence  
3 submitted, but we think that body of evidence  
4 does exist.

5 (Show of hands.)

6 CO-CHAIR BASKIN: Eight. That  
7 comes out to 14, right? So 1 yes, 5 noes, and  
8 8 insufficient but the evidence does exist.

9 MR. AMIN: Insufficient  
10 information presented in the form, so the  
11 question here is, is there general agreement  
12 that the information does exist but it just  
13 wasn't presented in the form, and would that  
14 body then meet the quality, quantity, and  
15 consistency? And if there isn't general  
16 agreement, that you can't make this decision  
17 at this point, because there's insufficient  
18 information, then you would just --

19 CO-CHAIR BASKIN: Now, wait a  
20 minute. I thought the vote went with number  
21 3, that that evidence does exist. I thought  
22 this vote only goes if you vote no, which was

1 the second option, which means that it wasn't  
2 presented and we didn't know it existed.

3 MR. AMIN: So let me go back. Can  
4 you go back one second to this? So, maybe I  
5 should have clarified this before we voted.  
6 If there's a need for a revote, I'm happy to  
7 do it.

8 So, 1 is that it meets. Second is  
9 that the evidence does not meet, or that  
10 there's no empirical evidence that exists.  
11 Third is that there's insufficient information  
12 in the form to rate the quality, quantity and  
13 consistency, but there is information that  
14 exists out there.

15 So what you do with number 3 is  
16 that the information -- since it's  
17 insufficient in the form, we ask the committee  
18 whether or not there's information that they  
19 believe, that there's a body of evidence. And  
20 number 2 would be -- just for the sake of  
21 completion -- number 2 would be that there's  
22 not information that exists, there's not

1 evidence, but we're going to make an exception  
2 here because the benefits outweigh the harms.

3 So the question here for the group  
4 is, is there evidence that you know of that  
5 would meet the quality, quantity and  
6 consistency? And if not --

7 CO-CHAIR BASKIN: Okay. So we had  
8 eight votes that people thought that that  
9 information existed. Now the question is,  
10 that information existing, if it had been  
11 submitted, would it have met our criteria?  
12 But even those that voted 1 or 2 can still  
13 vote on this one. It's not just the 8 votes.

14 But a comment first, before we  
15 vote, because this is a little trickier vote.

16 MEMBER REYNOLDS: Well, I guess  
17 the issue that was driving my vote is that,  
18 for example, we have two guidelines listed  
19 here, and at least one of them is based on  
20 evidence, but that evidence is not clearly  
21 presented. So it would then lead me to think  
22 that that evidence is out there.

1 I admittedly am not familiar with  
2 that evidence. I'm not sure I can, without  
3 further discussion, vote one way or the other.  
4 But it certainly seems like there's a hint  
5 that there's data out there, but we haven't  
6 been presented with it.

7 MR. AMIN: Again, there's a pretty  
8 high bar here, just like the exception rule.  
9 So the sense would be that the committee would  
10 need to put forward that evidence that does  
11 exist. And if it doesn't, or it's  
12 insufficient at this point, then you would  
13 vote no here, that there's not general  
14 agreement that it would meet -- it's  
15 insufficient, I guess, in this sense.

16 CO-CHAIR BASKIN: So if you have  
17 comfort that you're aware of that information,  
18 or comfort that you've accepted others are  
19 aware of it, that's fine. You can vote yes  
20 here. And if you don't have that comfort  
21 level that it exists, or those here that say  
22 it exists you're not comfortable that it's

1 sufficient enough for you, then you would vote  
2 no here.

3 And the result of this, though,  
4 would drive us to do what? If we were to vote  
5 yes here, then --

6 MR. AMIN: Then you would move on  
7 to gap.

8 CO-CHAIR BASKIN: Okay.

9 MR. AMIN: If you vote no here,  
10 then the concept stops.

11 CO-CHAIR BASKIN: The concept  
12 stops. Okay. So, let's take it to a vote.  
13 Those voting yes, raise their hands. A vote  
14 of yes would mean that this could go on to  
15 further evaluation.

16 (No hands.)

17 CO-CHAIR BASKIN: There are no  
18 yeses. And those voting no?

19 (Show of hands.)

20 CO-CHAIR BASKIN: Which is  
21 unanimous, it appears to be, so that must be  
22 14 of us.



1                   So we're voting no, that there's  
2                   insufficient evidence provided, and that this  
3                   committee is not comfortable that a body of  
4                   evidence exists that would meet our criteria.  
5                   So then, we stop here.

6                   I think, however, in this  
7                   particular case, there may be some comments  
8                   for the developers here, especially if -- and  
9                   I would say, just off the bat, that if the  
10                  evidence does exist, this committee would have  
11                  welcomed it, and just that the expertise in  
12                  this room is not aware of that body of  
13                  evidence.

14                  But other comments, please.

15                  DR. FALCK-YTTER:    Would you like a  
16                  comment on that?  This is Yngve Falck-Ytter.

17                  CO-CHAIR BASKIN:  You know,  
18                  actually, that's okay.  I think we would like  
19                  to hear it, as long as the comments are short.

20                  DR. FALCK-YTTER:  I'll make it  
21                  very quick.  Of course, for full disclosure,  
22                  I'm a co-developer for the grade system.  And

1 when we make recommendations and these kinds  
2 of things, there's a few things to consider.  
3 One is, we are not talking about that people  
4 who treat IBD patients should sent off  
5 patients to DEXA scanning all the time.

6 It's more about the awareness to  
7 actually think about those problems, to have  
8 a problem list, and to say "we have thought  
9 about and we have assessed that patient," and  
10 that it goes into their chart. So it's a very  
11 low-effort kind of thing, where people just  
12 have to do it.

13 Now, in terms of how you support  
14 this with evidence, it's very clear that this  
15 is almost like a good practice point, where  
16 you have a beneficial effect in the absence of  
17 harm. There's no harm in assessing bone loss.  
18 The harm starts when you think that you might  
19 actually order a DEXA scan or something like  
20 that. So this is only the assessment portion.  
21 Every time we have no-harm recommendations,  
22 even if the evidence quality is low, you can

1 still make it a point, make it a performance  
2 measure, in my opinion.

3 But again, these are situations  
4 where you have a little bit different way of  
5 looking at the quality of the evidence, where  
6 you have clearly no direct -- there's no  
7 randomized trials that looked at this  
8 assessment and see whether they have  
9 patient-reported outcomes that are improved.  
10 It's just my two cents. I'm sorry to keep  
11 you.

12 CO-CHAIR BASKIN: Thank you for  
13 that. Further comments from the group here?  
14 Go ahead, Zahid.

15 MEMBER BUTT: Would that fall in  
16 the -- and I hate to use that word --  
17 exception category, then, based on what we've  
18 heard?

19 CO-CHAIR BASKIN: As Taroon was  
20 saying, unless we feel that added information  
21 has been given to us to make us want to  
22 consider exception, we're able to do so. So

1 I mean, we could certainly talk about it. I  
2 don't know that any new information was given  
3 to me, other than to say that it sounds like  
4 good practice to do an assessment.

5 And yes, it sounds like it to me,  
6 too, but I'm not so sure that's a quality  
7 measure, and I'm not so sure that I know what  
8 the outcome of that is going to be, how that  
9 improves my patient's care. It's not as  
10 clearly obvious to me.

11 But others, please. John?

12 MEMBER MORTON: I mean, you're  
13 invoking a maxim we all employ in medicine,  
14 which is you don't order a test unless you can  
15 do something with it. Potentially, there can  
16 be something done with this. We just haven't  
17 seen the evidence for it yet.

18 MEMBER LIGHTDALE: We haven't  
19 discussed whether you could combine this  
20 measure into the other one. Are we going to  
21 be doing that?

22 CO-CHAIR BASKIN: Well, that would

1 be a comment. Let's take the measure in and  
2 of itself at this point in time.

3 And let's be clear, I think it was  
4 made clear to us. It's not just ordering a  
5 DEXA scan. That does meet the measure. But  
6 it's just if you did an assessment and didn't  
7 order a DEXA scan, you still get credit on  
8 this measure, which is even a different bar,  
9 I guess.

10 Any other comments to be made?

11 (No response.)

12 CO-CHAIR BASKIN: I don't see  
13 anything compelling here to make us be voting  
14 on an exception process here. I don't think  
15 that anything has been presented new that  
16 would make us do that. So unless I'm hearing  
17 a strong voice otherwise, then I don't think  
18 that's an appropriate vote.

19 I'm hearing that. Okay.

20 Any comments back to the  
21 developer, as this measure isn't going forward  
22 at this point in time?

1 (No response.)

2 CO-CHAIR BASKIN: Okay. I think,  
3 though, it's probably -- maybe it goes without  
4 saying that if there had been some evidence to  
5 show that you can improve the health of these  
6 patients, that there would be a better outcome  
7 for these patients based on this measure, that  
8 would be there. But simply whether you did an  
9 assessment or not just doesn't seem to meet  
10 that bar.

11 Zahid, you wanted to make one last  
12 comment? I'm sorry.

13 MEMBER BUTT: Yes. I was just  
14 going to say that the previous one will  
15 probably help this one. The assessment will  
16 become less important if all of these people  
17 are switched over to alternative therapies.

18 (Laughter.)

19 CO-CHAIR BASKIN: Okay. I  
20 appreciate that. But even those with added  
21 therapies, steroid sparing therapies, may  
22 still remain on steroids. They can't all get

1 off steroids, even with the other therapies.

2 But let's not go there.

3 All right. Then I guess we're  
4 going to move on to our last measure. Now, we  
5 have a time issue here.

6 MS. WILBON: So, a couple things.  
7 It's time for lunch. Lunch is out, so we have  
8 a few options. We are about 15 or 20 minutes  
9 behind. We can have lunch, keep going.

10 CO-CHAIR BASKIN: I'll suggest  
11 that let's get 10 minutes to get lunch, bring  
12 it back to the table here. It's wraps,  
13 sandwich-type things, so there's no reason  
14 why, after 10 or 15 minutes, we couldn't start  
15 discussion while we're eating.

16 Okay?

17 MS. WILBON: Well, quickly, before  
18 we break, again, this is a pilot group. So we  
19 have actually an evaluation team that's  
20 working internally to try and help us gather  
21 some information about the process as you've  
22 experienced it.

1                   And so I think some of my NQF  
2                   colleagues are in here, Lisa and Helen, and  
3                   they have a short survey they'd like you to  
4                   fill out while you're working on lunch. It's  
5                   five questions. It's really brief, shouldn't  
6                   take much of your time.

7                   So while you're eating and  
8                   gathering your things, they're going to  
9                   distribute the survey, and they'll collect it  
10                  from you before we start discussions again.

11                  CO-CHAIR BASKIN: So now that  
12                  means 15 minutes before we start the  
13                  conversation, because you get five minutes to  
14                  complete the survey.

15                  MR. AMIN: I also want to clarify  
16                  that our conference center staff distribute a  
17                  survey -- I hate to over-survey people, but  
18                  they distributed a survey that's on your desk.  
19                  This is a survey that they're handing out now.  
20                  So are they going to do a little orientation  
21                  to the survey?

22                  MS. WILBON: No, it's just five



1 questions. It's pretty straightforward.

2 MR. AMIN: So the one that is  
3 being handed out now is the one that's -- not  
4 that any one is more important than another --

5 (Laughter.)

6 MR. AMIN: -- but that would be  
7 the one that we'd want you to focus on. Thank  
8 you. Unless you didn't like the food, and  
9 then feel free to fill out the other one as  
10 well.

11 (Whereupon, the meeting recessed  
12 for lunch at 12:13 p.m., and was resumed at  
13 12:32 p.m.)

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(12:32 p.m.)

CO-CHAIR BASKIN: Why don't you go ahead, then?

MEMBER BORDEIANOU: So, Measure C2065 is a little bit different from everything we spoke about here before, because it actually focuses on measuring, not individual providers, but hospitals, and it focuses on measuring an outcome as opposed to measuring a process.

And what they propose to do is to look at the number of in-hospital deaths, from hospital to hospital, caused by GI bleed. And they don't stratify in terms of what the cause of the GI bleed is -- is it variceal bleeding, or diverticular bleeding -- so it's a very generic outcome measure.

So as far as the impact -- we're still going through the same motions, right, when we discuss it? As far as the impact, GI bleeding is a very common problem, and if you

1 include every form of GI bleeding you're going  
2 to get a huge number of patients that are  
3 affected.

4 And yes, there is a mortality rate  
5 associated with GI bleeding. And on page 4,  
6 they discuss the rates of mortality, and they  
7 say that they haven't changed much in the last  
8 14 years, but then they mention the health  
9 care cost and utilization project, and they  
10 say on that project they saw a decline in the  
11 rates of bleeding. So that sort of goes back  
12 to the second issue of the gap, which we can  
13 discuss later on. But from the standpoint of  
14 the impact, I would say that the impact is  
15 high.

16 OPERATOR: Excuse me. Dr. Romano  
17 has rejoined.

18 CO-CHAIR BASKIN: Dr. Romano?

19 DR. ROMANO: Yes, I am here.

20 Thank you.

21 CO-CHAIR BASKIN: Hi. We were  
22 just getting started on this one, so let's

1 back up for a second and give you a few  
2 minutes to introduce this measure to us,  
3 please.

4 DR. ROMANO: Yes, certainly. It's  
5 a pleasure to be here. My name is Patrick  
6 Romano. I'm a general internist based at UC  
7 Davis in Sacramento, representing AHRQ today.  
8 This is a risk-adjusted outcome measure, a  
9 mortality measure, as you've heard. Perhaps  
10 the only outcome measure that's under  
11 discussion by this panel.

12 The focus of it is on in-patient  
13 mortality among patients who were admitted  
14 with both upper and lower gastrointestinal  
15 hemorrhage. It is one of a suite of similar  
16 risk-adjusted outcome measures for major  
17 conditions and procedures that are offered as  
18 part of the AHRQ quality indicators program,  
19 so there are similar NQF-endorsed measures for  
20 heart attack mortality, heart failure  
21 mortality, pneumonia, and stroke mortality, as  
22 well as a couple of procedures.

1                   The basic approach here, as I  
2                   think people understand, is that it uses  
3                   administrative data of the type that hospitals  
4                   collect for their own internal purposes, as  
5                   well as for billing purposes and reporting for  
6                   state health data agencies. The data that  
7                   AHRQ actually uses for estimating and testing  
8                   the indicators is the data that comes from  
9                   state health data agencies, through what's  
10                  known as the Health Care Cost and Utilization  
11                  Project, so these are data that are widely  
12                  used for research purposes, as well as  
13                  generally tracking health system performance  
14                  and clinical epidemiology of major conditions.

15                  The risk adjustment approach is  
16                  based on the 3M APR-DRG system, which  
17                  incorporates a variety of factors related to  
18                  the severity of the patient's condition,  
19                  including comorbid illnesses, as well as  
20                  manifestations of the particular type of  
21                  bleeding, such as whether it's an esophageal,  
22                  variceal bleed for example, or a lower GI

1 bleed.

2 That's built into the APR-DRG  
3 system, and basically 3M has an arrangement  
4 with AHRQ to make available limited licenses  
5 for free, so that architecture is available to  
6 those of you who are interested in the  
7 details.

8 So this measure has been available  
9 and in use for several years, and we're  
10 pleased to have this opportunity to discuss it  
11 with the National Quality Forum for possible  
12 endorsement.

13 CO-CHAIR BASKIN: Thank you very  
14 much. Is there any question for the developer  
15 or the measure steward before we open our  
16 discussion?

17 Zahid?

18 MEMBER BUTT: Patrick, in the  
19 section 1b.4, there is data that is stratified  
20 for disparity analysis. Do you know why the  
21 race/ethnicity was just observed rate and not  
22 risk adjusted in the data that's presented?

1 If I'm interpreting it correctly.

2 CO-CHAIR BASKIN: I mean, the  
3 disparities data that's asked for is just to  
4 help us determine whether there are  
5 disparities related to this concept or not.  
6 Whether it's part of the risk adjustment is an  
7 entirely different issue of whether that's an  
8 appropriate risk adjustor.

9 MEMBER BUTT: Yes, but I think  
10 that the question is whether the difference is  
11 on a risk-adjusted basis or not, so you can  
12 make a different conclusion based on that  
13 whether the disparity exists or not.

14 DR. ROMANO: Right. I'm not sure  
15 that I can answer that question right off the  
16 top of my head. I'm not sure if anyone from  
17 our analytic team is on the call.

18 I think the focus here was really,  
19 in terms of the gap analysis, on the  
20 disparities across different types of  
21 hospitals. And you'll not substantial  
22 differences between teaching hospitals and

1 non-teaching hospitals, between small  
2 hospitals and larger hospitals, and between  
3 rural and metropolitan and urban hospitals.  
4 So those analyses are all risk-adjusted.

5 CO-CHAIR BASKIN: Thank you very  
6 much. So we'll return, then, to our  
7 discussion. So, Liliana, we're going to talk  
8 about the impact?

9 MEMBER BORDEIANOU: The summary of  
10 the evidence with regards to the high impact  
11 is on page 4 if you guys want to see. And  
12 essentially, the discussion is about how the  
13 GI hemorrhage in general is a very common  
14 medical problem. Pretty much any hospital,  
15 small or large, encounters it. The mortality  
16 rate, depending on the diagnosis, could be as  
17 high as 10 percent. And so it is definitely  
18 a high-impact measure in my opinion.

19 CO-CHAIR BASKIN: Any questions or  
20 concerns regarding that?

21 (No response.)

22 CO-CHAIR BASKIN: Then I think



1 we're ready to quickly go to a vote regarding  
2 impact. This will be another one where  
3 there's four choices: high, moderate, low,  
4 insufficient evidence.

5 So, those that think this meets  
6 our requirement of high impact, raise your  
7 hands.

8 (Show of hands.)

9 CO-CHAIR BASKIN: That appears to  
10 be everybody, so that's 14, which means  
11 obviously zero moderate, zero low, and zero  
12 insufficient.

13 The evidence?

14 MEMBER BORDEIANOU: My  
15 understanding is that we don't discuss  
16 evidence, because it's not a process measure.

17 CO-CHAIR BASKIN: Yes, it's an  
18 outcome. So what do we do with the outcome,  
19 that's my question. That's why I turned to  
20 you, is what do we do with evidence here?

21 MR. AMIN: I apologize. So what  
22 we're looking for is --

1 DR. PACE: Basically our criteria  
2 for health outcomes is that you don't need to  
3 present the quantity, quality and consistency  
4 of the body of evidence, because outcomes are  
5 generally influenced by multiple processes.  
6 And so we asked them to provide a plausible  
7 rationale or connection between processes and  
8 structures to that outcome.

9 MR. AMIN: And that's on page 10.  
10 Sorry, it took me a second. That's on page  
11 10, 1c.2.1, where we asked them to provide a  
12 rationale between a relationship between the  
13 health outcome and at least one structure,  
14 process, intervention or service, the goal  
15 here being that there is at least something  
16 that the health care community can do, or the  
17 measured entity can do, to influence this  
18 outcome. That's the rationale you have.

19 MEMBER BORDEIANOU: So on page 1,  
20 2, 3 and 4 of the addendum that everybody has,  
21 the proposal sort of goes through a variety of  
22 different interventions that one could use to

1 improve mortality. And some of them are  
2 medical therapies, some of them are systems  
3 therapies, and a lot of them are randomized  
4 controlled trials that are being quoted.

5 So there are definitely a variety  
6 of different interventions that a hospital  
7 could implement, if they are not implementing  
8 them already, to control and prevent  
9 mortality. I think that there is plenty of  
10 evidence.

11 CO-CHAIR BASKIN: So, plenty of  
12 evidence to support that there are  
13 interventions that will result in improved  
14 outcomes.

15 Any comments or questions  
16 regarding that?

17 MEMBER BUTT: I think in this, the  
18 highest evidence is in that subset of  
19 esophageal/variceal bleed and massive lower GI  
20 bleed. So I guess the question will be, would  
21 it be helpful to stratify this measure along  
22 those lines? Because it dilutes out the

1 impact when the entire --

2 MEMBER BORDEIANOU: I was saving  
3 my comments about the stratification and what  
4 the model is going to be, and how they're  
5 going to account for various comorbidities and  
6 other factors. I think that how this will be  
7 measured is key. As we're going through the  
8 motions, I figured that would be Phase 2. But  
9 is it high impact? Yes. Are there things  
10 that one could do to improve outcomes? Yes.

11 CO-CHAIR BASKIN: I think, though,  
12 part of your point, Zahid, if I'm reading it  
13 correctly, is that some of these interventions  
14 are obviously more impactful in terms of  
15 health outcomes than others, and those  
16 interventions are specific to certain  
17 diagnoses within this large range of  
18 diagnoses.

19 And I guess the question is, do  
20 these interventions and outcomes appreciably  
21 affect the entire measure as opposed to just  
22 small snippets of the measure, small snippets

1 of diagnoses within the measure?

2 MEMBER BUTT: Right. And they  
3 mention that in the submission itself.

4 CO-CHAIR BASKIN: So are you  
5 comfortable that there are interventions here  
6 that substantially affect the measure as it  
7 stands?

8 MEMBER BUTT: I think so. I think  
9 that it might actually be helpful if there is  
10 -- and perhaps that will come out later in the  
11 comment section. But I think overall, there  
12 are interventions that do improve the outcome.

13 CO-CHAIR BASKIN: Okay. So we're  
14 voting yes or no, the evidence meets what we  
15 need?

16 DR. PACE: Right, that it meets  
17 our criteria, which is basically for a health  
18 outcome that there's a link to at least one  
19 health care service or treatment or  
20 intervention.

21 CO-CHAIR BASKIN: Right. That's  
22 what I said. Thanks. I appreciate your

1 saying it for me. I couldn't have said it  
2 nearly as well.

3 So, everyone's comfortable with  
4 the question, so that we can vote?

5 (No response.)

6 CO-CHAIR BASKIN: It doesn't seem  
7 like any heads are shaking in the wrong  
8 direction. Okay.

9 So yes would be that the evidence  
10 meets our criteria, and our criteria are a  
11 little bit difference in that the evidence  
12 shows a link between interventions and health  
13 outcomes. 2 means that there's inadequate  
14 evidence, and 3 means that it's inadequate  
15 evidence but that we think that that evidence  
16 does exist.

17 So, let's vote. All those voting  
18 1, that the evidence has been submitted and  
19 exists?

20 (Show of hands.)

21 CO-CHAIR BASKIN: Okay. That's  
22 unanimous, so that means, obviously, there are

1 zero votes for the other two options.

2 And then we move on to performance  
3 gap. So Liliana, thank you.

4 MEMBER BORDEIANOU: So on page 5  
5 and 6 of the proposals, we get a breakdown  
6 that suggests that the odds ratio of bleeding  
7 ranges anywhere from 17 to 22 based on the  
8 type of the hospital, and then there is a gap  
9 based on age and social/income, and Medicare  
10 versus other insurance. That's page 6. And  
11 again, the odds ratios are anywhere from 14 to  
12 25 in the uninsured.

13 So there is clearly a gap. The  
14 concern I have is a more generic concern, and  
15 that's, I think, where Zahid is getting at, is  
16 that we don't know how they're adjusting for  
17 this. I think we need to see the formula on  
18 how this is being calculated.

19 CO-CHAIR BASKIN: Yes. Actually,  
20 I think that probably goes in the Stage 2  
21 discussion, to discuss the risk adjustment,  
22 whether it's appropriate, and whether it's

1 actually measuring what it says it's going to  
2 measure. So I don't really think we want to  
3 start down that path, because we can't finish  
4 that conversation here today.

5 But I think that, in terms of the  
6 gap, it's not just that the gaps were  
7 presented, but they're statistically  
8 significant. I mean, because a range of 17 to  
9 22 may or may not be significant, but  
10 apparently it is here.

11 Any particular comments around the  
12 gap?

13 MEMBER BUTT: I just wanted to  
14 clarify what I was saying. There is actually  
15 very good documentation and very solid risk  
16 adjustment methodology that they use. So  
17 that's not the issue. The question I was  
18 asking was that, in the gap section, where  
19 they have basically -- in the disparities  
20 section, they break down a whole bunch of  
21 different categories where they stratify the  
22 results. All of them are risk-adjusted except



1 for the race and ethnicity breakdown.

2 And my question was, is there any  
3 specific reason -- because there seemed to a  
4 difference between white, black, hispanic,  
5 asian, on the unadjusted rates. But whether  
6 that would hold up when the risk-adjusted --  
7 because the measure is risk-adjusted, and they  
8 risk-adjust everything else. And my question  
9 was, is there a specific reason why that was  
10 not risk-adjusted?

11 But there is definite scientific  
12 validity, and as a matter of fact these IQI  
13 and PSI measures are very well-thought-out and  
14 done. Extensive documentation is used for the  
15 risk-adjustment methodology that they use.

16 DR. PACE: I think that's a good  
17 question, and we can certainly ask that the  
18 developer make that clear when this comes  
19 back, unless it's something that will really  
20 hold you up.

21 MR. AMIN: Is the concern here  
22 also that race might be in the risk-adjustment

1 model, that that's the reason that they  
2 reported it?

3 MEMBER BUTT: No. Sometimes the  
4 observed rate can actually change when you  
5 risk-adjust it, and that's the reason to risk-  
6 adjust a rate, because based on comorbidities,  
7 and whatever other -- and they use the APR-DRG  
8 classification system to risk-adjust based on  
9 that.

10 In other words, so right now, the  
11 unadjusted rate -- if I, again, interpret this  
12 correctly, the mortality rate for blacks is  
13 .09 and whites is .14. But once you risk-  
14 adjust it, it might be different.

15 CO-CHAIR BASKIN: John?

16 DR. ROMANO: I can actually  
17 address that question now.

18 CO-CHAIR BASKIN: All right.

19 Thank you.

20 DR. ROMANO: It was really just a  
21 fluke, to be honest. Race and ethnicity are  
22 not in the risk-adjustment model. We do

1       adjust for age and gender, as well as the  
2       transfer status of the patient, whether the  
3       patient was transferred in from another  
4       emergency room or hospital.

5                       But we do not adjust for  
6       race/ethnicity, and so that requires a  
7       separate stratified analysis, and we just ran  
8       out of time to do that before the submission  
9       document went in.

10                      CO-CHAIR BASKIN:   John?

11                      MEMBER MORTON:   I was going to say  
12       that, oftentimes, risk adjustment is not made  
13       because these are administrative databases,  
14       and race is missing quite often in those  
15       databases.  Nationwide inpatient sample, it's  
16       missing upwards of 20 to 30 percent depending  
17       on which one you're looking at.  So that might  
18       be one reason.  But we already heard from Dr.  
19       Romano.

20                      CO-CHAIR BASKIN:   Judith?

21                      MEMBER TOBIN:   Just a question,  
22       because this comes up a lot with CMS.  If you

1 risk-adjust for things like race and  
2 ethnicity, then you're risk-adjusting away  
3 potential disparities.

4 CO-CHAIR BASKIN: As well as  
5 socioeconomic risk adjustment. This has come  
6 up in the CSAC on many an occasion, and the  
7 tendency has been to stay away from risk-  
8 adjusting based on those, because it does hide  
9 those disparities and potentially hinders  
10 improvement in those situations. Oh, and it's  
11 in the NQF guidance as well.

12 So yes, I think this was more of  
13 interest, not that it would stop this measure  
14 or the appropriateness of this measure, but  
15 since the data apparently could be available,  
16 it was of interest to us, as Zahid said, are  
17 there differences if you had risk-adjusted it?  
18 Not risk-adjusted the actual measure result,  
19 but are there actually -- when you're looking  
20 at it, just for informational purposes, is  
21 there an issue based on race or ethnicity?

22 MEMBER BUTT: Not to get too much

1 into the weeds of this and prolonging this any  
2 further, but I was actually looking at this  
3 more as a stratification of risk-adjusted  
4 rate, rather than using these components to  
5 risk-adjust itself. Again, I was looking at  
6 this as more of a stratification of risk-  
7 adjusted rate that I thought was being done  
8 using APR-DRG and a couple of other things  
9 that he mentioned.

10 CO-CHAIR BASKIN: All right. I  
11 think we're ready to take a vote here on the  
12 performance gap. We have four options here:  
13 high, moderate, low, insufficient.

14 So, all those raise their hands  
15 who feel that performance gap was demonstrated  
16 high, considerable variation.

17 (Show of hands.)

18 CO-CHAIR BASKIN: Ten. How many  
19 think moderate?

20 (Show of hands.)

21 CO-CHAIR BASKIN: Four. And that  
22 means zero lows and zero insufficients. So

1 then I think we can move on to whether we  
2 recommend the approval of this concept or not.

3 I'm looking around to see if  
4 anybody needs to make a comment. Otherwise,  
5 we can just take this directly to a vote. I  
6 think we'll go to a vote, then.

7 Those in favor of approving this,  
8 vote yes. Raise your hands.

9 (Show of hands.)

10 CO-CHAIR BASKIN: It appears to be  
11 14. It appears to be unanimous. So that  
12 would be zero nos. Thank you very much for  
13 that.

14 Any comments back to the measure  
15 steward that anyone wants to make at this  
16 time?

17 MEMBER BORDEIANOU: My only  
18 comment is the numerator and the denominator,  
19 they are only including patients that have as  
20 the first diagnosis GI bleeding. There is a  
21 lot of room for manipulation of that.

22 If the hospitals learn that

1 they're being measured on GI bleeding, they  
2 can code the first diagnosis as myocardial  
3 infarction, or whatever the cause of death  
4 was, as opposed to what the presentation cause  
5 was. So I think that this needs to be heavily  
6 considered in the feasibility part of the  
7 discussion.

8 CO-CHAIR BASKIN: Thank you, and I  
9 think that's come up with similar comments  
10 with the other similar measures that have the  
11 same issue.

12 Zahid, comment?

13 MEMBER BUTT: So I would strongly  
14 encourage them to look at if they could  
15 stratify it by variceal bleeding, because I  
16 think that has, probably, as a subgroup, the  
17 biggest impact.

18 CO-CHAIR BASKIN: So essentially  
19 you're suggesting that there may be large  
20 subgroups here for which there hopefully could  
21 be enough of a denominator that it may be of  
22 some interest to --

1                   MEMBER BUTT: Or even if they  
2 could somehow stratify this.

3                   CO-CHAIR BASKIN: -- to stratify  
4 out the components of the measure based on  
5 diagnosis.

6                   MEMBER BUTT: Yes.

7                   CO-CHAIR BASKIN: Any other  
8 comments for the developers?

9                   (No response.)

10                  CO-CHAIR BASKIN: Okay. I would  
11 think, though, that anyone that's actually  
12 implementing the measure could do that  
13 stratification, really, themselves, if they  
14 wanted to. Although the stratification could  
15 itself be a measure, of course, but you would  
16 have the ability to do that. If you have the  
17 ability to perform the measure, you have the  
18 ability to do that as well.

19                  Okay. Well, thank you very much.  
20 That concludes our review of the measures, and  
21 right on time. We've already had our lunch.  
22 We're going to open it up for member comment



1 and public comment. Member comment are those  
2 in the room, so if anyone in the room would  
3 like to make a comment, you have a microphone.  
4 Just state who you are when you make your  
5 comment, please. Thank you.

6 DR. PARK: Walter Park again, on  
7 behalf of the American Society of  
8 Gastrointestinal Endoscopy. We just wanted to  
9 make some brief verbal comments regarding  
10 measure concept 0259 by AGA. On behalf of the  
11 ASG, we do support the passing of this  
12 concept.

13 We do share some of the concerns  
14 raised by some of the members regarding  
15 further clearance on the denominator, and as  
16 we look forward to Stage 2 we only request or  
17 look forward to seeing the developer define  
18 the concepts in a manner that is registry-  
19 neutral. That would allow our fellow  
20 gastroenterologists who do not participate in  
21 the AGA registry to be able to comply with  
22 this measure.

1 CO-CHAIR BASKIN: Thank you. Any  
2 additional comments from anyone in the room?

3 (No response.)

4 CO-CHAIR BASKIN: Then we can open  
5 it up for public comment on the phone. Is the  
6 line open, operator?

7 OPERATOR: Yes, sir. All lines  
8 are open.

9 CO-CHAIR BASKIN: Thank you. Any  
10 comments?

11 (No response.)

12 CO-CHAIR BASKIN: Hearing none,  
13 then we'll close the public comment portion  
14 and we'll move on to the next topic area,  
15 which is potential for harmonization and  
16 identification of gaps in the GI measurement.  
17 Taroan, did you want to lead this or get us  
18 started?

19 MR. AMIN: Yes, I will just pose a  
20 few questions, actually, to the group. I  
21 think the two -- and Ashlie, please jump in  
22 here if there's anything else that you want to

1 add. It sounds like there were two related  
2 concepts from today, 0658 and 0659. 0659 was  
3 not recommended to move forward.

4 No, I have that wrong, sorry.  
5 It's C2059 and 2062. I apologize. So the  
6 question I have is, while 62 didn't move  
7 forward, can we get some clarification on  
8 exactly what the recommendation would be? I  
9 know we mentioned that we wanted to have  
10 components of 62 incorporated into 59, so  
11 maybe we could just have a little bit of  
12 discussion on that, of what you would like to  
13 see there, if anything. And then we go back  
14 to our discussion that we began yesterday,  
15 which is on 0653, the chronic liver disease  
16 with the hepatitis A vaccination, and look at  
17 -- Ashlie, did you have something?

18 MS. WILBON: It was 0635, instead  
19 of 53.

20 MR. AMIN: I apologize. I'm  
21 messing up all these numbers right now. So  
22 it's the chronic liver disease/hepatitis A

1 vaccination, along with the patients with  
2 hepatitis C who get hepatitis A vaccination.  
3 We put the side-by-side table up on the screen  
4 for you, to be able to see the side-by-side.  
5 The one that's the patients with hepatitis C  
6 who had hepatitis A vaccination, that measure  
7 was not in this project, and it's actually  
8 being reviewed in the ID project next door,  
9 but they are related.

10 So the question here is, is there  
11 anything that you would like to see related to  
12 how these measures relate to one another prior  
13 to moving into Stage 2?

14 CO-CHAIR BASKIN: So, let's talk  
15 about that combination first. Those two  
16 measures, I mean. I don't mean combining  
17 them, necessarily, but those two measures with  
18 the hepatitis A vaccination.

19 So not knowing the other measure  
20 off the top of my head, the one that's already  
21 in existence regarding hepatitis C patients  
22 getting hepatitis A vaccination, the

1 denominators, can we look and see, are they  
2 reasonably the same -- is one denominator  
3 essentially a subset of the other measure, the  
4 chronic liver disease measure, and completely  
5 included in it?

6           So all patients with a diagnosis  
7 of hepatitis C, and the other is patients  
8 diagnosed with chronic liver disease. And I  
9 believe the chronic liver disease group in  
10 relation to hepatitis C -- how do they get  
11 into that denominator?

12           So, basically, if you've had  
13 chronic hepatitis C -- and is that really the  
14 -- I don't know the interpretation here. Is  
15 this really the same populations?

16           MEMBER BUTT: So it looks like,  
17 when I looked at them side-by-side, because I  
18 think I did the one yesterday for the new  
19 measure, there are some significant  
20 differences. The big differences, at least  
21 from what I can see in this side-by-side  
22 comparison, is, number one, the data source is

1 a big difference. The new measure includes  
2 patient-reported survey data, all sorts of EHR  
3 data, HIE data, whereas this one is pretty  
4 limited to the type of data that would be in  
5 possession of a practice, which kind of leads  
6 into the next key question, which I think was  
7 raised yesterday as well: what level is this  
8 applicable at?

9           The new measure is being applied  
10 at the population level, whereas this old  
11 measure is being applied at a clinician,  
12 individual physician, level. And the  
13 importance of that is because that's where  
14 that sort of denominator comes in, that for  
15 the physician level you have to actually  
16 attribute it to a physician, and typically  
17 it's done through CPT, office visit type of  
18 data, that if you've had two office visits or  
19 one office visit, that sort of gets counted in  
20 the denominator.

21           But here in this other one, the  
22 denominator is sort of a big, large sort of

1 multiple data sources -- patients could have  
2 just self-reported, et cetera, et cetera. So  
3 the denominators are really very different in  
4 these two, and the level of application, at  
5 least the way it's presented, is totally  
6 different.

7           So, those are some of the key  
8 differences to me that would present, I think,  
9 some problem in harmonizing these. Also, the  
10 old measure is only for hepatitis C, whereas  
11 this new measure is for all chronic liver  
12 disease. So that's another big difference.

13           DR. PACE: So I think one of the  
14 questions is, what does the evidence say? Who  
15 should be receiving the vaccination? Should  
16 it just be restricted to patients with  
17 hepatitis C, or is it all chronic?

18           MEMBER BUTT: As we saw yesterday,  
19 the evidence would suggest -- and all three  
20 guidelines were very consistent -- that it  
21 should be for all chronic liver disease. So  
22 I think that the evidence would suggest that

1 it should be for all patients. So the  
2 hepatitis C would be just a subset of that.

3 CO-CHAIR BASKIN: But if you did  
4 apply attribution logic to those in the  
5 chronic liver disease measure -- because if a  
6 patient had seen a physician for two days you  
7 could do that measure at a physician level.

8 MEMBER BUTT: Right. So one  
9 harmonization might be that the old measure  
10 could expand its denominator to include all  
11 liver disease, and that would actually  
12 accomplish that goal. I don't see why it  
13 couldn't, because the body of evidence is  
14 there.

15 The new measure, obviously, is  
16 being applied for a different reason from, at  
17 least, what is being presented. So that would  
18 have to be evaluated, whether it actually does  
19 represent as a population measure or not, in  
20 Stage 2. But certainly, I think, in terms of  
21 trying to accomplish a part of what it was  
22 trying to do, would be to include all chronic



1 liver disease in the existing measure.

2 It's otherwise really well done.  
3 The existing measure seems to have been well  
4 thought-out and well done.

5 CO-CHAIR BASKIN: Any other  
6 comments?

7 MS. WILBON: Zahid, can you  
8 clarify what you mean by existing measure?  
9 Because they're actually both maintenance  
10 measures, so I was a little confused.

11 CO-CHAIR BASKIN: The measure we  
12 reviewed yesterday was not a new measure. It  
13 was a maintenance measure. So he was  
14 describing that was the new one, because it  
15 was the newest for us to discuss.

16 MR. AMIN: Just to clarify, when  
17 he was referring to the new measure, he was  
18 referring to 0635.

19 MEMBER BUTT: Yes, 0635 is what I  
20 was referring to as a new concept.

21 CO-CHAIR BASKIN: We don't  
22 normally have this back-and-forth, but I know

1 you have something to say that would probably  
2 be very relevant to this, so please just  
3 introduce yourself and go ahead and speak to  
4 that. Thank you.

5 DR. ANTMAN: Thanks. Mark Antman  
6 for the AMA-PCPI. Just to note that, knowing  
7 that this discussion would come up today, we  
8 did discuss the idea of potentially  
9 harmonizing with 0635 with our hepatitis C  
10 workgroup cochairs, and they certainly agreed  
11 that it would be appropriate to -- that  
12 hepatitis A vaccination obviously is supported  
13 by the evidence for all chronic liver disease.  
14 So we are interested in the recommendations of  
15 this committee as to how we can harmonize with  
16 the active health measure, recognizing that  
17 there are, as Dr. Butt pointed out, some data  
18 source challenges.

19 CO-CHAIR BASKIN: Okay. And I  
20 think that this connection can be made outside  
21 of this meeting, off-line, and see if those  
22 discussions can occur. Thank you, though, for

1 that comment.

2 Any other comment in the room here  
3 regarding these particular two measures, this  
4 pair?

5 (No response.)

6 CO-CHAIR BASKIN: Okay. So there  
7 seems to be some opportunity here that can be  
8 explored. The other pair that you mentioned  
9 was the IBD. So one that made it through  
10 today, and one did not, but there's a question  
11 of the fact that the IBD measures regarding  
12 the cortico-sparing therapy and those that are  
13 on chronic corticosteroid therapy, regarding  
14 an assessment for bone loss, is there an  
15 opportunity to incorporate the assessment or  
16 something to do to address the issue of  
17 potential bone loss and potential treatment or  
18 not? Only because if you're looking at the  
19 same populations in the denominator, and is  
20 there a way to do that?

21 Now, one of the issues is that  
22 just adding it in doesn't work, because we've

1 decided that that measure doesn't meet our  
2 criteria. So unless there was some way to get  
3 at more of what we were considering the  
4 outcome or the treatment, or something other  
5 than just performing or not performing an  
6 assessment for which there would be an  
7 evidence base to support that -- it's  
8 certainly a similar population, and would make  
9 some sense to enhance the other measure.

10 But I'll open that up for anyone  
11 that has anything more to say about that than  
12 I've just commented on.

13 MEMBER BUTT: I just think it  
14 would be hard to combine the two, because  
15 they're really -- the steroid sparing and the  
16 use of immunomodulator or anti-TNF therapy is  
17 sort of a different objective there, and this  
18 probably would be difficult to fit into that,  
19 is the way I think about it.

20 CO-CHAIR BASKIN: About the only  
21 thing they have in common is the same  
22 denominator and the fact that they're both

1 appropriate steps to take, but very different  
2 steps in terms of what their goals are. So I  
3 understand where you think that maybe it  
4 doesn't make sense to consider a combination  
5 there.

6 Any other comments?

7 MEMBER BORDEIANOU: Unless the  
8 measure in general is reformatted as a  
9 discussion about the risks of long-standing  
10 steroids, and a discussion about treatment  
11 options such as steroid sparing therapies,  
12 measurement of complications, et cetera,  
13 surgery.

14 CO-CHAIR BASKIN: So essentially  
15 the comments we've made regarding as to what  
16 we would have liked to have seen for that  
17 measure to even come back as its own measure  
18 is still valid, whether it be combined with  
19 another measure or not combined with another  
20 measure. Right.

21 No further comment on that?

22 (No response.)

1 CO-CHAIR BASKIN: Then a gaps in  
2 GI measurement discussion. Do you have  
3 anything in particular, other than we're  
4 asking?

5 MR. AMIN: Yes, exactly.

6 CO-CHAIR BASKIN: I don't have a  
7 list of the subset of other GI measures that  
8 exist, other than the ones we've discussed.

9 MS. WILBON: So there's kind of a  
10 similar scenario with the two endoscopy  
11 measures that were both submitted by AMA-PCPI,  
12 0658 and 0659. We have some comparison tables  
13 we can hand out, but I believe -- I think one  
14 of them was approved and one of them was not.  
15 Let me just double check here for one second.

16 Oh, no. They were both approved.  
17 So I guess the question is just to kind of  
18 bring it to your attention that they are both  
19 focused on polyp surveillance, and whether or  
20 not there's any room or discussion about  
21 whether or not harmonization can occur between  
22 those.

1 CO-CHAIR BASKIN: Certainly  
2 they're both talking about colonoscopy and  
3 interval under different circumstances, and  
4 one could argue that there's the possibility  
5 of having a measure out there that says "Hey,  
6 of any colonoscopy that was performed,  
7 depending on the results, was the appropriate  
8 interval either suggested or occurred?" And  
9 I guess that would be one way to do that. I'm  
10 not so sure that it's practical at this point  
11 to do that, so I'll just point that out as my  
12 own personal view. But it would be neat to  
13 have a measure that essentially included every  
14 colonoscopy, and was the appropriate interval  
15 adhered to or not adhered to, and that would  
16 be a great measure. But I'm sure there'd be  
17 some tremendous implementation and  
18 practicality issues on whether that measure  
19 could actually be performed and be accurate.  
20 But that is an ultimate, I think, fairly  
21 decent composite measure, to be honest with  
22 you.

1                   MEMBER SCHOENFELD: In my opinion,  
2                   it's not practical for harmonization at this  
3                   time. And what I would keep in mind is,  
4                   remember that the -- 0657, Taroon? Which is  
5                   the colonoscopy screening one.

6                   MR. AMIN: 0658.

7                   MEMBER SCHOENFELD: 0658 refers to  
8                   making a recommendation by the endoscopist.  
9                   After you do a colonoscopy for somebody who's  
10                  had a normal screen, you make a recommendation  
11                  to say it should be done in 10 years. 0659  
12                  states that, if I'm doing a colonoscopy  
13                  because a person has a history of polyps, that  
14                  I am documenting at the time I do the  
15                  colonoscopy that it's been at least three  
16                  years.

17                  We're really talking about two  
18                  very different aspects of minimizing overuse  
19                  of colonoscopy. So again, in my impression at  
20                  this time, probably not appropriate for  
21                  harmonization.

22                  CO-CHAIR BASKIN: Any other



1 comments to be made regarding that?

2 (No response.)

3 CO-CHAIR BASKIN: I mean, I'm all  
4 in agreement about the practicality of doing  
5 it, although I have to admit, at the time, I  
6 suggested that the other measure be reversed,  
7 and I still think that that's a better way to  
8 go. So I'm going to say it again, because  
9 I've got the microphone.

10 MEMBER SCHOENFELD: And maybe  
11 AMA-PCPI can take that one up, because I am in  
12 agreement with you about that as a general  
13 theme.

14 CO-CHAIR BASKIN: Okay. And with  
15 no other comment, then I think -- once again,  
16 if there's anyone that has a recommendation or  
17 a suggestion or a request, or an  
18 identification of gaps in measurement that  
19 they think would be reasonable for a developer  
20 to fill, now's a great time. But any time is  
21 a great time for that. That information can  
22 be relayed back to NQF. They are always

1 requesting any feedback regarding gaps in  
2 measurement.

3 So not seeing anyone quick to  
4 raise their card to be able to identify a gap,  
5 then I think we'll move on. We want to get  
6 some pilot feedback at this point.

7 MR. AMIN: Ashlie and I will tag  
8 team on this question, and Karen's here as  
9 well. But as we described at the beginning of  
10 yesterday -- I'll actually take a deep breath  
11 here. We're done with a lot of the heavy  
12 lifting.

13 MS. WILBON: Good job, by the way.

14 MR. AMIN: Thank you for all that.

15 MS. WILBON: Way to push through.

16 MR. AMIN: I know this is a tall  
17 order. So this is more of a reflection period  
18 on kind of where we've been over the last two  
19 days, and kind of hearing your feedback on how  
20 this pilot has been working. And in an  
21 overall standpoint of how this process is  
22 different than the current NQF process, since

1 many of you are new to the CDP process, is  
2 that we implemented a number of different  
3 components.

4           The first -- and we had some  
5 sidebar conversations about it as well -- is  
6 a technical review period which happened prior  
7 to measure submission, where we asked measure  
8 developers to submit at least one concept to  
9 Karen Pace and Alexis Forman, who did a  
10 thorough review of the evidence and a number  
11 of different components of the measure, and  
12 provided technical feedback on areas that  
13 needed to be expanded upon or needed more  
14 clarification.

15           We also split the process in two,  
16 which is why we call it a two-stage process,  
17 in which we broke out the importance criteria  
18 away from scientific acceptability, usability,  
19 and feasibility, which you'll evaluate in your  
20 second stage. And there are a number of other  
21 tools that we developed to support this  
22 process.

1                   So what we wanted to do now is to  
2                   try to get some feedback from you -- again,  
3                   knowing that many of you may not have  
4                   participated in the typical CDP process -- on  
5                   a number of key questions related to some of  
6                   the changes that we implemented.

7                   And I guess one of the first  
8                   questions that I will start with is that we  
9                   made some assumptions on how we can actually  
10                  define a concept, and the way we defined a  
11                  concept was around the numerator, the  
12                  denominator, exclusions, usability  
13                  information, taxonomy.

14                  Was that enough to really get a  
15                  sense of what the measure concept was that you  
16                  were trying to evaluate? Was that a  
17                  sufficient amount of information to evaluate  
18                  the concept? And was there information that  
19                  you didn't review, or you did not think it was  
20                  necessary for us to collect from the  
21                  developers?

22                  I think one question that seemed

1 to occur, one piece of feedback that already  
2 we seem to have gotten, is that while we  
3 looked at the information that was presented,  
4 it gave us a sense of the concept but we  
5 didn't actually evaluate, necessarily, the  
6 construction of the concept. So particularly  
7 the numerator, denominator, or if there are  
8 multiple components in the numerator and  
9 denominator, that was not explicitly evaluated  
10 in this process, because we're just looking at  
11 those importance criteria.

12 So I guess I'll start -- do you  
13 want to do each of them individually, or  
14 should I go through all the questions? What  
15 do you think?

16 MS. WILBON: Let's do them  
17 individually.

18 MR. AMIN: Yes. Let's stop there.  
19 And just so you know, I have three slides with  
20 sets of questions. Just so you're not  
21 overwhelmed.

22 CO-CHAIR BASKIN: So, comments?

1 And I'd like to make an initial comment, in  
2 that one thing that I struggled with a little  
3 bit and would have liked submitted was a brief  
4 statement by the developer on essentially what  
5 the intent was. I mean, what did they expect  
6 that this measure would do, or how did they  
7 expect that this measure would result in  
8 improved health outcomes? It wasn't always so  
9 clear to me.

10 And in fact, if we had asked the  
11 developer to say what, then maybe somebody  
12 that came in and said "Well, doing an  
13 assessment somehow or other" -- I mean, force  
14 them to -- I don't mean force in a bad way,  
15 but because we don't get a lot of back and  
16 forth discussion with the developers at this  
17 stage, to kind of get a feel for "Did you  
18 really think that this, somehow or another,  
19 links to some change in performance, or that  
20 people's behavior is going to change, either  
21 patients or doctors, whoever it is that you're  
22 measuring here?"

1                   So even if it's just a paragraph,  
2                   three or four sentences, with a kind of intent  
3                   and an expectation of how you think this  
4                   measure would play out in terms of affecting  
5                   care, that would have been helpful to me.

6                   MEMBER MERGUERIAN: Just to add to  
7                   that, I would totally agree. I think linking  
8                   the measure to outcome measures, and actually  
9                   having the developer think about what types of  
10                  outcome measures they're trying to -- or they  
11                  will develop in the future. The other thing  
12                  is really looking at that from a patient  
13                  perspective, looking at the value of this  
14                  measure as far as a patient is concerned. You  
15                  know, patient satisfaction, other types of  
16                  measures -- you know, value, patient values.  
17                  Because none of these concepts really looked  
18                  at it from a patient perspective.

19                  CO-CHAIR BASKIN: I lost track  
20                  completely. So I think, John, yours was up  
21                  before.

22                  MEMBER MORTON: I was going to

1 make the same point about the patient  
2 preferences, and making sure they're included.  
3 The other thing that came up, we didn't have  
4 a ready answer for, is to what degree does  
5 cost enter into any of this? And maybe it  
6 would be something good, to figure out what  
7 the playbook looks like, in figuring out what  
8 role cost should play. Maybe a bigger concept  
9 is value, cost and quality combined. So, just  
10 a thought.

11 MEMBER MERGUERIAN: There is  
12 actually a compass called the Value Compass  
13 that actually looks at four areas of measure:  
14 functional, satisfaction, cost. And so that's  
15 one area that I think -- it's developed by  
16 IHI, and you can actually get that. It's  
17 called a Value Compass.

18 CO-CHAIR BASKIN: Well, we have to  
19 get a feel for whether cost effectiveness  
20 plays a part in our decision making at all or  
21 not, to be honest with you. Because it's not  
22 something we asked for data on, and it's not



1 something that's intuitive, unless you're an  
2 expert in that particular activity.

3 MEMBER REYNOLDS: Right. So one  
4 of the things that you had asked for, and you  
5 had supplied, is usability info, but that was  
6 often not completed on the forms. And that  
7 would be a chance, so the people could put  
8 down what it's going to be used for, how it  
9 was going to be used, and it wasn't clear to  
10 me that we had a chance to really discuss that  
11 or evaluate that now. Now, granted, it might  
12 be part of the second stage.

13 And then the other part that  
14 people talked a little bit about is this  
15 concept of the proximity to the outcome. It  
16 came up a couple times, and I just wonder if  
17 pushing that to the first part of the two-step  
18 process would also be helpful. Because again,  
19 it might be high-impact and whatnot, but if  
20 it's really proximal to the outcome, we might  
21 want to flesh that out ahead of time, and not  
22 go forth on the second part.

1 CO-CHAIR BASKIN: So essentially  
2 asking that, if your measure is not proximal  
3 to the outcome, why isn't it proximal to the  
4 outcome.

5 MEMBER REYNOLDS: Well, the  
6 reasons --

7 CO-CHAIR BASKIN: The reason your  
8 measure had to be so distal.

9 MEMBER REYNOLDS: There's no real  
10 point in our evaluation to address that. I  
11 mean, we talk about that at the end, after we  
12 sort of voted it through. Like "Gee, this  
13 would be better if we were looking at, in  
14 fact, the number of colonoscopies that were  
15 done, rather than" et cetera. I think that  
16 there's a point where we could address that  
17 further before we get to the next step.

18 MEMBER BORDEIANOU: Maybe I'm  
19 saying the same thing in a different way, but  
20 any medical problem that we'll be discussing  
21 here is going to be high-impact. It seems  
22 like that's a no-brainer a majority of the

1 times. But what is not always being clearly  
2 discussed -- or maybe I'm missing it -- is  
3 "Does the particular measure have a high  
4 impact when performed?" I.E., doing a  
5 physical exam before surgery changes the  
6 outcome. This is where we really need to be  
7 digging into more.

8 CO-CHAIR BASKIN: That's  
9 essentially what the evidence review is all  
10 about, except to say that in many cases, for  
11 things like physical exams and asking a  
12 particular question before surgery, or before  
13 a procedure, there's often a little lack of  
14 evidence. And I think that's a problem, and  
15 we saw that over and over again. We struggled  
16 with that.

17 MR. AMIN: Right.

18 MEMBER MORTON: The other thing I  
19 was going to make, for the continuing  
20 measures, I know it's something that we ask  
21 for, but it would be great to have more  
22 emphasis on what has happened since that

1 measure came into play. I think that's key,  
2 closing the loop. We think of all these  
3 measures a little bit in isolation, but what  
4 happens in real practice? I think that's  
5 really important, particularly as we see some  
6 of the older measures become pretty mature.  
7 And it may be time to sunset some of these, or  
8 it may be time to say "You know what? That  
9 was good four years ago, but it's not good  
10 now."

11 CO-CHAIR BASKIN: When is the  
12 discussion of whether a measure should be --  
13 the discussion should be whether it should go  
14 into reserve or not. Is that really a Stage  
15 1 discussion, or is it a Stage 2 discussion?  
16 It's kind of hard to even discuss the measure.  
17 If we don't discuss it in Stage 1, why are we  
18 even talking about it for maintenance in some  
19 cases?

20 MR. AMIN: One of the other  
21 components that we're testing here is to take  
22 out the evidence form as the attachment, to

1 make it a little more clear than we've had it  
2 in the past. Just some experience in  
3 reviewing the evidence form: was it clear what  
4 type of information that we requested and why?  
5 Did you feel that the format of the evidence  
6 form was conducive to completing your reviews  
7 in an organized fashion?

8 So it's broadly about the evidence  
9 information that we asked for. Was it clear  
10 to you? And was it clear to evaluate, just in  
11 that sense?

12 MEMBER REYNOLDS: I think it was a  
13 little bit unclear. I think it was unclear to  
14 the developers exactly what we needed and what  
15 they needed to supply. And we struggled with  
16 that. I also think that when we are  
17 evaluating it, it could have been a little bit  
18 more helpful if we had stuck a little bit more  
19 closely to the quantity, quality and  
20 consistency, which when we did the preliminary  
21 evaluations, we were sort of asked to  
22 specifically rate those individually and then

1 a global thing.

2 I think that if we had had that  
3 opportunity, we would have been a little bit  
4 more strict on the evidence going forth. So  
5 if we had specifically had to say "Can we see  
6 that there are four or more studies in the  
7 form? Were they consistent? Blah, blah,  
8 blah," you'd at least get a little more  
9 granularity on what the issue was, rather than  
10 this global "We think there's enough evidence  
11 of pretty high quality."

12 We might have eliminated a lot  
13 more measures if we'd been a little bit more  
14 strict.

15 MEMBER TOBIN: I would second  
16 that. Just as a non-voting person, but  
17 observation, there seemed to be a lot of  
18 deviation from the strict rules that were  
19 established for the quantity. And the other  
20 was, is there compelling evidence, if it  
21 doesn't meet the criteria? And I found that  
22 a little -- because you're not obligated to

1 present evidence, but you could say that you  
2 think there's a compelling reason to still  
3 push the measure forward. I found that  
4 confusing.

5 DR. PACE: Can I ask a question?  
6 And this is actually broader implications than  
7 the pilot, but what would you think if NQF  
8 just took the hard line of "We're not  
9 accepting measures that are based on expert  
10 opinion and consensus, and that we want  
11 measures focused, that are proximal to the  
12 outcome, with that evidence-outcome link?"

13 You know, the reason for all that  
14 language is the continued push-back of wanting  
15 these more distal process measures. So this  
16 would go to a higher authority, but since it's  
17 brought up, I'll just see what your thoughts  
18 are.

19 CO-CHAIR BASKIN: Go ahead, John.

20 MEMBER MORTON: I agree that when  
21 you grade evidence around expert opinion, it's  
22 never very high. But there are going to be

1 occasions where there's compelling reasons to  
2 have expert opinion, because there's simply no  
3 data yet and the need is high to have some  
4 sort of quality measure out there. So when  
5 there's gaps like that, I would be reluctant  
6 to exclude it altogether. I think we have to  
7 grade it and get a better idea of "Does this  
8 rise to the occasion when we accept only  
9 expert?"

10 And there may be circumstances  
11 where there's a real compelling quality need  
12 that we only have expert opinion. But I agree  
13 it's not the best, but I wouldn't do away with  
14 it altogether.

15 CO-CHAIR BASKIN: I am just going  
16 to start at the end and work up in order since  
17 I didn't watch you put up the cards.

18 So go ahead, Zahid.

19 MEMBER BUTT: Yes, I agree with  
20 John, that probably it would be worth keeping  
21 it in. But I do also agree with what Judith  
22 was saying, that I think where it may be a



1 sort of opportunity to make the body of  
2 evidence section specific, where you actually  
3 have a small table that they have to fill out,  
4 the developer. Because some do count the  
5 studies in that section. Others don't.

6 So if you force them, or it  
7 becomes a requirement of filling that section,  
8 that they have to count the number of studies,  
9 they have to grade the quality, and they have  
10 to grade the consistency. So at least,  
11 whatever they present, they should do their  
12 part of it.

13 And then in the area of  
14 guidelines, that's where, to me, I had the  
15 most difficulty. Because one assumes, often,  
16 in practice, that practice guidelines,  
17 especially out of your professional societies,  
18 are the standard of care. Because we  
19 reference them all the time. You know, we do  
20 colonoscopies, and the first thing we say is  
21 "ACG, or ASGE, guideline says that I should do  
22 this."

1                   So there seems to be somewhat of a  
2                   disconnect in the perception of a guideline  
3                   and, perhaps, what NQF is looking for here.  
4                   And I don't know how that gets reconciled and  
5                   harmonized, but at least in the short run,  
6                   where there is a guideline, then the measure  
7                   developer should provide all that information  
8                   that backs up the guideline, so that at least  
9                   you can make a judgment "Okay, this guideline  
10                  is based on this number of studies and this  
11                  number of randomized controlled trials," or  
12                  "this amount of expert opinion."

13                  I think if all of that is nice and  
14                  concise and well laid-out in that 1c section,  
15                  then it would make the job for the steering  
16                  committee easier. Then you just have to sort  
17                  of validate what is there, to the extent that  
18                  you can. So I think that might be one other  
19                  area.

20                  The last comment that I'll make is  
21                  that there seems to be a lot of duplication in  
22                  the data that's presented. Like, there is

1 evidence for high impact, and then back down  
2 in 1c there is evidence again. And some of  
3 the developers are just repeating the same  
4 thing up there. They just reference the  
5 study, rather than take out the portion of the  
6 study that addresses high impact, the portion  
7 of the study that may only address a different  
8 section of the body of evidence.

9           So I think some of those things,  
10 if there could be some design of the form that  
11 sort of guides them through that process and  
12 makes it more clear as to what they have to  
13 provide, it would make the job of the steering  
14 committee easier.

15           MEMBER KOCH: So, to follow up on  
16 that, I think what the expectation of the  
17 developers should be is that they actually  
18 rate and grade the evidence. I mean, it's in  
19 their section, but the majority of the  
20 proposals didn't actually include that. Now,  
21 they could have, just like we ended up doing.  
22 They should have been expected to do that, and

1 they shouldn't get to submit something without  
2 that.

3           The issue in terms of the  
4 guideline, I think, as a process to this  
5 thing, I would suggest that things that are  
6 based on guidelines or not enough evidence  
7 should be considered later in the day or in a  
8 separate category. I think part of what  
9 happened to us is that the very first thing we  
10 did was spend 45 minutes -- and I'm not sure  
11 that that measure, if it had been presented  
12 later, with all the discussion we had, would  
13 have qualified.

14           So setting the day up so, if you  
15 have a brand new group, make the first one  
16 "This is a slam dunk, this is our best  
17 proposal, it's got great data." Then things  
18 that are coming back up for reevaluation,  
19 especially if they're -- you know, something  
20 that's just guideline-based should have a  
21 little asterisk. Three years later, the bar  
22 should be way higher and we should be seeing

1 way more data in order to substantiate that.

2 MEMBER MERGUERIAN: Again, I would  
3 agree. I would not take a hard-line approach,  
4 especially if you're going to delve into  
5 pediatrics, because there's really not a lot  
6 of data in pediatrics.

7 The second issue is grading the  
8 evidence, really having the developers grade  
9 the evidence, but then also giving them  
10 guidelines. Because there are two or three  
11 different grading systems, and so really just  
12 sticking to one grading system that you would  
13 then agree upon.

14 MEMBER LIGHTDALE: I actually  
15 agree with pretty much everything that's been  
16 said. My thought about consensus-based  
17 guidelines is that, right now, if we decided  
18 there wasn't enough evidence, we stopped and  
19 didn't ask about performance gaps. And I  
20 think it's okay to have a quality metric on  
21 something that there is basic consensus that  
22 it should happen, but there's also very good

1 evidence that it's not happening uniformly.  
2 And so stopping and not asking if there's a  
3 performance gap, I think, sort of defeated our  
4 purpose there. I don't know that the metric  
5 that we did that on actually had the  
6 performance gap evidence, but that could be  
7 compelling.

8                   And then, also, with guidelines  
9 themselves -- of course, the corticosteroids  
10 and bone loss one was the one I was really  
11 looking at, but we've all been involved in  
12 guideline development, and that was a 2006  
13 guideline from the AGA. Over the past six  
14 years, the rigor with which guidelines are  
15 being developed -- I think the understanding  
16 of the responsibility that the societies are  
17 taking on now has tremendously developed. And  
18 so a 2006 guideline was being held to a very  
19 different standard than a 2012 one, and really  
20 keeping an eye on that is going to be  
21 important.

22                   MEMBER MORTON: I was just going

1 to add my voice to the chorus's, in that I  
2 think the idea is terrific about the summary  
3 table. There's clear criteria that's laid  
4 out, so why not have them put it out there?  
5 And it gives them a better understanding as to  
6 what we do, and it makes it, frankly, a lot  
7 easier to just ratify what's been done. So I  
8 think that's a terrific idea. The other great  
9 idea is "What has happened since," if it was  
10 expert panel. So I totally agree with both of  
11 those.

12 MEMBER BORDEIANOU: I'll just echo  
13 the feeling in the room, that we shouldn't say  
14 "No guidelines, ever." Because at least in  
15 surgical research, you will never have a  
16 randomized controlled study for a lot of what  
17 we do, and so if expert opinion will not count  
18 at all, you'll never have a measure of quality  
19 for surgeons.

20 MEMBER TOBIN: And I guess I don't  
21 want to give the impression that I think the  
22 criteria should be so rigid that if there is

1 compelling expert opinion, that that should be  
2 ignored. I think what I was weighing back and  
3 forth is, I'm not sure during the last few  
4 days if it was always applied evenly. And I  
5 think if I were a measure developer who had my  
6 measure rejected, I might think "Well, gee,  
7 had I had somebody else at the table, they  
8 could have made a really compelling argument."  
9 So it was just sort of this back and forth in  
10 my head, that I was sort of on the side of, if  
11 you were rejected, what would your response  
12 be?

13 CO-CHAIR BASKIN: Thank you.

14 MR. AMIN: And the last set of  
15 questions that we have is more on the  
16 preparation. The overall theme here is the  
17 preparation that staff were able to give you  
18 as steering committee members.

19 So the first question, given the  
20 project timeline, this is slightly tighter  
21 than our general CDP in terms of how much time  
22 you had to review measures. But the amount of



1 project timeline, the volume of information  
2 that we asked you to review, is there any  
3 suggestions that you have in terms of how we  
4 can better disseminate this information to  
5 you, in terms of format?

6 The webinars, I know many of you  
7 had difficulty with the Sharepoint site.  
8 Specific parts of the criteria that you found  
9 particularly difficult to understand? Is  
10 there any better information that we could  
11 distribute to committee members in genera?

12 MEMBER PELLETIER-CAMERON: So,  
13 most of the measures that were distributed to  
14 us were 12, 13 pages, which I think is  
15 reasonable. I mean, that's a volume that you  
16 can reasonably make your way through, given  
17 the number.

18 I just felt that some of them,  
19 although they were 12, 13 pages long, there  
20 were some that had full pages where there was  
21 no information filled out, and I almost felt  
22 bad for the developers that they didn't have

1 a chance to maybe utilize some of that space  
2 to their advantage, whereas there were other  
3 measures that were, again, a hundred and some  
4 pages long -- I'm not sure how that fits in  
5 there.

6 But I think keeping it a  
7 reasonable length is good, but maybe finding  
8 a better way to utilize the space so that  
9 there's not so much blank. And maybe that's  
10 just that they didn't bother to fill it out,  
11 but I think that there'd be -- keeping it the  
12 same length is good, but allowing them to  
13 utilize it better so that there's more there  
14 for us to read. Because more information's  
15 better, but without being excessive.

16 MEMBER SCHOENFELD: I mean, this  
17 is a more general comment, which is that I'm  
18 not totally sure why we combined GI with GU,  
19 except to the extent that I understand that  
20 you probably didn't have enough separate GI  
21 proposals and separate GU proposals to  
22 justify, say, doing this meeting -- I'm

1 assuming -- in terms of maybe having the CMS  
2 representative non-voting, the consumer  
3 representative, et cetera.

4           Having said that, with the way the  
5 proposals were distributed, to a large extent  
6 I'm not sure I contributed a whole lot as a  
7 person who focuses on quality improvement in  
8 colorectal cancer screening to all the GU  
9 discussions. And I'll let my GU colleagues  
10 comment on how much they felt they  
11 contributed.

12           And for somebody like, say, Mr.  
13 Ellis? Sure, have him both days. Have the GU  
14 people here on Monday and the GI people here  
15 on Tuesday. If the issue is a quorum, because  
16 you need a certain number of votes, I think  
17 we're being a little bit artificial here, to  
18 the extent that yeah, maybe I'm a vote in  
19 terms of discussing a GU proposal, but I don't  
20 necessarily think it's a very informed vote.

21           MEMBER GILL: So I think reviewing  
22 all these -- it was a lot of work to review

1       them, but I think what was perhaps even more  
2       taxing for the first time reviewer was trying  
3       to figure out the process.  And I don't know  
4       if it's possible, or maybe there's  
5       confidentiality against it, but actually  
6       providing a whole measure to see how it flows,  
7       so we could just look at it, instead of having  
8       to figure it all out for each step, might have  
9       been easier for me, at least.

10                   MEMBER MARKLAND:  I would just  
11       like to add on one point.  I agree in some  
12       ways with separation of the GI/GU, but I'd  
13       like to see if there's some primary care-  
14       focused measures, maybe have some primary care  
15       impact that has cross-cutting into both of  
16       these areas, I think that would be an  
17       important addition, especially when measures  
18       are being focused in that arena.

19                   CO-CHAIR BASKIN:  Well, I am going  
20       to give my specialty colleagues -- I'm a  
21       primary care doctor -- more credit than  
22       perhaps they're giving themselves.  I honestly

1 think that the GU folks do contribute to the  
2 review of the GI measures, and the GI folks do  
3 contribute.

4           Because, yes, I mean, I've never -  
5 - well, actually, I have done a colonoscopy,  
6 but I've never done a cystoscopy. But there's  
7 -- many aspects of what we discuss aren't  
8 actually -- the knowledge of the actual  
9 procedure itself isn't really so important.  
10 We have our colleagues who are the specialists  
11 to be able to tell us that.

12           But to be able to review evidence  
13 that an assessment improves health outcomes,  
14 I don't think that's specialty-specific, the  
15 ability to be able to review that evidence and  
16 decide whether it meets certain levels of  
17 criteria. Knowledge of whether there's other  
18 evidence available, yes, certainly that's an  
19 issue. And knowledge about any details that  
20 you think are appropriate, we have the ability  
21 to ask each other that.

22           Is it ideal? No. Obviously, if

1 we had 25 GI measures, we could have had an  
2 all GI group, and the other way around, for  
3 GU. And there's no doubt that that would have  
4 been a better way to go if it were as  
5 practical. But I do still think there is some  
6 tremendous value in two specialties  
7 essentially representing themselves and then  
8 helping with the other. I think there was  
9 more contribution than, perhaps, people give  
10 themselves credit for.

11 Johannes?

12 MEMBER KOCH: I'll second Philip's  
13 point. I think that there is a value to  
14 having other ways of thinking about it. I'm  
15 not particularly clear that GI and GU per se.  
16 I think that the GI measures, having primary  
17 care, surgery, is really valuable. I think  
18 that for hepatitis C, you have to have an ID  
19 person.

20 I mean, there are people that  
21 bring a diversity of thought to it. And yes,  
22 we are all academically trained. We

1 understand how to evaluate processes. But in  
2 terms of contributing, I think we're another  
3 set of ears. So to the extent that there's a  
4 number that you need to vote, it feels very  
5 artificial, I have to say.

6 MEMBER MORTON: I was going to  
7 concur, Andy. I like the diversity in the  
8 group, and I like the fact that people bring  
9 in different viewpoints. I think finding the  
10 right mix is always a tough thing, as just  
11 pointed out by Johannes. What is the right  
12 mix? But we have something called Physician  
13 Practice Evaluation Committee, where we review  
14 cases for quality, and we've actually  
15 introduced different members of the hospital  
16 there.

17 And it's kind of interesting,  
18 because the surgeons -- if we review certain  
19 cases, there's an amen chorus that arises,  
20 like "You know, that's going to happen." And  
21 the nice thing is, when you have other people  
22 in the group, you go "Why does it have to

1       happen that way?" And I do think it's  
2       important to bring in diversity, so you don't  
3       bring in an echo chamber. Figuring out what  
4       is the appropriate mix is very important. I  
5       agree, ID would have been ideal. More primary  
6       care. All those come into play. But I like  
7       the diversity.

8                   MEMBER BUTT: Just one  
9       recommendation, since you were asking for how  
10      the information could be presented. I think  
11      a single PDF with all these tables in it as a  
12      cheat sheet would be a good thing to have.  
13      Because I know that they are scattered around.  
14      There's a separate grading PDF document, and  
15      then there are tables within the guidebook,  
16      but there's a lot of information, and if you  
17      are just looking for a quick reference, it's  
18      hard to sort of navigate yourself.

19                   So if there is a single PDF with  
20      all these tables in it -- just the tables. We  
21      understand the concept. We just need to  
22      reference it when you're grading it -- it



1 would be a good thing to have as a sort of  
2 cheat sheet.

3 MEMBER PELLETIER-CAMERON:

4 Speaking from the GU perspective, making my  
5 vote which had equal impact on all these GI  
6 measures -- really, I was acting as a  
7 physician, just an educated academician, on  
8 these topics. I felt that I'm not familiar  
9 with the body of literature, and that the  
10 concept developers didn't give me enough of a  
11 rating of the literature for me to be able to  
12 make an educated vote on it.

13 So I was voting on information  
14 that I don't know anything about, and I'm not  
15 given anything about. So I really felt blind  
16 in that way, whereas with the GU data I'm more  
17 familiar with it. So despite the lack of  
18 developer information, I could make a vote.  
19 But with lack of information on the quality,  
20 I can't guess.

21 MEMBER MERGUERIAN: I, too, think  
22 that diversity is important, because you get

1 a different perspective from people who are  
2 not in the field. But at the same time, I  
3 think standardizing and creating a standard  
4 way of actually creating those measures,  
5 analyzing them, so everything is pretty much  
6 standardized and equal, so that we actually  
7 get the same results every single time, is  
8 important.

9 CO-CHAIR BASKIN: Public comment  
10 about the process and the pilot itself? So if  
11 there's anyone in the room, first of all,  
12 outside of the committee, that wants to  
13 comment on the process, the pilot, and how  
14 this may or may not have worked well, please  
15 feel free to do so. No obligation.

16 (No response.)

17 CO-CHAIR BASKIN: No takers within  
18 the room. Then we would open up the line.  
19 Operator, if you could open up the line for  
20 the public comment? And this would be comment  
21 regarding the pilot itself and how this was  
22 operationalized, and whether this flowed well,

1 didn't flow well, and any potential comments  
2 or suggestions.

3 OPERATOR: Yes, sir. All lines  
4 are open.

5 CO-CHAIR BASKIN: Sometimes I  
6 think that the world has ended when we're in  
7 this room. It should only be so quiet when  
8 I'm at home. Well, thank you all. I think  
9 this ends this. We're just going to go to  
10 next steps and timelines so there's an  
11 expectation before we adjourn.

12 MS. WILBON: I just have a few  
13 wrap-up slides to make sure we're all on the  
14 same page as we depart from each other. So  
15 the next stage, I think everyone's fully aware  
16 now, will be discussing reliability, validity,  
17 which is within the scientific acceptability  
18 of measure properties criterion. And then the  
19 usability and feasibility.

20 We do have dates set for Stage 2,  
21 and I think maybe given some of the feedback  
22 we might see how we can arrange some of the

1 overlap of stuff. We'll have to talk about  
2 it. But anyway, please just save all the  
3 dates on your calendar for now, and we'll be  
4 in contact about further information on that.

5 We'll be taking all the notes that  
6 we have from today and creating a draft report  
7 that will go out for public comment, and it  
8 will likely -- we'll probably send something  
9 out to you to review, and it won't be very  
10 long, just to say that this adequately  
11 represents what we discussed, and then we will  
12 put that up for public comment.

13 I think that's it. Do you have  
14 anything else to add, Taroon?

15 MR. AMIN: I appreciate  
16 everybody's involvement and contributions.

17 CO-CHAIR BASKIN: One quick  
18 question. Just for when we return next time,  
19 is there interest in us having dinner together  
20 the one night we're here when we're here  
21 overnight, or would people prefer to just make  
22 their own arrangements? Obviously, people can

1 make their own arrangements anyway, but for  
2 those interested, are people interested who  
3 are traveling, to try and find a place and all  
4 have dinner together? Or would you rather  
5 split up in your own groups?

6 It seems like there's enough  
7 people that we can at least offer that, and  
8 just ask people ahead of time so we know about  
9 how many people. And then we could --  
10 obviously, there are enough places around. We  
11 could find something.

12 Okay, I just wanted to know if  
13 that was -- another comment?

14 MEMBER BUTT: I was just going to  
15 make another comment about Stage 2, and I was  
16 just thinking about it right now as this was  
17 flashed up. Maybe it would be a good idea  
18 that, as we give the feedback to the measure  
19 developers -- right now it's sort of  
20 unstructured -- that perhaps we could  
21 structure it according to the feasibility,  
22 reliability, those things. Because there are

1 lots of observations that I would have liked  
2 to plug into those sections that they would  
3 then have as specific items. So maybe  
4 formalizing that portion of it in terms of  
5 what is coming up in Stage 2 would be a good  
6 idea, since we're reviewing these and have a  
7 lot of observations which don't fit into this  
8 stage, but it would give the measure  
9 developers very specific feedback that would  
10 prepare them better for Stage 2.

11 MS. WILBON: We actually will be  
12 providing them, in the sense that it will be  
13 structured in a handout, that they'll get a  
14 checklist from us and say "These were the  
15 things that the steering committee suggested."  
16 So we have been documenting what those things  
17 are. But I like your suggestion of kind of  
18 structuring it in that frame of the criteria.  
19 Thank you.

20 CO-CHAIR BASKIN: Well, knowing  
21 that if I keep asking for comments, you'll  
22 keep giving them, I'm not asking anymore.

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(Laughter.)

CO-CHAIR BASKIN: The meeting is  
adjourned. You can comment amongst yourselves  
or with me, if you want.

(Whereupon, the meeting was  
adjourned at 1:50 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Gastrointestinal Endorsement

Before: NQF

Date: 08-28-12

Place: Washington, DC

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