NATIONAL QUALITY FORUM
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PATIENT REPORTED OUTCOMES
WORKSHOP #1
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MONDAY, JULY 30, 2012

The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Patricia Brennan and Joyce Dubow, Co-Chairs, presiding.

DR.S PRESENT:

PATRICIA BRENNAN, PhD, University of
      Wisconsin-Madison
JOYCE DUBOW, AARP, MUP, Co-Chair
RICHARD BANKOWITZ, MD, MBA, FACP, Premier
      Healthcare Alliance
ETHAN BASCH, MD, MSc, Memorial Sloan-Kettering
      Cancer Center
JIM BELLOWS, PhD, Kaiser Permanente

DAVID CELLA, PhD, Northwestern University
      Feinberg School of Medicine
ANNE DEUTSCH, PhD, RN, CRRN, Brookings
      Institution
STEPHAN FIHN, MD, MPH, Veterans Health
      Administration
LORI FRANK, PhD, Patient-Centered Outcomes

      Research Institute
BARBARA GAGE, PhD, MPA, Brookings Institution
TED GANIATS, MD, University of San Diego
      Health System
KATE GOODRICH, MD, MHS, Centers for Medicare
      & Medicaid Services
JENNIFER EAMES HUFF, MPH, Pacific Business

      Group on Health
DENNIS KALDENBERG, PhD, Press Ganey Associates
IRENE KATZAN, MD, MS, Cleveland Clinic

LEWIS KAZIS, ScD, Boston University School of
        Health
UMA KOTAGAL, MD, Cincinnati Children's
        Hospital Medical Center
KEVIN LARSEN, MD, Office of the National
        Coordinator for HIT
KATHY LOHR, PhD, RTI
ELIZABETH MORT, MD, Massachusetts General
        Hospital
CHARLES MOSELEY, Ed.D, National Association of
        State Directors of Developmental
        Disability Services
GENE NELSON, DSc, MPH, The Dartmouth Institute
KENNETH OTTENBACHER, PhD, OTR, The University
        of Texas Medical Branch at Galveston
GREG PAWLSON, MD, MPH, FACP, BlueCross
        BlueShield Association
ELEANOR PERFETTO, PhD, Pfizer
COLLETTE PITZEN, RN, BSN, Minnesota Community
        Measurement
CHERYL POWELL, Centers for Medicare & Medicaid
        Services (via telephone)
DAVID RADLEY, PhD, MPH, Institute for
        Healthcare Improvement
TED ROONEY, RN, MPH, Maine Quality Counts
DEBRA SALIBA, MD, MPH, UCLA Borun
        Center/VA/RAND

MARCEL SALIVE, MD, MPH, National Institutes of
        Health
BARBARA SUMMERS, PhD, RN, University of Texas-
        MD Anderson Cancer Center
KALAHN TALYOR-CLARK, PhD, MPH, National
        Partnership for Women & Families
MARY TINETTI, MD, Yale New Haven Health System

PHYLLIS TORDA, MA, National Committee for
        Quality Assurance
JOHN WASSON, MD, Dartmouth Medical School
ROB WEECH-MALDONADO, PhD, MBA, University of
        Alabama-Birmingham
LINDA WILKINSON, MBA, Dartmouth Hitchcock
        Medical Center

ALBERT WU, MD, MPH, Johns Hopkins Health
        System

NQF STAFF:

KAREN ADAMS, PhD, MT

HEIDI BOSSLEY, MSN, MBA

HELEN BURSTIN, MD, MPH

SHANA CAMPBELL

SHEILA CRAWFORD

EUGENE CUNNINGHAM, MS

LAURALEI DORIAN

LAURA MILLER

ASHLEY MORSELL

ELISA MUNTHALI

KAREN PACE

LINDSEY TIGHE

TOM VALUCK, MD, JD

JESSICA WEBER

C-O-N-T-E-N-T-S

Richard Bankowitz, Premier Healthcare
Alliance
Lori Frank, Patient Centered Outcomes
Research Institute

Moderator: Albert Wu, Johns Hopkins Health
      System
      David Cella
Reactor Panel:
      Jim Bellows, Kaiser Permanente
      Eugene Nelson, Dartmouth-Hitchcock
      Medical Center
      Kalahn Taylor-Clark, National
      Partnership for Women & Families
      Kenneth Ottenbacher, The University of
      Texas Medical Branch at Galveston
PROs INTO ELECTRONIC HEALTH RECORDS
Moderator: Patricia Brennan
      David Cella

Reactor Panel:
      Kevin Larsen, Office of the National
      Coordinator for Health Information
      Technology
      Ted Rooney, Maine Quality Counts
      Uma Kotagal, Cincinnati Children's
      Hospital Medical Center

Patricia Brennan & Joyce Dubow, Co-Chairs

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

 2   (9:04 a.m.)

 3   DR. BURSTIN: All right, everybody,

 4   we're going to go ahead and get started. Good

 5   morning. I'm Helen Burstin, the Senior Vice

 6   President for Performance Measures at NQF.

 7   Thank you so much for joining us today and

 8   tomorrow. We're very excited about this

 9   meeting that has been long in planning, and I

10   think will really offer us a great opportunity

11   to think about this next stage of measurement

12   that we all want to enter.

13   I'll do the introduction to the

14   group, and then I'll turn it over to our

15   incredibly capable Co-Chairs, Patti Brennan

16   and Joyce Dubow, who will serve as your

17   hostesses and keep the train moving through

18   the next couple of days.

19   I just want to personally thank

20   the two Karens who many of you have interacted

21   with, Karen Adams and Karen Pace, and all of

22   our staff, and Gene Cunningham in particular

1 who have just done a phenomenal job of pulling

2 this together.

3   So, I get to set the stage, and

4 part of the reason for setting the stage is

5 that we really want to try to, as best as

6 possible, try to make a distinction between

7 tools and measures. So, I think that's an

8 important issue for us. So, next slide,

9 Jessica.

10   So, briefly, a little bit about

11 the project scope and the activities before I

12 turn it over to Patti.

13   OPERATOR: Excuse me. This is the

14 conference Operator. You're not in the main

15 conference.

16   DR. BURSTIN: Oh, could you please

17 put us in the main conference, Farah. That

18 would be lovely.

19   OPERATOR: Okay, one moment.

20   DR. BURSTIN: All right. Great.

21 Good morning, everybody joining us on the web.

22 We prematurely started without you for a

 1 couple of moments but welcome.

 2   This is Helen Burstin. I'm just

 3 going to give a little bit of the project

 4 background before I turn it over to the Chairs

 5 for this workshop. So, briefly, a little bit

 6 about the project scope.

 7   The first is that this meeting, in

 8 particular -- many of you who have spent time

 9 at the NQF tables know we tend to talk about

10 endorsement of measures. Well, today we're

11 talking about the methodologic issues, almost

12 really a prequel, we think, to what will

13 ultimately, we hope, be some further work on

14 endorsement in the coming years.

15   So, essentially, our project scope

16 is under the guidance of the expert panel,

17 essentially, all of you in the room, we're

18 going to have these two workshops to help

19 bring together the stakeholders we think are

20 necessary to really facilitate the critical

21 path, the groundwork we need to get to the

22 development, testing, endorsement, and

 1   implementation of PRO-based performance

 2   measures, a pretty heavy lift from I think

 3   where we are now. But I think we felt that

 4   since there were so many methodologic issues

 5   that needed to be resolved, it was difficult

 6   to take a big leap and just call for these

 7   measures without really putting everybody on

 8   the same place, and really beginning to

 9   understand what the next steps would be.

10   You'll have the benefit of two

11   Commission papers, the first of which you have

12   today, thank you to David Cella and his team,

13   on the first one to think through next steps

14   about the selection of patient-level PROs for

15   use in performance measures. And the second

16   one which we'll get to in the fall will be the

17   path to developing reliable and valid PRO-

18   based performance measures that would, in

19   fact, be eligible for NQF endorsement, and

20   could be used for both accountability and

21   quality improvement.

22   Thanks to HHS for funding this

1   work. We think it is really important, and

2   we're really glad to be here. Jessica, next

3   slide.

4   So, just briefly, the time line to

5   give you a sense of where we're going, I've

6   given you a little bit about that today. So,

7   the workshop is today in July. We're going to

8   be working, the paper writers are here with

9   us. They're going to actually work through

10   some revisions of the paper based on the input

11   that you'll be providing over the next couple

12   of days.

13   We'll have the chance to prepare

14   that draft report, get a chance to hold that

15   second workshop. Here are the dates, September

16   11th and 12th, at which point we'll have a

17   second paper from Barb Gage and Anne Deutsch

18   of RTI. That one will be much more grounded in

19   how to move into performance measures. We'll

20   have a public comment period from October to

21   November. We'll get the expert panel, all of

22   you again to review those comments, finalize

1   the papers and then bring them through our

2   approval process before the end of the year.

3   Next slide.

4   So, a little bit about putting

5   this in context. We often talk about the

6   Quality Measurement Enterprise. And one

7   important thing I want to mention is the top

8   gold bar there is measure development. It's

9   outside the realm of the others, and that's

10   because very important distinction for NQF is

11   we are not measure developers. We do not

12   develop measures. It's a really important

13   firewall for us, because we are the neutral

14   evaluators of measures. But this does give you

15   a broad sense of how this work fits into the

16   broader landscape of the measurement

17   enterprise.

18   The National Quality strategy has

19   clearly indicated a goal for having more

20   patient-reported outcomes. There is a

21   standardized measurement process that we'll

22   talk a great deal about in the coming months

 1   that leads to NQF endorsement. But we also

 2   recognize it would be very difficult to do

 3   much of this without the emerging electronic

 4   data platform, also part of the work that

 5   we've been doing, trying to then think about

 6   the alignment of the various environmental

 7   drivers, how do people select measures, how do

 8   people find the right measures they want to

 9   use. And then, ultimately, evaluating and

10   seeing if these are driving both improvement,

11   as well as improved accountability. Next,

12   please.

13   So, just a high-level view, I

14   think, of where we're sitting in terms of what

15   we've been viewing in terms of performance

16   measurement.

17   The first is, there's definitely

18   been a drive towards higher performance. I

19   think as our criteria have gotten more and

20   more rigorous, we are beginning to see a good

21   number of the very basic process measures

22   falling to the wayside in favor of some of the

1 more difficult intermediate outcomes and

2 outcome measures which we think is very

3 positive.

4   I think there is a hope that with

5 more of a data platform we'll be able to

6 increasing measure disparities in all we do,

7 as opposed to the afterthought it often tends

8 to be now. If we have the data to always

9 stratify, then we insure that we do that in a

10 rigorous way.

11   We're seeing more of a shift

12 towards composite measures rather than single

13 process measures or single outcome measures,

14 trying to get a more complete picture.

15 Consumers and purchasers, in particular, find

16 these measures very, very valuable, and

17 clinicians and others find them useful when

18 they can be packaged, but still get the

19 broader view, and lots of different models of

20 this.

21   A major part of our work over the

22 last couple of years has really been about

 1   harmonizing measures. There is a lot of

 2   cacophony currently in the measurement space

 3   of measures that are just slightly different

 4   across different settings of care, slightly

 5   different for different payers, public and

 6   private. So, a great deal of our effort

 7   currently has been around trying to make sense

 8   of some of this, bringing them together,

 9   having a more parsimonious set.

10   And then, finally, there's been a

11   great deal of interest in moving towards a

12   more longitudinal view of what we can do in

13   measurement rather than everything being very

14   siloed of what I do in clinic on Mondays

15   versus what others do in the hospital, versus

16   the patient's experience at home care, really

17   making it a more longitudinal view. And if you

18   do that more patient-focused episode it does

19   naturally lead you towards outcome measures.

20   That's what patients care most deeply about,

21   and especially I think patient-reported

22   outcomes, in particular. Am I actually going

 1   to feel better as a result of this procedure,

 2   or measures along those lines.

 3   If they are process measures,

 4   increasingly there is a move to make sure

 5   they're process measures that have a direct

 6   impact on the desired outcomes. It also moves

 7   us towards more measures of appropriateness,

 8   and in this day and age hard to imagine that

 9   we could look at quality in isolation without

10   increasingly now bringing in measures of cost

11   of resource use to couple them with quality

12   measures including a view of overuse.

13   So, we had some work done a couple

14   of years back now that Karen Pace led for us

15   with David Shahian as chair of an evidence

16   task force. And this was one of the, I think,

17   really important pieces of work that emerged,

18   was a very clear hierarchical preference for

19   NQF for outcomes, as much as possible, linked

20   to evidence-based processes, outcomes of

21   substantial importance with a plausible link

22   to processes of ways to improvement, although

1 not necessarily. And then if they are going to

2 still continue to have process measures or

3 structural measures, they need to be closely

4 linked to outcomes. They can't be things so

5 distal from the outcome that just continually

6 measuring and improving those won't ultimately

7 improve what we care most about. Next, please.

8   So, this is just a visual view. We

9 have two visual views of it for those of you

10 who think differently, see things differently.

11 So, this is what we did last year of analysis

12 of our portfolio, breaking it down by process

13 and outcome measures.

14   And I realize this might be a bit

15 difficult to read, but just -- as you could

16 see from the lefthand side there are more of

17 the classic areas that have been in

18 measurement for years; prevention,

19 cardiovascular disease, safety, surgery,

20 musculoskeletal are the ones at the top of

21 that pinnacle there.

22   And as you start going down, you

 1 get to the very small ones towards the bottom

 2 there which, unfortunately, include patient

 3 experience and engagement and functional

 4 status. That's two of the lowest at the end

 5 there.

 6   We also broke it down into process

 7 and outcomes, so we're actually pleased to see

 8 more of that movement towards outcomes.

 9 Actually, about a third of our portfolio now

10 is outcomes as opposed to process measures and

11 structural measures.

12   And the blue here are outcomes.

13 And you can see that in some of the areas

14 there are certainly more process measures than

15 outcome measures. I think work we're going to

16 continue to work on, but in some areas, for

17 example, like surgery, way ahead in terms of

18 thinking about outcomes as opposed to more

19 process fields linked medicine which is my

20 next.

21   And this is a different view of

22 it, very similar, but this is the way we break

1   down our portfolio into what's crosscutting

2   and what's condition-based here. The white are

3   process measures, the blue are outcome

4   measures.

5   And just very briefly in this

6   lower box here, functional status, patient

7   engagement. So, two of the very, very

8   smallest boxes on that overall chart of our

9   over 700 measures now relate to those two

10   topic areas that we think in particular are so

11   important here. And those are, of course,

12   outcomes, and we want to try to get more of

13   those across the portfolio. Next.

14   So, before I hand it over to Patti

15   just one quick, I think, distinction that is

16   always difficult to transmit. We're going to

17   probably need to do this a couple of times

18   during the course of the meeting. So, the

19   first is that people often talk about

20   individual-level PROs, and then they talk

21   about performance measures. And they are, in

22   fact, different, and we need to make that

 1 distinction.

 2   So, the first is, NQF doesn't

 3 endorse individual-level instruments or

 4 scales. We wouldn't endorse, for example, the

 5 SF-12, or a tool like that in isolation. It

 6 would need to be as part of a performance

 7 measure. So, although they may be very

 8 reliable, highly valid in clinical practice or

 9 research, those individual patient scores

10 alone are not sufficient to really determine

11 performance of a given entity, or make

12 conclusions about the quality that's provided.

13 But we recognize those individual-level scores

14 are the data that are going to drive the

15 performance measures. What we do endorse,

16 though, are those performance measurements

17 that result in a score for the accountable

18 entity, a hospital, a practice, an ACO,

19 whatever the case may be and use data from all

20 those eligible patients.

21   So, at the same time, an endorsed

22 performance measure needs to be standardized,

 1   precisely specified so that the specific

 2   instruments and scales and scoring must be

 3   identified. So, these are highly linked, but

 4   at the same time, identifying just the PROs

 5   won't get us to where I think we need to go in

 6   terms of performance measures. Next.

 7   And just to put this in perhaps a

 8   bit more concrete terms, here's two examples

 9   of two measures we've endorsed in the last

10   year. The first was for Minnesota Community

11   Measurement. I know Collette is here with us

12   today, which is about use of the PHQ-9, which

13   is a tool to gauge depression. And we've

14   endorsed three measures, the first of which is

15   actually utilization of the question there in

16   the first place in clinical practice paired

17   with one of these two measures, depression

18   remission at six months, or depression

19   remission at 12 months. So, we have not

20   endorsed the PHQ-9. We've endorsed the

21   performance measure that uses the PHQ-9.

22   Similarly, a very recently

1   endorsed measure from American Academy of

2   Ophthalmology looks at visual function, and it

3   was the improvement in patient's visual

4   function within 90 days following cataract

5   surgery defined using the VF-14.

6   Again, we have not endorsed the

7   VF-14. That is a very well validated NIH tool,

8   but we have endorsed the measure that looks at

9   the degree of improvement. So, just to kind of

10   give you that sense of distinction.

11   It is something that we often find

12   ourselves flipping back and forth. NQF has

13   endorsed CAHPS. Well, NQF has endorsed the

14   tool -- has endorsed the measure that uses

15   CAHPS but we don't endorse the actual tool

16   itself.

17   So, I think with that, hopefully,

18   I haven't confused you completely. I'm going

19   to turn it over to Patti. So, next slide,

20   Jessica.

21   CO-CHAIR BRENNAN: Thank you very

22   much, Helen. I want to thank Helen, Karen Pace

1 and Karen Adams for the work they did to get

2 us to this point, and Eugene Cunningham

3 wherever you are for the work you've been

4 doing.

5   I am delighted -- yes, can you

6 hear? Can't hear. Okay. That's never been said

7 of me before, thank you. I'll try to speak

8 louder. I do have a Philadelphia slur. I

9 apologize.

10   I want to thank Helen, Karen Adams

11 and Karen Pace, and Eugene Cunningham for

12 their work that they've done to bring us here.

13 And I want to thank all of you here and on the

14 web for your work on the NQF, and particular

15 in patient-reported outcomes. It's a critical

16 part of the outcome assessment, and now we're

17 bringing the patient into the loop.

18   The purpose of our workshop is to

19 remind and to expand the idea that patients

20 are a valid and valuable source of outcomes.

21   Now, today we're going to be

22 focusing on identifying some of the

1 methodological issues related to patient-

2 reported outcomes.

3   Remember, as Helen first

4 introduced, that there are individual level

5 patient-reported outcomes. How are you feeling

6 today? How much are you able to walk? Can you

7 carry your groceries? Can you play with your

8 grandchildren? These are outcomes the patients

9 may know about and care about, but to

10 translate them into performance measures that

11 tell us about the ability of an institution to

12 provide care requires that we attend to the

13 methodological issues.

14   Individual-level patient-reported

15 outcomes are valuable to the patient and to

16 the clinician, the individual clinician. They

17 inform the care process, they provide patient

18 feedback and a guide for self-monitoring. And,

19 importantly, they can be contributory towards

20 shared decision making.

21   We're focusing on the second half

22 of this slide today, the aggregate level, the

 1   performance measure where we're identifying

 2   performance measures that can be used for two

 3   different purposes in health care; first of

 4   all, for quality improvement, to help an

 5   organization, a practice, a group of

 6   clinicians know how to improve. And, secondly,

 7   for accountability, public reporting,

 8   transparency, payment determinations.

 9   Now, we're going to be having a

10   lot of opportunity for your participation and

11   feedback today so get ready throughout the

12   agenda. You see opportunities for audience

13   engagement, and one will be coming your way in

14   just a few minutes.

15   I'm going to turn the podium over,

16   though, to Joyce Dubow who is our Co-Chair.

17   I've been delighted to work with Joyce. I

18   haven't worked with her before and she brings

19   a perspective from the AARP, and a citizen's

20   perspective on patient-reported outcomes. It's

21   extremely helpful to us. Thank you, Joyce.

22   CO-CHAIR DUBOW: Thanks, Patti. And

1   I want to add my welcome to everybody. And

2   it's a pleasure to have such a knowledgeable

3   Co-Chair. But, again, thanks to the staff,

4   they've been really terrific.

5   So, what you see here is the

6   famous bubble diagram. Can't hear? Okay,

7   sorry. Is that better? Okay. I've never had

8   that problem either. Gee, I have to tell my

9   kids.

10   So, this is the famous NQF bubble

11   diagram that describes the person-centered

12   episode of care. And it is a person-focused

13   model that demonstrates the episode from

14   looking at the population at risk through

15   follow-up care, and the various trajectories

16   that would depend on each individual.

17   Helen talked about the need to

18   look at patient-reported outcomes with a

19   longitudinal perspective, and this diagram

20   essentially helps us conceptualize and see

21   that framework graphically. And it takes in

22   health behaviors, health quality of life,

 1   functional status behaviors, et cetera.

 2   The next slide, please, helps us

 3   identify very clearly what our objectives for

 4   today's and tomorrow's -- this is today's

 5   objectives, and tomorrow's. This is the --

 6   these are the objectives of the workshop, and

 7   they are very clearly presented here.

 8   We want to be able to identify

 9   best practices and lessons learned from

10   initiatives that are already underway looking

11   at individual-level PROs in performance

12   measurement.

13   We want to discuss the major

14   methodological issues related to the

15   selection, administration, and use of the

16   individual-level PROs in performance measures.

17   We want to discuss key

18   considerations for inclusion of PROs in EHRs,

19   so we need to focus on how this stuff gets

20   integrated into electronic records.

21   We want to identify the

22   characteristics of individual-level PROs

 1   suitable for potential use in performance

 2   measures, and we want to identify the

 3   additional set that would be most suitable for

 4   further development.

 5   The key here is going to be the

 6   interaction and the discussion that this group

 7   that we get from everybody -- thank you,

 8   there's a good person back there who is --

 9   thank you.

10   It's very important for us to have

11   an interactive conversation today. Everybody

12   here brings something very important to the

13   conversation, so we want to encourage you to

14   participate and to share your knowledge and

15   your views so that we can move this effort

16   forward.

17   And with that, we have an

18   opportunity to hear from you. Are there any

19   questions or any observations about anything

20   you've heard so far before we get started with

21   out first panel? Karen?

22   KAREN: No, I was going to say

 1   let's go ahead and take a few questions.

 2   CO-CHAIR DUBOW: Is there anybody--

 3   (Off microphone comment.)

 4   CO-CHAIR DUBOW: Can you identify

 5   yourself, please? And we can't hear you.

 6   MS. KELLER: San Keller, American

 7   Institutes for Research, and there's an

 8   inherent tension between the longitudinal view

 9   of having the measure standardized over --

10   patient-centered but standardized over

11   different applications, and the definition of

12   the measure at the unit level. So, the units

13   are going to differ as the patient moves

14   through the system.

15   CO-CHAIR BRENNAN: I'm sorry that

16   engineering degrees doesn't work inside the

17   Beltway.

18   If I'm understanding the comment

19   directly, your remark is that a longitudinal

20   view of measures is following a patient

21   through a number of different episodes of care

22   at different points of care. So,

1 methodologically you're asking us to consider

2 how different contributors to the care process

3 can be appraised or evaluated by a single

4 point measure -- a single set of measures

5 across a number of points. And I think -- did

6 I get your comment correctly? Thank you.

7   (Off microphone comment.)

8   CO-CHAIR BRENNAN: Right. And when

9 you refer to units you mean sites of care as

10 opposed to units of measure. So, I think

11 that's a very important consideration, and

12 that's something we will need to be returning

13 to over the next two days.

14   CO-CHAIR DUBOW: Anybody else?

15   MS. LENTZ: Hi, Lisa Lentz, Centers

16 for Medicare and Medicaid Services. And I work

17 mainly on accountable care organizations and

18 physician and group-level outcome measure

19 development. And one thing that we've been

20 thinking a lot about is provider attribution,

21 particularly when we're talking about patient

22 reported outcomes that would be holding

1   individual physicians and groups accountable

2   because, of course, the providers are only

3   seeing patients in the office in a limited

4   time, and then the patient goes off, and they

5   adhere or they don't. So, I guess, what I'm

6   hoping that we can talk about in the next two

7   days, too, is about attribution, and how we

8   actually tie those outcomes back to the care

9   that patients are receiving.

10   CO-CHAIR BRENNAN: Thank you. If we

11   could have people go back to this corner area

12   where there's a microphone, I think that --

13   DR. GANIATS: This one works.

14   CO-CHAIR BRENNAN: Good, thank you.

15   DR. GANIATS: And no one has ever

16   said that to me before that they could hear my

17   voice. This is Ted Ganiats, University of

18   California-San Diego.

19   I think that one of the issues

20   that's interesting is that usually we have a

21   clinical measure that is valid at a clinical

22   level, and we try to aggregate them into a

 1   performance measure. And sometimes there is a

 2   problem because of issues related to are the

 3   patients the same from one institution to

 4   another, et cetera.

 5   Here we're dealing with measures

 6   that may or may not be applicable at an

 7   individual level. Many PROs have scoring

 8   mechanisms that are designed based on

 9   populations of patients and they are not

10   relevant at the individual level, some of them

11   are. So we have that fundamental difference

12   between PROs and most of what makes up

13   performance measures. Plus, we have the other

14   issues that make -- relate to the

15   generalizability, so it will be interesting to

16   see how we can capture that additional element

17   of complexity.

18   DR. LOHR: Can you hear me with

19   this mic? Okay. I'm Kath Lohr from RTI. And I

20   wanted to go back to a couple of your meeting

21   objectives which are really the last two

22   points, which I think are more for tomorrow.

1   I was curious to know whether when

2   you say you want to identify characteristics

3   of individual-level PROs, whether you're after

4   sort of criteria for choosing them, whether

5   you're meaning to have a family of attributes

6   for such measures and factors that would sort

7   of be pro or against selecting them. I just

8   want to clarify that that's kind of what you

9   mean when you say "characteristics."

10   The last bullet is to say pick an

11   initial set, but then I thought I heard Joyce

12   say maybe to pick an additional set, so

13   somewhere along the line today I'm wondering

14   if you could clarify a bit more what you're

15   after, because clearly you have plenty of

16   outcome measures from your earlier slide. And

17   I wasn't sure whether you're meaning to say

18   well, let's find some other ones, or we're

19   starting from scratch.

20   MS. PACE: I'm Karen Pace. And just

21   -- you're right on your first question that

22   we're looking -- when we say

 1   "characteristics," we're talking about

 2   criteria or attributes. We did not use the

 3   term "criteria" because we have criteria for

 4   our performance measures, and we wanted to

 5   make a distinction, but it's -- essentially,

 6   you're right. What are the things that would

 7   make an individual PRO something we should

 8   consider for inclusion in a performance

 9   measure?

10   And it is an initial set. As Helen

11   mentioned a couple of examples, we only have

12   a few patient-reported outcome measures as

13   performance measures. We have many more

14   outcome measures that are more clinical in

15   nature, but we are looking now to identify

16   those from patient-reported outcomes.

17   DR. LOHR: Thank you.

18   MR. YANG: Hi, Mr. DerShung Yang

19   with BrightOutcome. And I just want to get

20   clarification on the use of the term "PRO."

21   Are you we referring to specifically only

22   those tools that were assessed by patients

 1 themselves, or are we also including those

 2 that are assessed by providers or care givers

 3 or some other proxies?

 4   CO-CHAIR BRENNAN: At the present

 5 moment, the focus is on tool or observations

 6 that the patient individually makes, not an

 7 interpretation by a professional or anyone

 8 else. Thank you.

 9   CO-CHAIR DUBOW: Thank you for that

10 clarification. It's important. Linda?

11   MS. WILKINSON: Yes, Linda

12 Wilkinson from Dartmouth-Hitchcock. I'll be

13 very interested as the conversation unfolds to

14 see how we acknowledge the different cultures

15 and climates in which these measurements are

16 taken, and such symptoms of cultural behavior

17 as things like what sort of support is given

18 the patient to enable them, or to encourage

19 them to report, et cetera. I mean, I'm sure

20 these things will come up but that's of great

21 interest. Thank you.

22   CO-CHAIR DUBOW: Thank you.

 1   DR. GOODRICH: This is Kate

 2   Goodrich from CMS, and this builds off of that

 3   last comment, and also a little bit off of

 4   what my colleague, Lisa Lentz said.

 5   One thing I'd be interested in

 6   hearing about, although I think it may be a

 7   little outside the scope of what we're talking

 8   about today is the issue of provider buy-in to

 9   these types of measures. So, to the extent

10   that people who have -- that we're going to

11   hear about lessons learned. I think it would

12   be very helpful for us at CMS, and also just

13   us within the room to understand how

14   providers, whether it be physicians, or group

15   practices, or facilities, how they -- if they

16   did, and if so, how they developed buy-in into

17   these types of measures. I think that's a

18   major barrier, a major hurdle to the use of

19   these types of measures.

20   You know, eventually even if CMS

21   requires over time the use of these types of

22   measures we still would like to be thinking

1 about how we can do that, and how within the

2 construction of the measure, the

3 identification of the measure topic, that can

4 lead to better clinician buy-in.

5   CO-CHAIR DUBOW: An important

6 topic. I think we may get to that during the

7 first panel. We need to wrap-up. I want to

8 take one more. Who's got the mic? Oh, Albert.

9   DR. WU: Albert Wu from Johns

10 Hopkins. Just to clarify sort of the previous

11 question. So, PROs are obviously from the

12 individuals themselves, and not the clinician.

13 But are we excluding, for example, parents,

14 reported measures for children, since -- and

15 then, therefore, are we excluding all child

16 measures that are not directly from the child?

17   CO-CHAIR DUBOW: Proxies count.

18   DR. WU: Proxies count.

19   CO-CHAIR DUBOW: It's one of the

20 challenges, but we need to study that, and the

21 first paper addresses some of the issues

22 around proxies, but that's within scope.

 1   CO-CHAIR BRENNAN: Yes. I'd like to

 2   make sure that we recognize the origin is an

 3   individual who received care. Yes? Speak up

 4   more. The focus is the individual who receives

 5   the care service, and it may be through a

 6   proxy. We'll have to consider issues about

 7   family care givers for individuals unable to

 8   respond for themselves. And we will be hitting

 9   up against the boundaries that might be a

10   little fuzzy. If it's observed by a parent as

11   opposed to observed by a clinician, for

12   example. We'll have plenty of time to talk

13   about that in the next panel, though. Thank

14   you.

15   MS. PACE: Okay. We're going to

16   move to transition to our first panel, and

17   Joyce Dubow is the moderator.

18   Just one note from Patti, that we

19   didn't really introduce or give you logistics.

20   Those of you who need restrooms, they're out

21   across the hall through the other doors on the

22   other hallway, and there is coffee in the

 1   back. And we'll also have a break in a little

 2   while, but we'll go ahead and get situated.

 3   CO-CHAIR DUBOW: This is our first

 4   panel, Acknowledging the Patient as an

 5   Authoritative Source. I want to point out that

 6   the Planning Group -- is that better? Can

 7   everybody hear me? The Planning Group felt

 8   that it was very important to start out with

 9   this topic for the workshop just to reinforce

10   the importance and the authoritativeness of

11   patient-reported outcomes as a source of

12   important data in health care.

13   So, not only is the patient a

14   source of information about her own

15   preferences, for example, but also about --

16   sometimes a unique source, also about

17   functional status, quality of life, pain, et

18   cetera. Sometimes patients are the only source

19   of information, but we wanted to reinforce

20   that by starting out with this topic.

21   We think that generally this is a

22   view that's shared by everybody here, but just

1   for the record, that's just what we had in

2   mind.

3   We've already addressed the fact

4   that patient-reported outcomes have multiple

5   uses in addition to an expression of

6   preferences, for example. Patient-reported

7   outcomes can be used in quality improvement,

8   public reporting, payment programs, so they

9   have important functions and play an important

10   role in the measurement process.

11   We've just heard that there are

12   challenges to taking some of these validated

13   clinical instruments and making them into

14   valid performance measures. And that's what we

15   need to tackle with. Today we have a panel

16   that represents important perspectives in

17   addition to the author, who's going to give us

18   an overview, the author of the first paper who

19   will give us an overview of the range of

20   topics that the paper discusses. The three

21   perspectives coming from the disability

22   community, a provider perspective, and a

1   purchaser perspective are very important.

2   What we want to do is to tackle

3   these challenges, address them so that we can

4   move forward. If there is agreement that this

5   -- that patient reported outcomes really

6   represent an authoritative and valid source of

7   data, we have to figure out how to move to the

8   next steps. And that's what we hope to

9   achieve.

10   So, we have, like I say, we have a

11   very, very talented panel. Their bios are in

12   the materials that you've received. We're

13   going to start out with an overview from the

14   author of the paper, David Cella, one of the

15   authors. And we're going to go from there to

16   Charles Moseley of the National Association of

17   State Directors of Developmental Disability

18   Services, Steve Fihn from the VA, and

19   Jennifer-Eames Huff from the Consumer

20   Purchaser Disclosure Group and PBGH.

21   So, David, will you begin, please.

22   DR. CELLA: Good morning. Thank

1   you, Joyce. Do I ask you to advance or can I

2   advance from here? Okay, there's the first

3   one. Thank you.

4   So, you've all been sent a paper,

5   a draft of a paper, and I think I had a list

6   of contributors to the paper before this

7   slide. Is it not on this set? Okay. There we

8   go. I really want to show this first.

9   To those of you who said

10   congratulations on a nice draft, these people

11   deserve as much or more credit as I do. I get

12   to be the one standing here, but Beth Hahn,

13   Sally Jensen, and Zeeshan Butt, Cindy

14   Nowinski, and Nan Rothrock all contributed a

15   lot to this paper, so I want to acknowledge

16   them. To those of you who think the paper is

17   terrible, I'll take the full blame for that.

18   Next slide, please, or two slides.

19   So, I think the first question --

20   and I know whenever I work, which I don't

21   often do, but whenever I work with people in

22   the performance measurement field, the first

1   question I get either explicitly or implicitly

2   is why can't we just ask the clinicians? It

3   would be a lot easier, a lot cheaper. We know

4   our patients, why can't we do that?

5   Apart from the issue of possible

6   bias and conflict of interest in asking

7   doctors how their patients are doing when

8   they're going to be paid based upon their

9   answers, independent of that in the

10   literature, research literature there's a vast

11   amount of support that demonstrates that

12   clinical providers unfortunately don't

13   accurately capture outcomes that are only

14   logically obtained by direct patient query.

15   Certain symptoms, certain functional areas,

16   I'm afraid to say you have to ask the patient.

17   Next slide, please.

18   This is actually some work from

19   Ethan Basch, who's one of the moderators later

20   this morning just showing -- it's looking at

21   various symptoms associated with cancer

22   treatment. In the middle is agreement, that's

1   the light bars. On the left is where the

2   patient says it's worse than the doctor. On

3   the right is where the doctor says it's worse

4   than the patient. You get the impression here

5   pretty consistently that the error is in favor

6   of the patient acknowledging more problems

7   than the doctor or clinician seems to realize

8   or report on adverse events.

9   Now, these are people being asked

10   to rate the same thing, fatigue, pain, et

11   cetera. So, there is bias, and the bias tips

12   toward patients identifying more problems and

13   more issues than providers either are aware of

14   or report. Next slide.

15   And also, there's also work in

16   cancer done by Deb Bruner. When you look at

17   the correlation of adverse events, which is

18   what Ethan's study looked at with quality of

19   life, that is the broader sense of well being

20   and functioning, there's very little

21   correlation between the symptoms that patients

22   have associated with treatment or their

 1   adverse events and their overall general

 2   functioning and well being. So, for several

 3   reasons it's really important to get this

 4   information from the patient. And I realize

 5   this may be the choir, but it's an important

 6   choir. And if I can help with this refrain

 7   please let me know. Next slide.

 8   So, what's the potential for PRO

 9   use in clinical care? Well, there are many

10   which I'll run through. You can assist

11   providers in care management, you can enhance

12   efficiency as opposed to the myth that you

13   actually interfere with efficiency, you can

14   improve communication. This is usually at the

15   top of the list, identify patient needs in a

16   more timely manner, sometimes being able to

17   intervene more quickly and prevent problems,

18   and facilitate an atmosphere of patient-

19   centered care.

20   Despite all these possible

21   opportunities or advantages, routine care

22   assessment is still not common in clinical

 1 practice. Next slide.

 2   One area that's gotten pretty

 3 common is the patient experience of care,

 4 largely I think because of the endorsement and

 5 paying processes around getting information on

 6 the patient experience of care through CAHPS

 7 and other measures. So, broadening from

 8 patient satisfaction where there are questions

 9 like did your doctor seem to understand what

10 was important to you? Were you satisfied with

11 your visit? There is an extension in CAHPS to

12 things like reports of actual experience. For

13 example, in the last 12 months when you phoned

14 the provider's office during regular hours how

15 often do you get an answer to your questions

16 that same day? So, a very and much more focus

17 on the experience of care in a very drilled

18 down way, which I notice the all blue -- I

19 think it was the only all blue bar in that

20 figure that Dr. Burstin showed. Next slide.

21   Clearly, this is an area where

22 we're getting the information from patients

1   now. So, this concept of patient-centered

2   care, originally Epstein's concept, I think

3   has caught on in the minds of many, and as

4   implemented some places better than others,

5   involves a partnership between the informed

6   and activated participatory patient and family

7   member with an accessible and organized

8   responsive health care system that produces

9   better, more patient-centered and oriented

10   communication, that then logically would

11   improve health outcomes. So, this is the model

12   for why we would think we would want to do

13   this. Next slide.

14   Now, there are barriers. They've

15   been alluded to, and we're going to start to

16   talk about them throughout the day. Some of

17   the current practices or best practices to

18   minimize self-report barriers including

19   selecting an appropriate method and mode of

20   administration for your context, doesn't mean

21   that there's one-size-fits-all. In fact,

22   that's not the case that one-size-fits-all.

1   It's important to consider things like the age

2   of the patient, the functional status of the

3   patient going into an episode of care,

4   especially when you consider longitudinal

5   evaluation over time, and the cognitive

6   capability of the patient, whether because of

7   age or because of disease or disability as

8   those relate to your likely need for use of

9   proxies and assistive devices in helping the

10   patients provide information on their own

11   behalf.

12   In designing instruments, people

13   that use universal design principles that are

14   published and available tend to produce better

15   instruments. There are accepted and approved

16   methods for translating and culturally

17   adapting questionnaires so that they are more

18   likely to produce valid results across

19   different groups whether by language or by

20   culture, or by reading level. And you can

21   produce equivalent versions across these very

22   important sociodemographic and cultural

 1   differences that our patients manifest.

 2   There needs to be flexibility in

 3   the location from which you get the

 4   assessment, and sometimes there are

 5   differences based upon the location, white

 6   coat hypertension, for example, versus

 7   influences at home, maybe someone is cheating

 8   and having a family member help them at home.

 9   These are all issues that come up when you do

10   things -- the assessments in the clinic, at

11   the home, or at some facility, say a nursing

12   home or hospital.

13   It requires access to the

14   technology. If you're choosing to use an

15   electronic technology, then people -- if you

16   choose to do it at home people have to have

17   internet access, or some ability to get to

18   that technology. Or if it's telephone

19   technology, they have to have a phone.

20   And in every setting, particularly

21   the at-home settings health information

22   privacy and security have to be considered and

 1   protected.

 2   It's also important within that to

 3   address functional literacy, and health

 4   literacy. They're somewhat distinct, and

 5   they're critical really to delivering person-

 6   centered health care. The next slide has an

 7   illustration, a diagram of that.

 8   You can divide literacy and

 9   technology skills, and consider patients not

10   just in terms of their literacy by doing a

11   rapid literacy test, but whether they have

12   oral literacy; that is, being able to listen

13   and hear what someone is saying, process oral

14   information and speak back in conversation,

15   written literacy, and reading literacy. And

16   even reading literacy is divided into PROs,

17   that is being able to read some text and

18   understand what it's saying. Document

19   literacy, can you sort out figures and graphs.

20   You know what percentage means? Do you know

21   what probabilities are? And quantitative

22   literacy, as well, which gets into this

1   numeracy issue.

2   And then on the technology side,

3   if one moves as I would personally advocate to

4   an electronic environment whenever possible,

5   we need to make sure that people have

6   appropriate computer skills or other media

7   skills that might help give them assistance in

8   completing questionnaires, perhaps by reading

9   questions out loud to them if their oral

10   literacy is better than their reading

11   literacy. Next slide.

12   So, continuing on with practices

13   to minimize barriers to self-report, there are

14   some circumstances where it might be

15   difficult, or even impossible to directly

16   obtain the assessment by self-report.

17   We suggest in the paper that proxy

18   reporting, though it does have problems, can

19   be useful. It's really important if you want

20   to be able to be inclusive to include people

21   with cognitive or communication deficits, or

22   severe disease burden who can't speak for

1   themselves or respond as to how they're doing,

2   not to exclude them from the picture. And for

3   people who may be able to respond for

4   themselves but they may be in early stages of

5   dementia or malcognitive impairment who might

6   not recognize their impairment as it's

7   evolving, and yet a proxy, a family member

8   would be a good source of that information.

9   And, finally, for young children

10   who are not yet sufficiently reliable to

11   report the kinds of health status things that

12   we want to capture in performance measurement.

13   Next slide.

14   So, that's my introduction. And I

15   think I'm supposed to sit down now and have

16   the experts react.

17   CO-CHAIR DUBOW: Are there any

18   specific questions about anything? We don't

19   want to have the conversation now, but if

20   anybody has any specific questions about the

21   presentation? Okay, Charles.

22   DR. MOSELEY: Thank you very much.

1   It's a pleasure to be here. Can you hear me

2   okay in the back? No? How about now? Yes?

3   Okay.

4   It is, as I mentioned, a pleasure

5   to be here. And I was really interested to see

6   the focus of the discussion on the slides

7   highlighting the real need to address

8   indicators that will improve quality, and

9   provide accountability.

10   I'd like to add one more to the

11   list, and that is to produce indicators and

12   information that's actionable, that can be

13   used by policy makers, by service providers,

14   by family members and others to really make a

15   difference in the lives of the people who are

16   receiving the support.

17   As I begin today, it's

18   interesting, I feel a little bit like a duck

19   out of the water. We don't use the term

20   intellectual -- in the field of intellectual

21   and developmental disabilities, patient to

22   refer to the folks that we support. We

 1   typically use people receiving support or just

 2   people. And I think that's a very important

 3   difference because it does not distance the

 4   individual from the services and supports that

 5   they are receiving, like the word "patient"

 6   does.

 7   What I tried to do is organize my

 8   comments today around the three particular

 9   areas that you asked me to address; how do we

10   best build a value proposition for clinicians

11   and policy makers that individual input is

12   credible?

13   I think it's important to

14   recognize that the nature of the services

15   provided -- excuse me, important to recognize

16   the nature of the services provided in the

17   populations who are receiving them. Acute care

18   services, for example, typically are time-

19   limited and measured narrowly focusing on a

20   treatment regimen or course leading to some

21   type of cure or amelioration of a condition.

22   For people who are aging, long-

1 term care typically refers to support through

2 a nursing facility which lasts on average

3 about two and a quarter years per person

4 according to the CDC.

5   Many people with disabilities by

6 contrast receive supports throughout their

7 life span. The majority of the over one

8 million people with intellectual disabilities

9 and developmental disabilities currently

10 receiving publicly funded supports, for

11 example, enter the system following school and

12 continue to receive support throughout their

13 life times. Many never utilize a nursing home

14 at all.

15   Indeed, a disproportionate share

16 of the support is provided by family members.

17 Of all people currently receiving publicly

18 financed services right now, 57 percent

19 receive them within the home of a family

20 member.

21   Finally, it's important to

22 recognize that the various demographic and

 1   need profiles of Medicaid beneficiaries with

 2   disabilities are incredibly diverse. As noted

 3   by the National Council on Disability and

 4   Managed Care Principles, the type of services

 5   and supports required by an 85-year old widow

 6   with advanced Alzheimer's disease are entirely

 7   different than those needed by a teenager with

 8   significant behavioral or communication

 9   challenges caused by autism or other serious

10   neurological disorder, or an adult with

11   intellectual disabilities who has co-occurring

12   mental illnesses.

13   Each may require specialized

14   medical and prescription -- medical services

15   and prescription medications in combination

16   with ongoing personal assistance, but the

17   composition and competencies of the team

18   assembled to deliver those services will be

19   radically different in each case, as will the

20   types of medical, psychological,

21   pharmacological, and social intervention

22   services that are deemed to be appropriate.

1   What is it that people need? And

2   how do we know that the services will result

3   in the outcomes that are desired? People with

4   disabilities, just like all of us, need direct

5   support to access the community, work,

6   families, and friends. They need training and

7   assistance to enable them to learn the skills

8   they need to function as independently as

9   possible, and to direct their own services.

10   They need assistance in accessing

11   appropriate health care, therapies, through

12   service coordination and case management, and

13   they need ancillary services, transportation,

14   interpreter services, and a whole wide range

15   of other supports to enable them to fully

16   participate as members of society.

17   Long-term supports are as personal

18   as taking a shower, eating meals and getting

19   dressed. They're also a matter of public

20   policy. So, how do we develop value

21   proposition for clinicians and policy makers

22   that takes input from people receiving

 1   supports?

 2   It's important that we develop, I

 3   believe, population-specific indicators that

 4   are meaningful in the sense that they add

 5   value to people's lives, and to state policy,

 6   and individual practice; that they're

 7   credible, that they address areas of

 8   importance to service delivery and the

 9   achievement of individual outcomes, that

10   they're valid, measuring what they're intended

11   to measure, reliable, that they produce

12   consistent results across interviewers,

13   raters, and over time, and representative,

14   they're based on a representative sample. And,

15   finally, they include questions that are risk-

16   adjusted so that you can compare -- identify

17   trends and compare state-to-state data, and as

18   I mentioned, national trends, and by

19   addressing broader outcome and performance

20   variables that are relevant to individuals

21   receiving support, state policy and funding

22   decisions.

 1   And we're talking about indicators

 2   that measure access to appropriate health care

 3   at a point in time, and over time, identifying

 4   the number and percentages of people who are

 5   receiving -- of people receiving support who

 6   are working and are accessing employment, and

 7   stay on the job, documenting the percentages

 8   of individuals who choose where and with whom

 9   they live, and who they spend time with during

10   the day, identify individual and service-

11   related choices that a person can exert over

12   the course of the day, and by tracking the

13   extent to which measures produce data that are

14   used by policy makers, actually used by policy

15   makers, practitioners, individuals receiving

16   support, and researchers.

17   Now, the National Association in

18   collaboration with the Human Services Research

19   Institute has developed and implemented the

20   National Core Indicators Program which gathers

21   individual-level data, systems data, across 35

22   states, roughly pulling in information,

1   individually reported data on people's

2   perspectives on the places where they live and

3   work, the amount of choice that they're able

4   to use, the activities they engage in during

5   the day, the nature of the experiences that

6   they have with the supports they receive, and

7   their individual characteristics.

8   Currently, we gather information

9   on about 20,000 individuals each year. We're

10 working with a grant from the Administration

11 on Intellectual and Developmental Disabilities

12 to expand the core indicators to all 51 states

13 over the next four years, 50 states plus the

14 District of Columbia. Here I need to really

15 say 51 states, I think.

16   How do we insure that PRO data is

17 useful to patients as well as other users?

18 This is a really important issue, and I think

19 it's very important to identify and utilize

20 measures that reflect and assess what is

21 important to the person, and what is important

22 for the person.

1   There are two separate

2   perspectives there that are both valid,

3   they're both important, but for too long we

4   have identified only what's important for the

5   person as determined by someone else, whether

6   it be a clinician, a family member, a

7   guardian, or others. And it's really critical

8   to gather the information from the person

9   receiving supports.

10   And we certainly have found over

11   the past 14 years in gathering our data that

12   individuals with intellectual disabilities can

13   very easily, the majority of them, report on

14   information about the nature of the supports

15   that they receive, their choices, their

16   outcomes, their goals, and their life

17   expectations.

18   Provide regular -- the data set

19   really needs to provide regular user-friendly

20   reports summarizing key data trends and

21   issues. And as I mentioned, the core

22   indicators that are now being used by 35

1   states are being used in a number of different

2   ways.

3   I recently surveyed the directors

4   of the state agencies supporting these

5   individuals across the country. They said that

6   they used the data to meet CMS and HCBS waiver

7   quality assurance requirements with respect to

8   the plan of care, family involvement, and

9   health and welfare.

10   Now, the core indicators are

11   important to mention that these are system

12   measures and cannot be used by themselves to

13   really assess this kind of information, but

14   are best used in combination with other

15   information that is gathered by providers and

16   others.

17   Formulate key policy positions

18   with respect to the kinds of services that

19   should be delivered, compare performance

20   measures and outcomes by diagnostic groups or

21   across key service areas, residential size,

22   for example, employment and health access,

 1 bench marking system performance in key areas

 2 against that of other states, and providing

 3 information on key systems variables such as

 4 the impact of facility size on quality of

 5 life, loneliness, and community access, the

 6 extent to which people are able to control and

 7 direct the services that they receive, access

 8 to employment, improved choice and access to

 9 regular health care.

10   Finally, what are best practices

11 to minimize barriers to individuals being able

12 to self-report? We found that to a great

13 extent you have to go back to the survey

14 basics. Surveys need to be well-constructed,

15 that can utilize alternative methods of data

16 gathering, not only reading a survey

17 questionnaire but having questions explained

18 to them. We found, for example, that iPads are

19 terrific for people who have communication

20 problems because they can zoom right through

21 them and are pretty much in control of the

22 information. Trained and well-supervised

1   interviewers, the availability of people

2   receiving support to participate in the

3   process.

4   We talked earlier about proxy

5   respondents. They're very good; the responses

6   that they give are, however, different, and

7   it's important to note those differences even

8   though you may include them in part of the

9   data set.

10   The development of sound and

11   practical interview and survey administration

12   protocols, data analysis methodologies, and

13   data entry processes, targeting the right

14   people who have access to the data needed,

15   providing consistent and appropriate

16   methodological approaches for analyzing and

17   reporting the data, and providing processes

18   for releasing the data to researchers,

19   demographers, and others to document usage and

20   trends.

21   I want to loop back around to just

22   mention that it's really important that the

 1   data be used. We're very good, and I think

 2   across the health care field at gathering a

 3   whole lot of information, producing a lot of

 4   beautiful reports and leaving it on people's

 5   desks. We need to figure out ways to really

 6   drill into the information and use it to

 7   change practice. Thank you very much.

 8   CO-CHAIR DUBOW: Thanks, Charles. I

 9   think that your point what we call these

10   things is well taken. We are talking about

11   persons, individuals, but for the sake of our

12   discussion today, forgive us if we slip, but

13   I think everybody recognizes what you're

14   saying, and we appreciate that. Steve.

15   DR. FIHN: Good morning, and I'd

16   like to thank all of you for inviting me here

17   as a representative of the Department of

18   Veterans Affairs.

19   As many of you may know, the VA

20   has been undergoing yet another major

21   transformation over the past couple of years

22   under the direction of Secretary Shinseki, and

 1   the sort of three tenets of that

 2   transformation have been that we are Veteran-

 3   centric, that's our word for "patient,"

 4   results-driven and forward thinking. So, the

 5   notion of patient-centricity I think is

 6   central to our system at this point, so very

 7   appropriate to have this discussion.

 8   And along these lines, for

 9   example, VA is investing about $1 billion, for

10   example, in developing patient-centered

11   medical homes at the thousand sites that we

12   provide primary care.

13   And we do collect information from

14   patients along the lines of PROs. For many

15   years, for example, we've conducted a survey

16   we call the Survey of Health Experiences of

17   Patients of the Shop, which includes patient

18   experience, the SF-12V, that's collected on

19   about 600,000 people a year in a very highly

20   scientific survey methodology.

21   We've recently started the U Speak

22   for our rehab patients. We have detailed

 1   patient-driven recovery plans for severely

 2   injured veterans from Iraq and Afghanistan. We

 3   collect PIMS on all our primary care patients.

 4   We collect Audit C for alcohol use and the PSQ

 5   for depression.

 6   That said, actually, from my view

 7   point that's a relatively limited amount of

 8   information to get from patients. And we do

 9   have plans which we're working on actively now

10   to expand that repertoire, so for example

11   we're developing mobile health platforms with

12   actually a VA App Store, and some of the early

13   apps will be one for pain measurement, another

14   for PTSD symptoms.

15   We are going to release a health

16   risk assessment connected with our patient

17   portal, which is called "My Healthy Vet." And

18   we're actually experimenting with some

19   condition-specific measures particularly

20   related to ischemic heart disease to measure

21   the outcomes following elective percutaneous

22   coronary interventions.

1   So, I think from the VA's

2   perspective, and I'm speaking largely for

3   myself here, I think this is a good direction

4   and applaud these efforts. But I think also

5   from the perspective of a system that has over

6   6 million patients, we've also been acutely

7   cognizant of some of the limitations and

8   difficulties which I hope will be considered

9   in this process.

10   The paper, David's paper I think

11   eloquently outlines many of the concerns that

12   are fundamental, technical issues, bias,

13   problems with performance, respondent burden,

14   interpretability of measures, privacy; and in

15   our system that's multiplied by 6 million

16   people, so these are not, I think, problems

17   necessarily to be minimized.

18   And I'm going to reflect for a

19   second on my own personal experience. I

20   reconnected with one of my close colleagues,

21   John Wasson, and recounting a study we

22   collaborated on actually back in the early and

1   mid-'90s in which we actually randomized

2   30,000 patients in the VA to feedback of PROs,

3   both generic, as well as condition-specific to

4   primary care providers over a two-year period,

5   and failed to show, actually, any clinical

6   benefits in doing that.

7   More recently, we actually

8   conducted another multi-center randomized

9   controlled trial which we linked the use of a

10   condition-specific PRO to well-defined efforts

11   to intensify therapy for patients with

12   ischemic heart disease.

13   We've also done similar things in

14   heart failure, and in COPD. And none of those

15   cases actually have we demonstrated a clinical

16   benefit. And, in fact, in one of those cases,

17   actually, there was, as reported in the New

18   England Journal of Medicine, clinical harm.

19   And can talk about why that might be.

20   So, I think I would say that as an

21   organization, and as an individual, I think

22   I'm quite committed to this notion of patient-

 1 driven care. And I think Don Berwick has,

 2 basically, eloquently and very succinctly put

 3 that, is that the patient should drive the

 4 care. And the patient can't do that unless we

 5 know exactly what the patient wants. So,

 6 that's clear.

 7   I think jumping from that precept,

 8 though, to the sort of notion of performance

 9 measures and mandated instruments is a big

10 jump and one that needs to be taken with care

11 and thoughtfulness. And I'm delighted to be

12 invited to be part of this group. I think this

13 is the right group of people to start

14 addressing and confronting those issues, and

15 will be keen to participate.

16   CO-CHAIR DUBOW: Thanks, Steve. I

17 think your insights about why some of these

18 efforts didn't work would be very helpful. And

19 I hope we can get to that maybe during the

20 question and answer. Jennifer.

21   MS. HUFF: Good morning. Can you

22 hear me back there? Great. I'm also, along

1   with everybody else, really delighted to be

2   here today. It's really I think for me

3   personally very exciting to be having this

4   conversation. Early in my career, I had the

5   benefit of working at the Picker Institute, so

6   this is an area that's near and dear to my

7   heart. And the mission there, which I think is

8   very apropos to our discussion was just to see

9   care through the patient's eyes. And I think

10 that's what we're trying to do with the

11 information we're doing here.

12   It could also be akin to walking

13 in the shoes of the patient, you know. And it

14 brings for some of us that aren't as close to

15 a clinical encounter a real humanness to the

16 work that we're trying to do in terms of

17 improving care.

18   David Cella had talked about the

19 benefits of pros in clinical care, and I'm

20 just going to focus on one aspect which we've

21 actually heard underscored by the other

22 panelists, which is really getting to patient-

 1   centered care and the growing recognition that

 2   we really want to be truly about the patient.

 3   And to do that, patients need to be a part of

 4   the process.

 5   Asking them about how they report

 6   on outcomes and experiences, as well as

 7   engaging with them on the results and the

 8   interventions is an important piece to

 9   creating this patient-centered environment.

10   And I think we all recognize that

11   PROs also offer a valuable perspective that

12   can't be obtained for other -- from other data

13   sources. In fact, we could even argue that the

14   patient is an expert on some of those areas,

15   like the level of pain they're feeling, their

16   functional status, how their care is being

17   coordinated. And it's not meant to replace

18   other data sources, but it's a good complement

19   to the other information we're gathering as a

20   part of performance measurement.

21   And I think we'd also say it's

22   important to say that PROs have been

 1   increasingly shown to be linked to improved

 2   clinical outcomes. Patients that have more

 3   positive experience tend to get better

 4   outcomes we've seen in some studies, which is

 5   a compelling argument, I think, for all

 6   stakeholders in terms of using this

 7   information.

 8   And I think we all agree with

 9   these particular statements that I've just

10   said, and it creates value, but it's not,

11   necessarily, enough to move the system in

12   terms of using patient-reported outcomes. And

13   for that, I think we have to get really

14   practical on the information that's useful in

15   terms of the value proposition. And that's

16   really creating an evidence base that shows

17   how the use of PRO measurement programs can

18   save money, improve care, engage patients in

19   the care, and then incorporating that

20   information as we gather the evidence into a

21   variety of uses that were talked about,

22   payment programs, public reporting, say,

1   maintenance of certification or accreditation.

2   I'd also add clinical registries. There are

3   other places where this information could be

4   really helpful in terms of improving care.

5   A good place to focus initially

6   would be looking at places, and I think this

7   creates part of the value proposition of where

8   there's a lot of evidence of inappropriate

9   care. For example, back pain is a good example

10   of that, or with patients that have multiple

11   chronic conditions.

12   I'll give an example of a program

13   that the Pacific Business Group has been

14   involved in, and it will show, I think, not

15   just from a purchaser perspective but a

16   variety of perspectives the value proposition

17   I was talking about in terms of the different

18   elements.

19   PBGH members are using PROs in a

20   program that is called the Intensive

21   Outpatient Care Program. Some of you may know

22   this, as Boeing Corporation did a pilot on

 1   high-risk, high-cost patients. It's

 2   essentially what I'd call an ACO for a really

 3   chronic condition high-risk population in the

 4   primary care setting. It's a care redesign

 5   model that includes a dedicated staff person

 6   for the intensive primary care management.

 7   They do a case rate per member per month to

 8   cover non-traditional services, and as also a

 9   shared savings component.

10   What we found in the Boeing pilot

11   is compared to non-participating -- a matched

12   population, there was a 20 percent spending

13   reduction in the program and, as well as,

14   which is where this is really important, they

15   used the SF-12, and the PHQ-9, and they found

16   both improved physical and mental functioning

17   from baseline, and patients reported access to

18   care improved since the baseline, and they

19   also saw a decrease in absenteeism, again as

20   reported by the patients.

21   PBGH is spreading this model both

22   in Northern and Southern California, and it's

 1   been much easier to spread this model with

 2   this compelling evidence. I think this

 3   evidence really brings the value proposition

 4   to the purchasers that we're working with.

 5   We've been working closely with Humboldt

 6   County. Some of you may be familiar with it.

 7   It's an Aligning Forces for Quality site. And

 8   they've also added using the PIM as a part of

 9   the -- in addition to the SF-12 and the PHQ-9.

10   And they incorporate it into the patient's

11   action plan, so they have this information.

12   They use it in terms of how the care will be

13   delivered to the patients, and they are

14   regularly assessing over time how these things

15   change.

16   And I think this model has

17   something for everyone. It's improving care.

18   It's being more affordable. Patients are more

19   satisfied with the care they're getting. It

20   has patient engagement, and the clinicians are

21   also really engaged in using this information.

22   In terms of the other area we're

 1   asked to talk about, the usefulness of

 2   patients, I would agree with Charles that it's

 3   really important to use information that's

 4   important to the person, and for the person.

 5   And I also would say I think it's really

 6   important for us to consider how the PRO data

 7   will be used: will patients be using it in

 8   shared decision making; will they be using it

 9   in their treatment decisions or selecting a

10   provider; because those actions have different

11   data needs. So, really tying it to what the

12   use is is important when we're beginning this

13   path.

14   And I'd do another plug for

15   patient-centered engagement. This is making it

16   useful to patients. This is a place to engage

17   patients or their representatives as a part of

18   that process.

19   The other thing I'd add in terms

20   of useful to patients, which we've seen with

21   other performance information is the timing of

22   when this information is given of really

1 having those opportunities when the patients

2 need the information, or are making the

3 decision.

4 For best practices in collecting

5 PROs, I think integration of the PRO systems

6 into clinical care, making it a part of the

7 clinical process, using patient-reported

8 modules and patient portals that are

9 convenient, and I'd also add if there are ways

10 to use cell phone technology in terms of

11 making this really accessible.

12 And also, I think, with the

13 technology, I think David talked about some of

14 the challenges with using that, so also

15 recognizing what are some of the barriers that

16 would come of that, but it would be a great

17 place in terms of making the information much

18 more available.

19 And then I'd like to conclude with

20 an experience I had when I was working with a

21 doctor who was an oncologist and primarily

22 treated breast cancer patients. And he decided

 1   that it was really important for him to be

 2   tracking the SF-12 looking at the physical and

 3   mental functioning of his patients, so he

 4   bought a machine that he put in his clinic,

 5   and when patients came in for their visit,

 6   they filled out the SF-12 questionnaire. It

 7   was much like educational testing where you

 8   fill in the dots. It has all these dots, and

 9   there is a machine where you could put the

10   card right in there, and it spit out the

11   report in terms of the results. It would

12   calculate it.

13   And there is also a way that you

14   could download the information on a disc, and

15   do different analyses, but it was real time.

16   And then that was given -- the nurse took it

17   and put it in the chart, and it was something

18   that the doctor could use as a part of his

19   visit right then and there. And I'd just like

20   to add that was 17 years ago.

21   So, I think one of the things

22   you'll hear purchasers saying, as we're always

 1   saying there's an urgency to move things

 2   forward and not let some of the real nitty

 3   details keep us from making progress. And I

 4   think that's a great example of, "We've been

 5   doing this for a while." I'm really excited to

 6   be here and start talking about ways to really

 7   move this forward.

 8   CO-CHAIR DUBOW: Thanks, Jennifer.

 9   So, maybe we can conclude that this is an idea

10   whose time has come. And, you know, Jennifer,

11   I hope that during the conversation, and we

12   have about a half hour. Is that right, Karen?

13   That you'll have a chance to give us some

14   insight on how we can get other purchasers to

15   be thinking about asking for PROs to be

16   incorporated into their measurement

17   strategies, as well. PBGH is a fairly

18   enlightened and sophisticated purchaser on

19   behalf of other companies, but it would be

20   really useful to think about how to spread the

21   word to those who aren't quite.

22   With that, we have plenty of time

 1 for questions and answers. I think that the

 2 panel has given us lots to think about, and I

 3 urge you to just come forth with your

 4 questions.

 5   MS. PACE: And I think what we'd

 6 like to do during these discussion sessions,

 7 if we could ask the expert panel first to make

 8 their comments and questions, and then we'll

 9 go to the audience that's here in person and

10 on the phone, and then we'll have to ask the

11 operator to open up the phone lines when we're

12 ready for that.

13   CO-CHAIR DUBOW: Does the panel

14 want to --

15   (Off microphone comment.)

16   CO-CHAIR DUBOW: Right.

17   MR. CUNNINGHAM: And just a

18 reminder, at each roundtable is an individual

19 microphone that you can all use, as well.

20   (Off microphone comment.)

21   MR. CUNNINGHAM: Oh. At each

22 roundtable we have --

1   CO-CHAIR DUBOW: I just wanted to

2   be able to say that.

3   MR. CUNNINGHAM: At each roundtable

4   there is a microphone to use, as well. Just

5   push it on until it's green.

6   CO-CHAIR DUBOW: Is that Al there?

7   I can't see. Al Wu.

8   MS. PITZEN: Okay. This is Collette

9   from Minnesota Community Measurement, and I'm

10   sure we'll get to this later, but I just

11   wanted to make sure that we address the use of

12   the validated tools and potential copyright

13   issues with those developer holders.

14   For example, we're working on a

15   couple of orthopedic measurement sets with

16   definitive charge to access functional status.

17   We obtained permission from Oxford University

18   and the EQ-5D, but in a very narrow scope. So,

19   we can only use those tools for that

20   measurement. And as hospitals and clinics are

21   starting to implement these functional status

22   tools, they would like to use them a little

 1   bit broader than just spine fusion patients.

 2   So, we are continually running into those

 3   complications in terms of copyright. Thanks.

 4   CO-CHAIR DUBOW: That's a good

 5   point. Do you want to talk about the

 6   proprietary issues around that measurement,

 7   Helen?

 8   DR. BURSTIN: Sure, I could try.

 9   Oh, that works. It's a great question, and

10   it's something that's come up. Actually,

11   numerous tools have been proposed to us, and

12   people have sort of backed away because of the

13   issue around cost. So, NQF does have a carder

14   that allows proprietary measures to come

15   forward, where part of what is revealed, the

16   measure has to be fully transparent, the

17   Committees have to be able to review it fully,

18   but there is an opportunity to include the

19   charges as one of the considerations under

20   feasibility.

21   We have not had very many measures

22   make it through that way. Actually, recently

1   a couple of ICU measures did because it truly

2   was the only tool around to look at pediatric

3   ICU care.

4   But it is a real issue, and it is

5   something that does limit what's available.

6   And I think if there are opportunities, and

7   I'd be curious to hear, you know, David

8   Cella's perspective from NIH as some of those

9   sort of those sub-elements of those tools may

10   get looked at if there are ways to take some

11   of those building blocks and build them into

12   measures, perhaps, rather than the whole tool.

13   CO-CHAIR DUBOW: Al.

14   DR. WU: To save time hereafter,

15   I'm going to go as Al Wu. I think that we all

16   agree that the patient is the authoritative

17   source. And it struck me as we are thinking

18   about -- as we are discussing this, one

19   question which we probably need to ask, which

20   is a little bit of a measurement question, is

21   which the patient, becomes sometimes patients

22   are too sick to answer for themselves. Someone

1   else responds for them. They then at a later

2   point in time respond. Those two measures are

3   supposed to represent the same person, but we

4   now to figure out how to combine them. Some

5   patients may report things multiply over time.

6   How are going to use that information? Are we

7   most interested in the state of the patient at

8   one point in time, or are we measured in a

9   changed measure, or are we interested in some

10 area under the curve?

11   So, I think there are a number of

12 issues that we need to think about which sort

13 of relates to which patient, at least at the

14 individual level.

15   CO-CHAIR DUBOW: Greg.

16   DR. PAWLSON: I'll agree. I'm not

17 color blind. I actually tell red from green.

18 I had the privilege last night of, I guess,

19 that you'd call it that of spending about six

20 or seven hours on an airplane, and I had a

21 chance to really re-read the paper in some

22 depth. And when I got home and my 5-year old

1   granddaughter who lives with us engaged me in

2   doing a puzzle with her. And those two

3   experiences together sort of really helped

4   shape some thinking around acknowledging the

5   patient as an authoritative source.

6   I think one of the things that

7   would really help in this work is to -- and

8   specifically the paper, is to really start

9   with a little bit broader context.

10   We normally think about it as

11   helpers of a person who needs help, and I

12   think we need a new phrase, because persons is

13   a little bit too broad. But there are people

14   who need assistance of some kind or another,

15   input, and those people are the ultimate

16   source of information about what is going on

17   with them, what they are experiencing, what

18   they think they need, and their outcomes.

19   And I think that really

20   reinforcing that spectrum of where the patient

21   or where this person who is needing the help

22   is not only the authoritative source, but is

1   the critical and only source, and then how

2   that plays out in the interaction with the

3   persons trying -- the care givers, the people

4   that are trying to assist that individual, I

5   think it would really be helpful.

6   It gets back to -- because I think

7   it puts into context for clinicians of how we

8   gather information, and when we gather it, and

9   when it's really important. And that patient-

10   reported outcomes are one piece of the puzzle

11   that is absolutely critical, and has been

12   lacking, I think, a good deal, but is really

13   in this whole context of how the person we're

14   trying to help has to be the ultimate source

15   of a lot of the key, and then how that gets

16   played out in this new electronic age. Because

17   I was also watching my 1-1/2 year old

18   granddaughter use my iPad, which was very

19   impressive.

20   CO-CHAIR DUBOW: Wow.

21   DR. TINETTI: Mary Tinetti, Yale. I

22   just want to make one comment about

1   differentiating patient important outcomes

2   from patient-reported outcomes. And several

3   people have alluded to it, but I think I would

4   like it to be explicitly on the table that a

5   lot of the measures are what researchers think

6   are important. I just want to clarify that.

7   The second point I want to make is

8   I think I don't want to dismiss too quickly

9   the clinician reported. I think we need to

10   differentiate clinician ascertainment of

11   patient-reported versus clinician reported,

12   because ultimately we want to do with quality

13   improvement is to improve care. And if we have

14   separated what clinicians do versus what we

15   ascertain from patients we're not going to

16   accomplish our goal.

17   So, I really want to make sure,

18   because I -- both in sort of alluding in the

19   discussion today and an excellent background

20   paper, I think it almost too much dismisses

21   the clinicians that still need to be at the

22   center of the relationship between the patient

 1   and the outcomes, so I really want to make

 2   sure we differentiate those two points.

 3   CO-CHAIR DUBOW: That's very

 4   important. Patti Brennan keeps making that

 5   point over and over again, and I think we

 6   really need to keep it in mind.

 7   DR. BASCH: Hi, there. Ethan Basch

 8   from Memorial Sloan Kettering Cancer Center.

 9   I just wanted to bring up the issue of context

10   of use of measures, because many of the

11   measures that have been discussed are actually

12   generic measures, but as we start to think

13   about really getting very granular about

14   evaluating performance, some of the approaches

15   will really have to take into consideration

16   the context in which patients live, and what

17   they're experiencing.

18   And if we look at the regulatory

19   context in which many of these measures have

20   been used for many years, context of use or

21   fitness for purpose is really central to the

22   development of a measure. Demonstrating that

1   the measure being used is appropriate to the

2   patient population is meaningful to that

3   patient population. And generally speaking,

4   this is based upon up front qualitative

5   research demonstrating that what is being

6   assessed is meaningful in that particular

7   population. So, I hope that as we move forward

8   we will keep sight that as we develop patient-

9   reported performance measures, that it's a

10   whole package, and it's not just presenting a

11   measure, but demonstrating that in the context

12   of use for the population of interest that

13   measure is actually meaningful and can measure

14   something the patients care about.

15   DR. GANIATS: I love you all. I

16   hope you still love me. I'm Ted Ganiats,

17   again, from San Diego, University of

18   California-San Diego. And I will play a bit of

19   a role of a curmudgeon, I guess, because I'm

20   going to challenge the statement that patients

21   are an authoritative source. I don't doubt

22   that they can be, but are they?

 1   And I say that because as a

 2   clinician I'm able to sit there and listen to

 3   the patient, and the one who comes in with a

 4   positive review of systems, who has a positive

 5   serum porcelain level for whatever reason, I

 6   can then dismiss or partially dismiss, but

 7   when put into a performance measure we lose

 8   that ability. And are patients of that ilk

 9   equally spread among all practices? Then I

10   don't have to worry as a performance measure,

11   but if not, there's a problem. And we know

12   that they're not equally spread.

13   Are men and women equally likely

14   to respond to a given problem? We know that

15   there are gender differences. If there are

16   gender differences, we have a problem using it

17   as a performance measure. Does mood affect the

18   report of a patient-reported outcome? I

19   believe it does. I think people around the

20   table do.

21   I am not -- I mean, I'm a family

22   physician. I actually use this stuff, I

 1   believe in it. I'm a strong proponent, but we

 2   have to remember the limitations of the

 3   patient-reported outcomes, and not assume that

 4   just because it's from the patient it's

 5   automatically authoritative. I say that with

 6   love and respect.

 7   CO-CHAIR DUBOW: It's always

 8   necessary to have a curmudgeon. And we

 9   appreciate the push-back because, clearly,

10   there are challenges to implementation, and we

11   need to be able to address those. But I don't

12   think you actually challenged whether the

13   patient is an authoritative source, as you

14   simply identified some barriers that we need

15   to address when we get to the measurement part

16   of it. So, you're only a kind of quasi-

17   curmudgeon, and you have to work harder.

18   (Laughter.)

19   (Off microphone comment.)

20   CO-CHAIR DUBOW: Okay.

21   DR. MOSELEY: I have a quick

22   comment. I think you're raising an important

1 issue, and it gets back to the notion of

2 context that you've talked about earlier,

3 because we have certainly found as we gather

4 individual responses on people's perspectives

5 on their quality of life, that that changes.

6 It changes with respect to several variables,

7 not only the level of the person's disability

8 or the particular life situation, but also

9 changes with respect to people who are working

10 versus people who are not working.

11   People who are working clearly are

12 demonstrating more choice over the services

13 that they receive, over the people who come

14 into their lives, over the structure and

15 functioning of their individual support plan.

16   So, I think it's important to kind

17 of look underneath, just as you suggest, the

18 data to see which group is being

19 representative, and what are the various other

20 variables that could come into play.

21   CO-CHAIR DUBOW: Steve.

22   DR. FIHN: Yes, I was going to

 1   respond also. We've actually looked at the

 2   geographic distribution of health-related

 3   perceptions in our system, and there are huge

 4   geographic differences. A good example would

 5   be in the Southeast, health status is much

 6   worse than it is in other parts of the

 7   country. And it, obviously, closely correlates

 8   with socioeconomic status and other health-

 9   related conditions.

10   So, again, if we were to sort of

11   use this as a performance measure without some

12   sort of adjustment, we would arrive at some

13   probably erroneous conclusions.

14   DR. CELLA: This is Dave Cella

15   again. So, I see this particular discussion

16   as, for me, at least, the most important thing

17   for me to take away from the meeting, and it

18   comes back to Dr. Fihn's initial comment about

19   the jump from patient-driven care to

20   performance measurement mandate. And making

21   that jump, I see this group as the group that

22   can help that jump happen.

1   I guess I -- what I was saying was

2   that I see this group of experts and panel

3   reactors, reactor panels, I said in a

4   conference call that reactor panels sounded

5   like I was getting in front of a power plant.

6   (Laughter.)

7   DR. CELLA: And it is sort of a

8   power plant, I guess. But I think this is the

9   -- to me, this is the rub, this is the core of

10   what our challenge is to do here. And on one

11   level you can very simplistic and say well,

12   I'm not sure why patient-reported outcomes are

13   different than any other outcome that has to

14   be risk-adjusted. Maybe you could argue there

15   are more things to adjust for because of

16   culture, and language, and things that go into

17   patient-reported outcomes, and that might be

18   true. But I don't think, in my mind, at least,

19   I can -- I'm here to be educated, that it

20   necessarily is fundamentally or qualitatively

21   different to consider how we adjust patient-

22   reported outcome scores to do fair

1 comparisons, just as you adjust any other

2 outcome across providers. But I'd like to hear

3 what you think about that.

4 CO-CHAIR DUBOW: We want to open

5 this opportunity for questions and answers to

6 the audience, as well, as well as to the

7 people on the phone. So, can we ask the

8 operator to open up the -- are there people þ-

9 OPERATOR: At this time, ladies and

10 gentlemen, if you would like to ask an audio

11 question please press *1 on your telephone key

12 pad. We'll pause for just a moment to compile

13 the Q&A roster.

14 MS. MASTANDUNO: Good morning. I'm

15 Melanie Mastanduno from the Dartmouth

16 Institute. And I'm going to echo something one

17 of our experts, and that is going back to

18 survey basics. And thinking about the response

19 rate among the patients who are eligible to

20 report these measures, whatever instrument we

21 are using.

22 And I've had the pleasure of

1   visiting six different sites that are doing

2   some form of patient-reported measures on the

3   ground, and looking at their work flows, and

4   finding out their challenges, as well as

5   what's working well.

6   And two things that haven't been

7   mentioned this morning; one is the positive

8   attitude among providers when a patient does

9   provide their perspective, and wanted to be

10 acknowledged, thanked, and somehow integrated

11 into that provider-patient conversation as an

12 essential key ingredient.

13   And the second is the level of

14 trust some patients have for computers, for

15 example, or using a technology when their

16 whole social and socioeconomic circumstance

17 has not permitted them to be really power

18 surfers. And this is a key way we'll collect

19 data. And before we even get to Smart Phones,

20 this is a real cultural barrier from the

21 perspective of accessibility. Thank you.

22   DR. ROSS: Hi, I'm Clarke Ross. I'm

 1 a new member of the MAP workgroup on persons

 2 duly eligible for Medicare and Medicaid. And

 3 I represent the Consortium for Citizens With

 4 Disabilities, which is a policy consortium,

 5 volunteer consortium of 113 disability

 6 organizations.

 7   I wanted to throw out a couple of

 8 paradigm challenges, things that are happening

 9 with Medicaid dollars, both Medicaid managed

10 care dollars and Medicaid home and community-

11 based service dollars, and just keep the

12 thought in your mind as we work through the

13 two days. And this is the direct empowerment

14 of people with disabilities.

15   The payment of dollars not through

16 an agency, and not through an organization,

17 and not through a provider, and not through a

18 professional, the payment of dollars directly

19 to people with disabilities to make their own

20 purchase decisions.

21   We have in several states what's

22 called Cash Counseling programs. These are

 1   people who employ their own personal

 2   attendants, for example, and make those

 3   choices. And then in the area of mental

 4   illness, we have four states who have financed

 5   independent third-party consumer and family-

 6   operated community-based organizations that

 7   monitor services and engage individuals

 8   directly, service recipients directly. And

 9   these are all people who are in recovery

10   themselves from mental illness.

11   They are people with a history of

12   mental illness who have been trained to engage

13   their peers. So when we just talk about the

14   complexity of what we're talking about, these

15   are models that are actually operated,

16   financed, and have a lot of momentum behind

17   the consumer family movement to increase their

18   use. And I just wanted to remind you all of

19   those developments where the dollar empowers

20   directly the consumer and family member, and

21   doesn't go through all of the kinds of

22   organizations that we're talking about. Thank

 1   you.

 2   CO-CHAIR DUBOW: Operator, is there

 3   anybody on the line who has a question? Thank

 4   you for that observation, by the way.

 5   Operator?

 6   OPERATOR: At this time, if you'd

 7   like to ask a question please press *1 on your

 8   telephone key pads.

 9   CO-CHAIR DUBOW: Okay, then let's

10   continue with the audience.

11   DR. GIOVANNETTI: Hi, my name is

12   Erin Giovannetti from National Committee for

13   Quality Assurance.

14   One thing that I have not heard in

15   this discussion --and maybe this going to come

16   up later-- is, when you're using patient-

17   reported outcomes as performance measures, is

18   accountability, and specifically talking about

19   quality of life and function.

20   If we really think that the

21   evidence is there that we can hold providers,

22   entities, health plans, whatever accountable

1 for quality of life and function outcomes when

2 we know that there are a lot of outside

3 factors, social support, housing, income, et

4 cetera that are impacting these. And just kind

5 of thinking through are these -- is the SF-12

6 actually controllable by an individual

7 provider? Is that something that they can

8 change by their annual wellness visit?

9   So, I just kind of wanted to get

10 some -- hear maybe from the panel in terms of

11 what you think about function and quality of

12 life and its controllability.

13   CO-CHAIR DUBOW: That's an

14 interesting question, and I can't help but

15 observe that there is a functional status

16 measure that NCQA has which is in the HOS.

17   DR. FIHN: I'd like to respond. And

18 I'll just expose my own bias here. You know,

19 I think the -- and in David's paper, you know,

20 he actually addresses some of the areas in

21 which these have been used; one, in

22 particular, hip arthroplasties. In our case I

 1   mentioned we're looking at PCI as a very

 2   directed one.

 3   I find these attractive not only

 4   because in a sense we think about them as

 5   measures of technically how good people are,

 6   did they do a good job with the hip

 7   replacement, or did they put a stent in well.

 8   But I think in terms of measuring a health

 9   system, I like them because they also would

10   depend upon how well your patient selection

11   is, are you selecting great people? In the

12   case of hips, are you doing the appropriate

13   post op rehab. In the case of coronary

14   revascularization, you know, are -- one of the

15   big issues are you actually revascularizing a

16   lesion that is causing the symptoms? If you're

17   doing a lot of revascularization for lesions

18   that aren't a problem, patient symptoms are

19   not apt to get better.

20   So, my plea would actually be

21   let's start with some of these focused areas

22   where we do have validated measures, where

1   they've probably are better, if you will,

2   value proposition than the larger sort of much

3   more generic, and I would agree, difficult to

4   effect. There may be in intensive primary

5   care, some groups of patients in which we can

6   alter sort of the global health, but that's a

7   hard thing to move and control. So, that

8   would be my own personal bias, if we're going

9   to get started, to start is some very focused

10   areas where we've got some good evidence

11   already.

12   MS. HUFF: I would also show my

13   bias and agree with what Steven has said, as

14   well, in terms of really being careful to

15   select what population we're going to be using

16   in terms of looking at these measures.

17   But to the point around using some

18   of the general status, like the SF-12, I will

19   say what we have found is really -- it does

20   show sensitivity when you look at a chronic þ-

21   - a population that has chronic conditions.

22   So, if you're really careful in terms of

 1 selecting the population for which it has

 2 sensitivity, then it is useful. And we found

 3 that not only in the project that I talked

 4 about in my introductory remarks, but also in

 5 some other research that we've done.

 6 DR. MOSELEY: I just want to

 7 underscore the differences between performance

 8 measures for acute and long-term supports. As

 9 I listen to the discussion of remediation of

10 conditions and various surgical interventions,

11 those are really good. And I think it's very

12 important to have that as a part of the

13 person's overall treatment plan. But people go

14 back to life, and they go back to jobs, and

15 they go back to family members, and they go

16 back to living in situations, particularly

17 those who receive live-long supports living in

18 situations that are paid for and controlled by

19 others.

20 One of the biggest factors,

21 variables, in individual outcomes that we've

22 documented through the National Core

1   Indicators Program is state. The state is the

2   biggest variable. And why is that? It's

3   because state Medicaid programs, structure and

4   functioning of their Medicaid programs,

5   although they're all based on the same

6   statutory framework, they vary sometimes

7   significantly from one area to another. The

8   amount of supports that may be available to a

9   family to enable them to keep their son or

10   daughter with disabilities in the family home

11   for a period of time may very vastly. And,

12   actually, since 2007 when the economy has kind

13   of gone off the deep end, the level of

14   supports that are available to individuals has

15   declined significantly in many areas.

16   These have a very powerful impact

17   on the quality of life that a person has,

18   their ability to control their own services

19   and supports, and their ability to really

20   continue to interact with their families and

21   their communities.

22   MR. ROONEY: Hi, this is Ted Rooney

 1 from Maine. We're Force for Quality Community,

 2 and I want -- this is one of those both -and

 3 comments. I absolutely agree we need to focus

 4 on those patient-reported outcomes that are

 5 controllable by the health care system. And,

 6 at the same time, many of you are familiar

 7 with the work Robert Wood Johnson has done

 8 with Project Match, which is looking into

 9 social determinants come out of the University

10 of Wisconsin and others. And if we read that

11 right, it suggests that 80 percent of the

12 health of the population is not due to medical

13 care. We're hoping that the promise of the

14 accountable care organizations does begin to

15 look beyond those things that are directly

16 controllable by the clinician and look at the

17 community.

18   And at least in Maine, we're

19 actively talking about it. Granted we're a

20 smaller state, we're not going to have 14 ACOs

21 in one environment, but we have account -- you

22 now, ACO-type organizations that are actively

1   talking about the social determinants in the

2   community because they recognize the limits of

3   health care.

4   So, yes, I think we need to focus

5   on those things that are controlled by the

6   health care system, but at the same time I'm

7   hoping we absolutely look at the communities,

8   then, to determine 80 percent of the health

9   population, what can we do to support those

10   things in the community that are way outside

11   the control of the physician, but need to be

12   impacted.

13   DR. PERFETTO: I think I pressed

14   the button too many times. Eleanor Perfetto,

15   I'm with Pfizer.

16   I want to go back to something

17   that I think it was Ethan brought up a little

18   bit earlier. In the pharmaceutical industry,

19   our most vast experience using PRO data, and

20   I know David knows this well, is in the

21   clinical trial process, and incorporating

22   these tools in clinical trials. And it's a

 1   very difficult thing to do to be able to get

 2   something into a clinical trial and be able to

 3   differentiate whether or not you're finding

 4   some differences because of a treatment that's

 5   been provided. So, we've got some experience

 6   in looking at whether or not a PRO can change

 7   in a given clinical trial environment because

 8   of treatment versus placebo, or several

 9   treatments against one another.

10   And I think it gets back to

11   something Ethan brought up before, was this

12   idea of purpose of fit. And we have -- our

13   arbiter in the pharmaceutical industry about

14   whether or not the tool can do what we would

15   like for it to do in this differentiation

16   process is the FDA. And the FDA looks at the

17   data that we provide on the tool that we want

18   to use and gives us the yea or nay about

19   whether or not they think it's rigorous enough

20   to be able to do what we want it to do.

21   And I guess one of the challenges

22   that I see in this process is: If a tool is

1 going to be selected, or if a set of tools are

2 going to be selected, to be able to be used as

3 performance measures, who is going to be the

4 arbiter to say that that tool is good enough

5 to be able to do what we want it to do, and

6 that it's capable of doing those things; and

7 then from there, be able to have that tool be

8 translated into a quality performance

9 measurement process?

10   DR. KAZIS: So, think this has been

11 a very exceptional discussion. I'm Lewis

12 Kazis. I'm at Boston University. Our group, in

13 fact, developed the Veterans Rand 12-item

14 Health Survey which has now been adopted by

15 the Veterans Administration, as Steve

16 indicated, and also by CMS as part -- as the

17 principal endpoint in the health outcome

18 survey to evaluate the Medicare Advantage

19 Program.

20   My view, I think, is that one

21 needs to be as flexible as possible in terms

22 of the implementation of these assessment

1   tools. And that if one moves to very focused

2   disease-specific assessments, where one might

3   see an effect to the exclusion of a generic

4   measure, I think one might lose out and not

5   get all of the information, in fact, where a

6   lot of the information that might be conveyed

7   in terms of the kind of clinical care that's

8   being rendered.

9   So, I think it becomes important

10   to consider not only the disease-specific

11   assessments, but also the generic assessments

12   in terms of evaluating, and maybe to consider

13   in the larger health care systems whether one

14   can focus on the low-lying fruit to begin with

15   in terms of those particular populations where

16   one might get the biggest bang for the buck.

17   CO-CHAIR DUBOW: Okay. Thank you

18   very much. I think Erin really highlighted a

19   really important area, and that is that we are

20   talking about quality improvement, as well as

21   accountability, and we need to take that

22   challenge into account as we go forward.

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 1                    I hope you'll join me in thanking

 2      the panel for an excellent job for getting us

 3      started.

 4                    (Applause.)

 5                    CO-CHAIR DUBOW: I think we have a

 6      break for 15 minutes. Is that right? And we'll

 7      be back here at 11:00 for the next panel.

 8                    (Whereupon, the above-entitled

 9      matter went off the record at 10:47 a.m. and

10      resumed at 11:02 a.m.)

11                    MS. PACE:  We are going to

12      reconvene.  Greg Pawlson, Elizabeth Mort and

13      Gene Nelson, come to the table.

14                    DR. PAWLSON:  Okay, we are going

15      to get started now.  I'm very sure that there

16      is important stuff being talked about.  There

17      are probably about five new grants that are

18      being discussed.  All we need are a few more

19      funders in the room, and then we'd never get

20      back to going.

21                    It's always, I think, wonderful in

22      a gathering like this, the conversations that
```

1   are sort of offline are just as exciting and

2   interesting, and sometimes even more creative,

3   in some senses, than what actually gets

4   presented. So these meetings do have, I

5   think, a very important focus, and especially

6   this one.

7   This is an area that I suspect

8   almost everybody in this room has been

9   thinking about, kicking around sort of in the

10   background for a very long time. And in

11   different pieces of it, whether you're talking

12   about functional status or patient-reported

13   experience of care, or other aspects of POM,

14   it's been around for quite a while. But I

15   don't think it's been put together in this

16   coherent fashion.

17   And I do think this is an

18   incredibly interesting and opportunistic time,

19   because I think one of the things we have now,

20   that we didn't have even five years ago, is --

21   first of all, we have the developing

22   electronic capability, which I think is

1   incredibly transformative.

2   And I wasn't kidding. My one and

3   a half year-old granddaughter was actually

4   going online and finding stuff that she liked

5   using icons, which is very different. It's a

6   new language, in many ways.

7   So we have that. And then, on the

8   other side, I think, we have this emerging

9   concept of the patient-centered medical home

10   and accountable care organization, which, if

11   it's done right, can truly be a point of

12   accountability and take into account, and

13   factor in, for example, the use and

14   development of community resources as part of

15   their overall mission. So I think we have

16   both a receptor and an effector on site that

17   we didn't have before.

18   So having gone through

19   acknowledging, in the first panel, the patient

20   as an authoritative data source, what we're

21   going to focus on here is that it can be done.

22   I don't think anyone would say it's being done

1 perfectly, or as well as we would like to have

2 it done, but it is being done.

3 And we're going to have two

4 examples of that, which are sort of domestic,

5 U.S. examples. But I would also point out in

6 the paper that it was a very nice little

7 vignette about what's been going on in Sweden,

8 and I am told in our next meeting we are going

9 to actually have representatives from an even

10 larger, very extensive use of patient-reported

11 outcomes that the U.K. has embarked on, and

12 which they've now had about two or three years

13 of experience with. And this was implemented

14 across the entire National Health System, so

15 equivalent to sort of some of the things that

16 Steve talked about that the VA's trying to do.

17 I think what we're going to try to

18 convey is, this can be done. There are still

19 lots of issues. There are still

20 methodological barriers that keep popping up.

21 But we are making real progress. And here to

22 share their experiences with us are Elizabeth

 1 Mort from Massachusetts General Hospital and

 2 Gene Nelson from Dartmouth Hitchcock. And

 3 we're going to start with Elizabeth's

 4 presentation, since they're a little bit more

 5 in the formative stage. Gene's been at this

 6 a while, and can show us his scars a little

 7 more.

 8   But I think it's a nice balance,

 9 because we're sort of looking at one that's

10 getting up and started, and has overcome a lot

11 of the inertia and initial issues, and another

12 that's been in operation for a while. So,

13 Elizabeth?

14   DR. MORT: Thank you very much,

15 Greg, for that introduction. And thank you

16 very much, Helen and others at the NQF for

17 inviting me to come down and share this

18 exciting story, Lessons From the Field: Early

19 Experience with PROs at Partners Health Care.

20   We are just beginning, but we're

21 very enthusiastic, and we're in this to stay,

22 I hope. I think how this session today and

1   tomorrow, and the next part of this workgroup,

2   goes will determine if we're in it for the

3   long run. But at least, we are very, very

4   excited to start.

5   We are only in the beginning of

6   our data collection phase. We only started

7   data collection in March, and I'll get to that

8   in a minute. I wanted to spend a little bit

9   more time up front telling you about the time

10   and energy that we intentionally spent in

11   setting this up, hopefully for success in the

12   organization.

13   Partners Health Care is an

14   integrated delivery network in Boston. It was

15   founded in 1995. The founding hospitals of

16   the Brigham and Women's and Mass General

17   kicked it off at that time. We've had several

18   CEOs, and the most recent CEO set off a new

19   strategic plan that was launched in 2010.

20   When we launched that, we were looking broadly

21   at care redesign in two areas. We were

22   looking at primary care and population health.

1   And we were also looking at condition-specific

2   care redesign, and we selected CABG, stroke,

3   colectomy for colon cancer, AMI, and diabetes

4   as our focused conditions.

5   When we set this up, we organized

6   this around a key principle, which is that if

7   we were going to redesign care, we were going

8   to redesign care with the goal of improving

9   value. And we talked about this concept for

10   a long time, because our providers, when we

11   asked them to come to the table to work on

12   these projects in 2010, knew we were about to

13   undergo a large change in the way we were

14   paid.

15   They asked us "Well, how are we

16   going to be paid? How shall we do care

17   redesign?" And of course, in 2010, all we

18   knew is that it's likely to be different, but

19   we don't exactly know how. It's probably

20   going to be something in the order beyond

21   unfettered fee for service. So what we'd like

22   you to do is think about organizing care with

 1   the goal of improving value.

 2   So these overlapping Venn

 3   diagrams, we must have shown thousands of

 4   times, pointing out that, of course, our goal

 5   here is to improve care while keeping it more

 6   affordable. So we want to improve outcomes by

 7   reducing costs, and obviously the inner

 8   section is the value.

 9   So, when we brought people

10   together, we'd had a decade or so of teams

11   working on quality improvement, working on

12   measurements, working on process indicators,

13   working on outcomes indicators.

14   What really captured people's

15   imagination, and what really has stimulated

16   this work from the get-go, though, was

17   inviting our care teams to think about

18   outcomes that really matter to patients. We

19   want to start collecting patient-reported

20   outcomes. That's what patients, after all,

21   really care about, all the kinds of

22   conversations that we've had this morning.

1   So I tell you this because we got

2   everybody really fired up about this quest,

3   sort of two years before we even got into the

4   implementation tasks. So we selected five

5   conditions, four of which are acute, based

6   upon an episode starting in a hospitalization,

7   one of which is chronic, diabetes, looking at

8   chronic care over the course of a 365 day

9   period. But we were organizing this work

10   around episodic care population management,

11   and we decided to start with CABG, and we

12   actually added AVR, aortic valve replacement,

13   as well -- coronary artery bypass graft, I

14   should say, and aortic valve replacement --

15   for the purposes of getting adequate volume to

16   study these PROs. And then we selected

17   diabetes.

18   We spent about two years. We had

19   a very engaged physician from Israel, Eyal

20   Zimlichman. He may have interviewed some of

21   you in the room. He really led this project,

22   and did all the sneaker work, sneaker power,

 1   going around talking to people, and really

 2   doing a very, very thorough job of change

 3   management, managing us, by interviewing

 4   people. Interviewing researchers,

 5   interviewing folks who went up to Dartmouth,

 6   learned from Gene and his colleagues, to learn

 7   about how this works.

 8   So it was never one of those

 9   interventions where we said "Okay, we're going

10   to do this. Here are the measures. It's

11   going to start next Friday." It was all about

12   getting people engaged, getting iterative

13   conversations with high-level people, people

14   very invested in this work from the get-go.

15   And the kind of goals that we

16   thought about from the beginning, I put up

17   here on the slide. We said "You know, this is

18   likely -- when NQF gets its arms around this,

19   this is likely going to become the way we do

20   business in the future. At least, we all hope

21   that it does. So we want to organize this so

22   that we're positioned to be ready to catch the

1 wave when it comes."

2   So we wanted to make it

3 electronic. We said "Well, we can start it

4 with paper forms." No, no, no. We want to

5 make it electronic. Let's do it with

6 futuristic goals in mind. And then we didn't

7 want to spend time developing new instruments.

8 We thought possibly taking measures, or pieces

9 of instruments, and putting them together

10 would be okay, but we didn't want to start

11 from scratch, so we decided we would use

12 validated instruments.

13   We wanted to reduce respondent

14 burden, so we decided we would make the

15 instruments short. We may have gone a little

16 bit too short. And we wanted to align this

17 with our overall care redesign strategy, and

18 also some of our paper performance strategy.

19 So again, we spent a lot of time setting the

20 table for this important work.

21   So a summary of our tool for CABG

22 and AVR is on the left and diabetes is on the

1 right. The total number of questions for CABG

2 pre-procedure is 17. Ten questions on

3 functional status using the PROMIS-10, some

4 symptom-level questions from the medical

5 outcomes survey, receive health benefits again

6 -- that's a post-op question, obviously, in

7 retrospect -- and health utility from the

8 EuroQol.

9   So we had 17 measures pre-op, then

10 21 measures post-op. We engaged our cardiac

11 surgery clinical team. Hours and hours of

12 meetings, and tweaking, and discussions and

13 vetting. It's kind of the way we like to do

14 business there. It takes a long time to get

15 things done.

16   But on the diabetes side, we had a

17 very robust diabetes team. We decided to use

18 the same functional status measures. We

19 decided to use PROMIS-10. Actually, David

20 Cella was very instrumental. He came to

21 Partners and gave us some lectures, and again

22 we were very intentional and deliberate in

1 making sure we had run the bases on this.

2   We added an anxiety measure from

3 PROMIS, a burden of diabetes measure from one

4 of the American Diabetes quality of life

5 indicators. I'm blanking on the exact name of

6 the tool, I apologize. But this was a really,

7 really important measure.

8   We held focus groups with patients

9 who weren't familiar with this kind of

10 measure. We explained to them what we were

11 trying to do. And one of the patients said to

12 me "You know what I want to hold you

13 accountable for, Dr. Mort? I want to hold you

14 accountable for keeping me as normal as

15 possible. Just making things normal, so that

16 I don't have to think and worry about managing

17 my diabetes, or the symptoms or complications

18 associated with it."

19   I thought that was very, very

20 instrumental to me, to think about how we want

21 to organize this work. But we found a measure

22 that measured that pretty well, and then the

1 health utility measure as well.

2   So the way we wanted to roll this

3 out is, we have this working in a CABG and two

4 cardiac surgery clinics, doing a pre-op

5 assessment and then a post-op at 3, 6, and 12

6 months. Our plan for diabetes is a baseline

7 measurement and then every 6 months. Both of

8 these instruments, both of these data

9 collections, start in the office.

10   Data collection. Again, we wanted

11 to kind of channel the future here, so we

12 didn't want to spend a lot of time with our IT

13 folks developing internal data collection

14 systems. So we actually talked to a lot of

15 vendors, and we're partnering with a vendor to

16 do the data collection.

17   And on the slide you can see, we

18 start with tablets. And all the things that

19 have been said about one year-olds and iPads,

20 and so on and so forth, are very much

21 applicable to the patients that we have tried

22 this with in these waiting rooms. The tablets

 1   work very, very well.

 2   When the patient is given the

 3   tablet by the medical assistant or the

 4   secretary -- they are given a list of patients

 5   who are coming in. They hand the tablet. The

 6   patient goes and sits. Workflow-wise, that

 7   works pretty well, because they're sitting,

 8   and in most clinics you have at least a few

 9   minutes to do something while you're waiting

10   to get checked in, and we only have 17

11   measures. So it has not been a burden or a

12   workflow issue, once you get the group

13   engaged.

14   The patient is then asked how they

15   want to have their follow-up done, and they

16   can choose between using our patient portal

17   that we call Patient Gateway, again

18   anticipating that we want to move in an

19   electronically forward-thinking way, or IVR

20   with phone operators.

21   So we really are early in this.

22   We've only been in the field since March of

1   2012. We've only collected data on 264

2   questionnaires. 56 percent of the patients

3   who we've enrolled have chosen a method of

4   follow-up selecting the patient portal, the

5   internet option, so not the IVR. So I do

6   think that's going to be an increasingly

7   popular way to collect information in an

8   asynchronous way.

9   Our IT folks are working on

10 developing reports, both for patients and

11 providers. These are still being developed

12 and piloted and iterated, but the idea is that

13 these reports would be pushed out to the

14 patients through our patient portal. We're

15 getting good traction with that tool, and

16 increasingly getting more and more of our

17 patients across the entire system enrolled in

18 our patient portal.

19   And we have the electronic medical

20 record. We are undergoing a massive change.

21 We are actually installing an entirely new

22 clinical and business system across our entire

 1   network. But in the interim, we do have an

 2   LMR, and the goal is for these indicators to

 3   be tracked right along with -- this is hard to

 4   read, but it's a vital sign. It's a flowsheet

 5   for vital signs. And we have these kinds of

 6   things for clinical indicators, like

 7   hemoglobin A1c, blood pressure and the like,

 8   and we'd like to do the same with the

 9   functional status/quality of life measures.

10   So the feedback -- again, this is

11   early. The patients -- we have spent a lot of

12   time with research assistants at the

13   practices, working with the front office,

14   working with the staff, working with the

15   medical assistants, working with the doctors,

16   in large part to make sure it happens, but

17   also to learn from them and to improve things,

18   and to make some iterations as we go, early

19   on.

20   Patients say their doctor should

21   be asking these questions. They like it. The

22   tablet's fun. And they say they're willing to

 1   answer these questions at home.

 2   The staff experience, the practice

 3   administrators, once we make the case for this

 4   and they understand it's important, they've

 5   been quite flexible in helping us to get this

 6   embedded in the workflow. The medical

 7   assistants and nurses are very, very eager to

 8   get involved in this kind of information, and

 9   are great adjuncts to the nurse practitioners

10   and physicians who are actually seeing the

11   patients.

12   The physician experience is a

13   little mixed, not surprisingly. You know,

14   we've spent 15 years at Partners educating our

15   clinical colleagues about measurements, and we

16   don't have all the answers to "Well, is it

17   valid?" and "What's the tool?" and "What about

18   the scale?" and "How can you know if there's

19   a difference?"

20   We don't have the answers to all

21   those things that we've been telling people

22   for 15 are years are so important, and I said

 1   "But wait. People are working on this. The

 2   NQF has a workshop, and over the next couple

 3   of years these things will evolve. And in the

 4   meantime, let's get ahead of the curve." That

 5   usually gets you somewhere.

 6   (Laughter.)

 7   DR. MORT: It's honest. It's

 8   honest. But everyone loves the face validity

 9   of these things. The workflow is really an

10   issue, though, because doctors obviously --

11   this has been alluded to this morning already

12   -- doctors aren't used to getting this

13   information. How does it fit in?

14   You know, we have our script. We

15   ask the patients a good, open-ended question.

16   "How are you?" Your annual exam, "What are

17   your concerns?" But we have to figure out how

18   to get that piece of data involved in that

19   conversation, so that we can embed it in the

20   workflow of seeing the patients, as opposed to

21   saying at the end "Oh my God, here is this

22   quality of life sheet, let's talk," and it

1   doesn't work. So people are worried about

2   those things, but people honestly are working

3   hard at trying to make this work for us.

4   Concerned about "What do I do with

5   the results?" So if I get a critical result,

6   like a potassium of 5.6, doctors know what to

7   do with that. "But what if I get an indicator

8   from one of these scales that suggests the

9   patient's in trouble? Give me the tools to do

10 something with that information. Tell me what

11 to do in terms of referrals, but also make it

12 easier for me to know that someone else is

13 watching for those critical events and

14 flagging me, just like you do for the

15 potassium."

16   So, just some lessons learned.

17 Most of these I have already alluded to, but

18 we thought it was very important to spend a

19 couple of years doing the change management,

20 doing the research, educating ourselves and

21 bringing experts to the system, integrating it

22 with our data collection on our strategic

1 plan.

2   We have incredible support from

3 our senior executives, my colleagues at

4 Partners as well as the hospitals, all the way

5 up to the CEO of the entire system, who really

6 believes in this, understands that we have to

7 be cautious about going forward, we don't have

8 all the answers, but it seems to be

9 tremendously promising.

10   I think I've covered most of this.

11 So I am hoping that over the next couple of

12 days and the next few months, and subsequent

13 couple of years, we'll have the answers to

14 some of the questions that are being raised.

15 But I do hope and believe that this is work

16 that is here to stay.

17   So again, thank you very much for

18 asking us to come and share our preliminary

19 findings. Hopefully down the road we'll have

20 some more substantive results.

21   DR. PAWLSON: Thank you very much.

22 Just as Gene is coming up to start his

1 presentation, I was really struck with how

2 careful a process you've gone through in terms

3 of change management.

4   And also sort of something to

5 think about, perhaps for a later question, and

6 that is one of the real hallmarks of Partners

7 has been, for a number of years, it has been

8 doing incentive-based contracting, so that a

9 substantial, or at least a significant

10 proportion of reimbursement has been wrapped

11 around achieving some level of performance in

12 different areas. And I think that kind of

13 integration of payment with professionalism

14 and wanting to do right for the patient is a

15 very, very powerful sort of mover and shaker

16 in this area. So we'll perhaps take up on

17 that.

18   Any questions for clarification,

19 something that just you didn't understand? I

20 think it was a very clear presentation. Thank

21 you.

22   DR. BASCH: Just a quick question

 1   of clarification. In the development of the

 2   selection of the measures, was there patient

 3   input, or was it mostly the expert teams of

 4   clinicians that were consulted?

 5   DR. MORT: Ethan, we had focus

 6   groups up front to inform the domains that

 7   patients were interested in. I believe,

 8   though, in all honesty, once we identified the

 9   specific measures -- no, I stand corrected

10   here. I'm arguing with myself.

11   We did go back to our focus

12   groups. Because we had groups of patients who

13   were advising this care redesign process, and

14   they were a group that was interested in

15   parsimony, and they also felt one of the

16   concerns was "Don't make the questions have

17   lots of different ways to answer it." You

18   know, they wanted the response patterns to be

19   similar.

20   DR. PAWLSON: Another important

21   lesson.

22   DR. NELSON: I think you're going

1   to cue up some slides, and thank you for

2   inviting me. It's great to be with all of

3   you.

4   I've been asked to speak about the

5   Spine Center and its experience, and we're

6   going to start with a riddle, and it comes

7   from Amory Lovins. How is a kilowatt-hour of

8   electricity like a day in the hospital?

9   Nobody wants either. We want cold beer and

10   hot showers, better outcomes, better care,

11   lower costs, and use least costs. Value for

12   money.

13   So what Amory is saying is, he's

14   an energy expert. But when we're thinking

15   about value, it really does focus on the end

16   user. So that means our patients, our

17   clients, the families that the patients reside

18   in. And we have a sense that this is where

19   the great one, Gretsky, talks about the secret

20   of skating to where the puck is going to be,

21   and we think that focusing on person-centered

22   value, and incorporating patient-reported

1   outcomes in that, will be really essential.

2   This is going to be a brief

3   excerpt from about a 50 page technical paper

4   that's available to you. It's available on

5   the internet or in hard copy, and it actually

6   has three case studies: one from Karolinska

7   and rheumatoid arthritis patients, one from

8   Group Health in the Pacific Northwest and

9   primary care patients. And the third case

10   study is the Dartmouth Spine Center, and

11   that's the one I'm going to focus on now. But

12   there's a lot more that you can glean from

13   some systems that have been using patient-

14   reported outcomes for about a decade.

15   So this idea of value, that we

16   start with an individual living at home or in

17   the community, and then they interact with the

18   health care system -- processes of entry and

19   assessment, and a care plan, what's going to

20   help me become better, and then follow-up over

21   time to see what the outcomes are, what's the

22   new functional status, the new risk status,

1   the new disease status, if the person has a

2   disease or a condition, and what cost. And

3   what's my experience on the ride through the

4   health care system? How has that treated me?

5   So an image of value that's very person-

6   centered.

7   And we, like Mass General, have

8   really been focusing on the redesign of care

9   that becomes person-centered and that tries to

10   deliver on value. So you'll see this use of

11   patient-reported outcomes embedded in an

12   effort to redesign care for spine patients.

13   And more than 10 years ago, Dartmouth had

14   spine patients running all over the place.

15   They could have been seen in internal

16   medicine, or the pain clinic, or orthopedics.

17   It was a mess, like much care.

18   And so the idea was to redesign

19   the care program so that it's one-stop

20   shopping, and that it's very person-centered:

21   back to work, back to play, one back at a

22   time. This is Jim's initial idea. And to use

 1   the patient-reported outcomes to create a new

 2   information environment, and a better

 3   relationship with the patient to achieve the

 4   outcomes that they would wish to receive.

 5   What you'll see in just a moment,

 6   then, is a new information environment that

 7   Dr. Weinstein would say he can't be a good

 8   physician for his patients absent this kind of

 9   information. "It's essential to understand

10   where the patient's coming from and how

11   they're doing to be a good clinician," in

12   Jim's words.

13   So inn a schematic form, the

14   information environment was changed so that

15   when a referral is made or the patient

16   requests a visit to the spine center, that

17   they are actually requested to complete

18   information as they're oriented to the spine

19   center, what does it have to offer, and then

20   patient-reported information. And that moves

21   to the initial work-up and plan of care.

22   And that information can be

 1 completed at home, over a portal, or when the

 2 person shows up with a touchpad. And that

 3 touchpad or that portal information is

 4 uploaded to the electronic health record. And

 5 then that is the grist for trying to create a

 6 plan of care that meets that person's actual

 7 needs, in a way that you'll see amplified in

 8 just a bit. And then, depending on their

 9 need, they'll go into an acute care program or

10 a chronic care program, or a functional

11 restoration program, or, some people, end-of-

12 life.

13   And then that data on the

14 patients' outcomes is being fed forward with

15 that patient over time as follow-up occurs,

16 and it's fed back to create a registry. It's

17 fed back for clinical program improvement.

18 It's fed back to become part of a national

19 trial.

20   So, feed forward/feedback of

21 patient information. This is very dense, but

22 this is what Jim was talking about, Dr.

 1   Weinstein, that this is all based on patient-

 2   reported data, and it's meant to be same-page

 3   care, if you will, to put the clinician and

 4   the patient on the same page about "So, what

 5   are my risk factors? What's my history and my

 6   symptoms? What are any red flags that I might

 7   have? What's my functional status right now,

 8   and how is that changing over time?"

 9   On the right hand side, you can

10   see a trend line for physical function and

11   mental health, based on the SF-36 in this

12   case. You can also see pain portrayed in

13   terms of the body, and the patient's

14   experience of my own outcomes. So, "Can I

15   sleep better? Am I able to get back to

16   work?," et cetera. So this is used to create

17   the next step care plan, and it's all based on

18   patient-generated data.

19   So the patient-generated data can

20   also be used to actually go from the concept

21   of value -- easy to say, perhaps hard to

22   measure -- to measuring value. And this is a

 1   bit complicated, but the same feed

 2   forward/feedback patient-reported outcomes

 3   system that was started at the Spine Center

 4   became the data collection device for a

 5   randomized controlled trial that NIH funded,

 6   also an observational one as well, and in 12

 7   other centers, including Dartmouth.

 8   And then what it became was a

 9   comparative effectiveness research study, to

10   see how people in blue, who had surgery,

11   versus people in yellow, who were treated non-

12   surgically, did at 6 months, 12 months, 2

13   years, 4 years. And the patients are still

14   being followed.

15   And this is two-year results, and

16   it's one of three patients populations. It's

17   people with herniated disc. So the average

18   person with herniated disc is portrayed here,

19   on the east side. The west side is a disease-

20   specific measure called the Oswestry Index,

21   and higher scores here mean greater

22   improvement in disability. So blue, -38 on

1   the Oswestry, versus -24 in yellow, non-

2   surgically treated patients at two years. So,

3   favoring surgery.

4   North is the SF-36 physical

5   component score, and both groups had huge

6   gains, 44 points and 34 points respectively on

7   a 0 to 100 scale. So these are giant gains,

8   surgery a little bit more gain after two

9   years.

10   My perceived health benefit. "How

11 much was I helped by the treatment that I

12 got?" is on the right hand side, so perceived

13 health benefit, both strong but once again

14 favoring surgery.

15   But you see at the bottom these

16 better average results did cost more, so this

17 is an estimate of total direct and indirect

18 costs incurred by the patient or on behalf of

19 the patient, so about 25,000 dollars versus

20 10,000 dollars direct and indirect costs after

21 two years. And in the very middle is the

22 incremental cost per quality-adjusted life

 1   year, and that means about 74,000 dollars more

 2   per quality-adjusted life year for surgical

 3   care over non-surgical care, which many would

 4   consider in the United States a reasonable

 5   expenditure.

 6   So these results are then

 7   providing good information for research under

 8   these conditions. They're also used, on the

 9   lower right hand side -- if you go to our

10   website, you'll see different kinds of

11   outcomes and experiences publicly reported for

12   over five years. And so this is transparent,

13   these kinds of results, for people with

14   herniated disc, for degenerative spine, and

15   for stenosis, publicly reported.

16   This is a prototype, now, and

17   after 10 years and a collection of a lot of

18   data I can show up at the Spine Center and I

19   could see not just results for the average

20   patient, like I just showed -- after two

21   years, what might my results look like if I

22   got surgery or not -- but this is a risk

1   calculator.

2   So I would enter in my age and my

3   gender and answer, in this case, four

4   questions about pain on this screen, and I

5   would then get a personalized display on the

6   right hand side of what my estimated results

7   would be for people like me with respect to

8   pain relief. And that's, after two years, the

9   moderate versus the mild levels of pain.

10   Yellow is non-surgery, blue is surgery. So,

11   likelihood of better results.

12   And then the lower right hand

13   boxes have the face plots, and it shows the

14   proportion of people like me that would be

15   likely to benefit, or not, for personalized

16   risk assessment or benefit assessment, leading

17   to the possibility of very good shared

18   decision making, very good informed decision

19   making, very good patient engagement with

20   better data about what my choices might look

21   like and what they might get.

22   So wrapping up, we've gone into a

1   new electronic health record, and so a lot of

2   the functionality that took nine years to

3   build was lost in about a nanosecond on April

4   2nd. And so we've got this incredible group

5   of people that are recovering the lost

6   functionality, and putting it into the new EHR

7   environment.

8   There are now 18 different

9   clinical programs that are using the patient-

10   reported outcomes data at Dartmouth Hitchcock,

11   the oldest being the Spine Center, but many

12   others that have been used for more than five

13   years. And we think that it has real benefits

14   for patient care and for research, and for

15   where the health system is going.

16   We're shifting over to value-based

17   contracts. We're a pioneer ACO. Our basic

18   strategy is better value, better outcomes,

19   better experience, lower costs. Redesign of

20   care programs for people over time to

21   accomplish that. And so we think that this

22   information environment is really essential to

1   make that happen. The redesign of care is

2   essential, and the patient-reported outcomes,

3   as part of the information environment, is

4   critical to that.

5   So, lessons learned and a few

6   recommendations. A small comparative study

7   was done at the Spine Center and the

8   Rheumatoid Arthritis Registry in Sweden, and

9   the results are published in a paper that was

10   published a couple years back. And in this

11   small series of patients, as we thought, in

12   Mass General Hospital, patients tended to be

13   positive about giving their information. In

14   this case, 84 percent were positive about the

15   use of the patient-reported outcomes. A

16   statement visit became very helpful, thorough,

17   and informative.

18   Providers' reactions are mixed,

19   and in general when the provider is actively

20   using the information, it allows the patient

21   to become more involved in their care.

22   "Patients get more involved in their care" is

 1   a quote. It changes how health care is

 2   delivered, and there can be a real shift in

 3   the relationship when you're using the same-

 4   page care approach. We're now together

 5   looking in on my health outcomes and what we

 6   might do best next. And so it can change how

 7   care is delivered, and that can usually often

 8   be appreciated by clinicians, and sometimes

 9   not, because it is different.

10   Sustainable and replicable. We've

11   been going for a decade at Dartmouth in a lot

12   of different clinical programs. Some

13   recommendations are on the right, and this is

14   to make these kinds of systems work in busy

15   places.

16   Here's five suggestions. Fit the

17   PROs into the workflow, to make it easier for

18   patients and providers to do the right thing.

19   Co-design the system with stakeholder input

20   for best end user utility. It's got to be

21   useful for the patients and their families.

22   It has to be useful for the clinicians and the

 1 clinical teams. You can't just throw it over

 2 the transom.

 3   Educate the patients and the

 4 providers on how to use the PROs. And the

 5 providers have to pay attention to the data,

 6 because if I've taken the time to report and

 7 it's ignored, as a patient, you're

 8 disrespected, and what was the purpose of

 9 this? And so the clinicians using the

10 information is critical. Capture data from

11 other sources to improve the utility of the

12 information and then make it better over time.

13 So, thank you.

14   DR. PAWLSON: Thanks very much.

15 It's interesting, again careful planning and

16 dissemination, and also use in terms of

17 payment enhancement, potentially, again, in

18 the clinical care of the patient and in rapid

19 learning feedback research. And I think

20 having all three of those things as power in

21 this is to me, at least, more than sufficient

22 reason to be doing this. So hopefully these

 1   two, I think, very well-honed presentations

 2   have raised a number of issues and questions.

 3   And we'll start with the expert panel.

 4   Yes?

 5   DR. BASCH: Thanks for those great

 6   presentations. Ethan Basch again, Sloan

 7   Kettering. Something interesting that's

 8   alluded to in these presentations is that the

 9   collection of patient-reported outcomes in

10   practice itself, that very act, can be

11   considered as a quality measure or a

12   performance measure, right?

13   So it's a different way to think

14   about it. One way we could look at your

15   examples is to say "Okay, you've demonstrated

16   the feasibility of measuring various

17   outcomes," but another way is to think of the

18   integration of PROs into clinical care as a

19   structural process measure, which is another

20   interesting way to think about it, if we

21   believe that integrating these into practice

22   does enhance the delivery of care and the

 1 ability of practitioners to self-understand

 2 and benchmark themselves against other

 3 practitioners, and thus continuously improve

 4 their performance.

 5   DR. PAWLSON: Sort of just like

 6 ordering a statin, or a lipoprotein, or

 7 something.

 8   Next?

 9   DR. KAZIS: I'll keep the mic a

10 little further away this time.

11   I thought the presentations were

12 great. Having worked with clinicians for many

13 years who were on the front lines and are

14 dealing with the complexities of care, the

15 demands that are on them, the issue is

16 information overload.

17   And I've talked to a number of

18 clinicians given the electronic medical record

19 that are really frustrated, and find that the

20 information is often redundant. It's dated.

21 It doesn't convey what they really need. They

22 really don't have easy access to different

 1 parts of the electronic record. It becomes a

 2 real challenge.

 3   With new information that we're

 4 talking about in terms of patient-reported

 5 outcomes, how can we compel the doctors to

 6 better understand the importance of this

 7 information, so that in fact they're going to

 8 use it, rather than tossing it in the

 9 wastebasket?

10   DR. MORT: I think that's a really

11 great question, one that I hope will be

12 remedied by the change in the way we deliver

13 care, and will be delivering it more so under

14 ACOs and payment systems that are captitated,

15 global payment, that sort of thing.

16   Patients come to me. One patient

17 came to me last Wednesday. She said "Dr.

18 Mort, how come we still have 20 minute annual

19 exams? Aren't you a pioneer ACO, and aren't

20 you doing all these --" because she reads, she

21 knows how we're doing at Blue Cross and

22 everything.

 1   I said "Well, not yet. We're

 2   working towards that." But she's absolutely

 3   right. She's a health care consultant. She's

 4   absolutely right that we need to change the

 5   way we actually deliver care to make more

 6   access to group visits, patient portal, using

 7   non-physician providers, non face-to-face

 8   visits.

 9   So we can't do it in the current

10   20 minute, or 15 minute, or even half an hour,

11   an hour, face-to-face visit. That's just not

12   adequate to deliver all the care, and absorb

13   and react to all the data. So we're a little

14   bit out ahead of it, I think, but I think the

15   answers will be forthcoming as care redesign

16   ensues and more and more practices figure out

17   how to do it.

18   DR. PAWLSON: And I noticed you

19   were using graphs and stuff, and that's

20   another way. The whole way we display data --

21   you know, I was also on the plane, and I was

22   looking at the difference between an old 757

 1   and a brand new 737-800, and the display

 2   panels are just totally different. And I

 3   would guess that pilots get a heck of a lot

 4   more information the right way in the new

 5   cockpit. So that's a nice, I think, thing to

 6   think about, is how we deliver information.

 7   I think we want one more question

 8   from the audience, and then can you unmute the

 9   phones to see if we have any phone questions?

10   So first, I saw somebody back -- one more

11   expert, and then somebody in the audience. I

12   saw a hand.

13   DR. GAGE: Barbara Gage,

14   Brookings. I found the presentations very

15   interesting. I did have a question for Gene,

16   and one of the outcomes was a very important

17   outcome. It was a two-year out outcome. How

18   did you collect that from the patient, and in

19   your comments about sustainability, is that

20   something that you have on an ongoing basis?

21   And if so, how are you funding it, or doing

22   it?

1   DR. NELSON: Those particular

2   results were part of this larger NIH-sponsored

3   trial, so people were followed up in that case

4   as in a research study. We had a meeting last

5   week with the ortho group, and the issue was

6   "Let's make sure that we attain 90 percent

7   baseline PRO data, and 80 percent follow-up

8   PRO data for at least two years." That we

9   have to do this, it's important for our

10   ability to, again, provide care and measure

11   the results.

12   And so that becomes the design

13   challenge, to get the work processes and the

14   patients and clinical teams engaged enough,

15   and the design good enough, that we get 90

16   percent intake and 80 percent follow-up over

17   two years.

18   DR. PAWLSON: Isn't that close to

19   the British experience?

20   DR. NELSON: And to get at that,

21   it's a mixed-methods approach whereby portal

22   at home, possibly IVR has been mentioned,

1 iPads in the office for people that can't

2 report that information, advance scheduling

3 those people 30 minutes early to complete the

4 essential information, so that everything

5 works well.

6 DR. PAWLSON: And two years may be

7 a bit of a stretch, but the British actually

8 base payment on getting responses from

9 patients in the three to six months post-

10 surgical, so there are some levers out there.

11 I think we had one question back

12 in the audience? Go ahead.

13 MS. MASTANDUNO: Melanie

14 Mastanduno from the Dartmouth Institute. Just

15 one point to add to Gene Nelson. Those

16 orthopedic providers were very keen on having

17 some of their clinical team staff participate

18 in the review of the responses, so that

19 screening for positive results that land on

20 the doc's desk are the ones that are part of

21 the workflow, as opposed to noting the results

22 and integrating them into the record.

1   So screen for positives, and that

2   will reduce burden on the physician.

3   DR. PAWLSON: Thank you all very

4   much, and thank you to the panel. That was

5   very well done.

6   MR. CUNNINGHAM: Real quick, just

7   want to check with the operator. Do we have

8   anyone else on the queue for questions or

9   comments?

10   (No response.)

11   MR. CUNNINGHAM: Operator?

12   OPERATOR: Once again, if you

13   would like to ask a question, please press

14   star-one on your telephone keypad.

15   There are no audio questions at

16   this time.

17   MR. CUNNINGHAM: We do have one

18   quick question from the back.

19   MS. LENTZ: Thank you. Lisa

20   Lentz, CMS. I did have two questions, one for

21   Elizabeth and one for Gene. For Elizabeth, I

22   wondered if you could just elaborate a bit

 1   more on the process for involving patients in

 2   the selection of the domains and the measures.

 3   And for Gene, I wondered if you could

 4   elaborate more on how you've translated

 5   economic data, such as QUAL-Es, into something

 6   easily understandable to consumers on the

 7   website.

 8   DR. MORT: Involving the

 9   consumers, patients, was really interesting,

10   because the first couple of focus groups we

11   held, we even had difficulty as focus group

12   facilitators -- it wasn't me, it was people

13   who were trained focus group facilitators --

14   describing what we were trying to get at, in

15   terms of quality of life and outcomes. And

16   what was informative was that patients weren't

17   even thinking about it that way, because no

18   one had ever broached it with them and asked

19   for their thoughts.

20   But once they got it, we just had

21   -- you know, we did it through focus groups

22   and trained facilitators, to get people to

1 vocalize on what they thought was important.

2 And that's pretty much the methodology: focus

3 groups a couple of times for each one of these

4 projects.

5   Your question raises a question

6 for me, as to how are we going to do that on

7 an ongoing basis. So thanks for asking the

8 question.

9   MS. PACE: Okay. Could we have

10 our next panel come on up? We'll have to,

11 maybe during the lunch break, get a chance to

12 ask more questions.

13   DR. NELSON: Well, I'd like to

14 just answer this other question.

15   MS. PACE: Okay. Go ahead.

16   DR. NELSON: The question about

17 QUAL-Es on the website. We did not put the

18 QUAL-E, just as the cost data, on the website,

19 at this point. It's pretty complicated. But

20 what is on the website is an estimator of, if

21 you have a procedure or not, what your

22 expected out-of-pocket and insurance expenses

1 are going to be. So there is that kind of

2 proactive cost information. Satisfaction is

3 there, yes.

4   DR. BASCH: Hi again, I'm Ethan

5 Basch, Memorial Sloan Kettering Cancer Center.

6 I'm an oncologist and an outcomes researcher.

7 I run a research program focused on

8 informatics and patient-reported outcomes. I

9 am delighted to be here. Thank you very much

10 to the organizers for this invitation, and

11 many of us here are quite excited to see this

12 topic being discussed with such methodological

13 rigor.

14   I also stand between you all and

15 lunch. I often find myself in this position

16 at meetings, probably because I'm a New Yorker

17 and I talk fast. So you know, I can just

18 speed us along. We have a little over an

19 hour, and so I'm just going to set up our

20 session here very briefly, and then hand it

21 over to our panelists.

22   So, understanding the patient

1   perspective, or their experience with care,

2   involves more than just developing a

3   questionnaire. It's really a whole package,

4   right? It's the questionnaire, but also the

5   way that it's administered, the way that it's

6   interpreted, and then how it's acted upon.

7   Our panel now is going to focus on

8   the second piece of this: how the

9   questionnaire is actually administered once

10 it's been developed. And this is vitally

11 important for a couple of reasons. The first

12 is that how instruments or questionnaires are

13 administered can actually affect the

14 information that you get back, right? How you

15 ask the question affects the answer that you

16 get, and we really need to be very careful

17 that we don't alter the meaning of what we're

18 getting back.

19   But the second reason, which I

20 think is actually the most important, is

21 around missing data, missingness. There is a

22 real risk in real-world populations of having

 1   systematic missing data that's not at random

 2   from particular populations: populations at

 3   risk, populations who are traditionally

 4   underrepresented or hard to reach, those who

 5   are the sickest. Oftentimes, the patients

 6   whose perspectives we may care about

 7   particularly. And if we're not careful in the

 8   way that we administer our questionnaires, we

 9   can exclude those patients and lose their

10   perspective.

11   There's another issue, which is

12   that practices that are particularly good at

13   eliciting responses from their sickest

14   patients may actually look worse than those

15   practices that actually don't get as many

16   responses back from their sick patients. So

17   there are all sorts of biases that can be

18   introduced by the way the questionnaires are

19   administered.

20   So our panel is going to focus,

21   really, on three broad conceptual areas around

22   administration of questionnaires. The first

 1   are methodological issues. Methodological

 2   issues are things like the mode of

 3   administration. We've heard a little bit

 4   about IVRS automated telephone administration,

 5   there's web administration, good old fashioned

 6   pencil and paper.

 7   There are true scientific or

 8   methodological issues that are related to

 9   mixing these up within a population, to

10   developing a questionnaire in one mode and

11   then converting it, or looking at equivalence

12   in another mode, and so on.

13   There's an area of increasing

14   interest called CAT, or Computerized Adaptive

15   Testing. David Cella's about to give us a

16   demonstration of this in action using an

17   electronic questionnaire, so I'll leave it to

18   that, and it will also be discussed by one of

19   our panelists.

20   And then the second issue is

21   feasibility. So particularly with a very

22   large implementation, in a large population,

 1   substantial infrastructure has to be

 2   developed. Personnel need to be trained and

 3   put in place. This can be cumbersome. It can

 4   be complicated. And it needs to be

 5   sustainable. And there are real barriers and

 6   lessons to be learned from other contexts, so

 7   we'll be highlighting those.

 8   And then the third issue is around

 9   community or population engagement, patient or

10   person engagement. And this really has to do

11   with enlisting populations as our partners.

12   As we've heard already, there are focus group

13   approaches, but there are also community

14   outreach approaches. With some of these very

15   large engagements, there's a real need to

16   engage people or patients as our active

17   partners. So, methodology, feasibility, and

18   patient engagement.

19   We have three learned panelists

20   today. I won't belabor their introductions.

21   Their full bios are in the distributed

22   materials. We have Lewis Kazis from Boston

 1   University. He's a professor of health policy

 2   and management who directs the Center for

 3   Assessment of Pharmaceutical Practices. We

 4   have Richard Bankowitz from Premier Health

 5   Care, who is the chief medical officer, an

 6   internist and an informaticist. And then from

 7   the Patient-Centered Outcomes Research

 8   Institute, Lori Frank, who's the director of

 9   patient engagement research.

10   I'll stop there, and once again

11   introduce Dave Cella, my old friend, who's

12   going to give us a demonstration of CAT in

13   action for about 20 minutes.

14   DR. CELLA: It's me again. Thank

15   you, Ethan. This is going to be the densest,

16   most technical part of the day, so bear with

17   me.

18   Before I get to CAT, I thought I

19   would come back to the paper and review some

20   of the key points made in the paper for those

21   of you who might be seeing or hearing some of

22   these things for the first time. Reminding

1   you this is a session for methodological

2   issues, so forgive me in advance for getting

3   into what might seem like some technical

4   details.

5   So I'm going to talk about method

6   and mode of administration, and also the

7   source of data. And it's important to get

8   into this to some degree, because decisions

9   have to be made about the method by which you

10 get these data, and there are costs and errors

11 associated with surveys, however you go about

12 doing them. It's important to select the most

13 appropriate method for a particular question,

14 and to try to stick within that method when

15 possible. We can come back to that.

16   And most of all, know the impact

17 of a particular methodology that you're using

18 on errors and costs. Methods and modes differ

19 along various dimensions, which the paper

20 covers; that is, the degree of interviewer

21 involvement from none to complete, sometimes

22 something in between, the level of interaction

 1   with the respondent, or the person providing

 2   the information, the channel of communication

 3   that gets used, and also the degree of

 4   technology.

 5   One way to look at that is to

 6   start from the source, so the source is either

 7   going to be the person himself or herself, or

 8   a proxy or observer on behalf of that person,

 9   usually selected as a second choice, but

10   sometimes an essential one. And then mode, in

11   this context -- in the paper, at least, we

12   referred to mode as the recorder of the

13   information.

14   So if the person is providing her

15   information directly on a piece of paper or on

16   a computer screen, that's self-administration.

17   If the information is collected by talking to

18   another person, that's interview-administered.

19   We'll use that distinction for mode for this

20   context, at least. And the method, then,

21   would relate to whether you get that on paper,

22   whether you get it on a computer, or over the

1 telephone.

2   So, proxy reporting. What are the

3 pros and cons? It's useful, particularly when

4 it's difficult, or not even possible, to

5 obtain PROs directly from the patient. It

6 allows, therefore, broader inclusion and a

7 more representative range of patients. It

8 minimizes the missing data problem that Ethan

9 alluded to, increases the feasibility of

10 longitudinal assessment, because you may be

11 able to start with patient self-report, but

12 then need to move to proxy, which is better

13 than moving to nothing.

14   And so in that regard, proxies can

15 substitute, or they can complement, patient

16 assessment. There are situations where you

17 might want both to be done concurrently. That

18 may be a luxury in some settings, but it's

19 something that a strong case could be made for

20 that. You can involve proxies to assess

21 patients as they think the patient would

22 respond; that is, the proxy responding for

1 what they would believe, if the patient were

2 asked the questions, what the answer would be,

3 versus the proxy giving his or her own

4 perspective on the patient, which can be

5 different than what they think the patient

6 would say. "I think my husband would say he's

7 just fine cognitively, but I've noticed

8 slippage" would be an example.

9   Evaluating agreement between

10 patients and proxies is something that can and

11 should be done. Usually in the literature

12 there is better agreement -- it's never great,

13 but there is better agreement when the rating

14 is of something observable, like physical

15 function or activities of daily living, being

16 able to do things or function in the world,

17 and less agreement when it's about something

18 mental or in the social realm, such as pain or

19 cognitive status and emotional status.

20   The magnitude of the disagreement

21 can be minimized with careful attention, but

22 keeping in mind that disagreement between them

1 sometimes is actually useful, as I alluded to

2 earlier with the example of someone with early

3 cognitive impairment.

4   So, how about mode, that is, the

5 recorder? So, let's just consider the

6 objectives of the assessment, and then the

7 resources that you have available. So, there

8 are advantages to self-administration. One is

9 cost. You don't have to pay an interviewer.

10 You often get better disclosure, or more

11 disclosure of issues and problems on a non-

12 interview self-report, and people can proceed

13 at their own pace.

14   Disadvantages are that there's

15 more potential for missing data, and it really

16 does require that you have up-front careful

17 attention to survey design, using best

18 practices in survey design, because it's very

19 easy to do bad surveys, and not so easy to do

20 good ones.

21   Interview administration has

22 advantages of allowing you to not worry so

1 much about survey design, because the

2 interviewer can make up for the problems in

3 the design, and it's useful for patients that

4 have reading problems or writing problems or

5 vision problems. The disadvantage is, of

6 course, the cost and the potential for bias,

7 because the interview is a social exchange,

8 and in that social exchange that can influence

9 the way people report how they're doing. And

10 they tend to under-report in an interview,

11 compared to self-administration.

12   Concerns about the effects of mode

13 on data quality. So, the reliability is

14 actually high for both. That's good news.

15 Response effects tend to favor self-

16 administration, but they're inconsistent. We

17 weren't asked to make a recommendation, but if

18 I were I would recommend, when possible, self-

19 administration over interview.

20   Just to kind of run through this

21 fairly quickly, the paper and pencil versus

22 electronic, if you consider electronic to be

1 either by computer or by telephone -- and of

2 course, there's a range of electronic

3 administration options.

4   Paper and pencil has low start-up

5 costs but more downstream cost issues related

6 to data entry errors, scoring challenges, and

7 getting it incorporated into electronic health

8 records. So you may save money up front but

9 lose it later.

10   Electronic has advantages of being

11 interactive, very practical, more integrated,

12 easy to incorporate into the electronic health

13 record, but there's the up-front cost that's

14 incurred by setting up electronic data

15 capture.

16   There is a potential for

17 differences between paper and pencil versus

18 electronic based upon things like the

19 impersonality of the method, the cognitive

20 burden on the patient, who may find it easier

21 to use the tablet -- I find it interesting

22 that we use the word "tablet" in the medical

 1   setting for small computers -- Control over

 2   the questionnaire, which can be more easily

 3   managed in some settings when it's paper, and

 4   communication style.

 5   The increasing evidence of

 6   evidence equivalence is encouraging. That is,

 7   there aren't a lot of differences between

 8   different methods of administration. As new

 9   methods are developed, it's critical to

10   compare them to existing methods.

11   Probably the most vulnerable is

12   telephone interview administration. First of

13   all, for example, getting an in-clinic

14   assessment and then having people call up on

15   the phone and get information later is the

16   most vulnerable to having a systematic bias,

17   where you look like you're improving because

18   you're having that social exchange. But apart

19   from that, if you're careful about the

20   longitudinal picture, you can minimize if not

21   reduce this bias. And across these methods,

22   patient privacy is always a concern.

1   So we looked at this, and PROMIS -

2   - now, PROMIS, to those of you who don't know,

3   is the Patient-Reported Outcomes Measurement

4   Information System. It's a large, nearly 100

5   million dollar investment over an almost ten

6   year period from the NIH to develop generic

7   but responsive patient-reported outcome tools

8   in various domains that cut across multiple

9   chronic conditions.

10   And within that project -- I'll

11   say more about it later with the CAT demo --

12   we looked at a mode of administration, or

13   method of administration by this paper's

14   terminology, study, comparing paper and pencil

15   to computer to IVR, Interactive Voice

16   Response, and to PDA, to handheld device or

17   smartphone.

18   And we found, happily, that there

19   were no meaningful differences found between

20   modes of administration. Now, interestingly,

21   remember what I said earlier about interview

22   tending to boost up scores. The IVR was done

 1 by a computer. And this is my belief; it's

 2 not something we can prove. But I believe

 3 that the reason the IVR was equivalent to

 4 paper and pencil and computer, which is great

 5 news for PROMIS, is because the respondent

 6 knows it's not a person they're talking to.

 7 They know that they're interacting with a

 8 machine, and therefore they're treating it, I

 9 believe, more like an impersonal exchange, and

10 they're providing information. So it was not

11 a live interviewer.

12   This less than one and a half

13 points on a hundred point scale just

14 illustrates that -- the vertical dotted lines

15 represent what would be, even in the most

16 conservative sense, an important difference of

17 two points. That's two tenths of a standard

18 deviation either side of the average. The

19 estimates, whether you're comparing PC to

20 paper and pencil or to IVR, or to PDA, for

21 fatigue, physical function and depression were

22 always virtually identical to the PC

 1 administration.

 2   And I think this came up earlier,

 3 as well, and somebody alluded to it. We did

 4 ask what they preferred, and people preferred

 5 the computer administration. They like it,

 6 and I agree that our experience with tablets

 7 is quite positive. They're really easy to use

 8 for people that you might otherwise have

 9 literacy concerns about.

10   So how about the setting? Get it

11 in the clinic, get it at home. One of the

12 bigger problems is mixing the two. Although

13 it can be done, it should be done with

14 caution. The strengths of getting it in the

15 clinic are you're getting the real-time

16 assessment, it's easy to implement electronic

17 administration because you can feed it right

18 into the electronic records.

19   The limitations were, as we heard

20 earlier, impact on clinic flow, interruptions

21 in the assessment based upon clinic flow. We

22 once had a study that we couldn't get done in

1   the waiting room because they were so

2   efficient hitting one of their other

3   performance measures, and not having long

4   waiting times, that the waiting time we

5   anticipated to fill out the questionnaires

6   wasn't there, so we got missing data because

7   of the group hitting on the waiting time

8   performance. And patient distraction, anxiety

9   can be a problem in clinic, as well as staff

10   burden.

11   In the home setting, the strengths

12   are that it minimizes impact on clinic flow,

13   minimizes staff burden -- so, sort of the

14   opposite strengths on the home side. But

15   there are limitations to accessibility and

16   privacy and security and patient safety of an

17   anxious patient, or if an alert comes up and

18   the patient's at home, you have to engineer a

19   system to take care of that.

20   Last couple of things. Ethan

21   mentioned missing data and how to manage that.

22   There was a fair amount in the paper about

 1   that. I'll just say that there can be bias

 2   introduced by missing data. There often is

 3   bias introduced by missing data. I won't go

 4   through the methods to do that, to help enable

 5   some time for discussion.

 6   And there can also be this

 7   influence of, over longitudinal assessment,

 8   patient adaptation or even response shift,

 9   where the patient's own sense of what a number

10   means on a scale changes over time.

11   And you may then think that you've

12   measured change, when in fact you're actually

13   measuring the patient's internal barometer for

14   what an 8 means on pain, because they never

15   knew what a 10 could be until they had a 10,

16   and so now their former 10 is now an 8, as an

17   example.

18   So this leads into the CAT demo.

19   Most things that you've used in the past, and

20   we've all used in the past, have been built on

21   classical test theory, which estimates a

22   person's level based upon a summing up of all

1   the questions they answer, like the way the

2   SF-36 is scored. And that produces a test-

3   dependent measure. You have to ask all the

4   questions, and you really are dependent on

5   administering that entire test.

6   Item response theory is test-free.

7   You can create different tests from pools of

8   questions and estimate the underlying thing

9   that you're measuring, whether that's pain, or

10   depression, or fatigue, physical function, et

11   cetera. It enables you to do a customized

12   assessment that includes Computerized Adaptive

13   Testing, in which you can tailor the questions

14   to the individual that you're measuring.

15   So you can have shorter

16   questionnaires that maintain good precision or

17   accuracy, even at the individual level, and

18   you don't have to have those long tests to do

19   it. And patients don't have to complete the

20   same sets of questions along the way. They

21   can have different questions administered at

22   different times, if you prefer to have that,

1   or if the CAT selects that.

2   So the demo, this is just to give

3   you the framework for PROMIS, this divide into

4   physical, mental and social health, and then

5   within each of those areas there are as many

6   as 40 different banks across pediatrics and

7   adult, on the physical side measuring symptoms

8   and physical function, on the mental health

9   side measuring various affects, principally

10   negative affect but evolving positive affects,

11   behaviors and cognitions, and on the social

12   health side measuring social relationships and

13   social function.

14   So I mentioned this pool of

15   questions. They're calibrated. If you have

16   a calibrated set of questions, meaning that

17   every item is a measure of that underlying

18   thing, that underlying trait, that's called an

19   item bank. And when you have an item bank of

20   calibrated questions, any subset, including

21   one item from that bank, can be used to

22   provide a score for that domain. I think that

1 has a lot of possibility in this kind of

2 setting, where you might want to have

3 provider-based measures of something like

4 depression or fatigue or physical function

5 that don't require long assessments.

6   The metric for PROMIS is a T-score

7 metric with a mean of 50, standard deviation

8 of 10. It's referenced to the U.S. general

9 population, 2000 census demographics.

10   So the tools from PROMIS are

11 derived from item banks. They involve

12 Computerized Adaptive Testing, which is a

13 dynamic testing -- I'll show you an example of

14 that -- using fixed-length forms, or you can

15 do health profiles of 29, 43, and 50 item

16 length. And then there's this global health

17 index that Dr. Mort mentioned earlier, which

18 is 10 items measuring physical and mental

19 summary scores.

20   Okay. So, here's how the CAT

21 works. We assume from the beginning --

22 remember, it's referenced to the general

1 population, mean of 50, standard deviation of

2 10, so that's what's represented in the lower

3 panels, here. That's a distribution of around

4 50, a normal distribution of depression we

5 assume in the general population. So we're

6 just going to assume that any given person at

7 the start of a test has a score of 50, and

8 there's a large confidence interval around

9 that score.

10   The best item in the depression

11 bank to start the CAT is, lo and behold, the

12 question over in the top right, "I felt

13 depressed." And then the answers are never,

14 rarely, sometimes, often, always in the past

15 week.

16   The curves you see in the top

17 right show you the probability of responding

18 never, that's the black, rarely, that's the

19 red, sometimes, that's the green, often,

20 that's the blue, and then always, that's the

21 light blue. So the probability of responding

22 each of those answers increases as you get

 1   more depressed, so the more depressed you are,

 2   the more likely you are to say you're

 3   frequently depressed.

 4   And the lower plot shows you how

 5   much information that item has on that same

 6   metric. So it asks that question, the person

 7   gives an answer. And now we'll just run

 8   through the first question, the first answer.

 9   The person says "rarely." That statement has

10   a T-Score of 52, the standard error's a 4, and

11   finds the next question that's going to be

12   most informative, in this case "I felt like a

13   failure." You see the response characteristic

14   curves and the information curves that the

15   computer knows. That's why it picked that

16   question.

17   The person says rarely, it

18   estimates the score of 53, a little more

19   depressed. Standard error goes down to 3.

20   Then it picks the next question, "I felt

21   worthless," says rarely, and then estimates

22   55, standard of 2.

1   Now, we can go on and on, and if

2   you keep going -- that's three questions asked

3   so far. If you keep going on, it goes on to

4   eight questions, but you'll see the estimate

5   didn't change really much at all, vastly,

6   between 54 and 55. So we asked eight

7   questions, but really only needed to ask three

8   in this case, and got the same estimate. So

9   with three questions, got a very precise

10   estimate of this person's depression. That

11   takes about 15 to 20 seconds.

12   Now, the last couple of things

13   that I want to show you because I think it's

14   pretty germane to this discussion. We have a

15   fatigue item bank as well in PROMIS, and you

16   can imagine these different programs in

17   cancer, arthritis, heart failure, joint

18   replacement, pain management, using different

19   methods, different items, CAT's different

20   short forms. You're going to get the same

21   metric and the same meaning.

22   The PROMIS investigators did this

 1   in a research setting in COPD, heart failure,

 2   low back pain, depression and cancer, and in

 3   each case measured fatigue, so I'll show you

 4   the fatigue example. And this is an

 5   animation, so you've got to kind of go quickly

 6   through it.

 7   So it starts, remember, with mean

 8   of 50, standard deviation of 10, to remind you

 9   of that. COPD patients starting over at the

10   lower case, stable are around 56, exacerbators

11   are around 63, and patients that go from

12   exacerbation to stable actually, lo and

13   behold, go from 63 down to 56, which you'll

14   see down there under the dotted line. Heart

15   failure transplant patients start at around

16   58, and drop down to around 47.

17   Depression patients start up over

18   60, more than a standard deviation, and get

19   better with regard to their fatigue when their

20   depression is treated, after one month and

21   then after three months. And now back pain,

22   the same thing with back pain. So in all

 1   these cases, you have different clinical

 2   areas, but the same metric on fatigue, being

 3   able to compare changes.

 4   You see, they're all starting more

 5   fatigued than the general population, and all

 6   moving in the right direction after treating

 7   the clinical problem. Same thing with cancer,

 8   but we'll move ahead.

 9   This is the last concept I want to

10   put forward, because I think it's also pretty

11   relevant to what we're looking for in this

12   context, and that's a PRO Rosetta Stone, or

13   PROsetta Stone, which is a project that we

14   have to link many of these different measures

15   -- PH29, CESD -- with the PROMIS depression

16   measure, as an example. We've done that. We

17   haven't published it yet.

18   And therefore, you can express --

19   you can administer the PH29, you don't have to

20   give that up. But you can express it as a

21   metric. We heard earlier from Dr. Burstin

22   that NQF does not endorse the instruments;

1 they endorse performance measures. This is a

2 way one could think of it, that this metric of

3 the mean of 50, standard deviation of 10,

4 referenced to the general population, is a

5 potentially endorsable metric that you can get

6 by asking PROMIS questions, or PH29 questions,

7 or CESD questions, but you're putting them on

8 that common metric I showed you with fatigue.

9   This is a sample from work that

10 we've done, comparing a fatigue questionnaire

11 that we developed earlier in the cancer

12 setting to the PROMIS fatigue T-Score. You

13 can look them up and use these in your

14 reporting.

15   I think that's the last slide.

16 Thank you.

17   DR. BASCH: Great. Thank you. In

18 the interests of time, we're going to move on

19 to our first speaker. Lewis Kazis, why don't

20 you come up to the podium to speak, so folks

21 can see you?

22   And while you're coming up, I'm

 1   reminded to mention that, in addition to

 2   PROMIS, which is an NIH initiative, there is

 3   also a second government initiative under the

 4   NCI called PRO-CTCAE that some of us in the

 5   room have been involved with, that uses some

 6   advanced methods to develop questions to allow

 7   patients to report on issues related to

 8   adverse events, or safety and risk, for anyone

 9   who's interested.

10   DR. KAZIS: Thanks, Ethan. I just

11   want to mention that it's a delight to be here

12   today, in a conference that's really dear to

13   my heart. I've been involved in the use of

14   patient-reported outcomes -- in their

15   development, in the methods, and in their

16   implementation in the context of performance -

17   - for more than 25 years. And in fact, BU

18   just gave me a clock for being at BU for 25

19   years, so that sort of reminded me how long

20   I've been at it.

21   What I wanted to mention before

22   going into what I was charged with talking

 1 about today was that the VR-36 and the VR-12

 2 were developed in the VA under the support of

 3 the Health Service Research and Development

 4 Service. And the VA, I think, has been at the

 5 forefront of patient-reported outcomes and

 6 performance measures for many years, going

 7 back at least 20 to 25 years, when in fact

 8 performance measures in the VA took on real

 9 import in terms of VISNs and their

10 organization and resource allocation, and so

11 forth. And I think the whole move in that

12 direction began with Ken Kaiser, who was in

13 fact the founder of this organization.

14   So the VR-36 and the VR-12 have

15 been adopted by the VA in terms of some of the

16 assessments that they're currently doing and

17 have done historically in the area of

18 performance, and have been adopted by CMS and

19 the Medicare Advantage program specifically in

20 terms of principal endpoints in their

21 evaluation. The VR-12 is now used in

22 highlighting those particular plans in a

1   particular two-year cycle that are either

2   negative or positive outliers.

3   We've also recently developed and

4   published a utility metric that's generated

5   from the VR-12 that allows one to begin to

6   look at cost-effectiveness in the context of

7   plans, so that information is out there. And

8   also, it's in the public domain, and free of

9   charge, in terms of algorithms, imputation,

10   and contextual fixes, as it has been supported

11   by the federal government over many years.

12   So my charge today was to talk

13   about the issue of bridging measurement tools,

14   and the very first slide is what I consider to

15   be a binding framework for the use of legacy

16   measures. Those are the historic measures

17   that David Cella talked about, and relate

18   specifically to a set of items in a particular

19   questionnaire, like the VR-12.

20   Just to mention that the IRT

21   approaches have informed legacy measures, and

22   have been, I think, an important methodologic

1 advance in terms of allowing us to perfect and

2 come up with even more precise legacy tools.

3 And clearly, I think the legacy measures have

4 informed the development of item banks, as

5 they have been used in the context of CAT, the

6 Computer Adaptive Test. And clearly, I think

7 this becomes a very important aspect.

8   So there is clearly synergies

9 between legacy measures, IRT, and the item

10 banks that they have helped to inform. I

11 think as we move forward, the more bridges

12 that are established between legacy measures

13 and item banks, the better.

14   As I see it, there's no real

15 silver bullet in terms of any single

16 assessments, or even bank of assessments, that

17 will work totally in terms of the complexity

18 of our health care system, and I think one

19 needs to move in the direction of bridges

20 that, in fact, tend to combine the use of

21 assessments that, in fact, have been used for

22 many years, the legacy measures, and the newer

 1   CAT models that are out there.

 2   So I'll just mention a couple of

 3   points in terms of what I consider to be the

 4   advantages and disadvantages of the legacy

 5   measures, and then talk very briefly about the

 6   IRT CAT measures.

 7   The legacy measures have been

 8   extensively tested for reliability and

 9   validity across many settings, over many years

10   and populations. A good example is the VR-12,

11   which has now been administered to well over

12   5 million individuals in the VA, outside the

13   VA, in terms of CMS and the Medicare Advantage

14   program, and in other systems of care. In an

15   average week, I receive about six requests for

16   the VR-12 with their scoring algorithms.

17   Fewer resources now are needed to

18   implement the legacy measures compared to CAT,

19   and that clearly is an advantage, because the

20   CAT measures do require resources in terms of

21   their development implementation in clinical

22   settings. The expertise to implement them has

1   matured, and they can be integrated with new

2   technologies, and have been in the context of

3   the internet.

4   Disadvantages, of course, include

5   the time to complete the instrument that David

6   mentioned. It's usually longer than the CAT.

7   Instruments are less flexible to update and

8   calibrate compared to the CAT, and they

9   require larger samples to avoid spurious

10   results.

11   If one looks at IRT and CAT, the

12   advantages clearly are, they estimate personal

13   level traits within subsets of items, they

14   usually require smaller sample sizes, and

15   they're less vulnerable to floor and ceiling

16   effects.

17   The disadvantages, I think,

18   clearly have been controversial, and some of

19   them involve the differential item

20   functioning. That calculation may be

21   problematic for multidimensionality

22   assessments, and that's where the probability

 1   of responding in a different category varies

 2   across different subgroups, given equivalent

 3   levels of the underlying attribute. And an

 4   example of that would be age, for example, or

 5   gender, where in fact the DIF calculation may

 6   not be what we would want it to be.

 7   So clearly, there's no silver

 8   bullet here. The IRT CAT is an important

 9   methodology to be implemented, but there are

10   limitations in its use. They do require

11   front-end technology to implement the

12   instruments, and additional assistance is

13   usually necessary to facilitate successful

14   patient-technology interaction. So there is

15   a resource-intensive aspect to its use.

16   Clearly, I think, real advantages

17   are, it's useful in assessing change, there's

18   greater precision of measurement when compared

19   to the historic measures. There may be high

20   start-up costs, and the software and hardware

21   is commonly proprietary and expensive. So

22   clearly, there are advantages and some

 1   disadvantages.

 2   The other issue is the computer

 3   literacy of the population that one is dealing

 4   with, and whether the CAT method would require

 5   a population that's computer literate. So one

 6   has to consider populations where, in fact, it

 7   may not be as advantageous.

 8   So I do have more slides here,

 9   which will be in your packet. When you

10   testify before the Congress, you usually say

11   "It's going to go into the Congressional

12   Record."

13   So, let me summarize here. The

14   issue here is that I think there's no silver

15   bullet in terms of one assessment tool, or

16   even a simple set of assessment tools, that

17   will work in the context of a very complex

18   health care system. I think hybrid approaches

19   become really necessary, that bridge legacy

20   and IRT CAT approaches for purposes of

21   application to systems for measurement

22   performance, so that's really important. If

1 you take away anything from this talk, I think

2 the issue of flexibility and hybrid-ness

3 becomes really important in terms of what's

4 adopted and what's going to be used in a very

5 complex clinical setting.

6 Mixed mode approaches are

7 necessary, so that flexibility in the

8 protocols is possible in real world settings.

9 And David Cella, I think, did an excellent job

10 talking about the different modes of

11 administration. And clearly, I think, for

12 those non-methodologists, there needs to be

13 fixes in terms of the empiric data that, in

14 fact, might be biased by whether, in fact, the

15 administration is done at home, whether it's

16 in the clinic, or whether, in fact, it's face

17 to face, whether it's through computer, and so

18 forth.

19 Those things can impact on your

20 results, and one needs to adjust for those.

21 There are contextual fixes. We've spent many

22 years developing contextual fixes in the

 1   development of the VR-12, so that if there is

 2   a user out there, we have an algorithm, and

 3   those fixes can be made, so that when one

 4   generates a score from the VR-12, that metric

 5   can be considered to be reliable.

 6   So, mixed mode approaches are

 7   necessary, and there need to be fixes for

 8   these things. And then the issue of missing

 9   data, which is a fact of life in real world

10   settings, adjustments for missingness is

11   required to adjust for bias in results. We've

12   developed an algorithm called the Modified

13   Regression Estimate which, in fact, controls

14   for missingness.

15   So if you were to have as few, for

16   example, as three items present in the

17   administration, when you've administered the

18   VR-12, one can generate some scores on the

19   basis of that. So, one needs to consider

20   that. One needs to consider the biases that,

21   in fact, would be generated as part of that

22   missingness.

 1   And that's all I have to say.

 2   DR. BASCH: Great. Thank you very

 3   much. So, Richard, you're up next.

 4   DR. BANKOWITZ: Thank you. I'd

 5   like to speak about the experience that some

 6   of our premier members are obtaining in

 7   implementing some of these instruments. We

 8   are an alliance of 2,600 hospitals across the

 9   U.S., and we try to accomplish a lot in a

10   collaborative methodology. So we now have an

11   ACO implementation collaborative consisting of

12   30 health care systems, and in that context of

13   that laboratory we are trying to gain

14   experience with some of these instruments.

15   So we're looking at a variety of

16   things. We have two of our members, Fairview

17   and Geisinger, who are looking at the

18   Dartmouth Institute Primary Care patient-

19   reported measures pilot. We have two of our

20   members who are looking at the Southeast

21   Minnesota Beacon Community and Mayo Clinic

22   patient-reported outcomes. And then we've got

 1   three -- South Coast, Bay State, and St.

 2   Francis -- that are trying to implement the

 3   Dartmouth Institute "How's Your Health?"

 4   We've also been approached by the Gallup-

 5   Healthways, to see if we'd like to take up

 6   their well-being index, but so far that's in

 7   the very early stages.

 8   So I'd like to report on some of

 9   the very early information we're getting in

10   the use of the Dartmouth "How's Your Health,"

11   and I think that might help inform some of the

12   methodological questions.

13   So this is very early, and we've

14   got a very small sample size, but I think

15   we're getting some very interesting

16   information from it. First of all, the data

17   comes in in a variety of methods, so some are

18   filled out in the doctor's office, with paper

19   and pencil. Some are done via the internet,

20   before the patient appears. And none of these

21   three systems has anything like the

22   sophistication that Gene Nelson showed you or

 1   that Liz Mort showed you with the data

 2   infrastructure.

 3   So one big problem was, what do

 4   you do with the data? If it's filled out over

 5   the internet, how do you even get it to the

 6   physician? There's a concern about simply

 7   using email that's not secure, so you need to

 8   have a secure email server. One of the

 9   institutions is trying to put it on their

10   portal, but then the question was, how do you

11   get it to the right physician? It's fine that

12   it's in our portal, but how do we make sure it

13   goes to the right physician at the right time,

14   so that it gets incorporated into the record?

15   None of these systems can

16   integrate with the EHR a the moment, so the

17   best they can do is scan a document and that

18   goes into the EHR as basically a photograph.

19   I mean, you can't search it or do any kind of

20   structured analysis with it. So that's a big

21   problem, just in terms of implementation.

22   But we're getting some very

1   interesting feedback from both the physicians

2   and the patients. Some of the feedback we've

3   had from the providers -- and we only have

4   three, but they've said things like "The use

5   of this instrument really establishes rapport

6   with the patient." "It gives me a jumping-off

7   point for a discussion." It helped me

8   identify patients who had inadequate knowledge

9   of their condition." "It helped me identify

10   problems at home that I was unaware of,

11   problems with their feelings and social

12   phobias," so quite a lot of information. It

13   provided risk stratification for future

14   hospitalization," so maybe identifying

15   patients of particular risk. "It enhanced

16   patient empowerment." "The patients feel more

17   included." "I can identify confident

18   patients, and vice versa."

19   And then one physician said "The

20   most value came from identifying patients who

21   felt unable to manage their help problems.

22   This was really a good use of the tool, but it

1   took a lot of office time." So it's not

2   necessarily the case that just having this

3   information in front of you is going to make

4   the physical faster. It often makes it go

5   longer, because you've got more issues to deal

6   with.

7   The patients had a variety of

8   responses. First of all, most of them said

9   they would recommend it to others. 85 percent

10   said they would definitely recommend the How's

11   Your Health survey to other patients. One

12   patient said "I took the survey, and I'm

13   healthier than I thought I was." And that's

14   interesting, and I think it also has

15   implications for response shift. If the

16   instrument itself is making people have a

17   different expectation of their health, that's

18   an interesting finding.

19   The patients say "I'm glad to know

20   my physician was interested in what I'm

21   thinking." "It's good to have the information

22   available before I see the doctor." "I learned

 1   new things." "It gives me time to think about

 2   the answers to the questions." "I think it

 3   helps patients who don't ask questions while

 4   they're at the office." "I liked the reading

 5   materials." And then some said they wished

 6   they had more ability to put explanations in.

 7   So as I think about these

 8   responses -- and they are limited -- I think

 9   there are a couple of lessons, maybe, to be

10   learned. One, as we discuss these

11   methodological issues, I think it's important

12   that we not let the perfect become the enemy

13   of the good. And I think it really depends.

14   The first question you have to ask is "What

15   are we going to use the information for?"

16   Because that may dictate how precise we need

17   to be, and it may dictate the operating

18   characteristics of the test that are required.

19   So as I think about this concept

20   of useability, I think it's going to be the

21   most important concept as we go through the

22   measures endorsement process. So it may be

1 not precise enough to say this is a

2 performance measure. Is it a performance

3 measure for internal performance improvement?

4 Is it a performance measure for transparency?

5 Is it a performance measure to compare two

6 institutions? I think that's an important

7 question.

8   And so, as I thought about these

9 responses from the physicians and the

10 patients, they tend to fall into two classes.

11 Class one is actually dependent on the answer,

12 so we found some patients that are at high

13 risk, or we found some patients that don't

14 know a lot about their health, and we can act

15 on that. But then there's a second class

16 which is really not dependent on the answer:

17 establishing the rapport, being more included,

18 having the patient feel the physicians are

19 more engaged. That takes place just by the

20 process of the instrument alone.

21   So, how would we incorporate those

22 two things into performance measures? It came

1 up earlier as a structure measure. I think of

2 it almost as a surgical checklist. It's

3 something that should be done. I'm not sure

4 we would take each item on the checklist to

5 compare institutions. Institutions might want

6 their own running tallies, so they know if

7 they're getting better. But the use, I think,

8 is really going to be key.

9   So that's one challenge, and I

10 think the biggest challenge. The second

11 challenge, as I think about these measures --

12 and this has also come up today. We're moving

13 from measures of sickness and illness to

14 measures of health and well-being, which I

15 think is a very good progression. But I think

16 when we do that, we have a dilemma. Because

17 as we move to those measures of health and

18 wellness, we then begin to have shared

19 accountability, right?

20   So yes, the ACO, the health home,

21 is responsible for some things. But then we

22 have the school, we have the community, we

1 have access to fresh food and playgrounds. We

2 have a lot of items that impact health and

3 wellness. So how do we apportion that

4 accountability? It's going to be a very

5 important question. Not one of the

6 traditional methodological questions, but I

7 think a key one going forward.

8   So, I'll stop there.

9   DR. BASCH: That's great. Thanks

10 very much. So we're going to finish up with

11 Lori, and then we'll take some questions from

12 the audience.

13   DR. FRANK: Great. Thank you,

14 Ethan. So now I'm between you and lunch, and

15 also between you and the audience engagement

16 piece, so I'll move quickly through this.

17   I do want to discuss what patient

18 engagement means, how it is and is not

19 currently being implemented in the course of

20 PRO development and evaluation, with the hope

21 that reframing patient involvement in PRO

22 research can improve measure development and

 1   testing and enhance the value of PROs for use

 2   in clinical settings and for performance

 3   measurement. And I use the term involvement

 4   very mindfully, a point I'll return to in just

 5   a moment.

 6   PROs offer one way to capture

 7   outcomes meaningful to patients. They are not

 8   the only way. They don't always succeed, and

 9   they're not the only way to do so, which I

10   think is a point we all need to keep in mind.

11   When I was in kindergarten, I

12   remember we were promised that by the time I

13   was in sixth grade we would have the ability

14   to make phone calls to people and actually see

15   the faces of the people on the other end of

16   the phone. And I'm glad the technology is

17   finally here, but I still carry with me the

18   disappointment of all that delay, and the lost

19   opportunity, with the length of time it took

20   to bring that to be. And that's how I feel

21   about use of PROs generally, but method of

22   administration for PROs specifically.

 1   In the last century, I was part of

 2   a panel on the promise of ePRO, I think with

 3   some people here. And again, it's been a bit

 4   disappointing, the rate of adoption. I think

 5   that patient engagement might be a way

 6   forward, and I'm particularly interested in

 7   how that can apply to the tremendous

 8   contribution that the PROMIS initiative stands

 9   to make, if only we can get the uptake there,

10   like we need it.

11   I also want to say that I think

12   that -- I appreciated David Cella and his co-

13   authors' paper, with its thoughtful

14   consideration of all the methodologic issues

15   that we need to think through before going

16   full bore towards PROs in performance

17   measurement, but before we continue down this

18   track, or in keeping with the innovative

19   technology theme, the high-speed MagLev, I

20   think there are a couple of other trains that

21   need to be connected, and those would be

22   patient-centeredness and patient engagement.

1   In his 2009 Health Affairs piece,

2   Donald Berwick defined patient-centered care

3   as "the experience of transparency,

4   individualization, recognition, respect,

5   dignity, and choice in all matters related to

6   one's person, circumstances, and relationships

7   in health care." I think that there's a lot

8   in that definition, and a lot actually in that

9   piece, that's valuable as we consider the role

10   of engagement in improving measurement.

11   We do need to make that

12   distinction between patient-centered clinical

13   care, as he's talking about it in that piece,

14   and patient-centered research. For research,

15   we need to further differentiate between

16   clinical research and methods research, and

17   right now, as you know, PCORI is funding

18   clinical research, but we did just release the

19   funds for the methods research. And out of

20   the 50 funded projects, 11 of those dealt

21   with PROs. Nine of the 50 deal with Computer

22   Adaptive Testing or other technologies. So we

1   are moving forward, but I think that there's

2   a role for funding agencies here in this

3   dissemination and uptake.

4   I would add to clinical care, and

5   to research, when we're thinking from a

6   patient-centered standpoint, performance

7   measurement, obviously. What is the value to

8   adding engagement to a performance measurement

9   view?

10   In their discussion about the

11   paper, about the potential for PRO use in

12   clinical care, David and the co-authors

13   mentioned patient-provider communication and

14   identifying patient needs in a timely manner.

15   I think it helps to view those

16   sorts of statements from a patient-centered

17   perspective. Improving communication is a

18   form of patient engagement, which enhances

19   patient-centeredness. Identification of

20   patient needs ensures patient-centeredness.

21   So together, the engagement and patient-

22   centered orientation, from the clinician and

1 from the health system, can improve health

2 outcomes.

3   And I think that was well

4 catalogued, some of the empirical evidence for

5 that, in the paper. And certainly there's

6 evidence of the value for patient involvement

7 in improving content and construct validity of

8 our measures. But I suspect that, without

9 going further, we will miss out on some

10 opportunity for some more meaningful

11 information that we could get to improve our

12 measurements. So it's an exciting

13 opportunity, and I'll say more about that in

14 a moment.

15   I just wanted to review, then,

16 principles of engagement. You heard some in

17 the quote from Donald Berwick. Trust and

18 transparency, leading to respect. Partnership

19 and collaboration, including co-learning and

20 communication. There's an inescapable

21 interactive element to patient engagement, a

22 relationship element, which is why shared

 1   decisionmaking can be considered a form of

 2   patient engagement.

 3   So I have this virtuous cycle here

 4   of engagement, as just a way to show us that

 5   there's engagement in research. Right now, a

 6   lot of what's happening in PRO methods

 7   research is involvement, where patients are

 8   subjects, but this is a giant step back and

 9   showing an enterprise view of truly engaging

10   patients at all phases of the research

11   process, and not just as subjects. And the

12   idea is that there's some measurement value

13   that we can recognize with this view.

14   The next slide shows the same

15   schematic, but using performance measurement,

16   then, as the organizing principle. And there,

17   too, I think few have so far contemplated --

18   we've heard from some this morning, thankfully

19   -- what taking this engagement view can really

20   do to improve the methods behind performance

21   management. It can really anchor us.

22   So this morning, Lisa Lentz

1   mentioned patient attribution. I think this

2   framework can handle that. Linda Wilkinson

3   mentioned culture. Who's defining culture?

4   I think this engagement framework can help

5   with that. On the first panel, we talked

6   about walking in the patients' shoes.

7   Certainly, this is a framework that helps us

8   to achieve that.

9   How much collaboration do patients

10 really want? Nobody knows the answer to that.

11 We don't have good data. But the idea is that

12 there's an ethical argument to including

13 patients, engaging patients this way. We're

14 at the upward ends of our ability to use

15 empiricism here. I heard a lot of good,

16 empirical questions. Is clinician performance

17 improved by use of PROs, for example, one of

18 the questions raised this morning. But

19 there's the idea that we need to accept the

20 principle of engagement before we can move

21 forward for some of the methods improvement.

22   In Table 3 in the paper, it's

1 important characteristics and best practices

2 to evaluate and select PROs as performance

3 measures. I would suggest that we add patient

4 engagement in development and testing as one

5 of those important characteristics. We still

6 need to develop metrics for patient

7 engagement, so there's a lot of work to be

8 done, but I think that that would help us to

9 reframe in a positive way.

10   Under content validity, perhaps

11 that evaluation, whether the outcomes are

12 patient-centered or not. For performance

13 measurement, they need not always be, but

14 asking the question might help to improve our

15 output.

16   In the discussion specifically of

17 method of administration, the authors

18 reference patient burden. How do we know

19 what's burdensome to a patient? We're

20 inferring, and certainly as researchers we're

21 also patients, so we can figure this out. But

22 our special knowledge as researchers, we have

1   to remember, might actually disadvantage us to

2   understanding the patient view. So

3   incorporating patients into the research team,

4   then, is a way around this conundrum.

5   So I'd say consider a continuum

6   from low patient input to high, proximity to

7   patient voice to distance to patient voice,

8   and think about what we're doing. A

9   psychometric evaluation study, where is it on

10   that continuum? The patients are certainly

11   providing input, but through channels that

12   have been engineered by the researchers.

13   Cognitive interviewing is bidirectional.

14   We're talking to people. It's qualitative.

15   But here, again, patients go off-topic all the

16   time, and it's actually our job to keep them

17   in the channels that we, as researchers, have

18   engineered.

19   Focus groups, another great

20   opportunity to collect patient input, and

21   there's a lot of value to be derived from it.

22   But there, too, we're missing an opportunity,

1   by limiting ourselves to these methods, to

2   really sit down and get the full benefit of

3   researcher wisdom plus patient wisdom

4   together. So on that continuum, then, putting

5   the patient at the center would be patient-

6   centered outcomes research.

7   A lot of barriers noted in the

8   paper for use of PROs, I think many of those

9   might be system-centric and not patient-

10   centric. Just a point to note.

11   Of interest, the authors say "For

12   those developing or modifying measures

13   according to principles of universal design,

14   they're encouraged to consult with relevant

15   experts." Well, who are those experts? Will

16   it include persons with disabilities? Is it

17   going to be about us without us, as people

18   say? But it's another excellent opportunity

19   to improve measurement through engagement.

20   One idea, then, is to create a

21   task force on measurement error and invite

22   patients to participate. Are there some

1 things that we could learn about improving our

2 methods from the patients, that we just

3 haven't thought to ask? I think that method

4 of administration is a great entree into this

5 particular type of thinking.

6   A quick point. There were some

7 questions specifically about proxies. The

8 FDA, as you know, has a taxonomy of PROs,

9 ClinROs, observational measures. I think in

10 the case of proxies, we could come out with a

11 better taxonomy. There are true proxies,

12 people who really can accurately report for

13 the individual. Some parents can really tell

14 when their child is fatigued, for example.

15 There's quasi-proxies, people who can report

16 but with non-ignorable error. Then there's

17 just poor proxies, people who don't do it

18 well.

19   And to Mary's point earlier, I

20 think we need to always be mindful, are we

21 treating the reporter as a proxy or as an

22 informant? Someone who can have some insight

 1   into the patient, but not complete patient

 2   reporting in their stead. And Ethan reminded

 3   me, too, about always going to the proxy in

 4   the case of kids, or in my area, for those

 5   with cognitive impairment and dementia, when

 6   actually there's the possibility to obtain

 7   accurate reporting.

 8   And the question here is about

 9   truth. How do we know that we've gotten to

10   the truth, to the accuracy? To a certain

11   extent, I think we've been a little lazy in

12   the field, and more phenomenological research,

13   which is a form of patient engagement, can

14   help really get us to that truth of what's

15   accurate. When do you need the proxy, and when

16   is the patient truly the accurate reporter?

17   Missingness was also raised, and

18   my only point here is that missingness might

19   be a form of revealed preference, and there,

20   too, engaging patients as part of the research

21   team could help lead us to a wider

22   understanding of causes of missingness.

1   Some view patient engagement as a

2   shift in the power relationship. If you think

3   about it, the patient completing the survey in

4   the parking lot holds a lot of power. They're

5   going to ruin our study. They're going to ruin

6   our performance measurement. So let's

7   acknowledge the power that each party has

8   here.

9   It's a scary notion, to think

10   about giving away this power, but I think it's

11   one that's worthwhile and that can help us

12   with improving our PRO measures, and improving

13   our measurement overall.

14   DR. BASCH: That was terrific.

15   Thanks so much, Lori.

16   You know, I should mention Lori

17   and Mary Tinetti, who's here, and I, have done

18   a fair amount of work within PCORI around

19   patient engagement, including issuing a couple

20   of contracts to do a landscape overview and a

21   systematic literature review around methods

22   for patient engagement. And our conclusion at

1   the end is that we really do need systematic

2   research on approaches to engaging populations

3   that will be informative to the scientific

4   enterprise. I really do see a lot of synergies

5   between PCORI's interest here and NQF's

6   interest here, PCORI on the research side.

7   So we have about 15 minutes for

8   Q&A. Just to set this up before we start, we

9   really do want to focus on administration

10   methods. We recognize that many of the themes

11   cross over to other areas, but that really is

12   our focus. So we have Lewis, who talked about

13   scientific challenges, Richard, who talked

14   about implementation issues, and then finally

15   Lori talking about the special challenges in

16   developing PRO measures for performance

17   evaluation, because we need to actually engage

18   with those from whom we're gaining

19   information. We'll start in the front.

20   DR. FIHN: So, this isn't

21   specifically about administration, but one of

22   the themes here, at least that I've heard, is

 1   heterogeneity of multiple approaches. Is that

 2   in conflict, ultimately, with sort of

 3   organizational imperatives right now, in terms

 4   of accountability measures? What we see a lot,

 5   where we try to convey the complexity of

 6   measurement, at the end of the day what often

 7   trumps is comparables in a very competitive

 8   marketplace, and the question of sort of how

 9   those trade-offs will work out when we develop

10   a very complex and rich system of measurement.

11   And at the end of the day, for accountability

12   reasons, not for improvement reasons, but we

13   didn't name that as one of the goals here,

14   there's going to have to be some

15   reconciliation for comparability across

16   systems and organizations, or even within

17   systems.

18   So, how does this all play out?

19   DR. BASCH: From the panel?

20   DR. FRANK: I think the PROsetta

21   Stone is a great example of the way to begin

22   to really cross communicate.

1   DR. BASCH: Could you be a little

2   more specific about what you mean by

3   heterogeneity? Do you mean heterogeneity

4   across patients or across contexts, or do you

5   mean the measures themselves?

6   DR. FIHN: Yes.

7   DR. BASCH: You mean the measures

8   themselves. So, go ahead, Lewis.

9   DR. KAZIS: I think it's an

10   excellent question. We were involved in a

11   study done a few years ago that was published

12   in Health Services Research comparing the

13   Veterans Administration to the Medicare

14   Advantage plan. And we looked at mortality,

15   and then we looked at measures of outcome

16   using the VR-12. In that context, the VA

17   actually did better in the adjusted analyses.

18   In terms of the differences, they were quite

19   dramatic. And for those that would be

20   interested in discussing that further, I'd be

21   glad to talk about what, in fact, we

22   hypothesized as why there differences, but the

1 VA did a lot better.

2   Now, in that context, we had the

3 luxury of similar assessment tools across the

4 two systems. Going forward, I think that it's

5 going to be a real hodge podge in terms of the

6 assessments that are used nationally,

7 depending on the organization and what's

8 adopted, and so forth.

9   I think what is absolutely

10 necessary is that there are adjustments that

11 are developed to deal with those differences,

12 differences in assessment tools that are used.

13 I think David Cella can speak to the IRT and

14 CAT, which I think will allow for item banks

15 that, in fact, might permit comparisons across

16 different systems of care.

17   DR. BASCH: I think Albert had a

18 question.

19   DR. WU: On the topic of missing

20 data and biases that might come with missing

21 data, there's another thing to consider, and

22 that is that there may be biases in present

1   data. I don't actually have any data from our

2   system on this, but I'll give you an example.

3   I was teaching a course, and we wanted to get

4   student evaluations, essentially. Student

5   satisfaction data. And we wanted to get our

6   response rate up. We always got pretty good

7   response rates. We then made it mandatory.

8   We actually gave people a point on their final

9   grade if they would turn in their evaluation.

10   And what happened to our

11   evaluations? We got 100 percent response

12   rate, and our evaluation went down, because

13   the bias is that people who are more satisfied

14   are more likely to respond. So I think the

15   idea about looking at response rates is

16   something that we do need to consider, and

17   it's just another topic.

18   DR. BASCH: That's a great point,

19   actually. I think at the next meeting we'll

20   have another presenter from the NHS PROMS

21   initiative across England, and this was

22   actually a phenomenon that they observed

1   across the U.K., which is there were generally

2   lower scores for provider systems that had

3   higher response rates, and they've now had to

4   adjust for response bias.

5   Do we have a question over here?

6   Go ahead.

7   DR. GANIATS: I came here -- this

8   is Ted Ganiats. I came here today open-minded

9   but concerned that we would not be able to

10   come up with accountability measures, and I'm

11   just really happy to say that I was right.

12   (Laughter.)

13   DR. GANIATS: And everything

14   that's been said today is just absolutely

15   fascinating and absolutely wonderful, and it

16   promotes clinical use, it promotes patient

17   engagement, and it promotes quality

18   improvement. But I've yet to see anything

19   that gets to my methodologic concern, and

20   nothing that gets to my practical concern

21   regarding accountability, as was mentioned

22   earlier.

1   And the reason this is important

2   now is because, if we're able to limit

3   ourselves to quality improvement, that helps

4   address the methods approach that you asked

5   that we discuss during this question and

6   answer period.

7   The methodologic concern that I'll

8   just throw out is that, in general,

9   performance measures come from guidelines, and

10   guidelines come from evidence. And we are

11   bypassing the evidence, and we're bypassing

12   the guideline, and creating a performance

13   measure without the structure of a guideline.

14   So we're going to be inputting into practice

15   requirements prior to the guideline having

16   been created.

17   And if we want to do that for

18   quality improvement, that's fine. But I don't

19   think that's good for us -- the NQF won't, but

20   who's going to create the quality measure,

21   sans guideline, which the NQF is then going to

22   evaluate without the evidence and without the

1   guideline to support it?

2   It can happen. I hope it happens,

3   and I think it's years down the way. We have

4   the phone without the vision right now. But

5   for quality improvement, I think we have a lot

6   of good evidence that we should be moving in

7   that direction, and that will help us, then,

8   in selecting the methods for the questions,

9   which is what you wanted to address this time.

10   DR. BASCH: Yes. That is a long,

11   complicated question. One could argue that

12   guidelines generally describe the phenomena to

13   be measured, as opposed to the measures of

14   those phenomena themselves, which is what

15   we're talking about here. But it is a blurry

16   line. I think we probably would have to leave

17   that for another -- let that linger with us,

18   a very important --

19   DR. BANKOWITZ: Can I speak to

20   that momentarily?

21   DR. BASCH: Go ahead.

22   DR. BANKOWITZ: I think it's a

1   great question, and it also relates to the

2   question that was asked at the front of the

3   room here. And I think one way to look at it

4   is, we might want to think about leading

5   measures and lagging measure.

6   So a lagging measure is a big dot

7   measure. It tells you how well you have done.

8   It's too late to change it, but it tells you

9   how well you have done. So mortality, 30 day

10   mortality might be a lagging measure. And

11   there's no guideline that says "Don't kill

12   people," but it is a measurement that is

13   valid. So if we can come up with a big dot

14   measure, then we need to ask these questions

15   about how to we adjust it.

16   But we might have leading measures

17   where there might be more heterogeneity, which

18   might vary from place to place, which might

19   not be so well documented. And I think that

20   might be one way to address it.

21   DR. BASCH: Did you want to follow

22   up quickly?

 1   DR. GANIATS: Yes. I mean, just

 2   real quick, I've been on guidelines. I've

 3   been on performance measures. The 30 day

 4   readmission for heart failure, I co-chaired

 5   the committee that created that. Why 30 day?

 6   Why not 15 day? Why not 45 day? Where's the

 7   evidence that we're going to draw the line?

 8   And there was no evidence. Personally, even

 9   as chair, I didn't like the measure because it

10   is arbitrary, and I think that there are huge

11   problems.

12   Most of NQF-endorsed measures are

13   process measures or structure measures for a

14   reason. There are a few outcome measures, and

15   I think that we have a problem when we are

16   creating outcome measures without the

17   guideline, and we are pushing practice through

18   a performance measure accountability instead

19   of through a guideline process.

20   Believe me, I'm in favor of us

21   being better. I'm just worried about the

22   process. But I'll let others talk now.

1   DR. BASCH: In the middle.

2   MS. TORDA: Yes, I am Phyllis

3   Torda, from the National Committee for Quality

4   Assurance, and I'd actually like to pick up

5   this thread and the suggestions about

6   structural measures.

7   And I think, as Helen noted in the

8   very beginning, there is a maturity

9   progression from structure to process to

10 outcome, and that one of the things that it

11 might be really helpful for this group to do

12 is to lay out what should guide thinking about

13 structure, process, and outcome measures for

14 patient-reported outcomes.

15   And it does sound to me like we

16 might be getting to the point, based on the

17 presentations, where there is a good evidence

18 base for a structural measure. Structural

19 measures are good at signaling the need for

20 implementation, encouraging implementation,

21 without stifling innovation, because you're

22 not being overly prescriptive. And then, as

 1   you learn more, you move from structure to

 2   process to outcome.

 3   So I think there's a progression

 4   there. I probably agree that there's a lot of

 5   methodological reasons why jumping to outcomes

 6   might be premature at this time, but I think

 7   that thinking about that progression would be

 8   very useful.

 9   DR. BASCH: That's a very good

10   point. We're going to go over here, and then

11   we had a comment here.

12   Go ahead.

13   MS. HUFF: This is Jennifer Eames

14   with PBGH, and I want to thank the panel for

15   having a discussion on methodology that

16   incorporates the component of useability,

17   because I think we can't really separate the

18   two without knowing how we're going to be

19   using the measure that really influences the

20   methods.

21   And I think there's a general

22   belief of quality improvement, you don't have

1   to be as rigorous, public reporting, some more

2   rigor, payment, the stakes are higher. And

3   I'd like to challenge that belief in terms of

4   who's using the information for public

5   reporting and payment. You look at the users,

6   and I'll say that purchasers have a much

7   higher tolerance for error in this

8   measurement, and would rather have information

9   now as opposed to waiting for years for it.

10   Also, for consumers, there was a

11   study done by Judy Hibbard and Arnie Milstein

12   who looked at the tolerance for

13   misclassification when comparing providers,

14   and it's much higher amongst consumers, I

15   think, than what public reporting programs

16   usually do. So again, I think this is a

17   really important area, of tying the methods to

18   the useability, and looking at who's really

19   using the information.

20   And per the conversation around

21   using structural measures or checklist

22   measures, I just want to add a word of caution

 1   to that discussion. Because I think those

 2   measures are good. They're good at

 3   encouraging implementation, but they don't

 4   necessarily get at the quality of the

 5   implementation, and I think that's where the

 6   outcomes really come in, and why people are

 7   interested in outcomes is it gives a sense of

 8   how well the implementation is really

 9   occurring.

10   DR. BASCH: We've been given

11   authority to go about five minutes over, so

12   we're going to go to the back here, and then

13   we're going to go to the audience and the

14   phone.

15   DR. PAWLSON: Greg Pawlson, from

16   Blue Cross Blue Shield Association. I have to

17   weigh in on this, the need for guidelines for

18   outcome measures. NQF, and I don't remember,

19   Helen, the exact group, but I remember it was

20   a task force. Superb discussion, and it was

21   written up and published by NQF, about where

22   guidelines really come in.

1   And there was, I think, a fair

2   consensus that, for most outcomes, you don't

3   need a guideline. Pain, patient-reported

4   experience of care, we've never had guidelines

5   that said "Patients should be treated with

6   respect and trust and so on." And I would say

7   it's the same for many of the patient-reported

8   outcomes that we're talking about.

9   Now, as those get into areas that

10   are more process-oriented and need a guideline

11   like, to bring up one, Ted, hemoglobin A1c

12   levels, then clearly there is a need for

13   guidelines. I think it's a different kind of

14   evidence base that doesn't come out of

15   guidelines, but there is some evidence base in

16   most of the measures that we've been talking

17   about today, that some clinical intervention

18   does have some impact, especially at an

19   aggregate level.

20   You can't hold an individual

21   physician responsible for some of these

22   things. You can for patient experience, but

1   you can't for some of these others. But

2   clearly an accountable care organization, if

3   they don't have any effect on that, on

4   mortality or on readmissions or on a number of

5   other -- and I should stick to patient-

6   reported outcomes --then I don't know what

7   we're doing in health care, frankly.

8   So I wouldn't be so pessimistic

9   about our ability to have evidence-based --

10 not guideline-connected, but evidence-based

11 outcomes with very high face validity, that

12 can now be measured and can show change,

13 especially over time, at an aggregate level.

14   DR. BASCH: I think this speaks,

15 really, to the need for research, rationale,

16 consensus. And to Ted's comment, if you look

17 at a measure -- for example, in oncology, we

18 look at post-chemotherapy nausea, there are

19 actually guidelines that recommend improving

20 nausea after chemotherapy, but patient-

21 reported outcomes are generally not used to

22 measure that. So in some cases, there are

 1 guidelines. In other cases, it would be quite

 2 easy to develop consensus around those domains

 3 that merit measurement. But it does, again,

 4 speak to Lori's comment for the need for

 5 empiric research in this area.

 6   One could argue that, in fact, the

 7 rationale for developing these measures is, in

 8 fact, patient engagement, that engaging with

 9 populations to determine what is important to

10 patients as outcomes would then logically lead

11 to the development of measures of those

12 outcomes that are important to patients, and

13 then we could do research to demonstrate that

14 the measures being developed actually yield

15 meaningful differences in measurement between

16 practices, and that's probably the continuum.

17   To the audience?

18   (No response.)

19   MR. CUNNINGHAM: The phone?

20 Operator, can you tell us if we have anyone in

21 the queue for questions or comments?

22   OPERATOR: Yes, sir. As a

1   reminder, you may press star-one to ask a

2   question.

3   There are no questions at this

4   time.

5   MR. CUNNINGHAM: Thank you.

6   MR. BLUM: Hi, Steve Blum with

7   Forest. I just wanted to make a brief comment

8   relative to proxy. There's been some

9   discussion lately about potential utility for

10   proxy or observer-assisted reporting, where

11   there may be an opportunity to either assist

12   with recall or frame the question in a way

13   that the subject would understand, or provide

14   some context for their response, which may

15   address some of the shortcomings with both

16   proxy or patient-reported, maybe get closer to

17   the truth by putting the question within a

18   context that the subject is able to respond in

19   a way that they wouldn't otherwise, if they

20   did it by themselves.

21   DR. FRANK: Yes, and I would just

22   comment that, in the United States, we have a

1   political and a legal system that cherishes

2   the autonomy of the individual, but that's a

3   great example of when shared decisionmaking

4   with the family, being those whom you're

5   sharing it with, comes into play. And that

6   crosses over into measurement, then, as well.

7   Absolutely, it's patient, dyad, or family

8   grouping as the measurement unit.

9   MR. CUNNINGHAM: Are there any

10   other questions from the audience before we go

11   back to Barbara Gage?

12   OPERATOR: There are no questions.

13   MR. CUNNINGHAM: Thank you. Barb?

14   DR. BASCH: Go ahead.

15   DR. GAGE: Thank you. The

16   discussion is changing a little bit. There

17   were comments about, really, the insurer's

18   perspective, although we didn't call it that,

19   when we were talking about accountability and

20   value. And typically the accountability is a

21   measure of reduced readmissions which, while

22   we all talk about it as a measure of quality,

1   much of the force that's behind it is a

2   reduction in the cost.

3   But some of this discussion has

4   just broadened to identify patients'

5   preferences as a value metric, even though an

6   insurer may -- I mean, that's not a common

7   metric from an insurer's perspective. They're

8   typically more concerned about costs.

9   DR. BASCH: Panel?

10   DR. BANKOWITZ: I think one could

11   also look at the purchaser's point of view.

12   I think large companies who are employing and

13   insuring their populations do want to have

14   access to quality care. They are concerned

15   with the quality of decisionmaking. So maybe

16   if you take one step back in the chain, and

17   look at the purchaser, that might be helpful.

18   DR. FRANK: And I would just add

19   that preference-concordant care may actually

20   improve efficiency.

21   DR. BASCH: Richard, to follow up

22   and to draw that out, would you say that, on

1   the payer side, there's actually a preference

2   around improved symptoms, because of its

3   relationship to utilization?

4   DR. BANKOWITZ: To answer the

5   question, I do think that a useful metric from

6   the purchaser's point of view is probably

7   healthy days at work, speed with which one

8   returns to work, this kind of metric which

9   would be useful. I don't know how it plays

10   into patient-reported outcomes, but I think

11   clearly employers are concerned, increasingly,

12   with the physical, mental and emotional well-

13   being of the workforce. So it is becoming a

14   broader, I think, discussion.

15   DR. BASCH: I think we have time

16   for one more, and then we'll finish up.

17   DR. KOTAGAL: Hi, Uma Kotagal from

18   Cincinnati Children's. I wonder if I might

19   pull this together a little bit in a broader

20   context. So if we take children with asthma

21   and they are readmitted, it is not only a cost

22   issue, but it's a missed school day issue, and

1 an absenteeism or presenteeism issue for the

2 parents, and therefore for employers. And the

3 evidence for that is pretty strong.

4   Now, if we want to reduce

5 readmissions for asthma, and we publish this

6 data, it turns out that in parent self-

7 confidence and understanding, recognizing

8 early symptoms of asthma is important. And

9 when we first began this measurement in about

10 45 practices in Cincinnati, with about 15,000

11 children with asthma, half the time the

12 parents reported that they did not feel

13 confident about managing their child's

14 illness.

15   When this got filled in in the

16 waiting room, and the form was given -- this

17 was a paper questionnaire -- to the physician,

18 they were shocked at this response. And they

19 said things like "Really? You don't know how

20 to manage it? We've been talking about this

21 for so long."

22   Now, of course, when we recognized

1   that half the parents of these 15,000 children

2   didn't understand early signs of respiratory

3   illness for asthma, or how to prevent a

4   hospitalization, and began to work on it, we

5   not only could reduce our hospitalizations

6   significantly, but we improved functional

7   outcomes for the children, in days missed and

8   so on.

9   So I think it's difficult to think

10   about this conversation in a unidimensional

11   way without recognizing that there's both a

12   developmental sequence to it -- i.e., we don't

13   quite know how to incorporate all of this --

14   there's a research significance to it, how are

15   we going to measure the right thing as what's

16   important. But there's a larger context of

17   connecting the individual, the family, the

18   society and the context. And when we

19   dissociate these pieces, we end up with lots

20   of interesting conversations that don't

21   necessarily result in better health.

22   So I just want to use asthma as an

 1 example, to bring together the utilization

 2 question, the child question, the parent

 3 engagement question, and the employer

 4 perspective.

 5   DR. BASCH: It's a very nice

 6 comment to finish it off. I want to thank our

 7 terrific panel and everyone in the audience,

 8 and hand it back to Karin.

 9   MS. PACE: Just one quick

10 announcement. We have lunch for the expert

11 panel and authors. For the audience, I think

12 you were given as you came in some quick

13 places to go that are within a block of here,

14 to go get some lunch. We'll reconvene in 45

15 minutes, so 1:55. Anyway, thank you again for

16 your participation, and enjoy your lunch. And

17 we'll reconvene in about 45 minutes. Thank

18 you.

19   (Whereupon, the above-entitled

20 matter went off the record at 1:11 p.m. and

21 resumed at 1:55 p.m.)

22

 1   A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

 2   (1:55 p.m.)

 3   MS. PACE: We are going to go

 4   ahead and get started. So I will have the

 5   panel take their seats. And Al will start us

 6   off.

 7   DR. WU: Thanks. You almost said,

 8   "Take your sleep." And I realized that we are

 9   post-lunch. So we will try to keep this

10   lively.

11   So this is the session on

12   selecting patient-level PROs. I have to check

13   my notes. I am Albert Wu. My institution

14   thinks I'm from the Bloomberg School of

15   Health, but I am listed here as being -- I

16   think our corporate member is the Johns

17   Hopkins Health System.

18   So we have been -- we, like quite

19   a lot of other big academic medical centers,

20   have recently decided to go with a large

21   vendor-provided electronic health record. And

22   so we are now scrapping our legacy system that

1   has actually been working reasonably well

2   finally after 15 or 20 years.

3   And we are faced with a number of

4   choices. And one of the choices that we are

5   faced with is -- well, it's an opportunity,

6   really, to incorporate patient-reported

7   outcomes into the electronic health record.

8   And part of the reason is that our product

9   comes with a built-in patient portal that has

10   a couple of PROs built in, the PHQ-9 and the

11   RAND-36, a close cousin of the VF-36, I think.

12   But those are the only things that

13   are built in. And we now have the opportunity

14   to customize our system to include other PROs.

15   So the question is, which ones?

16   For those of you who are not among

17   the cognoscenti of this field, there are

18   thousands of PROs, dozens of generic measures,

19   quite a few utility-based measures, and then

20   hundreds and hundreds of specific disease or

21   treatment-specific PROs. And so which of

22   these are we going to include in our

 1 electronic health records?

 2   These conceivably will be used for

 3 research in the future, which we're certainly

 4 very concerned about. They could also be used

 5 for quality measurement, internal quality

 6 improvement, and ultimately for

 7 accountability. So we've sort of got our eye

 8 on all of those things.

 9   There are a number of issues we

10 are confronting, one of which is that there

11 are many proprietary measures that are among

12 the best tested, not a surprise, really.

13 Should we be using these? Are we going to

14 have to pay for them? Can we get a site

15 license for our five hospitals and God knows

16 how much in total dollars going through or are

17 we going to pay on a per-use, per patient-use

18 basis?

19   How do we know whether a tool is

20 good enough for research? And, perhaps a

21 little more problematic, how do we know which

22 are good enough for clinical use? And, not

1   identical to that, which are most suitable for

2   use for making comparisons across

3   organizations? Are there tools that have

4   known properties so we know how they are

5   related to other variables, particularly

6   things that are complicated, like patient

7   personality? Do we know anything about how

8   personality is related to the scores that

9   people give?

10   We have suspicions. And Ted

11 Ganiats was sort of voicing a little bit about

12 that. Some of my patients have profiles of

13 patients who have sort of a very similar

14 personality profile, maybe because they are

15 nicer than I am. And so how do we take that

16 into account or can we?

17   We understand that tools need to

18 be blended for research use and clinical use

19 and quality use. Which are the most

20 acceptable to both patients and providers?

21 Because, if nothing else, very selfishly, that

22 is going to affect whether people give good

1 answers, whether they give valid answers,

2 whether they give reliable answers, whether

3 they take it all seriously. This is another

4 way of saying that it has got to fit into the

5 work flow, but patients and providers are a

6 part of the work flow. So selection is

7 important.

8 We would like things to be

9 interpretable, both by patients and by

10 providers and ultimately by others we may be

11 accountable for. We would like them to be

12 actionable, if possible. So I hope we talk

13 about some of these things. I am sure we

14 will.

15 You have slightly detailed files

16 in the back of your materials, but we have got

17 a terrific panel of reactors, each of whom is

18 going to speak for seven minutes. And I will

19 try to be mindful of time.

20 Jim Bellows from Kaiser

21 Permanente; Gene Nelson, whom you have already

22 heard from but you are going to get a little

1 bit more from, from Dartmouth; Kalahn

2 Taylor-Clark from the National Partnership for

3 Women and Families; Ken Ottenbacher from the

4 University of Texas at Galveston. And, even

5 before that, I think David is going to tee

6 things off for the rest of our discussion.

7   MEMBER CELLA: Sorry. It's me

8 again.

9   (Laughter.)

10   MEMBER CELLA: Okay. Well, I

11 think we're getting into some things that many

12 of us have been waiting to talk about: how to

13 select PROs for performance measurement.

14   I think it is fair to say we

15 probably could all agree that we want

16 instruments that measure person or

17 patient-reported outcomes in a standardized

18 way and that we can know something about the

19 properties of the questionnaires.

20   There are a lot of guidance

21 documents available to address attributes of

22 patient-reported outcomes used in research,

1   but there is little guidance regarding

2   attributes for patient-reported outcomes to be

3   used as performance measures.

4   So we drew from one of the more

5   frequently, perhaps the most frequently, cited

6   guidance on user PROs in research. And that

7   is the medical outcomes trust.

8   So you will see in table 3 of the

9   paper and text accompanying it an outline or

10 structure that draws heavily from the medical

11 outcomes system original criteria.

12   So next slide. So there are some

13 differences, but before I get into maybe a

14 couple of the key differences in selecting

15 PROs as performance measures versus research,

16 there are I think more similarities than

17 differences in terms of wanting something that

18 is reliable and valid and interpretable, et

19 cetera. And we'll come to that.

20   But one thing that's pretty

21 different about performance measures, unlike

22 research, is that it is really important to

1   have short length. And the second thing that

2   is pretty obvious is that the stakes are

3   different and the stakes are higher in use of

4   PROs as performance measures than in most

5   research studies.

6   Established PROs have a lot more

7   evidence behind them in terms of their

8   usefulness as performance measures than the

9   newer PROs, the ones we have talked about,

10   like using IRT, but the newer ones tend to

11   have better measurement properties. So you

12   have this always-present tension between going

13   with something that has been around a long

14   time many have used, familiar with, lots of

15   literature, like the SF and VR tools. They

16   are limited in being static measures that are

17   scored using classical scoring methods that do

18   require you to administer the entire thing and

19   not have flexibility around that.

20   Future direction, which I talked

21   about this morning, in IRT-based measures,

22   like PROMIS, is a contrasting way to look at

 1   it.

 2   Next slide. So what we're going

 3   to do now just to sort of get the discussion

 4   going is to go through the criteria in table

 5   3 and review recommended characteristics for

 6   PROs as they could be useful in performance

 7   measures. And we're going to pick on the

 8   Western Ontario and McMaster Universities'

 9   osteoarthritis index, or WOMAC.

10   Many of you are I'm sure familiar

11   with that. It's one of the instruments that's

12   been around for a while. It's been used with

13   knee and hip osteoarthritis. It's got 24

14   questions covering the range of the last one

15   to 14 days, Likert-type with 5 discrete

16   choices and a 100-millimeter visual analogue

17   format is available as well.

18   There are three sub-scales: one

19   on pain, one on disability, and one on joint

20   stiffness.

21   Next slide. So we start with the

22   characteristics of a good instrument having a

1 conceptual and measurement model. In other

2 words, the documentation of an instrument that

3 we ought to be looking for should include a

4 description of the concepts that are being

5 measured and the intended populations for

6 which they would be used and how those

7 concepts organize into a measurement model.

8   The target of what you are

9 measuring, the PRO you are measuring, should

10 be a high priority for the system or it's

11 probably not going to be sustainable.

12   And so if you look at WOMAC as an

13 example, actually, it does not do so well

14 there. It is more one of these long-term,

15 has-existed-for-a-long-time instruments where

16 the factorial validity has not held up, has

17 not been deemed to be adequate from a

18 conceptual and measurement model standpoint.

19   But its grades get better as we

20 move on. So let's go to the next slide.

21 Reliability. The internal consistency should

22 be at least .7 or above for group-level

 1 comparisons or use and .9 or above for

 2 individual purposes. And also that is the

 3 internal consistency and also the other aspect

 4 of reliability. The more commonly referred to

 5 one is stability or reproducibility.

 6   It often depends upon the time

 7 window, shorter, of course, being better

 8 because people don't change. You want to be

 9 testing people at two points in time where

10 they don't change to show that something is

11 reliable as a rule or applied to the same line

12 twice.

13   So the Cronbach's alpha for the

14 sub-scales are quite good on the WOMAC, from

15 .86 to .98. So that's great. And the

16 stability has been adequate for pain and

17 physical function but less so for the

18 stiffness sub-scale if you look at the

19 literature.

20   Next slide. Next is validity,

21 three main types: content, construct, and

22 criterion validity. A limited number of

 1   instruments have been validated and with the

 2   validity of these sorts in the context

 3   performance measurement.

 4   The WOMAC development involved

 5   expert clinician input and survey input from

 6   patients as well as a review of existing

 7   measures. So it's got good content validity.

 8   And the scores correlate well with

 9   satisfaction with arthroplasty and other

10   clinical outcomes. So the validity looks

11   pretty good on the WOMAC.

12   Next slide. Responsiveness. So

13   it's an aspect of validity. You want to be

14   sure that what you are using is going to pick

15   up important change or be responsive to it.

16   It is important in performance measurement,

17   obviously, because there is an expectation

18   that you will detect change or hopefully

19   improvement or there may be consequences

20   associated with it.

21   And if you are going to expect to

22   tie action to scores, then you do want to be

 1   able to be sure that the scores will change as

 2   a result of action. So if you're going to

 3   have actionable assessment, then you want to

 4   be able to make sure the assessment actually

 5   is responsive.

 6   And the WOMAC has adequate

 7   responsiveness and ability to take change in

 8   response to focused clinical interventions.

 9   Okay. Next slide.

10   Interpretability, which really comes out of

11   experience with the measure and applying it in

12   context. You need to know what a low and a

13   high score represent; what is the average; and

14   what is the standard deviation; what is the

15   referenced population that you are pulling the

16   average and standard deviation from; and what

17   is a meaningful difference; and sometimes, you

18   know, if it's know, what's the lowest likely

19   meaningful difference, or a so-called

20   minimally important difference; and how do you

21   know when a change over time is meaningful in

22   a person; how do you know when a change over

1   time is meaningful in a group, a group of

2   people.

3   We talked about this earlier. For

4   performance measures, if different PROs are

5   used for the same concept, it's going to be

6   important to have a link or a crosswalk that

7   allows you to be able to interpret scores on

8   one instrument in relation to what they would

9   be on another or how they might relate to that

10   same underlying trait or thing that is being

11   measured, like depression or physical function

12   and to apply the criteria that you learn and

13   use for determining what is clinically

14   meaningful in this setting.

15   Now, the WOMAC does have

16   population-based age and gender norms. They

17   do have a published minimally clinically

18   important improvement that I use. And you can

19   use the WOMAC to translate into utilities for

20   economic evaluation. So because it has been

21   around a long time and been used a lot, it

22   does have good interpretability behind it.

1   Burden is the next item. And that

2   relates to the time and the effort and other

3   demands on the respondent as well as on the

4   administrator, on the clinical staff.

5   Performance measures, PRO

6   assessments then probably in this context do

7   need to be as brief as possible. And

8   reporting should be done in real time.

9   There is a short form available

10   for the WOMAC. And the average time to

11   complete it is a little under five minutes.

12   So it seems to do well in that criterion as

13   well.

14   Next slide. Alternatives modes

15   and methods of administration. We walked

16   earlier. Several people have commented that

17   it is important to be able to be as flexible

18   as possible without being blind to the issues

19   that one needs to consider.

20   There are validated mobile phone

21   and touch-screen platforms for WOMAC. So it

22   does seem to have a good means of alternative

1 modes available.

2 Next slide. And cultural and

3 language adaptations, again, hopefully done in

4 a way that is responsive to getting truly, not

5 just literally equivalent translations but

6 semantically equivalent translations on

7 culturally fair, if not equivalent,

8 translations to be able to use across people

9 of different cultures and languages.

10 The WOMAC is available in dozens

11 of languages. So that's also a good class, a

12 passing grade.

13 Next slide. This is the last one,

14 which is in the context of electronic health

15 records, critical features of performance.

16 Measures will be the interoperability of the

17 measure, having automated real-time

18 measurement and reporting capabilities. You

19 can get that instant report and not be in the

20 way of the clinic flow; instead, perhaps even

21 facilitate it and preferably sophisticated or

22 at least stay to our analytic capabilities

1 with the information that is brought into the

2 EHR.

3   Electronic data capture of WOMAC,

4 which is available, should allow for fairly

5 easy integration within the health record. So

6 I'll pass on that one as well.

7   Go to the next slide. That may be

8 the last one. I thought it would be useful

9 just to kind of run through. That's the

10 table, table 3. Maybe we should have a tenth

11 criterion of actionable from the discussion

12 and maybe have some discussion about that.

13   And my thanks to the developers

14 and validaters of WOMAC for allowing me to use

15 them as a guinea pig for this introduction.

16 Thanks.

17   DR. WU: Thanks, David. And

18 thanks for keeping us on time.

19   So who -- Jim, are you -- it's

20 time. So Jim is going to talk to us about a

21 couple of things, characteristics that

22 identify PROs as suitable for use as

 1   performance measures, relevance for use of

 2   PROs that are developed for controlled

 3   research to be used in clinical practice. And

 4   who knows? Maybe more.

 5   MEMBER BELLOWS: Thank you.

 6   So the space of curmudgeonly

 7   having been taken, I'm going to venture into

 8   slightly provocative and talk a little bit

 9   about what I see as the real importance of

10   useability, including actionability, which you

11   just mentioned, and meaningfulness in this

12   space. And perhaps they're even greater

13   importance than some of the other technical

14   aspects we talked about.

15   So when I look forward from where

16   we are now, I see two visions of how the whole

17   PRO enterprise might develop. And, on the one

18   hand, I see a vision much like what they've

19   done at Dartmouth, which to me is a thing of

20   such incredible beauty that I almost wish I

21   could get back pain and go to New Hampshire

22   and experience the Dartmouth model with all

1   the integration of the clinical care that we

2   have seen.

3   I know that in Kaiser Permanente,

4   we have a couple of uses that are working out

5   terrifically, the use of PHQ-9 to drive a

6   treatment model for depression, which is

7   really based on treatment to remission,

8   instead of counting how many medications we

9   are doing or how many follow-up visits we are

10   having, really has the potential and is

11   transforming our depression care.

12   We're working with an instrument

13   we use after total joint replacement that is

14   being terrific in helping us identify the

15   people who need the most follow-up. So that's

16   the part of the vision I really love.

17   I see another part of the PRO

18   transformation off into the future that could

19   look not nearly so nice and that could look

20   more like patients feeling spammed basically

21   by their clinical systems.

22   Here are some of the evidence

 1 points I have that bring that vision to bear.

 2 One is that I know that in all of the surveys

 3 that we do in our system, our customer, our

 4 patient experience and care experience

 5 surveys, our responsive rates are trending

 6 notably downward over the last few years on

 7 CAHPS and HCAHPS and those satisfaction

 8 surveys.

 9   I know that our responses to

10 clinical reminders, whether it's they'll get

11 your colonoscopy or breast mammogram or

12 whatever, our responses to those are going

13 down over the years. And we're going more

14 quickly through each new technology.

15   When we first knew how to use our

16 computers to send out letters on paper, it was

17 like a great thing. And people responded.

18 And then they stopped. And then we started

19 using IVR. Oh, that's so cool. People

20 respond to IVR. And then they stopped. And

21 then it was email. And then it was text

22 messaging. And with each one, there's a

 1   shorter and shorter message.

 2   (Laughter.)

 3   MEMBER BELLOWS: And so my fear is

 4   that if we're not judicious about how and

 5   where we use patient-reported outcomes, the

 6   patients will start to feel spammed by us

 7   asking all of these questions in much the same

 8   way they do in other things.

 9   The business of patient-reported

10   outcomes is so important and so precious to us

11   I think in a clinical context that we need to

12   be careful and judicious about how we proceed

13   so that we don't push patients over their

14   limits and get them to the point where they

15   stop responding.

16   I know for myself, I am at the

17   point where when online surveys pop up in the

18   middle of an internet experience, I just

19   dismiss, dismiss without even thinking about

20   it and similarly. And I don't want to get

21   there with patient-reported outcomes.

22   So how do we avoid that? To me

 1   one way to avoid that is that I think the

 2   traditional formula in a room of moving toward

 3   performance measure would be to consider the

 4   reliability and validity of measures first and

 5   only secondarily their usability and

 6   feasibility.

 7   And I would propose that for the

 8   patient-reported outcome space, that we make

 9   the useability of measures; in particular,

10   their meaningfulness and their actionability

11   by clinicians and patients, of paramount

12   importance and not even consider a use for

13   performance measure until it has been

14   demonstrated that it can be used productively

15   in a clinical system, that it can be

16   appreciated and acted upon appropriately at

17   scale and in real time and only then move on

18   and that if we get ahead of ourselves and

19   start pushing out a plethora of measures that

20   are coming not from the position of

21   improvement but of accountability and payment,

22   that we will end up in a space that is not

1   ever what we intended.

2   So I think that is the basis of my

3   idea. So I guess there were a couple of

4   specific questions. From the research

5   context, most of the measurements we have that

6   have the greatest validity have the most

7   number of items on the scale, duh. They're

8   most valid if they are really big patient

9   populations. But it's those measures that

10   have a lot of items on a scale and go to a

11   really big population that are going to most

12   saturate our patients' willingness to respond.

13   So to me moving judiciously means

14   going to narrowly targeted patient populations

15   that have a specific episode of care where the

16   care is very salient to their needs. That's

17   like the people who have had a total joint

18   replacement or CABG or whatever and are very

19   interested in what is going on with that care

20   and then, departing from the practice that has

21   been so common in research but going with

22   extremely short instruments that everybody can

1   understand.

2   So it's a little bit different

3   than the typical criteria, but that's what I

4   think will serve us best in the long run as we

5   develop and build.

6   Thank you.

7   DR. WU: Thanks. That was very

8   timely. I remember a time when I used to

9   answer my telephone at home.

10   (Laughter.)

11   DR. WU: But those days are long

12   gone. And so I think that this patients

13   feeling spammed notion is one that is going to

14   stick with me.

15   Next we've got Gene Nelson again.

16   Gene, are you ready to go?

17   MEMBER NELSON: Ready to go,

18   right. I am not as good at being

19   curmudgeonly. So I won't try.

20   The first question was, when can

21   general health status measures be utilized?

22   And when should condition-specific measures be

 1 utilized?

 2   And in general, I think at this

 3 point in time, it's wise to use both general

 4 and condition-specific measures when you are

 5 focusing on a particular clinical population

 6 so that we can start to learn what are the

 7 benefits and drawbacks of both. So conditions

 8 such as spine problems and heart failure and

 9 total joint replacement, depression would be

10 good candidates for both general and

11 condition-specific.

12   I think it's very important to use

13 general health status measures under some

14 conditions. So, for example, at Dartmouth

15 Hitchcock 76 percent of heart failure patients

16 have two or more co-morbid conditions. The

17 median is four. So to look at the whole

18 patient, it makes sense to use a broader

19 general health status measure that captures

20 physical health and mental health and

21 function.

22   Also, when screening for problems

1   that may be important but can easily go

2   undetected, go to use a general measure, so,

3   for example, people with open heart surgery or

4   AMI recovering or postpartum, it's easy to

5   miss mental health issues or in the new annual

6   wellness visit that pays for prevention that

7   Medicare is offering for the first time,

8   they're screening for both functional problems

9   and health risk problems. And so using

10   general and specific measures is helpful,

11   specifically there a depression measure as

12   well as a general functioning measure as well

13   as health risk indicators based on health

14   behaviors.

15   The second question is, are there

16   any setting-specific issues for selection of

17   PROs? Short answer, yes, many. First, what

18   are the clinical populations that are being

19   cared for there that matters to them? What

20   are their needs? So, really, knowing your

21   patients and then tuning the use of PRO

22   measurement to the common likely issues for

1   the patients and then tuning the measures to

2   the work flow, as mentioned earlier, to try to

3   create a richer and more useful information

4   environment for both the patients and the

5   clinical team. So it's easy to say but design

6   in and design it well so you get the

7   useability is not like falling off a log.

8   There are also issues of patients'

9   acuity and cognitive abilities as well, of

10   course, that does vary pretty dramatically

11   from setting to setting or point of time

12   within settings.

13   The third question was, what

14   conditions would be most sensitive to

15   measuring changes in patient health status and

16   outcomes? So here chronic conditions, such as

17   mentioned earlier, heart failure, depression,

18   ischemic heart disease, Parkinson's disease,

19   low back pain, osteoarthritis, rheumatoid

20   arthritis. All of these tend to have an

21   impact that rolls through the person's

22   well-being, physical, mental, and roll

1   impairments, all fairly likely.

2   So certain chronic conditions

3   would potentially be good starting points and,

4   as mentioned earlier, by any other surgical

5   conditions. Total joint arthroplasty,

6   bariatric surgery might be a really good

7   place, open heart surgery, spine surgery.

8   The third one is a little bit

9   different in terms of most sensitive to

10   measuring changes in outcomes. And that's

11   people that are not necessarily in serious

12   trouble yet, but they're at high risk of

13   avoidable death or of the onset of disease or

14   the accumulation of new diseases.

15   So health risk status measurement,

16   including health behaviors, and biometrics for

17   people, such as cardiometabolic syndrome, or

18   minor hypertension but at risk for other

19   conditions or high health risk behaviors.

20   So screening for avoidable risk of

21   death or onset of disability would be an area

22   where risk measures could be sensitive. We

 1   estimate that about 5 percent of the

 2   population aged 30 to 49 account for about 25

 3   percent of the risk of avoidable death. So

 4   there's a lot potentially there.

 5   We haven't talked very much about

 6   health behavior measures and health risk

 7   today, but I think if we wish to go upstream

 8   to promote health and to prevent disease and

 9   disability, very fruitful area.

10   Last question was, what is the

11   variation in patient-level scores related to

12   clinical interventions? I put together rather

13   eclectically one slide here that shows for

14   some general health status measures, -- this

15   is from the sport trial -- the differences in

16   people having surgery or not having surgery on

17   a zero to 100 scale of physical function.

18   And so a 44 versus 30, 23 versus

19   32, for example, herniated disc and stenosis,

20   depression, the PHQ-9, as many people

21   recognize, that a certain degree of elevation

22   is indicated.

1   And then getting to remission

2   means less than five, a score of less than

3   five. And some health systems and some

4   providers are much more successful than others

5   doing that. Within our Dartmouth Hitchcock

6   system, we have tremendous variation at the

7   clinical pod level on this measure. Carpal

8   tunnel syndrome using a disease-specific

9   measure, 3.1 down to 1.8, by people that are

10   looking at patients with the problem suggest

11   very substantial improvements, et cetera.

12   So a lot of the work that has been

13   done on clinical populations using either

14   generic or condition-specific measures and

15   associated with different interventions and

16   different kinds of health care can show very

17   substantial differences that would make a

18   large difference in how a person is doing and

19   feeling physically, mentally, and in their

20   role.

21   DR. WU: That was great. Thanks.

22   I like this last slide.

1   I do wonder, for screening

2   purposes, a lot of the conditions that people

3   have might sort of result in some general

4   depression, some haloed depression of

5   everything, but you would only suspect that

6   something is going on but not know what it is.

7   And I wonder if sort of something

8   which is generic but very comprehensive might

9   be a better screening test, I mean, something

10   like the old SCL-90, which went through a

11   whole laundry list or review of systems of

12   systems. I wonder if that is something that

13   would be better for that purpose.

14   But shall we go on to Kalahn?

15   DR. TAYLOR-CLARK: Sure. Thank

16   you.

17   I have to say that much of this

18   conversation has brought me back to nearly 15

19   years ago. I have a Ph.D. in health policy

20   and health economics. And the first day of

21   the program, we walked in. And the professor

22   said, "So, you know, we're going to calculate

1   these qualities."

2   And I said, "Well, what if a

3   quality falls below zero?"

4   And the professor looked at me

5   really strangely and said, "What do you mean?"

6   I said, "Well, what if somebody is

7   living below a zero and actually living worse

8   than death?" because zero was death. And that

9   was when I realized I needed to be part of the

10   patient community and the consumer community

11   to talk through these issues a little bit

12   better because I felt that the economics

13   weren't exactly measuring what I was hoping to

14   measure through the patient perspective.

15   So that brings me here today. And

16   I appreciate the opportunity to speak on the

17   consumer side.

18   I was asked to actually address

19   only one specific question, which was what

20   measures are important to patients. You know,

21   I kind of went through this a lot, especially

22   as we were sitting there and having the

1 discussion at our table about what would

2 really be important to patients but what is

3 also useable and feasible for the system to do

4 so. I'm always thinking about that balanced

5 perspective in providing this perspective to

6 you.

7   The first thing I will say is that

8 obviously -- and this has been brought up many

9 times today -- that the measures that have

10 been put forth so far through CAHPS and others

11 have been really useful for research purposes

12 but not necessarily as meaningful to patients.

13 That is something that has been brought up,

14 but that needs to be reiterated as we think

15 through what we are going to use for measures

16 of both quality improvement as well as

17 accountability in public reporting.

18   That is going to be

19 extraordinarily important when we think about

20 how patients actually read what this measure

21 means and then are able to use that for

22 decisions on terms of their preferences or in

1   terms of their decisions about the providers

2   and the treatments that they receive.

3   So I want to put that forward

4   because a lot of the measures that we think

5   about might not even necessarily exist in many

6   of these validated instruments. I hate to say

7   that because I hate to take two steps

8   backward. But I do think that there are ways

9   that we can think through this.

10   So the measures that we have

11   really been thinking through are some of the

12   ones that actually were mentioned. So

13   expensive surgical procedures certainly are of

14   import.

15   Shared decision-making,

16   particularly in maternity care, these are

17   measures that are both of import, obviously,

18   to purchasers but also very much to consumers.

19   And really thinking through some of those

20   measures will be important measures of

21   depression, as Gene mentioned.

22   But I wanted to also say that the

 1   measures of patient experience shouldn't

 2   completely be excluded. I think we have been

 3   mostly talking about patient-reported outcomes

 4   today as levels of functional status and some

 5   of these other types of measures. But I want

 6   to reiterate that patient experience is

 7   extraordinarily important to patients.

 8   I will give you an example. In my

 9   former life, I was a research director at the

10   Brookings Institution, where we were looking

11   at a pilot study where we worked with a major

12   health system that was now going to become an

13   accountable care organization.

14   One of the points that they made,

15   they said, you know, we really need better

16   measures of patient experience because what we

17   are finding is that some of the experiences

18   our patients are having are actually having an

19   effect on our retention.

20   Let me just take you just through

21   a moment there. They said specifically care

22   coordination measures from the patients'

 1   perspective as well as organizational access,

 2   which is usually defined by CAHPS as their

 3   ability to get after-hours care and things

 4   like that, those two particular measures were

 5   the most defining in actually predicting the

 6   patients' retention, the retention of their

 7   patients in the system, that they really

 8   wanted to actually define care coordination a

 9   little bit better than what CAHPS had been

10   doing previously but to really actually

11   include that in all of their measures, both

12   for quality improvement as well as for

13   accountability in public reporting. Those are

14   just two examples of experience where I

15   recognize that they have tended to be process

16   measures but can lead specifically to outcomes

17   of import to patients.

18   The other piece that I would say

19   is around the confidence piece. And certainly

20   patients' confidence in their ability to make

21   decisions in terms of self-management and

22   care, either from the patient perspective or

1 the proxy perspective, are going to be

2 extraordinarily important.

3   And then the final piece that I

4 would say around the measures specifically is

5 around this idea of access to social and

6 community resources. I want to take a step

7 back on that one. Ted Rooney suggested for

8 Maine -- got up and actually made a real

9 interesting point. He said, "Well, we can't

10 always put the onus on the provider." And I

11 think others have talked a lot about this,

12 that, you know, we're defining these measures

13 and then we're suggesting that the health care

14 system is the only fix-it.

15   The bottom line is that that is

16 obviously not true. Social determinants of

17 health, your ability to get transportation,

18 your ability to actually access the system, et

19 cetera, et cetera, are going to play an

20 extraordinary role in your ability to get

21 better.

22   And so one of the points that we

 1   were actually trying to make again when I was

 2   working at Brookings was to think about what

 3   a measure could look like in the health care

 4   system that would allow us to get as well as

 5   we could on what the system could do to

 6   actually provide access to those other

 7   resources.

 8   And we actually came up with a

 9   potential measure that said, how well does

10   your provider or did your clinician -- sorry.

11   I think the specific measure was, did the

12   provider link you to helpful and useful social

13   and community resources that helped you to

14   either self-manage or take care of your

15   diabetes or your asthma? And this gets to one

16   of our points about who we are actually

17   looking at.

18   These were very narrow

19   disease-focused, chronic disease-focused,

20   surveys. And I think I would echo the point

21   that Jim makes that we do want to have sort of

22   general questions around general satisfaction

1 and experience and outcomes, but we also might

2 want to look specifically at conditions that

3 are of import to these particular groups.

4   Obviously care coordination is

5 going to be important for certain groups and

6 not necessarily for others, the same with the

7 social and community resources. This is going

8 to be extremely important to patients that

9 have the need to get to these social and

10 community resources.

11   So as we think through what the

12 measures should look like, I don't want to

13 take patient experience off the table. I also

14 want to try to think a little bit outside of

15 the box about how we can actually link other

16 measures that are going to be of import to the

17 use, to patients' use, of the data.

18   And I will end there and take

19 questions later. Thank you.

20   DR. WU: Well, that was terrific.

21 Thanks very much. And in sort of the

22 out-of-the-box spirit, these could possibly

1 fall into sort of the health behavior bucket,

2 but they really are things like confidence,

3 self-efficacy, outcome expectancy, which, in

4 fact, health systems should be in many ways

5 accountable for improving in patients.

6   I know the Society for Behavioral

7 Medicine has been thinking about this a little

8 bit. And maybe it is worth revisiting a

9 little bit more.

10   Finally, Ken, can you clean up?

11   DR. OTTENBACHER: Thank you, Al.

12 I am going to go ahead and use the podium, I

13 think. It might make it a little bit easier

14 for you all to hear me.

15   I would like to begin by thanking

16 NQF and the conference organizers for the

17 opportunity to participate. Okay. Didn't

18 work, huh?

19   (Laughter.)

20   DR. OTTENBACHER: Okay. Let me

21 try it again or I could sit down. Again, I

22 would like to thank the NQF and the conference

1 organizers for the opportunity to participate

2 in the workshop.

3   My task today is to comment on

4 issues associated with selecting patient-level

5 PROs. Specifically I have been asked to

6 respond to the impact of patient

7 characteristics and baseline values on change

8 in PROs and on conditions or circumstances

9 under which stabilization or no change may be

10 a desired outcome.

11   Measuring change requires a

12 context. Targets for assessing clinical

13 change include the individual or patient, a

14 group or facility, and the population.

15   Defining the context is an

16 important first step in assessing change.

17 Approaches, methods, and even conceptual

18 frameworks may differ from one context to

19 another.

20   Assessing change has a long and

21 controversial history. A common approach has

22 been to calculate the absolute difference

1 between change from baseline to follow-up.

2 This is referred to as the change, gain, or

3 different score, a variation of this approach

4 is to compute the percent of change.

5   The limitations of these

6 approaches are widely known. Ward and others

7 demonstrated in the 1960s -- and I quote here

8 -- that differences between scores tend to be

9 much more unreliable than the scores

10 themselves. This quote is from a widely

11 referenced text, "Problems in Measuring

12 Change," published in 1963.

13   Percent change continues to be a

14 widely used measure, despite its limitations.

15 Percent of change is sensitive to variations

16 in baseline distribution. If the range of

17 baseline values is large, the variance

18 associated with the percent of change

19 increases disproportionately and the

20 sensitivity of this approach is reduced

21 dramatically.

22   An extension of change or gain

1   scores is to adjust for baseline using

2   analysis of covariants or regression models.

3   Sophisticated statistical approaches have been

4   proposed to adjust for baseline scores and

5   other covariants using general estimating

6   equations or hierarchical opinion modeling.

7   These procedures examine

8   interactions and relationships among baseline

9   score, time, other covariants, and intended

10   outcome. While they represent powerful

11   methods, they are not without controversy.

12   An article in the American Journal

13   of Epidemiology in 2005 by Glymour and

14   colleagues provides caveats regarding

15   adjusting for baseline values using

16   sophisticated statistical models.

17   A variety of indices have been

18   proposed to address some of the limitations of

19   traditional approaches. These include

20   reliability change index, the residual change

21   score, and various applications of effect-size

22   measures. Each of these approaches has

1 strengths and limitations that have been

2 described in the literature and are referred

3 to in the draft NQF methodology paper.

4   The approaches described above can

5 be classified as distribution-based, meaning

6 that change or gain scores are expressed in

7 terms of an underlying distribution and rely

8 on sample variation, standard error, and

9 measurement precision.

10   An alternative is anchor-based

11 approaches. Anchor-based approaches require

12 an external or independent standard, or

13 anchor, to determine the clinical importance

14 of change. The anchor-based approach provides

15 unique opportunities for stakeholder

16 involvement in determining the focus and

17 magnitude of change. It introduced other

18 measurement challenges.

19   Another alternative is referred to

20 as adaptive measurement of individual change.

21 Adaptive measurement combines the methods of

22 item response theory and computerized adaptive

1   testing to provide a different way of thinking

2   about a scale's ability to detect change. The

3   adaptive change approach has a number of

4   advantages, including the ability to

5   demonstrate when a measure includes better

6   precision across the range of a trait.

7   Combining IRT and computer-adapted

8   testing was described previously and is being

9   examined in several applications of

10   patient-reported outcomes.

11   There are instances where

12   stability or the ability to maintain a level

13   of performance is the desired outcome; for

14   example, in degenerative conditions, such as

15   Parkinson's disease. This is also true for

16   conditions that involve cycling diseases,

17   disease processes, such as multiple sclerosis.

18   For some populations, the best

19   outcome may be to maintain a desirable level

20   of function; for example, maintaining a level

21   of mobility or self-care that allows

22   independent function in older adults.

1   Providing evidence of stability

2   may be analytically less complex than

3   assessing change that requires adequate data

4   points, which can be a logistic or resource

5   challenge.

6   I will conclude with a couple of

7   observations regarding other challenges

8   relevant to assessing change or no change in

9   PROs. One important challenge is how to

10   risk-adjust. Quantitative methods for risk

11   adjustment in managing various forms of bias

12   have advanced dramatically in recent years.

13   The challenges of risk adjustment

14   will be particularly important as

15   patient-reported outcomes at the individual

16   level are translated to performance measures

17   and quality indicators at the facility and

18   population level.

19   A second challenge is how to

20   facilitate the evolution of patient-reported

21   outcomes to include patient-centered outcomes.

22   The Affordable Care Act and the creation of

1   the Patient-Centered Outcome Research

2   Institute have placed increased emphasis on

3   the role of stakeholders and consumers, not

4   just in the assessment of outcomes but as

5   partners in the decision-making process

6   regarding the content of what should be

7   measured.

8   A final challenge is how to

9   monitor, identify, and reduce unintended

10   consequences. We are all aware of examples of

11   unintended consequences resulting from changes

12   made in health care that were implemented with

13   the best intentions.

14   We don't want to create a

15   patient-reported outcome or quality indicator

16   that becomes the kudzu of health care.

17   (Laughter.)

18   DR. OTTENBACHER: My major advisor

19   will respond to telling his Ph.D. students

20   that doing outcomes research is a lot like

21   raising children. You always think you're

22   going to do a better job next time.

1   (Laughter.)

2   DR. OTTENBACHER: The careful and

3   thoughtful assessment of patient-reported

4   outcomes, as reflected in this workshop, and

5   the high-quality scholarship evident in the

6   draft of the PRO methodology paper indicate

7   that we really will be able to do a better job

8   next time in creating quality indicators that

9   reflect patient-reported outcomes.

10   Thank you.

11   DR. WU: Thank you. I will try to

12   unravel myself from the kudzu to say that,

13   interestingly, some of the problems that

14   plague individual-level change, measurement of

15   individual change, are less of a problem for

16   measuring group change.

17   So many of you with an

18   epidemiologic bent may have more insight into

19   this than I, but for some of the tasks for

20   quality measurement and accountability, we

21   actually may still be able to look at change

22   scores in one form or other.

1   Anyway, great discussions. And

2   every kept time sufficiently so that we have

3   I think -- now, do we have 20 minutes or do we

4   have a little bit more? Did we start a little

5   late? Great.

6   So first comments from the panel?

7   Oh. Yes, please?

8   MEMBER CELLA: I don't know if I

9   could just say something about people who are

10   gathering their thoughts. My experience of

11   Dr. Ottenbacher's brief presentation was that

12   it was really a marvelous overview of a lot of

13   work that has been done and that we have

14   learned about measuring change. So

15   congratulations. Very well done in this short

16   period of time.

17   It got me thinking about something

18   that I think could work very well in this

19   process that could bring also in this sort of

20   patient engagement side as well in a group

21   like this.

22   To do a technique that really

1 draws from educational testing and looking at

2 achieving standards. And that's bringing

3 together experts. In this case it could be

4 experts like people here in this room along

5 with patients that represent the patient

6 perspective in the community, showing them

7 data.

8   They are blind to scores. They

9 don't see numbers. They just see profiles.

10 They see people. Here's a person who's got

11 this much pain. Here's how they're

12 functioning.

13   And then you go through -- I won't

14 go into details of the methodology, but there

15 are various methods that allow groups to form

16 a consensus opinion about what kind of

17 difference would matter. And you can also put

18 in extra methodology to get a value for how

19 much would that be worth.

20   The essential thing would be to

21 bring experts, people like you and patients in

22 the community, together to come to consensus

1   on units of change that would matter. And you

2   also articulate why they would matter. And

3   then these could become standards that get set

4   for achieving either maintenance or

5   improvement.

6   DR. WU: Ethan?

7   MEMBER BASCH: I can comment on

8   some of our research within the oncology world

9   around symptom-specific or demand-specific or

10   population-specific measurement versus more

11   generic. And in general, adherence rates over

12   time are much higher with very

13   content-specific measures, measures that are

14   more common when there are fewer zero values.

15   It is actually a very strong relationship

16   between how specific we are to the world of

17   the patient and the patient interest and

18   willingness to report.

19   Similarly, interestingly, there is

20   also improved adherence when the provider is

21   involved in the process of collecting the data

22   when, for example, a letter is sent to the

 1 patient saying, you know, "Dr." so and so or

 2 "Nurse" so and so "is very interested in your

 3 participation in this information." In

 4 general getting buy-in from providers to do

 5 that is much greater, again, with

 6 context-specific measures.

 7   So it seems the closer we get to

 8 the context of use or the fitness for purpose,

 9 the more everybody kind of perks up and feels

10 that this is relevant. And they become more

11 enthusiastic about participating.

12   DR. WU: More comments from the

13 panel? John?

14   MEMBER WASSON: Yes?

15   (Laughter.)

16   MEMBER WASSON: Hello, Mother. I

17 saw a moment of silence there. I didn't want

18 to let it lie fallow.

19   In particular, in regard to Jim

20 Bellows' points, I just wanted to go on the

21 record as saying he is right on but not far

22 enough. By that, I mean we are all operating

 1   in a current paradigm mindset that is good

 2   Twentieth Century thought process. But the

 3   median is becoming the measure.

 4   And we have to recognize all of us

 5   use cell phones, for example, and we're still

 6   talking about portals for EMRs. And we're

 7   wondering why patients don't respond to new

 8   methodologies. And the answer is they're not

 9   in control. You don't want to answer surveys

10   that you don't control nowadays. You want to

11   control. We have to deal with that reality.

12   Just to echo the point that was

13   just behind me, in our experience, we have

14   been doing this a long time in primary care

15   and other practices. When the clinician

16   should say, "This is part of care. This is

17   part of the service to you," the response

18   rates one time around, even on the internet,

19   are well over 80 percent, not this 30 percent

20   cap stuff that goes out. That makes life so

21   much easier for analytics, et cetera.

22   While you are serving the patient

 1   needs, you can put in a few measures that

 2   matter. And each patient needn't have the

 3   response burden of the entire instrument

 4   because you can aggregate it over many

 5   patients to get at the accountable care

 6   organization.

 7   So, in other words, all I am

 8   saying is just what Jim said, that the

 9   useability and the service to the patient, put

10   that first. And then we can fold in measures

11   for accountability quite easily. And we'll

12   have high response rates and get away from a

13   lot of the issues that Ken just articulated.

14   You know, how do you deal with risk

15   adjustment, et cetera, et cetera?

16   So I just think there are

17   practical approaches. I know there are. And

18   I think Jim's right on the money. And I worry

19   that if we stay too locked into the old style

20   paradigm that is still in the back of our mind

21   of mail-out surveys, you have to complete all

22   or most of the items yourself, we're in

1   trouble.

2   But if we look at it from a

3   population point of view, where individuals in

4   my practice get three items and another

5   individual randomly gets three items, you can

6   still aggregate it up to my practice.

7   And, then, finally, you can

8   crosswalk the PRO measures across practices

9   very easily. There are just so many technical

10   solutions to a lot of the issues we're talking

11   about.

12   A Cronbach's alpha stands in our

13   way. All right? A Cronbach's alpha stands in

14   our way because it doesn't allow that thought

15   process.

16   DR. WU: So the ghost of Alvan

17   Feinstein is smiling, I think.

18   MEMBER WASSON: Absolutely. He

19   would call this quantiphrenia.

20   DR. WU: Yes. On the other hand,

21   I think that, even though some young people

22   are thinking nostalgically about remember when

1   we used to have PCs.

2   I think that patient portals don't

3   necessarily have to be the enemy. They can be

4   friendly. They can also be ported,

5   incidentally, to your cell phone. But in many

6   ways, if they designed properly, they can

7   provide the patient with a lot of value. They

8   can help them schedule appointments; cancel

9   appointments; look at lab tests; communicate

10   directly with the physician in a confidential

11   way; and, incidentally, fill out PROs. So I

12   am not sure that that is entirely dead.

13   MEMBER WASSON: Knowing they are

14   all intended.

15   DR. WU: Not yet. There. How's

16   that?

17   MEMBER LARSEN: I am Kevin Larsen.

18   I am from ONC. A little perspective from

19   where I came from before, which is Minnesota.

20   And we have been doing essentially

21   patient-reported outcomes for about five years

22   as part of structured programs called

 1   Minnesota Community Measurement.

 2   You know, in my own clinical

 3   practice as a primary care doctor, we were

 4   doing asthma control tests and a PHQ-9 test

 5   for five years as a statewide measurement

 6   program.

 7   My practice was in a country

 8   hospital, which 20 years ago had thrown away

 9   all patient forms because the patients never

10   filled them out. Our health fiduciary rates

11   were low. We didn't get any kind of response

12   to anything on paper because of reading levels

13   and language levels.

14   So we had a system-wide strategy

15   where we actually administered these verbally

16   to patients across our home care organization.

17   And it turns out that actually happened quite

18   a bit within the State of Minnesota.

19   In my own practice, I actually was

20   an early adopter because I was a medical

21   director. And so I had to make sure that I

22   was doing things that had to happen.

 1   So I actually administered these

 2   myself for three years, asked all my

 3   depression patients their own PHQ-9 scores.

 4   What I found is I got 100 percent

 5   response rate. And mostly it was because we

 6   used this as a tool to jointly decide about

 7   patient care. So it wasn't just for the

 8   patient, and it wasn't just for the doctor.

 9   It was used right in the point of

10   care. I would show them a graph on the

11   computer, "Here's how you were last time.

12   Here's how you are now. I think your

13   depression is worse. Let's think about

14   escalating your therapy."

15   And, all of a sudden, this tool

16   that we think of as an accountability tool

17   became the visibility tool for the patient and

18   the doctor to really think through what should

19   they do about care right now.

20   And to my mind, that's the most

21   exciting news of patient-reported outcomes

22   because it really moves health forward. It

1 doesn't just beat people up for not doing

2 something that we think they should do.

3   DR. WU: That is really what we're

4 talking about, about getting things into the

5 work flow for both patients and providers.

6   More comments? Yes? I see a

7 hand. It's attached to Ted perhaps.

8   MEMBER GANIATS: It's Dr. Ted. I

9 am sorry. I was being so good. Then Dr.

10 Wasson had to speak up.

11   Everything that is being said is

12 very good, though it's contradictory. And Dr.

13 Taylor-Clark brought up some excellent points.

14 And Dr. Wasson brings up some excellent

15 points. And this guy -- I can't read his name

16 tag -- brings up some excellent points. The

17 problem is that they all contradict each other

18 a little bit.

19   If what we want -- what do we want

20 the patient-reported outcomes to be? Do we

21 want them to be clinically actionable,

22 important, real time? Then that is going to

1   decrease the usability of an institution to be

2   able to increase retention rates.

3   Do we want it to be part of a pay

4   for performance to try to improve quality over

5   time? That may or may not be as actionable at

6   the patient bedside? Do we want to help

7   employers choose a health plan that might

8   require something different?

9   So I think all of the points are

10   excellent. I just think that we have to keep

11   reminding ourselves that sometimes we're

12   talking about different types of PROs. And

13   not all of them are going to be able to be

14   used for all of the purposes.

15   Gosh, as a clinician, I would love

16   to have everything be useful all the time, but

17   I just think we have to be really clear about

18   what is going to be used for quality

19   improvement, what is going to be used in

20   clinical practice, and what is going to be

21   used for the other purposes.

22   DR. TAYLOR-CLARK: I actually

1   don't think that what you are saying is that

2   we were contradictory. I actually think that

3   you made something much more clear in what we

4   said, which is that as we're thinking about

5   criteria -- I know we're not using the word

6   "criteria," but as we're thinking about how

7   we're going to choose these measures and what

8   we're going to actually end up using them for,

9   we have to make the distinction of whether

10   we're going to be able to use them for

11   purposes of accountability or useability or

12   whether we're going to be able to use them in

13   the clinical improvement process or for

14   self-management.

15   I loved the example that you just

16   gave about using the outcomes for shared

17   decision-making, which is ultimately what you

18   did. And so there are different ways that

19   these measures are obviously going to be used,

20   but I think that that has to be a part and

21   parcel of our thinking around how we're going

22   to develop and design the criteria for these

1   things.

2   DR. WU: Great. Shall we open

3   this to the back of the room? And also,

4   Operator, can you please open the phone lines?

5   We're moving on to the back of the room.

6   MR. CUNNINGHAM: We will pause for

7   the phone lines. Operator, if there is anyone

8   in the queue?

9   DR. WU: Operator?

10   MR. CUNNINGHAM: Are you still

11   with us? Farrah?

12   DR. WU: Hello?

13   THE OPERATOR: Yes. If you would

14   like to ask a question, please press *1 on

15   your telephone keypad.

16   MR. CUNNINGHAM: Thank you.

17   DR. WU: If anyone in the back of

18   the room wants to use their phone to ask their

19   question, that would be fine.

20   (Laughter.)

21   MR. CUNNINGHAM: I am not hearing

22   anything on the phone.

 1   DR. WU: One size does not fit

 2   all. Any questions in the back? Comments?

 3   Lew? Lew, could you please move to the back

 4   to ask your question?

 5   MEMBER KAZIS: Hi. I had two

 6   questions. One was for Dr. Taylor-Clark. I

 7   really liked your comments, especially the

 8   ones related to thinking out of the box.

 9   RWJ has had a real investment in

10   looking at community health and the issues

11   around assessment tools that, in fact, are

12   supposedly gauging the physician when, in

13   fact, there are much broader issues as the

14   community. There are issues of access,

15   something as basic as, does the ambulance, in

16   fact, come within ten minutes of an MI?

17   The question I have is, where do

18   you see those types of metrics moving, in what

19   direction; and how, in fact, can one begin to

20   think in terms of operationalizing them in the

21   context of our health care system?

22   DR. TAYLOR-CLARK: I think that is

1   a really tough question. And certainly those

2   that have been part of this what we call the

3   social determinants of the health world have

4   had this as a problem, you know.

5   And so the way that I would

6   actually see the measures as not necessarily

7   at this point, as Jim described, not

8   necessarily being used for purposes of

9   accountability or payment for the provider

10   but, one, as a monitor for understanding how

11   especially new delivery systems, integrated

12   systems, are actually working to improve the

13   health of their patients, not just the health

14   care processes of their patients and certainly

15   outcomes are getting us to that.

16   So one would be for monitoring,

17   but the second is, as we think about

18   accountability in terms of public reporting --

19   and Al and I had this question. I said,

20   "Well, what is accountability?" You know, I

21   have to go back to the basics on everything.

22   And he said, "Well, I think it's

1   actually, really, about public reporting."

2   Well, that's going to be an extraordinarily

3   important place for these types of measures to

4   be for patients to be able to make decisions

5   about, if they can, make decisions about,

6   where they get treated and how they get

7   treated.

8   But it will also be a check on the

9   system, not necessarily on the individual

10 providers but on the system, to be able to

11 say, "We need to be able to provide

12 resources."

13   And my example of linking to

14 social and community resources is one of

15 potentially many that we could consider and I

16 think that we should consider. But I think it

17 is going to put the onus on the system to

18 really think through how they engage with

19 other systems.

20   And I think that is where we want

21 to go. That is where I would like to see us

22 go. I don't want to stick just with health

1   care. And I don't think that this is a

2   revolutionary concept, but I think we spend a

3   lot of time talking about health care systems

4   and structures and we put the onus on

5   providers. And ultimately this is about

6   improving health broadly.

7   And so in order to do that, we're

8   going to have to start developing the linkages

9   and the relationships with other types of

10   systems so that we can improve health.

11   And I think that in order to do

12   that, we have to start the monitoring

13   somewhere.

14   DR. WU: Great. We've got

15   something back. I see a waving microphone.

16   MS. BARANOWSKI: Thanks. My name

17   is Rebecca Baranowski. I'm with the American

18   Board of Internal Medicine.

19   I have to say, first of all, as

20   someone who has a background in test

21   development, it was really exciting to hear

22   the discussion of CAT and DIF and IRT. It

1   took me back to a previous lifetime.

2   There was some discussion about

3   the need to keep patient surveys short. And

4   I have often heard that if patients consider

5   the questions relevant, that length is not so

6   much of an issue.

7   Can anyone comment on that?

8   DR. WU: Well, I will say from our

9   own experience that that is true. If someone

10   feels like you are -- we are doing a lot of

11   service with oncology patients. And if we are

12   asking them questions about their own health

13   needs, the things that maybe gaps in their

14   goals or achievements, they are happy to talk

15   about those things all day long on paper or

16   elsewhere.

17   On the other hand, they can be

18   very annoyed by very short surveys that they

19   don't think are worth their time.

20   Other comments?

21   MEMBER KALDENBERG: I think that's

22   true. I think the respondent's interest in

1   completing the questionnaire or an interest in

2   the topic of the questionnaire will lead them

3   to answer more questions.

4   So if a patient or any respondent

5   looks at a questionnaire and says, "I don't

6   understand its purpose. I am not particularly

7   interested in it," they're not going to

8   respond; whereas, if, as Albert said, it is

9   something that either has been demonstrated as

10 important to you, it's a part of your

11 treatment plan, it is important to you because

12 "I'm interested in my health. You can ask

13 about as many questions as you want." And I

14 think there's a lot of literature that says

15 that's true.

16   DR. WU: David?

17   MEMBER CELLA: Yes. You know, I

18 guess I would like to give an answer that's in

19 between what lies under your question and

20 things that Drs. Bellows and Wasson were

21 saying. So yes, patients like to be asked

22 questions about how they're doing almost

 1   universally and providers that aren't used to

 2   that and you see them in research studies.

 3   You know, you will hear patients

 4   say, "I think these questions should have been

 5   asked all along." And they're very happy

 6   about it for the most part.

 7   But, coming back to what Dr.

 8   Bellows and Dr. Wasson were saying, there's a

 9   point at which they reach a limit. And

10   sometimes that point comes by being asked the

11   same questions over and over again, you know,

12   every three months or for some period of time.

13   I've had the same experiences with

14   seeing technology be exciting for a while.

15   And then you lose it unless it has become

16   really ingrained in the clinical setting.

17   So I completely agree and from

18   experience as well, not as much as Dr. Wasson,

19   but we really do have to make these relevant.

20   But I don't think, unless I

21   misunderstood what you said, Dr. Wasson --

22   well, you know, if I'm doing IRT, I can agree

1   that Cronbach's alpha is standing in our way,

2   but I'm not sure if that's what you meant

3   because Cronbach's alpha is in classical

4   theory and you don't need it in IRT. In fact,

5   it's irrelevant. And you can get very short,

6   very relevant assessment.

7   So I think there is a solution

8   here. And just the other part of my response

9   to that is that it's not just the patient, of

10   course. It's the provider's side. They have

11   to continue to be enthusiastic about it

12   because they're the ones paying for it to be

13   done. So it's really a partnership in that

14   respect.

15   DR. WU: I will add to that. You

16   know, whenever you ask anyone to do things

17   repeatedly, their interest gradually

18   extinguishes. I think it's a physiologic

19   response that we can't do anything about.

20   On the other hand, if you, we,

21   respond to someone's complaint about their

22   satisfaction with an element of their care and

1   tell them what you're doing about it or,

2   alternatively, if you respond to some bit of

3   feedback that they give you about the amount

4   of pain they're having and tell them what

5   they're doing about it, the next time they're

6   much more likely to continue to respond.

7   So I think that, again, what we do and

8   how we handle all of this is very important.

9   MEMBER NELSON: One of the cases I

10   referred to but didn't explain very much was

11   the rheumatoid arthritis registry in Sweden.

12   And there the survey that patients are

13   completing is actually fairly long. It takes

14   them about 20 minutes.

15   These people have a serious

16   disease: RA. And it used to be that this

17   information was collected for research only.

18   It was a registry. And now it's actually

19   collected so that the nurse or the doctor

20   looks onto the patient's current and past

21   results against the treatment plan so that the

22   next steps in the care plan can be responsive

 1   to their disease activity and how they are

 2   doing.

 3   And, by report, when this

 4   scientific registry was redesigned to actually

 5   help the patient, patients like their care

 6   much better. It absolutely changes the

 7   fundamental clinician-patient relationship.

 8   It makes it much better.

 9   They've now added a care designer

10   to help the 60 RA centers in Sweden do this

11   well, embedded in the care design with a

12   person with RA. It helps the new centers take

13   it on.

14   And the trends over time show that

15   people are starting RA sicker, but they end up

16   at 12 months having much better disease

17   scores. And they're doing better.

18   So I think it is possible under a

19   focused context to actually have this

20   information be extremely relevant to me --

21   it's all about me as a patient -- to the

22   relationship and what that relationship is

1   doing for my care plan and actually seeing if

2   my outcomes are getting better.

3   And under those conditions, how

4   long it takes me to complete the survey, 10

5   minutes or 22 minutes, isn't relevant because

6   now we've got an instrument panel that guides

7   me and our care and how we're doing to monitor

8   our care.

9   And that's becoming a model that

10   the rest of Sweden wishes to adopt for all

11   relevant registries. And Michael Porter is

12   popularizing that in Sweden and now back in

13   the U.S.

14   So I think there are new ways of

15   doing this that can be rather -- what would

16   the term be? -- disruptive.

17   DR. WU: I think that rings very

18   true. We're coming to the end of our time.

19   I'm going to ask one more time if there's

20   anyone on the phone: Operator or anyone else.

21   THE OPERATOR: As a reminder --

22   DR. WU: Yes?

 1   THE OPERATOR: As a reminder, if

 2   you would like to ask a question, please press

 3   *1 on your telephone keypad.

 4   DR. WU: Wait. I think I'm

 5   getting a call from Kathy Lohr.

 6   MEMBER LOHR: This is just one

 7   minor observation or question. In talking

 8   about shorter forms versus longer forms, at

 9   least for some ways of answering

10   questionnaires, have people been trying to

11   build in ways that you can stop and then go

12   back?

13   Because I get this kind of

14   questionnaire in various ways and various

15   purposes, not so much for health care. And

16   beyond about 10 or 15 minutes, you're either

17   tired or you get interrupted. And if you

18   can't save what you've done and then go back

19   to it when you're either not so distracted or

20   whatever, it's extremely annoying. And you

21   might not the next time ever start knowing

22   that you are likely to be interrupted and

1   can't save it and go back.

2   So I'm really just asking whether

3   for people who are implementing a lot of these

4   things, through portals or almost any of these

5   mechanisms, do you build in ways for people to

6   say where they have gotten and go back?

7   MEMBER BELLOWS: We don't have it

8   yet, but our her vendor is delivering it in

9   its next release very shortly.

10   You know, to me, this is partly

11   coming back to the submerging theme that has

12   come out so great, which is that it's all

13   about context.

14   It's not just about the measure.

15   It's about the measure used, how often, with

16   how many patients, with what follow-up that's

17   really sensitive to people's care and with

18   what degree of control. And it's just built

19   out so beautifully.

20   DR. WU: Great discussion. I

21   think we are going to wrap up. I would like

22   to thank the panel members and members of the

1   audience and, of course, people on the phone.

2   MS. PACE: So we are going to have

3   a short break. And we'll ask you to try to

4   reconvene at 3:20. And Kathy is clapping. So

5   thank you, panel.

6   (Applause.)

7   MS. PACE: So we will try to

8   reconvene at 3:20 if possible.

9   (Whereupon, the above-entitled

10   matter went off the record at 3:10 p.m. and

11   resumed at 3:27 p.m.)

12   CO-CHAIR BRENNAN: Good afternoon,

13   ladies and gentlemen. I am Patty Brennan. I

14   am co-chair of the panel today. I am not sure

15   everyone is as excited about this session as

16   I am, but I am very excited about this

17   session. And I think we will get some more

18   people excited about it shortly.

19   When we speak about

20   patient-reported outcomes, we often look to

21   efficient ways to both understand the process

22   of care that a person has been engaged with as

1   well as a place to store the assessment,

2   perhaps that assessment of their outcome

3   having dual use for their individual care

4   processes as well as the accountability and

5   quality improvement goals that the NQF has.

6   The electronic health record as we

7   know it today is probably not the best place

8   for it, but it's a starting point to think

9   about the electronic infrastructure necessary

10 to acquire patient-reported outcomes, organize

11 them in a way that helps us make meaningful

12 interpretations for the patients' progress as

13 well as the care and also have a way to begin

14 to aggregate for the institutions' awareness.

15   This afternoon we have a report

16 from the Commission paper. I'm happy today

17 David Cella is back again to speak with us.

18 And we'll have a reactor panel of three

19 individuals.

20   I am going to be introducing

21 everyone now to coordinate the time best.

22 It's just about 3:30. We are going to go

1 until about 20 until 5:00. So we'll have

2 plenty of time for comments on this session.

3 And then we'll do a wrap-up between about 20,

4 a quarter of 5:00 and 5:00 o'clock.

5   But today in this next session,

6 we're going to be talking about the key

7 considerations for incorporating PROs into

8 electronic health records. And let's think

9 about those with small EHR, not large EHRs,

10 because the electronic health record you know

11 today is going to look very different within

12 two or three months, in fact, if not two or

13 three years.

14   David Cella will be giving us a

15 report from the Commission paper. And then we

16 will have three reactors' groups set up. Uma

17 will be speaking with us about the experience

18 at Cincinnati Children's Hospital. Kevin

19 Larsen from the ONC will be discussing

20 meaningful use and some of the indicators

21 linking quality and measurement of outcomes.

22 And then Ted Rooney from Maine will be

1   discussing the experiences in their outreach

2   group.

3   David?

4   MEMBER CELLA: Hello again. I am

5   happy to say I don't know if I am happy or you

6   will be happier to hear that this will be my

7   shortest tee-off. It's a par three session,

8   at least for the tee-off.

9   Okay. So let's try to broaden the

10   conversation and talk about the health or

11   health-related internet applications that

12   deliver a range of content, connectivity, and

13   clinical care, keeping in mind that most

14   e-health is driven by the electronic health

15   record that the provider offers to the

16   patient, although certainly not the only.

17   So what does that include? It

18   includes health information, individual and

19   group; online formularies, prescription

20   refills; -- I use it -- many of you probably

21   use it -- appointment scheduling and test

22   results; -- I've used it -- advanced care

1   planning and health care proxy designation,

2   not used that yet, but it's available in some

3   systems. And these applications tend to focus

4   because they were built for them on the needs

5   of the health care providers and the health

6   care organizations.

7   And this has I think been a theme

8   today that I didn't necessarily anticipate,

9   but it is in the paper that there is also

10   little evidence regarding whether these

11   services offered are those that patients

12   actually desire.

13   Next slide. So how about the side

14   of integrating PROs into electronic health

15   records and personal health records? PROs

16   will likely constitute and important aspect of

17   future stages of meaningful use.

18   Now, you could tell me I'm wrong

19   and maybe I am wrong, but three years ago I

20   went to a hospital administrator who will go

21   nameless and said, "Hey, I think you really

22   need to pay attention to PROs because you're

 1   going to need to for meaningful use."

 2   And he's a very nice guy. He

 3   said, "You know, I think we can kind of comply

 4   with meaningful use without worrying about

 5   PHO. So no thank you."

 6   I don't think that's true anymore,

 7   but you tell me. And if it's in the future of

 8   meaningful use, then we ought to try to make

 9   it meaningful.

10   So critical features involve

11   interoperability, as you know, widespread

12   health information exchange, automated

13   real-time quality and cost measurement, which

14   the PROs can fit into, and sophisticated

15   analytic capabilities that we certainly could

16   engineer into the PRO site.

17   Next slide. So some important

18   issues. First is the patients' perspective.

19   Patients do want to be involved as partners in

20   the flow of information, in health information

21   exchange. They're certainly in their own

22   personal health record.

1   You know, as we talked about in

2   the last session, the clinical buy-in is

3   really essential for good equality data over

4   time especially. In order to get that buy-in,

5   one important component that has to be

6   compatible with clinical flow, I mentioned

7   meaningful use.

8   And I suggested earlier eventually

9   an issue of patient privacy, the actual

10   physical transfer of patient-based PRO

11   measures from the patient/the provider, there

12   is a privacy, a possible, concern there. And

13   then the electronic transfer of data or

14   unauthorized access to patient-quoted data can

15   cause privacy concerns or alerts.

16   So some key design principles in

17   integrating PROs are to fit the measures into

18   the flow of care, as I mentioned. The design,

19   the system with stakeholder engagement -- it

20   has got to be relevant and meaningful -- to

21   merge the PRO data with other types of data so

22   it's not a set-aside, stand-alone system,

 1 although it is easier up front to build the

 2 stand-alone system, as we and others have, and

 3 to engage in continuous improvement of those

 4 systems based on user experience and

 5 technology, so sort of basic principles of

 6 getting it integrated; relevant; and,

 7 therefore, getting the buy-in and long-term

 8 sustainability.

 9   Next slide. One of the things we

10 developed with PROMIS, which I haven't

11 mentioned yet today, is an assessment center,

12 which is a web-based portal. I just mention

13 that we and others have done these sort of

14 set-aside systems.

15   So there is a web-based assessment

16 system that anyone can use. You can go to

17 NIHPROMIS.org. And you can take some CATs

18 yourselves this evening when you have got

19 nothing better to do other than watch the

20 Olympics and see how your depression and

21 fatigue levels are after this meeting.

22   So NIHPROMIS.org. And you can go

 1 test yourself on a demo. But it's a

 2 disconnected system. We don't ask you who you

 3 are. You don't tell us who you are. You can

 4 just try this out.

 5   But if you wanted to use an

 6 electronic health record environment, you

 7 would need to link it to the electronic health

 8 record. So, to that end, we've got SNOMED and

 9 LOINC codes and have been working with

10 different her vendors to integrate assessment

11 center or the data capture and scoring

12 algorithms into the electronic health record.

13 So that is work that is ongoing and should

14 help maintain a truly sustainable integrated

15 system.

16   So I think that's the last slide.

17 Those are my introductory tee-off comments.

18 Thanks.

19   CO-CHAIR BRENNAN: Thanks very

20 much, David. Are there questions before David

21 sits down for clarification and more

22 information? We don't want him to go just

1   yet. Comments or questions specifically for

2   David's section?

3   (No response.)

4   CO-CHAIR BRENNAN: Okay. Thank

5   you very much, David. I appreciate it.

6   I am going to ask Uma if you are

7   ready to begin your remarks. Please?

8   DR. KOTAGAL: Good afternoon.

9   Thank you very much for inviting me. Before

10   I make my comments about the PROs in the EHR,

11   which is the topic we were asked to focus on,

12   I would just want to give you some context.

13   So this will be in the context of

14   a large academic health center. About 50

15   percent of our patients come from outside our

16   region. A lot of our work is very specialized

17   care. And all of it is pediatrics. So our

18   patient-reported outcome conversation is in

19   the context of that.

20   Secondly, put the focus in terms

21   of our bias towards action and the fact that

22   we are really interested about

 1   patient-reported outcomes in the context of

 2   improvement, as opposed to thinking about it

 3   in the context of performance measures, so

 4   that our believe is that we will need to do a

 5   lot of work on practical applications of

 6   patient-reported outcomes and improvement

 7   before we could really look and say how this

 8   is going to fit into performance measures. So

 9   I just wanted to talk about that a little bit.

10   We have been engaged with patients

11   and families for a long time, starting in 2002

12   with cystic fibrosis, families that taught us

13   how to think about patient engagement. And

14   all of our chronic disease teams have patients

15   sitting at the table to help us think about

16   what is important to them. And we accompany

17   that with a fair amount of internal clinician

18   engagement and training that enable us to look

19   at patient-reported outcomes in the context of

20   improvement.

21   Our work on patient-reported

22   outcomes began with a five-year plan that asks

 1   us to think about transforming care for

 2   children in chronic and complex disease for 60

 3   conditions in the next 5 years. So we are

 4   looking at patient-reported outcomes in the

 5   context of clinical outcomes, patient-reported

 6   outcomes, and evidence-based processes, all of

 7   which we are looking to embed into our her

 8   with a combined reporting in the form of small

 9   multiples that allow us to look both at

10   clinical outcomes and patient-reported

11   outcomes at the same time.

12   A major interest, of course, is in

13   scale. And so we are beginning to build our

14   registries at this point primarily in Epic, in

15   the content of Epic, and then using our

16   reporting systems to be able to derive

17   population-based data so that the individual

18   patient data is within the system, the

19   population-based data is sort of ad hoc or on

20   top of it.

21   Our expectation is to build all

22   components of Ed Wagner's chronic care model

1 into our Epic registry, which, of course,

2 relates back to my earlier comments about the

3 role of self-management and self-confidence

4 and how the use of the patient-reported

5 outcomes can adjust that balance between the

6 provider and the patient, which, of course,

7 remains a gradient at this point in time.

8   Our early lessons have told us

9 that when we incorporate patient-reported

10 outcomes into the registry and into the

11 patient encounter, that provider behavior does

12 change. But it starts with engaged

13 clinicians. So our process does require us to

14 have engaged clinicians.

15   For the 60 diseases, we currently

16 have patient-reported outcomes in about 10.

17 We'll have another five at the end of about

18 ten months from now. And then we'll be

19 building our way up to the next 40.

20   So the clinicians with patients

21 choose the outcomes. And that's a really

22 important consideration. They choose both the

1   clinical outcomes of interest and the

2   patient-reported outcomes of interest. And we

3   are not at this point requiring every chronic

4   disease team to have patient-reported

5   outcomes, but we are offering the invitation.

6   If they are interested, we would work with

7   them to do that.

8   So then our process really allows

9   us to engage with the clinicians, consult with

10   them, with the patients, decide what the

11   outcome of interest should be, go back to the

12   methodologists, and ask them the right

13   questions to figure out what is the right

14   measure, what is the evidence, what measure is

15   out there, what needs to be modified so we

16   come up with the right reported measure.

17   And all of this is at the

18   disease-based level. In addition to the

19   organization level, we are piloting with

20   measures of care coordination; measures of

21   patient experience that are not embedded or

22   related to the ER; and in some cases PHQL as

1   a broader generic measure of quality of life,

2   as opposed to a disease-specific measure; and,

3   finally, patient self-confidence in the

4   context of self-management.

5   So that's the context in which we

6   work. The process -- and I want to just go to

7   my first slide here. I just used an example.

8   This is data from some time ago. These are

9   children with obsessive compulsive disorders.

10   And I picked this one, as opposed to

11   depression or functional outcomes or PROMIS

12   scores, just because, even in the area of OCD

13   in young children, we find that

14   patient-reported outcomes are and can change

15   the way it works.

16   This graph shows you data on four

17   segments of patients that the clinicians

18   self-classified. So we begin with a measure

19   called the Symbyax, which is a gold standard

20   of measure for patients, for OCD, but it's

21   very lengthy, back to our comments about how

22   dense the measurement can be.

1   We have modified it, proved that

2   it is scientifically valid. And we began with

3   paper and pencil, then with a self-standing

4   kind of electronic system. And now it is

5   incorporated into the electronic health

6   record.

7   So the child comes in and fills a

8   question, answering the question, "Did it get

9   you or did you get it?" answering it in the

10   context of burden of disease. This is then

11   printed off.

12   Actually, the patient is tagged as

13   sort of requiring a PRO measure at the clinic

14   so that when they check in, the registration

15   person gives them a confidential password as

16   well as the information. We're currently

17   doing it both using kiosks and tablets.

18   The patient fills in the data.

19   The data is printed off. The patient has the

20   data along with the family and the provider

21   has the data.

22   So the conversation begins similar

1   to some of our discussions at the last break

2   that say what is going on since the last time

3   you see and what is happening.

4   And then this is obviously

5   measured at each visit. The central concern

6   here is how do we improve outcomes for

7   patients. And when we do that, we find that

8   the encounter gets to be very interesting. So

9   it is for the individual patient that it

10   matters, which we then roll up into a system

11   or into a whole population level there.

12   Therapists find that they can stay

13   focused on treatment goals. The patients and

14   families find that they have a clear endpoint

15   in mind so that they may say that when your

16   symptom score gets to this level below 13,

17   that's the end of our treatment. The care is

18   more efficient because all of this information

19   is available and the conversation can be more

20   focused.

21   And, actually, what we have found

22   is that by putting these evidence-based

1   practices into place, giving providers and

2   clinicians a conversation to have with the her

3   and the patient that we are able to detect

4   these patterns.

5   So on the top right-hand side, you

6   will see the response rates are pretty fast in

7   some kids, high being not so good, low being

8   better. On the left-hand side, you see a

9   slightly different response rate. In the

10 third graph on the bottom left, you'll see no

11 changes in response. And the fourth is the

12 exact pattern.

13   This was really done by looking at

14 the data and segmenting it, sitting down with

15 clinicians to do that. When the clinicians

16 get together using this data to figure out

17 what is going on, they concluded that their

18 primary factor was actually a dose effect.

19   In other words, with children with

20 OCD, the primary treatment is exposure to the

21 compulsive disorder. And in the different

22 groups, they were exposing them to different

 1   dose effects, which they then through

 2   discussion were able to modify. And then on

 3   the next slide, you'll see I think the percent

 4   of children that have at least a 40 percent

 5   reduction in symptom scores. In this case, I

 6   think the number -- they have a target number

 7   that they use but find that they can make a

 8   big difference.

 9   So we are using this idea of a

10   kiosk or a tablet. We are not using portals

11   at the present time for entering data, teeing

12   it up to the clinician, a conversation by

13   clinicians agreeing both on the measure and

14   the target, and then a collaborative group

15   that together decides how they are doing, why

16   some people are doing better, why other people

17   are not with a goal, then, for improvement in

18   the functional measure.

19   So I'll stop with that and take

20   any questions at the end.

21   CO-CHAIR BRENNAN: Could you just

22   speak a little bit about how this gets into

1 your electronic record now? Is there a

2 special section or does it go as a narrative

3 note?

4   DR. KOTAGAL: So currently it goes

5 into the electronic record as a pulled-up

6 document that shows the graph. The graph that

7 we get at Epic looks more like the one you see

8 on the last one, not like the previous one,

9 which is a little bit more interesting. But

10 it does get that way.

11   And the population-level data also

12 gets pulled out and is reported that the team

13 looks at on a regular basis.

14   CO-CHAIR BRENNAN: Thank you.

15   Are there clarification questions

16 you would like to ask Uma before we go on to

17 our next comments?

18   (No response.)

19   CO-CHAIR BRENNAN: Okay. Thank

20 you very much. Our next speaker will be Kevin

21 Larsen. Kevin joins us from the ONC.

22   DR. LARSEN: Hi. I am the Medical

1   Director of Meaningful Use for the ONC, a

2   general internist by training and was doing

3   that up until March, when I moved here and

4   will hopefully be doing it again soon here in

5   D.C.

6   I would start with a brief story.

7   I grew up the brother of a type I diabetic.

8   And so he was diagnosed with type I diabetes

9   when we were both young children. And I lived

10 through the change, the paradigm shift of

11 doctor-directed care to patient-owned care

12 through the eyes of my type I diabetic

13 brother.

14   And it was really about 20 years

15 ago that we stopped calling the doctor for

16 every insulin injection. For the first 15

17 years of his diabetes, every single time we

18 were going to change insulin, it was a phone

19 call to his doctor, sometimes in the middle of

20 the night. And that shift to self-management

21 was a radical, wonderful shift that my brother

22 undertook.

1   He is a software engineer and very

2   bright and able to do this stuff. He recently

3   got a continuous blood sugar monitor. And he

4   now is in the best control he has ever been

5   because he has the best real-time instant

6   feedback.

7   That virtuous cycle of feedback to

8   patients and tools to help them self-manage is

9   really where I think we are headed. And that

10   is really where I want to think about, how do

11   we support that infrastructure much more

12   broadly than just my brother and type I

13   diabetes.

14   For meaningful use, for those of

15   you who don't know, it's an incentive program,

16   a CMS incentive program for hospitals and

17   eligible providers, largely doctors but

18   dentists and nurse practitioners as well, to

19   implement in electronic health records. And

20   they don't just get paid for plugging a

21   computer into their office.

22   They actually have to demonstrate

1   that they're using it in a way that improves

2   patient care. And that way is measured as

3   clinical quality measures. And those clinical

4   quality measures that have a secondary goal is

5   that we start to make electronic and automate

6   the capture of quality measurement that has

7   historically been done as either claims or

8   chart abstraction.

9   So many of us are living the life

10   of innovating around how to take one type of

11   measurement and now put that into a new world,

12   a new way, the clinical quality measure. And

13   I see many of my e-clinical equality measure

14   friends here.

15   The program has three stages. The

16   second stage is just about to -- the policy is

17   about to be launched, but it won't actually

18   happen until 2014. And we're in the process

19   of building requirements ideas for the third

20   stage.

21   This is really the infrastructure.

22   This is the chance to really influence the

 1 infrastructure of electronic health records

 2 across the country because this is a giant

 3 cash infusion with quite a bit of incentives

 4 from CMS.

 5   We are thinking about how can this

 6 infrastructure contain the building blocks

 7 that we want for the future of patients, the

 8 future of health, the future of health

 9 quality. And so this is our opportunity to

10 say, "Here are the things. Here is the focus,

11 few things, that we should invest the

12 country's money in so that we can have the

13 infrastructure that we want to assure that we

14 are able to let people live healthier lives."

15   In the process of this, we have to

16 think of things in a new way. And one of

17 those ways is measures now become software.

18 Instead of a measure being a piece of paper

19 that lives in a document for someone to read

20 through, the group of us that is working on

21 these e-measures think of it as software.

22   So if a measure contains 15

1   different possible survey instruments,

2   somebody has to encode 15 different survey

3   instruments into whatever computer system

4   there is, keep those up to date, make sure

5   they all work, make sure that they all provide

6   the kind of results that they provide.

7   That is completely possible. The

8   question is the cost. Is that the right way

9   to spend the money?

10   And also, just like you can have a

11   proliferation of Apple and Microsoft and

12   everybody else with their own kind of

13   platform, the more that the electronic health

14   record measurement world has its own way that

15   each group wants to do things, the more it

16   costs everybody to keep up, maintain, and use.

17   So we have really been working

18   towards this building blocks idea. How can we

19   take tools that we can use as we build

20   infrastructure and use them over and over and

21   over again for multiple different purposes, as

22   opposed to building software that's only

1 specific for one little, tiny purpose and

2 can't be leveraged for other things.

3   An idea around that is something

4 like an app store. So you could imagine, any

5 of you that use an iPhone, Apple built the app

6 store. And then lots of people can put an app

7 in there as long as it conforms to all of the

8 rules to fit into that app store.

9   And so we are starting to think

10 about what we call a flexible platform, which

11 might be something like PROMIS has stood up.

12 It might be any number of things. But the

13 ideal world, at least to my perspective, is a

14 world that the infrastructure exists that can

15 very easily accommodate new instruments, new

16 tools, new ways without us having to stand up

17 something specific for each new thing we want

18 to use.

19   And we had a lot of talk about

20 work flow. Work flow is actually very

21 important in the implementation of these

22 measures, as anyone who has done it will tell

1   you. And I would say you have to think about

2   not just the work flow of the provider. You

3   have to think about the work flow of the

4   patient because now the patient is engaging

5   with the system and the patient has a work

6   flow. And their work flow should be paramount

7   as we think about patient-reported outcomes.

8   And articulating that and having

9   an ability to accommodate lots of different

10   styles of patients in lots of different ways

11   they might want to engage in the system is

12   going to be very important. So we need to be

13   really flexible.

14   I'll leave with another example

15   from where I just came from. So in Minnesota,

16   the Patient-Centered Medical Home Program has

17   a very specific set of requirements. And one

18   of those requirements was actually that we

19   have patient-defined care goals and that we

20   track the patients' response to their own

21   defined goals. And they didn't have to be

22   care. They could be anything the patient

 1   wanted.

 2   So we had to build an electronic

 3   system that could track response to any goal

 4   that a patient could articulate. And we did.

 5   We built a system that could take a free text

 6   thing. And it built a five-point scale. And

 7   the patient got to determine what that thing

 8   was "I want to be able to dance more."

 9   "How well can you dance now?"

10   would be the item on there and they would get

11   to score them one to five. And then each time

12   they came back, we would rescore and say, "Are

13   you dancing better this time than you did last

14   time?"

15   This was a home run hit with the

16   patients. They got to frame the whole

17   discussion, not around our scientifically

18   validated survey instrument. They got to

19   frame the discussion about "This is what is

20   important to me right now. This is what I

21   want us to talk about." And then it helped

22   the provider also frame that visit around this

1 is where the patient wants to go.

2   So I think that it is really

3 important that we have goals that we can use

4 across different organizations to compare one

5 provider type to another provider type in

6 different scientific frameworks.

7   It is also really important that

8 we have things that patients say, "This is of

9 value to me." And thinking about how we can

10 do that might lead us down a very different

11 path than thinking about what makes the most

12 sense in the context of a specific disease

13 state or specific category.

14   Ideally, they are complementary, I

15 think, rather than exclusive.

16   CO-CHAIR BRENNAN: Thank you very

17 much, Kevin.

18   Any comments or questions for

19 Kevin before we go on? Yes, Steve? Steve,

20 you have to pick up the microphone. Thank

21 you. And make sure it's red. It's red.

22 Green, green, green. These are red. Those

1 are green.

2   MEMBER FIHN: Well, not to be

3 outdone by my curmudgeonly colleagues, I want

4 to sort of pursue I think a potential line of

5 discussion that emanates from this. And bear

6 with me for one second because I think it is

7 important when we think about the EHR.

8   So I really appreciate the

9 comments, particularly of Kevin. So the VA

10 has been engaged in a very tortuous dance with

11 one of our other federal partners for the last

12 couple of years to build a joint medical

13 record.

14   And the upshot of that is that in

15 order to do that, actually, we have had to

16 take an approach which Kevin is suggesting of

17 reusable code. Actually, I'm told next week

18 we'll have an agreement with Apple for an app

19 store.

20   But if you take that and you think

21 about PROs, so we talk about apps where people

22 put stuff into the record. These apps

1   ultimately patients are going to want to get

2   stuff out of the record, too.

3   Once you have established that

4   paradigm of patients being able to right the

5   record, get back from the record, we no longer

6   own the records anymore. In fact, one could

7   then go down the road and think about we

8   actually don't have an her anymore. The

9   patient has an EHR. If you want to talk about

10   patient empowerment, actually, that's where I

11   think we're going, that we will cling

12   selfishly for a lot of economic reasons for

13   the record, but it's going to be an uphill

14   battle.

15   So if you then sort of say -- you

16   know, I mean, I think one of the points I

17   wanted to make is we are putting -- this

18   really may be the foot in the door or the

19   camel's nose under the tent that actually

20   leads to medical centers having spent tens of

21   millions, hundreds of millions of dollars on

22   records which no longer actually may not be as

 1 relevant to them anymore. We could talk about

 2 that, in which these patients will actually

 3 own their records and have full access to

 4 them, which I think if you start thinking

 5 about patient recording, I think it is really

 6 important.

 7   I think Kevin's other point about

 8 patient-identified goals, actually I kind of

 9 mentioned that before you came in. We have a

10 program with the severely wounded OEF/OAF

11 veterans who come in. Actually, they have

12 something called a federal recovery plan for

13 a person, you know, work for the government.

14   You know, they're really cool.

15 And, actually, they ask the patient, you know,

16 "What is your goal?"

17   It's "I want to walk in five

18 years." And that becomes a plan. And all the

19 care gets built around that, those sets of

20 goals. And that's incredibly powerful from my

21 perspective.

22   But, you know, I think, actually,

1   you want to throw some bombs here. One of the

2   bombs may be that, you know, we don't have a

3   medical record anymore.

4   CO-CHAIR BRENNAN: I appreciate

5   that as a starting point. We are going to

6   hear from Ted Rooney in just a moment, but I

7   want to see if Kevin has a quick comment he

8   might want to make on that.

9   DR. LARSEN: So the advisory

10   committees that really inform our work for

11   meaningful use have been thinking about that

12   exact same thing for quite a while. And what

13   I'll say from being an organization that did

14   invest a lot of money and had a great big EHR,

15   I think it becomes like do you own the stuff

16   on your computer anymore.

17   And you start to know which stuff

18   you do own and which stuff you don't own. And

19   you kind of know where the interface is. And

20   so there's some stuff you really do own and

21   you know you own it. And there's other stuff

22   that you know that you always go back to the

1 same website. And that might change, but you

2 don't really care. And there's some stuff

3 that's really somebody else's.

4   So I think that the more you live

5 it, that that becomes less of an anxiety

6 provoker for you. But I think when you start,

7 when you have only ever had a computer not

8 connected to the internet, the internet is

9 scary.

10   But when you are actually there,

11 you start to figure out, "Well, the internet

12 isn't that scary. I still can control my

13 stuff. And I can get other things and share."

14   CO-CHAIR BRENNAN: We are going to

15 have a very lively discussion I'm sure about

16 this one.

17   (Laughter.)

18   CO-CHAIR BRENNAN: And the other

19 people in the room, don't worry. You didn't

20 waste your money.

21   Let me move to Ted Rooney's

22 comments. And then we'll open for the whole

 1   discussion. I remember the people on the

 2   phone and on the internet. You're welcome to

 3   pose questions also. Ted Rooney from Maine.

 4   MR. ROONEY: Hi. I am Ted Rooney,

 5   obviously. I work with two groups in Maine.

 6   One is the Maine Health Management Coalition,

 7   which is an employer/union-led regional health

 8   improvement collaborative that focuses on

 9   performance measure, public reporting, payment

10   reform, benefit design, consumer engagement.

11   I also work for a provider of that

12   multi-stakeholder group, Quality Counts, which

13   really focuses on quality improvement and

14   getting consumers involved in the partners in

15   care. Together they run the Aligning Forces

16   for Quality initiative in Maine. So I'm sort

17   of in the middle there.

18   We also have an active health

19   information exchange. So everything has to be

20   electronic anymore. We do our performance

21   measurement through NCQA and Bridges to

22   Excellence. And we have got about 500

1   different physician and PCP offices in Maine.

2   We define a practice as a physical office

3   location. So even a group may have seven

4   offices. We count one practice.

5   And there are probably about -- I

6   don't know -- 60-70 percent of those having

7   reported got recognition from NCQA or Bridges

8   to Excellence in something, whether in office

9   assistance survey diabetes or heart disease.

10   And the diabetes are clinical outcomes

11   embedded in there.

12   And one of the things we realize

13   is we have these steering committees that help

14   run the program, you know, 14 docs and 6

15   employers and 3 health plans. And a year or

16   two ago, we were talking about getting

17   recognition. And there is this doc over here

18   who talks about having spent 20 hours trying

19   to get data out from his chart and even from

20   the EMR in order to apply to NCQA to get

21   diabetes recognition.

22   And so I turn to Frank Bragg, who

 1   is a straight doc with Eastern Maine Medical

 2   Center. And I say, "Frank, how long does it

 3   take you to get recognized?"

 4   He said, "Well, I don't do

 5   anything" because he happens to have

 6   Centricity. Centricity works with MQIC.

 7   Every night his data gets uploaded, and he

 8   gets reports every month. He's just looking

 9   at increasing reports. And he gets recognized

10   as a byproduct of giving great care.

11   And then he takes that data. And

12   he works within his own group of docs, like a

13   performance assessor. You know, they

14   aggregate the data. They work together. They

15   drive performance up.

16   And we have been fans with the D5,

17   which is the Minnesota measurement that looks

18   at the five elements of diabetes and they

19   track it over time. And we looked at that

20   like five years ago. And there were people

21   doing maybe five or ten percent of getting all

22   their patients the goal of all five areas.

 1   And we like that because that is a

 2   patient-centered measure.

 3   Typically you measure how many of

 4   the doc's patients have a hemoglobin at this

 5   level, how many of the doc's patients have an

 6   LDL of that level. But they changed the

 7   paradigm by saying, "How many patients are for

 8   all levels?"

 9   And, all of a sudden -- I haven't

10   looked for the last month or two, but some of

11   the practices are up in 50, 60, 70 percent of

12   their patients echo for all those measures.

13   They dramatically change the paradigm, I

14   think, in delivering good care.

15   And that's what we began to see

16   happen when people have data electronically

17   that they control, they believe, and they use.

18   Now, I'm absolutely convinced that

19   there's no way in hell Frank would have had

20   all the time and resources to do that if there

21   wasn't a performance measure, that his

22   practice wasn't rated publicly on it, he

1   wasn't paid on it, there's no way he would

2   have had the time to do it.

3   So we talk in Maine a lot about

4   doing the head and the heart. I mean, the

5   heart is the right thing. It gets the

6   physician energized. This is good care. But

7   the head is the business case. Every

8   physician needs resources. You can't get

9   resources without a measurement.

10   And I actually think that CMS has

11   got it -- well, they've got a lot of things

12   right, but I have been trying to figure this

13   out. I think I finally figured out today

14   where they have this list of 33 measures that

15   ACOs are to be measured on. And I am

16   particularly interested in this because we

17   have one pioneer and three shared savings

18   models in Maine. So I know they are going to

19   be measuring it.

20   And they have this functional

21   status, health status section that I guess was

22   going to be part of CAHPS that has got about

1   5 or 6 SF-36 questions that I could see as

2   well as some other neat health risk questions

3   and everything.

4   And, whereas, every other

5   mechanism is reporting the first year and to

6   pay the second year, pay for the third year,

7   this one is reporting all three years.

8   Well, I know for a fact that when

9   I go back to Maine, I am going to start

10 talking a lot about this. And even though

11 these providers won't get paid on this for

12 three years, they are going to pay so much

13 attention to it because they know that's where

14 it's going.

15   We've got at least providers who

16 used to pay for performance. So you just have

17 to threaten pay for performance down the road.

18   (Laughter.)

19   MR. ROONEY: And that gives time

20 for the clinicians to work the heart because

21 most of this stuff is the right kind of thing

22 to do.

 1   And so if you can set the system

 2   up in place where you know it's going to be

 3   reported, you know it's going to be paid for

 4   eventually, but you give the docs the right

 5   measures at the right time and let them work

 6   with it. I think we're going to see

 7   tremendous improvements.

 8   And I think, at least for me,

 9   we're big fans of the patient-centered medical

10   home concept or advanced primary care. And

11   it's no longer the docs by themselves anymore.

12   And so when I think of the

13   clinical data, I think you want the doc or the

14   clinician getting some of the data from PROMIS

15   or health risk appraisal stuff, but maybe in

16   that practice, it's not the doc who is the

17   care manager or maybe it's an aide. I mean,

18   how does the practice take that data and get

19   the right data and the right time so in the

20   clinician in that encounter with the patient,

21   they do the right things?

22   Like, do we want our PCP spending

1   five minutes of every visit counseling someone

2   to stop smoking? No. But we probably want

3   them to spend 30 seconds telling the

4   importance of it and giving the warm handoff

5   to a care manager, who spends a half-hour with

6   them, refers them to a stop smoking clinic,

7   and follows up to see how they are doing.

8   So I think the more we can get

9   this data electronic, the more we can sort of

10   have it as being part of a practice. And the

11   more we can think about who needs to see that

12   data in order to make right decisions, I think

13   some of this stuff will work itself out, but

14   we've got to start because if we don't start,

15   what we find is our clinicians are our best

16   innovators.

17   If you wait until you have it

18   perfect and then hand it to them, it's too

19   late. If you give it to them in a safe enough

20   space, like -- again, maybe we'll publicly

21   report it next year or the year after -- it's

22   going to happen, but give them some time to

1 work with it and refine this up. I think

2 we'll see tremendous innovation.

3   And if we think of the system of

4 care, it's not just about the doc. You know,

5 I'd like our practices to tell us. You know,

6 even in the docs I talk to, it's funny. You

7 know, we're all individuals. Some docs really

8 want to see the data themselves. They want to

9 go in there, and they want to strategy it and

10 look at it.

11   And another doc doesn't care about

12 that. He wants his care manager to do it. He

13 just wants to know which patient should I pay

14 attention to? What are the key points? And

15 what should I do with them?

16   We've got to begin to think about

17 that in a team-based environment. Different

18 members of the team will do different things

19 and do it well. And we talk a lot about

20 practicing the top of your license. So you

21 get the least paid person doing the most. In

22 fact, that's probably what the VA and the feds

1   have done for a long time.

2   How do we think of a system of

3   care? And then how do we think of the

4   patient-reported outcomes? What do we measure

5   in the right way? You know it has to be

6   electronic, but who needs to see it when? How

7   often do we do it?

8   And how do we know or how do we

9   point to -- how does a person know what to do

10   about that? So, for example, if we do a

11   yearly survey of everybody in a practice with

12   a functional status measure and you get an

13   aggregate data, how do you know -- of the

14   2,000 people who made up that panel, how do

15   you know who to do what with?

16   So you've got to do it on an

17   individual level, but at an individual level,

18   you know, if you do it on an individual level,

19   can you roll it up hopefully? Because one of

20   the things we're big fans of is that

21   performance measure should be a byproduct of

22   giving great care, like Frank does.

1   I mean, we don't want our

2   clinicians, we hate it when our clinicians,

3   start to worry about which measurement program

4   to follow. It's a waste of time. We say,

5   "Well, just give great care. You know, let us

6   try to figure out how the measurement and

7   reward systems help you give great care and

8   reward you for it. And do it in such a way

9   that they know they have to do it, but give

10   them enough time so that they have a chance to

11   do it right, at least the early majority

12   folks."

13   And so that's sort of my take on

14   it. If we don't get it in the electronic

15   health record, no one is going to pay

16   attention to it. But we've got to do it in a

17   way that is helpful and that we find this

18   balance between improvement and reporting and

19   accountability. And I think it's doable.

20   It's just not easy.

21   CO-CHAIR BRENNAN: Thank you very

22   much.

1   Comments or questions for Ted?

2   Yes, Kathy? Go for it, then.

3   MEMBER LOHR: I am stuck. I am

4   one of those Luddites who sort of doesn't do

5   a lot with computers and that sort of thing,

6   really. But I haven't heard anybody say about

7   whether much of this stuff can be stored on

8   and the software placed on the cloud.

9   And it's as if people are still

10   talking about storing all this stuff on

11   servers someplace or something like that. I

12   may be wrong, but that was kind of the sense

13   I had. That was one question.

14   Another, Kevin, is really for you.

15   Is there a time frame for the specs for

16   meaningful use 3? Because would that help to

17   put in some time perspective what NQF is

18   trying to do with this whole effort? And I

19   don't know what the dovetailing is of the time

20   frame.

21   And the third question, which is

22   maybe for everybody, is, but perhaps picking

 1 up on what Ted was saying about, "We'll start

 2 now. And then three years down the road,

 3 people will be ready," are medical school or,

 4 let's say, stick with physicians. Are medical

 5 schools trying to teach this stuff?

 6   Is the AAMC on board? Are the

 7 specialty boards and so forth on board, if you

 8 will, with moving in this direction? And if

 9 they're not part of the conversation soon,

10 should they be? And I don't know the answer

11 to that one either.

12   DR. LARSEN: So I can tackle the

13 first two. I'll start on the third one. The

14 question about the cloud, we really have a

15 high bar of performance we need to have for

16 patients. And that is we need to be flexible

17 and adaptable to what patients want and need.

18 And we need to give them access. And they

19 need to be in complete control of their own

20 data.

21   So they need to be able to tell us

22 when and where that data should go and need to

1 be able to tell us which data they want to go

2 where. So that is a lot of the work that ONC

3 does: building the standards for how that

4 works, certifying that systems can do that,

5 and starting to provide a regulatory

6 environment that allows all of those sort of

7 challenging concepts to live together and make

8 sure that happens.

9   Can it happen? Of course, it can

10 happen. Your bank does that, right? So your

11 money flows all around electronically. And

12 you have trust in your bank that somehow

13 through a combination of incentives and

14 regulation, that they keep track of your money

15 and it doesn't just slip out electronically

16 through someone else. We have to do that same

17 kind of thing in this more complicated

18 landscape of health care.

19   So, to the cloud question, yes, we

20 could use the cloud. Currently the regulatory

21 environment and the certification environment

22 are a little bit new for people to trust the

1   cloud to say, "I'm going to put my data there

2   because I believe that it is going to be

3   protected in the same way that the bank

4   protects my data." We have to get to that

5   level of trust in order for people to want to

6   use the cloud for their data to be stored.

7   It's part of the reason hospitals

8   are a little bit nervous about sharing with

9   each other. It's not because they don't think

10   it's the right thing to do. It's because

11   they're nervous that they'll be held

12   accountable if the information gets shared

13   with somebody else and somebody else doesn't

14   have the same level of security that they do.

15   Back to the sort of easiest

16   question of yours, which is the meaningful use

17   3 timeline. The rule, preliminary rule, will

18   probably be out in a year to 18 months or

19   something like that. And so right now the

20   reason I had to step out is we were on a call

21   with the Quality Measures Workgroup. And

22   they're busy framing up what their initial

 1   thoughts will be for how meaningful use 3

 2   looks for doing it over the next couple of

 3   months.

 4   And then that comes out as sort of

 5   a series of questions to the country as a

 6   whole, "Hey, what do you think about this?

 7   What do you think about that? Please send us

 8   comments." This is a very, very public

 9   process. And we are really open. We really

10   welcome and open everybody's opinion.

11   But this fall we're starting to

12   try to frame what will be the major themes for

13   meaningful use 3. And then over the course of

14   the winter and next spring and summer, we'll

15   be refining those, sometimes directing them to

16   specific committees or task groups or other

17   places to say, "Hey, give us some really

18   specific thing that we can go on with this."

19   And the last to this start-now

20   question, interestingly, I was at a meeting

21   the American College of Surgeons put together.

22   And it was a fantastic meeting with surgery

1 representatives from a lot of the major

2 surgical societies. They were all on board

3 about this. This was not someone from outside

4 driving this. This was the surgeons saying,

5 "We want this. We think that the outcomes of

6 our patients are what is really important to

7 care."

8   And they wanted to measure safety.

9 They thought that safety was really important.

10 Surgical outcomes as measured by patients were

11 really important. I can't necessarily speak

12 to all of the other places being on board.

13   I know that there is a lot of

14 culture change that we will likely need to

15 have health care undergo to really move this,

16 but from the leadership standpoint, I can see

17 it happening.

18   DR. KOTAGAL: I can speak to some

19 of the other societies. I think all of the

20 boards are certainly working together around

21 this question of quality outcomes. The

22 American Board of Internal Medicine, the

1   American Board of Pediatrics are all doing

2   that.

3   And it's all linked now to

4   recertification. So that if you want to be

5   recertified, you have to sort of show data and

6   show evidence around improvement in the

7   process and in the outcomes. And there are

8   some standards for that that have to be met.

9   So that's happened.

10   CO-CHAIR BRENNAN: Are there other

11   questions? Yes?

12   MEMBER TORDA: Phyllis Torda from

13   NCQA again. We're working with Kevin and our

14   colleagues from Dartmouth -- and we're almost

15   all here as well -- on three measures that use

16   patient-reported outcomes with some portion of

17   those measures designated for meaningful use

18   stage 2 and were included in the draft reg and

19   then some for stage 3. So I thought it might

20   be helpful to just share what we have been

21   able to accomplish and what we haven't.

22   So the three measures are

1 measurement of functional status before and

2 after hip replacement, before and after knee

3 replacement, and for patients with CHF.

4   In each of those cases, the goal

5 for meaningful use stage 2 was what we called

6 a building block measure. And that was to get

7 some agreement on a defined set of tools, not

8 one tool but a discrete set of tools, and to

9 begin to be able to document that those tools

10 are being used to measure in the case of hip

11 and knee replacement before and after and CHF

12 periodically.

13   So we have gotten that far. We

14 have applied for the codes, the LOINC and the

15 SNOMED codes, to be able to document that.

16 There are some barriers in terms of the sort

17 of current standardized structures for quality

18 measures and being able to accommodate all of

19 that data, but that is probably more important

20 for the future.

21   Our goal for meaningful use stage

22 3, which we're really hoping to start

 1   beginning virtually tomorrow, is to then be

 2   able to say what improvement would be.

 3   So the task that we have before

 4   us, which is a little bit scary in light of

 5   the paper and all of the discussion today, the

 6   task that we have before us, is we have three

 7   measures. We're hoping to sort of be able to

 8   do hip and knee replacement at the same time,

 9   multiple tools.

10   And for each of those tools, we

11   need to be able to define in a standardized

12   way what would clinically meaningful

13   improvement be so that we can then come up

14   with the algorithms and test them to measure

15   it.

16   So that's where we are and where

17   we are not.

18   DR. LARSEN: I will make just a

19   quick comment that I look to the NPRM2. We've

20   got about five other measures that, in some

21   way or another, you could talk about or think

22   about their patient-reported outcomes, so

1   things like the PHQ-9 for depression, asthma

2   control test scores, fall risk assessment,

3   suicide risk assessment. Depending on how you

4   phrase something like a suicide risk

5   assessment and you think is at a

6   patient-reported outcome or is that just an

7   assessment, it kind of depends on your

8   perspective.

9   The systems think of those as,

10   hospital systems think of those

11   patient-reported outcomes because they have to

12   administer a survey, which feels to them like

13   something else that other people would call a

14   patient-reported outcome. I think that from

15   the measurement community, they think of those

16   as an assessment, not as an outcome.

17   But, anyway, there are a number of

18   proposed measures that take in account this

19   standardized collection of patient data into

20   the EHR.

21   MEMBER BASCH: A quick comment

22   again. Sorry, folks. Focusing a little bit

 1   on Kevin's comments, the first is I believe in

 2   meaningful use, I think in phase 1, there was

 3   engage patients and their families --

 4   DR. LARSEN: Right.

 5   MEMBER BASCH: -- in health care,

 6   which I think was more focused around

 7   providing a copy of the record to the patient,

 8   but the spirit is sort of there. I mean, the

 9   functionality wasn't. It probably was

10   developed early on.

11   I remember a conversation with

12   David Blumenthal way at the beginning. I

13   said, "Well, what about patient-reported

14   outcomes?"

15   He says, "Well, you know, we're

16   really far from that." But, you know, we've

17   got to focus on the nuts and bolts first.

18   But, you know, it seems that the spirit was

19   there.

20   One area where this is perhaps

21   immediately applicable is in the review of

22   systems. So if you think about it, you know,

1   physicians do review of systems all the time.

2   That's a part of the EHR. But they are

3   symptoms, right?

4   So the way that we think about

5   these things now, 2012, is those things that

6   the patient is in the best position to report,

7   right, should be reported by the patient. A

8   review of systems is nausea, vomiting,

9   fatigue, shortness of breath, chest pain, leg

10   swelling, skin rash, all these experiences

11   that the patients have, but we as clinicians

12   report that.

13   And we know from abundant research

14   that we as clinicians systematically

15   underreport both the incidence and the

16   severity of those phenomena.

17   And one could argue that there

18   should be the immediate capacity for an her to

19   collect PRO data for the review of systems as

20   a part of functionality of EHR, some

21   interesting thoughts.

22   DR. LARSEN: I think it is a great

1 idea. I think the kinds of things that we are

2 trying to get to apply to lots of patients and

3 lots of providers. And we can actually

4 certify them that the system can do this.

5   And so those are exactly the kinds

6 of ideas we are looking at because we could

7 apply that to lots of patients. We could

8 apply that to lots of doctors. And we could

9 certify that an electronic health record could

10 do that.

11   Then it's up to people like the

12 people in this room to figure out what to do

13 with that information once it's entered in.

14   As far as I know, there's not a

15 particular national standard review of systems

16 other than what CMS requires for E&M billing.

17 And CMS is pretty prescriptive about what they

18 want for evaluation/management billing. So

19 that could become the standard by which we

20 capture these symptoms, but you might imagine

21 a different standard that had more meaning to

22 patients.

 1   CO-CHAIR BRENNAN: Ted has a

 2   comment.

 3   MR. ROONEY: As far as meaningful

 4   use, two examples that just make you want to

 5   cry. You know, I mentioned before what we're

 6   doing, NCQA and Bridges to Excellence, which

 7   are really the only real outcome measures out

 8   there for primary care.

 9   And the story I told about Frank

10   Bragg with Centricity being able to report

11   through Bridges to Excellence, we have been

12   working to Bridges to Excellence and all the

13   major EMR vendors for a year now. We can't

14   get any other EMR vendor to do it because it's

15   not a meaningful use.

16   The second story, we're working

17   with Gene Nelson at Dartmouth. He's helping

18   us with some ACO measures. And we have this

19   wonderful practice right in my hometown called

20   Emerges of Family Doc. And he's totally

21   bought into this stuff. He wants to take

22   PROMIS and integrate it into his practice,

1   among other things.

2   And all he wanted to do was get it

3   in a way that makes the work flow. He's got

4   Centricity. He's got a hospital that supports

5   him. And for four months, he's been trying to

6   get his IT folks to get some help to go ahead

7   and implement the PROMIS into the work flow.

8   And he hasn't been able to do it.

9   I was just talking to Melanie

10   about, you know, being able to do that. And

11   why hadn't he been able to do it? Well, the

12   hospitals are so focused on meaningful use

13   that they are not doing this thing.

14   And so here you have this really

15   dedicated clinician and his team who wants to

16   do the right thing who can't. So I'm going to

17   talk with Kevin about what I can do to get

18   this stuff into meaningful use. But if we

19   don't get it in now, more and more I think --

20   there are clinicians out there in the field,

21   maybe not in the Beltway, in the field, who

22   want to do this. This is the right thing to

1   do. And we've got to help them.

2   CO-CHAIR BRENNAN: Mary had a

3   comment first and then Rita.

4   MEMBER TINETTI: I just wanted to

5   begin by addressing Kathryn's questions about

6   medical schools. I am hitting our patient

7   care curriculum for Yale University, which is

8   certainly not known as a forward-thinking

9   medical school. Nobody is here listening.

10   (Laughter.)

11   MEMBER TINETTI: But everybody is

12   on board. And I'm hitting it. We have ED,

13   surgery, et cetera. And what we're trying to

14   do is decide, throw out the curriculum that

15   was great to training doctors for the

16   Nineteenth Century and make them for the

17   Twenty-First Century.

18   And we're all about this stuff.

19   And, in fact, it's kind of the chicken and the

20   egg. We're waiting to see what are the

21   measures we should be training our docs in.

22   So I think this is all informing

 1   everything. And we're finding a lot of other

 2   medical schools are doing it as well. The

 3   problem is the faculty are so far behind where

 4   their students are. But I think it is going

 5   to happen.

 6   I want to sort of address Ted's

 7   point. I think, like everything, this seems

 8   to be sort of a top-down approach. We're

 9   going to be telling docs what to do and

10   patients what to do, but I think your point is

11   well-taken. I've spun that over and over

12   again.

13   There are docs that are just doing

14   it. You know, we machinate about it. We have

15   meetings. And there are people that are just

16   doing it. They don't report it. They don't

17   publish it. And I know it sort of challenges

18   the entire group to find those people.

19   And we can talk about the

20   barriers, why we can't do it. Let's talk to

21   the people that are doing it. And I think

22   this would be sort of a great form to sort of

 1 begin to get that to happen.

 2   What is useable? What is really

 3 happening out there that's really informing

 4 clinical practice as well as policy. And I

 5 think that is something I hope this group

 6 won't forget about.

 7   CO-CHAIR BRENNAN: Thank you.

 8   Rita and then Lori. Yes? Am I

 9 calling you the wrong name? I'm sorry.

10   MEMBER GAGE: It's all right.

11   CO-CHAIR BRENNAN: Thank you.

12   MEMBER GAGE: There is a lot going

13 on, actually, even within the Medicare

14 program, not so much -- well, I can't speak to

15 the physician. And the hospital end is kind

16 of coming along. But when it comes to the

17 area of post-acute care, the rest of the

18 delivery system, the skilled nursing

19 facilities, the rehab hospitals, the specialty

20 long-term care hospitals, the home health

21 agencies, CMS has been pretty busy the last

22 five or ten years in running a consensus-based

1   approach to identify what types of assessment

2   items or clinical items ought to be measured

3   on the different populations so that they can

4   monitor quality in the Medicare program, set

5   payment rates, all of that.

6   And, in complement to that, they

7   have been working on a lot of these

8   interoperability issues to develop the

9   HL7-associated terminology to be able to

10   transfer data across the different settings.

11   So, as this change is going on in

12   all of the ACOs and the A4FQs and the CVEs,

13   out here on the other part of the system, they

14   are kind of moving ahead. And, you know, they

15   have the LOINC codes, and they have the

16   interoperability. And they are working with

17   the standard committees to move it forward.

18   So, going back to Mary's point

19   about building on what is going on, there's

20   quite a bit going on outside of the physician

21   community and perhaps even within -- I just

22   don't know the physician community.

 1   CO-CHAIR BRENNAN: Thank you.

 2   Comment here? Okay. Lori? Wait

 3   a second. Kevin has a comment.

 4   DR. LARSEN: The only thing I will

 5   say is that the national surveys show that the

 6   penetration for electronic health records is

 7   much higher in the acute care and ambulatory

 8   care and that the long-term care penetration

 9   and home care penetration of electronic health

10   records is actually much, much lower. The

11   adoption is quite low depending on how you

12   define the electronic health record.

13   MEMBER GAGE: Thank you. Very

14   important point about language. And what we

15   found in traveling across the country and

16   speaking to all of the different communities

17   is that language differs.

18   So the electronic health record,

19   the electronic medical record, you have the

20   little slice over here with the personal

21   health record, not completely duplicative.

22   And you have the existing system, which the

1   provider is using to manage their patient

2   care, manage their billing, submit the bills

3   to the payers.

4   So yes, I think we are just at the

5   start of it, but there's a lot in place on

6   which you can build.

7   MEMBER FRANK: Hi. Lori Frank,

8   PCORI. I was quite taken with this notion of

9   goal attainment scaling. When you put into

10   Pub. Med. "goal attaintment scaling" and

11   "performance measurement," three articles pop

12   up, one of them from 1984.

13   I mean, that's not necessarily an

14   index of how widely this is used, but I am

15   interested in your opinion and others'

16   opinions about the advisability of GIS for

17   performance measurement.

18   And then perhaps David could

19   comment on whether there's an opening here for

20   some form of adaptive testing that could be

21   used for the goals.

22   DR. KOTAGAL: I can't speak to the

1 her pursuit, but I think goal attainment is

2 very much a part of the self-management work.

3 And, as providers are trained in really

4 working with patients on self-management,

5 posing the question really starts with asking

6 what your goal is. As part of our registries,

7 we are incorporating those into our models for

8 measurement and reporting.

9   There is a two-part process to it,

10 as we talked about. And the very important

11 part of it, as I said earlier, is flattening

12 the gradients between the provider and the

13 patient so that the conversation about

14 meaningful goals is real and not just simply

15 something that we pass on into the electronic

16 record. But if we are able to do that, I

17 think we will see much bigger shifts in

18 outcomes than we have to date.

19   DR. LARSEN: And I can speak to

20 the Minnesota perspective that I lived

21 through. So our patients in the medical home

22 program -- in Minnesota, it's actually called

1   the health home program. And it's not NCQA.

2   It's actually an 85-item Joint Commission-like

3   certification process, where they do site

4   visits and require a whole number of system

5   organizational culture and processes be in

6   place.

7   It's a fairly new program in

8   Minnesota. And I led the implementation at

9   our site. And it was really through that

10   process that they would come and assess, "Were

11   you living out the spirit of what we had in

12   our program, rather than looking for just

13   numbers?"

14   So it was a sort of accountability

15   program, but accountability, much more like a

16   Joint Commission certification accountability,

17   rather than a 60 percent of your patients

18   reached 5 or more.

19   They didn't really care about

20   that. They cared that when they watched our

21   clinicians talking to patients, our clinicians

22   really asked about the patients' goals. And

 1   we really had a system to track the patients'

 2   goals.

 3   That's a fundamentally different

 4   sort of qualitative approach to measurement

 5   that there is some experience, especially

 6   through the Joint Commission, in doing, but

 7   it's really the approach that Minnesota took

 8   in certifying its health homes.

 9   CO-CHAIR BRENNAN: What you are

10   hearing is that the electronic health record

11   doesn't exist in a vacuum. It exists in a

12   context, in a system.

13   I see David. And did you also

14   want to speak? Yes? So David and then you.

15   MEMBER CELLA: Lori actually asked

16   about whether there would be an opportunity

17   for measurement or use of item response 3 with

18   goal attainment scaling or goal setting.

19   Actually, I used to work with Amy

20   Peterman, who is now at University of North

21   Carolina, Charlotte, developed one of these

22   goal attainment measures. They're very tricky

 1   to score because you have to make an

 2   assumption that, despite the variety of goals,

 3   that the underlying thing that you're

 4   measuring is attainment of that goal. And

 5   it's difficult to pull that off.

 6   However, I do think there is

 7   potential here when I think about a goal of

 8   being able to dance. You know, where I would

 9   go with that is so -- so if I'm this patient's

10   doctor and this patient says that she wants to

11   be able to dance more, well, why can't she

12   dance as much as she wants? Is it fatigue?

13   Is it pain? Is it limited range of motion?

14   Now, we measure fatigue, pain, and

15   range of motion. We don't measure dancing.

16   But we measure the things that are interfering

17   with that person's ability to dance.

18   So I guess I would go down that

19   direction and say to the extent that the goals

20   can be broken down into clinically

21   intervenable elements that are PROs, then

22   you're back to the point where you're to help

 1   the patient dance.

 2   I assume that the doctor is not

 3   giving a dance lesson.

 4   (Laughter.)

 5   MEMBER CELLA: You know, they're

 6   treating the problem that the patient -- you

 7   know, it could be depression. It may not be

 8   something physical.

 9   So that's a great idea. It's very

10   personalized. Of course, that's what means

11   something to patients. I guess I would work

12   toward breaking that down to the components

13   that are the clinical intervention points.

14   CO-CHAIR BRENNAN: Up here in the

15   front. And then we'll also check on the phone

16   line in just a minute to see if there's anyone

17   waiting to ask a question.

18   MEMBER WASSON: Just to carry

19   David's point further, frankly, very few

20   people have dance as a goal. And I think that

21   is an important point that when you look at

22   tens of thousands of people who do

 1   problem-solving online -- and we have done

 2   that -- they have pretty much come into

 3   patterns, four or five patterns, for which

 4   then you can ask the secondary question of,

 5   how confident are you that you can reach this?

 6   And you can norm across all the sites

 7   immediately. So it's really not a difficult

 8   issue technically.

 9   CO-CHAIR BRENNAN: So there are

10   multiple approaches to getting that level of

11   a targeted, patient-focused --

12   MEMBER WASSON: Yes. I mean, you

13   just picture, for example, adult population.

14   You already know that about 80 percent, it

15   turns out, right now of adult Americans,

16   either they are overweight, they are not

17   exercising, they are smoking, or maybe they

18   are having a few too many drinks. You're up

19   to that number already.

20   And that can be fed back online in

21   real time "Which one do you want to work on?"

22   Which is their goal? They'll pick one of them

 1   for starters. And then "How confident are you

 2   right now?"

 3   And they'll say, you know,

 4   whatever the number, however you rate it. And

 5   then they go into a registry, and you follow

 6   them up. And you can see change over time,

 7   however you decide to measure it. It's not

 8   technically difficult just because, again, you

 9   are going with the 80 percent rule. You're

10   not going with the dancing, which is probably

11   one of the one percent rules.

12   CO-CHAIR BRENNAN: I think what I

13   am also hearing is that there are emerging

14   information tools that might be external to

15   the clinical care facility that might be

16   useful in measuring, identifying achievement

17   of our accountability and quality improvement

18   and goals under NQF that may be useful to

19   examine.

20   MEMBER WASSON: Just to carry

21   Steve's point, Steve Fihn's point, further and

22   Kevin's point, as we move toward more and more

 1 patient control of their information, it then

 2 can be moved into the electronic health

 3 record, but it need not be strangled by the

 4 electronic health record, which is the problem

 5 we have when we have 200 electronic health

 6 records. And you just articulated an issue in

 7 Maine.

 8   CO-CHAIR BRENNAN: Let me check

 9 and see if there's anyone on the phone. And

10 then we can go with the gentleman from

11 Hopkins.

12   MR. CUNNINGHAM: Excuse me.

13 Operator, would you check to see if anyone is

14 in the queue for questions or concerns?

15   THE OPERATOR: If anyone would

16 like to ask a question, please press *1 on

17 your telephone keypad.

18   CO-CHAIR BRENNAN: And while we're

19 waiting, please --

20   MEMBER WU: I would like to ask a

21 question. I guess I didn't get the exit

22 right. So I agree that, John, if you ask

1 people sort of what they want to work on,

2 they'll think of sort of -- most of them will

3 think of four pretty medicalized things, which

4 have been repeated to them over and over and

5 which the media repeats them over and over.

6   But I think that in the spirit of

7 it getting late in the afternoon, I would say

8 that we're not being very imaginative about

9 goal attainments. And, in fact, most people

10 have other goals that they want to achieve

11 that don't have to do with any of those

12 things. And so I still think there is some

13 room to develop this.

14   There's one tool that you're aware

15 of I'm sure that's called the C-Qual. It was

16 developed by an Irish group. And it basically

17 asks people to identify activities that they

18 would like to -- that they find important.

19 And they might include dancing or might not.

20 They might include going to church or all

21 sorts of things. But, in any event, they then

22 rank them in importance and so forth.

1   I think that there is more room to

2   come up with goals that are really more like

3   people's actual goals.

4   MEMBER WASSON: Just one point.

5   The tens of thousands of things that I've

6   alluded to are all open-ended. So I wasn't

7   medicalizing it in that sense, but I was using

8   the medical example as one to relate.

9   CO-CHAIR BRENNAN: Thank you.

10   Is there a question in the back

11   and then one up here in the front? Yes, sir?

12   MR. YANG: All right. So I am

13   going to comment on this from a health IT

14   vendor perspective.

15   CO-CHAIR BRENNAN: Okay.

16   MR. YANG: I know there has been

17   some mention about data standards. Kevin, you

18   mentioned some of those. And there are

19   several levels of data standardization.

20   And one of the things, actually,

21   as a vendor that we try to implement to some

22   sort of types of systems is to code whether,

 1   for example, each questionnaire, you need to

 2   have a code for it, right? And then maybe

 3   down to the item level, you have to have a

 4   code.

 5   For that right now, LOINC and

 6   SNOMED are the two places that have been doing

 7   that. However, for LOINC, there is an issue

 8   with the copyright. So they couldn't code out

 9   of the questionnaires that are out there.

10   They can code only a few of them.

11   So I wonder if like an

12   organization like ONC is going to be able to

13   bring this issue up a level to see maybe what

14   LOINC -- because the way LOINC implements this

15   solution is assuming the instrument that they

16   are all treated as laboratory results. And

17   I'm not sure that's actually the right model

18   for it, but I just wonder if ONC is assisting

19   in that sort of a matter to maybe working with

20   LOINC or maybe HL7 to see how they can

21   incorporate that into the HL7 standards.

22   DR. LARSEN: Yes. Thank you. A

 1   lot of us have been involved in this, Phyllis

 2   from NCQA. We've talked to NQF about this.

 3   There is this fundamental question

 4   that if you're a researcher or a corporation

 5   that develops an instrument and you have

 6   invested a lot of R&D time and energy into

 7   that instrument, how is it that we keep a

 8   landscape of people willing to keep those up

 9   and to keep those coming?

10   So intellectual property has

11   really been part of the way that that works,

12   right? It's just like drugs. However, as we

13   try to put these into federal incentive

14   programs, it's a hidden cost for a federal

15   incentive program if now everyone that uses

16   this instrument has to pay a licensing fee to

17   whomever is the holder of that intellectual

18   property.

19   And so I won't necessarily speak

20   for CMS, but I think I speak for CMS in that

21   they are looking for things that don't have

22   hidden costs. And ideally CMS would like to

 1 pick public domain instruments, things that

 2 don't have a hidden cost.

 3   As we have been working through

 4 some of the building out functional status

 5 measures for the HR, we run into these

 6 questions that if an organization or a

 7 university or an individual holds intellectual

 8 property and now we try to put it into the

 9 measure for a federal incentive program and we

10 can't really resolve the intellectual property

11 questions, do we just eliminate that

12 instrument from an intellectual property and

13 hidden cost point of view and just go with

14 others instead?

15   If we do that, then we don't

16 necessarily have a landscape where people

17 develop those things because now they don't

18 have an incentive to develop those things

19 anymore.

20   So I don't know that I have an

21 answer to that question, but I think it's a

22 great thing for a group like this to think

1   through. I think it's especially good for NQF

2   as a measure endorser to think through.

3   We are taking tactical approaches

4   to figuring out how to build data standards

5   around those. And so far it has been pretty

6   easy except if the IP owner is in Europe

7   because they have no sort of reason to move at

8   our timelines here in the U.S. And although

9   they're nice enough, they don't feel the same

10   kind of pressure to get into a U.S. program

11   that a U.S. IP owner might.

12   CO-CHAIR BRENNAN: Thank you,

13   Kevin.

14   We are going to have to have the

15   last question now or comment here from the

16   table. And then I'll let the panelists have

17   the final remarks. You are all right. Okay.

18   Let me ask the panelists if you

19   have a closing remark. And if you don't, if

20   you could address one of the questions we've

21   left unaddressed, which is, what needs to

22   happen to get patient-reported outcomes into

 1 an electronic health record? What would be

 2 the first thing you would do?

 3   And while you're thinking, I'll

 4 start and say mine is I would resolve the

 5 issue of at what point is it appropriate and

 6 at what point is it risky for patient-reported

 7 outcome to be released into a clinical record

 8 system, where it enters back into the care

 9 process in ways they may not understand, the

10 patient may not understand?

11   For example, experience data put

12 into the clinical record seems to me to be

13 inappropriate. But other patient-reported

14 outcomes might be actually quite useful.

15 However, there may be things patients will

16 refer to control.

17   MEMBER WILKINSON: I would be very

18 curious eventually how one would determine

19 what was important for the patient to know and

20 what the patient would actually understand.

21   The reason for my question is

22 probably obvious. It is that so many times

1   experience shows that, just as clinicians can

2   underreport something that the patient views

3   quite differently, as was shown on one of the

4   slides, I think that principle could be

5   extended to a lot of other settings in which

6   measures and others presume they know what is

7   understandable or important and they leave out

8   of the equation communication.

9   CO-CHAIR BRENNAN: Yes.

10   MEMBER WILKINSON: I am

11   oversimplifying for the purposes of time.

12   CO-CHAIR BRENNAN: No. We will

13   have a whole day for more conversation

14   tomorrow. So let me go down the road and let

15   Ted start and then Uma and then Kevin.

16   MR. ROONEY: I don't know the

17   right lever, but getting PROMIS and a general

18   health risk appraisal into every EMR so a

19   clinician could use it would be huge.

20   CO-CHAIR BRENNAN: Thank you.

21   DR. KOTAGAL: I think engaging the

22   clinicians through incentives in a way that's

 1 meaningful to shift from clinical outcomes to

 2 patient-reported outcomes.

 3   CO-CHAIR BRENNAN: Excellent.

 4 Kevin?

 5   DR. LARSEN: So I am with Ted. I

 6 have a little bit of mantra of just start.

 7 Don't get worried that you don't exactly know

 8 the whole ending goal. You've got to start

 9 someplace.

10   And so then I am working very

11 tactically. What can I start with with

12 meaningful use 3? What is the right thing

13 that we can use that lever to build

14 infrastructure that gets us the furthest the

15 fastest in the best way?

16   And so I am open to your input.

17 Please help me and help our FACAs figure that

18 question out.

19   CO-CHAIR BRENNAN: And, David, you

20 have been so good to us all day I'm going to

21 let you have the very last word of the panel.

22 Thank you.

1   MEMBER CELLA: I like the idea of

2   just starting. You know, the kind of work

3   that we do and others of us, others of you who

4   do similar work, we can get very bogged down

5   in the detail and worry a lot.

6   And there is a lot of good

7   information that we can already capture. And

8   we are ready to go. And we'll get better

9   along the way.

10   CO-CHAIR BRENNAN: Thank you very

11   much. It's been a really excellent day. And

12   I want to just remind you, first of all, that

13   the panel would be here mostly for tomorrow.

14   Speak up more. All right. The panel will be

15   here mostly for tomorrow.

16   We're going to have a couple of

17   closing comments before the day is over. I

18   will be at -- I want you to just reflect for

19   a few minutes about the key points that you

20   heard through the day since tomorrow's work,

21   we'll be moving into small workgroups.

22   Now, several of you have noticed

1   that there is a small dot on the back of your

2   name tag. That identifies which workgroup

3   you're going to be in. And for those of you

4   who need a reminder, there is a paper on your

5   table that summarizes that. And there is also

6   a screen up here.

7   It is color-coded. If you don't

8   have a dot on your name tag, please see one of

9   our staff. The NQF staff will make sure you

10 are in a workgroup tomorrow.

11   The workgroups will be focused

12 tomorrow throughout the morning on, first of

13 all, breakout session for selecting

14 individual-level PROs for performance

15 measurement. And then there will be a

16 discussion on the next steps for what

17 characteristics should be used for selecting

18 PROs.

19   I am going to now turn to Karen or

20 Karen Adams or Helen to see if you have

21 closing remarks that you would like to make

22 for the day.

1   MS. PACE: I will just make a

2   quick note. As Patty said, if you don't have

3   a colored dot on your name tag, see Gene

4   Cunningham. And if we didn't receive your

5   request, we tried to honor first and second

6   requests. There is a limited availability to

7   switch, but one of the groups is totally full.

8   So, again, you would need to see Gene

9   Cunningham about that.

10   We really appreciate all of your

11   engagement. It's been very nice to see

12   everyone involved, including our audience.

13   And I'll just give it back to

14   Patty. And also, Joyce, do you want to make

15   any comments?

16   CO-CHAIR BRENNAN: So on behalf of

17   Joyce and myself, we want to thank you for

18   taking the time to be here. We want to thank

19   you to all the speakers today and particularly

20   to David for a great deal of work and

21   provocative thinking.

22   We want to thank all the

1   curmudgeons and the provocateurs in the room.

2   Please come back tomorrow and be provocateurs.

3   Thank you very much.

4   (Whereupon, the above-entitled

5   matter went off the record at 4:45 p.m.)

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In the matter of: Patient Reported Outcomes

Before: NQF

Date: 07-30-12

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

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      neal R Gross
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    Court Reporter
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