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NATIONAL QUALITY FORUM + + + + + PATIENT REPORTED OUTCOMES WORKSHOP #2 + + + + + + TUESDAY SEPTEMBER 11, 2012 The Workshop met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, NW., Washington, D.C., at 9:00 a.m., Patricia Brennan and Joyce Dubow, Co-Chairs,

presiding. PRESENT:

PATRICIA BRENNAN, PhD, University of Wisconsin-Madison, Co-Chair JOYCE DUBOW, AARP, MUP, Co-Chair RICHARD BANKOWITZ, M.D., MBA, FACP, Premier Healthcare Alliance ETHAN BASCH, M.D., MSc, Memorial Sloan-Kettering Cancer Center

JIM BELLOWS, Ph.D., Kaiser Permanente DAVID CELLA, Ph.D., Northwestern University Feinberg School of Medicine ANNE DEUTSCH, Ph.D., RN, CRRN, Brookings Institution STEPHAN FIHN, M.D., MPH, Veterans Health

Administration

JACK FOWLER, Ph.D., Informed Medical Decisions Foundation LORI FRANK, Ph.D., Patient-Centered Outcomes Research Institute BARBARA GAGE, Ph.D., MPA, Brookings Institution TED GANIATS, M.D., University of San Diego

Health System KATE GOODRICH, M.D., MHS, Centers for Medicare & Medicaid Services

Page 2 JUDITH HIBBARD, DrPH, University of Oregon DENNIS KALDENBERG, Ph.D., Press Ganey Associates IRENE KATZAN, M.D., MS, Cleveland Clinic LEWIS KAZIS, ScD, Boston University School of Health UMA KOTAGAL, M.D., Cincinnati Children's Hospital Medical Center KEVIN LARSEN, M.D., Office of the National Coordinator for HIT KATHY LOHR, Ph.D., RTI ELIZABETH MORT, M.D., 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, Ph.D., OTR, The University of Texas Medical Branch at Galveston GREG PAWLSON, M.D., MPH, FACP, BlueCross BlueShield Association ELEANOR PERFETTO, Ph.D., Pfizer COLLETTE PITZEN, RN, BSN, Minnesota Community Measurement CHERYL POWELL, Centers for Medicare & Medicaid Services (via telephone) DAVID RADLEY, Ph.D., MPH, Institute for Healthcare Improvement TED ROONEY, RN, MPH, Maine Quality Counts DEBRA SALIBA, M.D., MPH, UCLA Borun Center/VA/RAND MARCEL SALIVE, M.D., MPH, National Institutes of Health LAURA SMITH, Ph.D., Brookings Institution BARBARA SUMMERS, Ph.D., RN, University of Texas-MD Anderson Cancer Center (via telephone) KALAHN TAYLOR-CLARK, Ph.D., MPH, National Partnership for Women & Families MARY TINETTI, M.D., Yale New Haven Health System PHYLLIS TORDA, MA, National Committee for Quality Assurance

JOHN WASSON, M.D., Dartmouth Medical School ROB WEECH-MALDONADO, Ph.D., MBA, University of Alabama-Birmingham LINDA WILKINSON, MBA, Dartmouth Hitchcock Medical Center ALBERT WU, M.D., MPH, Johns Hopkins Health System NQF STAFF: KAREN ADAMS, Ph.D., MT HEIDI BOSSLEY, MSN, MBA HELEN BURSTIN, M.D., MPH SHEILA CRAWFORD EUGENE CUNNINGHAM, MS KAREN PACE, Ph.D. JESSICA WEBER EVAN WILLIAMSON

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1	P-R-O-C-E-E-D-I-N-G-S
2	9:00 a.m.
3	DR. BRENNAN: Good morning.
4	Welcome to the National Quality Forum's
5	Patient-Reported Outcomes. This is our second
6	workshop.
7	I'm Patti Brennan. I'm from the
8	University of Wisconsin-Madison. I'm very
9	happy to see familiar faces in the audience
10	today. Welcome back to those of you who were
11	at our first workshop in August. I also want
12	to extend a special welcome to the number of
13	people who are connected to us via the phone
14	and the internet. We'll be doing our best to
15	monitor to make sure you have the
16	participation in the meeting over the next 2
17	days that can help us grow and accomplish our
18	task.
19	However, before we get onto the
20	tasks today I want to take a moment to
21	remember that this is a very special day in
22	the history of our country and just pause for

	Page 7
1	a moment to those who might need to have us
2	remember with them what they lost and perhaps
3	learned on this day.
4	(Moment of silence)
5	DR. BRENNAN: Thank you. This
6	morning we have a lot to get going with on
7	understanding the difference between PROMs and
8	PROs and PRO-PMs. And we'll have an opening
9	session here that will take you through some
10	of the foundational concepts. We'll have
11	several different panels today on workshops on
12	working panels on validity and reliability.
13	And we have some tasks ahead of us
14	to come to some consensus about the process
15	that we'll be recommending to the National
16	Quality Forum of how to endorse the PRO-PM and
17	by the end of the day you will know what that
18	means.
19	I'm going to turn over to my co-
20	chair Joyce Dubow from the AARP who's going to
21	take us through our introductory remarks.
22	Thank you, Joyce.

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1	MS. DUBOW: Thanks, Patti. Good
2	morning, everybody. Yes, if we can all master
3	the vocabulary we'll be in great shape because
4	it's going to be quite challenging I think.
5	All right.
6	All right, well the first, can we
7	go back to the first slide, please? Starting
8	with the meeting objectives because here's
9	what we want to accomplish this morning
10	actually, during the entire meeting.
11	First, I hope you can't hear?
12	Okay. Okay, better? All right.
13	We're going to one meeting
14	objective is to discuss the methodological
15	issues related to reliability and validity.
16	The paper is very specific. This is not a
17	paper that's supposed to answer all the
18	questions about patient-reported outcomes. It
19	was specifically commissioned to identify and
20	to discuss these issues around reliability and
21	validity when aggregating PROM data into a
22	performance measure. We're going to come back

Page 9 1 and talk about those terms in a minute. 2 We also need to remember that 3 ultimately we're going to want measures that NOF can endorse. And so what we need to do is 4 5 to think about patient-reported outcome 6 measures in the context of the NQF criteria, 7 the evaluation criteria. 8 And what we need to think about is 9 whether these particular types of measures 10 present unique circumstances, are there specific or unique attributes about these 11 12 types of measures that need to be taken into account within the evaluation criteria? 13 So 14 we'll need to be thinking about that. 15 And finally we're going to want a 16 pathway, a critical pathway from the PROM to 17 the PRO-PM endorsed by NOF for use in 18 accountability and quality improvement. Okay, 19 next slide, please. 20 So, a word about terminology. And 21 I personally have a lot of trouble tripping on 22 these terms but we're going to be using the

	Page 10
1	terminology very, very specifically and I
2	think throughout the day we'll try to remind
3	you. But you may want to refer back to this
4	particular slide.
5	The patient-reported outcome or
6	the PRO is the concept of any report of the
7	status of a patient's health condition that
8	comes directly from the patient without
9	interpretation of the patient's response by a
10	clinician or anybody else. So this is what
11	the patient says.
12	The PRO measure or the PROM is the
13	scale or the instrument or a single item
14	measure I use that word softly to assess
15	the PRO concept as perceived by the patient.
16	So an example is the PHQ-9. So it's the tool,
17	it's the instrument. It's not that which we
18	will be endorsing. Next slide, please.
19	So just a reminder about what a
20	performance measure is. It's a numeric
21	quantification of healthcare quality for a
22	designated accountable healthcare entity like

	Page 11
1	a hospital, or a plan, a nursing home, et
2	cetera, physician.
3	The PRO-PM is the PRO-based
4	performance measure that is based on the PROM
5	data aggregated for an accountable entity. So
6	the illustration here is the percentage of
7	patients in an accountable care organization
8	whose depression score as measured by the PHQ-
9	9 improve. So it's the PRO-PM that we are
10	seeking to endorse, okay? All right.
11	Now, in addition to these terms
12	around PROs, PRO-PMs, we also have to remember
13	and had discussion at the last workshop you
14	may recall about the proper way to refer to a
15	person, an individual, a patient, a consumer.
16	And this is subject to very wide debate and
17	discussion a lot at NQF and elsewhere.
18	And I think we need to be very
19	clear up front in the report about what we
20	mean. These terms are circumstantial and they
21	really depend on the context of what we're
22	talking about.

	Page 12
1	Admittedly we all use shorthand so
2	sometimes people like to say "person,"
3	sometimes people will say "consumer." I think
4	there is broad recognition that these terms
5	while not interchangeable are sometimes used
6	that way because we are speaking shorthand.
7	The disability community in
8	particular is sensitive to the use of
9	terminology and we heard this last time from
10	Chas and from others about their perception of
11	the words. So I think we need to remember to
12	be very sensitive to the language. Vocabulary
13	matters.
14	We will understand if each of us
15	lapses into the vernacular that we're most
16	comfortable with but I think, at least I hope
17	we'll be understanding, but I think we have to
18	recognize that these terms do mean something
19	particular to different groups and different
20	people and different individuals, and we need
21	to be sensitive to that.
22	We discussed this, Patti and I

	Page 13
1	discussed this with Karen and Karen and what's
2	her name over there, Helen.
3	(Laughter)
4	MS. DUBOW: Our leader. Our
5	leader, Helen Burstin. And we hope that we
б	will be able to identify a way perhaps, a way
7	of being sure that we meet everybody's needs
8	and understanding without doing violation to
9	sensibilities and sensitivities. So, we are
10	aware of it and we will try to address it.
11	Okay, next slide, please.
12	So here we have our bubble diagram
13	that NQF has used for a long time that shows
14	basically an episode of care. And this tries
15	to illustrate the concept I'm not going to
16	go through this in detail how patient-
17	reported outcomes would be taken into account.
18	And if you look at the far right,
19	lifestyle and health behaviors, and look at
20	the illustrations on the right-hand side
21	you'll see the types of areas that we will be
22	discussing today that need to be taken into

	Page 14
1	account as we consider these episodes and how
2	a patient person experiences these episodes.
3	But we are interested in functional status,
4	health-related behaviors, symptoms, symptom
5	burden, et cetera. So if we could move to the
6	next slide, please.
7	Just a reminder about what NQF
8	does. It endorses performance measures, not
9	the tools. So it endorses PRO-PMs, not PROMs.
10	NQF endorses PRO-PMs for use in accountability
11	such as public reporting and quality
12	improvement. So remember, we have two
13	purposes. It's we need to be sure that these
14	measures that ultimately are endorsed are
15	suitable both for quality improvement and
16	accountability, not one or the other but both
17	of them.
18	NQF has criteria as we mentioned
19	earlier to evaluate measures that come through
20	the endorsement process. And these are NQF
21	board-approved. They have been widely vetted
22	and as I said earlier we're going to have to

	Page 15
1	think about whether these criteria need to be
2	tweaked in some way if at all for purposes of
3	considering the patient-reported outcome
4	measures.
5	So, just to remind you and I think
6	we'll go through these in a little bit more
7	detail later. Karen Pace will take us through
8	that. Importance to measure and report is one
9	criterion and it's a must-pass criterion. If
10	a measure doesn't is not cannot be
11	determined to be important it doesn't go
12	through the rest of the criteria.
13	In addition, the measures under
14	consideration by NQF committees are evaluated
15	for their scientific acceptability,
16	feasibility, usability and use. And this
17	slide simply gives you a little bit more
18	information about what the criteria look like.
19	I think we'll probably be paying a lot of
20	attention to the second criterion, scientific
21	acceptability of measure properties because
22	we're going to be talking about reliability

	Page 1
1	and validity. Okay, next slide, please.
2	So, finally I did this very
3	fast. We're going to have a conversation.
4	Finally, what we want out of the workshop.
5	And you see in your materials a straw man
6	pathway that is probably too big to show on
7	the screen. But you have it in your diagram,
8	at least it's too hard to read here. You have
9	it in your diagram. And this we will go
10	through this, you know, at another time.
11	Everybody says it will be excruciating detail.
12	But I mean, it's important to understand how
13	this stuff is all going to work and so we have
14	developed a pathway, a straw man pathway to
15	think about how this will happen.
16	But ultimately we would like to
17	reach consensus by the work group at this
18	workshop on what the pathway should look like.
19	So with that I think we're ready to have
20	questions and discussion and oh, did we
21	want to talk about the there's a time line.
22	Yes, okay.

6

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1	So, and we are you can see
2	where we are here. We're right in the middle
3	of the process. There's going to be a review
4	of the paper which I think you've all
5	received, public comment. The expert panel
6	will review those comments and ultimately this
7	report is going to the CSAC and the board for
8	their approval.
9	So, is there conversation,
10	questions, observations? How are you, Ethan.
11	Yes. Speak up. And oh, could you Ethan,
12	could you reintroduce yourself so the people
13	on the phone can hear you, please?
14	DR. BASCH: Oh, sure. Hi,
15	everybody. Good morning. Ethan Basch,
16	University of North Carolina.
17	A couple of quick comments. I'm
18	very glad to see these red boxes at the top
19	which I know wasn't we, I think our initial
20	conversation was starting with the measure and
21	now it looks like we're going back and
22	starting with the population of interest and

Page 18 1 finding outcomes that are meaningful and 2 important to the population. So I think that's a terrific addition and is consistent 3 with the thinking in other quarters about how 4 5 to develop tools that are meaningful to 6 patients. 7 One thing, one question or comment 8 I have is we spend a lot of time talking about 9 the methods for assuring the measurement 10 properties of the tool once we have figured out what we want to use, the validity, the 11 12 reliability, all this. But we don't really specify how to identify outcomes that are 13 14 important and meaningful to the target population, number one. 15 And I wonder the extent to which 16 17 we want to be a little bit prescriptive about 18 how somebody who's proposing a measure can 19 actually assure to us that the outcomes, 20 right, are actually meaningful in the 21 population for the context of interest. 22 We are going to have MS. DUBOW:

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1	more discussion about meaningfulness. And in
2	fact Patti just a little while ago volunteered
3	to fill in on a panel where she will be
4	specifically addressing that and we'll have a
5	chance to talk about that in greater detail.
6	I think it's a really important question.
7	Greg? Greg, you have to tell us
8	who you are, please.
9	DR. PACE: So let me just orient
10	us to these microphones just to remind because
11	it's a little bit different. The ones on the
12	table, the red light means that it's activated
13	and then you press the button till you get a
14	green light. That means the microphone is
15	actually on. Thanks.
16	DR. PAWLSON: Okay, and that was a
17	good instruction. We've got the green light.
18	I'm Greg Pawlson.
19	Sort of an observation. I think
20	that this is going to be, in the continued
21	sort of evolution of NQF endorsement this is
22	going to be a very interesting test case if we

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	Page 20
1	really are saying that you're going to endorse
2	PRO-PMs.
3	And why I say that is that if you
4	are really talking about accountability
5	measures for a specific population I think
б	you're going to be into what we're going to
7	actually talk about in the first panel is
8	measurement reliability and parameters in a
9	much perhaps deeper way than before.
10	What I'm talking about is measures
11	that will be endorsed for a specific purpose
12	for a specific population perhaps with
13	specifics around how big the sample size has
14	to be and that kind of stuff. Not necessarily
15	an endorsement of the measure for general use
16	if you will.
17	And I think this is going to be an
18	interesting dialogue that will have to be
19	played out in the review panels and so on.
20	How far down that road do you really need to
21	go to say that we are endorsing a pro-
22	performance measure, almost measurement

	Page 21
1	approach, rather than the PROMs. And I think
2	that that's going to be a very interesting
3	challenge.
4	DR. BURSTIN: For Joyce's sake I'm
5	Helen Burstin. I'm the senior vice president
6	of performance measures at NQF.
7	I just want to respond briefly to
8	Greg's point. I think it's a really
9	interesting one. I think the closest analogy
10	we have currently are the CAHPS surveys which
11	actually do have a very similar approach to
12	giving much more details on some of those key
13	nuances around measurement that we've had
14	before.
15	But you're absolutely right, this
16	is going to be more complex, and we've already
17	seen that for example with the few PRO-PMs we
18	have brought forward and endorsed, including
19	the one on improvement in visual function or
20	the one on depression where I think, you know,
21	all these issues come forward in a much more
22	significant way than I think some of our more

Page 22 1 classic process or outcome measures. 2 The issue about whether it needs to be assigned to a specific use I think is in 3 I think the goal would be that you 4 question. 5 would want to select performance measures 6 based on PROMs that in fact can drive 7 improvement as well as accountability. But I 8 think that's a good question for us to talk 9 about today. 10 MS. DUBOW: Other questions? Observations? Kathy? 11 12 DR. LOHR: One question about your 13 time line. 14 MS. DUBOW: -- who you are? 15 I'm Kathy DR. LOHR: Oh, sorry. Lohr from RTI in North Carolina. 16 17 And I know you're on a fast track 18 and you have to get moving and so forth and I 19 know that the panel is supposed to be giving 20 you some feedback in October, November, 21 whenever it is, but after we kind of see a 22 second round of the second paper and so forth.

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1	But I was wondering whether you've
2	given any thought to sort of in some sense
3	reconvening 6 months or 9 months or somewhere
4	down the road not only to see whether we've
5	done a good job with sort of giving you all
6	some advice and guidance and our best thinking
7	on all this which is I think a point that Ted
8	might make as well.
9	But then also to see whether
10	you're making the progress you want, whether
11	we can give you any feedback on mid-course
12	corrections and that sort of thing. So it was
13	really a question of is that the end of the
14	time line kind of thing or can we be of help
15	down the road.
16	MS. DUBOW: That's a question for
17	staff.
18	DR. LOHR: I don't necessarily
19	need an answer. You all may need to sleep on
20	it but I wanted to put it forward.
21	DR. BURSTIN: I think it's a great
22	suggestion, Kathy, and I think the question

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1	for us as well is if we move forward in fact
2	and do a consensus development project on PRO-
3	PMs.
4	But I think one question might be
5	we'd love to sort of pepper that committee
б	with some of you. But I think it might be
7	nice to have a couple of test cases to bring
8	back for reaction to say did we get it right
9	as part of that process. That's a great
10	suggestion.
11	MS. DUBOW: It does speak to the
12	broader question that NQF faces with other
13	measures and that's to get feedback. I mean,
14	feedback is really very important for all
15	measures, not just these. I mean these are
16	obviously of interest at the moment but NQF
17	needs to get feedback to understand how these
18	measures are working, whether they are
19	accomplishing what we seek through the
20	endorsement process. So it's a really good,
21	good marker for doing it. I think it's a good
22	idea.

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1	Other observations or comments
2	that somebody wants to make? Is there anybody
3	on the phone who would like to weigh in? Do
4	we have to ask the operator to do that?
5	OPERATOR: At this time in order
6	to ask a question press * then the number 1 on
7	your telephone keypad. At this time there are
8	no questions.
9	MS. DUBOW: Okay, thank you. Is
10	there somebody in the audience who wants to
11	make an observation or a comment? No? Okay.
12	Karen?
13	DR. PACE: We have a few minutes
14	before we can begin the next panel so if
15	anyone wants to make any other observations
16	about the pathway. As we said we're going to
17	come back to that in great detail tomorrow.
18	But you know, if you want to make any comments
19	now we can address that or if you have any
20	questions that we can address we can take
21	those now. Otherwise we'll check in with our
22	other speakers and see if they're ready yet.

	Page 2
1	Kathy?
2	DR. LOHR: This is Kathy Lohr
3	again and I did have one question. I would
4	second what Greg said about the, you know, red
5	boxes across the top. But I will confess,
6	maybe it's just where I grew up, that I wasn't
7	certain about the process performance measure
8	versus outcomes.
9	And so in the green boxes like
10	with six and all, is that supposed to be an
11	example of what you would do now with what
12	classically we would think of as process of
13	care measures rather than outcome measures or
14	is it something else?
15	But I also wasn't certain why
16	you'd have PROM in there, you know, for a
17	patient-reported outcome measure attached to
18	process performance measurement. And it may
19	just be me and age and you know, cohort or
20	something, but the distinction between process
21	and outcome has been around a long time and I
22	wasn't certain why I was seeing outcomes

Page 27 mushed up there with processes. 1 2 DR. PACE: Right, good question. And this comes from our discussion last week 3 and I'll just give you a real clear, hopefully 4 5 clear distinction of a process measure would be just the process of using a PROM in your 6 7 clinical practice. So the process measure 8 might be percentage of your patients or 9 percentage of your depressed patients that 10 were administered a PHQ-9 versus using that actual PROM data value on the PHO-9 to say the 11 12 percentage of your patients who were depressed who are now in remission. 13 14 So it's a distinction but it's 15 very important for us to keep in mind. And one of the discussions that we had last week, 16 and that's why it'll be definitely open for 17 discussion, is that the pathway we should 18 19 I mean, ultimately we're interested in take. 20 And so there's some thinking that, outcomes. 21 well, the first step is to get people using 22 these PROMs before we can get to the step of

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1	having an actual outcome measure.
2	Maybe there's some concepts that
3	we need to do process measures first. Maybe
4	there's some that we can go directly to
5	outcome measures. And so the pathway kind of
6	shows two ways to get there and that's
7	something that we'll definitely want to have
8	some discussions about.
9	MS. PITZEN: Hi, this is Collette
10	from Minnesota Community Measurement. I just
11	wanted to make a couple of observations.
12	One in terms of identifying a
13	population or having something where you have
14	a gap in care that you want to start with I
15	think is really important. And then if a
16	functional status or a healthcare quality of
17	life is key in improving that quality of care
18	then one goes and selects the appropriate
19	instrument to collect that information.
20	The second point I wanted to make
21	is we've found that in implementing some of
22	these measures in our state we really do need

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1	to do process and outcome measures together
2	because as you're putting this in place in
3	clinical practice you want to make sure that
4	you're capturing enough of your patient
5	population and how successful are you at
б	measuring these patients.
7	For example, we have some
8	orthopedic measures that we're collecting at
9	1 year post-op. So at the same time we are
10	giving groups that feedback of what percentage
11	of your patients are you actually capturing at
12	1 year before we can determine if we have a
13	valuable measure that we can use for public
14	reporting. Thanks.
15	MS. TORDA: Hi, I'm Phyllis Torda
16	from NCQA. I think a number of us, I'm going
17	to add myself, are making the same point and
18	that is that the context in which the PROMs
19	are used is very, very important for a number
20	of reasons.
21	The point that Collette just made
22	is it's important because it's going to give

Page 30 1 you the sufficient sample size to actually 2 measure outcomes but it's also important because these processes are much less immature 3 4 than many other processes that we measure 5 through clinical quality measures. And we 6 need to really recognize that, use measurement 7 to promote adoption of the processes before 8 you can get to outcomes. 9 MS. DUBOW: I'd just make an 10 observation before I call on you. You know, think that in the endorsement process this is 11 12 going to be a challenging idea because of where NQF, where the CSAC has been going, and 13 14 that is really to emphasize outcomes. 15 And the notion that these 16 processes are immature and that we might need 17 to think about processes on the way to having 18 the outcomes I think needs to be well 19 understood. At least, that's one former CSAC 20 member's opinion. 21 Would you like to make a comment? Yes I would, thanks. 22 DR. FIHN:

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1	And I was just going to say exactly what you
2	said, Joyce.
3	So, we discussed this in the
4	taxicab on the way over here. I work in a
5	system where we have mandates for lots of
б	these to measure with process measures.
7	And just as a cautionary note we
8	just finished a large survey of all our
9	primary care providers throughout our system.
10	Morale is actually quite low and the greatest
11	barrier to care that they identified was
12	clinical alerts and reminders which include,
13	you know, the mandated screening for
14	depression and so on and so on.
15	So, you know, I think the problem
16	is they, unless these are really linked to
17	systems and to identifiable mechanisms for
18	care improvement then that could actually be
19	a self-defeating process to put in place
20	mandates for data collection prior to
21	understanding, a good understanding and
22	implementation of the systems to which they

	Page 32
1	need to be connected. So, and I think so
2	I would really argue more for Joyce.
3	I think part of that is part of
4	the validation process. And on one hand I
5	know you're under pressure to get things out
6	and time lines, et cetera. But you know,
7	we're reminded again and again what happens
8	when measures get hurried to market. And we
9	just we're also discussing this morning one
10	in which CMS probably hurried to market in
11	terms of the catheter-associated UTIs. And we
12	now learned this week that it's probably a
13	seriously flawed measure despite the fact now
14	it's tied to the payment system.
15	So you know, I just, I'm not
16	arguing against doing that but I think we
17	ought to be cautious. All too often I've
18	heard people defend this as the not letting
19	good be the enemy of perfect being the
20	enemy of good here and you know, sometimes we
21	want, you know, we won't get perfect but we
22	may want better than good.

	Page 33
1	MS. DUBOW: That was Steve Fihn.
2	John's going to be the last question.
3	I just want to be very clear. I
4	think this is a necessary step in the pathway
5	but ultimately we know where we want to go.
6	And as a consumer representative you can be
7	sure that there is going to be a sense of
8	urgency to get where we want to go. But
9	recognizing that this is very hard, this is
10	very challenging, just to be clear.
11	John, you get the last word before
12	we adjourn this session.
13	DR. WASSON: I hope it's not the
14	last word. But in any case the other point on
15	the diagram and also amplifying what Steve
16	said is when we start talking about outcome
17	measures we are talking about re-contacting
18	patients which really does require consent.
19	And that's a killer in the real world in terms
20	of people even willing to measure before if
21	they know they're going to be contacted later
22	as an after. A lot of people will stop right

	Page 34
1	there. So that's not in your diagram and
2	you're going to have to put consent in there
3	somewhere, and that is a very important
4	practical step.
5	DR. BRENNAN: This is Patti
6	Brennan. I want to thank John for that
7	comment because it's a segue way to my message
8	to you.
9	This afternoon at 4:30 we're going
10	to be breaking up into small groups as we did
11	in the past. This is in part response to the
12	comments from our expert panel and from the
13	last session there was a great need for more
14	discussion.
15	We will have a half an hour to be
16	talking specifically about what are the
17	aspects of the NQF evaluation process that
18	need to be tailored for patient-reported
19	outcome primary performance measures and
20	aspects of what John identified just now will
21	be important.
22	So as we go through the day today

	Page 35
1	please jot notes on your sheet and we'll have
2	time in small group discussion with a recorder
3	from the NQF at each table to get those
4	thoughts down.
5	And I'll now turn back to Karen to
6	continue the program.
7	DR. PACE: Okay, we'll ask Greg
8	Pawlson to come up. He's our moderator for
9	our next session. And I understand that all
10	three of our panelists are online so I'll let
11	Greg get started and then we'll go from there.
12	DR. PAWLSON: Good morning,
13	everybody. Well, we hope the technology is
14	going to work on this. It's a great test of
15	both doing things locally and across the pond
16	shall we say.
17	You know, as a very veteran as you
18	can see by my white hair, my granddaughter
19	points out my hair is now white. So, I don't
20	get excited about meetings very often but this
21	one I did and especially this session.
22	I think that where we are with

	Page 36
1	this although we still have clearly some
2	challenges in terms of the importance of these
3	measures and how we can illustrate the
4	importance of these measures. And in
5	assessing the scientific kind of
6	characteristics of the measures themselves I
7	think we're actually farther along in that
8	than appears to be the case.
9	But in terms of the feasibility
10	and usability of these measures and really
11	getting even past the PRO-PM stage and moving
12	from the concepts to the measures to
13	performance measures and then to measurement
14	and the actual application of these measures
15	in practice I think is our greatest challenge
16	in this area.
17	And I think the panel that we've
18	assembled this morning is really an exciting
19	one to give us some insights on that because
20	it represents efforts in three different
21	countries including the United States to use
22	PROMs in a very direct and structured way, and
	Page 37
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1	in some cases to actually have results of
2	these in terms of application to specific
3	populations either of disease-specific or
4	condition-specific kinds of measures, or in
5	the case of the Health Outcome Survey that CMS
6	uses the health status of a general
7	population, and what some of the contrasts are
8	between those two approaches.
9	To guide us along this pathway
10	this morning we're very fortunate to have
11	first of all David Nuttall who's the deputy
12	director of the PROMs Programme with an "e" at
13	the end which I always find interesting. And
14	he is the deputy director for patient-reported
15	outcome measures at the Department of Health
16	of England and he's actually been with that
17	program really from its outset.
18	Secondly, we have Elizabeth or Liz
19	Goldstein whom I think a lot of you know who
20	is director of the Division of Consumer
21	Assessment and Plan Performance at CMS. And
22	she's going to talk about the Health Outcome

	Page 38
1	Survey. Liz has always been a very strong
2	proponent of patient-reported outcomes and has
3	also been a very major player in the CAHPS
4	survey process.
5	And finally, from Sweden we have
6	Stefan Larsson who is the senior and managing
7	director of the Stockholm office of Boston
8	Consulting and has been deeply involved in the
9	program that has been developed for the use of
10	patient-reported outcome performance measures
11	in Sweden.
12	So without further ado I hope we
13	have David to start off the process. David?
14	MR. NUTTALL: Hi, good morning.
15	DR. PAWLSON: And by the way,
16	David, congratulations on your Scotsman's
17	victory last night.
18	MR. NUTTALL: Thank you very much.
19	Well, good morning. Can you hear me okay on
20	the line?
21	DR. PAWLSON: Yes, we hear you
22	quite clearly.

	Page 39
1	MR. NUTTALL: Can you hear me
2	okay?
3	DR. PAWLSON: Yes, we can.
4	MR. NUTTALL: Okay, fantastic.
5	Well firstly, thank you for inviting me to
6	this Quality Forum meeting. I've put some
7	slides together which are intended to give an
8	overview really of the program of work that we
9	are doing here.
10	And I think by its nature in 15
11	minutes it will be a relatively quick overview
12	of some of the issues but I think maybe the
13	important thing is to sort of set out what
14	we're doing completely and then obviously at
15	the end if there's any specific questions I'm
16	happy to go into those in a bit more detail.
17	So, if I could just go onto the
18	first slide, fantastic. And I don't know if
19	this is going to work with testimony but
20	there's this little animation that will bring
21	in four pieces, a jigsaw puzzle. And I use
22	this slide really to try and demonstrate why

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Page 40 we're interested in patient-reported outcome 1 2 measures at the Department of Health and what we're trying to achieve. 3 And in a nutshell I think that the 4 5 National Health Service here has got a good history of collecting information about care 6 7 but to some extent it's a bit partial. So I 8 think historically we've had a good set of 9 information about patient's experience from 10 the viewpoint of patients through national survey programs which have been in existence 11 12 for some time. And I think we've got a wealth of data about healthcare professional's view 13 14 of patient experience from other routine data 15 sources. In terms of the effectiveness of 16 17 care I think again we've got a long track 18 record in measuring from a professional's 19 point of view how effective care is through 20 things like clinical audits and clinical 21 indicators which we derive from routinely 22 collected administrative data.

	Page 41
1	What I'd argue though is that the
2	effectiveness data is relatively partial
3	insofar as clinical audits are not carried out
4	continuously. They tend to be carried out at
5	point in time looking at particular issues and
6	clinical indicators that we have are generally
7	focused on where things go wrong. So they
8	would be looking at things like mortality,
9	complication rates, transfers to high-
10	dependency care, that sort of thing, less
11	focused on the quality of care for let's say
12	the majority where there isn't an adverse
13	outcome as part of their care. So that
14	problems patient-reported outcome measures
15	data is important not as a replacement for the
16	other sorts of information that we collect but
17	really to complement and complete the quality
18	picture that we have about care in the round.
19	So that's kind of the overarching reason and
20	rationale for collecting this kind of
21	information.
22	If I just go onto the next slide

	Page 42
1	then. Great. So, in terms of the history of
2	the program we actually carried out or
3	commissioned rather I should say a piece of
4	research in about 2004 which was to look at
5	all of the available patient-reported outcome
6	measures that were available sort of off-the-
7	shelf and to assess their relative merits and
8	performance, psychometric property and come up
9	with recommendations for what would work best
10	in a small number of acute elective
11	interventions.
12	So the four on the list there, hip
13	replacement, knee replacement, varicose vein
14	surgery and groin hernia repair, and there was
15	a fifth originally around cataract surgery as
16	well.
17	And what that research concluded
18	was that there was merit in putting together
19	a generic patient-reported outcome measure
20	alongside a condition-specific for each of the
21	five areas we were looking at and made various
22	recommendations as to what each measure ought

	Page 43
1	to be.
2	We then commissioned some further
3	work which ran between 2005-2007 to pilot the
4	collection of those measures in a range of
5	different sorts of units from large hospitals
6	through to much more smaller, elective
7	ambulatory care units and to see how the
8	administration methodology would work, to have
9	a look at collection, to have a look at the
10	acceptability of these sorts of measures from
11	the point of view of both the patients that
12	were completing them and the staff that were
13	administering them.
14	A couple of points to make from
15	that. I think the first was that we concluded
16	that this was a scheme that had merit, that
17	was cost-effective and ought to be rolled out.
18	But equally that there were some really tricky
19	methodological problems around the collection
20	of this kind of information for cataract
21	surgery with the instruments we had at the
22	time so that the size became flawed over a

Page 44 period of time. 1 2 In terms of the final point there 3 where I say it evolved over time I think really that's just to say that at the outset 4 5 we were looking at the collection of this kind of information because we were concerned about 6 7 the relative performance of different types of 8 units in the NHS where we had good information about cost models and clinical approaches but 9 10 less good information about outcomes data. And I think the aims and 11 12 objectives have changed over time as we've 13 become much more interested in facilitating 14 patient choice of provider, of providing much more comprehensive information. 15 So it's evolved over a period of time until now in 16 17 terms of the sorts of uses of the data, but it 18 continues to attain strong support across the 19 board as a program with merit. 20 If I can just go onto the next 21 slide. The questionnaires that we administer 22 are administered to patients at two time

	Page 45
1	points, once preoperatively and a second
2	questionnaire post-operatively at either 3
3	months or 6 months depending on the
4	intervention that's in question.
5	And we have questionnaires which
6	are effectively batteries of measures. They
7	comprise a standard EQ-5D profile and the EQ-5
8	currently. And we paired those up with a
9	condition-specific for three of the conditions
10	apart from hernia where we didn't identify a
11	condition-specific measure which was of
12	sufficiently good performance.
13	And around that core battery we
14	then have on the preoperative one demographic
15	information. We collect information about
16	patient comorbidity and so on. And on the
17	post-operative one we don't replicate the
18	patient demographic information but we would
19	also collect some information about
20	complications, infections, allergy, whether
21	they'd been back to hospital, and so on. And
22	that pair of health data measures then give us

Page 46 1 a sense of outcome when we look at the 2 difference between them for any individual 3 patient. I won't get into detail about 4 5 precisely how we do this but we have contracts 6 in place with a range of organizations which 7 help on the logistics side distributing, 8 producing those questionnaires, scanning them in and turning them into electronic records. 9 10 But during this point in the process is that it comes back into a body, organization known 11 12 as the Health and Social Care Information Centre which is not part of the Department of 13 14 Health but a related organization who have responsibility for publishing end results as 15 what we call official statistics. 16 17 If I could just go onto the next 18 Just very quickly in terms of the page. 19 program we think it's large and significant. 20 Each -- well, the four interventions comprised 21 about 250,000 patients per annum. We've been 22 collecting the data since 2009 and the table

	Page 47
1	shows the sorts of volumes of information that
2	we've had returned to date.
3	A large and growing data set I
4	think and I think one of the perhaps the
5	most comprehensive data set of its nature as
6	we have a census approach and although
7	voluntary we'd approach everybody that's
8	eligible for interventions from as well as NHS
9	to complete questionnaires.
10	And we had quite a lot of interest
11	in the program and have spoken to
12	representatives across a whole range of
13	countries about what we've been up to and how
14	some of this can be reproduced. Next slide.
15	This is just to demonstrate the
16	return rate that we had got. And what the
17	graph is showing that for orthopedics we have
18	historically enjoyed a very high rate of
19	patient participation at around 80 to 90
20	percent. And we've done less well over time
21	at collecting information for general surgery.
22	There's a bunch of reasons why

Page 48 this might be the case from complexity of the 1 2 questionnaire in the case of varicose veins to how much time individuals spend in hospital. 3 It tends to be admitted whereas the general 4 5 surgery procedures will tend to be day cases and people are in hospital for less time. 6 So 7 there's a bunch of reasons. 8 But I think the key message that 9 comes from this slide is that actually it can be done at very high rates. And actually even 10 within varicose veins and groin hernia which 11 12 have slightly lower -- rates. There are hospitals that will be doing this at nearly 13 14 100 percent and have been doing so for a long period of time. Next slide. 15 16 And once the preoperative administration is within gift of the providers 17 18 they physically distribute the questionnaires 19 to people in their clinic. The post-operative 20 questionnaire which is sent out through the 21 post mail 6 months later, the response rate is 22 much more of a parameter. And the parameter

	Page 49
1	is about 85 percent for orthopedics of those
2	that complete a pre-op will go on to complete
3	a post-operative questionnaire, about 75
4	percent for groin hernia and slightly lower
5	again for varicose vein. And that's being
6	consistent if we ignore the kind of the
7	wobbly line on the very right-hand side of the
8	data, it's a bit more recent in this graph,
9	then you'll see that they're effectively
10	constant over a period of time. Next slide.
11	Now, in this slide I'm kind of
12	summarizing an awful lot of information quite
13	quickly but this is really to say that the end
14	product of that data collection, there is a
15	large number of steps which go on in period
16	but the data that's collected will form
17	electronic records.
18	It's linked together with
19	routinely collected administrative data on the
20	sort of nature of the episode. So what
21	interventions took place, how long are they in
22	hospital, what comorbidities were recorded in

	Page 50
1	the patient record, et cetera, et cetera. All
2	that data is stitched together into an
3	electronic record for each patient. Outcomes
4	are calculated in terms of distance between
5	the pre-op and post-op scores. Measures are
6	available for just like the index, the
7	bands in a condition-specific measure.
8	And we apply a case-mix adjustment
9	to take out of differing case loads of each
10	hospital in this case before constructing
11	average outcomes per unit. This will be
12	displayed on a graph like this. And the
13	funnel plot has become a standard way of us
14	reporting this information back to the
15	providers themselves. And I'm sure many of
16	you are very familiar with it. I think that
17	the volume of records across the x axis, the
18	adjusted health gain changes to the pre- or
19	post-op score accounts for patient case
20	experiences plus unit control limits at 99.8
21	percent, 95 percent limit.
22	And then we would publish this

	Page 51
1	data on a quarterly basis back to providers
2	indicating where their statistically
3	different from the national average. They
4	where expect the providers to take action as
5	a result. So, as I say unfortunately
6	there's an awful lot of work that goes on and
7	needs to be included. This is one of the
8	sorts of output that we would generate for the
9	program. Next slide.
10	Effectively I started off by
11	saying that one of the rationale for, one of
12	the main reasons for collecting information
13	was to round out and complete the quality
14	picture by giving us a complementary source of
15	information about outcomes and quality. But
16	actually being a bit more specific about that
17	there's a whole range of particular
18	applications that we can use this data for.
19	And I think the general point is
20	that we don't see that being as primary or
21	necessarily predominantly application of data.
22	We see the outcome information as being a

	Page 52
1	resource which could be applied to a whole
2	range. So, I won't get into this in detail
3	but it ranges from things like using the
4	outcomes measure at a local hospital level to
5	look at the relative performance of clinical
б	meetings, to have a look at whether the care
7	that's being offered has particular
8	consequences on specific domains of the
9	outcome measures, patient pain or what have
10	you.
11	We have an initiative, the name is
12	Quality Counts where all hospitals have to
13	provide reports on their performance, provide
14	a descriptive narrative of why their metrics
15	look a particular way. And PROMs is being
16	made a mandatory component of that. So each
17	provider would have to explain why their data
18	shows what it shows. Through patient choice
19	right up to the national level where we can
20	use this data in aggregate to tell us
21	something about the relative efficacy of
22	different interventions from the patient

	Page 53
1	effectiveness point of view. Next slide.
2	I just noticed the time so I'll
3	just move through these. But I think over the
4	3 years since we started collecting this
5	information routinely the data has become part
6	and parcel of the information landscape that
7	we have. I think when we started this
8	initiative the data was seen as very much
9	something which collected in a one-off program
10	and you know, you have to be convinced that
11	there's merit. And I think 3 years on it's
12	just seen as part of the fabric, the set of
13	information that we collect has become
14	terminology that people are comfortable with
15	and are familiar. And it is embedding itself
16	into a whole range of things. We have
17	something, maybe the outcomes framework which
18	is a method for holding the NHS to account and
19	appears comprise patient-reported outcome
20	measures. Sort out quality account.
21	And I think most interesting from
22	my point of view, it's taken a few years but

	Page 5
1	we're now starting to see the academic
2	research using this data to flow with some
3	interesting papers coming out. Next slide.
4	And just picking up on that point,
5	I mean particularly looking at case studies
б	too. This is an example of the sort of
7	academic research which is coming out. We've
8	just seen a peer-reviewed paper appear which
9	is looking at the relative effectiveness of
10	unicondylar or unicompartmental knee
11	replacement relative to total knee
12	replacement. And although I think the
13	unicondylar are of increasing popularity I
14	think the research has shown that from a
15	patient outcome point of view they were very
16	similar in terms of their effectiveness and
17	yet the unicondylar has a high revision rate.
18	So the paper sought to question doing that.
19	From my point of view I think that's a really
20	interesting piece of research because it's
21	getting leading it away from being just
22	about patient outcomes and you know, the

Page 5
softer side of things, to driving some really
meaty clinical next slide.
And this is just coming to the
end. So, looking into the future we've
covered four elective interventions. We have
quite a lot of work in the pipeline which is
looking to extend the scope of the program.
And this includes a trial which is currently
underway for coronary revascularization, CABGs
and angioplasties where we are piloting some
competent measures with 11 providers. We have
done a cancer survivorship study which was
using elements of the FACS questionnaire and
was sent out much like a general population
survey out to patients which got a very high
participation rate. And looking at other
areas like mental health, care and treatment
of depression, lots there as well.
A few things that we're doing at
the moment. One is the development of a, what
we're calling a shorter, sharper generic PROM
questionnaire the point of which will be to

	Page 56
1	use a much wider range of intervention. And
2	then very briefly we have made some quite
3	significant changes to the way we collect and
4	report the data which allows much greater
5	access to the patient level identifiable data
6	for clinical teams which is something that
7	clinical teams have asked us for. And we are
8	starting to introduce new methods of
9	collecting the data including iPad touch
10	screens, electronic data capture as well as to
11	try and make this the best around.
12	Then the final slide. To
13	summarize I think our PROMs collection at a
14	national scale with comprehensive coverage
15	gives us a pretty unique insight into the
16	effectiveness of care from the patient's point
17	of view. And we feel confident that the
18	volume and response rate that we've got make
19	the kind of findings that we're coming to
20	quite robust.
21	You know, a huge amount of work
22	has gone into devising and developing the

Page 57 methods for getting this data. I think when 1 2 we started the program there was relatively limited evidence-based literature about how we 3 use this kind of data in the context of 4 5 routine performance management assessment of this as opposed to the use of it for the 6 7 appraisal of let's say drugs and the like. 8 I think there's a huge variety of 9 uses we can put the data to and we're now 10 starting to see the evidence build up about the kind of conclusions we can make from this 11 12 data. I think we'd view it successful and that's why we're starting to roll it out into 13 the other clinical areas. I think that's 14 15 easily my 15 minutes so I should probably stop 16 there. 17 Okay, thank you very DR. PAWLSON: 18 much for I think a very good overview of a 19 very complex and somewhat longstanding program 20 that I think is very exciting. 21 I just, as we start some comments 22 and discussion of this presentation. It's

Page 58 interesting to me that this is one of the few 1 2 ways, and from a measurement wonk's perspective very exciting way of starting to 3 4 get at clinical appropriateness. 5 We have I think been very stymied in trying to measure the quality of procedures 6 7 in this realm because of the lack of data of 8 appropriateness. If the procedure wasn't done 9 for appropriate reasons the quality of it I 10 think is very much sort of perhaps even an insubstantial kind of question. 11 12 Do you want to comment on how this is beginning to be used in the determination 13 14 of the appropriateness of some of the procedures that you're looking at? 15 16 MR. NUTTALL: Sure. I mean, I 17 think we -- I think our general position is 18 that we don't oppose using the data as a sort 19 of preoperative screening tool. So our 20 position is that it's always at clinical 21 discretion as to whether a procedure is needed 22 or not. And so we wouldn't oppose the use of

	Page 59
1	PROMs as any sort of screening or rationing
2	mechanism, however you want to think of it.
3	Instead, the way we see it is
4	actually the value is added by looking post-op
5	and having an assessment of whether actually
б	in different parts of the country we could
7	adopt better scores, had clinical referral,
8	specialty different. So, it's not that the
9	data in itself will allow us to conclude who
10	should have an intervention, that's left to
11	clinical discretion. But we would use the
12	data to assess after the event whether there's
13	something in there which can inform the
14	clinical decision-making if that makes sense.
15	DR. PAWLSON: Okay. Follow-up
16	comment on that back there?
17	DR. BASCH: Yes, hi. Hi David,
18	it's Ethan Basch at the University of North
19	Carolina. Nice presentation as always.
20	A quick question, actually a two-
21	part question about missing data which has
22	come up a bit in our conversations here. The

	Page 60
1	first is a question about response bias, that
2	certain of the hospital trusts may have higher
3	or lower response rates. And in general when
4	they are lower response rates there may be a
5	lower response from patients who are sickest
б	who have the worst outcomes. And therefore,
7	those institutions with the better response
8	rates may actually be at a disadvantage
9	because higher response is associated with a
10	higher number of people reporting worse
11	outcomes. And how you adjust for that.
12	And the second is what has been
13	your approach to missing data not at random,
14	particularly from hard-to-reach patient
15	populations who may systematically be missing,
16	particularly in some of your lower response
17	rate groups like the varicose vein cohort.
18	MR. NUTTALL: Sure. Yes, I think
19	good questions. And we have a piece of advice
20	which we've put out to providers which is that
21	we're looking for 80 percent preoperative
22	participation to ensure that the data we're

	Page 61
1	collecting is being representative. And the
2	work we've commissioned suggested that over 80
3	percent participation then the data is
4	generally going to be reliable in and of
5	itself. So that's kind of a first point.
6	And obviously some providers don't
7	meet that, particularly if you look at
8	varicose veins with a lower average
9	participation rate. So there is an issue to
10	deal with around missing data and potential
11	response bias.
12	And I think two ways of dealing
13	with that. One is that we have done work
14	which has looked at response bias and allowed
15	us to get a handle on what the impact of
16	missing data from particular patient
17	populations is so that we can get, you know,
18	understand what the data is actually telling
19	us when we look at it.
20	I think the second thing that we -
21	- perhaps most important when we're looking at
22	provider comparisons is through our case-mix

Page 62 and risk adjustment process then we can 1 2 effectively give a provider a sort of national 3 average basket of patients and look at what their scores would have been for them. 4 And 5 that's kind of the underpinnings of how our case-mix adjustment works. So, we can take 6 7 into account the patient mix, we can have a 8 look at what we would have expected to see from them, what we actually got, and correct 9 10 the data in some sense. So I think two bits of response. 11 12 One is that we do the work which actually 13 tells us what the consequence and response 14 bias is and allows us to get a handle on that 15 in the first instance. And secondly, in 16 reporting the data adjust it to take account 17 of that to some extent. I think 18 Thank you. DR. PAWLSON: 19 in the interest -- I mean this question that 20 you raised and I suspect some others are going 21 to apply to all three data sets. And I think 22 we've just begun to scratch the surface of the

	Page 63
1	richness of the information they've collected
2	I think and how it impacts.
3	So what I'd like to do is go onto
4	Liz Goldstein, get that perspective, and then
5	Stefan and then come back and loop in some of
б	the questions. So, after Liz's presentation
7	we'll take questions that are sort of
8	specifically about the issues or methodologies
9	of that set alone. Okay? So Liz, do you want
10	to go ahead?
11	DR. GOLDSTEIN: Yes, thank you.
12	So today I'm going to be talking about our
13	Medicare Health Outcome Survey, or often it's
14	referred to the HOS survey. So for the next
15	slide.
16	The goal in implementing this
17	survey in the Medicare program was to gather
18	valid, reliable and meaningful health status
19	information for Medicare Advantage enrollees.
20	So we use this information in quality
21	improvement, plan accountability, public
22	reporting, to focus on improving the health of

	Page 64
1	our Medicare beneficiaries. And I'll be going
2	into some of these activities in more detail
3	in this presentation.
4	The intended uses for the HOS
5	data, as I said, public reporting. And I'm
б	going to be talking a little bit about our
7	public reporting program and how HOS is
8	integrated into this public reporting program.
9	Most recently we're using it for our pay-for-
10	performance program and I'll quickly review
11	that today. It's used for quality improvement
12	activities of the plan, program oversight and
13	in general to advance the science of health
14	outcomes research. There's a wealth of
15	studies that have been done using the HOS
16	survey.
17	In terms of the HOS overview the
18	survey was implemented by CMS in 1998 so it's
19	been going on for many years. All Medicare
20	Advantage organizations or health plans with
21	at least 500 members are required to
22	participate in this survey.

Page 65 1 The survey is done annually with a 2 2-year follow-up period and I'll explain that in a moment a little more. The focus of the 3 survey is to measure whether the health plan 4 5 has been able to maintain or improve the physical and health of its members. 6 7 In terms of the survey design and 8 questionnaire the sampling unit is a Medicare contract. And as I said before if a contract 9 10 serves less than 500 enrollees, and we in the Medicare program have a lot of small contracts 11 so this does exclude a number of our contracts 12 13 that are just very small. The number of small 14 contracts has been decreasing over time so 15 hopefully eventually most contracts will be 16 doing the survey. 17 If a contract serves anywhere between 500 and 1,200 enrollees all the 18 19 enrollees are included in the survey. And if 20 they have more than 1,200 enrollees a random 21 sample is taken. 22 So a beneficiary is surveyed in a

Page 66 1 baseline period and then 2 years later we go 2 back to those same enrollees with the same 3 cohort to do the follow-up survey. So a 4 contract at any given year is doing both a 5 baseline survey as well as a follow-up survey. Just to give a little information 6 7 about how the survey is done, our contracts 8 have to contract with HOS survey vendors that 9 are certified or approved by the National 10 Committee for Quality Assurance. So they can't use any survey vendor. The survey 11 12 vendor has to be approved or certified to do 13 the survey. It's very important to us for all 14 of our survey activities that contracts use approved vendors because we provide oversight 15 of these vendors, ensure that they're 16 17 following standard protocol. 18 In terms of survey administration 19 it starts out with a pre-notification letter, 20 then goes to a first mail survey. Then the 21 sample member gets a reminder postcard and 22 then a second mail survey if they haven't

1	
	Page 67
1	responded yet. If a beneficiary does not
2	respond to the first two mailings then
3	telephone follow-up is used.
4	And we have found in a lot of our
5	survey activities using this mix mode
6	methodology gets the highest response rate and
7	also gets people more likely to respond by
8	mail or by telephone. Just to note, the
9	survey is done in English, Spanish and
10	Chinese.
11	The HOS 2.0 survey has 64
12	questions. And I'll be giving a little bit
13	more information about the questions in a
14	moment. The one thing I want to emphasize
15	here, that this survey is population-based,
16	it's not condition- or disease-specific.
17	This slide provides just some
18	sample questions on the HOS survey. As I said
19	before the current version of the survey
20	includes 64 questions. It includes the
21	Veterans RAND 12 Item Health Survey. It
22	includes questions about activities of daily

	Page 6
1	living, chronic conditions. It includes some
2	measures that we collect for our HEDIS survey
3	which includes measures such as monitoring
4	physical activity. It includes information
5	about height and weight, clinical symptoms
6	such as depression and pain items, and a
7	series of sociodemographic questions that are
8	used for our case-mix adjustment model.
9	The next slide. The HOS survey
10	focuses on two outcome measures of physical
11	and mental health changes for Medicare
12	beneficiaries as I said over a 2-year period
13	from baseline to follow-up. There are I
14	just want to give you a little bit more detail
15	on that.
16	There are eight scales that form
17	the basis of these two summary measures, the
18	physical and mental health status changes.
19	I'm just going to quickly go over these eight
20	scales so you can get some picture of the
21	types of things included in this measure.
22	They are two questions related to

	Page 69
1	physical functioning such as the extent to
2	which a respondent's health limits their
3	physical activities. There are a couple of
4	questions related to whether the respondent's
5	physical health limits them in the kind of
6	work or other usual activities they perform in
7	terms of time and performance.
8	There's one question that
9	determines the extent to which pain interferes
10	with a respondent's normal activities.
11	There's one question that asks respondents to
12	rate their current overall health status.
13	There's one question that asks
14	respondents to rate their well-being by
15	indicating how frequently they experience
16	energy. One question asks respondents to
17	indicate limitations in social functioning
18	specifically because of their health.
19	There are a couple of questions
20	assessing whether emotional problems have
21	caused respondents to accomplish less in their
22	work or other activities in terms of time and

	Page 70
1	performance. And there are a couple of
2	questions that focus specifically on how
3	frequently they felt calm and peaceful and
4	felt downhearted and blue. So these eight
5	scales as I said before provide the basis for
6	the two summary measures.
7	On the next slide the HOS survey
8	was developed under guidance with a technical
9	expert panel. A lot of industry experts have
10	provided input into the initial development of
11	the survey.
12	We continue each year to look at
13	the survey, look at new methodologies as the
14	state of the art changes. For example, next
15	week we have a technical expert panel that's
16	going to be looking at the survey and seeing
17	if there are additional items to add related
18	to patient-reported outcomes as well as are
19	there any revisions to that current
20	instrument.
21	Just to provide a little bit more
22	detail, the HOS outcomes are determined by

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comparing observed to expected changes in the
physical and mental health for individuals in
the sample.

One thing that we continue to 4 5 evaluate each year and it's something that we're going to be paying close attention to in 6 7 the coming year to see if we want to make some 8 revisions is that the case-mix adjustment 9 methodology is very critical to producing 10 valid plan-to-plan comparisons. The current adjustment for HOS includes variables such as 11 12 age, gender, education, socioeconomic status, chronic conditions and functional limitations. 13 14 I'm going to spend a couple of minutes talking about how we use the HOS data. 15 16 So HOS for public reporting, and you can go to 17 the next slide. We have a five star plan 18 rating system and HOS is included in this 19 So for our health plans that offer system. 20 drug coverage they're rated on approximately 21 50 different measures. And so HOS is part of 22 So we produce, for every that measurement.

	Page 72
1	health plan and drug plan in the country we
2	produce a five star rating and that's our
3	overall rating.
4	For health plans that offer drug
5	coverage we have nine domains or topic areas.
6	So the topic areas cover things such as
7	staying healthy, managing chronic conditions,
8	experiences of the health plan members,
9	patient safety. So for public reporting
10	purposes we roll it up to these nine domains.
11	If someone who's using one of our
12	websites wants to look at the individual
13	measures they can go down and look at the
14	individual measures that make up each domain.
15	And for each individual measure we provide a
16	five star rating as well as a numeric number
17	that goes with the measure.
18	So for HOS it's included in this
19	plan rating system. Last year we made some
20	changes to our public reporting system. Prior
21	to last year all measures were treated equally
22	in the plan rating system so our process
	Page 73
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1	measure and outcome measure were weighted
2	equally, suggesting that they had equal
3	importance.
4	Last year we moved away from that
5	and right now outcomes and intermediate
6	outcomes receive a weight of 3, patient
7	experience and access measures receive a
8	weight of 1.5, and process measures receive a
9	weight of 1. So the health outcome, those two
10	measures receive a large weight in our system,
11	receiving a weight of 3.
12	The next slide just is one
13	screenshot from our website. And this shows
14	you when you pull up a plan. Some of the
15	basic information you get up front is our
16	overall plan rating. And then you can drill
17	down to more detailed information as I was
18	talking about.
19	I'm going to switch just for a
20	couple of minutes and talk about pay-for-
21	performance. Next slide. As part of the
22	Affordable Care Act CMS implemented a quality

Page 74 1 bonus payment system for health plans or 2 Medicare Advantage contracts. As part of the Affordable Care Act 3 it said that in implementing this system it 4 5 should be based off of a five star rating system. And so CMS decided that the quality 6 7 bonuses would be based off the Medicare 8 Advantage plan rating. So it's the same 9 system that we use for public reporting. 10 CMS is conducting a demonstration for the first 3 years of the implementation. 11 12 And through this demonstration CMS adjusted the amount of money or the percentages that 13 contracts would get for each of their star 14 ratings, trying to really generate more 15 16 quality improvement, more rapid and larger 17 year-to-year quality improvement. 18 The slide that's up right now 19 shows the different amounts for the different 20 star ratings. So the current -- under current 21 law contracts would only get a quality bonus 22 if they had four or more stars. During the

	Page 75
1	demonstration they do get quality bonuses if
2	they have three or more stars. Once the
3	demonstration ends we'll go back to current
4	law and it will be four or more stars.
5	So, we've seen since the quality
6	bonus payments were announced to plans there's
7	a lot more emphasis on quality improvement by
8	the plans. A few years ago when we put out
9	the plan ratings each year some plans paid
10	attention but they weren't paying a lot of
11	attention. Right now since they do get paid
12	based off of HOS and our other data collection
13	activities they do pay a lot of attention. We
14	get a lot of questions about data and using it
15	for quality improvement. So there's clearly
16	a lot of emphasis right now among Medicare
17	Advantage plans and seeing how they can
18	improve performance across all of their
19	quality performance measures.
20	The last slide is really just a
21	summary of what I've gone through. CMS uses
22	the HOS data to determine performance of

Page 76 1 Medicare Advantage plans and to reward high-2 performing plans. It's really used for quality improvement activities and to just 3 monitor how plans are doing. Medicare 4 5 beneficiaries can use this information to make a decision about which plan to go into. 6 And 7 researchers have used a lot of this information to advance the state of science 8 9 and patient-reported and functional health 10 outcomes measurement. So, I think I'll turn it back to Greg to open it up for questions. 11 12 Thanks very much. DR. PAWLSON: This is sort of a little hidden gem of the 13 14 Medicare program that a lot of people don't know about. So I hope this gets it to a wider 15 audience than in the past in terms of both its 16 17 use for performance improvement but also in terms of health services research. 18 19 Questions specifically? Judy? 20 And just identify yourself so Liz knows from 21 whence the questions are coming. 22 DR. HIBBARD: Hi, this is Judy

	Page 77
1	Hibbard from the University of Oregon. Hi,
2	Liz. My question for you is about the
3	sensitivity of these measures to change. And
4	I was wondering when you developed the
5	measures was that a criteria and what has your
6	experience been over these years of use.
7	DR. GOLDSTEIN: So when it was
8	developed that was something they really
9	looked at, how sensitive it was to change. I
10	think the thing that we're the struggle
11	that we have right now and it's something
12	we're spending a lot of time looking at is
13	that there's some variation across plans but
14	there's not a lot of variation.
15	So we're spending some time right
16	now in the coming year really looking at that
17	and seeing how the measurement could be maybe
18	improved or tweaked to, you know, increase
19	that variation across plans. But looking at
20	the sensitivity to change, that was
21	incorporated in the initial development
22	activities.

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1	DR. PAWLSON: I think, Judy, you
2	brought up a very key issue with a lot of
3	patient-reported outcomes in contrast to
4	patient experience measures where we've got
5	some pretty good indicators that a lot of the
б	variance is provider-specific. In this case
7	I think and actually David brought one of
8	his PowerPoints where it has the outcomes data
9	published by provider organizations adjusting
10	for differences in case-mix. If you look at
11	that it shows very clearly the 99 percent
12	confidence limits around an estimate of the
13	adjusted average health gain. And they're
14	pretty broad.
15	It reminds me of when we did the
16	resource use measures and the costs where you
17	see pretty wide variation. And that means the
18	sample sizes for these two have adequate
19	reliability and adequate amount of variance
20	due to provider-specific factors is up in the
21	two, three, four hundred range. And so I
22	think that's a real challenge to a lot of the

Page 79 measures we're going to see in this field. 1 2 Yes. DR. KAZIS: Hi, this is Lewis 3 Kazis from Boston University. Hi, Liz. 4 Ι 5 enjoyed your presentation. I've been involved with -- as a 6 7 consultant to the CMS project for HOS for many 8 years and what Liz says is absolutely correct. 9 There are some weaknesses in the variability 10 that we're seeing across the plans using the VR 12 broken out into physical and mental. 11 12 There is new work that we are currently conducting where we combined both 13 14 the physical and mental into a utility metric 15 called the VR 16. And in very preliminary 16 work we are seeing more signal across the 17 plans as a result of that. So I just wanted 18 to mention that. 19 DR. PAWLSON: I think that's 20 another good point in terms of how one 21 aggregates different measures into a Starts to build and I know there's 22 composite.

	Page 80
1	some methodological approaches that can start
2	to filter out some of the noise and boost the
3	signal which is I think a real challenge here.
4	Thank you very much. Can we go
5	on? And I understand, Stefan, you're going to
6	have a little bit of an extra challenge
7	because you've got some internet problems and
8	you aren't going to be able to see the slides.
9	Is that right?
10	DR. LARSSON: Yes, that's true. I
11	have them in front of me. So as long as we're
12	looking at the same slides we should be fine.
13	DR. PAWLSON: Well, if you can
14	just as you address a slide perhaps just use
15	a brief introduction of the title of the slide
16	to make sure we're on the same one, okay?
17	DR. LARSSON: Yes and I'll ask you
18	to switch slides for me. Okay, thank you very
19	much for having invited me to the meeting. So
20	I'm Stefan Larsson. I'm a partner with BCG in
21	Stockholm. I'm a medical doctor by training
22	but I am a management consultant nowadays

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1	although scientifically trained. I've worked
2	as an advisor as BCG does to the healthcare
3	industry broadly, to governments and to
4	corporates and I have worked very broadly in
5	the industry.
6	One of the things that struck us
7	was very, you know, it's been striking and I'm
8	sure it has been to all of you is the very,
9	very strong focus on budgets and the cost of
10	healthcare over the past years. And we've
11	found an anti-innovative climate that led us
12	to start looking at these registries.
13	And being a Swede and quite close
14	to the scientific community here I started
15	looking at disease registries, or we did
16	locally in Sweden, and discovered that there
17	is in fact a means to combine the analysis of
18	cost of care with disease-based high-quality
19	data on the outcomes of care.
20	And we have since well, the
21	past 3 years invested heavily in what we and
22	others call value-based care which is on a

	Page 82
1	disease-by-disease basis to thoroughly make
2	sure that we have data on outcomes, both
3	traditional outcome measures as well as PROMs,
4	and then use that as the numerator to then
5	compare to the money spent on that particular
6	disease along the entire care chain.
7	Registries in Sweden were started,
8	the first ones in the seventies. If we switch
9	to the next slide today there are about 100
10	registries covering and they're all
11	disease-based with maybe there are a few
12	exceptions. There are one or two which are
13	registries monitoring outcomes for elderly
14	care patients, so multi-disorder patients.
15	But 95 percent of these registries are
16	disease-based.
17	The focus is on outcomes. These
18	have been research registries from the
19	beginning where clinicians, the specialist
20	societies and not government and not payers
21	took the initiative to set up these registries
22	to discover within the clinician community

	Page 83
1	what determined good outcomes in terms of
2	which clinical procedures, which medical
3	devices were better than others and so on and
4	so forth.
5	This has evolved to become
6	increasingly a tool to drive continuous
7	improvement. That's where we as management
8	consultants and interested in transformation
9	of healthcare, the improvement of healthcare
10	found this to be an extraordinarily exciting
11	tool.
12	The majority of these 100
13	registries have over 75 percent of the patient
14	population covered which means that from a
15	reliability point of view at least in terms of
16	coverage these are quite unique repositories
17	of rather complete populations.
18	Furthermore, as these have been
19	used primarily for research purposes validity
20	and so on and so forth has been a lot of time
21	invested into making sure that the data
22	quality is high. And that's also why the

	Page 84
1	results, the analyses of these registries have
2	had a lot of impact on the medical community.
3	The measures chosen, the way the
4	data has been captured through genuine
5	engagement by the clinicians and then the
6	validity done by highly qualified peers has
7	led to the analysis resulting to have been
8	interpreted as very important to determine
9	best practice and change clinical procedures
10	and clinical guidelines.
11	A majority of registries have
12	PROMs as part of the tool set that they use.
13	And there is a lot of interest in PROMs which
14	has grown over the past couple of years. Some
15	of the registries were fairly early to look at
16	PROMs and I'll come back to that. And the
17	data they have shown and the impact that has
18	had on clinical practice has led many others
19	to say we also need to find good PROMs that
20	will let us, would allow us to be smart about
21	how we treat patients. And as was said
22	earlier, to make sure that we have appropriate

Page 85 treatment and not overuse of surgery and so 1 2 on. The next slide has four points to 3 These are the official arguments why 4 it. 5 there is a strong surge of pushing for PROMs across the Swedish registry. You know, as we 6 7 understand the diagnosis and treatment of 8 disease we realize the complexity of patient 9 segments and we need to gather more phenotypic 10 data than before. There's an increasing view that personalized medicine will not be 11 12 answered through genomics alone, but we need -- we understand by obviously combine genetics 13 and genomics with phenotypic data, that's 14 where the observational registries play a very 15 16 important role. 17 Secondly, there is the continuous 18 growth of the treatment options for patients. 19 And we need to find ways of understanding who 20 should have what. If we were trying to 21 discover that through classical prospective 22 double-blind studies that would take forever

Page 86 1 and therefore these registries turn out to be 2 a very important tool by which we were able to match treatment alternatives to patient 3 4 segments, patient cohorts. 5 Thirdly, the healthcare system is changing very rapidly. There are new players 6 7 The Nordic in Sweden is coming in. 8 privatization happening. There's concern that 9 there will be slippage of indications for 10 elective surgery for instance. Therefore PROMs have been seen as a very important tool 11 12 to make sure that we don't treat in ways that don't benefit the patients. 13 And finally, and that's the point 14 I often made above, the individualized 15 medicine need, this is seen as a very 16 important contribution or tool as well. 17 On the slide after that I've just 18 19 summarized a set of points to illustrate that 20 there is a national organization for payers in 21 That organization has defined as one Sweden. 22 of its top strategic priorities to promote the

	Page 87
1	use of PROMs in Swedish healthcare.
2	So they brought together a group
3	of highly qualified experts who are advisers
4	to the registries who are seeking to develop
5	PROMs to make sure that that's done the proper
6	way through a dialogue with other colleagues
7	who have experience from it, and that the
8	validation models, et cetera, are thought
9	through properly so that the data can be
10	interpreted correctly.
11	I'm not either an epidemiologist
12	nor a statistician so I will not be able to
13	answer questions about the methodologies used
14	for validation here, but as I understand it
15	this is a well-equipped team that's supporting
16	the registries to do the right thing.
17	The next page, page 4, illustrates
18	the types of PROMs which are being used to the
19	right of the graph with the dark green color.
20	We've grouped the PROM categories into four.
21	And as you see roughly somewhere between 40-60
22	percent of the registries use PROM. And more

	Page 88
1	than half of the registries use at least one
2	of these categories of PROM measures in the
3	surveys they have to patients. So, both
4	activities of daily life, the patient
5	perception of the symptoms they have, general
6	satisfaction measures as well as quality of
7	life measures are being used. Often some of
8	the standardized tools, international tools,
9	in many cases but some cases these are unique
10	for the particular disease and thus specific
11	for the registry question.
12	On the next page, page 5, I just
13	wanted to illustrate something that we've seen
14	also internationally. I'll come back to that
15	when we look at PROMs in registries across the
16	world. That is differences between segments
17	of medicine.
18	The orthopedic registries were
19	some of the first ones in Sweden. A hip
20	arthroplasty registry was founded in 1979.
21	Cancer registries were also quite early. But
22	it is interesting to note that, it shouldn't

Page 89 1 be surprising maybe, but the orthopedic 2 registries have quite early on invested quite heavily in PROMs and more so than in most of 3 the other disciplines that we have represented 4 5 on this and the next slide. It is interesting that in the 6 7 cancer field even for cancers such as breast 8 cancer where a very large number of the 9 patients treat, you know, nowadays survive for a long time PROMs are very uncommon. 10 And we've seen that globally when we've looked 11 12 through cancer registries in many countries. 13 Here the survival data completely 14 dominates and even the -- if the patient survives and many do in some cases, you know, 15 16 these quite heavy treatments we're not really 17 following up how that influences the activity 18 of daily life short- or long-term. And I do 19 think that if we want to have -- our view as 20 advisers to the drug industry for cancer drugs 21 is many of the innovations do not necessarily 22 extend the length of life but may have

Page 90 radically better outcomes in terms of other 1 2 consequences for the patients. And we're not really looking at that in most of the 3 registries. And here we think adding some of 4 5 the PROMs for some of the conditions will be important in order for the pharma community 6 7 for instance to drive innovation in a way that 8 also benefits the patients beyond survival. 9 We can skip the next page. Ιt 10 just shows a set of therapeutic areas that we've -- in Sweden and the degree to which 11 12 they use PROMs, and move over to page 7. We have over the past year initiated an effort 13 14 together with Michael Porter and the 15 Karolinska Institute formed something we call the International Consortium for Health 16 17 Outcomes Measurements, ICHOM. 18 This is a not-for-profit effort 19 that will be launched first of November this 20 And what we've done there is we have vear. 21 gathered the measures from 55 registries 22 across 16 conditions around the world, and in

	Page 91
1	a very systematic way organize those measures
2	to make it easy for clinicians around the
3	world to be able to search and compare what is
4	being measured across different diseases and
5	then across geographies.
6	The intent of it is by having
7	chosen registries that are perceived to be
8	leading for, you know, this limited set of
9	conditions we want to make it easy for
10	clinicians who want to start measuring to
11	choose measures that others have chosen and
12	validated and where there are large amounts of
13	data so they could easily start comparing
14	themselves to others.
15	So the intent of this effort is to
16	contribute to a standardization of what we
17	measure disease by disease, and therefore
18	contribute to a general standardization of the
19	way we look at outcomes and thus allow the
20	medical community across borders to an
21	increasing extent compare identify best
22	practice, compare results, identify best

	Page 92
1	practice and share that and thus drive the
2	development of clinical practice forward much
3	faster than will happen if we don't have these
4	measures and are enabled to compare apples
5	with apples.
6	If I could I won't dwell longer
7	on that but will be happy to could be a
8	topic for a separate discussion. But we, this
9	is a very exciting effort and we can talk more
10	about that if somebody has any questions.
11	But this particular slide
12	illustrates some of the PROMs that we have
13	pulled together and which ones are used, which
14	instruments are used for some of the different
15	registries we've looked at. You see for
16	instance the Swedish spine registry, Swespine.
17	We have the Singapore General Hospital low
18	back pain registry. There's a Norwegian
19	arthroplasty registry, et cetera. They're all
20	using EQ-5D for some of the PROM measurements
21	they do.
22	You see that the same registries

	Page 9
1	also use other instruments and there is a fair
2	amount of variation. We hope that
3	transparency on this will allow for comparison
4	discussions and maybe ultimately a larger
5	degree of standardization making comparison
6	across diseases and geographies easier.
7	The final two slides I wanted to
8	show you are the question of so how is this
9	being used, how are these PROMs being used.
10	Do they really influence clinical practice or
11	not? And one of the registries there are
12	two registries I'll talk about. The first one
13	is for hip arthroplasty, the other one is for
14	rheumatoid arthritis.
15	The hip arthroplasty registry
16	started using PROM protocols in 2002 and it
17	came about because of the fact that they had
18	registered for many, many years the duration
19	of the hip arthroplasty. So, and found
20	surgical techniques and medical devices which
21	led to much longer survival rate of the
22	implant and thus higher degree of satisfaction

3

Page 94 1 of the patient. 2 But it took maybe 10 years to optimize that and then they've had 3 difficulties in improving further. So they're 4 5 now turning to say we've taken innovation and 6 development of the surgical technique as far 7 as we can. How can we improve the health of 8 the patient further? And of course the indication of 9 10 hip arthroplasty is that you have, you know, pain or you are unable to function normally. 11 12 You are impaired quality of life and yet the measurements, quality measurements have often 13 14 been the more mechanical one, whether the 15 implant has a long survival time or not. So in 2002 they started looking at 16 17 And without going through the details PROMs. 18 there was a THA thesis published 2 years ago 19 about the PROMs. I spoke Friday met with the 20 leader of the registry and discussed a bit of 21 this with him. 22 One of the observations they've

	Page 95
1	made which is very interesting is that there
2	is a strong correlation between the mental
3	status of the patient preoperatively and the
4	degree to which they find that the surgery has
5	become better or has led to significant
6	improvement of their health. We've of course
7	seen that in other conditions in medicine but
8	here numerically it's become quite clear.
9	They've also found that if a
10	patient has been taken off antidepressive
11	antianxiolytic drugs prior to surgery well
12	then the outcome post surgery is also worse.
13	So what they're doing now is
14	they're translating some of the data into
15	decision support to try to help the surgeons
16	customize the treatment depending on the
17	profile, pre-surgical profile the patient has,
18	and to make sure that the outcome in terms of
19	quality of life and functionality is
20	significantly better. So the PROMs turns into
21	a decision support tool for the clinicians in
22	order to optimize the outcome beyond the more

classical outcomes looked at. The next page and the final one is from the rheumatoid arthritis registry that quite early also started using PROMs in 1996. They have taken this further than any other registry in Sweden and earlier. It fully integrated the PROMs into the registry. Every patient fills in a set of questions prior to visiting the doctor. In the doctor's office the results from the registry are visibly seen graphically and the patient gets immediate feedback as well and can see how the functionality has changed over So it becomes a disease management, you time. could say a support tool for the patient. Ιt increases their disease awareness at the same time as it allows the physician to be more effective during the patient visit by having seen what the patient has reported in the balance of the interview, the meeting. The PROMs in this registry, you

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know, has led to generally a much more

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	Page 97
1	holistic view on the disease. It has raised
2	the patient's knowledge and influence over the
3	treatment and enabled them to influence the
4	choices to be made.
5	It's actually also, because it's
6	been done in a very rigorous, scientifically
7	sound manner actually increased the status of
8	the subjective dimensions of rheumatoid
9	arthritis discussion or diagnostics within the
10	physician community. So it's now seen now as
11	a very beneficial way of contributing to
12	better clinical outcomes.
13	And finally, it's the results,
14	the outcomes, the PROM-based outcomes is also
15	leading to changes in resource allocation so
16	that more resources are placed in some of the
17	subcategories of patients. And they're
18	classified partially through the PROMs now
19	which contributes to the choice of
20	pharmaceutical intervention which has been
21	shown to lead to a better outcome and thus
22	more productive use of some of the expensive

Page 98 drugs that you have as treatment alternative 1 2 for this patient group. So I'll stop here. 3 I wanted to provide you with an overview specifically from 4 5 Sweden where there are more registries than in any other country in terms of high coverage 6 7 registries where PROMs have been used for 8 quite awhile. 9 And I think we're seeing some very exciting examples of how it leads us into not 10 only continuously improving clinical practice 11 12 but also serving as an online decision support 13 tool to the clinicians as well as a tool to 14 help patients manage their disease. And thus 15 contributing to more efficient care while at 16 the same time improving the outcomes and the 17 quality of care. 18 So I'll stop there and open for 19 questions. 20 DR. PAWLSON: Thank you. You 21 know, two quick observations. One is isn't it 22 striking that we're just getting around to

	Page 99
1	including the patient perspective on diseases
2	that are defined by patient symptoms and
3	patient functional status in terms of
4	outcomes.
5	And the second is I have this
6	vision dancing in my head of orthopedic mental
7	health teams collaborating.
8	(Laughter)
9	DR. PAWLSON: That may be a little
10	farfetched. Questions specifically for
11	Stefan? And then we'll open it up for general
12	questions. In the back, all the way in the
13	back on the right then I'll move this way.
14	DR. SALIBA: Hello, this is Deb
15	Saliba from Los Angeles, UCLA VA and RAND. I
16	think it's phenomenal what you guys have done
17	to use your data and to take a look at it and
18	ask questions about improvement and what's
19	been driving improvement and why you've seen
20	a flat line in some areas of improvement.
21	One thing you may want to think
22	about when you're looking at arthroplasty, I'm

	Page 100
1	not seeing a whole lot about post-acute care
2	or rehabilitation issues. And I completely
3	agree that mental health is really important
4	but I think you also want to look at what's
5	happening in that recovery period.
6	DR. LARSSON: Yes, that's
7	absolutely right. Today reimbursement is
8	increasingly looking at the 2-year period and
9	the outcomes achieved in that 2-year period is
10	what some of the prior providers are being
11	paid for. That of course includes the whole
12	recovery phase and it provides a strong
13	incentive to do not only the surgery well and
14	avoid surgical infections but actually be very
15	early on in mobilizing the patient.
16	I think that what the registry
17	allowed to do quite early was to, you know, to
18	at the same time as you put the RG system in
19	place you have the registries in place. So
20	the length of stay for hip arthroplasty
21	patients is extraordinarily short as I think
22	it is in many places in the U.S. But it's

	Page 101
1	been demonstrated through the registries that
2	that early mobilization has many advantages
3	and not the opposite. So absolutely, the
4	patient part is absolutely an element of what
5	they measure that didn't show that properly.
6	DR. WU: Yes. Hey, Stefan.
7	Albert Wu.
8	(Comment in Swedish)
9	(Laughter)
10	DR. LARSSON: Nobody has
11	understood that, but that was Swedish.
12	(Laughter)
13	DR. WU: Oh sorry, I forgot where
14	I was.
15	(Laughter)
16	DR. WU: I think this is fantastic
17	and I wonder if you could give us some
18	examples or if there have been examples where
19	you have used PROMs to compare one institution
20	to another since you have such good coverage,
21	particularly for some conditions.
22	DR. LARSSON: Let me see. I think

in the rheumatoid arthritis registry seen big differences between centers they have what they have achieved And the registries take a fairly act: in not only making the data public. they each there are roughly I thin many of the registries somewhere arou hospitals involved and much of the data	
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<ul> <li>6 they each there are roughly I thin</li> <li>7 many of the registries somewhere arou</li> <li>8 hospitals involved and much of the data</li> </ul>	You know,
<pre>7 many of the registries somewhere arou 8 hospitals involved and much of the data</pre>	nk for
8 hospitals involved and much of the da	und 70
	ata is
9 made publicly available today. So no	ot only
10 can you see where you are yourself bu	it you see
11 where all your peers are.	
12 So, the outliers typical	ly will be
13 contacting those and have those with	ith poor
14 results contact those who have very g	good. And
15 for some of the PROMs in the rheumato	oid
16 arthritis registry there have been be	ig
17 differences between centers. And that	at
18 typically leads to a dialogue where t	they then
19 figure out what to do to improve.	
20 I can't give you an examp	ple of
21 specifically what those, you know, ex	camples of
22 those measures but I have heard sever	

	Page 103
1	examples were cited that the big differences
2	that are leading to learning across and
3	changes in clinical practice.
4	DR. BASCH: Hi Stefan, it's Ethan
5	Basch at University of North Carolina. Nice
б	presentation.
7	To Albert's question because I
8	think that actually is, it's a really
9	important question. So the Swedish Rheumatoid
10	Arthritis Quality Register collects data at 64
11	clinics and it actually looks at change scores
12	over time and compares them between those
13	clinics. It looks at swollen joints, tender
14	joints, EQ-5D and a couple of other measures
15	of functional status.
16	But to my knowledge that's the
17	only one of the registries that's really
18	actively been comparing between practices.
19	And I think it really highlights the
20	difference between using registries for
21	effectiveness research versus performance
22	assessment.

	Page 104
1	There are lots of registries that
2	use PROs but they haven't explicitly been
3	designed to compare performance either within
4	or between practices. So I think the
5	challenge here is to take some of the
6	techniques that have really been honed in CER
7	and various contexts and bring them into the
8	performance improvement setting.
9	Nice presentation. Thank you.
10	DR. PAWLSON: Very good point. I
11	think we'll open up now to all the
12	presentations. So if you can just direct your
13	questions on who and we'll go to the back
14	there and then we'll move forward.
15	DR. GAGE: Thank you, Greg.
16	Barbara Gage from Brookings.
17	A little bit of a follow-up on
18	Ethan's point. In thinking about that was
19	a very nice presentation and in thinking about
20	the use of performance measures for payment
21	policies and some of the monitoring that
22	happens in a regulatory nature, Stefan, could

Page 105 1 you say something about the discussions that 2 occurred regarding holding a provider or a clinician responsible based on the patient-3 reported outcomes relative to the clinician's 4 5 assessment of those outcomes? That's been 6 kind of a critical issue over here in the 7 States. DR. LARSSON: 8 Well, first of all 9 there's been no reimbursement linked to the 10 outcomes of the registry so far. There are some early events that are happening in 11 12 Stockholm that have actually been so far no reimbursement, you know, difference linked to 13 14 the performances. Sorry, I lost part of your 15 question. Could you repeat that? 16 DR. GAGE: Sorry about that. The 17 question had to do with the discussion even in holding -- even in using the registries in 18 19 order to make the decisions about the 20 treatment options to --21 DR. LARSSON: -- to the physician 22 responsibility. Yes. So, what the view is in

	Page 106
1	many of the registries that use this is that
2	the team treating the patient has a very
3	essential role to play in ensuring that the
4	patient reports satisfaction or that the
5	functionality for a newly operated hip joint
6	patient, et cetera, is high.
7	In discussions with the hip
8	arthroplasty registry, they clearly see that
9	as a failure on their part if the patient is
10	not reaching the target levels of satisfaction
11	and physical function that they had set out.
12	So there is no responsibility in legal terms,
13	that's obviously of big importance in the U.S.
14	because we don't have the litigation component
15	very much at all in the healthcare system, but
16	it is more from a professional integrity and
17	peer pressure point of view very important.
18	And you're seen as in charge of making sure
19	that the team, be it rehab team or others who
20	or physical therapy teams that will
21	contribute to your reaching the functional
22	target. You as the physician are seen as

Page 107 responsible but not in a legal sense. 1 I hope 2 that answers your question. I wanted to compliment 3 DR. LOHR: 4 all three of the speakers, I thought they were 5 terrific presentations. And this question is directed at any of you who might care to 6 7 answer. And it has to do with, say, 8 feasibility and usability and costs. And I'm 9 curious whether any of you have any information that would tell us something about 10 the administrative burden, the burden on 11 12 patients, what these systems cost for getting this kind of information. 13 14 And sort of moving on from that set of questions to whether anybody has ever 15 really tried to look at the cost-effectiveness 16 17 of doing this. I mean, we're all here because 18 we believe passionately perhaps in using 19 patient-reported outcomes and so forth but 20 lots of people are more skeptical and I'm 21 curious whether there have been -- any 22 analyses of sort of the cost-effectiveness,

Page 108 the return on investment of doing this kind of 1 2 effort. Thanks. MR. NUTTALL: It's David here. 3 Ι 4 can have a stab at that if that helps. In 5 terms of from my experience --6 DR. PAWLSON: We just --7 MR. NUTTALL: Hello? 8 DR. PAWLSON: We're losing our 9 foreign end. Not so foreign speakers. 10 MR. CUNNINGHAM: Are you still on the phone? 11 12 MR. NUTTALL: Yes. Okay. So David or 13 DR. PAWLSON: 14 Stefan or Liz, would you address that issue? 15 DR. LARSSON: David started I 16 think, at least I heard him well. 17 MR. NUTTALL: I'm not sure how 18 much you got. I'll have another go. I'11 19 keep it short. But I'll just say from my 20 experience that I think the cost question is 21 probably going to be contingent on the nature 22 of the system in which you're trying to
Page 109 1 collect this data. 2 So, in England, in the NHS we make the collection of this data a mandatory 3 requirement. It's a contractual term that 4 5 anyone that's providing NHS-funded services must collect this data as, you know, a term 6 7 and condition of doing business with the NHS. 8 So, in terms of the burden around administering a preoperative questionnaire, 9 10 that falls to the provider. We have done some work to have a 11 look at what that burden is and to be honest 12 I think it's correlated highly with let's say 13 14 the quality of management of the institution. So, some providers tell us this is trivial, we 15 fit it into existing practice, it takes no 16 time at all. Others tell us you know they had 17 18 to appoint a senior manager to oversee the 19 entire process. 20 And so the kind of cost of that 21 side of it go hand in hand with how 22 complicated they've made the administration

	Page 110
1	method. I think the message would be it can
2	be done very light touch and easy.
3	And then the way we have
4	implemented the actual collection of the data
5	and the processing is to do that through an
6	outsourcing contract. And I think it's
7	while I can't go into the detail in terms of
8	unit costs of that contract I think it is fair
9	to say that over time as people have
10	understood the "ask" a bit better and
11	understood precisely how to collect and
12	process information, then the unit costs are
13	falling. As people become more familiar with
14	what's required we learn how to iron out some
15	of the bit that we put into specifications
16	which perhaps are less necessary and we've
17	streamlined the collections and so on and so
18	forth.
19	So I think burden is dependent on
20	how it's implemented. I think costs are
21	dependent on the nature of the system which
22	are implementing it, and I think over time

	Page 111
1	those costs will come down.
2	DR. PAWLSON: Stefan or Liz?
3	DR. LARSSON: Yes. The situation
4	in Sweden is similar to in Great Britain. The
5	majority of healthcare is publicly delivered
б	and publicly funded. But even now that the
7	privatization is growing quite rapidly
8	contributing with data to the registries is
9	compulsory for the private providers as well.
10	It's part of the contract that you have to
11	submit the data. And it becomes part of the
12	quality control also of the private providers.
13	The costs involved have been you
14	could say hidden in the monthly salaries of
15	the staff. It's been seen as one of the tasks
16	of team members to gather the data and submit
17	the data. And there have been some
18	calculations done as to so how much is that
19	all in all. We've seen some of those. I'm
20	not sure they're accurate.
21	The specific funding that's come
22	from the government to support these efforts

Page 112 1 were very, very small. You know, at the time 2 a couple of years ago when we did our first study on this there was 6 million Euro being 3 paid by the government to the registries which 4 5 supported some staff across some 65 6 registries. 7 We did a business case for the 8 government on this and said you should at least fivefold this allotment to make sure the 9 10 registries are sufficiently staffed and that IT platforms are being built appropriately, et 11 12 So now the -- and the decision was cetera. taken by the government to do so. So this 13 14 year the budget is 20 million Euro and it's 15 growing to 30 million over the next year or 16 two. 17 But that's still a quite, you 18 know, small amount of money. So much of the 19 time is in fact salary time paid by the health 20 system as such. 21 When it comes to the return on 22 investment, you know, one of the things that

Page 113 1 PROMs would allow you to do is to look at the 2 appropriateness of care. And we have a team currently looking at the U.S. healthcare 3 system from the point of view of if it was 4 5 managed more on outcomes and value what would 6 be the savings. 7 I would argue that it would be 8 hard not to have a business case that would be 9 convincing for PROMs when you compare the healthcare cost in the U.S. and the outcomes 10 compared to other OECD countries. 11 T'm 12 absolutely convinced that the business case would be staggering. I don't know if that's 13 14 the right word for it -- that's the word that 15 comes to mind. 16 But there is, I mean a challenge is data-gathering is done by clinical staff 17 18 that are pressed for time and who if they 19 spend time gathering data like this would see 20 one or two fewer patients a day which is where 21 the bread comes in. So the challenge will be 22 not that the business case overall from a

Page 114 1 societal payer point of view wouldn't be 2 convincing, it would be to motivate finance to gathering of data and to motivate the 3 clinicians to do so at the expense of 4 5 potentially seeing fewer patients and reducing 6 revenues. So I think that's one of the key 7 hinges here. 8 And finally, I think it would be 9 key to make sure that the data-gathering is as 10 simple as possible, that some of this is integrated into the electronic medical record, 11 12 some of it is web-based, automated as David described in his presentation is happening 13 14 over in the UK. And in Sweden that is 15 happening but it's been reasonably slow. So it's actually taking a lot of time from 16 clinicians to gather the data so far. 17 But I think the business case 18 19 would be absolutely convincing, you just need 20 to find the -- move money from one place to 21 another in order to fund it. 22 DR. PAWLSON: The point you just

i i	
	Page 115
1	made I think is really important to keep in
2	mind, and that is the extent to which this
3	information is really critical in treating the
4	patient. And I think a reasonable amount of
5	it is, or at least should be. It's nice to
6	know what our outcomes are.
7	I think we can probably take two
8	more questions. So, here.
9	DR. FRANK: Hello, this is Lori
10	Frank. I'm with the Patient-Centered Outcomes
11	Research Institute. Thank you all for those
12	presentations.
13	My question is a follow-up to the
14	last question about optimizing use of
15	collection of these PROMs. In what ways is
16	the full value of the PROMs being recognized
17	in terms of their value for direct-to-consumer
18	communication? So, you know, for David I know
19	there's some efforts with regard to choice and
20	for Liz, I'd be interested in hearing more
21	about the rating scale and how that's
22	communicated and how PROMs play into that.

	Page 116
1	DR. PAWLSON: Okay, Liz, you want
2	to address it first and then David?
3	DR. GOLDSTEIN: Sure. So for the
4	Health Outcomes Survey we've made these
5	outcome measures very prominent in our system,
6	or at least prominent in our calculations of
7	our overall rating for a health plan. So,
8	these measures receive our highest rate as an
9	outcome measure. So, we're trying to convey
10	to the public that this is really critical
11	information, actually, one of the most
12	critical pieces of information in our rating
13	system.
14	We encourage we do a lot of
15	testing of our displays for Medicare
16	beneficiaries. And so it's really hard to get
17	them to drill down to this detailed
18	information. Some of them are really
19	information gatherers and go down to the
20	details a lot, just use that overall rating
21	and ignore the details below it.
22	But something at least CMS is

	Page 117
1	doing a lot of work on as well as doing more
2	research about how to get people to drill down
3	and really see the value of these measures as
4	well as the other measures included.
5	DR. PAWLSON: Thanks. David?
6	MR. NUTTALL: I think certainly
7	with our program we have a challenge in terms
8	of making best use of this data and conveying
9	it to patients. I think when we set up the
10	program our thought was that the data would be
11	used primarily by patients to help them make
12	informed decisions about where to go and we
13	would publish it via website and we would go
14	from there.
15	And I think actually the key piece
16	of learning has been that the main audience
17	for the data at the moment other than kind of
18	managers of organizations looking at the
19	aggregate stuff is the clinical teams who want
20	to have much greater access to the
21	disaggregated data so they can have a look at
22	which dimensions their patients are doing

	Page 118
1	particularly bad in, you know, is that pain,
2	is it to do with pain control, and so on and
3	so forth. So, I think that's been a really
4	important learning point, that it's the
5	clinical teams that has the bigger oversight
6	than patients in the first instance.
7	And I think the other learning
8	point was that we have a lot of work to do to
9	try and convert EQ-5D profile scores, EQ-5D
10	index scores into meaningful information for
11	patients that's kind of digestible. I think
12	aggregate scores saying one is better or worse
13	than the national average is probably fine but
14	turning in a kind of 2.7 percentage point move
15	on the EQ-5D index is kind of meaningless to
16	a lot of people. So that is a challenge I
17	think.
18	DR. PAWLSON: Thank you. Steve?
19	DR. LARSSON: If I could just
20	comment
21	DR. PAWLSON: Sure.
22	DR. LARSSON: on the way it's

1	Page 119
T	been used in Sweden. You know, the data has
2	been public but oftentimes the data has, as
3	David said, very complex to interpret. And I
4	think an effort to just broadly disseminate
5	this information I think would be completely
б	confusing to patients. And in order for it to
7	be a useful tool we, clinicians need to spend
8	time making sure that we help with the
9	interpretation of it so it becomes meaningful.
10	So I think the specialist societies play a
11	very important role here in making it
12	available in a way that makes it useful for
13	patients.
14	We just did a survey across 9
15	nations for 1,000 consumers randomly picked in
16	each country. And it turns out that clinical
17	outcomes is the determinant that patients
18	primarily want to see in their choice of
19	medicine. It's often been viewed that
20	proximity and a hospital close to home is
21	important but it's clear that patients don't
22	have access to the information but when the

	Page 120
1	question is asked if you had access to high-
2	quality information what of all these
3	variables would you be using, would be most
4	important to you, and by far clinical outcomes
5	comes out as the measure they want to have
6	access to. So I think we would do medicine as
7	well as the public safer by helping package
8	that in a good way.
9	In some cases media has done it
10	reasonably well with, you know, scientific
11	journalists who understand enough of medicine
12	to make sense of the data. But there can
13	often be errors there as well.
14	DR. PAWLSON: Steve.
15	DR. FIHN: I think this question
16	is directed mostly to David but perhaps Stefan
17	could respond as well. I'm curious about the
18	extent to which you've been able to evaluate
19	whether implementing the PROMs has changed the
20	case mix of patients who are undergoing the
21	procedures. You could think about changes
22	that would be both in a positive and negative

	Page 121
1	direction. And I'm just curious the extent to
2	which that front end part has been evaluated
3	as well as the sort of change and outcome
4	piece.
5	DR. PAWLSON: And that was Steve
6	Fihn from our VA.
7	MR. NUTTALL: It's a good
8	question. To be honest I don't think we've
9	done a huge amount of work to have a look at
10	changes to, you know, as you suggest the case
11	mix which is going through. I think there's
12	probably a couple of points I'd try to make
13	there.
14	One is I think, you know, although
15	it has been running for some time since 2009
16	I suspect it may be too early to tell in terms
17	of it's only really it feels that now, kind of
18	3 years later that we're getting a lot of
19	traction with people looking at this data in
20	a very serious way and using it to kind of
21	think about clinical practice.
22	So it's almost like the first

	Page 122
1	couple of years were just embedding the
2	collection and getting it firmly lodged into
3	people's minds as a valid data collection
4	tool. So it may be too early to kind of do
5	that kind of analysis although it is feasible.
б	I think the other sort of factor
7	to bear in mind with all of this is the impact
8	of the general impact of the economy in terms
9	of our funding of interventions. There's a
10	line of argument which is that we will be
11	irrespective of the data set we would be
12	seeing the more severe cases going through now
13	as commissioners decide to or implicitly or
14	explicitly put more stringent referral
15	criteria on. And I think that's something
16	that we could look at in time.
17	And then the only other kind of
18	final, final point on that would be I think
19	what we have seen is that on average the mean
20	scores have gone up over those 3 years. And
21	so that would be consistent with either
22	quality of care going up which would be great

1but that's a short period of time for that to2happen in, or that we're actually focusing on3the cases where there's most potential4clinical benefit. So that's not really a full5answer, more just a set of things to think6about I guess.7DR. PAWLSON: And Stefan, do you8have a quick comment on that?9DR. LARSSON: I can't say that10it's influenced case mix to my knowledge. I11know one of the observations done in the12rheumatoid arthritis registry was the13observation that smokers turn out to much less14responsive to TNF-alpha inhibitors. I think15that piece of information came through the16PROMs. That clearly led to changes in the17prescription pattern for those patients. So18I think that might be an example but it's not19the typical PROM measure either. So I would20have to look into that.21DR. PAWLSON: Well, on behalf of22everyone here I'm sure thank you so much for		Page 123
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22 everyone here I'm sure thank you so much for	21	DR. PAWLSON: Well, on behalf of
	22	everyone here I'm sure thank you so much for

	Page 124
1	your really excellent presentations.
2	(Applause)
3	MR. NUTTALL: Thank you very much,
4	it's been a pleasure.
5	DR. LARSSON: Thank you.
6	DR. PACE: David and Stefan and
7	Liz, thank you for joining us. And you're
8	welcome to stay online and listen as long as
9	you like but we're going to take a short break
10	here. And again, thank you so much for taking
11	time out to share your experiences with us.
12	We'll take a break now and try to
13	limit it to 10 minutes. We'll reconvene the
14	next panel at 11:25.
15	(Whereupon, the foregoing matter
16	went off the record at 11:13 a.m. and went
17	back on the record at 11:28 a.m.)
18	DR. ADAMS: Okay, so our next
19	panel is going to be on a recap of the key
20	characteristics for selecting PROMs for use in
21	performance measurement. First I'm going to
22	introduce our panel to you but if you recall

Page 125 1 from our first workshop we spent quite a bit 2 of time on these characteristics and also 3 everyone was sent out a survey because staff took an attempt to distill that information 4 5 which was very rich. So we're going to have a chance to 6 7 do a bit of recap not so much to spend time on 8 the first workshop but to really use this as a springboard for our discussions as we take 9 deeper dives into discussions around 10 reliability and validity. 11 12 So I did want to introduce our 13 panel for this session. My colleague, Karen 14 Pace, who is our evaluation methodologist 15 expert here at NQF. And Karen's going to for 16 each panel you'll see she's going to go through in a bit more detail the NOF 17 endorsement criteria and how this relates. 18 19 And of course what we're going to 20 be asking from you and including our audience 21 and those listening on the line is what are 22 some considerations we might need to take in

	Page 126
1	regards to PRO-based performance measurement.
2	I'm also pleased that Liz Mort is
3	joining us from Massachusetts General Hospital
4	and Laurie Burke from the Food and Drug
5	Administration. Regrettably, Jennifer Eames
6	who was also going to be on the panel could
7	not join us today. She does send her regrets
8	but Patti Brennan is going to fill in for her.
9	So, I want to thank our panelists for the prep
10	that really helped shape this and for their
11	contributions during the session.
12	So I'm just going to get started.
13	If we could have the next slide, please. So,
14	we're always going to touch back to this
15	terminology. As Joyce said earlier, the terms
16	we use of course are important. And here
17	we're going to be talking about the
18	characteristics that you had identified for us
19	last time from a PROM which is an instrument
20	or scale to a PRO-based performance measure,
21	a PRO-PM.
22	And as we think about the entire

	Page 127
1	day we're building a pathway. So we have a
2	schematic representation that was sent out in
3	your handouts. We have a color version at
4	your seats. But what we're trying to do very
5	pragmatically is build this tool or these
6	building blocks as we think of how we would go
7	from a PROM to a PRO-PM. So we're keeping
8	that in mind as we go. So if I may have the
9	next slide, please.
10	So I'm going to do a little bit of
11	history. At our last workshop, the expert
12	panel, we discussed what I would consider the
13	highest leverage characteristics for
14	identifying PROMs which are most ready for
15	prime time as we start to think about
16	performance measures.
17	And I think that there was general
18	consensus that the psychometric properties
19	that were very elegantly detailed in the paper
20	with David Cella and colleagues was really a
21	baseline. And so David, allow me to thank you
22	and your team for the terrific work you did on

1	
	Page 128
1	the paper but also from the last workshop,
2	some really great discussions.
3	So we felt that what we're calling
4	affectionately it was Table 4 in your handout
5	really was a very good baseline for us.
6	However, I think that the discussions last
7	time really offered some very helpful
8	guideposts. You know, what do we hold true
9	particularly as we think about moving this
10	into accountability type of programs.
11	And so from that rich discussion
12	the NQF staff I say this humbly because we
13	got such great feedback we tried to distill
14	that into some additional statements which you
15	provided input on. And those were sent out to
16	you and you completed a survey saying, you
17	know, did you agree, did you agree with some
18	modification or did you disagree.
19	From a survey perspective we're
20	very pleased with the response rate, over 70
21	percent from our expert panel so thank you
22	very much. And I think particularly since

	Page 129
1	this was done during holiday time at end of
2	August I thank many of you for doing that from
3	your vacations.
4	So today we're going to really
5	spend time on refinement of these
6	characteristics, and I think in particular
7	looking at this in relationship to the NQF
8	endorsement criteria. And I think from my
9	perspective having done some of the synthesis
10	here with our team these are very mutually
11	reinforcing. So I'm going to ask for the next
12	slide.
13	So, if you'd like to look along in
14	your handouts that you received we provided an
15	attempt to do some redline edits to the
16	statements. And we had statements around
17	actionability and meaningfulness and
18	facilitating shared decision-making and
19	implementableness.
20	As opposed to going through the
21	redlines at this time we really wanted to
22	focus on the high-level concepts and of course

Г

Page 130 our reactor panel here will be helping us. 1 2 And as we said, terms and words are important. So as we go throughout the day we will further 3 refine these statements. 4 But I thought it 5 would be important to share back some of the 6 comments that were received and some of the 7 themes that converged around this survey data. 8 And I hope that we've captured 9 your voice adequately but I know that you'll 10 be able to help us out here. But I think in this theme around actionability it's this 11 12 notion that key end users, and importantly patients and persons and providers and systems 13 14 should be motivated by the PROM to lead 15 improvement. And this thing of amenable to 16 17 change or would this spur, but I think this was an important theme, particularly in the 18 19 written comments that came through. Also, 20 that the evidence should indicate that care 21 can be improved in a relatively short time 22 period for the patient respondents. So we're

	Page 131
1	always taking our patient- and person-centric
2	view and that there should be value with this.
3	And many felt that this was very much linked
4	to our meaningfulness criteria. So many of
5	these characteristics aren't mutually
б	exclusive but I would say mutually
7	reinforcing.
8	Also, it was pointed out that
9	certainly randomized control-level information
10	or evidence is critically important, but that
11	we should, and particularly when we're looking
12	at this now and in our early stages take into
13	consideration a range of evidence. And
14	certainly what we're doing now with expert-
15	based opinion, face validity, other things
16	that those would also be important things to
17	consider. I think we had this discussion last
18	time, that certainly evidence is along a
19	continuum and it needs to be applied
20	appropriately to what's being examined. So,
21	but this was reinforced with several of your
22	comments so I did include it here.

	Page 132
1	And then this was a very
2	enlightening comment for me. I think that we
3	touched on this a little bit but I welcome
4	additional insight here. It's that some
5	outcomes are worth measuring that might not be
б	amenable to change by providers but patients
7	need to make informed decisions and it could
8	be quite useful to them. And so some of the
9	examples were given were pain after
10	intervention and functional status and
11	treatment.
12	And because I spoke with Jack
13	about this earlier I'm going to tee him up for
14	that. And I thank you for raising that for us
15	because I think that is it's beyond a
16	nuance and I'd love for us to have a bit more
17	further discussion on that.
18	And so these are the key themes
19	from our first area around actionability.
20	We're going to go to our next area in the next
21	slide and meaningfulness.
22	And when I looked at the

	Page 13
1	qualitative comments that were provided we saw
2	lots of intersections with meaningfulness and
3	burden, and in particular burden to
4	respondents and administrators, and the
5	implications for that.
б	In our chart that David Cella and
7	team very succinctly distilled for us burden
8	was called out as a characteristic in and of
9	itself. It raised to that level. But I think
10	Patti, you as well as others remind us but
11	also saw very strong connections to the
12	meaningfulness.
13	And when we think about the PRO
14	it's the concept that the PRO is capturing,
15	that it's we have to think about what the
16	PRO is capturing, not just the PRO itself.
17	And that it's important to include the
18	patient's perspective on the impact of the
19	condition or the treatment and this impact on
20	their life. And I think when Karen speaks to
21	the NQF criteria this certainly is something
22	that we'll touch on a bit more.

3

Page 134 1 I think many in our disability 2 community emphasize for us and we tried to capture that in the redlines but we welcome 3 further refinement here is that we often think 4 5 of things like health-related guality of life, 6 symptoms, et cetera, but that also we would 7 want to think of certain long-term care 8 service and supports that you would want to 9 capture that move us beyond an acute episode 10 of care and into our community support. So keeping in mind that we have been pushing 11 12 beyond the hospital walls. 13 And importantly that when we think 14 about perspectives that caregiver's 15 perspectives would be important to include as 16 well. 17 So I'm going to go to the next category. And this is the facilitate shared 18 19 decision-making characteristic that we would 20 like to apply to PROMs. Based on the comments 21 and naturally we welcome discussion here I 22 don't think that the respondents disagreed at

	Page 135
1	all. They supported that certainly shared
2	decision-making is a critical concept and a
3	critical process that needs to take place.
4	What there was some indecision and
5	so I put this forth simply to capture some of
6	the insights that were shared is that not all
7	performance measures need to facilitate shared
8	decision-making. This was a common theme
9	amongst a couple of the respondents. And so
10	if this is going to be a characteristic that
11	we apply universally is this something we
12	should consider. I put that forth. Obviously
13	this is up for discussion but since it was
14	raised.
15	And also there was a comment that
16	shared decision-making, not all patients want
17	this or it may not be evenly distributed, et
18	cetera. So are these things we need to take
19	into consideration.
20	And a couple of respondents
21	thought that this might actually have some
22	redundancy or duplication with actionability.

	Page 136
1	Once again, not to say that the respondents
2	firmly supported shared decision-making and
3	that this part of engagement is critical, but
4	just some considerations in that regard.
5	If you recall we, in some of the
б	discussions from last time we talked about how
7	there might be a how we might sufficiently
8	standardize some of these outputs and roll
9	them up to a population or accountable entity.
10	And some felt that saddling that only onto
11	shared decision-making wasn't quite fair
12	because really these aggregation issues apply
13	across all our PROMs.
14	But I think here it was, you know,
15	how do we since we want to look at
16	patient's preferences and things like that how
17	might we standardize that. Because you're
18	customizing but you need a level of
19	standardization. So, whether we should in
20	that statement not hang the aggregation issue
21	specifically on that because it is
22	crosscutting across all of these.

Page 137 And then you know, there was a 1 2 comment around is shared decision-making too broad, should we say that this is patient 3 4 engagement, that certainly patient engagement 5 and using PROs as a step. We can discuss that I think the important thing is that we 6 more. 7 wanted to bring out patient engagement and 8 shared decision-making. And there could be 9 certainly additional wordsmithing to the actual statement but where we stand on these 10 other issues is part of our dialogue today. 11 12 And then last but not least we had the criteria which I have difficulty 13 14 pronouncing but implementableness or is it -you know, when you're typing this stuff it's 15 like how do you -- is it -ability, is it -16 But anyhow, implementable. And so --17 ness. 18 That was a tongue-twister for me. thank you. 19 And you know, in this 20 characteristic I think we were trying to 21 capture a lot of things. We talked about IP 22 issues. We talked about many things. And so

Page 138 1 several respondents did say you're covering a 2 lot here and it may be hard to map to all these requirements. And what measure, not 3 only a PROM, could possibly meet all these 4 5 requirements. 6 But the important message is that 7 implementation issues and as we learned from 8 our prior panel are very critical and they should inform our decision-making. 9 And as we 10 look on our action pathway when we go from PROM to PRO we have number 5 which talks about 11 12 how do we implement this in clinical practice. 13 However, maybe this criteria we 14 might want to look at how we can streamline 15 Some felt it was already covered under this. the other topical areas of actionability and 16 17 meaningfulness. And then we kept wanting to 18 insert disparities because that was very 19 important to this group but some felt that 20 disparities were not indicators -- disparity-21 sensitive measures were not indicators of 22 implementability.

	Page 139
1	And then importantly it was raised
2	that we need to think about ease of fielding.
3	I think a lot of this gets into missing data
4	elements and things like that, but ease of
5	fielding this and testing it could have impact
6	on implementability.
7	So this is a quick synopsis of
8	your feedback. And then if we can go to the
9	next slide. Okay, great. Just wanted to make
10	sure we were at the last.
11	So, with that discussion it was
12	just a bit of a primer. We wanted to feed
13	back to you what we heard from the survey,
14	what some of the key themes are. We'll
15	continue to refine those statements over time.
16	We're going to discuss in this order. Liz is
17	going to speak with us about actionability,
18	Patti about meaningfulness and then Laurie
19	certainly last but not least but certainly
20	around the implementableness. And certainly
21	you have experienced that. But Karen's just
22	going to give us a brief overview of the

Page 140 intersections here with the NOF endorsement 1 2 Thanks, Karen. criteria. DR. PACE: Good morning. 3 So, what I'll be doing at each session is just giving 4 5 a brief overview of some of the criteria. Next slide, please. 6 7 So we'll be always -- next one. 8 There we go. So again keep in mind that NQF 9 does endorse the performance measure which we're referring to as PRO-PM versus the 10 instrument. However, our criteria, there's a 11 12 lot of overlap of how these things apply to 13 the data that are going to go into the 14 performance measure. So I'm going to just highlight some of the criteria that although 15 16 we're talking about performance measures also have an intersection with the PROM, the 17 instrument or scale. Next slide. 18 19 So, I'm just going to quickly 20 mention psychometric properties. We're going 21 to have three panels talking about that. But basically our criterion about scientific 22

Page 141 1 acceptability of measure properties 2 specifically focuses on reliability and validity. 3 And we do allow for testing at the 4 5 data electronic or the performance measure score. And we'll get into some of those 6 7 distinctions in the specific panels. But just 8 wanted to mention that we do have reliability 9 and validity of the data which would be from the PROM instrument or scale. And then we're 10 very interested in the reliability and 11 12 validity of that actual performance measure or the score that a hospital or a healthcare 13 14 facility would receive. Next slide. 15 So in terms of actionability we would see this falling under our major 16 17 criterion of importance to measure and report. And there's a couple of related sub-criteria. 18 19 One is a performance gap or opportunity for 20 improvement. And generally when we endorse a 21 performance measure we like to endorse 22 something where, you know, everyone's not

Page 142 1 doing well because we want to put our 2 resources for data collection, reporting, 3 analysis on those areas that are really going to push us forward in improving healthcare and 4 5 health. 6 But the key one here is our 7 criterion about evidence. We do under 8 importance to measure and report have a criterion about evidence. We say under this 9 10 criterion that the measure focus is a health outcome or it's evidence-based meaning that 11 there's evidence that links the structure, 12 13 process or intermediate outcome to a desired 14 health outcome. And when we're looking at 15 this evidence we're looking at the quantity, 16 quality and consistency of the body of 17 evidence. 18 And I want to emphasize that our 19 criteria do not require that this be 20 randomized controlled trials. Depending on

21 the focus of measurement and healthcare in 22 general there's lots of different kinds of

	Page 143
1	evidence but we are talking about empirical
2	evidence, not just expert opinion. Next
3	slide.
4	The reason we have "health outcome
5	or" and Helen mentioned this at our last
б	workshop, that we really have a preference for
7	health outcomes. And we think that health
8	outcomes by their nature have a special place
9	in terms of performance measurement because
10	that's the reason for providing healthcare
11	service, it's the reason for seeking
12	healthcare service. And for these and also
13	there's multiple processes that influence any
14	particular health outcome.
15	So we really for health outcomes
16	ask for a rationale that supports the
17	relationship of that health outcome to
18	processes or structures of care. So some of
19	the PROMs that we're talking about would be
20	considered health outcomes. Some might be
21	considered intermediate clinical outcomes.
22	And I think that's an area where we'll have

Page 144 1 some discussions. 2 Certainly for intermediate clinical outcome and an example of this in a 3 clinical sense would be something like blood 4 5 pressure or a particular lab value or a process or structure is that we really want to 6 7 see a systematic assessment and grading of the 8 quantity, quality and consistency of the body 9 of evidence, that that particular aspect of 10 healthcare that's being measured actually is linked to desirable health outcomes. 11 12 And then certainly experience with care, what our guidance states is that the 13 14 evidence -- there should be evidence that the 15 measured aspects of care are those valued by 16 patients and for which the patient is the best and/or only source of information, or there 17 may be evidence that experience with care is 18 19 correlated with desired outcomes. 20 So, all of these things that are 21 already in our criteria we think relate to the 22 idea of actionability but we probably will
	Page 145
1	need some more discussion about where we have
2	our emphasis on health outcomes. Next slide.
3	So, meaningfulness. We think this
4	again relates to our NQF criterion of
5	importance to measure and report, certainly
б	evidence that the measure is a health outcome
7	or is evidence-based and what I just mentioned
8	about experience with care relate to
9	meaningfulness. We also have a criterion, a
10	sub-criteria of high impact, that it's related
11	to a national health goal or priority. And
12	we've heard that patient engagement, patient
13	experience are certainly important aspects of
14	our national health goals and priorities.
15	And certainly we look at the data
16	on numbers of persons affected, high-resource
17	use, severity of illnesses or consequence of
18	poor quality. And then our criterion about
19	usability and use also relates to
20	meaningfulness. Next slide.
21	And this is a criterion. In your
22	handout it's an addendum. We're in the

	Page 146
1	process of revising this particular criterion
2	so this is the new information here. But this
3	really focuses on accountability and
4	transparency and improvement.
5	And we've already mentioned that
6	NQF-endorsed measures are intended for use in
7	an accountability application. And we really
8	want to see that they end up being in use or
9	that there's a credible plan to get them in
10	use. But certainly all of the measures should
11	be available for improvement. And again, we
12	want to look at how these measures are really
13	helping with progress in achieving high-
14	quality and efficient healthcare. Next slide.
15	And implementable really relates
16	to our criterion about feasibility. And next
17	slide.
18	And the elements that we look at
19	under feasibility are that the data if it's
20	clinical data generated and used during care
21	process we think that this certainly makes it
22	more feasible. And I think this again is an

	Page 147
1	area that we'll talk about. What we're
2	talking about here is if it's something that's
3	done outside of the care process it becomes
4	more burdensome.
5	And I think that's part of our
6	discussions about PROMs actually being used in
7	clinical practice. If they're relevant for
8	clinical practice then the data will be there.
9	Certainly electronic sources make things more
10	feasible. And we want to see information that
11	the data collection strategy can be
12	implemented.
13	Okay, I think that's the end of my
14	slides. And we'll turn it over to Liz.
15	DR. MORT: Thank you, Karen. Can
16	everybody hear me okay? No. The mike is
17	can you hear me now? Okay.
18	So, I've been asked to speak a
19	little bit about accountability. I think some
20	of the comments that Karen and Karen made were
21	very clear and I don't want to be redundant
22	but I do want to put some focus on this from

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1 the provider's perspective.

2 I think the actionability issue is critical and that actionability defined as 3 responsiveness to healthcare interventions, if 4 5 we don't have a healthcare intervention that's going to advance or improve a patient-reported 6 7 outcome that measure really has no business 8 being in an accountability framework. That. 9 measure may have a very important role in a 10 measure to help stratify patients or understand what basis you're dealing with from 11 12 a patient's perspective, and that measure may have a very important role in research in 13 14 quality improvement but I think it's just not 15 a good thing to be taking measures, as compelling as they may be, as interesting as 16 they may be, as important to patients as they 17 18 may be, I don't think unless there is an 19 intervention that those should be in an 20 accountability framework. 21 And then the reason I say that is that we have enough to do in the course of 22

Page 149 taking care of patients where there are 1 2 interventions that are known that we should be spending our time working on the things that 3 4 we know we can improve. And I know myself and 5 my clinical colleagues feel bothered when they're asked to do things that they feel 6 7 detract from the clinical value that you can 8 bring to a conversation. Again, not that 9 many, many of these things that we want to do 10 aren't important in the research environment, but until you have a defined and either proven 11 12 through RCT or other forms of evidence they 13 really don't belong in the accountability 14 framework. 15 So, what about those actionable 16 Now, there are actionable measures measures? and there are very actionable measures and 17 18 there are barely actionable measures. And 19 that's one of the reasons why I think the ones 20 that are clearly not should just not be on the 21 table. And I think it's important when we 22 look at these measures and we evaluate them

	Page 150
1	for endorsement that we consider the spectrum
2	of actionability because it's very, very
3	important.
4	So let me start. And this really
5	comes ripped from the headlines. We're trying
6	to implement these. We are implementing PROMs
7	at Partners Healthcare. I gave those of you
8	who were here last time a brief overview.
9	Well, it's marching ahead apace
10	and many, many of our clinicians are extremely
11	enthusiastic and anxious to get onboard this
12	data collection effort. And not surprisingly
13	the clinicians who are interested in
14	participating are those that have measures
15	that are highly actionable.
16	So let me give you an example. In
17	the urologist world we have lower urinary
18	tract symptoms. So frequency, urgency and the
19	like. I won't get into too much of the
20	clinical details.
21	But you can scale those, we've
22	been scaling those for decades, and you can

	Page 151
1	intervene in many, many different ways
2	including everything from watchful waiting if
3	that's what the patient's preference is to
4	lifestyle changes, to medications, to
5	minimally invasive surgery and to surgical
6	surgery. And guess what? The symptoms
7	change. So that is I would say a PROM measure
8	that is a very highly actionable measure.
9	And that the other key point I
10	would say is that what we find in RCTs in
11	efficacy studies translates reasonably well in
12	real life or in effectiveness. And so that's
13	why I think this particular example hits on a
14	bunch of different issues that are important
15	when you tease apart actionability. So it has
16	to be highly actionable and it has to be
17	demonstrated outside of an RCT that you can
18	actually do this in practice. So I think that
19	kind of a clinical scenario with those kind
20	of measures and those kind of interventions is
21	well suited.
22	Another one that I'm getting lots

Page 152 1 of interest in is from the orthopedic surgeons 2 who are very, very interested in shoulder repair, either rotator cuff or shoulder 3 4 replacement. And there are good measures, and 5 there are strong interventions, and there's demonstrable improvement. Again, it's 6 7 important to stratify and so on and so forth 8 but it's highly actionable and there are 9 strong interventions. 10 So let's move to the next category that I would say is more moderate, depression. 11 12 So we can measure depression and we can act on 13 depression. You can't treat everybody. You 14 can try and there's lots of different things and there's referrals so I'm saying it's a 15 16 very important measure to have as an 17 accountability measure but we have to take 18 that into consideration when we set it up. 19 And how it's used as an 20 accountability measure because the last thing 21 you want to do is put out a measure that 22 incents providers to treat and treat and

	Page 153
1	treat, to add medications, to try referrals
2	that may end up for some patients not working
3	and potentially harm them. So that's what I
4	would say is kind of a middle ground.
5	And then I'll give you an example
6	of what I would call a weakly actionable,
7	probably weak to not actionable would be
8	dementia, Alzheimer's dementia. There are two
9	classes of medications that are used now in
10	practice to help slow the rate of decline in
11	patients who have Alzheimer's-type dementia.
12	But it's very hard to really demonstrate
13	improvement in clinical trials let alone in
14	practice. So I would not as a physician at
15	this point in time want to be held accountable
16	despite the fact that there are drugs out
17	there that have been shown to have impact on
18	some patients. It's a weak intervention,
19	therefore a weakly actionable, weak to not
20	actionable measure if you're looking at some
21	kind of functional status for patients with
22	dementia.

	Page 154
1	So I think that gives you the
2	range of types of actionability that must be
3	considered, that should be considered when
4	you're trying to set something through a
5	process to decide whether it's a good measure
6	for accountability.
7	But I hope I've made the point
8	that if there's no evidence for actionability
9	that it really should be off the table.
10	There's too much disease burden on the table
11	that we can treat. That's what we should
12	focus on first. And then all the cautionary
13	notes about strength of actionability,
14	differences between efficacy and
15	effectiveness.
16	And the last point I'll leave with
17	because I'm looking right at Jack Fowler and
18	I can't help myself is that and another really
19	important consideration is patients, how they
20	view all these symptoms. So you might have a
21	patient with a symptom that's highly
22	actionable, but if their tolerance or their

	Page 155
1	preference or their bother with it thanks,
2	Jack. Jack's one of my very favorite mentors.
3	If they're not bothered by the symptom and
4	it's perfectly legitimate for them to have the
5	quality of life they want then trying to move
б	that symptom would be harming the patient. So
7	I think you have to take that into
8	consideration as well.
9	DR. BRENNAN: Hi, I'm Patti
10	Brennan. I'm among other things the director
11	of the National Program Office of Project
12	HealthDesign which has been a multi-years
13	project trying to better understand health in
14	everyday living. So much of the work I'm
15	going to be talking about today and the basis
16	for my comments will come from my experience
17	with Project HealthDesign.
18	The concept of meaningfulness is
19	well laid out in our early discussions here.
20	And the idea that a patient-reported outcome
21	measure or a person-reported outcome measure
22	should be meaningful largely is linked to the

	Page 156
1	idea that it's meaningful to the individual
2	patient, meaningful to the individual or the
3	persons involved in that individual's care.
4	So I am going to be focusing significantly on
5	how meaningfulness intersects with the patient
6	and the person's experience of their health
7	services rather than meaningful in the course
8	of a treatment plan which I recognize is also
9	important.
10	Then we've been asked to talk
11	about two issues, how do we engage patients in
12	the selection of PROMs and then how do we
13	document that engagement.
14	So I wanted to begin discussing
15	meaningfulness by using three C's, three
16	words. First of all, meaningfulness on the
17	conceptual level, secondly, meaningfulness on
18	the contextual level, and third,
19	meaningfulness on the consequential level.
20	On the conceptual level we're
21	focusing on to what the PROM actually
22	measures. What is the patient-reported

Page 157 1 outcome or the concept underlying this. And 2 often those PROs, the outcome -- sorry, the concept is linked to some kind of clinical or 3 professional definition of what is health and 4 5 what is healthcare. As a starting point we 6 need to relax that a little bit and we need to 7 listen to the way patients identify their 8 health, their health experience, what they 9 understand. And while we divide the world up 10 into clinical specializations or locations of 11 12 care, patients live in one body and they divide the world up inside of the inside and 13 14 outside of their body, period. So as we're 15 talking about the conceptual basis of a PROM 16 listening and engaging the patients in a 17 dialogue and engaging people in a dialogue 18 around how the language shapes and determines 19 and provides meaning to the concepts that will 20 be measured is a critically important first 21 step. 22 In our case we use the phrase

Page 158 1 "patient-defined and patient-generated" to 2 describe two rather separate areas. Patientgenerated are the sensations, the experiences, 3 the ideas that an individual and only that 4 5 individual can report. But they may be reporting them in response to things that we 6 7 say, how is your pain, how much can you bend 8 vour arm. Those are things that have clinical 9 meaning in our professional practice. Patient-defined is the 10 individual's experience of that stimulus that 11 12 leads them to be able to report or generate a response about it in response to their health 13 14 And that may include, for example, status. can I lift up my child. Can I walk to work 15 holding hands with my son. 16 The idea of not can I flex my arm this much but can I do what 17 18 I want to do in my life. 19 Other aspects of patient-defined 20 may become much more abstract. The tenor of 21 a conversation at dinner being tense or not 22 tense is something that's really quite

Page 159 1 difficult to map to a specific professionally 2 validated indicator but it may for that individual patient be the concept that tells 3 them that their medication for depression is 4 5 improving or not improving. 6 So as we begin to bring patients 7 into the concepts and setting meaningfulness 8 of our patient-reported outcomes we need to 9 recognize that we first have to listen to 10 We don't stop at that point. them. There may be very good reasons to have professionally 11 12 selected, professionally defined and patientgenerated PROs and patient-reported outcome 13 14 measures, but we can't begin the process without first listening and finding the cross-15 mapping between what is meaningful in the 16 patient's language and what is meaningful to 17 us about that individual. 18 19 The scope of care defines this 20 And I heard discussions in our very much. 21 earlier comments today of the tension between 22 a clinically targeted measure and a general

	Page 160
1	measure. And in fact I guess I'm asking to
2	think about a third way of defining the
3	measures, neither clinically specialty-focused
4	or general, but actually patient-focused in
5	terms and the experience that individuals
6	have.
7	Their experience of care is not
8	divided up based on the offices in a hallway.
9	Their experience of care is the experience of
10	the individual. So we may need to think about
11	indicators that transcend different points of
12	care as we find which concepts are most
13	meaningful to the individual.
14	Second, I want to talk about
15	contextual. Where do PRO and PROMs become
16	meaningful to the individual? They often
17	become meaningful we heard earlier today in
18	being able to learn of a provider's
19	performance and therefore begin to select
20	providers. This provider is responsive to or
21	has interventions for something that is
22	important to them.

	Page 161
1	But people also find it meaningful
2	to participate in the larger social exercise
3	of health. And there is an altruism
4	experienced by individuals when they believe
5	their input is sought and respected in
6	determining the quality of care for themselves
7	and those around them.
8	So to make the experience of
9	patient-reported outcome measures and
10	selecting PROMs for individuals meaningful to
11	patients may include thinking about how it
12	allows them to participate in the larger
13	social discourse about care.
14	Third and importantly, we heard in
15	our previous slides about the usefulness of
16	PROMs for an individual's own care. And I
17	want you to think about that from two
18	perspectives, one in the moment when we're
19	capturing that information, how meaningful is
20	it for a person to know this about him- or
21	herself at that moment, and second in the
22	clinical encounter. How meaningful is it for

	Page 162
1	that person to share that observation or share
2	that PROM with their clinician to make a
3	determination about how their own care is
4	progressing.
5	I've heard a lot of discussion
б	about the second kind of care, that it would
7	be nice to have measures, PROMs that can be
8	both useful to tell us about how a system is
9	functioning and how this particular patient is
10	improving or not improving. But I want you to
11	also think about the meaningfulness of the
12	individual who's capturing that, who may not
13	be sitting in the clinic waiting for a visit
14	or filling an after-survey, but may be 2, 6,
15	8, 12 months after the encounter and being
16	asked to recall something provide something
17	about their daily life to help us interpret
18	how good the care that they received was. At
19	that moment it would be also useful for the
20	individual to use that marker as a self-
21	assessment, as a way to meaningfully
22	understand how they have changed in their

	Page 163
1	life.
2	Now I want to move onto
3	consequential. The meaningfulness of PROMs
4	can be established by looking at the
5	consequence of knowing about them. And
6	although we don't think of this as a patient-
7	valued or patient an individual patient
8	experience, by ensuring that there's good
9	quality providers around we are providing
10	something for the patient. So the measurement
11	or the use of PROMs is in fact useful on a
12	consequential level.
13	So it is incumbent upon us as we
14	begin to observe, as we begin to collect
15	patient-reported outcome measures that they
16	feed back into assuring that the practice is
17	of good quality, that the clinicians are
18	fairly compensated, that the practice can
19	financially sustain itself or the institution
20	can sustain itself.
21	Assessment of patient-reported
22	outcomes through PROMs can in fact have

Page 164 1 important consequences on the availability of 2 health services for individuals, the type and the responsiveness to the individual's needs. 3 4 I want to close my remarks by making two more points. The first is that our 5 work today is really not about PROMs. 6 It's 7 about PROMs -- patient-reported outcome 8 performance measures. We're here to discuss -9 - recommend to the National Quality Forum how to address the performance measurement. 10 And we don't specifically think 11 12 about how patients will be engaged at that level, what thresholds should be set, or how 13 14 much of a gain or loss is tolerable. And yet it's important that we consider not only 15 having patients involved in the selection of 16 17 the measures but also in the way that they are 18 used and interpreted and reported. 19 So moving forward I have four 20 points for a national agenda related to 21 meaningfulness and engaging patients in 22 selecting PROMs.

	Page 165
1	The first is that we need to have
2	a national agenda. We need to have the
3	kindergarten curriculum of patient outcomes so
4	that it becomes a national everyday experience
5	for individuals to know that their reaction to
6	the care services they received is not only
7	important but meaningful in terms of shaping
8	their own care as well as shaping the
9	availability of care in society.
10	The reports we heard from England
11	and Stockholm today didn't occur because there
12	was a 2-year or a 5-year national program.
13	They occurred because of the context that took
14	many years to develop. And it's timely for us
15	to think about how we develop this.
16	Secondly, the patient voice
17	matters. The patient voice matters. That
18	means not only the individual who speaks for
19	him- or herself at various points in time, but
20	the ability for an individual to set policies
21	that are subsequently respected over time, the
22	inclusion of surrogates where appropriate and

Page 166 1 properly denoted, and the inclusion of 2 careqivers who may not speak for the patient but speak about the patient in a PROM-type 3 It may be as useful to know that 4 situation. 5 there's a difference between what a spouse and the care recipient perceive about the quality 6 7 of care that an individual received. 8 So recognizing that the patient voice comes in three different forms as I see 9 10 it, the person him- or herself, the surrogates and the caregivers, and sometimes it's 11 12 important to keep those separate as opposed to 13 aggregating them together. 14 Third, I've heard over the process of these two workshops some indication that we 15 will have a national list that institutions 16 can select from -- of PROMs that institutions 17 18 can select to measure concepts, some 19 indication that there might be a set of 20 explicit measures. 21 We need to consider at the point -22 - that the involvement of patients in

	Page 167
1	selecting PROMs will vary based on whether
2	we're talking about setting a national agenda
3	or we're talking about a clinic in a small
4	town who's trying to pick certain outcome
5	measures. There are different ways to engage
6	patients over those times to do each of those.
7	And we can't simply call patients up and
8	assign them to a task force immediately. We
9	need to cultivate and build the skill sets for
10	that.
11	And finally, I'm going to call for
12	some perhaps non-traditional ways of
13	understanding the patient's voice and the
14	patient's experience. I'm going to encourage
15	groups that are trying to bring the concept of
16	patients meaningfully into the selection of
17	PROMs to not only think about sitting patients
18	down at a table but also to look to see how
19	the creative literatures can help us
20	understand the patient experiences and help us
21	to target what might be useful or meaningful
22	about an adolescent who's facing a pregnancy,

1	
	Page 168
1	or an older person living alone. Think about
2	ways to engage not just the person of patient
3	but the concept of patient as we select
4	participation.
5	We also need to find increasing
6	ways to use social media to get reactions from
7	individuals over time. Not only in the
8	selection of the PROMs, perhaps even in their
9	assessment, but at this point in time I think
10	using social media, using Twitter, using
11	Facebook as a way of making it more widely
12	known that there is an interest in selecting
13	PROMs and an interest in hearing the patient's
14	voice about them might give a way to get a
15	very broad and very diverse set of viewpoints
16	on the selection process.
17	I thank you very much for your
18	time and for listening to me instead of
19	Jennifer. I hope that I represented this
20	perspective well in the conversation.
21	(Applause)
22	MS. BURKE: I made one slide.

	Page 169
1	Everything I have to say is on one slide. I
2	have five points and I just thought it might
3	be helpful if I put those up in front because
4	I might not be able to read what I scribbled
5	on my paper.
6	But my I'm assigned the topic
7	of implementability but I think that the
8	implementability depends on this topic of the
9	key characteristics that we started out with
10	here and for selecting PRO measures.
11	First of all, my first point is
12	that we 2001 is the year that's the 11-year
13	anniversary of the birth of the term "patient-
14	reported outcome." And I can keep track of
15	that because of the monumental nature of that
16	year 2001.
17	And it was generated because there
18	was an initiative called the Health-Related
19	Quality of Life Harmonization group that were
20	deliberating on how to define health-related
21	quality of life. And we finally accomplished
22	that but then we realized that everybody was

	Page 170
1	using health-related quality of life to mean
2	everything else that health-related quality of
3	life does not mean. And so we needed a larger
4	grouping term for everything patient-reported
5	and that's when that term was developed.
6	And it's really important that we
7	maintain the meaning of that term just for
8	communication purposes. And I really
9	appreciate NQF and their efforts at doing that
10	for this meeting.
11	And so there's good measurement
12	science that's under development right now and
13	that we're talking about profusely in this
14	last workshop and today. It does not apply
15	only to patient-reported outcomes, however.
16	It applies to measures, all measurement used
17	in healthcare. And I wanted to make sure we
18	keep that point in mind because of course
19	there could be other things besides patient
20	reports of things that may be useful to use as
21	performance measures.
22	My second point is that the key

Page 171 1 characteristics that we're talking about are 2 not characteristics of the PRO measure. These characteristics apply to the use of the PRO 3 4 measure in a particular context. And this is 5 really important to know about because when 6 you select a PRO measure you have to think 7 about these characteristics in the context 8 that you're going to then apply it to. 9 I think that we very often lose 10 sight of that. And the red boxes at the top of the diagram were added for this meeting and 11 12 I really appreciate that. And so if we continue to keep that in mind. 13 This is a very 14 key point for the implementability of these measures in terms of future use. 15 16 My third point is that contrary to 17 classic psychometrics teaching it is not 18 efficient to test reliability first. Now, I'm 19 sure I'm going to get some pushback on this 20 topic but that our experience in the 21 regulatory setting where we're talking about good measurement has really borne this out. 22

	Page 172
1	And for example, you have to first
2	decide what you're going to measure because
3	when you're going to measure something it's
4	not just grouping a bunch of things together
5	to create a score. You need to somehow
6	characterize a meaningful state in a context
7	of use that you're planning to measure it in,
8	in a disease group, in a patient group.
9	It's the score has to represent
10	a meaningful concept. I just was in a meeting
11	last week about an instrument to measure
12	suicide ideation, for example. And this is a
13	checklist where we have five graduating more
14	serious ideation concepts that the patients
15	check yes or no.
16	And it's an excellent measure.
17	But when I said, "Well, what does this score
18	represent?" they said, "Oh, we don't have a
19	score." But yet when you collapse the data
20	you try to assess whether or not we have
21	suicide ideation you do actually look at
22	everybody who checked for the fourth or the

	Page 173
1	fifth one and that's your score of suicide
2	ideation. So, we have to think in terms of
3	scores and what we're trying to make the
4	instrument actually represent. In this case
5	it is suicide ideation.
6	The items and responses need to be
7	available, need to be presented in a
8	hierarchical order so that we know that it
9	makes sense to a patient as they are assessing
10	and trying to match what they're reading on
11	the page and marking as a response to this
12	question.
13	There needs to be adequate
14	coverage in the target population. All of
15	these things represent what we would call
16	validity of the item.
17	Now, if you wait to assess all of
18	that until after reliability is tested you may
19	find out that the PRO measure is not measuring
20	the thing that you have been targeting. And
21	the content may need to change. And if that's
22	the case then repeated reliability testing

	Page 174
1	needs to take place. And if that and if
2	the content is not changed you will have some
3	compromised sensitivity to change with the
4	measure.
5	And this has been borne out over
б	and over in our experience in reviewing
7	clinical trial data. I do not think these
8	principles for good measurement are any
9	different outside of the clinical trial and in
10	the healthcare setting.
11	So then my fourth point is that
12	validity testing is iterative as the PRO
13	measure content develops. So that if you
14	spend adequate attention to the validity of
15	the measure to measure the concept that you
16	have intended in the context of use that you
17	have intended then you can very much influence
18	the reliability of this measure and therefore
19	its ability to change in the clinical setting.
20	For example, there are four major
21	types of variability as far as I can identify.
22	There is true patient heterogeneity. So that

	Page 175
1	is very much related to your context of use.
2	You need to identify all the ways that your
3	patient population really does validly vary
4	and you want to be able to consider that for
5	the PRO measure. So, that can be considered
6	in the early stages in this iterative approach
7	to generating validity of your measure.
8	Then there's random variation
9	which is often called error which is also
10	something that can be impacted by careful
11	consideration to the content of the instrument
12	and minimized during that early phases of
13	instrument development.
14	And then there's systematic non-
15	random variation, also something that can be
16	considered based on your population. What are
17	the characteristics of your population that
18	would cause what are the items in the
19	instrument that may be obscure or not
20	understandable to certain parts of your
21	population that are going to introduce this
22	non-random variation.

Then there's the experimental design and the conduct error which is a huge concern when you start administering your instrument in large populations. This is a big reason for a lot of the missing data concerns that we've heard about earlier today and it is the reason why we are focusing more and more on the training and instruction component that goes along with an instrument so that it is adequately administered in the way it's intended so that you can in fact

12 collect the results that you're looking for. 13 We find that training and 14 instructions are always an afterthought and in the past we rarely even asked to see it or 15 review it. But it's really an important 16 17 aspect of being able to understand what you're 18 collecting and how you can actually implement 19 it. And if it's being administered in a way 20 that's not intended then you have to think 21 about that validity. So, this is just 22 following on the point that validity really

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Page 17 1 needs to be thought about first, not last, and 2 some of the aspects of that. 3 Then finally, because of all these 4 things that I've already mentioned and lots of
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4 things that I've already mentioned and lots of
5 other examples we I think it's really
6 important that we quit, in terms of the
7 terminology that we use going forward, that we
8 stop calling we stop talking about a
9 measure as being validated. And this is
10 people who are in the inner circle of
11 measurement like all of you are need to be
12 really careful about this because people who
13 don't understand validation are going to take
14 and run with it and say well, they said it's
15 validated so we can use it and plop it into
16 whatever context of use is currently under
17 consideration. And so I think that this would
18 be really useful as we're focusing on
19 terminology and how we think about measurement
20 that we stop using that phrase.
21 Okay, those are my five points.
22 DR. ADAMS: Well, first I'd like

Page 17         to thank all our reactors for really providing         us some thought-provoking comments. And I'm         going to open up to the room for some         discussion questions.         First, I want to tee up the         operator because we do want to be able to         bring in our people who are participating with         us virtually so that they can start queuing up         while we're doing a few questions. And I want         to make sure that our external audience that's         here with us live today, we do have         microphones and stands for you too so we         welcome your participation.         But I'm going to start the         moderating now. And I feel I need to stand up         because I can't see in the back.         OPERATOR: At this time in order         to ask a question press * then the number 1 on         your telephone keypad.         DR. ADAMS: Great. Yes, please,         Ted.         DR. GANIATS: Ted Ganiats in San		
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22 DR. GANIATS: Ted Ganiats in San	21	Ted.
	22	DR. GANIATS: Ted Ganiats in San

	Page 179
1	Diego. Not in San Diego but from San Diego.
2	I wanted to thank folks. The
3	morning just, you know, I've always been
4	excited about patient-reported outcomes and
5	the morning's presentation, the beginning just
6	increased my already high enthusiasm. And
7	then these three talks were able to highlight
8	one of my big concerns for performance
9	measurement but that means I can list all
10	three people.
11	You know, Laurie talked about
12	scores, so important. Not all PROs have a
13	score. Could just do a count of number of
14	joints, for example. But we oftentimes try to
15	collapse them into a score.
16	And I think that's left that
17	means Patti whose presentation was just so
18	great forgot one thing in that she talked
19	about it being patient-defined and patient-
20	generated but I think it should be patient-
21	scored.
22	And I think we have a very, very

	Page 180
1	hard time if we're going to try to be
2	actionable if we take a population preference
3	scored or just an average of I'm going to
4	count up the number of yeses and give us a
5	score and have that be actionable because it
6	may not mean anything to the patient. So
7	that's my opinion and I'm wondering if the
8	panelists would react to the idea of how
9	important it would be for an outcome
10	performance measure instead of a process
11	performance measure to be patient-scored.
12	In my opinion if it's not patient-
13	scored it should be a process measure. If it
14	is patient-scored it might be able to be an
15	outcome measure.
16	DR. MORT: I'd like to make a
17	comment. I think it's a really important
18	point. I think it's there are ways to
19	address it maybe that get at what you're
20	talking about without necessarily having a
21	patient score everything, every aspect of it.
22	But understanding how bothered the patient is
	Page 181
----	--
1	or how satisfied they are with the outcome
2	might be one way to do it.
3	I have a story of a patient with a
4	shoulder problem and the shoulder PROM didn't
5	really improve but he was happy as a clam
б	because he could do what he needed to do
7	because he figured out a way to play curling
8	was his thing, ice sports, and he figured out
9	how to use a broom in a different way that
10	didn't so he was pleased with what had
11	happened but you wouldn't have been given a
12	good rating because the shoulder functional
13	measure hadn't changed.
14	So I think you have to be a clever
15	in the way you assess patient's preferences,
16	how much they're bothered by it. And that
17	also gets complicated because they may not
18	have known enough to realize that they could
19	have actually improved more and so on and so
20	forth. But it's a very important point
21	because the clinical or the provider-based
22	assessment may not tell you the whole picture.

	Page 182
1	MS. BURKE: Well, I can't agree
2	more with the importance of the score because
3	the score is how you're going to make your
4	conclusion. If your score doesn't first of
5	all, if it doesn't represent the thing you
6	think it represents that's a big problem. And
7	that's part of the validity of an instrument
8	is making sure at the end of the day that the
9	people who are filling out the are actually
10	providing the input that generates the score
11	will agree at the end of the day that the
12	compilation of what they have reported
13	represents the thing that the score represents
14	in a way that they intended.
15	And this is a very complicated
16	issue, a lot of weighting of items and making
17	sure you have the right things that represent
18	the score. And change in the score represents
19	change in the thing that they're telling you
20	about. And this is critically important, yes.
21	DR. GANIATS: For example, the EQ-
22	5D which I'm going to understand every single

Page 183 1 question that's there and I'm going to respond 2 appropriately for every single question that's there but the score is irrelevant to me 3 because the score is based on population 4 5 preferences which may or may not reflect mine. 6 So, that's an example of my seeing 7 an EQ-5D score or worse if a clinician tries 8 to improve a patient's EQ-5D score you may end 9 up going in the wrong direction because those 10 scores just like the shoulder, it may not move the patient in a way that the patient is 11 12 getting better, it's just that the score is getting better. 13 14 Ethan, you have a DR. ADAMS: 15 response to this? 16 DR. BASCH: Yes, I was just going I mean, I think this is 17 to comment to this. 18 one of the reasons that many have really 19 focused on specific symptoms or very specific 20 dimensions of functionality. Certainly 21 regulatory agencies have focused on this recently and that's because we want to know 22

	Page 184
1	what we're measuring. And we also want to
2	make sure that a change in that score is
3	meaningful to a patient.
4	And there are techniques for
5	demonstrating that a particular score change
6	is clinically or I should say meaningful to
7	patients. And it's much harder for example
8	with the EQ-5D to demonstrate that, a
9	composite EQ-5D score of those five different
10	dimensions is meaningful to an individual
11	patient. I couldn't agree with you more. I'm
12	sure Laurie would follow up.
13	DR. ADAMS: Yes, and I know,
14	Patti, you wanted to respond as well. Is that
15	a direct response, Laurie? Go ahead.
16	MS. BURKE: Yes, and I think that
17	it's really important to think about how we
18	present the results of whatever we measure.
19	For example, if you are in a clinical care
20	situation you're measuring an individual
21	patient and that individual patient's change
22	with respect to whatever the thing is you're

Page 185 measuring, that is -- it's critical that your 1 2 instrument is adequately assessing that thing on an individual basis. 3 Now, when we take that instrument 4 5 and move it into a clinical trial or in an observational setting where we're looking at 6 7 populations of people then we're looking at 8 change in terms of an average or a proportion 9 of responders or whatever that metric becomes. 10 We -- that same degree of change is not -does not carry the same meaning in that mean 11 12 score, for example. So, this is why we're looking at other ways of displaying data so 13 14 that you can understand the distribution of 15 response across a population, for example. And that has to be -- that's probably another 16 17 whole conference on how to display and present 18 the results that are being measured in a 19 population of people because it's very 20 difficult to understand the range of response 21 and how a patient can look at that population-22 based data and interpret it in terms of the

Page 186 1 meaning that it brings to them personally. 2 DR. BRENNAN: That's a nice seque 3 way into the comment I wanted to make which is a call for greater research into the 4 5 methodologies of aggregation. 6 We make a lot of presumptions that 7 everything is monotonically related and 8 increasing in an equal fashion and then we add things up. Most of the time they don't. 9 10 And the question about the extent to which a score maps to my personal 11 12 experience versus the population as a whole remains somewhat ignored by the methodologists 13 14 in the field and it may not be able to be over 15 time. Because if we want an individual to interpret a gain from 7 to 9 is the same 16 17 degree of change as a gain from 14 to 16. We have to be pretty sure for that individual 18 19 that experience is in fact trustable and has 20 that kind of an underlying process. 21 I think the other part is while we 22 need to look at summative measures they might

	Page 187
1	not all be scores. They might be
2	classifications, they might be displays, we
3	might be looking at Euclidian distances. So
4	think flexibly when you think about scores.
5	Thank you.
б	DR. ADAMS: Ted, did you have?
7	And I see we have someone in the back. Can
8	you come up to the microphone and Evan, if you
9	can have our audience member teed up after
10	Ted. Thank you, Ted.
11	MR. ROONEY: Ted Rooney from
12	Maine. This is a terrific panel and terrific
13	day. So I'm thinking as the discussion goes
14	as part of my informed decision-making if I
15	had I'm a male so and I'm going to have a
16	prostate problem someday. And I remember
17	seeing the videotapes of the informed shared
18	decision-making, you know, the differences
19	between the two docs explaining it.
20	So I'm going to come down this
21	road. I'm going to want to know although
22	there's different approaches who gets the best

Page 188 outcomes and the quality of life and so I want 1 2 to see that there. 3 And then I want as part of my informed decision-making I want to know if I 4 5 have three or four urologists over here who gets the best scores on their treatment of 6 7 patients, so I want to know that. 8 And then when I go in and I 9 potentially have my procedure, afterwards I 10 want to know how my score relates to what potentially could have been. 11 Is it worth it 12 for me to go through whatever else I might have to go through to get a better score. 13 So 14 this is an incredibly rich discussion and very 15 complex. 16 But you know, so I want to make 17 sure that whatever I choose fits me but I want 18 to have enough standardized information that 19 I could choose among different treatment 20 options and among the people who deliver those 21 treatment options because I'm sure there's a 22 difference between the people who do medical

	Page 189
1	management and the people who do surgical
2	management. So, this is a great discussion.
3	DR. ADAMS: So those may be things
4	to benchmark against. Go ahead, Patti.
5	DR. BRENNAN: I want to comment on
б	that. The challenge is in part the
7	mathematical literacy of a population and
8	trying to help people understand that the guy
9	with the best score still might have had a
10	turkey day one day. And so they're not
11	necessarily a guaranteed performance but
12	rather a typical, not even likely-to-happen-
13	to-you performance.
14	DR. ADAMS: And Liz?
15	MR. ROONEY: And I think that's
16	part of what I would want to know so that if
17	I make my decision that that's I play the
18	odds.
19	DR. MORT: I love your summary of
20	the complexity and it makes me think do we
21	advise NQF to go slowly and go deliberately
22	rather than just throw a whole bunch of

Page 190 1 measures through. 2 We've learned the hard way through process measures that throwing a whole bunch 3 through may end up doing some harm that we 4 5 would have avoided had we don't it a little 6 differently. 7 So it's very complicated to do the 8 patient-reported work. So many issues, it 9 just makes me think boy, let's do a few really 10 well so we understand before we open the 11 floodqates. 12 DR. ADAMS: Sure, Ted, and then we're going to go to our audience. 13 14 MR. ROONEY: So in Maine we're playing around with a lot of these things. 15 And I agree, for the ones that have strict 16 accountability I absolutely agree with you. 17 But how about having some others in the field 18 19 that people could work with that get us 20 directionally towards where we want to go that 21 may not be a clinician accountability but may 22 be a group or an organization accountability.

	Page 191
1	So, I think there's a lot of room in there.
2	DR. ADAMS: Okay, we're going to
3	go the back. Thank you.
4	DR. KELLER: San Keller from the
5	American Institutes for Research. And this is
6	kind of related to what the last speaker said,
7	that I think we're talking about the context
8	of use. There's always been a tension between
9	meaningfulness in terms of the semantic
10	meaningfulness and precision of measurement
11	and the need to make decisions. So, a single
12	symptom is meaningful to the patient but may
13	not be precise in a statistical sense. And
14	that's why we create composites for the
15	signal-to-noise ratio, but also to allow us to
16	make decisions. So what we've done in the
17	past is take a composite score and then show
18	the relationship between that score and a
19	single symptom or a single ability to do this
20	or that so that you could have the best of
21	both worlds. I'm not sure that that's
22	possible but it's a longstanding tension.

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Page 192 1 DR. ADAMS: Thank you. Any 2 comment or reply from the reactor panel? And I think we'll get into it a little bit too as 3 4 we get into our next two panels. Go ahead, 5 Laurie. 6 MS. BURKE: San, are you talking 7 about a composite of many things that you put 8 together in a score or are you talking about 9 a general concept of measurement that the 10 score represents? Is that the composite that you're talking about or is it -- I'm thinking 11 12 of composite as multiple scores that are then used in a way to get sort of a profile. 13 DR. KELLER: I think there are two 14 15 different things. If you want a composite to 16 make a decision, so you want to accumulate 17 across different kinds of outcomes and you 18 know, have them come up with a single answer 19 even though they're very different that's --20 I think that's what people usually call a 21 composite. 22 But if you want to increase your

Page 193 1 signal-to-noise ratio then you want things 2 that are very similar that just, you know, enable you to do that. So, thanks for 3 pointing that out because I was kind of 4 5 conflating both of those. 6 MS. BURKE: Sure. And I just, my 7 response would be that it doesn't really 8 matter. If you have a score and your score 9 represents something that's -- we should be 10 able to name what that thing is and then the measurement properties in terms of key 11 characteristics should relate no matter if 12 we're talking about a general, a score for a 13 14 general concept or something very specific 15 like a single pain intensity measure. The key characteristics still apply. 16 17 DR. ADAMS: We have another 18 question. Go ahead. 19 Thank you. I'm Sally MS. OKUN: 20 Okun and I'm from PatientsLikeMe. 21 I really appreciated this panel. 22 I think there's been a lot of really important

Page 194 1 points that have been brought out. I'm 2 wondering whether the -- it will be important for us to consider things like we consider now 3 clinically important differences. 4 5 Maybe we need to be really 6 thinking about is there a measure for patient-7 important differences and really understanding 8 with patients targets that they might want to 9 set that they can reach and that the individual clinician can help them reach in 10 terms of how they're measuring how they're 11 12 doing, but then also being able to that into consideration when you aggregate that data. 13 14 Because I think as we start talking about patient-reported outcome information it's 15 going to vary so much by all the different 16 17 circumstances that patients putting into what 18 they want as their target versus what the 19 target composite score might indicate for 20 performance. 21 So the incentives that a patient has to feel better, the incentives that the 22

	Page 195
1	clinician has to help them feel better and
2	then also to get paid particularly I think are
3	aligned quite differently. And so
4	understanding what the minimal clinical
5	important difference is and then what the
б	minimal patient-important difference would
7	look like I think will be something that we
8	can begin to talk more about.
9	DR. ADAMS: Okay, thank you so
10	much for that insight. Al, you had a comment?
11	And then I'm going to we queued up people
12	on the phone. I don't want to forget them.
13	So after, for those on the phone you're up
14	next. Go ahead, Al.
15	DR. WU: On the last point, the
16	idea of what is a or how much is a patient-
17	important difference is a very good question
18	but it's not so easy to measure because it's
19	one person. And so there is going to be a lot
20	more noise around that measurement. And it's
21	just a difficult question to confront. I
22	think it deserves to be looked at.

	Page 196
1	DR. ADAMS: Okay, I'm going to
2	check with the operator. Do we have anyone on
3	the line that has a question?
4	OPERATOR: At this time in order
5	to ask a question press * then the number 1 on
6	your telephone keypad. Please hold for the
7	first question.
8	DR. ADAMS: Thank you. So we're
9	ready to take the question from the person on
10	the line.
11	OPERATOR: Your first question
12	comes from Susan Tavernier.
13	DR. TAVERNIER: Hi. I was
14	wondering if the panel would address the issue
15	of response shift and the fact that that can
16	be defined in a number of ways, whether it's
17	in the scoring of it versus conceptual
18	response shift and how the panel feels that
19	relates to these patient-reported outcomes.
20	DR. BRENNAN: I think that's a
21	great question if I'm understanding response
22	shift the same way that the caller means it to

	Page 197
1	be. And I was thinking of this actually a few
2	minutes ago as Sally was speaking.
3	When we talk about the variability
4	in measures we need to consider the same
5	measure over time with the same person,
6	populations at the same time, variability
7	within that, and then populations over time.
8	So we have all these different dependencies.
9	And there is a I would imagine
10	that there's both a testing effect and as well
11	as historical effects that need to be
12	considered as we get socialized to be more
13	mindful or less mindful of certain things,
14	whether it's prescription drug in the news
15	because of our sports players or the
16	expectation that you should live to be 90 and
17	still play tennis. There's a shifting in what
18	we expect as a baseline.
19	And measures need at one and the
20	same time to be both sensitive and resilient.
21	And so I all I can simply say is yes, I
22	think that's important. No, I don't know the

	Page 198
1	methods to handle it.
2	MS. BURKE: Well, we're fortunate
3	in a clinical trial which is most of the data
4	that I review that we well, at least we
5	hope we're fortunate in that the randomization
6	between groups takes care of the response
7	shift that no doubt happens in both groups.
8	So, we don't have to worry about it too much
9	in that setting. But in an observational
10	setting that is clearly a concern and that has
11	to be taken into consideration somehow.
12	DR. ADAMS: Thank you. Any other
13	comments? Oh, Lewis, yes.
14	DR. KAZIS: I had a fellow a few
15	years ago who we published an article looking
16	at response shift. And what we found is that
17	if you ask a subject how much their health has
18	changed over the past year, over the past 12
19	months they're basically going to be telling
20	you about their current health and that's
21	correlated much higher with the current health
22	than an actual change score that you've

	Page 199
1	derived. So that's been published and I think
2	there have been other articles as well.
3	DR. ADAMS: Thank you. Ethan, you
4	have a response?
5	DR. BASCH: Yes. I mean response
б	shift happens but it's a small effect overall.
7	We know from many, many, many, many studies
8	done over time that we are able to detect
9	change over time, that people's scores do
10	change over time both in response to
11	interventions and as a part of disease
12	trajectory. So I think response shift is
13	real.
14	That said, you know, the answer
15	that many people have to this is that what the
16	patient says about how they're feeling is how
17	the patient is feeling. And so if the patient
18	changes the context in which they think about
19	a particular experience because their general
20	outlook has altered then that is actually an
21	accurate subjective portrayal of how they're
22	actually feeling at that point in time, right?

	Page 200
1	So you know, perhaps I'm an
2	oncologist, right, so you know perhaps the
3	patient's view of nausea or fatigue changes
4	after they've had multiple rounds of
5	chemotherapy, but how they feel about those
6	symptoms is actually at a later time point
7	is actually an accurate portrayal of how they
8	actually feel.
9	And so when we compare between
10	groups if you want to I don't want to
11	belabor it, but if you want to say to if
12	you want to portray to a patient before
13	starting chemotherapy how patients like them
14	will experience chemotherapy-related symptoms
15	later on it is actually a more accurate
16	conveyance, some feel, to explain to them how
17	people at the later time frame who have had a
18	response shift experience those symptoms
19	because that's where a patient might actually
20	be.
21	DR. ADAMS: Well, we're one minute
22	away from lunch so I'm just going to I

	Page 201
1	think we have one more question. We're going
2	to break for lunch at 12:45 and resume back at
3	1:30. But we have time for one more question.
4	I don't see any hands up. Oh, great.
5	Phyllis. Give us our great closing remark,
6	yes?
7	MS. TORDA: I thought that Patti
8	made some really important points about the
9	importance of the process of going through
10	patient-reported outcome measurement to the
11	patient. And I just wanted to note that if
12	that's the case that suggests that process
13	measures might measure that and we shouldn't
14	be apologetic about it. If it's a process of
15	being asked about how you feel and your
16	symptoms and all of that is important to
17	patients we can measure that in and of itself.
18	DR. ADAMS: Thank you, Phyllis.
19	So with those closing remarks let us thank our
20	panelists here. Well done, thank you.
21	(Applause)
22	DR. ADAMS: And lunch is in the

	Page 202
1	back and we'll see you back at 1:30. Thank
2	you.
3	(Whereupon, the foregoing matter
4	went off the record at 12:45 p.m. and went
5	back on the record at 1:29 p.m.)
6	DR. PACE: Okay, good afternoon
7	and welcome back from lunch. So we're now
8	going to really focus on the performance
9	measure. And this first panel is about
10	reliability of the PRO performance measures.
11	I'm going to introduce the panel and then I'll
12	make a few introductory remarks about our NQF
13	criteria just to put that in context.
14	So, we will be hearing from our
15	Commissioned paper authors and RTI and
16	Brookings are our authors. We selected them
17	because they have experience in developing
18	organizational performance measures and have
19	brought performance measures to NQF for
20	endorsement. And our speaker about
21	reliability from the Commission authors is
22	Laura Smith who's from RTI.

	Page 203
1	Our panel then will be Lewis Kazis
2	from Boston University School of Public
3	Health, Lori Frank from Patient-Centered
4	Outcomes Research Institute and Jack Fowler.
5	And his organization name has changed slightly
6	so it's Informed Medical Decisions Foundation.
7	Is that correct, Jack? Okay, great. All
8	right.
9	So without further ado I'll dive
10	into NQF criteria related to reliability.
11	Next slide.
12	So, again, just to put us on the
13	same page we refer to the PROM, that's the
14	instrument or scale or single-item measure
15	used to assess the outcome of or concept as
16	perceived by the patient. And then that
17	patient level scores or values on those PROM
18	instruments will be aggregated in some way for
19	a performance measure, aggregated for the
20	healthcare entity providing services. And
21	that's what NQF would be endorsing in terms of
22	these performance measures.

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	Page 2
1	So, although and actually in
2	this session, reliability and validity, we
3	talk about data electronic and performance
4	score. We are our Commissioned paper
5	authors will specifically be addressing the
6	performance score. So let's go to the next
7	slide.
8	So in terms of NQF criteria
9	regarding reliability our subcriteria related
10	to this is first of all that the measure is
11	well-defined and precisely specified so it can
12	be implemented consistently within and across
13	organizations and allow for comparability.
14	Remember that NQF endorses
15	performance measures that will be used not
16	only for quality improvement which is of
17	paramount importance but also in
18	accountability applications. So we need to
19	have some standardization. And this starts
20	with having measures that are precisely
21	specified.
22	And how this relates to

	Page 205
1	performance measures based on PROMs is that in
2	order to you need to also specify what the
3	PROM instrument is that's going to be used in
4	the performance measure and if multiple ones
5	are going to be used then they would need to
6	have comparability or some equivalents as we
7	talked about last workshop.
8	The other aspect of our
9	reliability criteria so we think that
10	precise specifications form a foundation to
11	have reliability but it's not the only thing
12	that we look for. So we do look for some
13	reliability testing that demonstrates the
14	measure data elements are repeatable and
15	producing the same results, or that the
16	measure score is precise.
17	So we do allow in our current NQF
18	criteria for quality performance measures
19	testing at either the level of the data
20	element or the performance measure score. So
21	next slide and I'll talk about that a little
22	bit more.

	Page 206
1	So, in 2010 we had a task force
2	that specifically looked at measure testing.
3	NQF always had criteria for reliability and
4	validity but we wanted to get more guidance on
5	how our steering committee should evaluate
б	performance measures on these areas.
7	And so I'm just going to mention,
8	we have a whole report on this but I'll
9	mention a few key things. And one is that
10	reliability and validity require empirical
11	analysis. And it should be based on the
12	measure as specified.
13	Again, our task force and guidance
14	at this point in time suggested that we allow
15	for testing at either the data element level
16	or the performance measure score. So an
17	example of that is if we have a performance
18	measure about percentage of patients that
19	achieve a blood pressure below 140/90 the data
20	that goes into that is the blood pressure
21	value. And is that data reliable or your data
22	for identifying patients who have a diagnosis

Page 207 1 of hypertension, is that reliable. 2 And in this case, and then at the 3 performance measure score we're looking at the 4 signal-to-noise analysis that people have 5 mentioned. If you have data on many providers do you have good signal to be able to 6 7 distinguish among the providers who are being 8 measured. 9 In this case the PROM data would 10 be the data element. So we've already talked 11 about basing performance measures on PROMs 12 that would be reliable and valid, and I think we all agree in the context for which they 13 14 were developed, but the question is should we require that there be also testing at the 15 performance measure level whereas currently 16 our criteria would say at either level. 17 So 18 these are some things that we'll get into as 19 we get into discussions. Okay, next slide. 20 Is that the last one? Okay. 21 So that's kind of the background 22 just on reliability in the NQF criteria. And

	Page 208
1	now Laura Smith is going to tee up some of the
2	issues and considerations in regards to
3	that were pulled out in the paper.
4	DR. SMITH: Thank you, Karen. So,
5	in this section I am going to talk about some
б	methods for evaluating the reliability of the
7	provider-level performance measures and also
8	potential strategies for designing your
9	measure in order to address potential
10	reliability issues. Next slide.
11	Before I dive into that though I
12	just wanted to pause for a moment just to
13	acknowledge sort of the broader context that
14	we need to think about reliability within.
15	And so this first bullet is basically sort of
16	your basic psychometrics that the reliability
17	is necessary but not a sufficient precondition
18	for validity.
19	And when we think about
20	reliability of the performance measure there's
21	also a very direct importance relationship
22	with validity, especially if performance

	Page 209
1	measures are being used to rank facilities or
2	providers for public reporting or other types
3	of policies like pay-for-performance that if
4	you have the performance measure scores
5	largely determined by noise or measurement
6	error you're going to end up with
7	misclassification of the ranking of providers
8	which would be a serious threat to validity.
9	So just for that backdrop.
10	And then the last piece, I just
11	want to acknowledge that any of the
12	suggestions that I'm making about evaluation
13	methodology, all of this needs to be taken in
14	the context of a lot of the issues about
15	meaningfulness and validity that have been
16	discussed in the sessions earlier today. Next
17	slide, please.
18	So here I've shown how you can
19	basically depict reliability as an index. And
20	starting with patient-level, the classic
21	Streiner and Norman way of thinking about
22	reliability as the ratio of the subject

Page 210 variability to the total variability in the 1 2 measure. And here in this first equation it's 3 decomposed into two parts. So it's the subject variability, the true variability, and 4 5 then measurement error. And so if you have a lot of measurement error then your reliability 6 7 score index is going to go down. 8 And in the next equation you can 9 see that actually this is an analogous way of 10 thinking about reliability at the performance measure level. And so using the language from 11 12 NQF that we have the ratio of signal-to-signal plus noise. And that noise can be decomposed 13 14 into measurement error at the patient level and measurement error at the provider level. 15 16 So reliability can be quantified as this index which has a range of zero to 1, 17 18 zero indicating that the entirety of the variation that you see among providers is 19 20 attributable to noise, and a 1 indicating that 21 the entirety of variation that you see among 22 providers on the performance measure is

	Page 211
1	attributable to true differences among
2	providers.
3	And so the literature suggested
4	that a good threshold for evaluating the
5	reliability of your performance measure is
6	having a reliability index of 0.7. Next
7	slide, please.
8	So, to discuss further the
9	determinants of performance measure
10	reliability the components, the important
11	components are the magnitude of the true
12	differences among providers so that numerator
13	value and then the magnitude of within-
14	provider variation. So the measurement error
15	that you see at the PROM level and also at the
16	provider level. And then the size of the
17	provider sample or that denominator for your
18	performance measure.
19	So, one question that we started
20	talking a bit about earlier today are the
21	implications of how you might aggregate the
22	PROM data into a provider-level performance

	Page 212
1	measure. And in this case we need to pause
2	and think about how choice of using an average
3	change or a threshold might have on the
4	reliability of the performance measure.
5	I don't necessarily have an
6	endorsement of a particular strategy, but
7	rather a couple of examples to weigh in this
8	decision. So, one issue with using an average
9	amount of change, and I'm not editorializing
10	on this particular measure but to give you an
11	example of where this approach is used there's
12	the excuse me, "Change in Basic Mobility as
13	Measured by the Activity Measure for Post-
14	Acute Care."
15	And so what this measure does is
16	look at the average change from a baseline
17	score for mobility to a follow-up. And so one
18	concern about using an average change is that
19	this type of measure is vulnerable to
20	measurement error at both the baseline data
21	point and at follow-up.
22	For the threshold measure, and

	Page 213
1	another example would be from the nursing home
2	world the percent of patients who are able to
3	self-report moderate to severe pain. And in
4	this case one consideration would be what the
5	reliability is around that threshold where the
6	decision has been made that the patient would
7	be counted in the numerator as having moderate
8	to severe pain.
9	And then the last consideration
10	for this particular issue that I wanted to
11	touch on although I know there's lots more
12	that could be discussed is that also that
13	choice of threshold. So what I was just
14	talking about with both of those examples is
15	the impact on the within-provider variability,
16	but this choice of threshold could also have
17	an impact on the between-provider variability.
18	So if you chose a threshold that
19	was either very low and very easy for most
20	patients to clear, or very high and something
21	that would be very rare you'll end up with
22	very little variability for the most part at

	Page 214
1	the provider level and therefore reliability
2	is reduced. Next slide.
3	So, to sum up some of that
4	discussion, the performance measure
5	reliability is therefore dependent on the
6	characteristics of the set of providers but
7	also the patients included in the measure.
8	And also, another side effect is that
9	reliability is not static. So you can have
10	basically a set of reliability indexes for
11	providers at the beginning of public reporting
12	and if people's if providers begin to
13	improve performance and everyone is converging
14	on a similar score the reliability of the
15	measure is going to be reduced.
16	Then lastly, estimates for smaller
17	providers are more vulnerable to random error.
18	Next slide.
19	So in the next few slides I'm
20	going to discuss methods for reliability
21	testing that would help provide evidence to
22	support the endorsement of a PRO-PM score.

	Page 215
1	And for the most part what is included in the
2	paper and in this discussion, we really
3	haven't treated PRO-PM measures differently
4	from any other in terms of methods.
5	However, there are potentially
6	other conceptual considerations that I think
7	have been brought up earlier about whether or
8	not the decision to include the requirement of
9	reliability at the measure level should be
10	considered. I'm going to leave that panel to
11	discuss though. All right, next slide,
12	please.
13	So, here's a list of performance
14	measure reliability testing methods. In the
15	interest of time I won't go into a lot of
16	detail, but point out two of the strategies
17	here, so the two-level hierarchical model
18	allows estimation of the signal and noise that
19	I referred to in the initial slides. And it
20	basically results in a reliability estimate
21	for every provider.
22	The interclass correlation

	Page 21
1	coefficient also allows the estimation of a
2	reliability index for each provider which can
3	be very useful in some of the subsequent
4	discussion about trying to determine the
5	adequate sample size for your measure
6	necessary to have a reliable measure.
7	These two strategies have been
8	used in some recent measures that have gone
9	through NQF endorsement and were the two-
10	level hierarchical model is explained in some
11	detail in a recent paper by the Committee of
12	Presidents of Statistical Societies. And so
13	there's a lot of good information out there in
14	terms of how to implement this testing. And
15	also there's a report by RAND. All of this is
16	referred to in the paper.
17	There's other strategies that have
18	been used in the literature to examine
19	reliability, to examining the overlap in
20	confidence intervals calculated for every
21	provider. You can give a visual depiction of
22	the reliability of that particular measure.

6
	Page 217
1	Inter-unit reliability can be
2	derived from ANOVA and GLM that's derived from
3	the F test generalizability theory and Monte
4	Carlo simulation or other strategies. And
5	I'll refer you to the paper for references for
6	those.
7	So in the next section we talk
8	some about the issue of provider size. Just
9	remember that given the different components
10	that determine reliability provider size is
11	not the only determinant but it's an important
12	one. So actually we can go on to the next
13	slide.
14	So those two strategies that I
15	mentioned, the hierarchical modeling and the
16	intra-class correlation, because they give you
17	a reliability estimate for every provider
18	allows you an opportunity to look at what the
19	relationship between provider size and
20	reliability is and potentially identify a
21	threshold where your reliability estimates for
22	providers are 0.7 or higher. Next slide.

ſ

Page 218 So if you find that a large 1 2 proportion of providers in your target population have a reliability that are lower 3 than 0.7 you may want to consider some 4 5 additional strategies for improving performance measures. 6 7 It was mentioned earlier today one 8 strategy would be to design a composite which 9 is combining two or more performance measures. 10 So at the provider level in order to increase the data points that are being used in the 11 12 calculation of the performance measure. 13 Another strategy that increases 14 data points would be to change the time window over which the measure is being calculated. 15 16 So if the measure is looking at results within 17 one guarter consider increasing the time 18 period to two quarters or a year. 19 One concern about this strategy is 20 that your performance measure is going to be 21 less sensitive to changes in quality which can 22 have multiple concerns, one having to do with

1	
	Page 219
1	the use of the usability of the measure for
2	quality improvement but also in terms of the
3	acceptability to providers in terms of their
4	being able to make changes that appear later
5	and quickly in public reporting.
6	One other strategy is to work on
7	improving the reliability of the underlying
8	PROM which could have to do with changing the
9	way that questions are phrased or instructions
10	are made.
11	And then lastly which I'll spend a
12	little bit of time on is to apply reliability
13	adjustment. Next slide, please.
14	So reliability adjustment which
15	again can be applied using the hierarchical
16	modeling, in connection with the hierarchical
17	modeling that I mentioned earlier and then
18	also intra-class correlation coefficients.
19	Basically instead of dropping from
20	public reporting or whatever format that you
21	might be presenting results, instead of
22	dropping facilities that have small sample

	Page 220
1	sizes from being publicly reported, you can
2	actually adjust the provider scores by
3	shrinking their estimates towards the mean
4	value. And this mean value could be for all
5	providers or if there's a wide distribution of
6	sizes of providers you might consider
7	stratifying into a larger excuse me, you
8	might consider shrinking towards providers of
9	a similar size.
10	However, there's some concern if
11	you're using volume for provider size. This
12	might be something that's particularly an
13	issue if you're looking at physician practices
14	where there isn't sort of a hard way of
15	counting size other than patient volume, is
16	that there's endogeneity of volume with
17	quality, that current volume of patients that
18	a provider might be providing services to can
19	be affected by prior quality perception of
20	quality by patients.
21	So in light of that shortcoming
22	you may want to use in addition to volume

	Page 221
1	other provider characteristics. And nor
2	surprisingly given that smaller providers tend
3	to be more vulnerable to poor reliability the
4	smaller providers are more likely to be are
5	shrunk towards the mean values.
6	And then just in closing wanted to
7	bring back sort of my initial comments about
8	the importance of the relationship between
9	reliability and quality excuse me,
10	reliability and validity. And that you can
11	see in cases where there's poor reliability of
12	the provider performance measure that you can
13	have misclassification in public reporting and
14	other uses of performance measures. Thank
15	you.
16	DR. PACE: Okay. Jack? Or,
17	sorry, Lewis. Looking right at you and saying
18	the wrong name.
19	DR. KAZIS: Can you hear me? It's
20	indeed a pleasure to be on this panel today in
21	particular because of Jack Fowler. And in
22	fact Jack was my first instructor at the

	Page 22	22
1	Harvard School of Public Health more years ago	
2	than I'd like to think. And Jack and I	
3	haven't changed in our appearance since then.	
4	But I'm delighted to be on the same panel with	
5	him.	
6	So, my charge today for this panel	
7	is to speak about the relationship between	
8	reliability and validity, or what is the	
9	connection between these two concepts. In	
10	some respect being in this field for more than	
11	25 years has provided me with some historical	
12	perspective I think on this issue and on	
13	things going forward.	
14	For a number of these years much	
15	emphasis has been on the patient-reported	
16	outcome measures with a view to assessing	
17	reliability and validity of the instruments.	
18	And this was clearly a mandate for a number of	
19	years with such organizations as ISOQOL, the	
20	Academy of Health and other organizations	
21	where you go to the meeting and you hear about	
22	reliability and validity of your particular	

Page 223 instrument or questionnaire. 1 2 More recently these meetings I think have taken on a different context and 3 for that reason have become much more 4 5 interesting given that the instruments, questionnaires and so forth are now for the 6 7 first time being applied to the front lines of 8 care in terms of how care is being rendered and also in terms of the organization and 9 processes going forward to improve quality. 10 So Figure 1 is a pyramid. 11 And 12 what the NQF calls PROMs includes the focus on the consistency of the metrics using 13 14 approaches that build on the signal and noise concept that Laura talked about earlier. 15 The precision of the measure --16 17 and these assessments include such things as 18 test-retest, internal consistency reliability 19 which has not really been talked about here 20 but that's the Cronbach alpha that we all know 21 about. And other methods including 22 hierarchical models, Markov, all kinds of

1	
	Page 224
1	things that are fairly sophisticated and bring
2	an appreciation for reliability.
3	The precision of the measure in
4	the world of legacy measures has been
5	considered as important to a reliable
6	assessment. The validity of the assessment or
7	more generally does the measure measure what
8	it purports to measure is really the bottom
9	line in my opinion as one can have a reliable
10	assessment but if it isn't valid then the
11	exercise becomes pretty futile.
12	More recently, the use of the
13	HRQOL assessments that measure a range of
14	functioning from the physical to the
15	psychological have undergone a continued
16	transformation with the advent of the PROMIS
17	approaches using IRT and CAT. And David Cella
18	did a great job at the last workshop detailing
19	those approaches and applications.
20	These assessments have important
21	applications in the measurement world and now
22	have begun to be applied in a range of

	Page 225
1	settings to evaluation healthcare. Both
2	legacy and PROMIS measures are now being
3	introduced to a new world of performance
4	measurement applications. The use of these
5	measures in this context is fairly recent in
6	the United States and present important
7	challenges as we begin to think about how such
8	measures can be used in the context of
9	evaluating the healthcare processes at the
10	provider practice levels, among hospitals,
11	between plan organizations, and so forth.
12	The relationship of the metric for
13	performance measurement is well established
14	from a statistical and scientific vantage
15	point. The validity applied to a performance
16	measurement, however, is really in my opinion
17	very early on in its development. Clearly the
18	validity issues will become established with
19	more experience.
20	An analogy that I thought of this
21	morning, and maybe it wasn't a good one, and
22	it might be a bit of a stretch, but to use

Page 1 this in the context of the space program, to 2 launch an astronaut to the Moon. This took 3 nearly a decade when John Kennedy announced 4 this challenge and goal in the early sixties. 5 Maybe being from Massachusetts I thought it 6 would be appropriate. 7 The physics for this had 8 historically been in place since Sir Isaac 9 Newton, many years, actually centuries before. 10 However, the proof in the pudding or of the	
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10 However, the proof in the pudding or of the	
11 physics was not established until we actually	
12 put a man on the Moon.	
13 While we have many instruments and	
14 metrics out there, the proof of concept of the	
15 application and validity of these remains to	
16 be applied and tested in the use of the	
17 metrics in the real world, and then ultimately	
18 to improve the quality of care in the	
19 healthcare system. Perhaps we should develop	
20 a time line with goals as this moves forward.	
21 For purposes of performance	
22 measurement and just to be a little technical,	

	Page 227
1	reliability can be defined simply in terms of
2	what I call the expected and the residual
3	reliability. Expected reliability tests for
4	the consistency of the case-mix differences in
5	predicting outcomes among entities being
б	compared such as physician practices,
7	healthcare plans, et cetera. Case-mix is
8	based upon the sociodemographics and clinical
9	characteristics that are covariates in the
10	model. So, expected reliability would be the
11	consistency of those case-mix of that case-
12	mix across different entities that you're
13	comparing.
14	And Steve Fihn in fact you asked a
15	question this morning about case-mix and this
16	type of reliability in fact can get at that
17	issue as to whether case-mix in fact might be
18	changing amongst what's being compared. A
19	very important point I think.
20	The residual reliability on the
21	other hand which is actual values minus
22	expected values is an indicator of whether the

	Page 228
1	signal can discriminate amongst the entities
2	being compared which would be practices,
3	plans, or whatever, and is based upon the
4	magnitude of the signal among the entities and
5	the sample size of each of the entities where
6	there's baseline and follow-up data for the
7	outcomes that are being compared.
8	And this can be calculated using
9	intra-class correlation coefficients. Markov
10	modeling techniques can also be used which was
11	in the very nicely done report by Laura.
12	The residuals measure the extent
13	to which a member's experience exceeded or
14	failed to meet the expected health change. So
15	you are comparing these plans in terms of
16	whether in fact expectations are exceeded or
17	whether they failed. The reliability of these
18	residuals then describe the extent to which
19	the entities being compared are truly
20	different compared with measurement error or
21	noise.
22	So the science for measuring

	Page 229
1	reliability for purposes of performance
2	measurement is in place and the challenges as
3	I see them are in demonstrating the validity
4	or whether the measurements are resulting in
5	a meaningful difference in the comparisons
6	being made. So a couple of questions related
7	to this.
8	Are we measuring correctly the
9	appropriate domains for the purposes of
10	performance? Are the populations being
11	targeted correctly for this purpose? Are the
12	populations sufficiently homogenous so that
13	one is able to find meaningful differences
14	that one can act upon in terms of the HRQOL
15	outcomes being assessed? Is what is being
16	measured truly measures of outcomes that are
17	impacted on by quality or processes of care?
18	Could you go the next figure?
19	So, my charge was to look at the
20	differences between reliability and validity,
21	or to talk about the interface. And you'll
22	notice that the arrow there is bidirectional

	Page 230
1	with a question mark because I think there are
2	some that will think it should go only in one
3	direction, from reliability to validity.
4	Others that have a broader
5	perspective I think see it as bidirectional.
6	And the reason for this is that reliability
7	will give us a metric that is precise and
8	provides an understanding of the measurement
9	characteristics. Validity on the other hand
10	will determine if we're on target. Both can
11	inform each other. In the event that the
12	metric is not sensitive to the comparison
13	being made among, for example, doctor
14	practices, this could be a function of the
15	content and construct validity.
16	The content validity may be that
17	the domain of content being measured needs to
18	be modified or added to, or that the construct
19	being measured needs further refinement.
20	Also, are we measuring what is relevant to the
21	provider and patient? This then points to
22	both issues of reliability and validity.

	Page 231
1	The organizations being measured
2	which is at the top there are also an
3	important consideration. Is the measurement
4	being taken seriously within the organization?
5	And how much or in fact are they just
б	giving lip service to it? How much emphasis
7	is being placed on interventions that will
8	impact on the outcomes being assessed?
9	The measurement also may be so
10	rigid and specific that the processes of care
11	and interventions are not being reflected in
12	the outcome metric and the dynamics of what is
13	occurring in the entities being measured and
14	compared are not adequately represented.
15	Does this measurement provide a
16	depth and breadth of content so that the
17	dynamics of the processes of care impact
18	adequately on the outcomes being measured? Do
19	we need to consider generic measures and
20	disease-specific metrics as well? Is the
21	overall net of what is being captured
22	reflected in the signal in the entity being

	Page 232
1	compared with other entities so that
2	interventions and processes of care are
3	reflected in the variability and the outcomes?
4	And just a couple of last points.
5	Gaming is something which is at the bottom
6	there of that figure that can be defined as
7	meeting the target or threshold but clearly
8	missing the point. There are proprietary
9	efforts in companies designed to consult with
10	health plans or insurers designed to improve
11	the Stars ratings that was discussed this
12	morning. In fact, one of my former students
13	works for such a company.
14	And basically they'll go into the
15	insurers, to the health plans and they'll look
16	at how in fact can we improve the Star rating.
17	So some gaming clearly is going on,
18	influencing the metrics and in the future it
19	may be important to develop methods to better
20	understand gaming approaches and how this can
21	be revealed through the patterns of the
22	results.

Page 233 Is it possible that the metrics, 1 2 for example, may influence the nature of the case-mix to provide the physician practices or 3 4 plans with more favorable patient mix for 5 purposes of outcomes? This goes back years ago to what we used to call adverse versus 6 7 preferential selection. But I think we all 8 know that some of that is out there. To conclude, I think that the 9 10 science of performance measures for reliability is far advanced in evaluating the 11 12 reliability of the metrics. On the other hand, the validity of the metric as a 13 14 performance measure is pretty much in its 15 infancy. Validity I view as when the rubber 16 hits the road. It involves the success of the 17 18 measure in adequately measuring entities among 19 health plans or physician practices or 20 whatever with sufficient precision and 21 variability that the results are found to 22 accurately reflect the outcomes of processes

	Page 234
1	of care.
2	Are the measures in populations
3	studied covering what needs to be measured for
4	purposes of improving performance in quality
5	of care? There are a number of methodological
6	issues that need to be addressed I think
7	related to the validity of performance
8	measures, and this includes face validity,
9	construct validity and criterion validity.
10	And I think you all are aware of what that is.
11	The sensibility and consequently
12	usefulness of what is being asked of the
13	patients needs to be present. And similarly
14	for the clinicians and administrators that
15	they also view the metric as important and
16	useful. So I think the clinical sensibility
17	issue becomes really paramount in this
18	context.
19	A last point is that much of this
20	work goes back to the buy-in of the patients
21	and providers at the front lines of care.
22	That's where it's at. And I begin to see that

	Page 235
1	as I age and I see clinicians and you know,
2	clearly that's where everything is happening.
3	That view of the metric of what is
4	being evaluated is very important. I think
5	that more experience with validity of
6	performance measures is needed as we move into
7	what Aldous Huxley used to say, a brave new
8	world, where performance measures become a
9	mainstay of healthcare. Thanks.
10	DR. PACE: Okay, thank you, Lewis.
11	And just also looking ahead we have two panels
12	that will specifically be targeted on validity
13	issues. But thank you for that relationship,
14	that's what we needed.
15	Okay, Lori? Or Jack? Which one?
16	DR. FRANK: All right, I'll go
17	next. All right, thanks very much. The
18	outline for my comments since reliability
19	relates so much to variation is variation on
20	a theme. I'll discuss how the concept of
21	patient-centeredness relates to reliability
22	and as with the last time my goal is to

	Page 236
1	explore how re-framing patient involvement in
2	PROs can improve measures and enhance the
3	value of PROs for use in clinical settings and
4	for performance measurement.
5	Communication, trust and
б	perspective are my main themes as I think
7	about performance measure reliability. And I
8	had a visual slide up as well.
9	DR. PACE: Yes, Jessica will put
10	it up.
11	DR. FRANK: Okay, great. First,
12	the authors made a distinction, an important
13	one between generic and condition-specific
14	PROs. And the distinction has implications
15	for psychometric assessment. How you approach
16	psychometric evaluation differs by the type of
17	PRO. I think that it's useful for us to think
18	about performance measures and whether they
19	are setting- or process-specific or setting-
20	or process-generic which is a point Laurie
21	Burke made in terms of context of use.
22	So my question to address is are

	Page 237
1	there any differences or unique considerations
2	for demonstrating and evaluating the
3	reliability of a PRO performance measure.
4	Really the question is what's special about
5	patient report. Psychometrically, nothing.
6	Is reliability of the PRO
7	performance measure score needed in addition
8	to reliability of the PROM? I would say yes
9	but it connotes something different for the
10	performance measure than it does for the PRO
11	which is a point I think made very well in the
12	paper.
13	Reliability is foundational which
14	is why I chose an image that had a table with
15	a strong base there. So we need to know for
16	an individual PRO that it demonstrates
17	adequate internal consistency reliability as
18	well. Are the items all pears or are there
19	some apples mixed in? Are there things there
20	that don't fit in? So I picked in image that
21	had different fruit in it as well.
22	And then we also need to know

	Page 238
1	about test-retest reliability. At a different
2	time and with no changes expected from time 1
3	to time 2 will we get the same results?
4	That's why I chose an image that also had a
5	clock in it.
6	And relatedly, at what time point
7	does it make the most sense to assess
8	reliability and for that matter, quality?
9	Have patients provided input into the timing
10	of the assessment?
11	For the theme of perspective which
12	is part of why I chose something that came
13	from a cubist tradition although this is
14	technically futurist which I think fits with
15	this meeting well, it makes us think about
16	perspective. Do we have trust in our PRO for
17	use with individual patients and do we have
18	trust that aggregating the responses will lead
19	to sound conclusions? So what's required for
20	us to have trust once we aggregate up? What's
21	required for the patients to have trust?
22	They're important reporters but also important

	Page 239
1	consumers of the information. What is it that
2	they need in order to trust this information?
3	So what's different about patient
4	report when we consider PRO performance
5	measures? As I said earlier, psychometrically
6	nothing but because we're dealing with
7	information obtained from people and
8	heterogenous people, everything's different.
9	People are variable. There's inter-individual
10	differences, there's inter-individual change
11	and a reliable measure needs to work across
12	different perspectives and faithfully transmit
13	differences and faithfully report on those
14	true changes.
15	The authors raised an important
16	issue, that of the provider-specific care
17	quality which requires that the provider is
18	considered in terms of the match with
19	individual patients. For this we're talking
20	about sample means or ratings, and what could
21	be termed goodness of fit between a provider
22	or a system profile and a patient's

preferences. There was some talk this morning
 about the role of patient preferences in
 performance assessment.

A separate type of reliability to 4 5 contemplate then is the extent to which the provider consistently scores well for patients 6 7 with similar preferences on key variables. 8 This is a perspective issue which I think 9 those strange wavy lines on there help to 10 communicate beyond what we usually consider. It's something we don't usually see. 11

12 How best can we communicate the 13 reliability of the quality measure, quality or 14 performance measure, to patients and to other non-clinicians? How can we do so in a way 15 that builds and maintains trust? 16 What else 17 should be communicated? Which goes to what we 18 were talking about this morning about 19 squeezing every last bit of value out of a 20 patient-reported outcome measure which would 21 include considering the direct-to-consumer 22 communication possibilities.

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	Page 241
1	Creating trustworthy measures,
2	measures truly worthy of trust, is a very
3	important way to do this. Among the issues
4	that are hard to address let alone communicate
5	to a wide audience is when quality of the
6	evidence and the ability to draw inferences
7	from the data varies systematically by some
8	variables of interest as with the example the
9	authors gave of the shrinkage towards the mean
10	strategy which works better for top hospital
11	quality than bottom-quality hospitals.
12	How do we establish trust in our
13	measures? In the section on aggregating data
14	the authors rightly point out that means can
15	be misleading when the population of interest
16	is diverse in some important ways. Obtaining
17	reliability estimates of a measure can be
18	similarly misleading if a measure truly
19	performs differently in different populations.
20	So, getting back to perspective the shrinkage
21	technique referenced earlier, the performance
22	may differ by a specific variable.

Page 2 1 In the case of measure reliability 2 that differs by populations clinicians and 3 also patients should have input into drawing 4 the meaningful distinctions between groups and 5 then the researchers can go onto hypothesis- 6 test the differences in terms of impact on 7 reliability. Cut points, for example, might 8 differ by patient groups in ways that we 9 haven't explored with patients helping to 10 define what those groupings should be. 11 Part of the point of involving	
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10 define what those groupings should be.	
11 Dart of the point of involving	
12 patients in performance measure development	
13 and selection is opening up performance	
14 measurement exercise to things that we as	
15 clinicians and researchers have not considered	
16 as important but in fact may actually be. So,	
17 things that patients see that we might not be	
able to until we view it from the patient's	
19 perspective.	
20 The authors reference a notion of	
21 similar patients with similarity defined by	
22 researchers or clinicians generally. But	

	Page 243
1	there's room there to consider other types of
2	definitions of similarity, and even having
3	patients comment on those definitions.
4	An example of patient preference
5	given in the paper is an example of a
6	caregiver proxy measure. So I'd be remiss if
7	I didn't make the point that family and other
8	caregiver reporters are important but we need
9	to be mindful about loss of fidelity which
10	might be more of a validity issue but missing
11	the mark a little bit despite reliably hitting
12	that same spot on the target. Proxy report,
13	obviously not the same as a caregiver-reported
14	outcome, a point I think that we're all clear
15	on here.
16	The authors correctly point to
17	inter-interviewer variability as a threat to
18	validity. I would say it's a concern for
19	reliability as well. The example they gave
20	was a script used in the minimum data set to
21	support inter-interviewer reliability.
22	It's interesting to consider when

Page 244 1 the standard step that we've all used to 2 minimize variation might actually introduce unwanted variation in some cases. 3 So are there patients who need a different script? 4 5 Are there those who need the interviewer to be able to bury the script in order to collect 6 7 the most reliable and most accurate data? 8 I want to end with the concepts of 9 "in" and "of." We talked last time about 10 patients involved in the research as subjects but also helping to define the outcomes, 11 12 helping with recruitment, et cetera. And then patients of the context of research, helping 13 14 to define the topics and prioritize, and helping with some of the funding decisions. 15 I think that same in -- way to conceptualize 16 17 it can be applied to performance measurement 18 too and it's very exciting as we think about 19 futurism for us to contemplate that here. 20 As Ethan said, how are patients 21 involved in defining meaningfulness? How do 22 we measure meaningfulness of scores reliably?

1	Page 245 Are patients involved in this?
2	And I really appreciated what
3	Patti Brennan said in terms of listening to
4	the patients about how they think about their
5	own care. And it's somewhat analogous to
6	hearing the patient voice in development of a
7	PRO. All of this reinforces the
8	trustworthiness of the measurement enterprise.
9	Should performance measurement be
10	patient-centered? Not always and not
11	necessarily, but I would challenge us to think
12	about situations in which inclusion of the
13	patient perspective does not improve the work.
14	Last time I discussed the idea of
15	involving patients in discussions of sources
16	of measurement error in performance
17	measurement. For this topic today I stand by
18	that recommendation. We have to recognize the
19	patients who are not being asked about their
20	healthcare in the best possible way for them
21	have the power to bring measurement error
22	including reliability in.

	Page 246
1	So last time I referenced Donald
2	Berwick's 2009 Health Affairs piece on
3	patient-centeredness. These are radical and
4	disruptive shifts as he would call them in
5	control and power. And if they improve care
б	quality then I think they're worth it.
7	Thanks.
8	DR. PACE: Thank you. And now
9	Jack.
10	DR. FOWLER: It's neat to follow
11	two people. You've covered a lot of things.
12	And the paper was very good. And I'm not
13	going to talk much about the calculation
14	strategies which I think there are other
15	people here better qualified to talk about
16	that.
17	But as I thought about the
18	reliability issue I keep thinking that there
19	are these two steps here, and without the two
20	steps working then it doesn't work. And so
21	the question that was raised I think that was
22	framed initially and is it enough to assess

	Page 247
1	the reliability of the patient-reported
2	measure or do you have to assess the measure
3	of the performance measure? And you've got to
4	do both.
5	And there are two steps, and there
6	are two sources of reliability that are here.
7	You've got whatever amount of error there is
8	in the measurement of how the patients turned
9	out and how well or badly we are measuring
10	what kind of shape they're in. And then we've
11	also got this relationship between whatever it
12	is the providers do and this outcome. And
13	that if that's got unreliability too, I
14	mean I think you reduce the reliability bad
15	reliability times bad reliability gets you
16	wherever you get.
17	And I think you've got to do both
18	steps. And without doing them both I don't
19	think you're there.
20	And so we do have quality measures
21	that are not two steps and I just want to
22	point that out, that these process measures

	Page 248
1	that folks talk about don't involve those same
2	kinds of two steps. So the CAHPS measures
3	involve saying did they talk to you in terms
4	you can understand. How long did you wait in
5	the waiting room to see a doctor. There are
б	not two steps there. You had the clinical
7	experience and you reported on it, and that's
8	got its own reliability but it's one step,
9	it's not two. We don't have to have a
10	hypothesis between waiting time in the waiting
11	room or in anything else, we just wanted to
12	hear about that.
13	We've been working a lot on
14	decision quality. And actually, the three
15	things we think you need for a good decision
16	are a process that involves interaction with
17	a physician in a certain way, being informed
18	and having a decision that is matches your
19	goals and values.
20	So, the first one, the one about
21	the process, again is a one-step thing. We
22	can ask people did the doctor how much did

Page 249 the doctor talk about the cons as well as the 1 2 pros. Did he talk about alternatives and did 3 she ask you what you wanted to do. Those are 4 things with no steps in between, they're just 5 reporting on what you experienced. The 6 questions can be perfect or medium but the 7 measurement problem is just the one thing. 8 But then if you go to the next 9 step to say, you know, did you get a concordant decision then you've got to have 10 some kind of link between the way the 11 12 physician interacts with a patient or whatever you think the action is and the outcome that 13 14 you're measuring. So you've got to have both 15 of those steps. 16 And one of the things I sat around and thought about, building on what Liz Mort 17 18 was talking about this morning is what are the 19 kinds of situations or patients that we can 20 think of where you could really say with some 21 confidence we think that the way the doctor 22 treats them could make them better, or keep

	Page 250
1	them from getting worse. Or at least you
2	could predict what the outcome would look like
3	or the change would look like if they got good
4	care, whatever that means.
5	And I had trouble making a list of
6	those things. You know, there are just a lot
7	of things so you know, and I know others in
8	the room have wrestled with this sort of
9	thing. For example, you take low back pain
10	and that's pretty cool but the problem is that
11	about 80 percent of low back pain resolves
12	itself in a couple of weeks. So probably no
13	matter what you do to them a bunch of people
14	are going to get better. So there you go.
15	So you say, well you've got to get
16	the right back pain patients in order to study
17	whether the intervention or the support they
18	get. And that, I keep going back to the
19	problem of how well can we do at identifying
20	the patients whose outcomes we're going to
21	measure.
22	I notice the Europeans, both of

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their approaches were to take surgical patients. So they actually ducked the patient identification problem of who's eligible for this by just picking the ones that got intervened with.

6 Now, we thought a bunch about this 7 and that is the easy one to do. If you want 8 to do something reliable to sort of measure 9 outcomes you can measure people who get cut or 10 intervened with in some other serious way and find out if they got better or enough better. 11 12 One of the nifty things for providers is that with a few exceptions there are a whole lot of 13 14 interventions like that that make people better at least if you measure symptoms before 15 and after. You kind of end up looking better 16 17 though we could say whether the Hopkins people 18 turned out as well as the MGH people turned 19 out as well as the UNC people or something 20 like that. We can work on that. 21 (Laughter) 22 But the real problem DR. FOWLER:

	Page 252
1	with that is the point that Liz Mort brought
2	up also, is that the where I'd really like
3	to start the evaluation of how do we treat
4	people are with people who have got the back
5	pain or who have got the knee pain or have got
6	BPH or whatever it is they've got. And I
7	don't want to and I don't want to give
8	people bad scores just because they're less
9	interventional. And if you just take the
10	people who get the big interventions you're
11	likely to get pretty big improvements but you
12	don't get to give credit to the providers who
13	let the guys live with their BPH symptoms or
14	who let the guys say that I'm willing to kind
15	of work with my herniated disk and treat it
16	conservatively, and if you measure me 6 months
17	later my back's going to hurt worse probably
18	on average than if I got surgery for my disk
19	but I didn't want to go through the surgery.
20	And that's I got better care in some way
21	even though my symptom score may be higher.
22	And I say I would hate to build in
	Page 253
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1	interventions, you know, incentives for
2	interventions that will fix problems at some
3	cost and you're not measuring the cost so much
4	as just measuring how the symptoms come out.
5	And the other so I worry about
6	that and I keep coming back to the fact that
7	maybe the most complicated problem we have is
8	how to identify the patients whose outcomes we
9	really want to track. And how do we do that.
10	We've been working with a bunch of
11	medical practices to work again in this case
12	on quality of decision-making. And so one of
13	the things that we need to do is identify
14	people who were candidates for making
15	decisions who are not and that's a pretty
16	good group of the people that you might want
17	to see how things turn out for.
18	And boy, do practices have a hard
19	time identifying people who have a certain
20	symptom situation or medical condition. They
21	have trouble identifying their diabetics. And
22	if they do identify diabetics, maybe everybody

	Page 254
1	who's got a diabetes score at a primary care
2	visit, they can be in all kinds of different
3	stages and places in where they are.
4	Arthritis was another one that you
5	picked out as maybe could monitor pain. But
б	boy, the arthritis people, just because you've
7	got a code of arthritis, you know, you could
8	be somebody who's been managing it for a long
9	time, had it under control and you're just
10	sort of maintaining it, or you could be a new
11	onset person for whom actually how things get
12	managed could make a big difference.
13	And I think the patient
14	identification thing it seems to me is one of
15	the greatest challenges. And it is a
16	reliability problem, not a validity problem
17	because I think every practice is going to do
18	it differently.
19	And I was again interested in I
20	think it was the Swedes who seem to be
21	managing to get patients to fill out sort of
22	baseline questionnaires about what their

	Page 255
1	status is about things. And that would be a
2	big help in terms of patient identification
3	for these symptoms. But we don't do that in
4	this country and there's nobody who's got
5	or hardly it's unpredictable who might
6	happen to have a back pain score or a BPH
7	score or something on their general practice
8	thing.
9	So the notion of who could you
10	reliably identify so I could have the same
11	patients with the same kind of clinical
12	characterization across a bunch of practices
13	is a problem I haven't been able to think of.
14	And that is a genuine reliability problem
15	because as we were talking about earlier
16	today, you know, the impact and the validity
17	of measuring performance, you've got to even
18	the playing field about treating the same
19	patients and how they're coming out.
20	And if there's differential
21	information about who they are and different
22	ability within practices to identify the same

	Page 256
1	people that really is an important source of
2	unreliability I think in the measurement
3	that's going to be really hard to wrestle with
4	and get right.
5	So there are a bunch of challenges
6	here and you know, it's such important and
7	good work, and there are there probably are
8	some cases where we can identify reliably some
9	people the care of whom we could take as an
10	outcome of care. But it's not a really,
11	really long list I don't think and I think the
12	problem of patient identification has got to
13	be paramount, and whether you can make a
14	reliable and meaningful assessment of whether
15	or not medical care is actually better, worse
16	or whatever for that set of people. Thanks.
17	DR. PACE: Okay, well thank you to
18	Laura and our panel. And now we'd like to
19	open it up for discussion with the rest of our
20	expert panel and audience. So again those of
21	you on the phone you can get ready. We'll
22	take your questions in a little bit but I'll

	Page 257
1	start with any questions or comments for our
2	panel. Patti. At the table they're green.
3	Sorry.
4	DR. BRENNAN: Sorry. Hi,
5	everybody. I woke you all up. This can be
б	addressed by anybody on the panel. I see an
7	oversimplification of the healthcare system
8	that we're going to have patients within
9	practitioners and practitioners within
10	practices and everybody's going to stay where
11	they're supposed to be.
12	And so can you help us think about
13	how we're going to deal with me who has a
14	primary care doc who I never see, a nurse
15	practitioner that I always see, but sometimes
16	I see the person who's covering that day
17	because one of those people is sick or I've
18	come on the wrong day. And I know that you
19	can't solve all the problems but are there
20	ways we can think about reliability and
21	validity at the level of the practice that we
22	could actually sum across clinicians?

	Page 258
1	DR. FRANK: Yes. So I just wanted
2	to raise the idea of the quantified self and
3	big data, and data are getting bigger and
4	bigger. So if we start from the patient up
5	then we can systematically review data for
б	patterns and come to some reasonable
7	conclusions about quality from that direction.
8	You're absolutely right, we're not there yet,
9	but it's to me an interesting notion. It has
10	to be top-down also. But I'm excited about
11	the possibilities for patient up.
12	DR. FOWLER: I mean I think the
13	only other thing I'd add is that the CAHPS
14	people have been wrestling with that for a
15	long time too. And partly it's sort of what
16	your unit of analysis is. And I think, you
17	know, a care team or a care provider or an
18	ACO. And if you get a little bigger then we
19	give the whole system credit for it and that
20	may be helpful. You still could have two
21	systems treating you too but that at least
22	that solves the problem for a lot of people.

	Page 259
1	DR. PACE: Okay, Greg?
2	DR. PAWLSON: I think I've been
3	abandoned at this table. They're all up
4	there.
5	Two observations and a question.
6	One, I can't agree more with Jack about the
7	need to really characterize populations very
8	carefully. And even where we think we have
9	accurate diagnostic information we don't for
10	the most part. And there is so much range in
11	the labeling that we use at the current time
12	that it's almost meaningless. And so I think
13	if we're going to minimize the huge variance
14	that is introduced by patient-level variation
15	rather than provider effect, if that's what
16	we're actually trying to do I think that's
17	sort of a numero uno problem.
18	The second I think poses a real
19	problem for NQF. If we are to go beyond the
20	characteristics that of reliability and
21	validity that are sort of baked in at the
22	measure level and get into the performance

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1measurement level in a way it would be2interesting to get the panel to reflect a3little bit on how far do we think NQF has to4go in requiring testing at that second level.5In other words, I think most6people would agree what we want to see in7terms of reliability and validity8characteristics of the measure piece itself.9But when you're testing as both the paper and10a couple of panelists pointed out the11particular reliability that you find is12dependent somewhat on the population that you13tested in. So what's going to be sort of the14practical advice for the NQF panels in what15should we require, how much testing, how broad16does the population have to be, what can we17accept as enough to give us a reasonable idea18that this will work in most populations let's19say, or at least if you don't go way far20My favorite example is actually		Page 260
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21 My favorite example is actually	20	afield?
	21	My favorite example is actually
22 one from the VA. There was a paper published	22	one from the VA. There was a paper published

	Page 261
1	slamming the colon cancer screening measure
2	and it was done in a VA clinic in San
3	Francisco that was end-stage COPD. Well, we
4	never anticipated when we developed the colon
5	cancer measure that that's where it would be
6	used and obviously that population the measure
7	had no real validity or reliability for that
8	matter. So, the question is what do you think
9	NQF should do.
10	DR. KAZIS: Yes, it's a very good
11	question. I think that my recommendation
12	would be to begin with what I call low-lying
13	fruit and start with some success stories that
14	are going to get the clinical community
15	interested and involved in the process rather
16	than going after something that might be
17	initially viewed as being out in left field
18	and more difficult to reach.
19	So, perhaps to target some
20	populations very specifically and apply some
21	assessment tools that have some track record
22	already. And then provide the ability for

	Page 262
1	those metrics to be understood and recognized
2	by those that are using them through
3	recommendations and through other means. But
4	I think what's also important is not just to
5	provide a metric but to provide those that are
6	using it with some understanding of what they
7	need to do with it.
8	DR. PAWLSON: You were also
9	suggesting sort of post-marketing surveillance
10	after in other words, if we accept, you
11	know, testing. And I guess to use an example
12	that Jack was pointing out, if we sort of
13	focus on surgical procedures I would guess
14	that there is a fair amount of variance in
15	whom to whom surgical procedures are even
16	applied. So what level of testing would we
17	start with and then what about the sort of
18	post-marketing surveillance of, you know,
19	further evidence of its reliability and
20	validity as it's used more widely?
21	DR. KAZIS: Could I just mention
22	one thing related to that which is

	Page 263
1	variability. And the whole idea of health
2	services over the years was to reduce
3	variability. And is that I think we could
4	raise sort of a skeptical question, you know,
5	looking at it as a skeptic is variability
б	necessarily a bad thing. And are there
7	situations in medicine and clinicians out here
8	might clearly have some examples of this where
9	in fact a procedure is done in a very
10	different way by two different groups of docs
11	but in fact both are success stories?
12	DR. PACE: Right. And then in
13	that case you would have similar outcomes so
14	I don't think people would quarrel with that
15	as long as you had two effective processes.
16	Jack?
17	DR. FOWLER: That is my question a
18	little bit. And variability may not always be
19	bad but I think we have tons of data that show
20	that it's physician-driven most of the time
21	and is not related to either the patient
22	preferences or their conditions. And so while

	Page 264
1	I would not want to say stamping out
2	variability should be our goal by any means,
3	I think making sure that it's related to
4	outcomes and patient preferences and their
5	needs should be a really high priority here.
6	DR. FRANK: And I'm glad that you
7	raised the notion of post-marketing
8	surveillance because I think the FDA
9	regulatory pathway is instructive here. You
10	know, a measure is never valid or reliable for
11	that matter. We need to iterate and then it's
12	just drawing the line, when is it good enough.
13	DR. PACE: Al?
14	DR. WU: It seems to me that there
15	could be sort of a best case scenario for what
16	the reliability of the measure might be. At
17	least at the first phase I had two thoughts.
18	One was that the procedures, the prescribed
19	procedures for how to collect the measure
20	include in order to attempt to achieve good
21	reliability, acceptable reliability, should be
22	specified very clearly.

	Page 265
1	The second thing I wonder about is
2	it seems like this lack of reliability,
3	variability results from lots of things. And
4	I wonder if and a lot of those things could
5	be termed metadata. And I wonder if at least
6	when something is being rolled out if we
7	should make a concerted effort to collect some
8	of that metadata so we can parse out where the
9	variability is coming from.
10	And you know, for example if you
11	were to say have a checklist for an
12	administration procedure and checking boxes 1
13	through 5 essentially went along with the
14	score that you got and you could then
15	calculate your reliability you could see what
16	the relationship was of those boxes being
17	checked to whether or not you got an
18	acceptable reliability. And that sort of
19	thing might be worth thinking about as we go
20	from just PRO to PRO measure.
21	DR. PACE: Right.
22	DR. WU: I'm sorry, PRO quality

1	
	Page 266
1	measure.
2	DR. PACE: All right, Laurie?
3	DR. WU: Whatever.
4	(Laughter)
5	MS. BURKE: This is Laurie Burke
6	from FDA. And I appreciate that last diagram
7	that showed the relationship between
8	reliability and validity because I think that
9	really is key in understanding what's going on
10	here.
11	But yes, and I agree, Al, that
12	there are many I have to think about four
13	sources of variability and the first one is
14	true heterogeneity amongst the people you're
15	trying to measure. So, and I also agree, Lori
16	Frank that there's never complete validity or
17	optimal reliability. It's always something
18	that can be improved upon.
19	However, if you're not measuring
20	what you think you're measuring at all that's
21	a big problem. So, I mean we can identify
22	validity that's not adequate. And we can also

	Page 267
1	but the amount of reliability that's not
2	adequate depends on what you want to use your
3	measurement for.
4	So in clinical trials where we are
5	always measuring very small differences
б	between treatment groups we have to have very
7	good reliability in order to be confident of
8	the differences that we're measuring so that
9	we can make a conclusion that's valid that a
10	treatment works.
11	So therefore when we're looking at
12	a measure to use as an endpoint in a clinical
13	trial we look very carefully at the entry
14	criteria for that clinical trial because
15	companies that are developing drugs are very
16	careful about who they let into their clinical
17	trial. They're going to exclude all kinds of
18	people and it's not, you know, and this is the
19	whole real world, not real world controversy.
20	But the clinical trials are very
21	clean. And they're going to exclude those
22	with certain severity of illness, they're

1	
	Page 268
1	going to exclude those with concomitant
2	illness, they're going to exclude those with -
3	- in certain age groups.
4	And so when we look at a measure
5	to evaluation whether it is well-defined or
6	reliable for the purpose of use in this
7	clinical trial we compare the results of all
8	that validity and reliability testing before
9	the trial with this measure. We compare that
10	population that it was tested in to the
11	clinical trial entry criteria. So, because
12	you want to minimize that variability so much
13	that we can be confident of the effects that
14	are demonstrated in terms of an effect size.
15	So, for performance measures
16	that's what you're going to have to figure
17	out, how much reliability is necessary to be
18	able to use the population size that you're
19	going to use to make some sort of conclusion
20	and come up with a result.
21	I mean, we have, you know, the
22	argument that Dr. Fowler, the discussion that

	Page 269
1	Dr. Fowler presented in terms of identifying
2	the right population and the right
3	comparability between this is you're
4	describing the whole reason for the evolution
5	of the clinical trial methodology is because
6	we have to be able to compare and know what
7	we're measuring.
8	DR. PACE: Right. And just to
9	MS. BURKE: So that's not possible
10	in performance measurement, we understand, so
11	we have to come up with another standard.
12	DR. PACE: Right. And we'll get
13	into this more in one of the validity panels
14	but obviously in clinical practice people
15	aren't being randomly assigned or selected as
16	Laurie talked about in clinical trials. And
17	so you know, we rely on methods such as risk
18	adjustment, stratification, et cetera. And
19	that definitely is important in terms of
20	looking at the validity of the conclusions you
21	can make from a performance measure score. So
22	definitely important in terms of getting to

Page 270 that. Ted? 1 2 DR. GANIATS: I'm thinking about 3 cholesterol and it varies by season. We know that. We heard earlier today that mood can 4 5 affect a patient-reported outcome and we know that and that's just all variation that's 6 7 going to affect reliability. And we just have 8 to hope that it's going to wash out across the 9 groups. 10 So I'd like you to address something different and that is a 11 12 controllable, a game-able reliability. Ι 13 mean, when I go to my car, get it fixed, they 14 say hey, we're going to mail you this 15 satisfaction questionnaire. Make sure you mark them all fives. And we haven't talked 16 17 about external threats to the reliability that 18 would be important to the NQF. And I'm just 19 wondering if the panel can think about it. 20 I mean predominantly I think we 21 have satisfaction, information perhaps on 22 satisfaction though I don't know it, but it

	Page 271
1	would seem that patient-reported outcomes
2	might be game-able in a way that we're not
3	used to seeing in most other performance
4	measures.
5	DR. PACE: Go ahead, Jack.
б	DR. FOWLER: Actually we have
7	again I'll use the CAHPS experience. We have
8	pretty good data that they've experimented
9	with having physician's offices collect the
10	data by handing out questionnaires, et cetera.
11	You get much better ratings if you do it that
12	way it turns out, much.
13	So the standard is really that you
14	have an external contractor that has to
15	collect data and you do it in a way that's
16	anonymous so that patients don't have to worry
17	about you seeing my report, guessing who I am
18	and knowing that I'm not pleased or something
19	or that I'm not doing well. So we haven't
20	talked about the protocols and there are all
21	kinds of ways to do it.
22	I did notice again in all three of

	Page 272
1	the ones I think this morning that presented
2	have outside people collecting I think at
3	least the follow-up data. I'm not sure about
4	the baseline data in Sweden. But I think
5	outside data collectors are pretty important
6	and some way to protect the patients from
7	feeling like they're exposed to their
8	providers.
9	There's some other reasons you
10	might collect data that you would feed into
11	providers but performance evaluations are
12	probably not the right one.
13	DR. PACE: Could we see if anyone
14	in the audience would like to ask a question
15	and Evan can get you the microphone. And
16	Operator, would you also ask the people on the
17	phone to signal if they want to ask a
18	question?
19	OPERATOR: At this time in order
20	to ask a question press * then the number 1 on
21	your telephone keypad.
22	DR. PACE: Go ahead.

Page 273 MS. MASTANDUNO: Hi, this is 1 2 Melanie Mastanduno and I'm from the Dartmouth Institute and working with clinicians at 3 Dartmouth in an observational setting as 4 5 opposed to a research study on collecting patient-reported outcomes. 6 7 And so my question to the panel is 8 in the interest of promoting patient- and 9 family-centered care would not the panel of 10 patients or the clinical team, the practice level be the right unit of analysis for 11 12 evaluating the aggregate results in order to say we are not pitting one provider against 13 14 another but rather the approach in this clinic is consistent because they share nurses, they 15 share medical assistants, the secretarial and 16 17 appointment staff are organized at the front 18 desk. And it's not one clinician practicing 19 at wide variation within a practice. And so 20 could you please respond to that given the 21 discussion of the very granular methodologic 22 concerns that you've raised?

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1	DR. KAZIS: I think what you're
2	raising is an important point. The unit of
3	analysis clearly becomes really important at
4	the practice level in order to who you're
5	evaluating. And whether in fact, you know,
6	one can assume but maybe not always that if
7	you're dealing with a practice with a number
8	of clinicians and nurse practitioners and
9	others, there's a culture within that group.
10	And there may be more homogeneity within that
11	group then if you compare that physician with
12	somebody outside of that particular practice.
13	So there may be some and there's been data
14	to suggest that over the years.
15	There may be some evidence then to
16	suggest that dealing with a unit of practice
17	that includes a number of providers and others
18	that make up that practice is an approach and
19	one that might work.
20	DR. PACE: Okay, one more. Go
21	ahead.
22	DR. JAMES: Hi, Tom James from

	Page 275
1	Humana. A question that I have has to do with
2	that of attribution. That's a word that was
3	not on the listing of all the definitional
4	phrases.
5	Attribution is something that at
6	least in traditional medical measurement has
7	wide variation and no standardization. And
8	it's something which drives physician
9	practices crazy. It's clear that we can
10	expand the universe so that we don't have to
11	deal with attribution but then we lose some of
12	that accountability.
13	How do we get to the point of
14	having some common definitions on attribution?
15	DR. PACE: I'll just it's
16	something that comes up often at NQF and it is
17	one of those areas of measure harmonization
18	that we'd like to see some movement in terms
19	of having more standardized rules regarding
20	attribution. But it is something that plagues
21	us. So thank you for bringing that up again.
22	It's definitely going to be appropriate in

	Page 276
1	these types of measures as well. John?
2	DR. WASSON: Just to follow up on
3	Jack's point. This is just dirty laundry part
4	2 because a lot of issues being laid out are
5	certainly reasons for caution.
6	Jack mentioned, well it's very
7	important to have vendors. This morning we
8	were asked the question about cost and
9	everybody fudged it. The bottom line is that
10	when we play a vendor game it's billions of
11	dollars, everything we're talking about here
12	when you multiply it across the physicians.
13	When you think of newer
14	methodologies that are patient-driven from the
15	bottom up like internet you're talking a
16	fraction of that. And we haven't we'll
17	maybe get into this in terms of administration
18	but we're being rather glib about the cost
19	side of things and I think we do have to be
20	careful.
21	DR. PACE: Okay. Operator, do we
22	have anyone online that wants to ask a

	Page 277
1	question or make a comment?
2	OPERATOR: At this time there are
3	no questions.
4	DR. PACE: Okay. All right. Al?
5	And I think we've got to wrap it up.
6	DR. WU: Just in response to that.
7	This morning we had a terrific presentation
8	from Sweden and he mentioned the cost that
9	they had invested which was something like 20
10	to 30 million Euros. So, which doesn't sound,
11	you know, multiply it by 1.3. It's not that
12	much.
13	Then you remember that Sweden has
14	a population of about 9 million. So if you
15	scale it up it's \$1, \$1.5 billion U.S. for
16	what which would be an equivalent amount to
17	what they spent. Now, certainly there's some
18	economies of scale, maybe it would be a little
19	less than that, but it's still a big number,
20	not inconsequential.
21	DR. PACE: Okay. All right. Any
22	other questions or comments? Yes, Chas. You

	Page 278
1	want to tell us who you are?
2	DR. MOSELEY: This is Chas
3	Moseley. I'm with NASDDDS. And I'm on the
4	long-term support side of the discussion which
5	is a little bit different than a lot
6	different than what you're talking about with
7	the very narrow acute care measures.
8	But I think it's important to note
9	that even when you're doing the patient-
10	reported measures for folks who are receiving
11	clinical care it's important to recognize and
12	to characterize the populations very
13	carefully. It's important for the tool to
14	characterize the various populations closely.
15	People with intellectual
16	disabilities and cognitive disabilities
17	receive acute care along with everybody else
18	and would be expected to respond to various
19	types of survey instruments. We found in our
20	research with national core indicators over
21	about 20,000 people a year that there are very
22	strong factors that influence the response.

	Page 279
1	Level of intellectual disability is one. Home
2	residential situation, age, the type of care
3	a person receives, whether it's in an
4	institution or a community, a wide variety of
5	variables that could be expected to influence
6	how they're responding to a patient-reported
7	outcome in a narrow clinical setting.
8	And I think it's important that
9	whatever instrument is used be able to be
10	adapted for people who have different types of
11	learning styles so that they won't be excluded
12	from the numbers.
13	DR. PACE: Okay. All right, one
14	last comment.
15	MR. ROONEY: Hi, Ted Rooney from
16	Maine again. I actually work for a lot of
17	groups who pay the bills, employers and
18	organizations, consumers and unions. And in
19	Maine we have a \$7 billion spend. If you
20	believe most of the experts 25-30 percent is
21	waste. We have a totally un-patient centered
22	system.

	Page 280
1	So if you could say that we're
2	going to institute PROMs in the context of the
3	overall measurement system and the overall
4	measurement system would implement measures
5	that would help drive efficiencies and return
6	on investment in the system and make it
7	patient-centered I think you'd have people
8	rushing to do it.
9	So I think it's the cost is a
10	lot if it's done like we've traditionally done
11	things, one-offs that are marginally
12	effective. But if we can make this the
13	centerpiece of how we do performance
14	measurement going forward and use it to drive
15	real changes I think it's a bargain and that's
16	from the people paying the bills.
17	DR. PACE: Okay. Well, thank you
18	to our panel.
19	(Applause)
20	DR. PACE: And we'll take a break.
21	You can get a little bit of refreshment and
22	we'll reconvene in 15 minutes.

	Page 2	81
1	(Whereupon, the foregoing matter	
2	went off the record at 2:50 p.m. and went back	
3	on the record at 3:08 p.m.)	
4	DR. PACE: Okay, if everyone would	
5	take their seats we're going to get started	
б	here. All right. So, our next panel is about	
7	demonstrating validity of PRO-PMs. And this	
8	is part one. We'll have part two tomorrow	
9	morning. There's a lot that goes into	
10	validity and we've already talked about the	
11	relationship between reliability and validity.	
12	I'm going to introduce the panel	
13	and then I will make a few comments about the	
14	NQF criteria, again, just to put that in	
15	perspective in terms of our mission to endorse	
16	performance measures. So, next slide. Okay.	
17	And again, you know, most of this	
18	panel will focus on the performance measure	
19	versus the PROM because we dedicated last	
20	workshop to the PROM instrument. But	
21	obviously once again the validity of that PROM	
22	instrument for the context in which it will be	

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used for performance measurement is an
 essential building block to having a valid
 performance measure.

So, let me introduce our panel. 4 5 And for our Commissioned paper authors this 6 time we'll have Anne Deutsch from RTI and 7 Barbara Gage from Brookings Institution. And 8 then our expert panel members are Steven Fihn from Veterans Health Administration and Albert 9 Wu from Johns Hopkins. So all of our expert 10 panel bios are in your handouts as well. 11 So, 12 next slide.

So, I'll make a comment about a 13 14 couple of things and get into our specific 15 I know Laurie Burke mentioned this criteria. 16 morning that in terms of testing they found it 17 to be more efficient to start with validity 18 testing and then go to reliability testing so 19 that you don't have to repeat. From NQF 20 perspective we're evaluating measures after 21 they've been tested and we tend to look at 22 reliability first and then validity. But I

	Page 283
1	think that's certainly an interesting strategy
2	for those who are going to actually be
3	developing and testing measures and probably
4	does have some efficiencies attached to it.
5	So, in terms of what NQF is
6	looking for with validity is that our first
7	thing is that we want measure specification
8	that are consistent with the evidence that's
9	been provided to support the measure focus.
10	And again, we see this as foundational so that
11	if the evidence if the measure is specified
12	to be consistent with the evidence that's a
13	foundation for validity, but then we do
14	require validity testing.
15	And we want validity testing that
16	demonstrates that either the measure data
17	elements are correct and/or the measure score
18	correctly reflects the quality of care
19	provided, adequately identifying differences
20	in quality.
21	Again, in the context of NQF we're
22	endorsing performance measures that will lead

	Page 284
1	to improvement but also will be used in
2	accountability applications. And so it's key
3	that you can make valid inferences about
4	quality. If you see a list of providers and
5	their scores on a quality performance measure
6	can you say can you know that higher scores
7	mean better quality versus lower scores, poor
8	quality or in some instances vice versa. So,
9	next slide.
10	In terms of NQF guidance on
11	validity testing again we'd like to see
12	empirical analysis. And again, currently we
13	allow for demonstration of validity at either
14	the data element or the performance measure
15	score. And in this case the data that would
16	go into a performance measure is actually the
17	PROM value or score on that particular PROM.
18	The other thing is that we do
19	currently allow for measure developers to
20	submit a demonstration of face validity of the
21	performance measure. We ask that this be
22	systematically assessed but this is kind of an

Page 285 area of weakness in terms of face validity 1 2 done by a group of experts and then another group of experts may have a different view of 3 the face validity of that particular 4 5 performance measure. So, it's something that comes up periodically in just the quality 6 7 performance measures. 8 And again, you know, with any of 9 the testing we want an appropriate scope and 10 method and acceptable results. I think as was already talked about validity is really 11 12 something that's built on over time. And so we do expect that that will increase over time 13 14 and that our criteria for testing, our really initial entrance to get NQF endorsement and 15 16 for you to be thinking about, you know, what 17 is the minimum amount of testing or demonstration of validity and as we talked 18 19 about in the last panel reliability that means 20 it could be endorsed as a performance measure 21 that could be used in accountability 22 applications.

	Page 286
1	So with that I think I'll turn it
2	over to our authors and we'll go from there.
3	Thank you.
4	DR. GAGE: All right. I'm going
5	to start us off and then turn it over to Anne
6	to talk about some of these issues on the
7	validity. So, thank you.
8	So I'm going to kind of refocus
9	us. As Karen just mentioned we've been
10	talking a lot about performance measures,
11	about organizations or providers and holding
12	them accountable. We've also had a lot of
13	discussion in here about quality improvement
14	and about thinking about the measures that are
15	necessary for ensuring quality in the
16	organization or in the provider. And there's
17	a lot of I like to think in terms of a 2 by
18	2 cell.
19	So you have the instrument as we
20	talked about with the first paper gathering
21	and all of the issues associated with that.
22	And then we have the performance measure. And

Page 2
what happens when you take that measure, that
instrument up to the organizational level and
start applying it? What are the differences
in the validity and the reliability as we
heard earlier?
But there's also the second row
are the differences between the performance
measures that are clinician-based and those
that are patient-reported. And really what
we're here to talk about today is that fourth
cell, the patient-reported voice in the
performance measurement.
And so it's a little bit different
than traditional thinking in developing
quality measures because you have to think
about if you're holding an organization or
provider accountable then you want to make
sure that that measure is appropriate to that
population as we talked about this morning.

б

And tomorrow I think we're talking about some of the issues of risk adjustment so that you know who's in, who's out, how to apply it.

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Page 288 But keeping that in mind, that 1 2 what we're really talking about is how do you incorporate that patient's voice in the 3 4 performance measure and keeping in mind some 5 of the issues that came up this morning in terms of if you're holding -- if you're trying 6 7 to measure quality at the organizational level who -- what is the difference between the 8 9 clinician's assessment of that outcome because we're talking about outcomes or the patient's 10 assessment of the outcome. And how is that 11 12 patient viewpoint affected by their preferences, their knowledge of the care. 13 14 Some of the examples that Anne will give come out of the rehab field and 15 there you have a real disconnect between what 16 17 the patient thinks will happen now that 18 they've had that nice little hip surgery and 19 what the physicians or therapists know is 20 possible. So it takes measuring performance 21 to a whole different level when you start 22 talking about accountability and the patient's
	Page 289
1	voice.
2	On that I'll turn it over to Anne
3	to go into some of the details.
4	DR. DEUTSCH: Great, thanks. Next
5	slide. Terrific. So can everybody hear me
6	okay? Great.
7	So one of the first questions that
8	we were asked to address is what are the
9	implications of various approaches to
10	aggregating the PROM data, for example, an
11	average or a medium amount of change percent
12	to improve or reach a benchmark. And what is
13	the validity of the conclusions about quality
14	and the ability to discriminate performance
15	among accountable entities. So next slide,
16	please.
17	So last workshop we spent a lot of
18	time talking about reliability and validity of
19	the instruments and so now as Barb and Karen
20	mentioned we're moving to aggregating that
21	data up to the provider level.
22	So there's really two options when

	Page 290
1	we have these measures. So one option for
2	looking at the information at the provider
3	level is to calculate a change score. And so
4	the example here is a decrease in pain or
5	perhaps an improvement in functional status
6	between the start of care and end of care.
7	Also, you could look at a
8	threshold which is the level that the patient
9	achieved at the time that care either was
10	ended or at a certain time point after care
11	was initiated. So here the example might be
12	percent of patients with moderate to severe
13	pain. Next slide.
14	So in many cases change is often
15	thought to be a good way to look at things.
16	And as Barb said I come from the rehab world
17	and so a lot of times we've looked at
18	improvement in function over time between
19	start of care and end of care.
20	But there's some limitations with
21	change. And I think this was mentioned a
22	little bit last time by Dr. Ottenbacher but I

	Page 291
1	just wanted to reinforce some of these issues.
2	So, an individual's change score
3	can vary in terms of the magnitude and the
4	direction. So you can have improvement of
5	positive 10 units or minus 10 units or you can
6	have an improvement of plus 2 or anywhere in
7	between any of those or even more. And so
8	individual differences can really be masked
9	when you start doing an average. So 10 plus,
10	10 minus, the average is zero. And so you
11	know, you had two very different outcomes and
12	yet your average really doesn't tell you what
13	happened to either one of those patients.
14	Change scores also tend to have a
15	lower reliability than the baseline at follow-
16	up scores. And Laura mentioned this this
17	morning, that basically if you have error in
18	your baseline and you have error at your
19	follow-up you might actually be adding those
20	errors up together.
21	Also, there's floor and ceiling
22	effects. I know this was also discussed in

Page 292 1 the previous workshop. And so you might 2 actually have real changes that occur but your instrument is insensitive at the low end 3 perhaps and so you don't see people gain when 4 5 there's a floor effect, or you may have patients who are at the high end of the scale. 6 7 They have real change but your scale isn't 8 sensitive enough at the high end and so you 9 might have some patients who the scale really doesn't fit them at either end. 10 And then also it's unclear 11 12 sometimes what the clinical meaningful change -- what the change score really means. 13 So 14 again, from my world in rehabilitation we 15 measure functional status. And so you can have an improvement of 10 units. What does 16 17 that really mean? And actually one of the research 18 19 projects that I've done recently is we 20 actually presented information to people in 21 the community and said, you know, if you were 22 trying to pick a good rehab facility which one

	Page 293
1	looks like it would be better. And we gave
2	them fictitious data. And we actually did
3	give them a change score and they looked at it
4	and they were like, well you know, I can look
5	at this but what does it really mean. So
6	nobody really knew what it meant. And I will
7	tell you a lot of rehab hospitals do actually
8	put that information on their web pages. But
9	it really is hard to know what it actually
10	means. Next slide.
11	So just some examples. There are
12	some patient-reported outcome measures that
13	are endorsed by NQF and so I wanted to
14	highlight some of those as examples of some of
15	the issues that I'm talking about.
16	So, and Laura mentioned this one,
17	the "Change in Basic Mobility as Measured by
18	the AM-PAC" is an instrument that has been
19	used in both outpatient and inpatient
20	rehabilitation programs. And that basically
21	is a change measure. And I'll get into more
22	detail about that when I talk about some of

1	the other methodologic issues.
2	There's also the measure that was
2	mentioned this morning the percent of
5	
4	patients with moderate to severe pain. And
5	that is a threshold value.
6	And then the last example I wanted
7	to highlight was depression remission within
8	6 months. And that basically is a threshold
9	value but the way that's designed, actually
10	the patients who are included in that measure
11	are people who at baseline have a PHQ-9 score
12	that indicates depression, possible
13	depression, and then the follow-up score looks
14	at how many patients moved into the area of no
15	depression based on the PHQ-9 score. So it
16	actually is threshold but it's kind of an
17	indirect measure of change. Next slide.
18	So the next area I wanted to talk
19	about is again aggregating this up to a
20	provider level. You can calculate a number of
21	different statistics. So you can calculate a
22	mean, a median, you can calculate a percent or

	Page 295
1	a ratio.
2	So I know in school you know we
3	were taught use as much data as you have. So
4	if you have age, use it as a continuous
5	variable when you're doing risk adjustment or
6	when you're doing analyses.
7	And so I think a lot of the work
8	that people initially think about is to
9	calculate a mean. But a mean or even a median
10	might not necessarily represent the diversity
11	of patients when you have a pretty
12	heterogenous population. And in many cases
13	when we're looking at these outcomes data they
14	really are heterogenous in terms of the
15	population.
16	And then also again when we're
17	looking at the provider level if the data
18	aren't normally distributed a mean or a median
19	may not really represent what's going on in
20	that particular provider. Next slide.
21	So a lot of the performance
22	measures that actually are endorsed by NQF are

	Page 296
1	percent measures. And so there's different
2	ways of calculating percents. So basically
3	it's how many patients reach a certain
4	reach or exceed a benchmark.
5	And so one way to do that is to
6	say, you know, what's the national expected
7	value and what percent of patients meet that
8	expected value, whether it's a threshold or a
9	change. And again it should be similar
10	patients. I think that was mentioned earlier.
11	The second option would be what
12	percent of patients meets some kind of fixed
13	amount of change. So if there's some kind of
14	clinically meaningful difference that's been
15	identified that's, I don't know, 10 units,
16	what percent of people or patients actually
17	meet or exceed that 10-unit defined
18	difference. Or a minimal detectable change.
19	A third option could be a
20	threshold value that's associated with a long-
21	term outcome. So for example, if you wanted
22	to look at balance confidence with somebody's

	Page	297
1	ability to with balance you might say well,	
2	this threshold is important because that	
3	threshold is associated with a reduced risk of	
4	falls.	
5	So for PROMs that have established	
6	clinically meaningful thresholds or cut points	
7	I think it's easier to create quality measures	
8	out of them. For areas like functional status	
9	where there really aren't good clinically	
10	meaningful thresholds or stages it's a little	
11	bit harder I think or more challenging to	
12	develop some of these quality performance	
13	measures. Next slide.	
14	So the last option I talked about	
15	was a ratio. So basically that's a score that	
16	may have a value of zero or greater and it's	
17	derived from dividing the count of one type of	
18	data by another count of data. And so the	
19	example would be the number of patients	
20	reporting a pain score of seven or higher	
21	divided by the number of inpatient days. So	
22	the number of days there is the bottom of that	

	Page 298
1	metric.
2	So a ratio may be preferred when
3	the amount of time, in this case the number of
4	days that the patient is at risk for the
5	outcome is important to consider. Next slide.
б	So some of the examples I wanted
7	to highlight in this particular area. Again,
8	the depression remission within 6 months that
9	I mentioned before. Again, this classifies
10	patients into clinically meaningful groups.
11	So the people who are depressed at baseline
12	and then they change 6 months later into this
13	category of not being depressed.
14	Second example again is the change
15	in basic mobility a measured by the AM-PAC.
16	And this is a percent of patients who change
17	and the change here is defined as a difference
18	of more than one minimal detectable unit
19	basically.
20	So a minimal detectable change for
21	those of you not familiar with that term it
22	refers to the minimal amount of change that is

	Page 299
1	not likely due to measurement error and that
2	represents a true change. So one of the
3	questions that I would have about using that
4	threshold is whether there's a lot of
5	variability, whether all patients should be
6	expected to gain and you might have some
7	providers who have a lot of gain and that
8	wouldn't be reflected if you have this
9	threshold that's the minimal detectable
10	change. Next slide, please.
11	So the next set of questions were
12	about validity testing. So the first
13	question, what methods of validity testing
14	would support the demonstration of validity of
15	performance measure scores that are making a
16	conclusion about the quality of care. Second
17	question, are there any differences or unique
18	considerations for demonstrating and
19	evaluating the validity of PRO-PMs as compared
20	to other quality performance measures. So,
21	next slide, please.
22	I want to start off talking about

	Page 300
1	face validity. And I know that face validity
2	is not necessarily the strongest but I do
3	think it's a really important step personally.
4	As somebody who's been involved in measure
5	development and been involved in a lot of
б	TEPs, both participating and also running TEPs
7	I feel like you always learn when you hear
8	different people's points of view. And so I
9	do think it is an important step. So I
10	personally feel it would be important to have
11	face validity testing at a performance measure
12	level.
13	There is various methods that NQF
14	has put in their materials in terms of
15	recommended ways of systematically looking at
16	face validity including modified Delphi
17	survey, some kind of formal consensus process,
18	the UCLA/RAND appropriateness method, and then
19	there's also the American College of
20	Cardiology and American Heart Association has
21	a paper that outlines steps for considering
22	face validity, next steps.

Page 301 So, of course we always talk about 1 2 expert panels being experts. And so I just 3 want to highlight here our experts here are probably our patients. So sometimes patients 4 5 are included in expert panels but it seems to me that we could do a whole series of validity 6 7 testing really using gualitative methods. So 8 for example, focus groups, semi-structured 9 interviews and cognitive testing with expert 10 patients. I also want to highlight that the 11 12 patients would need to be people who are well informed what they were being asked to do. 13 14 And there is actually a fabulous article that Dr. Judy Hibbard wrote, and I know she's here 15 in the audience that I think could really help 16 It's "What is Quality, Anyway?" 17 frame this. 18 And so she actually conducted some focus 19 groups and asked patients what terms that they 20 thought about in terms of quality. 21 And again, I've done research in 22 this area where I went out to senior centers

	Page 302
1	and gave people information, percent of
2	patients with moderate to severe pain and
3	asked them to interpret the data. And I
4	certainly gained a lot of insight into what
5	people really, you know, when they look at the
б	data what they're really looking for. And a
7	lot of the people that I spoke to without any
8	without much orientation were really quite
9	sophisticated in terms of what they were
10	looking at and were not sure that they wanted
11	to make decisions just based on one piece of
12	data.
13	So, I'll bring up some more
14	examples I think probably tomorrow when we
15	talk about threats to validity. But I do
16	think that there is an important role for the
17	public, patients, whatever word we're using to
18	be more involved in validity testing for the
19	performance measures based on the PROMs.
20	But I guess I also would say, just
21	to follow up with what Barb said, there's no
22	reason why non-PROM measures shouldn't have

	Page 303
1	more testing with actual public patients also.
2	So, next slide.
3	So the next area to talk about is
4	criterion validity. So again this is the
5	extent to which the measure agrees with the
6	gold standard.
7	So, one potential example of
8	testing here could be a PRO-PM being used and
9	the data compared to a performance score based
10	on clinician observation. So again the
11	patient-reported information being compared to
12	a clinician observation if it taps into the
13	same construct, so for example, functional
14	status. And let's say the clinician
15	observation measure was really found to be
16	valid and then you had this patient-reported
17	outcome that agreed with that. That would be
18	one potential way. Next slide.
19	The next area is construct
20	validity. And so this speaks to how the
21	measure performs based on theory. And so I
22	kind of made up this idea that and this is

	Page 304
1	all very theoretical, but a way to test this
2	would be basically if you had national data.
3	So everybody collected PROM data.
4	So I know I'm dreaming here but I
5	have national PROM data and I had some
6	facilities who did quality improvement
7	projects and it was focused on whatever topic
8	we're talking about, maybe it's functional
9	status or pain. And I was able to compare
10	their data before and after. And then also I
11	had all these control facilities who I know
12	they didn't do quality improvement projects.
13	And so you'd be able to really look at whether
14	there was improvement in the places because
15	the quality intervention quality
16	improvement project really did work, by the
17	way. That was the other assumption. And so
18	there would be improvement that you could see
19	there.
20	So I think this is probably an
21	important point to highlight that I think in
22	order to really do validity testing we

	Page 305
1	actually need people to collect this data. We
2	cannot test validity beyond the face validity
3	unless we have multiple providers collecting
4	this information and we're able to compare.
5	If we just have two places collecting data and
6	oh, aren't we good Karen and Barb, our three
7	facilities, you know we really are not in a
8	good position to make a judgment about
9	quality. And so we really need a lot more
10	implementation in order to really be able to
11	test validity at the level that we would love
12	to.
13	So I think it's ideal to obviously
14	have a lot of validity testing but I think
15	realistically at this point face validity is
16	very important and we can certainly learn a
17	lot with that. But I think the construct
18	validity, we need more widespread data
19	collection before we could expect to be able
20	to have measures meet those standards. Next
21	slide.
22	So the last question is is

	Page 306
1	validity of the performance score indicator of
2	quality needed in addition to the validity of
3	the PROM. So as I said I personally think
4	face validity is an important issue at the
5	performance measure level. I think the other
6	levels, it's ideal but we're not probably
7	going to be ready for that for awhile.
8	And I think that's my last slide.
9	Yes. Okay, great. So turn it back to Karen.
10	DR. PACE: All right. Steve, you
11	want to?
12	DR. FIHN: So, I had actually
13	prepared some remarks and slides but as we get
14	later and later in the presentations I think
15	the speakers are going to find that there's a
16	great deal of overlap in the comments. And
17	instead I decided to sort of abandon that
18	tack.
19	I was actually going to walk
20	through we thought with all the sort of
21	theoretical discussions that sort of a
22	practical story might be useful. And I was

	Page 307
1	actually going to walk through the story, a
2	20-year-old story actually of developing a
3	PROM related to ischemic heart disease and how
4	we went through the reliability test retest
5	and so forth, the validity assessment,
6	responsiveness, defining the minimal clinical
7	detectable or important difference. And the
8	use of this measure which is called the
9	Seattle Angina Questionnaire now and something
10	like two to three hundred clinical trials.
11	And make the point that we went
12	through a lot of this and it obviously
13	overlaps with much of the material from the
14	first workshop too. And then sort of pose the
15	question given all that work would I then
16	trust it because that's what we're talking
17	about. Do we trust these measures to be a
18	performance measure. And what would make me
19	want to trust that aside from the fact that
20	you know we did all that work.
21	(Laughter)
22	DR. FIHN: And you know, I think

Page 308 all the previous panels have walked through a lot of the concerns about rolling these up in terms of statistical and methodologic and many of the issues that I would have -- was going to delineate. And I think the answer to the question really was even after 20 years not yet. And this discussion for me has been during both the earlier workshop and this one has been I think very interesting and exhilarating but in some ways also sort of frustrating because we've been hearing similar discussions now as I think back for two or three decades. And the question then that keeps getting posed is sort of what do we need actually to move these measures into clinical or organizational use. And what would move us forward. And I think what I'm hearing is again to sort of develop beyond the methodologic and scientific basis a framework,

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	Page 309
1	a use framework. And I was saying to Liz Mort
2	earlier I particularly liked the framework
3	that she presented which was I think, you
4	know, in terms of the tight linkage between
5	measurement and effectiveness of intervention
6	I think that's a key piece and she walked
7	through examples of that.
8	And why is that important? Well,
9	in our own measure we just completed and
10	reported a clinical trial in which we selected
11	out people with extreme scores and subjected
12	them to what we thought was a very effective
13	intervention. And by provider, almost 200 of
14	them, and found really no effect. And made me
15	then go back and wonder about sort of the
16	mutability of this measure in terms of linkage
17	to our therapeutic interventions. And I think
18	Liz pointed out there are some areas where we
19	do have, you know, good linkages there.
20	I also particularly like the NHS
21	examples. And you know, I think they are as
22	was mentioned picking on surgical or

	Page 310
1	procedural interventions which might actually
2	be a good place to start for a few reasons.
3	One is these are episodic episodes
4	of care. And one thing that hasn't been
5	talked about a lot today is sort of when you
6	apply these to longstanding chronic illnesses
7	you get into a whole `nother set of issues of
8	repeated measures, change over time or lack
9	thereof, what do you do in those
10	circumstances.
11	An example would be we've had
12	mandated screening for depression and PTSD in
13	the VA for years now. And annual at a minimum
14	and more often if it's positive. And we have
15	a prevalence of chronic depression of about
16	20-plus percent. So we, every time I'm in
17	clinic I have two or three patients who have
18	got to be re-screened. I know they're
19	depressed, they've been on therapy, they've
20	been through most of our treatments and they
21	represent sort of our residual chronic
22	depressed population. It's mostly prevalent,

	Page 312
1	very little incident depression.
2	So then you know how do you deal
3	with that in the context where you want to see
4	change and most of the literature really
5	demonstrates change with incident depression,
6	not chronic or sort of intractable depression.
7	So, episodic.
8	We largely have pretty good
9	measures as we heard for hips and GU and
10	cardiac disease. We know there's high
11	variability as Jack pointed out in many of
12	these areas. And the numbers I think actually
13	will be tractable.
14	One of the scary things in primary
15	care we face for instance in the VA is that
16	we've got 6 million people in primary care.
17	And if we're going to start surveying all
18	these people, you know, it gets back to what
19	John Wasson pointed out, just the logistical
20	and expense of it is actually I think
21	daunting. Whereas if we were just to do
22	certain limited procedures at least to start

	Page 312
1	like hips or cataracts or something that
2	that's probably tractable and a way to get
3	started.
4	And so I personally sort of like
5	the idea even though yes, it's biased, and no,
6	it doesn't get us to sort of the real
7	population base we want. It is a place to
8	sort of get going.
9	One of the interesting things also
10	I thought and Jack Fowler also brought this up
11	in terms of the issues of patient selection.
12	And I think there's a paradox here. In fact,
13	one of the uses, I think one of the goals of
14	using PROMs would be actually to influence
15	patient selection.
16	You know, in fact one of the
17	concerns I think we have, people have talked
18	about the waste in the system is the use of
19	procedures for individuals who don't
20	necessarily stand to derive a great deal of
21	benefit. And one of the things I think that
22	would be a positive if you started to do this

	Page 313
1	was to see a sort of up-shift of the patients
2	who started going, you know, who actually have
3	some who aren't floored out, you know,
4	already, or ceilinged depending upon your
5	perspective and could stand to benefit. You
6	know, you might actually see a bit of a Will
7	Rogers phenomenon where everybody sort of you
8	know gets a stage shift, gets better.
9	So again that was really the issue
10	I asked about case-mix was to sort of sense if
11	you're asking providers to demonstrate
12	improvement then they're really going to focus
13	on people who have an opportunity for
14	improvement as opposed to people who might be
15	mildly symptomatic.
16	And I think also just to comment,
17	I think Lew Kazis brought up the issues, he
18	brought up several important issues, but I
19	think the issue of gaming which we've seen a
20	lot in the performance measurement world of
21	ways in which these things can be gamed.
22	I think the PROMs actually present

Page 314 1 us with some new avenues that will be 2 interesting to observe as we get in here in terms of not only gaming by systems and 3 providers but by patients. We talked earlier 4 5 about the notion that occasionally there's the temptation to drill down to the patient level 6 7 on these measures. 8 I mean, we're sort of in a reverse 9 situation where traditionally we've had 10 measures that we know work on groups and the question is can they work on individual 11 12 patients. And now we're being asked let's 13 think about measures that we now think work 14 okay at the individual level. Can we roll 15 them up but roll them up in a different way, 16 not to the original populations but to the 17 providers they're seeing or to the systems in 18 which they're enrolled. 19 But nonetheless at the patient 20 level you could see where patients actually 21 now that they're contributing data to systems 22 might have motivations for eligibility for

	Page 315
1	certain procedures or drugs or whatever might
2	actually now have some motivations to frame
3	their responses in some ways.
4	You know, I think I have, you
5	know, a lot of concerns about the broad-scale
б	implementation of these. Nonetheless I do
7	think it's time. We're actually as we speak
8	implementing the heart disease measures for
9	the 30,000 or so elective cardiac caths that
10	we do to sort of look before and after as a
11	start in our system similar to what I think
12	the Brits have been doing for a couple of
13	years it sounds like and the Swedes for
14	longer.
15	But I think in systems that the
16	larger systems can get started doing these
17	things. So thanks very much for the
18	opportunity.
19	DR. PACE: Thank you, Steve. And
20	Al?
21	DR. WU: So, Steve this morning
22	had all his slides prepared. I had scribbles

Page 316 1 on some, on you know, my clothing and my hands 2 and index cards. And so we've done a little role reversal because to clarify my thinking 3 I put together some slides and so now I have 4 5 a couple of slides. But they still resemble 6 things that you might scribble on your palm 7 while you're thinking. Next, please. 8 So, first of all this is, you 9 know, sort of going back -- we keep going forward and back a little bit and there's a 10 little bit of a theme to all of that. 11 But. 12 maybe we, you know, two steps forward, one step back, two more steps forward. 13 I think 14 we're getting there. 15 Sort of a must-pass criterion is 16 that our performance measures should have 17 scientific acceptability in measurement. Next, please. 18 19 So I just -- I'm here to tidy 20 things up a little bit. And this is a -- it's 21 sort of maybe the second or third most famous 22 painting by Seurat, you know, que sera sera.

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	Page 317
1	But it's late in the afternoon. But in any
2	event so my purpose is to sort of tidy up all
3	of these difficult pesky little questions that
4	we have almost like individual dots of pigment
5	on a page. So next slide, please. So there
б	we go.
7	(Laughter)
8	DR. WU: That's where we hope to
9	be. But though I'm worried that I don't
10	think we're going to get there this afternoon.
11	Next, please.
12	So here are the four questions
13	that were posed to our panel and I'm going to
14	actually only just comment on each of them.
15	First, please. Next slide.
16	So, various implications for
17	aggregating data. And I actually
18	aggregating could be taken in two ways and as
19	we're thinking about this it's probably worth
20	thinking about on the one hand scoring,
21	generating scores, and then separately on
22	aggregating rolling up more than one score

Page 318 a score from more than one individual into a 1 2 score that is used for a performance measure. And sort of maybe as we look back at the 3 4 report and so forth maybe it would just be 5 worth splitting it out like that because I found that I was confusing myself which is not 6 7 that difficult really. Next slide, please. 8 A couple of issues. There can be 9 some problems with aggregating at the individual level and then there can be some 10 problems with -- I'm sorry, in terms of -- I 11 12 realize this is actually not so much aggregation but scoring so the slide's a 13 14 little bit mislabeled. 15 But if we look at an item that's 16 used very often and in fact some version of 17 this is I quess an NQF measure. If you take 18 a visual-analog pain scale or a 1 to 10 pain 19 scale, rate how much pain are you having, on 20 the individual level first of all there's some 21 problems because measurement tends to be very 22 Even though you might theoretically coarse.

	Page 319
1	have 10 or 11 or an infinite number of points
2	between you know sort of 1 and 10 or zero and
3	10 in fact a lot of people are 5, a lot of
4	people are zero, really a lot of people are
5	zero perhaps legitimately. And then there's
6	quite a few people who are 9 or 10.
7	And I saw someone the other day
8	who was sitting very comfortably in the exam
9	room chair, not crying, not grimacing, not
10	wringing her hands and tearing her hair and
11	she had indicated a pain score of 10.
12	And I said, "So are you in any
13	pain?" She said, "Oh, you know, a little
14	bit." And I said, "So, you wrote 10 down
15	here. Why did you do that?" And she said,
16	"For emphasis."
17	(Laughter)
18	DR. WU: And she did have some
19	arthritis pain, she'd been a little stiff, and
20	she wanted to make sure it got taken care of.
21	And so at the individual level people are
22	interpreting what this is for for different

	Page 320
1	reasons. We think of it for measurement,
2	maybe for screening and she for making sure
3	something got taken care of which is
4	completely legitimate and probably more
5	worthwhile than what the Joint Commission asks
6	us to do, but nonetheless.
7	At the group level those biases
8	actually probably tend to iron out. But I
9	have observed and there's some data that
10	suggests that provider panels differ with
11	regard to the patients who they attract.
12	Another example. I recently, we
13	had a very good and a very nice physician
14	leave our practice recently, Dr. Rochelle
15	Brown. Is this a HIPAA violation? Maybe not.
16	So she's a terrific physician and she left and
17	her patients loved her. And so I've inherited
18	a bunch of them. And the average pain score
19	for all of these people, what do you think the
20	median is? Ten, yes.
21	And basically she is so nice that
22	all of these people who are, you know, very,

	Page 321
1	who are in a lot of distress gravitated to her
2	and stayed with her. And if she were examined
3	for proportion of patients who had pain scores
4	cross-sectionally of 10 she would look
5	terrible when in fact, you know, everyone
6	really would like to have her as their doctor.
7	So, at the group level there are some other
8	things to consider.
9	When we're testing validity of
10	aggregation strategies I think we need to do
11	a few things. One is first we need to look at
12	the distribution of scores period which I
13	think has been done but we probably need to
14	look at them at several levels including at
15	the level that we're going to be aggregating.
16	If we're looking by provider if we
17	see that some people have very skewed
18	distributions of pain scores, some providers
19	have patients with a very skewed distribution
20	and others with a very normal distribution we
21	should worry about our ability to compare them
22	fairly.

Page 322 Of course there is genuine 1 2 heterogeneity as we heard. And some of it is heterogeneity by provider. Some patients 3 really are in a lot of pain and some people 4 5 less so. And we do want to be able to detect that. Oh, next please. I don't mean to touch 6 7 these buttons. 8 So, I actually shouldn't get into 9 this very much but we know that measure of --10 that asking people about change is unreliable, that in fact measurement of individual-level 11 12 change you ask -- even if you measure it twice and then calculate the change, since there's 13 error measured at both time points those 14 individual change scores may have a lot of 15 noise in them, especially if there are 16 17 different things happening to the people at different time points. When you aggregate 18 19 change scores, if you look at average change 20 scores some of that noise gets taken out. 21 A question which I realized I 22 didn't know the answer to is is it more useful

323	Page	
	for the purposes of quality for performance	1
	measures to measure mean change or median	2
	change or the percent achieving a benchmark or	3
	the percent with a meaningful change of some	4
	sort. It seems like that could be done in	5
	some data sets, maybe even the HOS data. I'm	6
	not sure but I think that I would like to know	7
	the answer to that question before I start	8
	deciding that my measure is going to be based	9
	on for example a same/better/worse for example	10
	scoring system.	11
	An example from several of you	12
	were involved in a Medical Outcomes Study and	13
	one of the maybe the most impactful study	14
	that included actual results from the Medical	15
	Outcomes Study was John Ware's study in 1996	16
	looking at the 4-year outcomes for the panel	17
	of chronic disease patients. And overall	18
	there was no difference between HMO and fee-	19
	for-service care. However, if you looked at	20
	some subgroups and you used a	21
	same/better/worse scoring method then people	22

	Page 324
1	who were in fee-for-service and particularly
2	people who were more disadvantaged or older
3	did better than people in HMO. And the
4	results are probably true but the same
5	differences were not as prominent when you
б	looked at comparisons of mean scores. And
7	someone please correct me if I'm wrong. I
8	just had glanced over this paper again
9	recently.
10	And that makes me think. And
11	these data in some ways are equivalent to
12	something, to data that we might use in a PRO
13	performance measure. It made me wonder and
14	worry a little bit about if you score things
15	differently do you get different conclusions.
16	Next, please.
17	Some patients can't improve. We
18	heard a little bit about that from Floyd
19	Fowler. If you look at an ambulation measure
20	and you've got people who are paraplegic. If
21	you on the other hand look at people who don't
22	need a surgery and who get it it's possible
	Page 325
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1	that they won't benefit.
2	(Laughter)
3	DR. WU: So first of all it made
4	me think that maybe we, in some of our
5	validation studies we need to look at
6	appropriateness too as another piece of
7	metadata so that we can weed out those people
8	who really didn't need the surgery.
9	This is a shameless plug for a
10	book that I'm not connected to but my
11	colleague just wrote, Marty Makary just wrote
12	a book called "Unaccountable." He's a surgeon
13	and he's talking about how the system is not
14	very accountable. It's coming out I think on
15	Monday.
16	And he told a great story of a
17	surgeon who at a terrific institution. I
18	won't, Liz, I won't mention what institution.
19	And he who operated on sort of a VIP and
20	who should have been a hernia. It turns out
21	it wasn't. But he said oh, we'll fix it
22	anyway. And so they fixed his non-hernia.

	Page 326
1	The guy had a bunch of complications. And you
2	know, he was not better and he probably could
3	not have benefitted because he didn't actually
4	have a hernia as it turned out.
5	So, in any even if some people
6	cannot improve then we need to understand the
7	heterogeneity of people who we are measuring
8	quality on. This just gets at defining your
9	measure carefully, defining the specifications
10	very carefully, are they chronic patients, are
11	they acute patients, are they people who could
12	possibly benefit. Next, please.
13	What methods of validity testing
14	would support and are there differences or
15	unique considerations. Next, please.
16	So, we were having this
17	conversation at our table and a little bit
18	even in between this meeting and the last, and
19	we're really confronting a little bit of there
20	and back again which is basically PROs were
21	originally developed in order to be able to
22	measure the effects of health services

Page 327 interventions at the level of Group Health 1 2 Cooperative of Puget Sound or the Medical Outcomes Study or the RAND health insurance 3 4 experiments or trying to measure sort of the 5 utility of populations. 6 And we actually have quite a lot 7 of data on the validity of PRO measures 8 developed for group comparisons for these and later for clinical studies. So we've got 9 10 actually loads of data. Maybe not enough, we could always use a little bit more validation, 11 12 thank you, but we're sort of -- we're not in terrible shape. 13 14 PROs are now beginning to be applied quite a lot for individual patient 15 care. There really is a dearth of data at 16 this moment on the validity of measures used 17 18 for that purpose. We know about the greater 19 unreliability for individuals. There haven't 20 been so many validity tests for individuals. 21 We don't know if those measures are responsive 22 for individual people.

	Page 328
1	And so I'm actually sort of
2	diverging a little bit from Steve in saying
3	that they have been used in individuals but we
4	actually don't have enough evidence yet. So
5	now we're at the point where we're going back
6	to groups and we want to use PRO performance
7	measures typo here again for group
8	assessment.
9	And we have maybe some advantage
10	of the fact that we're looking at groups
11	again. But the data that we have developed
12	for group comparisons of services research is
13	not may not all be applicable because we
14	have the added complication that we're
15	defining these measures for specific
16	populations, specific contexts, to answer
17	really specific kinds of questions. Next,
18	please.
19	So, we're looking at validity of
20	PROs for group comparisons, PROs for
21	individual use which I'm not going to talk
22	about so much and PROs for quality

Page 329 1 improvement. Next, please. PRO performance 2 measures. It's worth -- this is a little 3 4 simpler than the measures that we -- than some 5 of the figures that we were provided with 6 today but I like looking -- I like this figure 7 because it's really easy to remember. And 8 this is from Ira Wilson and Paul Cleary's JAMA 9 paper, the relationship of pathophysiology to 10 symptoms, a relatively direct link. Most of our treatments, the things we're trying to 11 12 measure the quality of are mostly aimed at improving -- reducing symptoms, improving 13 14 pathophysiology. All of those things affect 15 physical and mental health and all of those things affect quality of life, maybe social 16 functioning, maybe role functioning. 17 18 The problem is that as you get 19 further and further away from treatment and 20 pathophysiology there are other variables that 21 come in. There's lots of things that affect your quality of life, for example. 22 And it

	Page 330
1	becomes more and more difficult to demonstrate
2	that, the effect your intervention had on
3	those more distal variables. So it is worth
4	keeping this in mind. Next, please.
5	So, when we're trying to validate
6	PROs for group comparisons we're going to do
7	the usual things, content validity, construct
8	validity, responsiveness which is maybe, you
9	know, which another way of thinking of that is
10	longitudinal validity, perhaps predictive
11	validity which in my experience is very useful
12	to convince clinicians that something is
13	that a measure is worthwhile.
14	I'm not going to talk about
15	validating PROs for individual use now but in
16	and this is really my last slide. In
17	validating PRO performance measures for
18	quality improvement within groups I think that
19	we're interested in construct validity but we
20	almost immediately need to think about risk
21	adjustment I think. We'd like to be able to
22	discriminate one group from another and a test

	Page 331
1	would be to take known groups and see if our
2	performance measures can discriminate one from
3	another at a point in time.
4	I think that's almost unless
5	you do great stratification or are very, very
6	careful about how you specify those groups I
7	think you're going to have to immediately get
8	into risk adjustment. And we can talk about
9	this more tomorrow.
10	Another test of validity would be
11	to look at the responsiveness of the measure
12	to an intervention of known effectiveness.
13	And I'm going to actually sort of disagree
14	with Anne just a little bit because I think
15	it's too optimistic to think that quality
16	improvement efforts at a national level are
17	going to improve quality. You know, every
18	improvement requires change but not every
19	change is an improvement. And a lot of times
20	things get worse before they get better while
21	you're sorting things out.
22	And so I think that if we have

Page 332 interventions that we know are effective and 1 2 they don't have to be at a national level. They could be more focused. But we then again 3 probably need to either randomize -- we either 4 5 need a randomized design or we need to risk-6 adjust again in order to see if our PRO 7 performance measures are able to detect the 8 change that's caused by that intervention that we know is effective. 9 But I think that those would be 10 11 sort of doable tests. We've got loads of 12 interventions happening. It seems like it's 13 doable. 14 We certainly need to test in 15 populations that we're interested in and the narrower the better initially. And in the 16 17 context that we're talking about, again, the 18 better specified the better. 19 I think that's it from me. So, 20 we've got some time. Good. Thank you. 21 (Applause) 22 DR. PACE: Okay. So we have time

	Page 333
1	for some comments and questions from our
2	expert panel and audience. So I'll open it
3	up. Kathy?
4	OPERATOR: At this time if you
5	have a question or comment please press * then
6	the number 1 on your telephone keypad.
7	DR. LOHR: This is a comment, a
8	great panel as the ones were this morning and
9	lots more questions for us to juggle. But two
10	or three particular things. And this may be
11	for you and Barb more than for Al and Steve.
12	You mentioned clinically
13	meaningful differences. You mentioned minimal
14	detectable change or differences. And I was
15	under the impression that at least for some
16	PROs if not PROMs and whatever we know some of
17	that information already. And it's possible
18	that trying to find certain kinds of measures
19	maybe in depression where those things are
20	already kind of documented and known might be
21	a useful step. Not necessarily for your paper
22	but more generally as NQF sort of moves down

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1 this path.

2	But the other question that I had
3	and I'm nobody ever accused me of being a
4	statistician is whether the minimal
5	detectable changes are not in fact driven to
6	some extent by sample sizes. And whether that
7	has to be taken into account about whether you
8	have very large numbers of patients that are
9	more or less alike, say have the same
10	condition or something, or you have only a
11	few. Or as you aggregate up to across
12	practitioners to healthcare systems or
13	whatever that concept and the actual measures
14	of it might change.
15	The third thing that I had
16	wondered about is your definition of ratio
17	which puzzled me because it isn't the way I
18	think about ratios. And so I was just sort of
19	calling that out.
20	The other thing that I wanted to
21	maybe pick up on with Al Wu is one of your
22	questions, Al, is that you said you weren't

	Page 335
1	sure about the answer is which is better,
2	whether it's mean or median change, for
3	example, or percentage meeting or exceeding a
4	threshold.
5	And you didn't mean it this way I
6	think but that was cast a bit as an either/or
7	kind of question. And in fact it's not an
8	either/or kind of question across the board.
9	It's definitely going to matter depending on
10	the purpose of the measurement and so forth.
11	And it's not that it's not a it's an
12	appropriate question but it's not a
13	generalizable one. And I think the purpose
14	and context for the measurement may to some
15	extent drive the answer to that particular
16	question you had.
17	DR. PACE: So Anne, do you want to
18	start and then we'll go to Al.
19	DR. DEUTSCH: So I think your
20	first question about the PROMs where there
21	actually are known clinically meaningful
22	differences, so I agree with you. I mean

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	Page 336
1	those are going to be perhaps easier to
2	develop performance measures based on those so
3	I agree with that.
4	Second question was about sample
5	size. So yes, I would agree and I think Laura
6	touched on this, the larger your sample size
7	the more comfortable you're going to be that
8	you really are being able to distinguish
9	quality. So.
10	DR. PACE: Can I add something
11	there? Because the other thing is that just
12	because it's detectable statistically doesn't
13	mean that it would be meaningful change to a
14	patient. So I think there's some tradeoffs
15	there.
16	DR. DEUTSCH: Absolutely.
17	DR. FIHN: I just would recommend
18	Gord Guyatt's series on sort of how to
19	calculate that which I think separates out the
20	issues of statistical versus clinical, the
21	sample size issues and tries to sort of get at
22	what the underlying sort of construct of an

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16 with adverse events, you know, the number of	
17 events to the aggregated time. So it's on a	
18 different kind of scale but I'm sure there are	
19 different ways to look at that and we can	
20 certainly get your definition.	
21 DR. DEUTSCH: So I think I'll pass	
22 it off. Barb, did you want to add anything?	

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1	DR. GAGE: I would only point out
2	I realize since we got to the end of the
3	presentation that it sounded like boy, there's
4	nothing out there when in fact we know darn
5	well that I know we've submitted measures
6	on patient reports of pain and many of those
7	things. So the world is moving along in
8	limited ways.
9	DR. PACE: Okay, Al?
10	DR. WU: I would just say, Kathy,
11	I agree with you entirely. It's not one, the
12	other, either/or. Yet another thing to think
13	about is other things that are important about
14	what's the distribution of whatever it is
15	really in the population and how well does
16	your measure measure that. And another thing
17	is what's the functional form over time of
18	health. After surgery if you measure, you
19	know, at 1 day, 1 month, 6 months, a year
20	you'll get different answers and so that's
21	also important to know.
22	And which measure you use could

	Page 339
1	one way of rolling it up could be better or
2	worse depending.
3	DR. PACE: Okay. Yes, Judy.
4	DR. HIBBARD: I appreciated the
5	comments on patient face validity and earlier
6	we talked about meaningfulness for patients.
7	And Anne pointed out the need to sort of give
8	people a context for thinking about quality
9	because we do know that patients and consumers
10	often don't have a context for thinking about
11	quality. They don't share our assumptions and
12	understanding. And so when you ask them about
13	quality to give them some context.
14	But I would go further than that
15	in thinking about querying individuals about
16	their the face validity or the value, the
17	meaningfulness of this in the sense that a lot
18	of times different words that you'll get a
19	different response because people don't have
20	this context and understanding. So if you
21	describe something one way you may get a very
22	different response than if you describe the

	Page 340
1	very same thing with different words. So,
2	thinking about how to get at face validity I
3	think we need to be aware of that.
4	DR. PACE: Okay. Would you say
5	your name.
6	MR. ROONEY: Tim Rooney from
7	Maine. I'm thinking about when do we hold
8	communities accountable, you know. Because if
9	you look at the work that RWJ in Wisconsin has
10	done on social determinants they suggest that
11	morbidity and mortality is 20 percent due to
12	clinical care, 30 percent due to health
13	behaviors. And PROMs start getting into
14	health behaviors, but that's only 50. And
15	then there's the built environment.
16	And in Maine we're doing a lot of
17	work around patient-centered medical homes,
18	community care teams, whatever. We're doing
19	some interesting work with area agencies in
20	aging where they have people on Meals on
21	Wheels who go into homes. And lo and behold
22	you talk to the people that deliver the meals

	Page 341
1	and they're saying well, we find people with
2	10 pill bottles living alone and they had 5
3	before the hospitalization, 5 after. They had
4	no idea which to take and they're not sure any
5	of them have worked well. Well, we're trying
6	to connect that back to the PCP or care
7	management or whatever it is.
8	And then you've got some work that
9	you look what United Way agencies at least in
10	Maine do. They do a lot of what I would call
11	healthcare type of stuff. They run a lot of
12	behavioral health stuff, they do a lot of
13	stuff.
14	I think of Steve's comment about
15	intractable depression. Well, it's
16	intractable to the traditional medical care
17	interventions but is it intractable if you
18	start to look at community interventions to
19	address that like AA programs and things like
20	that.
21	So, I'm thinking at some point is
22	our PROMs really for medical care, or are they
1	

	Page 342
1	for healthcare, or are they for care. And I'd
2	love to think about because the thing that
3	if you go to the RWJ website they have this
4	terrific video on their project match where
5	this community in Iowa or someplace like that,
6	I apologize if someone's from Iowa but it's
7	somewhere in the middle. They were the worst
8	ranked county in the state. So the whole
9	community got together and they built a
10	grocery store in an area where there wasn't
11	any food. So, that's the power of a community
12	coming to address issues that affect it. So
13	I wonder if we could think of PROMs or PROs as
14	not just a way to hold this doctor accountable
15	but to hold a community accountable in a way
16	that makes them want to do something.
17	Any perspectives on that or is
18	this too far afield for this discussion?
19	DR. PACE: Well, NQF does endorse
20	population-based measures but I think that's
21	been an interesting discussion in terms of,
22	you know, then who's being held accountable.

Page 3- And you know, will they ignite change. But we'll see if the panel wants to add anything else to that. DR. FIHN: You know, I'm reminded, Ted, of the, you know, there was an ACC/AHA performance measure regarding time to PCI. And you know, the issue was what do you do about transfers, you know, which was I think NQF struggled with that one, the door-to- balloon time one. And it's sort of a micro of what you said. On one hand no hospital wanted to be responsible for the fact that they said well, if we could do our part but the other, either the sending or receiving hospital might not do their part. And then the community- based sort of approach would be to say that doesn't matter, what really matters is does the patient get the procedure in the prescribed time. And you know, I don't know what		
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21 And you know, I don't know what	20	prescribed time.
	21	And you know, I don't know what
the right answer is to that. I guess it	22	the right answer is to that. I guess it

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1	depends upon what the goal is here, who, as
2	you say, who's being held responsible. And
3	you know, what's the purpose of the
4	performance measure. You know, I think those
5	are, you know, good and very hard questions.
б	DR. PACE: Helen?
7	DR. BURSTIN: Just an interesting
8	side note to that. So actually what wound up
9	happening is we do in fact have the time-to-
10	thrombolysis measures. There's also a set of
11	measures for rural hospitals that are actually
12	the time with which they're able to package
13	somebody and transfer them rapidly for their
14	thrombolysis for their PCI.
15	So, it may be sort of in some ways
16	almost a balancing measure that of course your
17	end goal is to get the right therapy at the
18	right time for the right person but that not
19	everybody can play in that space. And so
20	having measures that actually fit what
21	everyone's role is may make sense.
22	DR. PACE: Ethan?

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1	DR. BASCH: Yes. This is a great
2	panel and I think really brought essential
3	issues to the forefront of the discussion.
4	I'd like to say in thinking about
5	the day so far I'm actually not so worried
б	about reliability or about construct validity.
7	To me the areas, and we've talked about this
8	in the last meeting particularly, that are of
9	greatest concern are first, what's I think
10	sort of being alluded to here as face validity
11	which others of us call content validity.
12	Others call it qualitative research.
13	But you know, the piece which
14	involves going out to the patient population,
15	assuring that what you're measuring is
16	important and meaningful, number one, and
17	number two, that the so that's up front.
18	And then that the measures themselves are
19	understandable to the patients, right. They
20	understand what you're saying. And that the
21	terminology within the measures maps to the
22	underlying concepts of interest which one has

	Page 346
1	a priori identified as being the important
2	concepts, i.e., outcomes that one wants to
3	look at.
4	And to me really that's central.
5	And without that, whatever we want to call it,
6	you know, I call it content validity but
7	others have argued that they'd like to call it
8	something else. That is a fundamental initial
9	step.
10	The other piece that I think is
11	key that has been touched upon both in the
12	reliability and the validity conversations is
13	sensitivity to change over time. And that's
14	sort of been wrapped into the conversation
15	about reliability and validity but it really
16	is separate. And I think again is so
17	essential to this idea of evaluating
18	performance or quality because really what
19	we're talking about is the ability of a tool
20	to measure change within or between practices
21	over time because I suspect that's really what
22	most of these measures are going to turn out

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1	looking at. There may be some threshold
2	measures but I really do think we're going to
3	be looking at change measures.
4	And without being able to detect
5	change over time then, you know, as has been
6	pointed out accountability really is sort of
7	you know irrelevant if you can't change it.
8	But you know, we're not sure is it that you
9	can't change it or is it that you can't
10	measure the change. And so I think to
11	establish up front whether your measure is
12	capable of measuring change is really
13	essential. And I bet Laurie Burke has a
14	follow-up to that.
15	DR. PACE: And I was just going to
16	say, and that is one of the things in the key
17	characteristics, the table from the first
18	paper is responsiveness to change. So I think
19	that's maybe something that will be emphasized
20	in that way. Okay, Laurie, were you going to
21	add something?
22	MS. BURKE: Oh well, I completely

	Page 348
1	agree, Ethan. Content validity is critical.
2	If you don't know what you're measuring then
3	how are you going to what good are the
4	reliability and correlations or lack thereof
5	with other measures.
6	So, and I also think that content
7	validity really alleviates a lot of the need
8	to do an abundant amount of responsiveness
9	testing because if you know what you're
10	measuring you understand how your measure
11	responds across the full range in your
12	population on that concept that you're
13	measuring then you have a better idea of what
14	change is in that continuum.
15	And we have psychometric methods,
16	a new, modern theory that can help us
17	understand that we're, you know, that what
18	gradations along a continuum of a scale mean.
19	And that we have comparable, equally spaced
20	intervals between scores. And I think that
21	that is this iterative approach to content
22	validity that holds a lot of promise right

	Page 349
1	now.
2	We're really able to we have a
3	whole lot of hope that these things can be
4	developed much more quickly and much more
5	be much more applicable to the situation that
6	we want to put them into.
7	Now, the validity, the content
8	validity of the performance measure I think
9	has got to be fairly similar except you need
10	to know how the patients feel about that
11	performance measure in terms of how you're
12	going to calculate it.
13	But content validity isn't just
14	patient input. If it's something that
15	requires expert input of one type or another
16	also is a part of content validity.
17	DR. PACE: Okay. Are there any
18	comments or questions from the audience
19	members? Evan's got the and Operator, what
20	about on the phone line? Are there any people
21	in the queue for comments?
22	OPERATOR: There are no questions

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1	at this time.
2	DR. PACE: Ethan?
3	DR. BASCH: Sorry, I don't want to
4	monopolize the microphone here. But you know,
5	there's something else I was thinking about
6	listening to this which is, you know, once one
7	looks at the measurement properties of the
8	PROM how much do you really have to do on the
9	what you're calling the PRO-PM?
10	And it really seems to me that,
11	you know, and I think you're getting to this,
12	that you know it kind of depends. It appears
13	that there are probably a lot of, you know, as
14	Laurie would say it's a review issue. I think
15	there are probably many settings in which one
16	really does not have to repeat that testing if
17	the PROM has been tested in that sort of
18	target population or context.
19	For example, I'm an oncologist.
20	There are good measures of nausea. If one is
21	interested in looking at the proportion of
22	patients who experience alleviation of their

Page 351 nausea following a highly emetogenic chemotherapy, right, and one has a measure, a PROM that has been shown to be responsive to
nausea following a highly emetogenic chemotherapy, right, and one has a measure, a PROM that has been shown to be responsive to
chemotherapy, right, and one has a measure, a PROM that has been shown to be responsive to
PROM that has been shown to be responsive to
change, be reliable and valid in patients
receiving chemotherapy there probably isn't a
whole lot one has to do to then consider that
as a performance measure.
DR. PACE: Okay. Jack?
DR. FOWLER: I guess I want to
argue with that a little bit. I think this is
the difference between effectiveness and
efficacy. I think the trials that we're
likely to have are that, you know, you give
somebody a drug and it'll fix whatever it's
aimed to fix, or you'll do surgery and you'll
improve something or other.
But if we're going to be patient
and holistic about this that's implying that
doing the intervention which will fix the
problem is quality care. And we've talked
about it's not always quality care. And I
think that because it's not always I think to

	Page 352
1	just intervene more and that that makes you a
2	better that's a better quality of care.
3	In fact, that's one of the reasons
4	that people are pushing for quality care
5	measurement from a patient perspective is to
6	get beyond just doing stuff to people as a
7	measure that you're doing good stuff and to
8	find out if you're really doing good for
9	people.
10	So I think the idea that you also
11	need to know what does a body what happens
12	to a bunch of patients who are subjected to a
13	particular provider in terms of what their
14	overall outcomes are including the things they
15	care most about which may or may not be that
16	symptom that that drug with all the side
17	effects actually fixes.
18	So I think that's why you need the
19	studies of the interventions in practice and
20	reality both the condition and also how it
21	works in practice. And overall measures of
22	how patients are doing as well as the efficacy

	Page 353
1	trials when you subject people with a
2	particular problem to a drug and see the
3	outcome.
4	DR. PACE: John? Could you use
5	the mike? Sorry.
6	DR. WASSON: All I wanted you to
7	do was just clarify a bit more. His comment
8	triggered you to make a general statement.
9	Could you just give us a specific? So he's
10	happy with a nausea scale of whatever and you
11	then reacted to it and said no, I'm going to
12	disagree. I'm not sure, maybe it's just me.
13	I'm dense and it's late in the day, but what
14	exactly were you saying is wrong with that?
15	Is it necessary but not sufficient, was that
16	your point?
17	DR. FOWLER: Yes. I think that
18	the idea that I mean, if you're really
19	focused on nausea and if it was really that
20	narrow, well even then I think. He was saying
21	that the trial that showed that the drug works
22	to fix the problem is evidence enough that you

	Page 354
1	no, I think you were. Evidence enough that
2	the intervention, you know, that the
3	intervention is a good idea.
4	DR. BASCH: I actually think we're
5	agreeing with each other. I think there are
6	two different pieces here. You know, I think
7	maybe what it sounded like I was saying is
8	that if a measure has been evaluated for its
9	properties in a highly restricted context, for
10	example, in regulatory trials it could then be
11	brought out into a CER, into a registry or
12	into a quality assessment context which isn't
13	what I'm saying.
14	I'm saying that if the measure has
15	been evaluated in a satisfactory way itself as
16	a measure then when you drop that measure into
17	a similar context you probably don't have to
18	go back and, you know, retest it. So if
19	you've gone out and looked at hard-to-reach
20	patients and different languages and all like
21	the good stuff that we care about that's
22	probably okay. We good? All right.

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1	DR. PACE: Steve.
2	DR. FIHN: I was just going to
3	take you know, and I realize some of the
4	comments were for reaction. But you know, I
5	do think we have to take a balanced view of a
б	technical evaluation of some of the measures.
7	You know, a good example would be the CAHPS
8	satisfaction, outpatient satisfaction scores.
9	Those of you who are in the VA
10	right now know we've been for the last 2 years
11	struggling to put out patient-centered medical
12	homes in all 1,000 sites of care that we have.
13	It turns out when we started
14	looking at the CAHPS for trying to discern
15	which places were doing better than other
16	places we didn't see any differences. And we
17	went to Commonwealth and we went to NCQA and
18	they said well, we know. That instrument
19	isn't responsive. We've known that for a long
20	time and we're in the process of developing a
21	new measure. And we've got the new one now
22	rolled out which we hope will do it.

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1	But you know, I think we can look	
2	at these measures, they may look good, they	
3	may have a lot of the testing, et cetera. And	
4	when you actually put them into practice they	
5	actually don't perform. And I think we should	
6	make sure that actually before we do that that	
7	we understand that they do perform.	
8	In this case for us it's a pretty	
9	high-stakes issue. We're investing \$1 billion	
10	in this and we can't tell what's working. So,	
11	you know, I think there's something to be	
12	said.	
13	I think you're right, if you just	
14	focus on the technical issues of the measures	
15	then we might be measuring something that we	
16	don't understand or don't care about. But on	
17	the other hand I think if we don't do that	
18	we're, you know, liable to perhaps not be able	
19	to measure things we really want to.	
20	DR. PACE: Helen?	
21	DR. BURSTIN: And perhaps just one	
22	very concrete example that we just went	

	Page 357
1	through in our surgery projects. There was a
2	measure put forward that looked at improvement
3	after cataract extraction within 90 days using
4	a very well-validated tool. I know Al knows
5	this work well, the VF-14.
б	No question about it, this is as
7	validated a tool as it could be. When you
8	apply it to a performance measure all the
9	issues we've been talking about today came to
10	the fore.
11	The first is what does improvement
12	mean. In those research studies any degree,
13	any sort of increase plus up was good enough.
14	What's actually a meaningful difference of
15	cataract improvement? And so, there are a
16	whole series of issues.
17	It was administered in a very
18	structured way as part of the original
19	studies. Now it's going to be submitted, you
20	know, sent to patients by mail from their
21	ophthalmologist's offices. So you can see how
22	of course the tool itself is pristine, but

	Page 358
1	when you put it in a performance measure in
2	the real world it gets kind of messy.
3	DR. PACE: Okay. One last
4	question? Okay.
5	DR. LOHR: It's one last question.
6	Part of your paper in the validity section
7	dealt with how to cope with patient
8	preferences. And I wanted to sort of throw
9	out an alternative universe that asks whether
10	that is an element of validity per se, or
11	whether it needs to be considered but as a
12	somewhat different or separable measurement
13	activity. Or even a set of items or some
14	other way of getting at things related to
15	patient preferences that aren't categorized
16	inside validity. And that was just, that's
17	just my
18	DR. GAGE: Well, it's a very good
19	question because the issue comes up. If you
20	take a measure like pain, you know, one of the
21	earliest measures of the patient's perception,
22	but their threshold for when it's impairment

	Page 359
1	is very different from patient to patient.
2	So as you're thinking about the
3	use of the patient's information you know part
4	of what we keep struggling with, this whole
5	notion of taking a patient-reported outcome
6	and using it for the purpose of
7	accountability. Not just QI, not just
8	modifying the treatment but actually holding
9	somebody accountable is how much do you allow
10	for that more subjective nature of the
11	patient's preference and the patient's voice
12	and all the other factors that are
13	unmeasurable that might be affecting the
14	patient's response on that particular day.
15	And yes, we can risk-adjust, we
16	can stratify within different subgroups but
17	you're still, there's still that issue out
18	there. And when you talk about QI the
19	clinical communities are all for giving the
20	best care and taking into account the
21	patient's view. When you talk about
22	withholding payment or some of these other

	Page 360
1	accountability actions there's less consensus
2	about the importance of the patient's voice.
3	And it's really something we'd like to hear
4	from this group about because it's a difficult
5	issue.
6	DR. PACE: Okay. So we have one
7	more thing to do before you leave and that is
8	we thought we would spend this last few
9	minutes of you people of our expert panel
10	at their tables. And to just kind of as a
11	group, as a table group kind of identify those
12	unique considerations about PRO-based
13	performance measures in relation to NQF
14	criteria. And also thinking about the pathway
15	that we're going to look at tomorrow in terms
16	of the unique considerations of getting from
17	a PROM to a PRO-based performance measure.
18	So we're going to just stay at
19	your tables. We'll have an NQF staff person
20	at each table to take some notes. And we'll
21	just ask you to do that. And Patti is going
22	to make a few additional comments before we
Page 361 1 start that. Go ahead. 2 DR. BRENNAN: Yes. And could I invite all of our guests -- ladies and 3 4 gentlemen, I am the second eldest of 10 5 children and I know how to make a room get 6 quiet. You all have to do the dishes. 7 Could I invite our guests to 8 please come up and just join a table because 9 we're going to be spending the next 25 minutes 10 or so getting everyone's input on the notes they've been jotting down all day of what has 11 12 to be done uniquely or with the consideration of patients as a contributor to patient-13 14 reported outcomes in contrast to all of the other NQF work. 15 16 So if you'd come up and join a 17 table I'll get you started on your activity. 18 There are eight tables I believe and there's 19 plenty of seats up in the front. Don't be 20 shy. And there's going to be an NOF staff 21 member at each table to take notes. There 22 will be people coming up to join you. And our

	Page 362
1	experts, please be nice to the company coming
2	to join your table. Don't make faces at them.
3	Perfect. Okay, everybody has a table to sit
4	at and a chair to sit on.
5	Now, this is going to require a
6	little bit of thought which is going to mean
7	that you have to have oxygenation in your
8	brain. Most of you don't have any left up
9	there, it's been draining down all day so I'm
10	going to ask you to do one chair exercise to
11	get some oxygen back up in your brain. All
12	right? So I want you to put your right arm
13	over your head, grasp your right elbow with
14	your left hand and pull slightly and bring it
15	back down. Now, put your left arm over your
16	head, grasp your left elbow with your right
17	arm, pull slightly and bring your arm back
18	down again. That's a kind of hydraulic pump.
19	There's oxygen back in your brain now.
20	Okay, if you look on the front
21	boards in front of you we're not doing the
22	hokey-pokey till tomorrow. If you look on the

	Page 363
1	projectors in front of you you'll see that
2	there are the four major endorsement criteria
3	for NQF. Your job in the next 25 minutes is
4	just to brainstorm a little bit about do any
5	of these four require special consideration
6	for PROMs. If you want to follow along in
7	your electronic handout it's on page 43, 44
8	and 45. If you have the full packet from
9	today. And if you have a paper handout it's
10	on the same pages, they just happen to be on
11	paper. But mostly discuss these four. There
12	will be no report out. At 5 o'clock we will
13	call a quick stop and we'll see you all in the
14	morning. Thank you very much.
15	(Whereupon, the foregoing matter
16	went off the record at 4:37 p.m.)
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#### CERTIFICATE

This is to certify that the foregoing transcript

In the matter of: Patient Reported Outcomes Workshop 2

Before: NQF

Date: 09-11-12

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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NATIONAL QUALITY FORUM + + + + +PATIENT-REPORTED OUTCOMES WORKSHOP #2 + + + + + WEDNESDAY SEPTEMBER 12, 2012 The Workshop met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Patricia Brennan and Joyce Dubow, Co-Chairs, presiding. PRESENT: PATRICIA BRENNAN, PhD, University of Wisconsin-Madison, Co-Chair 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

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Page 4 T-A-B-L-E O-F C-O-N-T-E-N-T-S INTRODUCTION TO DAY 2 METHODS THAT CONTRIBUTE TO TRUST -ADDRESSING THREATS TO VALIDITY Overview of NOF Endorsement Criteria on Threats to Validity of Conclusions about Quality and Differentiation between PRO & PRO-PM Commissioned Paper Authors Tee-Up Key Issues and Best Practices or Strengths/Weaknesses of Approaches to Aggregating Individual-Level PRO data and specifying PRO-PMs Reactor Panel: Anne Deutsch. . . . . . . . . 33 . . . . . . Robert Weech-Maldonado. . . . . . . . . . . . . . . . 63 Expert Panel and Audience Engagement. . . . . 73 IDENTIFICATION OF UNIQUE CONSIDERATION RELATED TO NQF ENDORSEMENT OF PRO-PMs . . . . 99 REVISIT PATHWAY FROM INDIVIDUAL-LEVEL PRO TO NOF-ENDORSED PRO-PM Eleanor Perfetto. . . . . . . Expert Panel and Audience Engagement. . . . . 133 Closing Remarks and Next Steps FUTURE DIRECTIONS 

	Page 5
1	P-R-O-C-E-E-D-I-N-G-S
2	(8:30 a.m.)
3	DR. PACE: Okay, good morning
4	everyone. Thank you for getting with us
5	bright and early. And Joyce Dubow is going to
б	come to the front. I heard that yesterday
7	some people were having trouble hearing us.
8	So please waive your hand if we aren't
9	speaking into the microphone so we can try and
10	make an adjustment. And I am going to turn
11	this over to Joyce for some introductory
12	remarks and then we will go to our first
13	panel.
14	MS. DUBOW: Thank you, Karen and
15	good morning everybody. You know I want to
16	thank everybody for your participation
17	yesterday is this loud enough because
18	this is a big hunk of time from, I know, every
19	busy schedules. And I thought the
20	conversation yesterday was very, very helpful.
21	I know it is going to be helpful to the staff
22	and to the committees that get formed when

	Page 6
1	everybody has to get down into the business of
2	finding measures on patient-reported outcomes.
3	So I think the work that you all are doing
4	here is really, really important and I want to
5	say thank you and I want to thank the staff.
б	They again did a remarkable job and I am about
7	to go through some slides that Karen and Karen
8	created. They are just amazing. So thank
9	you, both, and to Helen, of course.
10	Well I know they did it but you
11	know it is always good to have a spine that
12	sort of keeps everything straight.
13	So if we could have the first
14	slide, we are going to spend about ten minutes
15	and Gene, thank you, too. I just eyeballed
16	him.
17	We are going to spend about ten
18	minutes or so just reviewing some of the
19	highlights of yesterday's work and these are
20	what occurred to us as being very significant
21	but I am going to ask you to think about
22	whether there is anything we ought to be

Page 7 1 adding to this list. 2 So thinking about the main issues that we discussed, the overarching 3 considerations, one of the first issues that 4 5 jumps out is the need to assess meaningfulness 6 and how to demonstrate evidence that 7 stakeholders think the PROM is meaningful. We 8 talked about the importance of getting consumers involved in this. And the brilliant 9 10 Patti Brennan helped us think about this in terms of the three C's. Patti's presentation 11 12 in my view was masterful yesterday. I think everybody else did, too. And if I mangle 13 14 this, Patti will clarify. 15 She identified three C's, the 16 conceptual which helps us identify the PRO by 17 engaging people in a dialogue to hear from them what matters to them to define the 18 19 concepts. So that helps us identify which PRO 20 to think about. 21 The next phase would be the 22 contextual, how the information is captured.

	Page 8
1	This, the contextual takes into account not
2	only patients, which is who are people or
3	individuals, remember I am using shorthand
4	here, but for clinicians as well. For them to
5	consider how they capture and use the
б	information as well. That would be the PROM.
7	And finally, to think about this
8	in the contextual sense in the
9	consequential sense oh. Well, here, we
10	have some illustrations of the contextual.
11	How people will participate in the large
12	social enterprise in using this information.
13	For example, if an individual using the
14	information selects a provider or to
15	understand the information with respect to
16	one's individual health situation and then
17	finally to consider the consequential. What
18	happens when the information is used? This is
19	the PRO-PM, to assure that good quality is
20	available and to understand its impact on the
21	availability of services.
22	I think I mangled that Patti. Do

	Page 9
1	you want to do anything to clarify a little
2	bit?
3	DR. BRENNAN: I think you
4	translated me lovely and thank you.
5	The one thing I would say first of
б	all is these are concepts that are evolving.
7	So these are not written in stone and there is
8	no citation for this. What was important for
9	me to do is to stress that we begin first with
10	what matters to the patient before we can
11	event define a PRO, we have to figure out what
12	really matters. Second, we have to think
13	about both the capture and use of information
14	relative to an individual, patient, or patient
15	clinician engagement. And third, we have to
16	think about the impact on practice and policy.
17	So that is really how I see them.
18	And I think you did a nice job laying those
19	out. Thank you.
20	MS. DUBOW: But each one of these
21	things speaks to which level we are talking
22	about, either the PRO, the PROM, or the PRO-

	Page 10
1	PM. Could we have the next slide, please?
2	So for additional considerations
3	that we mentioned, there was a lot of emphasis
4	on actionability. And again in the same
5	panel, Liz helped us understand that we would
6	think about the spectrum of actionability
7	because actionability is a criterion, an
8	attribute that we talked about last time as
9	well as yesterday. This is an ongoing theme
10	that we have acknowledged to be very
11	important.
12	A hot, something, a PROM that will
13	be highly actionable, will be subject to
14	intervention and it is suitable and able to be
15	demonstrated outside of a clinical trial so
16	that it can be actually implemented in
17	practice. Something that is highly actionable
18	will have high credibility in the clinical
19	community, of course, and it will have an
20	impact on patients as well.
21	If it is moderate, someplace in-
22	between, those that have low actionability

Page 11 1 probably should be off the table because they 2 will not necessarily be useful to patients. You know, it may not reflect symptoms that 3 matter to patients, for example. And if we 4 cannot demonstrate this type of actionability 5 to clinicians, it won't be particularly 6 7 credible either. 8 So this spectrum is very important 9 and when we start thinking about PROMs to 10 select, we ought to be going to the low hanging fruit, which would be those that are 11 12 highly actionable. Next slide, please. 13 I'm sorry. 14 It's so hard for me to understand that I can't be heard. My children would never agree with 15 that. Closer? I'm breathing into it. We are 16 17 going to need to -- okay. So then we talked also about the 18 19 business case, the ROI. And you know, this is 20 a very pragmatic consideration and we had a 21 couple of people talking about this. 22 We heard from Larsson, Dr. Larsson

	Page 12
1	in Sweden, that they use their registries to
2	do CER and to demonstrate appropriateness.
3	There are opportunity costs. There are
4	benefits to using this stuff and we know that.
5	But there are also costs to it. The cost of
6	administration, the vendor-driven
7	administration expense. The cost of CAHPs for
8	example. Liz didn't talk Liz Goldstein
9	didn't talk about the cost of fielding the HOS
10	but obviously there is a cost to that.
11	And John Wasson talked about the
12	issue around getting consent from patients.
13	So we need to take these issues into account.
14	But it was interesting to hear Dr.
15	Larsson talking about the ability to make
16	assessments of appropriateness of care using
17	their registries. Of course, they have a
18	completely different system. The idea of
19	having 64 relatively compatible registries in
20	this country is mind-boggling but it certainly
21	is a system that would lend itself to some
22	economies.

Page 13 1 We heard talk about phased 2 implementation to link the systems and mechanisms for care improvement before we rush 3 to market. I think Steve talked about this a 4 5 lot and others did, too that we want to 6 express a sense of urgency, at the same time 7 recognizing that we may have to think about 8 processes that relate to the outcomes that we 9 want to achieve. 10 And we talked about looking at the impact of implementation of measures by doing 11 12 some kind of post-market surveillance of these 13 But you know I think that we new measures. 14 also acknowledge that we need to do that 15 generally with all measures, but in particular 16 learning from implementation of these patient-17 reported outcome measures will be very 18 important. 19 Next slide, please. So we heard a 20 few of our colleagues talk about the iterative 21 nature of reliability and validity and the 22 suggestion from Laurie that the validity

	Page 14
1	testing actually take place first, you know,
2	to get the concept down before going on to the
3	reliability but that this was an iterative
4	process. I can't remember whose slide it was
5	who showed the Lewis' slide for me was
6	really very helpful to see that iterative
7	process. He showed it with arrows.
8	We talked, again, we kept
9	emphasizing the importance of engaging
10	patients and determining the face and content
11	validity. I think that got mentioned a lot.
12	Identifying the patient populations whose
13	outcome you want to track. I think Jack gave
14	us important insights here. And that if you
15	only measure those who get the intervention,
16	you could be penalizing those clinicians and
17	those patients well probably the clinicians
18	who are engaging not in the intervention but
19	in watchful waiting.
20	And Jack I don't recall that you
21	actually had good solutions for how we do
22	this. Okay, well we will need to think about

	Page 15
1	it.
2	Unfortunately, Jack, the mike
3	wasn't on but Jack was talking about having
4	records so that we could identify these
5	patients just the way they do in Sweden. But
6	this is going to be a challenge, I think, for
7	us.
8	Is there a next slide? I can't
9	remember. That's it.
10	So could we have a quick
11	conversation about things that we neglected to
12	put here on these slides just to remind us or
13	any other observations?
14	There is somebody from could
15	you use a mike, please?
16	MS. OKUN: The two characteristics
17	of importance to the patient and
18	actionability. What if something is important
19	to the patient but not actionable? And for
20	example, fatigue. For a long time no
21	treatments for fatigue. Fatigue due to cancer
22	treatment, very important to the patient. If

	Page 16
1	it is not measured, then it is not it
2	doesn't become a focus and ultimately treated.
3	MS. DUBOW: Yes. You know, thank
4	you for that. You know, we also had our last
5	half hour where we had an opportunity to look
6	at the NQF evaluation criteria to see whether
7	we had any ideas about whether or not they had
8	to be tweaked. I know I was in a conversation
9	at our table where we didn't get past the
10	importance criterion. And I haven't seen the
11	notes from the other tables but we had a kind
12	of lively conversation about the need to
13	consider the audiences when thinking about
14	importance, including figuring out how to
15	engage consumers in the process of making a
16	determination about importance.
17	Ethan?
18	DR. BASCH: You know, I think it
19	is a great question. I think certainly there
20	are contexts in which there are non-actionable
21	pieces of information about the patient
22	experience that may be valuable for patients

Page 17 1 to understand but may not necessarily be 2 appropriate for this kind of use. But to directly address the 3 4 question, there actually are some contexts in 5 which fatique or tiredness would be 6 appropriate to measure. For example, for one 7 you brought up the cancer example, one could 8 look at inappropriate use of chemotherapy in 9 patients who are too fatigued to baseline. 10 And that would be one potential example. Another would be there are certain kinds of 11 12 cancer where patient's fatigue does actually 13 improve with active treatment. So I think 14 that those are two potential examples. 15 MS. DUBOW: I thought the point 16 here was things that were clearly not actionable --17 18 DR. BASCH: Example. 19 -- but still important MS. DUBOW: 20 to patients. And I think --21 DR. BASCH: Absolutely. 22 MS. DUBOW: -- that is really

Page 18 1 important. 2 DR. BASCH: Right. You are absolutely right. 3 4 MS. DUBOW: Because there may be 5 some things that are not actionable. 6 Phyllis? 7 MS. TORDA: Good morning. In 8 going through the small group exercise, I actually was struck by how often I could think 9 10 of an issue that applied actually both to the reported outcome measures and other measures 11 12 as well. 13 So in some cases, things like these measures are more similar to other 14 15 measures than different. In other cases, it seems like maybe there is an issue that is 16 17 really magnified for these kinds of measures and then there may be some ways in which they 18 19 are very specifically different. 20 But I think it behooves us to make 21 those distinctions. 22 MS. DUBOW: Yes but you know -- I
	Page 19
1	think that is important. But I think Helen
2	and Karen and Karen, I think Karen Pace
3	actually said that it might be an opportunity
4	to tweak the criteria so that we could broaden
5	the applicability to embrace these measures as
6	well.
7	MS. TORDA: Yes, I think a lot of
8	the issues that we discussed could have broad
9	application to considering measures in
10	general.
11	MS. DUBOW: Right. Gene?
12	DR. NELSON: I think Patti Brennan
13	mentioned patient-defined outcomes and
14	patient-generated outcomes. And this idea
15	about me as an individual patient, I may have
16	certain health goals and certain health
17	outcomes in mind that are very important for
18	me. I want to go to sit in the bleachers at
19	the Red Sox game. That is what I am hoping to
20	do with my grandson. And then we have very
21	important general measures of health status
22	that most people would wish were good;

	Page 20
1	physical health, mental health, well function,
2	et cetera. So there is this tension between
3	individualized outcomes of importance and
4	general outcomes of importance and how we try
5	to understand that and make this operational
6	in the real world, the general measures as
7	well as individualized measures. I think that
8	is one of the like motifs that we keep hearing
9	and thinking about.
10	MS. DUBOW: Thank you. Ted, did
11	you want to make a comment?
12	DR. GANIATS: Ted Ganiats from San
13	Diego. And just two comments related to the
14	actionability issue. I mean first of all in
15	my mind
16	I'm still Ted. Two comments on
17	the actionability. One of them is the cost of
18	doing this is so great that we have to be
19	careful about it being actionable. I mean,
20	just because it is important, the resources it
21	requires to gather and try to act on the
22	information is so great we want to be careful.

	Page 21
1	But more important, I think it is important
2	for us not to be comprehensive. If I am
3	thinking of heart failure or diabetes and all
4	the guidelines and all the things that I could
5	measure to make sure that good care is being
6	provided, but we only have a couple of quality
7	indicators and I think that the same thing has
8	to hold here, that even though patient-
9	reported outcomes are, in my mind, the most
10	important outcomes, we don't want to be
11	comprehensive. So we don't want to list all
12	actionable ones. We don't want to make sure
13	that we do everything because we are going to
14	be spending too much time measuring and not
15	enough time providing the care. So these
16	should be indicators, not comprehensive.
17	MS. DUBOW: I'm going to give
18	David Cella the last word and then we are
19	going to have to go to our next panel.
20	DR. CELLA: Good morning. I'm
21	Dave Cella from Northwestern and I was at some
22	of yesterday but not all of it. So I

Page 22 1 apologize for not being double-booked. 2 Most of you know, maybe all of you know, that there is a teacher's strike going 3 on in Chicago. And the holdup on the strike 4 5 isn't actually money, at least pay raises. That part is settled. The holdup is that 6 7 teachers don't want to be evaluated based on 8 standard scores. And there is a parallel here 9 that I think relates to providers who I think, 10 not all providers, but many are probably afraid of being evaluated based on standard 11 12 scores or PRO scores. And so I really strongly endorse the issue of the spectrum of 13 14 actionability and I was here when Liz pushed 15 that and I was persuaded by that that it is important to be careful about setting up 16 expectations that something can be improved 17 when there isn't a whole lot of control in the 18 19 hands of the provider, similar to the teachers 20 that are complaining that they shouldn't be 21 judged by the quality of their work by the 22 standard scores and yet if the district wants

	Page 23
1	federal funds, it has to apply that directive.
2	So I guess I would like to push
3	this group to answer the question where do you
4	want to jump in on assessing meaningfulness on
5	the conceptual issues? Because we could dance
6	around those issues and talk about those
7	issues and convince ourselves that PROs are
8	not perfect or they are not quite right for
9	this setting and, therefore, we had better
10	hold back or we could decide to jump in and do
11	it cautiously but to jump in.
12	And you know, not hearing all the
13	discussion yesterday, I may be off target but
14	I hope to see a continued commitment to start
15	somewhere, start with high actionable areas
16	and jump in with measures that you know are
17	important to people, perhaps not proven to
18	everyone's satisfaction with that particular
19	group of patients in that particular setting.
20	Because we could go down that road and reject
21	everything every time if we go too far down
22	that road.

	Page 24
1	MS. DUBOW: Well before we
2	adjourn, I will just inject a personal
3	opinion. And that is that the horse is out of
4	the barn and that we are moving down this road
5	and we want to do the best possible work we
6	can that is fair and that gives us valid and
7	reliable information to inform decisions that
8	reflect patient input. So with that, I think
9	we should let the day begin.
10	DR. PACE: So if we could have our
11	panel come forward, we will get started.
12	Okay, so we are moving on to
13	validity part 2 and I am going to introduce
14	the panel and then I will do a little overview
15	of NQF evaluation criteria that relate to this
16	area.
17	So for this panel we have Anne
18	Deutsch from RTI, who is one of our commission
19	paper authors. Next we have Ken Ottenbacher
20	and Ken will also be addressing some of these
21	thorny issues about validity. I'm sorry.
22	Let' me find my place. Ken is with the

Page 25 University of Texas Medical Branch at 1 2 Galveston. And then we have Rob Weech-Maldonado from the University of Alabama at 3 Birmingham who also will be addressing these 4 5 issues. So I am going to start with just a 6 7 little bit about NQF criteria that relate to 8 this and we are calling this validity part 2 9 because yesterday we talked about validity in 10 general and about the actual performance score that will be used to make some inferences 11 12 about quality. And today what we want to talk about additional aspects of validity but these 13 14 are things that can kind of threaten validity or throw a ringer into what we are trying to 15 So next slide, please. 16 do. 17 So again, just to orient 18 ourselves, NQF is not endorsing the individual 19 PROM but I think we have all agreed that the 20 PROM needs to be valid for the context and the 21 target population it is being used in. That 22 is definitely going to be a foundation to have

	Page 26
1	a valid performance measure. But we are
2	talking about using those patient or
3	individual PROM scores or values and trying to
4	use that for a particular healthcare provider,
5	whether it is a hospital, a physician
6	practice, accountable care entity so that we
7	would have a score on that accountable care
8	entity in terms of how they are performing.
9	Okay, next slide.
10	So we have talked about some of
11	these threats to validity and certainly we
12	have talked about conceptual, which can occur
13	at either level of the PROM or the performance
14	measure. We have talked about the
15	relationship of reliability to validity. But
16	some of the other specific things that we get
17	into this section are very much part of how
18	the performance measure will be defined. So
19	what patients end up being excluded from the
20	performance measure and is that appropriate?
21	So just again, outside of the PRO-
22	PM, NQF often sees performance measures that

	Page 27
1	come in with very broad general exclusions.
2	And the question comes up are too many people
3	being excluded that you are really not knowing
4	what to make of the actual performance
5	measure.
б	Certainly we have talked about
7	differences in patient mix for outcome
8	measures that need to be adjusted for because
9	patients are not randomly assigned to
10	healthcare providers. And if we are going to
11	use this to make inferences about quality, we
12	need to account for those difference in
13	patient mix that come up.
14	Measure scores that are generated
15	with multiple data sources or methods. So if
16	we are going to say that you can use two
17	different PROM instruments for the same
18	performance measure, do we have evidence that
19	they are really equivalent and comparable so
20	that again we can use these in an
21	accountability framework.
22	And then certainly systematic

Page 28 1 missing or incorrect data affect validity. 2 And we know that with these types of surveys, we have talked about response bias, et cetera. 3 So all of these things, even though we have a 4 5 good idea about the performance measure, when we actually go to implement this in the real 6 7 world, in real clinical situations, we have to 8 at least consider these and ask for some 9 assurances that these have been addressed. 10 Next slide. So an NOF has some very specific criteria about each of these. 11 12 So we have very specific criteria about That first of all they should be 13 exclusions. 14 supported by the clinical evidence. So you don't want to exclude patients unless -- if 15 the clinical evidence indicates that a certain 16 patient subgroup should be excluded, then that 17 obviously should be done. But and this is one 18 19 that I think we will have to grapple with 20 It is one that comes up a lot is here. 21 patient preference. And you know, some people 22 see that as kind of a catchall, a quick way to

	Page 29
1	check a box to exclude patients from a
2	measure. Oh, the patient doesn't want it.
3	Others mentioned that the provider
4	intervention can actually affect patient
5	decisions. And we have had lots of those
6	discussions here about how much time you spend
7	with the patient, how much they are informed.
8	And so high exclusions because the patients
9	are rejecting something may also indicate a
10	quality problem.
11	So you know, this is a delicate
12	balance here and I think where we are right
13	now with NQF criteria is that if patient
14	preference is specified as an exclusion, that
15	we have to have some way of making that
16	transparent, so that everyone is aware of
17	differences across providers about patient
18	preference but I am sure we can have some more
19	discussion about that.
20	Next slide. So this next one is
21	specifically about outcome measures that we
22	need to have an evidence-based risk-adjustment

	Page 30
1	strategy. This should be based on patient
2	factors that influence the measured outcome
3	but not factors related to disparities in care
4	or the quality of care. That is what we are
5	trying to make see differences in.
6	These should be present at the
7	start of care, not things that develop in the
8	middle of the care process. And we want risk
9	models that demonstrate adequate
10	discrimination and calibration. You know,
11	sometimes we see risk adjustment handled
12	through risk stratification versus a
13	statistical risk model. Sometimes we see
14	measures that are not risk outcome measures
15	that are not risk-adjusted but again there
16	would have to be adequate rationale and data
17	to support that no risk adjustment is
18	necessary.
19	In terms of risk factors, I think
20	one that has come up frequently in our
21	discussions about PROM or PRO-PM is patient
22	baseline scores in terms of is that a risk

	Page 31
1	factor that should be considered.
2	Okay, next slide. Okay, another
3	one is that computed measure scores
4	demonstrate that methods for scoring and
5	analysis allow for identification of
6	statistically significant and practically or
7	clinically meaningful differences in
8	performance.
9	So generally again, NQF is
10	endorsing performance measures for not only
11	improvement but also for accountability
12	applications. So if a performance measure
13	really can't discriminate good and poor
14	quality, and again, this relates to validity,
15	then maybe it is not an accountability
16	measure. However, the exception to that could
17	be that we may have all decided yes, there is
18	not very much discrimination and it is because
19	in general we are doing a really poor job
20	across multiple providers of a particular area
21	of interest.
22	And then the last one in this area

	Page 32
1	is again about the multiple data sources or
2	methods. That if a measure is going to be
3	specified, that you can use multiple PROM
4	instruments, then what is the demonstration
5	that you would get comparable scores?
6	And I believe that is the last one
7	or one more? Okay. All right, so from there,
8	I am going to turn it over to Anne and then we
9	will get our panel and your comments and
10	questions. Thanks.
11	DR. DEUTSCH: Great. Can everyone
12	hear me, including the back? Okay, great.
13	All right, so I will just wait for
14	this slide to come up here. Great, thank you.
15	So next slide.
16	So one of the first questions that
17	we are going to address as part of this whole
18	threats to validity section is are there any
19	differences or unique considerations for risk
20	adjustment for a PRO-PM as compared to other
21	quality outcome performance measures? Next
22	slide please.

	Page 33
1	So the short answer, I think, is
2	no. I don't think there are differences.
3	Certainly patient factors are important and
4	those should be based on evidence that those
5	could affect outcome. Evidence can certainly
6	include peer reviewed research, clinical
7	expert opinion. I would also say just in line
8	with my presentation yesterday, that informed
9	patients could certainly provide some very
10	valuable insight into potential covariates
11	also. And I am not sure to what extent that
12	has been done with other performance measures
13	but it certain applied to other non-PRO
14	performance measures also.
15	The covariates would be very
16	different, based on the different PRO
17	concepts. And in the paper we give a couple
18	of examples. And actually I would like to
19	highlight the area that I work on is
20	functional status. And functional status can
21	be clinician observation as well as patient
22	self-report and I would say the risk factors

Page 34 or covariates you would consider for either 1 2 self-report functional status or the clinician observation would probably be the same. 3 So in this case, I don't think there is really 4 5 differences between the PRO versus the other kinds of performance measures. Next slide. 6 7 So in terms of examples, patient 8 demographic factors that are often adjusted 9 for are age. One of the areas of controversy 10 and we talk about this in the paper related to race, ethnicity, and limited English language 11 12 proficiency. And that is a controversial area and perhaps we can get into a conversation 13 14 about that as part of the panel discussion but I would say the issues that are a concern for 15 16 other measures are equally a concern here. The different SES, race/ethnicity variables 17 18 may be associated with outcomes but it may be related to disparities and so in general those 19 20 are not adjusted for in performance measures. 21 Patient clinical factors that are 22 present at the start of care would also be

	Page 35
1	important, obviously, and typical factors
2	included are things like diagnosis, severity
3	of illness, comorbidities, and baseline
4	scores.
5	When we put the outline together
6	for this, it was a suggestion from somebody on
7	the expert panel to include psychological
8	factors like adherence, motivation,
9	understanding, engagement, and readiness for
10	change. Certainly those may be important for
11	patient-reported outcomes performance measures
12	but I want to highlight that if those are
13	being included, then it probably would mean
14	some additional data collection. So in
15	addition to the PRO outcome, there may be some
16	additional data that would need to be
17	collected on these things and patients or
18	persons may have questions about why this
19	information is being collected. But
20	typically, this is not information that is
21	available in a medical record already. So it
22	might be something that in addition needs to

1 be collected. 2 And I would also say that motivation is certainly something that we have 3 talked about when we have been working on this 4 5 measure for functional status because certainly patients who are more motivated 6 7 might actually do better but therapists who 8 are very good might actually motivate patients 9 a little bit more. And so you don't want to 10 remove that effect that a clinician may be really good at motivating their patients. 11 And 12 so their patients actually get better and we want to give them credit for that as part of 13 14 their care. Next slide, please. 15 So as Karen mentioned, there is 16 various ways to adjust for these covariates. 17 So a very simple way is to stratify by risk 18 And out of the current performance groups. 19 measures that our patient-reported outcomes 20 endorse by NOF, I don't think any of them 21 actually do that at this point. Certainly 22 others do but in general, you would be able to

	Page 37
1	stratify based on kind of one factor or a
2	factor that can be split into two or three
3	groups.
4	DR. PACE: Wait one second.
5	Helen?
6	DR. DEUTSCH: Oh, and the
7	cataract. Thank you Helen. Sorry.
8	Regression modeling is another
9	alternative and then a third option would be
10	that you both stratify and then use regression
11	modeling with your strata.
12	There is definitely some
13	controversy in terms of regression modeling
14	and so there is quite a debate about whether
15	we are using these hierarchical generalized
16	linear models is better than using fixed-
17	effect regression models. And in the paper we
18	do talk about the paper that recently came out
19	that was commissioned by the Committee of
20	Presidents of Statistical Societies called
21	statistical issues in addressing hospital
22	performance. So if anybody is really

	Page 38
1	interested in this topic, they should
2	definitely see that paper. Next slide.
3	So one of the issues that we
4	talked about is incomplete or missing data,
5	the next topic. So the question is what are
б	the implications of exclusions,
7	incomplete/missing data, and response rate
8	bias on validity of the performance measure
9	and the testing needed to assess impact on
10	validity?
11	And I mentioned yesterday that I
12	had a project where we actually presented some
13	fictitious quality data to some people in
14	senior centers and asked them which facility
15	is doing better. And I just want to bring up
16	one example that is pertinent related to
17	missing data.
18	So one of the measures that we
19	tested on asked people about was percent of
20	patients with moderate to severe pain. And
21	one of the seniors that I interviewed said
22	that she would pick the place that had the

	Page 39
1	higher percentage of patients with moderate to
2	severe pain. And so I asked why. We asked
3	why, regardless of their answer. And she said
4	well I think probably they probably asked a
5	lot more people. I think the places that had
6	lower percentages, they probably didn't ask
7	everybody. So I want to go to the place where
8	they really care about it and that would be
9	the place with the higher percentage. So I
10	thought that was kind of an interesting answer
11	and probably correct. All right, next slide.
12	So there is kind of two categories
13	in my mind in terms of why there is missing
14	data. So for measures that have self-
15	administration, people may just decide they
16	don't want to respond. For interviewer-
17	administered measures, basically the clinician
18	didn't ask the question. So that is you
19	know, it was just not done but there is not
20	necessarily a reason behind it other than it
21	just wasn't done.
22	There are obviously more

	Page 40
1	challenging issues where the person is unable
2	to respond, due to cognitive limitations,
3	young age, language barriers, other things
4	like that. Next slide.
5	So I guess one of my thoughts is
6	that as part of the testing of performance
7	measures when they are being put forward to
8	NQF, during the testing that is done, pilot
9	testing or whatever it is being called, the
10	response rate for the proposed PRO-PM should
11	be reported as part of the testing results.
12	I think that is important because oftentimes
13	the testing is kind of an almost ideal
14	circumstance. And so if you start
15	implementing things in real life, you are
16	probably going to have a lower response rate.
17	So it would be obviously very helpful to know
18	if there is a low response rate in the first
19	place, in practice you might actually even
20	expect a lower percentage. So I think that is
21	available information.
22	The PRO-PM description should

Page 41 describe the mode of administration. 1 And this 2 just, one example, one of the measures that is currently endorsed, a lot of the testing was 3 done as a research project and research 4 5 assistants, research project managers were out 6 collecting the data, interviewing patients. 7 But in terms of the implementation, it had 8 been implemented basically with patient selfreport. And so the staff working in the 9 clinic have been the ones who had to decide 10 were there cognitive limitations for the 11 12 patients who couldn't be interviewed or trying to get patients to fill out the form. 13 So the 14 response rate can really vary. And so I think 15 knowing what the expected mode of administration is is important both for the 16 17 testing and the implementation. And 18 obviously, they should be consistent as much 19 as possible. 20 For the PRO-PM description, it 21 should address the use of proxy responses and 22 methods of data collection. So I think in

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	Page 42
1	general that is not something that explicitly
2	is asked for at this point but I think going
3	forward that would be really helpful to have
4	that information.
5	Some of the measures I think
6	explicitly address missing data issues and
7	others don't. So I think that would also be
8	very helpful as part of the review.
9	So one of the examples I just
10	wanted to highlight as part of this
11	administration issue is the percent of
12	residents with moderate to severe pain, which
13	is the performance measure that I mentioned a
14	few times yesterday. So those data actually
15	are collected based on an interview from the
16	Minimum Data Set. So for those of you who are
17	not familiar with the Minimum Data Set, it is
18	a mandated instrument for skilled nursing
19	well nursing homes. So skilled nursing
20	facilities and nursing facilities. And
21	it has resulted in relatively low missing
22	rates because it is actually part of this

mandated assessment tool.

1

2	I think the other thing I like
3	about that instrument is that the actual
4	script is written on the instrument. And so
5	clinicians really know what they are supposed
6	to ask. So Deb Saliba, who is in the back,
7	developed the MDS-3 and so she might be able
8	to give us some comments about that
9	performance measure later when we have the
10	discussion. Next.
11	So another issue is the use of
12	proxies. So the question we were posed, what
13	are the implications of using proxies on the
14	validity of the performance measure and the
15	testing needed to assess impact on validity.
16	Next slide.
17	So in order for the use of proxy
18	responses within a performance measure to be
19	pooled with the other data, it would be
20	important for obviously the proxy responses to
21	be reasonably accurate.
22	Proxies have demonstrated

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1	acceptable reliability for some PROs, like
2	functional status where there is actually an
3	observation of the person but proxy responses
4	may be a little bit more challenging to
5	include for the more subjective patient-
6	reported outcome concepts like pain, nausea,
7	depression symptoms. It is just really hard
8	to be able to know what somebody is feeling in
9	those areas accurately. But certainly
10	functional status could be included. Next
11	slide.
12	Proxy responses are reasonable to
13	consider for child health measures where
14	parents are proxies and the research has shown
15	small differences in patient-child parent-
16	child reports. Use of proxies may minimize
17	missing data but it may introduce errors,
18	obviously if they are not compatible or not
19	easily crosswalked. So it could definitely be
20	a threat to validity. Next slide.
21	Another question is what are the
22	implications for specifying more than on PROM,

	Page 45
1	so more than one instrument or scale in a
2	performance measure and the testing needed to
3	assess impact on validity. Next slide.
4	So the use of different PROMs to
5	measure the same construct could certainly be
6	done. Research demonstrating the agreement of
7	the assignment to clinically important groups.
8	So for example, if the depression measure was
9	being used, it would be important to know that
10	the sensitivity specificity of the two
11	measures were very similar so they could be
12	crosswalked. So it is not, I think, let's
13	see. Some of the work on well that is
14	actually another topic.
15	But anyway, there would need to be
16	agreement in the way that it is being
17	classified. If assignment into clinically
18	meaningful groups is not well aligned, this
19	may introduce systematic errors for the
20	instruments that are selected. Next slide.
21	So the example I want to use here
22	is the percent of residents with moderate to

	Page 46
1	severe pain, which I mentioned before. And
2	within this measure on the MDS, there is
3	actually two different options for the data
4	collection of pain. One is the numeric rating
5	scale, which goes from zero to a hundred and
6	then the verbal descriptor pain scale which
7	allows the patient to describe pain as mild,
8	moderate, severe, very severe or horrible. So
9	within that performance measure, the
10	clinicians and patients have the option of
11	completing one or the other. And within the
12	performance measures, those are basically,
13	they were crosswalked and, again, Deb Saliba
14	can probably address this during the
15	discussion.
16	But just as an example, for people
17	with severe pain, that is basically linked up
18	to the ten and the very severe and horrible.
19	So there has been research to basically link
20	up and crosswalk those two categories. And so
21	they are included in the currently endorsed
22	performance measure.

Page 47 1 I know Rob is going to talk a 2 little bit more about that. So I will let him go on to that a little bit more. 3 I think that is the end. 4 Right? 5 Yes, okay. Thank you. 6 DR. PACE: Ken? 7 DR. OTTENBACHER: Okay, well good 8 morning everyone. Can you hear me okay? Ι 9 want to make sure everyone can hear before I 10 get started. I would like to thank the NOF and 11 12 the conference organizers for the opportunity to participate in the workshop and also 13 14 acknowledge Anne and her colleagues at RTI for 15 the intellectual work in doing a very 16 comprehensive job in their paper on a difficult, complex topic. 17 18 My task today is to comment on 19 issues associated with a litany of PRO 20 performance measures. Specifically, I have 21 been asked to address the following questions. 22 Are there differences or unique

	Page 48
1	considerations for risk adjustment of PRO
2	performance measures and what are the
3	complications of exclusions, incomplete and
4	missing data and response rate bias on
5	validity of PRO performance measures?
6	I will make a few general comments
7	about validity and then address the two
8	questions. Defining the context is an
9	important first step in examining both
10	reliability and validity, as we have heard
11	from the previous speakers. Context is
12	particularly important in considering PRO
13	performance measures. The approach, the
14	methods, even the conceptual frameworks may
15	differ from one context to another.
16	One important challenge in
17	determining the context for validity is
18	variation in language. The terminology
19	regarding validity can be confusing, even
20	contradictory. Similar concepts can be
21	defined using different words and, at times,
22	the same words or terms are interpreted in

	Page 49
1	different ways by individuals from diverse
2	disciplines.
3	The terms used to classify types
4	of measurement validity include content, face,
5	criterion, concurrent, predictive,
6	discriminant, convergent and construct
7	validity. The NQF Measurement Testing Task
8	Force Report uses another term to describe
9	validity, the correctness of measurement.
10	Correctness is a term used by Dr. Deutsch and
11	her colleagues. In the NQF context, validity
12	of a performance measure refers to the
13	correctness of conclusions about the quality
14	of the facility provider that can be made
15	based on the performance score. That is, a
16	better score reflects higher quality.
17	This definition of correctness is
18	linked to other more commonly used terms such
19	as criterion and construct validity. And
20	these are described by Dr. Deutsch and her
21	colleagues. The use of the term correctness
22	illustrates the importance of clearly-defined

	Page 50
1	and operationalized language in the context of
2	performance measures, which Dr. Deutsch and
3	her colleagues do very nicely.
4	In dealing with conceptual issues
5	such as validity, it is essential that the
б	context and relevant definitions be made
7	clear. If they are not, we may find ourselves
8	in a situation similar to Alice in her famous
9	conversation with Humpty Dumpty. "'When I use
10	a word,' Humpty Dumpty said, in rather a
11	scornful tone, 'it means just what I choose it
12	to mean nothing more, nothing less.' 'The
13	question is,' said Alice, 'whether you can
14	make words mean so many different things.'
15	'The question is,' said Humpty Dumpty, 'which
16	is to be master þ that is all.'"
17	NQF has been a very good master in
18	defining our terms for us related to PRO
19	performance measures. If we are not careful
20	in our definitions of validity and related
21	terms, we will find ourselves in a Wonderland
22	and, like Alice, we will be hopelessly lost in

	Page 51
1	a rabbit hole of our own construction. This
2	is particularly true in dealing with unique
3	challenges of risk adjustment in PRO
4	performance measures.
5	One of the key lessons learned
6	during the development of quality indicators
7	and performance metrics through the 1990s is
8	that appropriate risk adjustment must be
9	content-specific.
10	Lisa Iezzoni who has written
11	extensively on this topic argues that creating
12	appropriate risk-adjustment strategies
13	requires answering four questions. Risk for
14	what outcome, over what time frame, for what
15	population, and for what purpose.
16	A fundamental distinction
17	regarding the purpose of risk adjustment is
18	between risk adjustment at the individual
19	patient level versus the facility provider
20	level. Risk adjustment at the patient level
21	is designed to better target interventions and
22	resources to individual patients. In

	Page 52
1	contrast, risk adjustment at the facility
2	provider level is used to develop quality
3	metrics for public reporting, understanding
4	financial incentives, and to provide
5	benchmarks for performance comparisons.
6	Dr. Deutsch and her colleagues
7	provide an excellent overview of the important
8	issues relevant to risk adjustment for PRO
9	performance measures. These include selecting
10	factors for risk adjustment, data collection
11	sources and modes, and the technical methods
12	of generating risk adjustment models.
13	Selecting factors for risk
14	adjustment presents some interesting
15	challenges. In creating models for a PRO
16	performance measure, typically factors are
17	selected using previous literature,
18	theoretical models, clinical expertise, and
19	pilot research or other analyses showing
20	statistically significant relationships
21	between potential covariates and the outcome
22	measure.

	Page 53
1	Dr. Deutsch and her colleagues
2	note that patient factors used in risk
3	adjustment modeling can be categorized into
4	patient demographic factors and patient
5	clinical factors present at the start of care.
6	They state that informed patients could
7	provide very valuable insights into potential
8	covariates.
9	Along this line, Iezzoni suggests
10	asking clinical experts or panels of
11	practicing clinicians to participate in the
12	risk-adjustment model building process. She
13	states involving clinicians in developing risk
14	adjusters helps achieve essential clinical
15	credibility. The same argument could be made
16	for soliciting input from knowledgeable
17	patients and consumers in selecting factors to
18	include in risk adjustment models.
19	Soliciting patient input to help
20	identify factors for risk adjustment is
21	consistent with the patient-centered approach
22	to quality assessment. A challenge facing the

	Page 54
1	NQF and other healthcare organizations and
2	providers is how to facilitate the evolution
3	of patient-reported outcomes to include
4	patient-centered outcomes. The Affordable
5	Care Act and the creation of PCORI have
6	highlighted the role of stakeholders, not just
7	in the assessment of outcomes, but as partners
8	in the decision-making process regarding the
9	content of what should be assessed.
10	Examples of strategies to actively
11	include patient input are emerging in several
12	areas of medical care. For example, the work
13	on activity limitation staging by Steinman and
14	colleagues that assigns consumer values to
15	functional daily living skills across
16	different impairment groups and settings
17	illustrates a systematic approach to
18	incorporating stakeholder input into complex
19	healthcare processes.
20	In the widely referenced text Risk
21	Adjustment for Measuring Healthcare Outcomes,
22	Iezzoni and colleagues list eight dimensions
	Page 55
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1	of validity that should be considered when
2	evaluating risk adjusted measures. They
3	include face validity, content validity,
4	construct validity, convergent validity,
5	discriminate validity, criterion validity,
б	predictive validity, and attributional
7	validity.
8	Attributional validity refers to
9	the degree to which a change in outcomes can
10	be attributed to the care being evaluated.
11	Iezzoni notes that in the context of using
12	risk-adjusted measures to motivate practice
13	changes or to monitor provider performance,
14	attributional validity is the key dimension.
15	There are many issues that must be
16	addressed in achieving attributional validity
17	in selecting factors for risk adjustment. For
18	example, whether to include patient
19	characteristics such as race, ethnicity or
20	socioeconomic variables associated with
21	disparities. Do we really want to adjust or
22	control factors that may potentially mask

Page 56 1 disparities in care? 2 Another complex issue in establishing attributional validity is how to 3 deal with missing data. Missing data is a 4 5 common problem in clinical research. The 6 impact and approach to dealing with missing 7 data once again is dependent on the context. 8 The question of how to address missing data is 9 one that a priori has no correct response. There are multiple approaches to 10 addressing missing data from relatively 11 12 simple, such as substitution of the most common missing value, to complex imputation 13 14 procedures. Each approach has advantages and disadvantages. For example, substitution of 15 common or expected values referred to a single 16 17 imputation might appear to be a weak strategy; 18 however research on risk adjustment using the 19 APACHE and ICU studies suggest that single 20 imputation can be a useful method. The 21 assumption made with the APACHE is that 22 unmeasured parameters are likely to be normal

1 common values. 2 Using substitution of common values to manage missing data would probably 3 not be satisfactory in other clinical context. 4 5 The approach to dealing with missing data has 6 important implications for creating risk 7 adjustment models. For example, the amount of 8 information available will depend on how 9 missing data are managed. Some statistical 10 software programs drop an entire case or patient record if any values are missing, 11 referred to as list-wise deletion. 12 This means that many cases could be eliminated during 13 14 statistical modeling and data sets with a large number of variables. 15 Risk adjustment models using a 16 17 list-wise approach to managing missing data may produce different results than a risk-18 19 adjustment model using pair-wise deletion of 20 missing data. Pair-wise deletion only removes 21 a specific missing value from the analysis, 22 not the entire case.

Page 58 1 Over the past several years, a 2 number of sophisticated statistical methods for imputing missing values have been 3 developed. The robustness and limitations of 4 5 the newer imputation strategies are not 6 completely understood. It is important that 7 the methods used to manage missing data be 8 clearly described and justified, since how missing data are handled will influence the 9 final model. 10 11 For PRO performance measures, an 12 important potential missing data issue is non-13 response rates to surveys or health questions 14 or questionnaires. And extensive research literatures exists regarding non-response 15 rates and a wide range of potential methods to 16 17 improve rates are available. 18 The approach to addressing non-19 response bias will depend on the outcome of 20 the performance area or the performance area 21 being examined, the setting, the population, 22 and a number of other patient factors.

	Page 59
1	Deutsch and colleagues acknowledge
2	the problem of missing data as a threat to
3	validity. They discussed the issue of non-
4	response bias in assessing PRO performance
5	measurement and suggest that an important
6	first step is to adopt consistent definitions
7	and methods for calculating response rates,
8	cooperation rates, refusal rates and contact
9	rates based on recommendations from the
10	American Association for Public Opinion
11	Research.
12	I would like to include with a
13	final comment regarding risk adjustment and
14	missing data and that is a comment for
15	transparency. Valid PRO performance measures
16	based on risk adjusted models must be
17	replicable. Replication requires
18	transparency.
19	In this widely cited, public
20	knowledge the British philosopher of science
21	John Ziman states "the ability to reproduce
22	observations and replicate experimental

	Page 60
1	findings is at the very heart of the
2	scientific method."
3	When performance measures are
4	either mandated or de facto required, policy
5	makers, professional organizations in the
б	scientific community should work to ensure
7	that details of the methods are available to
8	the public or subject to external evaluation.
9	One way to examine the validity of risk
10	adjusted methods would be to compare different
11	models by applying the same data set.
12	Proprietary organizations, health information
13	vendors, and others have developed and
14	promoted risk adjustment methodologies for a
15	range of purposes. They would argue that
16	putting their models in the public domain
17	would harm the ability to market their
18	product. That concern has merit. Carefully
19	designed policies are needed to balance
20	private sector interests with public needs.
21	Iezzoni and others have suggested the
22	establishment of an external, independent, and

Page 61 1 objective body that would operate an 2 accreditation process and develop standards of evaluation to ensure that risk adjustment 3 methods meet established, explicit criteria of 4 5 clinical validity and scientific soundness. 6 This is not a solution but it is a potential 7 step to a solution. Such a task is outside 8 the purview of the NOF. But the NOF and other 9 agencies involved in quality measure could 10 certainly contribute to ensuring the future transparency of risk-adjusted methods 11 12 associated with PRO performance measures. In his book The Man with a 13 14 Thousand Faces, one of my favorite authors, Joseph Campbell, explores the role of myth and 15 legend in the development of culture. 16 Не makes the observation that as an individual or 17 18 a society, we can only have those adventures in life that we are ready for. 19 20 Based on the discussion at the 21 past two NQF meetings, it is obvious that we 22 are ready for the adventure of figuring out

<ol> <li>how to use patient-reported outcomes to</li> <li>improve the quality of the healthcare that we</li> <li>all receive. Thank you.</li> <li>DR. PACE: Okay, Rob?</li> </ol>	
<pre>2 improve the quality of the healthcare that we 3 all receive. Thank you. 4 DR. PACE: Okay, Rob?</pre>	
<ul><li>3 all receive. Thank you.</li><li>4 DR. PACE: Okay, Rob?</li></ul>	
4 DR. PACE: Okay, Rob?	
5 DR. WEECH-MALDONADO: Yes, hi,	
6 everyone. Rob Weech-Maldonado at the	
7 University of Alabama at Birmingham. I also	
8 would like to thank the NQF for the invitation	
9 and also congratulate Anne Deutsch and their	
10 colleagues for an excellent paper.	
11 I have been asked to address two	
12 particular issues in the paper; one of them	
13 dealing with proxy use and the other in terms	
14 of having multiple PROMs in developing	
15 performance measures.	
16 Most of my comments will probably	
17 be centered more on CAHPS, since that is where	
18 a lot of my experience, since that is where a	
19 lot of my experience has been. Next slide,	
20 please.	
Just to remind you, you know in	
22 terms of the use of proxies, very important	

Page 63 1 especially in addressing the reports of 2 vulnerable populations, at least on the research that has been done with Medicare and 3 patient surveys of Medicare beneficiaries, 4 5 they tend, those that use proxy, they tend to 6 have lower education, more likely to minority, 7 and have poor physical health and slightly 8 worse mental health. 9 So definitely, they have a very 10 important role in patient surveys or patient reports. However, we also know on the other 11 12 hand that they do have an effect on survey 13 outcomes. And this may be because a proxy has 14 different cognitive perceptual strategies in 15 addressing the questions. There may be issues, I think this was brought yesterday, 16 17 that the person serving as a proxy may be of 18 a different age category than the intended 19 respondent. So there is definitely 20 differences. 21 Now one good thing about the 22 studies that have been done is that the proxy

	Page 64
1	effect tend to be smaller when you have more
2	objective reporting items versus global
3	ratings. For example, in CAHPS we have the
4	ratings that ask the patient or the person to
5	rate their healthcare, rate their physician in
6	a zero to ten scale. So those tend to be
7	"more subjective."
8	Then you have the more objective
9	that would ask for specific experience. For
10	example, how often was it difficult for them
11	to get an appointment in a reasonable manner.
12	How often do they have to wait beyond 50
13	minutes beyond the appointment time? How
14	often did the physician explain things in a
15	way that was easy to understand? So those we
16	tend to call them reports of care. They tend
17	to be more objective versus, again, kind of
18	the more global ratings. Next slide, please.
19	Research also finds, especially in
20	the CAHPS literature that it also depends is
21	the proxy actually responding for the person
22	or is the person or the proxy assisting?

	Page 65
1	Perhaps the intended person may only need
2	assistance in reading, completing the
3	questions, but they still have an active role
4	in completing the survey. And actually the
5	CAHPS have tried to capture that data and
6	distinguish between weather they are proxy
7	respondent versus assisting and actually has
8	found that those that are proxy respondents
9	have even less positive evaluations than those
10	that provide assistance. So that may be
11	important in distinguishing that.
12	The other thing is that it also
13	depends on who the proxy is, the relationship
14	of the proxy to the intended person. Spouses
15	and those that live with the person tend to
16	provide responses that are closer to those of
17	the intended respondent and that may make
18	sense because this person may have more of a
19	day-to-day interaction with the person and
20	know exactly how they interact also with the
21	healthcare system versus non-spouse proxy that
22	tend to be less positive than the intended

person. Next slide.

1

2	So some of the ideas in terms of
3	addressing proxy effects. You know, in CAHPS
4	we do use case-mix adjustment to adjust when
5	it is, say respondent, a proxy respondent.
6	Beyond there is only very few variables that
7	are used in case-mix adjustment, age, gender,
8	education, and this is also one, especially
9	the Medicare surveys. The other alternative
10	is kind of called propensity score matching.
11	It is a little bit more complex but the idea
12	is that there is selection bias in terms of
13	the people that actually use a proxy. So that
14	would be a better way of actually
15	differentiating or getting a better sense
16	about how different the assessment of proxies
17	are versus the intended person.
18	The other key thing is that we may
19	want to emphasize more objective reports. I
20	think Anne alluded to that in terms of some of
21	the measures that she was talking about,
22	especially when you are serving the population

	Page 67
1	that you may expect to have a high proportion
2	of proxies, perhaps administering more by
3	survey by phone, even in person.
4	Also paying particular attention
5	to the health literacy. You know, sometimes
6	people just have problems understanding the
7	measures and so that is always something that
8	we tried to emphasize in CAHPS. And you may
9	even want to consider alternative measures to
10	capture the proxy perspective. And an example
11	is CAHPS with their family member survey for
12	the nursing homes, where they have the one for
13	the resident and then they have a parallel one
14	for the family member. And they tend to ask
15	very similar questions but then you get those
16	two different perspectives. Next slide.
17	Now we get into the whole issue of
18	multiple PROMs and how to deal with them.
19	Anne did an excellent summary already. I just
20	want to reiterate a couple of things here. We
21	are talking about when you have basically
22	substantive prompts. And a great example is

Page 68 1 where you have two screening tools for 2 depression; PHQ-9 and BSI, the brief symptom inventory or index, one of the two. 3 And so you have those two alternatives and they have 4 5 been found equally valid, reliable. So which 6 one do you use or you may have some people 7 using one versus the other. So that is what 8 this is trying to address. 9 And so Anne alluded to how the MDS 10 3.0 team, Deb Saliba, will be able to provide more information on this, how they dealt with 11 12 one particular area in terms of pain, the intensity of pain. So in the current MDS 13 14 survey, they tried to provide alternatives. So some people may be better able to answer on 15 a zero to ten scale while others it may be 16 easier to provide more of a verbal description 17 18 of pain. And I was asking her this morning, 19 I was thinking that maybe those with more 20 cognitive impairment may lean more towards the 21 verbal versus the zero to ten that requires 22 perhaps greater cognitive skill but that was

	Page 69
1	not the case. Apparently they function fully
2	well regardless of cognitive function.
3	Can I go to the next slide and
4	then come back to this one? I just wanted to
5	provide you so I was looking at this is
б	really not my area. But in terms of pain
7	management or pain intensity of pain, so this
8	is yet another scale, the Wong-Baker faces.
9	And as you can see, there is the English
10	version and the Spanish version. Two
11	interesting things about this one, that the
12	Spanish is not just a translation into
13	Spanish, they also use different faces. And
14	apparently this was trying to capture not only
15	the linguistic adaptation but also cultural
16	adaptation that a level of pain in one
17	language may have a different connotation in
18	terms of the face that you see and how you
19	relate to that type of pain.
20	So that is something I guess I was
21	trying to bring also again that cultural
22	linguistic differences that may sometimes may

Page 70 have to be capturing these measures, as well 1 2 as -- so we have these alternative measures that we could use and Deb was telling me that 3 this one was problematic because we have the 4 5 Spanish and English but it didn't necessarily 6 translate as well into other languages or other cultures. So they stick more with the 7 8 numeric and the verbal. 9 But assuming that we have again 10 these different measures, going back to the previous slide, please, basically you would 11 12 use some type of IRT methodology to create a crosswalk between the two or more scales that 13 14 you have and developing what is the right threshold in one scale versus the other. 15 So 16 perhaps ten being extreme pain and what would 17 that represent in the other scale, you know, severe/horrible. So that would require that 18 19 crosswalk so that we can actually then have 20 comparable measures. Next slide. 21 And this is the last slide. 22 Another way that I guess I was thinking about

	Page 71
1	the multiple PROMs is that you could actually
2	create a composite score with some type of
3	performance measures. And the one that came
4	to mind as overall health status, you have the
5	physical and mental health scores but you may
6	want to combine those two into one overall
7	score. So then you have to think about the
8	weights that you provide to each of the
9	different scales.
10	You know, the first thing that you
11	would probably think about is using equal
12	weights but that may not always be desirable.
13	And this is where you may want to capture the
14	values preferences of those using the
15	measures, depending of patient versus
16	providers. You may want to use regression-
17	based weighting if you have like a gold
18	standard that you can that some of the
19	scales predict better, that gold standard.
20	And one interesting thing about combining
21	measures is that if there is some of them that
22	have a greater standard deviation, they will

	Page 72
1	have a greater influence in the performance
2	measure.
3	So you have to think about a way
4	of standardizing those scores or having a
5	weight that would be more for reciprocal of
6	the standard deviation of that domain.
7	I just wanted to kind of bring the
8	two options that may be possible when
9	combining the multiple PROMs. Thank you very
10	much.
11	DR. PACE: All right. Thank you
12	again to another excellent panel. So we will
13	stop here and open it up for questions and
14	comments from our expert panel and audience.
15	And Operator, you can queue up anyone on the
16	phone line also at this point.
17	OPERATOR: At this time, I would
18	like to remind everyone in order to ask a
19	question, press * then the number one on your
20	telephone keypad.
21	R. PACE: Okay, so why don't we
22	we have a lot of food for thought here. Deb

Page 73 1 Saliba, do you want to? 2 DR. SALIBA: Thank you. So a lot of mention was made today of the minimum data 3 set, work that we did. Let me start by saying 4 5 this is one of 450 items on the instrument. 6 So minimum is a bit of a misnomer. 7 But to start with this item, it is 8 sort of a case study in patient-reported outcomes. And I think we started with the 9 10 fact that in focus groups, patients and families told us that pain was a very 11 12 important construct to them. When we talk to 13 ombudsmen that hear complaints in nursing homes, this is a big source of contention with 14 15 families and residents in nursing homes. So it really started from the fact that patients 16 17 and families feel that this is a very 18 important area. 19 But pain is multidimensional. Ι 20 mean you have heard today just about the 21 severity items and we tested other items as 22 well to go into the minimum data set. It had

	Page 74
1	already been identified as a fifth vital sign
2	in a lot of healthcare systems, not just in
3	nursing homes, but also in hospitals. In the
4	veteran's administration, our entire
5	healthcare facility is a fifth vital sign and
6	everyone has asked about it or supposedly
7	asked about it.
8	The challenge is that it was being
9	asked in different ways in different
10	organizations across different providers.
11	There was a lot of variability in how it was
12	being asked, as well as whether or not it was
13	being asked systematically. Some nurses will
14	just look at the patient and say I can tell
15	and fill out the item. So we had to face that
16	challenge as we were thinking about putting
17	that into an instrument.
18	And we had the problem, as Anne
19	mentioned earlier, of detection bias because
20	those facilities that were systematically
21	screening better for pain tended to have
22	higher pain reports than those facilities that

	Page 75
1	are being less systematic in how they were
2	looking for pain.
3	And then we also found that when
4	they were having to report it in the old
5	minimum data set, they were using various
б	scales and it didn't crosswalk into the scale
7	that they were being asked to report. So it
8	was very problematic for them as well because
9	they were having to translate it and didn't
10	really have the instruments for translation.
11	So even those facilities that were doing it
12	well.
13	So we looked across the
14	instruments that were out there and saw that
15	the two that were the most common and seemed
16	to have the least operational problems with
17	the zero to ten scale, and when we say zero to
18	ten scale, we are really talking about the
19	visual analogue scale, where you actually show
20	the scale anchored verbally at zero, anchored
21	at ten, and you ask the items as you show
22	the scale at the same time that you are asking

	Page 76
1	the items. And the verbal descriptor scale.
2	And there was a lot of debate in
3	the pain community. There are multiple scales
4	that various providers advocate, often the
5	ones that they developed. So we sort of tried
6	to work through that with stakeholders and
7	worked through that with the pain community as
8	well.
9	Cognitive came up today. And we
10	started, to be honest, with the assumption
11	that there was an absolute cognitive cut point
12	below which people could not answer these
13	items. And we were told again by stakeholders
14	that that was wrong, that we couldn't do that
15	for multiple reasons, that people could self-
16	report their symptoms, even with some
17	cognitive impairment and also that it would
18	send a signal of disenfranchisement of an
19	entire segment of the population that was not
20	appropriate.
21	So we said okay, well this is
22	empirical. We can test that, as opposed to

Page 77 1 going in with assumptions. So we actually 2 tested everyone who was capable of responding and looked at response rates, consistency. 3 We also went in and looked at reliability of 4 5 responses, asking daily for five days every morning with one interviewer and then going 6 7 back at the end of the third day and back at 8 the end of the fifth day and looking at recall 9 ability and saw that residents were, even 10 people with moderate cognitive impairment, were able to recall moderate to severe pain 11 12 that had occurred in the prior period. 13 So we were surprised by these 14 findings. They were right. We were wrong. And it wasn't the first time in the study that 15 16 that happened. 17 So then we tested it. A lot of 18 the people in the pain community felt the 19 verbal descriptor scale was better for persons 20 with cognitive impairment. Again when we 21 tested in a sample of 3,000 nursing home 22 residents with nursing home staff asking the

	Page 78
1	items, there was no systematic difference in
2	whether cognitive impairment were able to
3	answer zero to ten versus the verbal
4	descriptor scale.
5	So we ended up sort of at a
б	quandary because a lot of people were using
7	verbal descriptor, a lot of people were using
8	zero to ten, and we didn't want, as much as
9	possible, we didn't want to change people that
10	were already doing something that was
11	appropriate just for ease of use.
12	And as one of the stakeholders
13	said to us when we sort of when to them and
14	said please make a choice. They said, you
15	know, you are at RAND. Can't you figure this
16	out?
17	So we used item response methods
18	to item response theory methods to
19	crosswalk the two instruments and found that
20	we were able to crosswalk the zero to ten
21	visual analogue scale to the verbal descriptor
22	scale for this population when staff were

Page 79 asking. 1 2 So it is sort of a case study in how we ended up with a severity measure in the 3 minimum data set that includes both types. 4 5 Was it, you know, has it been embraced necessarily? Nursing home staff aren't 6 7 particularly -- were not initially 8 enthusiastic about asking patient reported 9 items. So I ultimately had to take off my 10 researcher hat as a UCLA person and put on my trainer hat and work with staff to help them 11 12 understand that you can talk to your residents and you can get this information from them. 13 14 So it is really a multi-step process to look at how just this one item out 15 of 450 ends up being part of a standardized 16 17 instrument. And you have to look at it -- we 18 have to look at it as measurement people all 19 the way from identifying the importance, 20 testing its performance in a very specific 21 population, and then how it is actually doing 22 to be used by the providers when they have it.

	Page 80
1	So it has been referred to a great
2	deal today. I mean when you just see it as
3	first and you think, God they are doing it
4	with cognitively impaired people and what are
5	they thinking. But we really went through an
б	empirical systematic process to decide on that
7	item.
8	DR. PACE: Okay, thank you. Gene?
9	DR. NELSON: The discussion about
10	risk adjustment factors and demographic or
11	clinical and psychosocial, a tricky area of
12	course, but one thing that created red flags
13	for me was what was labeled as psychosocial
14	but then the examples were more things having
15	to do with activation or engagement or
16	motivation, which are often mutable, as you
17	said, by the care before or after and so
18	sometimes if viewed as at least a proximate
19	outcome for good outcomes, health engagement
20	being generally valued by consumers or
21	patients.
22	So my sense is this is not a good

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Page 81 1 thing to consider for risk adjustment. Others 2 might wish to comment on this; John Wasson or Judith Hibbard, or others that are actually 3 experts in risk adjustment methods. 4 5 DR. PACE: Lewis? 6 DR. KAZIS: Can you hear me? 7 DR. PACE: Yes. 8 DR. KAZIS: I had a couple of 9 points. The first was, in terms of the --DR. PACE: Now we are kind of 10 11 losing you. 12 DR. KAZIS: Can you hear me now? DR. PACE: Yes. 13 14 DR. KAZIS: On the issue of 15 imputation of missing values, we have gone through some extensive work for CMS related to 16 17 the HOS study, which you heard about 18 yesterday, and this includes the modified 19 regression estimator which in effect would 20 allow us, based upon our outcomes, using in 21 the past SF-36 and now the BR-12, we are able 22 to capture 90 percent of the missing values on

	Page 82
1	the basis of this particular approach, which
2	was developed by Bill Rogers and is available
3	in the public domain and we have extensive
4	documentation and reports that have been done
5	that are available on the HOS website with
б	publications that we have subsequently shared
7	basically that have been published. So
8	that is available and this approach tends to
9	be quite useful, does not require high
10	computer power, and might in fact be an
11	approach that folks want to consider, whatever
12	the outcomes, that are used that are patient-
13	centered.
14	The separate point is in terms of
15	the risk adjusters. We have used what is
16	called a cascading approach where we have
17	developed a number of different models, with
18	a minimal set of variables that might be
19	required. So one starts with all of the risk
20	adjusters that are in your model and then you
21	cascade across different models until you get
22	to a minimal set of variables that would be

	Page 83
1	required in your risk adjustment. So you
2	could literally start off with, for example,
3	12 variables that become your risk adjusters,
4	and then in the minimal data set, it would be
5	as few as say three. That would still allow
6	us to risk adjust adequately for a particular
7	case.
8	So those algorithms have been
9	worked out and are also available through this
10	HOS website.
11	The last point has to do with in
12	the report there was a mention made in the
13	paper that we have all reviewed of an initial
14	covariate adjustment using the baseline value
15	of your outcome. And this is quite
16	controversial. And in fact there is a
17	correlated error problem that unless the
18	design of the study is randomized, a
19	randomized clinical trial design, if you are
20	dealing with an observational naturalistic
21	data set, it can become quite problematic with
22	that initial covariate adjustment. And I

	Page 84
1	think that that needs to be considered.
2	DR. PACE: Okay, thank you.
3	Collette.
4	MS. PITZEN: This is Collette from
5	Minnesota Community measurement. I had a
6	couple comments. One was on the whole idea of
7	missing data. And I wanted to make the point
8	that, and I will use the PHQ-9, our favorite
9	tool, as an example. We don't have much of a
10	problem with patients not completing that
11	simple instrument. So less of an issue of the
12	actual missing items within that tool. But a
13	bigger threat to the validity of this measure
14	is the longitudinal measure over time and the
15	ability to connect with those patients at the
16	measurement points in care.
17	For example, our current follow-up
18	rate with these patients at six months is
19	about 25 percent and we keep working on that
20	to make it better but that is the reality of
21	implementing these tools in clinical practice.
22	The second point that I just

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	Page 85
1	wanted to add on to Lewis's risk adjustment.
2	When we are developing new measures, we are
3	working with our expert measure development
4	workgroups. And again, we are picking
5	variables based on evidence and literature and
6	expert opinion that the group thinks would be
7	important variables for risk adjustment and
8	then we start collecting that data and running
9	those variables through the models to see
10	which, indeed are good risk adjustment
11	variables.
12	Thanks.
13	DR. PACE: Okay. Ethan.
14	DR. BASCH: Thanks, just a couple
15	of comments. This was a great panel. I have
16	three comments.
17	The first, regarding bias. You
18	know, I do agree with the comments about
19	response bias or what you called detection
20	bias. I think it is really an essential
21	adjustment that needs to be made in this kind
22	of work and one that the NHS PROMs initiative

	Page 86
1	has a fair amount of experience with and I
2	mentioned that before.
3	And I think this really touches on
4	the issue of optimizing response rates for
5	minimizing missing data. And in work that we
6	have done in cancer populations, we have found
7	that the principle reason for missingness of
8	data in nonclinical trial populations is that
9	people were too busy or forgot. And then when
10	patients become very ill, they are unable to
11	complete, unable or unwilling to complete.
12	Although, patients have to really be quite ill
13	not to complete. In general, we found within
14	a month of death in cancer populations.
15	What we found in general is that
16	there are strategies that can optimize missing
17	data, which obviously is preferable to using
18	imputation in post-production. One way to
19	optimize response rates is by making
20	completion of questionnaires a standard part
21	of operations, rather than sort of a voluntary
22	or a carve out in a sub-population. We found

	Page 87
1	that response rates are boosted about 30
2	percent when it becomes mandatory. And I
3	think that is probably reflected in both the
4	Swedish and the English experiences.
5	The other strategy is using backup
6	data collection methods. In particular if
7	there is a mailed questionnaire, an electronic
8	questionnaire to have actually have a human
9	person call people who don't complete their
10	questionnaires and that boosts response rates
11	by about ten percent.
12	And in general what we found is
13	that it really only takes one call. And after
14	the first time people feel, oh you know,
15	somebody is watching, so I had better complete
16	my questionnaires in the future or I am going
17	to be bugged about it, which is sort of
18	interesting.
19	Regarding proxy, I actually had a
20	question for Rob, which is whether one would
21	advocate for proxy reporting as a substitution
22	at a point where there is lost data or if you

Page 88 advocate for longitudinal collection of both, 1 2 you know, patient and proxy reports, that you can impute based on the trajectory when you 3 have a population at risk, because that would 4 5 substantially increase the burden, although my understanding -- it is not my area -- is that 6 7 imputation is improved when you actually have 8 the trajectory of the proxy reports. 9 My other question for Rob about 10 multiple PROMs is about multiplicity problems, which we think about in the registration 11 12 context all the time but that we really didn't touch on here. 13 14 DR. PACE: Rob, do you want to 15 respond to that? 16 DR. WEECH-MALDONADO: Yes. Well 17 basically for the first question that Ethan 18 asked about if I am understanding Ethan, you 19 are saying whether it is recommended more for 20 at the first point or as well as over time. 21 Because if you use it over time, then you may 22 have also kind of perceptions right in the

	Page 8
1	follow-up surveys and all that.
2	I think to the extent that you are
3	able to somehow take that into the adjustment,
4	you know, the case mix, it should be okay,
5	especially if you are thinking about, you
6	know, when we are thinking more about
7	performance measures. You know, as long as
8	you are able to case-mix that over time, I
9	think it would be definitely preferable to
10	have that proxy in the follow-up, rather than
11	having missing data.
12	So if it definitely improves your
13	response rate over time, it definitely would
14	be preferable.
15	But in terms of the CAHPS surveys,
16	they do discourage proxy use. They are really
17	more limited to the high-risk populations like
18	Medicare in populations like that. So it is
19	not universally recommended but when you have
20	again an at-risk population. I don't know if
21	that answers your question but yes, it
22	definitely would depend on the population.

9

	Page 90
1	DR. BASCH: And the other was
2	multiplicity issue.
3	DR. WEECH-MALDONADO: The
4	multiplicity of
5	DR. BASCH: If there are multiple
6	PROMs.
7	DR. WEECH-MALDONADO: If there are
8	multiple PROMs and
9	DR. BASCH: That are being used to
10	individually score.
11	DR. WEECH-MALDONADO: Oh, that are
12	individually scored, yes. Yes, so that is
13	where figuring out the right combination of
14	those PROMs, in terms of the weights that you
15	provide, it is where it gets to be critical
16	and that would have to be subject to
17	appropriate testing to determine what those
18	weights would be in order to aggregate them,
19	ultimately. Because you want to aggregate
20	them, depending on what the performance
21	measure, the idea would be to be able to
22	aggregate them.
Page 91 The first case was more about 1 2 using one or the other, which is it is a little bit easier but if you are actually 3 4 going to create a composite of them, then the 5 main issue is how to address the waiting that you are going to be doing. 6 7 DR. PACE: Before we take any more 8 in the room, Operator, are there any questions 9 from those on the phone? 10 OPERATOR: At this time, there are 11 no questions. 12 DR. PACE: Okay and what about in our audience? Evan will you -- and we are 13 14 just about out -- we are a little bit over time but we will take a few more questions. 15 16 MS. MASTANDUNO: Melanie Mastanduno, Dartmouth Institute. 17 18 I just want to add to what Ethan 19 was saying. While I do not have the 20 statistical basis for this statement, when 21 providers -- a boost in response rate will 22 also come when providers and patients are

	Page 92
1	talking about the results of their survey and
2	if the provider goes as far as to say this is
3	important because I now understand you better.
4	Thank you for filling out this survey. And we
5	do see that across 14 different specialties
6	where Dartmouth is collecting these data now.
7	DR. PACE: Okay. Evan, behind
8	you.
9	DR. ROSS: Hi, I'm Clarke Ross.
10	I'm a new member of the MAP Workgroup on
11	Persons Duly Eligible for Medicare and
12	Medicaid and I represent the Consortium for
13	Citizens with Disabilities, which is a
14	national coalition a cross-disability
15	organization which has most of these
16	organizations as one of those members.
17	And I raised this issue at the
18	July meeting. I wanted to just get on the
19	radar a supplemental approach to documenting
20	the consumer person, sometimes called patient,
21	experience with the system. And this is
22	approach that is used in four states and it

	Page 93
1	has been used in two of those states for over
2	a decade, paid for by health plans mandated by
3	state Medicaid programs for persons with
4	mental illness. And these are third-party
5	independent consumer- and family-operated
6	monitoring teams and their whole approach is
7	to interview consumers and their families
8	where they are, not on the site of delivery
9	but where they are; where they live, where
10	they participate in the community, where they
11	work sometimes.
12	And so what I am asking is that
13	the National Quality Forum recognize and
14	acknowledge that there are supplemental
15	methods used around the country to supplement
16	the core of what you have been talking about.
17	And again, these are paid for by state
18	Medicaid organizations. In Massachusetts, the
19	managed mental health company is mandated out
20	of its contract with the state to locate and
21	finance an independent consumer and family
22	monitoring team. These are not ombudsman

programs. These are monitors. That is their
sole purpose.

3	And so I just wanted to, as you
4	focused on where these things are delivered
5	and who does it and how to measure it, all
6	fundamental questions, there are alternative -
7	- not alternative supplemental efforts
8	going on and I think it is important for the
9	quality forum merely to recognize that there
10	are some of these supplemental strategies
11	going on, used today to ensure accountability
12	of health plans to their enrollees. Thank
13	you.
14	DR. PACE: Okay, thank you. Can
15	we do one more question or one more comment?
16	Kathy.
17	DR. LOHR: Two quick questions,
18	don't necessarily need an answer or
19	discussion. On the concerns about proxies, we
20	have heard lots of really interesting options
21	but the point that I didn't hear is whether we
22	know much about whether there are systematic

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1	directionality issues that can be dealt with
2	or is that just in its infancy in terms of
3	understanding which kinds of proxies will
4	overestimate or underestimate and whether that
5	can be taken into account.
6	On the multiple PROMs, I think
7	that is a very complicated issue for NQF and
8	for Anne and everybody to deal with in the
9	paper. But on one particular thing, I
10	wondered about whether we need to know more
11	about the and this was from Roberto's
12	slides the pluses and minuses of doing
13	composite scores. Because that just seems to
14	me to make life even more difficult and
15	whether that is a direction for NQF to go in
16	moving on towards performance measures and so
17	forth. Is that sort of a bridge too far to
18	try to do that, rather than just keep it more
19	simple with individual measures and cope with
20	all the measurement problems there?
21	DR. PACE: You're right.
22	Composite measures have a whole other set of

Page 96 methodological issues and we do have composite 1 2 performance measures, some, but it does increase complexity and it may not be the 3 4 place to start. But again, I think it is 5 something to consider in terms of addressing these issues. 6 7 Okay, we are going to take the 8 next 20 or 25 minutes until break time to 9 again, at our tables -- yes, and Patti you 10 want to -- okay. So we will ask the people in the back to come up front. Again, as we did 11 12 yesterday evening. And you can go to the table -- I guess if you want to rejoin the 13 14 group you were with, that might be useful. 15 We are going to kind of continue 16 on -- and Jessica you may want to put up that slide again -- to look at the NQF criteria and 17 18 are there unique considerations when NQF starts looking at these PRO-PMs in terms of 19 20 our criteria. 21 We have talked about and you have 22 seen that our criteria map to a lot of the

1	
	Page 97
1	issues we have talked about but we want to
2	really have you pull out any unique
3	considerations where we may need to tweak or
4	think about unique ways of applying these
5	criteria. And this will also apply to our
6	next panel after the break where we will be
7	talking about the pathway from PRO to an
8	endorsed measure where we also kind of
9	identify the NQF criteria along the way.
10	So we will continue with that.
11	And Patti, do you want to add anything?
12	Yes, the audience in the back,
13	please feel free to come up and join a table,
14	even if you weren't at a table last night. We
15	welcome your participation.
16	And we will go until 10:30 and
17	then we will take a break and then resume.
18	(Whereupon, the foregoing
19	proceeding went off the record at
20	10:09 a.m. and went back on the
21	record at 10:52 a.m.)
22	DR. ADAMS: Okay, may I ask

Page 98 1 everyone to rejoin their table? And if we 2 could queue up the slides. So for this panel, we are going to 3 4 try to tie it all together. And so not only 5 will it incorporate our thinking from 6 yesterday and today, but really it takes us 7 back even to the first workshop, where we started to look at characteristics for PROMs 8 9 and what would make them most ready for 10 primetime for performance measurement. And we had all agreed that we thought that a visual 11 12 or a flow would be helpful, not only to inform 13 the field but I think to kind of collect our 14 thinking. 15 So this panel today is going to, 16 based on the input that we received at the 17 first workshop as well as today and with our 18 expert panel and our panel prep, so lots of 19 thinking went into this flow diagram. And of 20 course we are going to be further refining it 21 based on your feedback. But we are going to 22 try to tie it all together right now and we

Page 99 1 would like your input in that regard. 2 In regards to our reactors, we have Ethan Basch with us, thank you. 3 And he is going to cover what we are calling steps 4 5 one through four on the diagram, which where we are going to kind of think about more how 6 7 we would frame this up-front with the 8 conceptual basis. We have Jim Bellows and he is 9 10 going to walk us through the process 11 performance measure steps. And Eleanor 12 Perfetto and particularly with experience with Pfizer around the outcomes element of this. 13 14 But I am just going to kind of give us a high-level overview before we take 15 a dive into that. 16 17 I am really excited about but 18 anxious to get your input on this flow because 19 I think it will be very useful, not only for 20 a performance measure committee that is going 21 to be looking at endorsement. But I think as 22 we start to play this out with the field and

Page 100 we talked about yesterday perhaps, you know, 1 2 would we have a few use cases? Would we put a few things through this to kind of test what 3 4 we have been saying? And I thought that is 5 really brilliant advice. So not to put a lot of pressure on our pathway panel but I just 6 7 think that I really appreciate the effort that 8 has gone into putting this now into a diagram, 9 which in some ways you could get overwhelmed 10 with all the things we discussed but in other ways, we are starting to see a path along this 11 12 journey. So I am really taking a glass half full versus half empty because sometimes the 13 14 methodological considerations can seem a bit daunting. 15 So if we look at this 16 Okay. 17 pathway, I mentioned the first part, which is 18 going to be the conceptual considerations and 19 I think that this, when we talked about what 20 Joyce had recapped this morning, it relates back to meaningfulness. And certainly we want 21 22 to identify PRO-based performance measurements

	Page 101
1	that are meaningful and important up-front to
2	patients and their families and caregivers,
3	and to all end users.
4	And I wanted to thank Ethan
5	because when we did our prep call, you really
6	you know, we dived right into the process
7	and you really offered us the opportunity to
8	step back and say hey, let's think about what
9	some of the prequel or preamble to this. So
10	I did want to acknowledge that.
11	And if we could have the next
12	slide. Now on this slide we have lots of
13	discussion around implementation or state of
14	readiness and should we first think about how
15	this applied into practice and should we go a
16	process measure route. We weren't advocating
17	for maybe just checking a box, but would we
18	look at this from the process and what we have
19	learned, I think particularly when we talked
20	about actionability and how this would
21	influence.
22	And Jim, I am going to call that

	Page 102
1	the Jim Bellows box. I know I did that on our
2	call. But number five, particularly from the
3	first workshop, particularly struck and we
4	got that from our different levels of high
5	medium and low from Liz Mort yesterday around
6	actionability and the process there.
7	And then we get to the next slide,
8	which is what we are always aiming for,
9	ultimately is around the outcomes. And I
10	think that Steve Fihn, I know he is not with
11	us today, but he spoke that maybe there are
12	some lower hanging fruit. Maybe there are
13	some are ready for outcomes if we think about
14	things like HIP where got these urology
15	example yesterday. Maybe we can pass go and
16	go to outcomes. But ultimately that would be
17	where we want to be.
18	So with that bit of an overview,
19	so we are trying to put together that picture
20	of the pathway and we are going to break down
21	each individual part and our reactors are
22	going to solicit your feedback there.

	Page 103
1	So I'm going to turn it over to
2	you, Ethan. Thank you yes.
3	Oh yes, thank you, Karen.
4	So in your package you received
5	this. We also put these on the table. Here
6	is the color diagrammatic what we are going to
7	be talking about. We also, as a supplement,
8	put the NQF criteria and how this maps to it,
9	and also some of the characteristics we talked
10	about yesterday. So this is kind of your
11	cheat sheet, so to speak, as we go through
12	this. Thank you, Karen.
13	Ethan?
14	DR. BASCH: Great, thanks. So
15	before we start, I think we have a special
16	slide to put up. Do you guys have that?
17	(Pause.)
18	DR. BASCH: Do the presentation
19	first and then the special slide. Okay,
20	that's fine.
21	So if you all have the I'm
22	going to borrow this the diagram from your

	Page 104
1	packet, each of us is going to go to
2	thanks, Vanna.
3	(Laughter.)
4	DR. BASCH: So each of us is going
5	to go through several of the steps. So I was
б	asked to go through the first four steps.
7	So as you can see, these initial
8	four steps really are what Karen called the
9	prequel. So first identifying outcomes that
10	are important and meaningful to the target
11	population; determining of patient reporting
12	of the outcome of interest is appropriate;
13	identifying existing measures to evaluate the
14	outcome of interest; and then number four,
15	applying characteristics identified at the
16	last workshop and in this workshop. A lot of
17	them in the technical paper that was
18	developed. And this includes looking at
19	measurement properties. And I am just going
20	to march through these. Could I have the next
21	slide.
22	So if one thinks about this, I

	Page 105
1	have tried to emphasize the importance of
2	patient engagement or consumer engagement,
3	person engagement and I would argue that
4	patient engagement begins with box number one.
5	This is really the first time point at which
6	one touches the population of interest.
7	Because without doing probably a qualitative
8	and quantitative research you can go to the
9	next slide.
10	So without doing qualitative and
11	quantitative work, which may involve surveys,
12	focus groups, key informant interviews or
13	longitudinal observational research or cross
14	sectional research, it is very difficult to
15	know if those outcomes of interest are
16	actually important in the target population.
17	Go to the next slide.
18	Now I would argue that box number
19	four is a potential second time point for
20	patient engagement. And you know in
21	evaluating the characteristics of a PROM, this
22	would usually begin with a literature review,

Page 106 a landscape overview. One could take a look 1 2 at the measurement properties, whether the measure has been evaluated in the comparable 3 4 population. But as was pointed out yesterday, 5 very likely a second step of patient engagement would occur here. So you can go to 6 7 the next slide. 8 And this would involve qualitative work to establish what I call content 9 10 validity. Other people call it face validity or other kinds of -- you know, patient 11 12 understanding in the target group of what is being measured. And this would include a 13 14 diversity of patients within the target population, to make sure that people who may 15 16 not have been a part of patient interaction 17 during development of the tool are now a part 18 of it. This may include patients whose 19 literacy is different from the initial 20 population, their performance status is 21 different. Their linguistic orientation is 22 different, cultural orientation and so on.

Page 107 1 You can go to the next slide. 2 So I thought I would try to make this real with a hypothetical example. 3 So 4 looking at men with prostate cancer one can 5 think about two different populations; say a 6 post-prostatectomy population. Let's say 7 hypothetically we went out to a group of men 8 who had just had their prostates removed and 9 asked them about what was most important to 10 This is all hypothetical because I them. haven't done this. Right? So I'm just saying 11 12 if we went out and talked to patients based on actually existing literature, these are the 13 14 two most important domains to patients, although admittedly the target population may 15 16 differ, urinary symptoms and sexual function. 17 If you look at a metastatic population, 18 actually pain and tiredness or what we 19 classically have called fatigue are the most 20 important domains. You can go to the next 21 slide. 22 So now we have identified the

	Page 108
1	outcomes of interest. You know, we conclude
2	that probably patient self-report is the most
3	appropriate approach. That is number two.
4	So number three, we want to
5	identify PROMs. We go out. We review the
6	literature for post-prostatectomy. We think
7	about the IPSS. And for number two, pain and
8	tiredness, we think maybe we will use some
9	PROMIS items.
10	So now we get to number four,
11	which is we want to evaluate the measurement
12	properties as applicable to our target
13	population. You can go to the next slide.
14	And so we do our literature
15	review. We find both were developed with
16	patient input. Both have been evaluated in
17	similar populations, looking at construct
18	validity, reliability, sensitivity to change
19	and so on. And we ask ourselves a question,
20	do we now need to conduct additional
21	qualitative research. I'll stop there.
22	And now we have a special slide.

Page 109 1 No, we don't? Okay. 2 (Pause.) DR. BASCH: 3 What do you guys 4 think, are we going to get it? You don't think so. Okay, well we were going to have a 5 6 birthday cake on the slide because Laurie 7 Burke whispered in my ear that somebody has a 8 special day today. It's Eleanor's birthday. 9 (Applause.) 10 DR. BASCH: So we are all going to 11 sing. 12 (Singing of "Happy Birthday.") 13 (Applause.) 14 DR. ADAMS: Not all methodologists are serious. Right? 15 16 So Jim, we will pass that on to 17 you now. DR. BELLOWS: Okay. So first of 18 19 all, thank you so much for naming a box after 20 me, box 5. I am sure there is people in this 21 distinguished room that have items and scales 22 and instruments named after them, which I will

Page 110 never have, but at least for one day I will be 1 2 happy to have a box. 3 So and I want to come to a couple 4 of things. One of the questions is, does it 5 make sense to start with process measures first before we go on to outcome measures? 6 Or 7 I think the way the question is really written 8 is should process measures proceed. And my 9 answer to that is going to be with respect to an experience we are having inside Kaiser 10 Permanente with the PHQ-9. Both the process 11 12 measure, namely did you do a baseline testing and did you a follow-up at approximately six 13 14 months, and the outcome measure of whether you treated to remission. 15 16 And so my answer to should the 17 process measure proceed the outcome measure is 18 It is could proceed. And it is based on no. it is informed by our experience. 19 20 In treatment of depression, it 21 really could involve the entire system. We 22 are not talking one specialty. We are talking

	Page 111
1	about everybody in primary care, presumably
2	many specialties. So for us in Kaiser
3	Permanente, that means getting 15,000
4	physicians to change their behavior and to
5	change the data stream that they are tying
6	into, and changing the behavior of 15,000
7	physicians in any direction is a gigantic
8	change management challenge. And I guess one
9	thing that I have learned about change
10	management is that there isn't a simple
11	formula.
12	And within our Kaiser Permanente
13	regions, different ones have made different
14	choices. There are some who have elected to
15	implement we have made it clear across the
16	system that our intent by the end of 2013 is
17	to be driving performance on both measures,
18	both the process of did you do initial and
19	follow-up testing and on the outcome are we
20	treating people to remission. But our
21	individual regions, roughly states, have taken
22	different pathways and some have elected, as

Page 112 1 a matter of their change management, to focus 2 on the process measure first, and some are focusing on both. And it really represents 3 different hypotheses about how individuals 4 5 change. So asking people to do the process 6 measure first really reflects a belief in the 7 sustainability of provider-driven change. 8 Namely, if you give a bunch of 9 physicians the right information about whether 10 their patients are actually getting better by requiring them to do the initial and follow-up 11 12 testing, then smart and well-meaning people will begin to ask a bunch of questions like 13 14 hey, are we doing the right thing? What is it we are actually doing? What did I do for that 15 patient? And to set in motion a change of 16 17 improvement activities driven from the ground up by providers. 18 19 There is, of course, another 20 theory and hypothesis that accountability is 21 required and that putting in not only the 22 performance -- not only the process measure

	Page 11
1	but the outcome measure is actually going to
2	drive people to final results. I suspect many
3	people in this room are familiar with the
4	paper by Brent James and Molly Coye and others
5	about two pathways to improvement and
6	accountability and local process improvement
7	and their mutual reinforcement. And
8	ultimately I think we have to get to both but
9	to me it would make sense for NQF, as these
10	things come along, to offer both a process and
11	an outcome measure for people to be able to
12	make that choice about how their change
13	management will proceed.
14	There is a question about whether
15	the boxes are in the right order. And
16	certainly the 6, 7, 8, 9 boxes make lots of
17	sense to me in their placement with respect to
18	other boxes. I would like to suggest that
19	there might be two other boxes that might
20	either or semi well, one might be part of
21	a box and another is another box somewhere
22	else that might be missing.

3

	Page 114
1	One is that box five basically
2	asks us to use the measure in clinical
3	practice or, as Ethan put it so well, pilot
4	it. And this is pilot it in representative
5	practice. Obviously, many of these measures
б	have been piloted. That is where the
7	information about reliability and validity
8	comes from. This is about piloting it in a
9	representative setting to find out stuff about
10	the actionability, about the meaningfulness of
11	patients and clinicians and really,
12	ultimately, about the value of the measures.
13	Is asking this work the perturbation of the
14	system it causes?
15	And a box that I think is missing,
16	which is specify how you think this measure is
17	going to be used. And we have talked about
18	this in a number of settings. I think
19	sometimes it has come under the label of
20	fitness for purpose. And five is really about
21	piloting fitness for purpose but a person
22	can't pilot fitness for purpose without a

Page 115 1 specification of what the purpose is. Is this 2 a measure that we think is going to be introduced into clinical practice, namely, 3 asked in the exam room or in a clinical 4 5 workflow versus a measure that is being used 6 like in a Swedish example where people are 7 getting queried at home as a part of a 8 national system? They have really different 9 implications. So it seems to me that a person 10 couldn't do box 5 of piloting and testing for not only implementability but actionability 11 12 and all those other good things in a representative without really specifying what 13 that representative setting is and how we 14 envision that the measure will be used. 15 And I guess I think what I need to 16 do is call attention to my own belief and bias 17 18 that these measures, as they come through NQF 19 will have to be quite a bit more specific 20 about what is the setting and make 21 distinctions between measures that are going to be used in a clinical workflow versus those 22

	Page 116
1	that are going to be used in other kinds of
2	contexts.
3	Is that little bell my time bell?
4	No? Okay.
5	And the other box that I think
6	might be absent from this diagram is one that
7	has come up a couple of times, which is the
8	post-market surveillance box. And how is it
9	that once new measures are out of the gate we
10	know when they are existing real life whether
11	they are working or not.
12	And I don't know that any of us
13	really know what the post-market surveillance
14	could look like. I imagine from the NQF
15	perspective it has something to do with what
16	comes up with measurement, measure maintenance
17	because there is a process where how measures
18	are actually functioning in the real world
19	could exist.
20	What I do know is that when I go
21	to my car dealership and they give me their
22	thing about how I have to check box five or

	Page 117
1	their kid left to drop out of college and all
2	that stuff, I dearly wish that whoever created
3	that measure was doing their own post-market
4	surveillance in that somebody who is not part
5	of that process was asking me occasionally is
6	that thing working. And I would be able to
7	tell them, no. Your measure has been
8	corrupted. It is full of garbage people are
9	distorting it. And the fact that it has been
10	turned from what was probably a really great,
11	wonderful, well-intentioned improvement
12	measure has been bastardized in the process of
13	turning it into an accountability measure. I
14	really wish somebody was checking up on that.
15	So, I guess my recommendation to
16	NQF is that the measure maintenance process
17	includes not only stuff about what have we
18	learned additionally about validity or
19	reliability and about harmonization, but
20	really goes out and collects data about how
21	this is being used in practice and is it
22	creating unintended consequences and so forth,

Page 118 1 but to put some rigor into that part of the 2 process. 3 There is also a question about whether the criteria are right. So the 4 5 criteria, that is the stuff on this accompanying second page that Karen just 6 7 called our attention to. And I think with 8 respect to the process measures, many of the 9 criteria seem exactly right and are really terrific. 10 There is perhaps a little bit more 11 12 of an emphasis on how the data are collected and collecting the outcome data as well as the 13 14 process data that I am not sure quite belongs But also I would like to just suggest 15 there. 16 a couple of other possible criteria that might go in here. 17 18 One has to do with systemness. 19 and there is a way in which PHQ-9 process 20 measure, for example, asks for what proportion 21 of patients we have collected, the baseline 22 and follow-up PHQ-9. There is a whole bunch

Page 119 1 of other stuff that is implied and really 2 important about how we are actually embedding 3 that into a system, how we are embedding that into a clinical workflow in returning the 4 5 information back to physicians at the right 6 time and place and how we are embedding that 7 into a performance improvement system to learn 8 from and improve on that measure over time, all of which is outside of the answer to the 9 10 measure itself. So I would love to see some 11 12 component, if we are going to have process measures, not only about the performance on 13 14 the actual measures, as specified, which is, of course, important, but the sort of 15 16 reporting out on the context and what is the system in which that information is being used 17 18 and reported. 19 So there is almost a level about 20 disclosing as another kind of metadata, how is 21 this being used. It is a really important 22 accompaniment about what the actual rate is

	Page 120
1	and I think we haven't often paid much
2	attention to that in our external reporting.
3	And then a second aspect that I
4	would love to see and I know it is part of the
5	NQF process about harmonization. So first of
6	all, bless NQF for the additional work it has
7	done on harmonization. I know this is coming
8	up in many contexts. But I believe in this
9	PRO context, it is especially important for us
10	to get harmonization right so that we don't
11	get a bunch of measures that have come in
12	especially from the research environment and
13	from a bunch of disparate and wonderful
14	measure developers who have each taken their
15	own approaches but where collectively we could
16	have a lot of noise and a lot of different
17	kinds of scales and different kinds of look
18	and feel. I don't think that is the process
19	we want. I think we want something that, over
20	time, looks more like a design process and
21	looks more like repeated use of the same
22	response scales and looks more like the same

	Page 121
1	kind of lead-in in introduction or the same
2	number of items, so patients know what to
3	expect and they don't say yes, thinking that
4	they are going to get four items and instead
5	they get 60 or whatever. So some kind of
б	uniform look and feel. And I think the way
7	that might come in is in the harmonization
8	process where if someone wants to introduce a
9	new measure that is measuring the same concept
10	but has a different kind of a scale or a
11	different number of items, that there be a
12	really, really high bar about what is going to
13	be allowed, just to avoid that possibility we
14	have talked about of having a bunch of noise
15	in the system.
16	And I think I will leave it at
17	that. There is many other aspects that I
18	think if we pay attention, not only to the
19	individual measures but to the system this is
20	going into. Actually I am tempted to go one
21	step further.
22	There is many ways in which we are

	Page 122
1	at risk of talking to ourselves here in this
2	room. We have got a bunch of measurement
3	experts and measurement nerds and we know a
4	bunch about how to use item response theory to
5	do crosswalks between measures and all that
6	stuff, which is all stupendous but we also
7	know from the world of improvement and
8	improvement science that having multiple ways
9	of doing things makes improvement really,
10	really, really hard. So just to take a screwy
11	little example, we know there is many ways of
12	measuring weight and they are all perfectly
13	cross-walkable. We know exactly how to relate
14	pounds to kilograms to stones and however many
15	other things are used in other parts of the
16	world. But in many parts of improvement and
17	maybe nowhere better than anesthesiology,
18	people have taught us the importance of using
19	the same measures all the time so a person
20	doesn't have to translate. So we don't have
21	to give people the additional cognitive burden
22	of understanding how this kind of pressure

measurement relates to that kind of pressure
measurement.

3 So I would suggest that in addition to, if we want to consider multiple 4 5 measures, in addition to saying whether we, as measurement nerds, can crosswalk them and 6 7 relate them that we also subject this to 8 empirical testing with real providers. And if 9 you put real providers in an environmental 10 with multiple measures that overlap, whether you give them a crosswalking opportunity or 11 12 not, whether they really understand when there is multiple different measures, whether they 13 14 really are actionable or whether they create confusion. 15 16 And you mentioned the word 17 multiplicity and I think you were using it in 18 the measurement sense, Ethan, but I think 19 there is also the multiplicity problem in the

20 cognitive burden sense for providers. If 21 there is multiple different instruments going 22 on, can people really understand it and act on

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19 20

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1	it in the same way as if we had a more
2	coherent and simpler, cleaner system?
3	DR. PERFETTO: Thanks. After the
4	last meeting, I walked up to Karen and I gave
5	her this diagram that I had been drawing in
6	the back of the room. And she looked at me
7	like I can't read this. And I mean, this has
8	come such a long way from a scribble. And I
9	am pointing that out because I am going to
10	make some suggestions and I don't really have
11	answers for some of the questions that I am
12	going to raise. But I figure if she could do
13	this with the doodle, then she can resolve any
14	of these things that I am going to raise. So
15	thank you, Karen, because I am very visual and
16	I have to have pictures to look at.
17	On the orange part of the outcome
18	performance measure part, I want to get back
19	to the point, some of the points that Patti
20	made. And they are going to overlap a little
21	bit with what Jim was talking about.
22	The first part is on contextual.

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1	And we have had a lot of discussion over the
2	last couple of days about context of use. And
3	so I think what happens is when we get to the
4	precise specification, when we get to that
5	specifications document, I think one of the
6	things that we might need to see is some more
7	detail in what the specifications document
8	will have to have in it, in order to be able
9	to capture context of use in the way that we
10	have been talking about it because I think we
11	are going to need a little bit more on the
12	setting, a little bit more on the patient
13	population, all the kinds of things that you
14	were talking about in that testing phase.
15	When we start to operationalize, we have got
16	to make sure that the population is the right
17	one and the specifications can get at that.
18	So the one example that I can
19	think of where in a process sense where this
20	isn't quite as detailed is a measure that
21	exists now where if you are a patient who is
22	over the age of 65 and you are hospitalized

	Page 126
1	for any reason, you are supposed to be asked
2	whether or not you had a pneumonia vaccination
3	in your lifetime and if you your answer is no,
4	you are supposed to get a pneumonia
5	vaccination. So the specifications there are
б	pretty straightforward and pretty simple.
7	But if you are getting to the
8	point where you are going to be asking
9	hospitalized patients a PRO that has to do
10	with their pain or their function, then the
11	specifications document is probably going to
12	have to be more detailed than you might think
13	about for something that is a process measure.
14	And the next step is in the
15	conceptual aspect that Patti was talking
16	about. And when I was thinking about this, I
17	was thinking about in the area of what is
18	important to measure and report. And I think
19	this actually comes out in a couple of ways.
20	And it is getting to that. What is really the
21	rationale for why we wanted to measure this
22	particular thing and thinking about that early
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1	Page 127 on, and trying to figure out if when we are
- 2	describing in this endorsement process what
4	describing in this endorsement process what
3	our rationale was for why we think we need to
4	do this and why it was selected. That we
5	start to think through just kind of what
6	Laurie and I might talk about in terms of the
7	benefit risk sense, what are we going to get
8	out of this that makes it worth doing that
9	helps us answer the question that we started
10	off to answer or try to resolve the problem
11	that we started off trying to resolve.
12	And that made me think, along with
13	some discussions that we had at our table,
14	that maybe we had something that was missing
15	on the diagram. Right up front where we have
16	kind of gone to this outcomes that are
17	important and meaningful to the target
18	population. But we didn't really start off by
19	specifying what the problem was that we were
20	trying to solve. What is the quality or
21	accountability problem that we are targeting?
22	And then get to that point of what is

	Page 128
1	important to patients and can those things
2	help us solve this problem in terms of the
3	quality issue or the accountability issue that
4	we are trying to gather the data to resolve.
5	And that if we can do that and
б	articulate that clearly as part of this
7	importance of the measure and the rationale
8	why we decided to go this route, then we
9	actually solve that problem of having that
10	blank up-front because then we can make sure
11	that these two things are connected when this
12	information is being put together.
13	I think that also has a spillover
14	on the consequential that Patti was talking
15	about. And it also overlaps with some of the
16	things that Jim was talking about in terms of
17	what is our post-marketing surveillance. We
18	kind of have another missing box at the bottom
19	for that post-marketing surveillance
20	consequential piece. And that ties into this
21	issue of what is the problem we are trying to
22	resolve. If we want to have a feedback

Page 129 mechanism where what we have done at the end 1 2 starts to feed back into the process, then we could feed back into well are we running into 3 some methodological issues? Maybe we are 4 5 running into a logistical problem in terms of implementing or a validity problem. 6 That 7 would feed back into different parts of that 8 methodological piece. But I think what we 9 really want to know in terms of that missing 10 box is if we have implemented this, has it really helped us solve what this problem was 11 12 up in the front that we defined, the quality problem or the accountability problem. 13 14 So I think that helps us by 15 connecting those two pieces, the up-front 16 piece and that downstream piece and having 17 that feedback mechanism be able to go through and in that feedback look that can be 18 strengthened. 19 20 One of the things that Laurie is 21 famous for saying is we are not going to just measure for measurement sake and use these 22

	Page 130
1	PROs for measurement sake. And so I think
2	what I am saying is this probably applies to
3	not just these PRO outcome measures but it
4	probably jumps forward more because this can
5	be burdensome. It can be costly. It can
6	cause confusion when there are lots of
7	different measures. And so it is probably one
8	that needs to be thought through more clearly
9	in this instance because of the complexity of
10	going about gathering this data and making the
11	choices that we would want to make when we are
12	gathering these data.
13	So those are the three pieces that
14	I thought tied in well with where Patti was
15	going but kind of help round out this picture
16	of being able to say we have got a diagram
17	that not just walks us through endorsement but
18	gets us through in trying to resolve the issue
19	of when we have got this endorsed measure,
20	what is the problem it is helping us solve and
21	is it really doing that if we start to use it.
22	DR. ADAMS: First I would like to

	Page 131
1	thank our reactor panel for lots of thought-
2	provoking questions. I think Eleanor, you
3	went back to the beginning, as Ethan reminded
4	u, and it is like defining the problem. What
5	is the magnitude of the quality issue. And
6	then Jim, lots of practical guidance to NQF
7	but I think to the field, too, around measure
8	and measure use and context and how look at
9	that.
10	And I think twice we heard about
11	the importance of this surveillance or the
12	feedback loop and how I know we have a
13	regulatory incentive, particularly with the
14	FDA. And Laurie, you shared some of those
15	insights, too, around we do this in that realm
16	but we don't routinely do what I would call
17	surveillance of measures and use. I mean
18	certainly there are mechanisms but I think we
19	are hearing for a stronger call for that
20	feedback loop and that rapid kind of cycle
21	learning.
22	So lots of great take-aways. I

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1	want to open it up for questions to the group.
2	I am going to ask the operator to please queue
3	up those joining us virtually. And certainly
4	our audience participants, please join us.
5	So I might start oh, I see.
6	Lori, would you like to? Okay, great. Thank
7	you. And then I will work my way around.
8	DR. FRANK: Hi, thanks. And
9	thanks to the whole panel. That was
10	excellent.
11	My question is for Ethan. I
12	appreciated how you brought patient engagement
13	in and showed the specific points of contact.
14	Who gets to determine if the patient report of
15	the outcome is appropriate? And should
16	patients be involved at step number two on
17	that part of the flow chart?
18	DR. BASCH: You mean who
19	determines if the patient is in the best
20	position to report on a particular outcome?
21	DR. FRANK: So step number two is
22	

	Page 133
1	DR. BASCH: Yes, determine if the
2	patient report of the outcome is appropriate.
3	I don't know. What do you think?
4	(Laughter.)
5	DR. FRANK: I think that could
6	present an opportunity for patient engagement
7	as well. But it is a really important
8	question about the pathway. Who gets to
9	decide before we go on to the next step in the
10	flow chart? Right now the way it is framed,
11	it seems like it is limited and that there is
12	not consumer and patient involvement.
13	DR. ADAMS: Lori, do you recommend
14	I know from the first workshop you
15	identified certain touch points. You looked
16	to the PCORI model of where there would be
17	touch points for research and you identified
18	some touch points. And I think certainly
19	number one was in that touch point. So as we
20	think of this pathway as Ethan, I think you
21	did on your slides, you started to identify
22	touch points for the patient or person. So

	Page 134
1	maybe we should be more specific about that.
2	DR. BASCH: I would actually make
3	a comment, too.
4	So one initiative I have been
5	involved with is the PRO CTC, which is the
6	NCI's initiative to create a patient,
7	basically an item library for patient
8	reporting of harms of treatment in the context
9	of cancer trials. And in selecting what
10	adverse events are appropriate for patient
11	reporting versus clinician reporting versus a
12	lab system, a set of criteria were created
13	based on the level of subjectivity of the
14	outcome. And then a modified Delphi process
15	was used with multiple stakeholders to figure
16	this out. And there are actually five
17	categories. I can't recall exactly offhand
18	but assuming like totally subjective, you
19	know, experiential with no observable
20	component, and then a little of both, and then
21	totally observable. So maybe starting all the
22	way over here with nausea which really only

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the person experiencing it can truly know over
to something like rash or alopecia which a
patient or an observer could potentially
report on. In fact, in the case of rash, the
conclusion was perhaps a patient can report
the incidence of a rash but to characterize a
rash actually requires some sort of expert
training.
So I think that there are actually
methods that have been used to try to
determine this.
DR. FRANK: Yes, to determine
that. So I would just want to add that
clinician interpretation can be a really
important step. So depression is a good
example. It is an internal experience and yet
a lot of people make the compelling argument
that you must have clinician report about some
aspects of the experience of depression
because they are able to gather the evidence
in a way that the patient cannot. But another
example would be cognitive impairment and it

1 was already raised. 2 So it would be a big no, for many people, step number two. Oh no, we can't ask 3 cognitively impaired patients to report on 4 5 this. But I think we need to question a lot of those assumptions and so I would just 6 7 encourage us to all to think about that as a 8 point of contact as well. 9 DR. PERFETTO: Also had another 10 way of thinking about this in terms of reframing number two a little bit. Because I 11 12 think if we think about this issue of framing a problem and figuring out what is important 13 14 to the patient, and then we have to have that step of saying okay well maybe these things 15 16 that are important to the patient might be 17 patient-reported outcomes that we might want 18 to get to that are important to the patient 19 may not be the ones that would resolve that 20 problem. And so when we say appropriate, it 21 may be is there a match between the problem 22 and the measure because it could be a process

Page 137 1 measure that resolves the problem and then you 2 would make the determination. But to your point, I think it 3 4 would be good to have patients involved in 5 that discussion and that decision-making 6 because even if the end conclusion is oh no, 7 a PRO is not needed, a process measure will 8 do, it is good to have patients understand 9 that decision and be a part of that decision. Okay, I am going to 10 DR. ADAMS: start in the back. And so Ted, you and then 11 12 Phyllis, and then I will come back up to 13 Kathy. 14 DR. GANIATS: I'm Ted from San 15 Diego. This is great. I really appreciated 16 everything that was said. And it stimulates two ideas; one an editorial suggestion and 17 then second I will be selling tickets for the 18 19 fight between Jim and Eleanor later today. 20 I'm joking. 21 A dotted line from the green to 22 I think the way the diagram is the orange.

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1	listed now, all process measures will become
2	outcome measures. And it might be something -
3	- we have said they don't all but the diagram
4	isn't consistent with what was said.
5	Now Eleanor brought up a wonderful
б	idea that there is a box zero stating what the
7	problem is. And Jim brought up that not
8	all measures, this is box five, not all
9	measures may be incorporated into the
10	practice. It might be that there is a survey
11	that was done. And I think that box zero and
12	box five have to interface somehow and that
13	box zero may tell us that we are interested in
14	a process measure. The problem is that
15	doctors aren't asking about pain. The process
16	measure is are they asking about pain, in
17	which case we might want to incorporate it
18	into practice. But there may be some times
19	when we want to just survey that having
20	something incorporated into the practice is
21	too burdensome and all we want to know is as
22	an outcome how do the groups compare. And we

	Page 139
1	could do a survey of a small number. So I
2	think extrapolating or expanding box five to
3	allow for a survey instead of implying, it is
4	only going to be incorporated into practice
5	allows Jim's comment to be incorporated. And
6	it feeds back into box zero.
7	And obviously I am joking about
8	you two fighting but the love fest will be
9	DR. BASCH: I was just going to
10	comment that in box five, we talked about box
11	five a little bit and what does it mean
12	exactly. Does box five actually mean pilot
13	testing in practices where the target
14	population is represented in order to assure
15	that the measure is performing the way that
16	you believe it will perform, based on all of
17	your assumptions? Or does it actually mean
18	integration into practice as a process
19	measure?
20	DR. GANIATS: I go back to the
21	diabetes foot exam measure where an option was
22	to ask patients did the doctor examine your

	Page 140
1	feet or did you take your shoes off? And that
2	would not be in clinical practice as box five
3	words it. And so it is just allowing an
4	expansion of how we think we might test them.
5	DR. ADAMS: Any other response to
6	that?
7	DR. BELLOWS: So that was an
8	excellent comment. I totally agree that the
9	box zero and the specification have to be
10	tightly related. And I also agree that some
11	of the language of box five, as specified, is
12	incomplete in terms of how I would hope to
13	me it is not just about whether the measure is
14	performing as anticipated, it is about how is
15	the entire system responding. What is the
16	impact on the key stakeholders? If it is a
17	clinical measure in particular, what is the
18	overall in the interaction on the key
19	stakeholders? And that is bigger than the
20	performance of the measure itself. It is what
21	are the expectations created? What are the
22	expectations realized? All that kind of

	Page 141
1	stuff.
2	DR. ADAMS: Phyllis?
3	MS. TORDA: So I have several
4	reactions, mostly to Jim's presentation.
5	I think it is fine to do process
6	and outcome measures simultaneously. I will
7	say that our experience at NCQA is that
8	whether you should start with one or the
9	other, in large measure, depends on the
10	sophistication of the organization. In
11	organizations that have more experience with
12	quality improvement, and that is how I am
13	using the term sophistication in this case,
14	can go to the outcome measure and do the
15	analysis necessary to figure out the paucities
16	that will lead to better outcomes.
17	But organizations that don't have
18	that expertise really find it useful to have
19	the process measures that provide the roadmap
20	to good outcomes. So that is just an
21	elaboration.
22	With regard to the remarks about

	Page 142
1	harmonization, a couple of remarks. One is it
2	is much easier to achieve harmonization in
3	virgin territory than it is once people are
4	really attached to one tool or another. And
5	I think telling the whole nation that it has
6	to use one tool is a difficult thing.
7	I think some of your remarks, Jim,
8	went more to the disadvantages of using
9	different tools in the same organization as
10	opposed to the disadvantages or advantages
11	as opposed to using tools in different
12	organizations that can be mapped. And some of
13	the waste and inefficiencies go away if one
14	organization is at least using the same tool.
15	And then those results could be crosswalked or
16	mapped across organizations.
17	I think we have given a little bit
18	short shrift to the unit of analysis issue.
19	And there is always feasibility issues and
20	statistical reasons why larger units of
21	analysis are easier than smaller ones but I
22	don't think we focused very much and it is

	Page 143
1	worth thinking about conceptually what is the
2	right unit of analysis. And some of these
3	discussions about box five and whether it is
4	clinical practice or it is really a bigger
5	group of people get to the unit of analysis
6	issue. You know, which individuals are making
7	contributions to the outcomes that we are
8	measuring?
9	And finally, a lot of talk
10	involving patients, which is great. A little,
11	I certainly would appreciate guidance about
12	how to do stuff because in real situations, it
13	is hard to recruit patients to participate in
14	many of these activities. And so any wisdom
15	that can be offered from the experts or the
16	audience and communicated by NQF around that
17	would be welcome.
18	DR. ADAMS: Any response?
19	DR. BELLOWS: Just a couple of
20	things really quickly. I think sophistication
21	is one really important aspect in how to go
22	but I don't think it is the only thing, by

	Page 144
1	far. It also has to do with priorities and
2	portfolio management and all that sort of
3	thing.
4	And we tend to think of these one
5	measure at a time but actually people in
6	operations in our delivery system are working
7	on 20 different things at the same time and it
8	is partly a matter of, on this particular,
9	with the use of the PHQ9, how far up it is in
10	their priority scheme and how hard they want
11	to push it. So I think there is a bunch of
12	factors of which sophistication is one.
13	On the harmonization, you are
14	totally right. A part of it is about within
15	institutions but also there is the thing that
16	our patients are crossing across many
17	different settings. And as they go from
18	hospital to primary care to skilled nursing or
19	whatever, they are going to be touching many
20	different institutions. So I actually think
21	that even for the sake of consistent
22	expectations for our patients, it makes sense

	Page 145
1	for us to have harmonization across
2	institutions as well. You know, I know if I
3	am going to be asked about pain, I know what
4	that question looks like. And I know if I am
5	going to be asked about symptoms, I know how
б	many questions to expect, that sort of thing.
7	So it is just a small thing.
8	And with respect to how to include
9	patients, to me there is a really important
10	distinction in the sort of box one through
11	three stuff. We are asking patients rather
12	hypothetical questions, in a way. What do you
13	think would matter to you and what do you
14	think we should measure. It is kind of like
15	asking people to reveal their preferences, as
16	if they had preferences that they could just
17	reveal. And to me, that is why I partly put
18	more stock in the box five, where you can
19	create an environment where something real
20	happens and then do the kind of qualitative
21	stuff that everybody in this room in some ways
22	knows how to do about what was this experience

	Page 146
1	like. What happened? How did it work out?
2	Did we miss something? That kind of stuff.
3	So I think the methods are clearer
4	in box five. Do it and learn, as opposed to
5	the methods in boxes one through three that
6	are somewhat more abstract and that I think
7	maybe none of us understand quite as well
8	because it is more conceptual.
9	DR. PERFETTO: I think to add to
10	that, I would turn to someone like Laurie
11	Frank and say you know, this is kind of where
12	PCORI is headed, to try to flesh out and
13	further develop those patient engagement
14	methodologies. I think to date my own
15	experience has been that we recruit patients
16	depending upon the circumstance and the
17	question from a variety of places, anyplace
18	from online having them submit information
19	online to various kinds of things to focus
20	groups. And they could be people who are
21	patients who are being seen by particular
22	kinds of physicians to any kind of general

	Page 147
1	focus group. So it is any and all at this
2	point and I think we are still going to be
3	tweaking those methodologies as we go.
4	DR. BASCH: I would just add very
5	briefly I have participated in a number of
6	panels that have recommended that a variety of
7	different measures could be used in the same
8	context. Many of those panels have assumed in
9	the future that there will be good approaches
10	for crosswalk and there are a few of those
11	initiatives going on but the truth is that
12	either there are a lot of problems crossing
13	between measures.
14	I actually personally would
15	strongly advocate for recommending a single
16	measure in a single context here and that the
17	bar be, as Jim I think aptly put it, very high
18	to unseat that. And if an investigator wants
19	to come along and demonstrate that a new
20	approach performs better, then they could
21	maybe unseat the first comer.
22	But you know, I think that it will

	Page 148
1	avoid some confusion. Some may disagree with
2	that.
3	The other thing that I would say
4	about patient engagement is again, you know,
5	I think boxes one through three rely on
6	qualitative research that would include, as
7	Eleanor pointed out, focus groups, key
8	informant interviews, cross-sectional surveys,
9	longitudinal surveys and there are fairly well
10	established approaches for aggregating and
11	analyzing that information.
12	DR. ADAMS: So I'm going to talk
13	about the queue because we have lots of hands
14	up. I know Kathy you have been waiting
15	patiently. And we do have one of our panel
16	members who also queued up earlier, Barb. So
17	I am giving Barb the signal now that after
18	Kathy she will come because she queued up
19	after you. And then I will get the four that
20	raised their hands in these two tables. Thank
21	you.
22	Kathy.

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1	DR. LOHR: I thought this was a
2	wonderful discussion and thank you all.
3	I think the box zero is really
4	important. And boxes one through three I
5	would just reiterate what Ethan and others
6	have said. We have been doing some of this
7	kind of thing for 20, 30 years.
8	What might be missing from one
9	through three is some understanding that you
10	may have to, if you will, pay your patients
11	back. There may have to be something that is
12	given back, whether it is a pure incentive or
13	some other pieces of information, to thank
14	them but perhaps to make, if you will, worth
15	their time. So we need that.
16	On box two I wanted to say this is
17	another one of these perhaps it is not an
18	either/or question. And it can be phrased as
19	you want to determine whether and to what
20	extent the patient reporting on the outcome is
21	the appropriate thing because there is a
22	spectrum and gradations there. And I would

Page 150 recommend that you change that. 1 2 I also have to say coming out of long sort of Donabedian guality of care triad, 3 I could not work with this diagram because I 4 5 immediately got off onto process measures, as one of structure process outcome, and I did 6 7 not understand why you would go from a process 8 measure of any sort to an outcome when this is 9 about patient-reported outcomes. 10 And so I am just wondering whether at a minimum box six and the other ones, some 11 12 other term that is a synonym if you will, for 13 process, might be used. I mean there is 14 operational, there is event, there is use. There is a bunch of words that maybe would 15 16 serve you better so you don't send people like me off thinking why would we be talking about 17 18 process measures and then only after we have 19 done all those process measures am I getting 20 back to outcome measures. 21 Ted or somebody said maybe a 22 dotted line down from your green back to your

Page 151 1 orange might help but following the way this 2 is here, and then talking about process measures before you ever get to outcomes, I 3 think it runs a risk of misleading some of the 4 people, certainly in the quality of care, 5 6 maybe not so much accountability, but in the 7 quality of care world. 8 DR. ADAMS: I think, I know Barb's 9 been waiting on the virtual line for us. So 10 I am going to ask the operator to please queue her up so she can ask a question. 11 12 Hi, I have my mute DR. SUMMERS: 13 off. Can you hear me? 14 DR. ADAMS: Yes, we can. 15 DR. SUMMERS: Oh, great. Thanks 16 so much for the opportunity to comment. Ιt has actually been lovely to be able just to 17 sit back and listen to the rich dialogue that 18 19 has been going on yesterday and today. 20 I had just three quick 21 comments/questions. The first really goes --22 and they relate to measure use and the context

Page 152 1 of measure use. 2 First going back to the notion of risk adjustment. And one question that occurs 3 to me is how do we, how could we, and should 4 5 we include the patient perspective as it relates to the relative significance of a PROM 6 7 in their overall care experience? For 8 example, can we somehow develop some patient-9 reported risk adjustments? 10 And the example that I think about could relate to an individual with prostate 11 12 cancer who, in treatment, sequence number one 13 may experience relatively little fatigue as a 14 consequence of the therapy being used. But if their disease progresses and they advance to 15 16 a different therapy, that therapy could cause significant fatigue. So although patients 17 18 would generally prefer to have no fatigue, I 19 think most patients would prefer some fatigue 20 to the alternative of death. 21 And then following on some of 22 Ethan's really excellent points, I think we

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1	really should continue to focus on the
2	necessity of incorporating the patient-
3	reported outcome performance measures into
4	clinical workflow. Because it is not only
5	going to improve our response rates, it is
б	also going to hard wire incorporation of PROs
7	into clinical practice.
8	And then following on some of the
9	most recent discussion, the use of the PRO
10	performance measures in clinical practice is
11	also meaningful in achieving improvement. So
12	I believe that outcome measures should also
13	have utility in clinical practice as
14	clinicians look at their data and aggregate in
15	an attempt to determine how is it that they
16	can, as a practice group, achieve improvements
17	in their PRO performance measures. Thank you.
18	DR. ADAMS: Thank you, Barb. Any
19	comments for Barb?
20	So I am going to go back to our
21	table and work our way around. And Ted, did
22	I see your hand go up? Yes, and I will go to

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1	this and David, I did see you, yes.
2	MS. WILKINSON: Hi, Linda
3	Wilkinson, Dartmouth-Hitchcock, Coordinator of
4	Patient and Family-Centered Care. And I
5	mention that because I think there are lots of
6	people addressing the desire to include
7	patients in either the formation of or the
8	evaluation of these PROMs. And I am heartened
9	to hear that from people whose focus is often
10	measurement itself and the protocols and so
11	on.
12	What I am hearing that I would
13	like to address very briefly is I am hearing
14	the concern that it might be hard to, or might
15	be confusing to, or dangerous to include
16	patients in the process sooner. I would like
17	to debunk that.
18	But what is also true is that
19	people have said where are we going to get
20	them. I mean, they have said it in many
21	languages. How are we going to do this? How
22	are we going to administer it? I guess we

Page 155 1 could say you would us, meaning our 2 institution, as a test case. I can't tell you how eager are patients are to share their 3 impressions and how amazingly revealing of 4 5 things that skilled clinicians and skilled 6 designers of programs have been to find the 7 things that they have not turned their 8 attention to that they realized was important. And I would invite anyone who 9 10 wants to explore how we mechanically have gone about this, what standards we have used for 11 12 who we are asking to join us and the like. We are very happy to share. But I would, at 13 14 least for this meeting, urge people not to 15 discount it because we are not yet used to doing it. It is in fact a lot easier. 16 Ιt 17 takes work. It takes attention. It is 18 exceedingly awarding and I would encourage you 19 to contact anyone like us who has had some 20 experience doing this and have found ways to 21 make it workable and very profitable. 22 So ollie ollie umphrey. Thank

	Page 156
1	you.
2	DR. ADAMS: I would like to thank
3	you for that offering to us because I think
4	within many of our processes, how we can
5	engage patients authentically at those various
6	levels. Any comments in regards? We are
7	grateful to your expertise that you could
8	offer for us there.
9	Dave?
10	DR. CELLA: Thank you. Dave Cella
11	from Northwestern. I agree it was a great
12	panel discussion.
13	I have a couple questions that
14	sort of I will follow I think, if there is
15	enough time, with a suggestion or a thought.
16	One question is box zero. Could you help me
17	differentiate that from context? Because when
18	people have been talking about context of use,
19	I think about box zero, what you described as
20	box zero but maybe I am missing something. I
21	just want to make sure.
22	DR. PERFETTO: I am just simply

Page 157 1 saying that we have to articulate what box 2 zero is. DR. CELLA: Which is the context 3 4 of use. 5 DR. PERFETTO: It could be the 6 context of use but it could be the reason why 7 we want to do this in the first place. And 8 that could be part of the context of use. 9 DR. CELLA: Yes, okay. All right. DR. PERFETTO: But I think what we 10 have been talking about in terms of context is 11 12 describe the patient population. Describe the 13 setting. We haven't really said describe --14 DR. CELLA: So as long as we have 15 a broader --16 DR. PERFETTO: -- the question you 17 are trying to answer. DR. CELLA: All right, so broader 18 19 definition of context. 20 DR. PERFETTO: Yes. 21 DR. CELLA: We are basically in 22 that -- okay.

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1	DR. PERFETTO: Yes.
2	DR. CELLA: Okay. I just thought
3	it was missing something from the earlier
4	discussions.
5	The other question is about what I
6	think are Jim and Ethan's suggestion that we
7	pull back from standardizing and equating and
8	focus on one measure. Partly I am confused
9	and then I have a comment to make. But the
10	confusion is that I thought I had it nicely
11	and very positively drilled into my head that
12	NQF endorses performance measures, not PRO
13	measures. And as such, why would we be even
14	talking about the idea that only one measure,
15	PRO measure, unless I misunderstood that,
16	should be endorsed because NQF doesn't even do
17	that. Maybe I missed something there.
18	And then I have a comment about
19	PRO measures and equating and stones and
20	kilograms and pounds.
21	Did I miss something there?
22	DR. ADAMS: So Karen, do you want

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1	to respond to the we don't endorse the tools
2	but why we would
3	DR. PACE: So you are absolutely
4	right. We don't endorse the individual PROMs.
5	But by virtue of specifying a performance
6	measure that is going to be standardized, we
7	need to identify which PROM will be used to
8	collect the data.
9	So you know, although we don't
10	just endorse the PROM by virtue of the
11	performance measure, obviously we have some
12	relationship there. And I think the
13	discussion was should we endorse performance
14	measures that say you can use only one of the
15	instruments or two or three. But I think that
16	is where your equating comes in and maybe you
17	want to add something.
18	DR. PERFETTO: Can I give an
19	example here? Can I give an example on this
20	one?
21	There is a measure that exists now
22	and I am not sure I am remembering whether it

	Page 160
1	is NQF-endorsed, but there is a measure right
2	now that is used in rheumatoid arthritis. And
3	I don't remember off the top of my head if it
4	is endorsed or not but it is a good example.
5	There is a measure that says on an
6	annual basis, if a patient has rheumatoid
7	arthritis, they should have a functional
8	assessment done. It doesn't say how. It
9	doesn't say what tool to use. So it is really
10	a process measure. It is a check the box yes
11	or no, on an annual basis did this functional
12	assessment measure. I think the discussion is
13	in the process stream on here, does this go
14	the next step to say is a functional
15	assessment done with XYZ tool, which still
16	would be a process measure, versus it turning
17	into an outcomes measure that says functional
18	assessment function for this particular
19	group improved by Y based on the tool that
20	gets specified. And I think your question is
21	a very good one. Would NQF go that next step
22	to actually list which tools would be included

	Page 161
1	or excluded from that measure, whether it is
2	process or outcome. And that is the crux of
3	the question because right now, they are not
4	specified in that kind of detail.
5	DR. CELLA: So if I could then
6	with the comment, because it does kind of
7	follow I know those people want to talk.
8	So we used the Jim you used the
9	analogy of kilograms and pounds and then you
10	threw in stones. So one thing that got me
11	thinking was if today's measure is in stones
12	and yet, the one that is used in practice and
13	it is out there but yet we are aware that
14	there are better measures, you know, scales
15	that can measure in kilograms and pounds that
16	can truly be equated to one another with a
17	simple look-up table, why wouldn't we push for
18	the kilograms and pounds over stones?
19	And I think that is what you were
20	saying, Ethan, is that there ought to be an
21	ability to prove something is better and
22	switch to it.

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1	But if the current could be a
2	metric that is indifferent to how you get that
3	metric as long as you have a way of getting to
4	that metric, like a kilogram or a pound, we
5	don't care what scale is used to come up with
6	that. I mean, usually I don't think NQF or
7	CMS asks which scale did you use or who
8	weighed the patient; or even was it self-
9	report weight or you do ask that. Okay.
10	Well, thank you. I'm glad to hear that.
11	But maybe I am making the point
12	and maybe not. It seems that there are areas,
13	not all of them but there are areas of health-
14	related quality of life like depression, which
15	is in many of the current guidelines where you
16	can link across different instruments. And I
17	thought I was hearing sort of an argument
18	against doing and I guess I disagree with that
19	argument if that I heard it correctly because
20	it seems like we care more about the pound
21	than about the scale and we care more about
22	the depression than we do about the
Page 163 1 questionnaire. 2 And I am not advocating this in areas where it is not ready but there are 3 areas where it is ready. So I guess that is 4 5 my comment. 6 DR. ADAMS: Now I am going to have 7 the panel to reply and I know Helen, you had 8 some response to the direct NOF question. 9 DR. BURSTIN: Could I just respond 10 very briefly? So I think those are really great 11 12 questions. And I think the key thing is we are trying to get to a set of standardized 13 14 measures that really allow people to compare 15 apples to apples. So if there is information, for 16 17 example, and you talked about this, it was 18 very excited at the first workshop, David, 19 that there might be opportunities to provide 20 sort of almost equivalency tables, and I 21 forgot the exact term that you used, that 22 would say in fact that PHQ-9 versus the PROMIS

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1	depression scale or equivalent. Use either
2	and there is a way to make them both work.
3	That's wonderful. But I think what we don't
4	want to have is to have a thousand flowers
5	bloom and not at the end of the day, allow the
6	measure itself to provide the comparability
7	that drives what we hope is standardization
8	and improvement.
9	Karen, does that work for you?
10	DR. ADAMS: Ethan.
11	DR. BASCH: I would just add we
12	also don't want to have since patients have
13	multiple conditions, maybe seeing multiple
14	providers have them answering multiple
15	depression scales in different context.
16	DR. ADAMS: So Ted, I know you
17	have been waiting patiently. And then I will
18	Ted Rooney, sorry. And then I will go back
19	and then Gene. Okay, go ahead
20	MR. ROONEY: Okay, thanks. First
21	a quick question for Jim. On your extra two
22	boxes, it seemed like you were pleased enough

	Page 165
1	to have one box named after you. Now you want
2	three?
3	(Laughter.)
4	MR. ROONEY: But the real question
5	is, I live in the world of implementing
б	measures, both for accountability and
7	improvement. And we have been using the
8	Berwick NQF diagrams about ten years ago,
9	talked about the box, and QI on one side and
10	COM on the other. I don't believe one works
11	without the other. And we have been working
12	with this group for ten years now that meets
13	six times a year or five times a year or half
14	days with 14 PCPs, employers, health
15	planners, consumers, whatever. And we are in
16	the throes of this stuff. And I can't
17	emphasize enough the importance of
18	harmonization and benchmarking because if we
19	can't get one stand like if we could have
20	a PROMIS database like we have the CAHPS, it
21	would be phenomenally helpful because what our
22	docs want to know, they want to know how do

	Page 166
1	they compare to other areas. And then what
2	can they do about it to improve it?
3	And then in addition like if you
4	can get the PROMIS or something like that, you
5	know, standardized data base, you have no
б	problems with copyrights, it is easy to do,
7	and then have some technical assistance, I
8	don't know what it would be for us, but with
9	AHRQ they sponsor this CAHPS database. And we
10	are doing a state-wide project, in physician
11	practice and CAHPS is pretty straightforward
12	but I can't tell you how important it was to
13	have someone like Dale Shaller who we get to
14	do some technical assistance who meets with us
15	and talks with us about how we implement that.
16	And we involve our providers in that, too.
17	And it is just so important. And we don't
18	it is so important to have some guidance on
19	how we can implement something so that at the
20	end of the day it makes it work in Maine but
21	we can compare Maine to Minnesota and other
22	places.

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1	And then right now in Maine we do
2	really well on quality. Like we are some
3	better quality in the country. We are the
4	worst in cost. It works both ways. And then
5	sometime providers will say well we are
6	already better than the national average in
7	quality. Why are you pushing so hard? Well
8	the national average stinks but that is
9	besides the point.
10	We wanted to get to the point to
11	say well it is not just a look at your quality
12	compared by a state but is there a place in
13	Minnesota or Colorado or Texas that really has
14	superb quality? And then we can benchmark to
15	that and then show what the difference is.
16	Our providers would respond because they are
17	working as hard as they can. And when they
18	think they are doing really well, they sort
19	of, you have got to understand why are they
20	working so hard? Or when they find out that
21	over here they have figured out a better
22	mousetrap, we can get that imported.

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1	But you can't do that unless you
2	have harmonization and standardization. And
3	you can't build a database with technical
4	support unless you have the harmonization. So
5	I know NQF just does the harmonization piece
6	but I implore us, if we can get like a PROMIS
7	database like we have with the CAHPS and get
8	some of the support technical assistance, it
9	would drive tremendous improvement.
10	DR. ADAMS: Jim, did you have a
11	comment to make?
12	DR. BELLOWS: Well first of all,
13	Eleanor and I have conferred on this and the
14	post-market surveillance box is going to have
15	her name on it and not mine.
16	(Laughter.)
17	DR. BELLOWS: So we do have
18	equanimity here.
19	DR. ADAMS: He's one through
20	three.
21	DR. BASCH: Always the bridesmaid,
22	never the bride.

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1	(Laughter.)
2	DR. BELLOWS: David, with respect
3	to your questions, I totally get it but NQF
4	doesn't have the charter or the mandate to
5	design an entire system. But I guess it is
6	just my feeling that they have their hands on
7	an incredibly important control that could
8	move us either towards the thousand flowers
9	direction or more towards the greater
10	consistency direction. And the more those
11	that control is shifted in a way that brings
12	us towards harmonization and consistent use of
13	the same scales, I think the better off we are
14	in some ways, I think. Not on everything but
15	on some basic things.
16	And I know that there is one thing
17	for us is one really great aspect of use of
18	PROs within our system, for example, is as
19	people transition across settings and return
20	from specialty care back to primary care, from
21	primary care to skilled nursing, that it can
22	give a common language. And as people move

Page 170 1 through our spine pain care for example, they 2 have consistent metric of what their pain was. And the more we go into different scales and 3 different places, we just erode that. 4 5 So I think there is just things about little preferences. If you use one of 6 7 the three established response scales you 8 automatically get a pass on some aspect. But 9 if you want to come bring in some other 10 different response scale, you have a higher bar, it is just things like that, little 11 12 preferences to bring more coherences is what I am hoping that they can do. 13 14 DR. ADAMS: David do you want to respond to this, and then we will have time 15 for two more, which will be Ted and Gene. 16 17 DR. CELLA: Yes, although you 18 might also need to respond back to his points, 19 Ted's points. 20 And I actually I am breaking in 21 and I apologize for that because I think we 22 actually agree. And we are using language,

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1	interestingly, somewhat differently but maybe
2	saying the same thing. So let me try again.
3	I am against a thousand flowers,
4	unless those flowers relate to a common
5	underlying unified metric. And when those
6	flowers relate to a common underlying metric,
7	I am in favor of those flowers because they
8	give people choice. But the metric is what
9	gets reported. And we can do that in some
10	areas and not in others. And so I have been
11	working on that for many years to get common
12	metrics and common language, as opposed to all
13	the flowers and people selling their wares.
14	So I think we actually agree on that and NQF
15	is in a good position, I think. And it works
16	well with that performance measure
17	certification as opposed to the PRO measure
18	certification because they can say we certify
19	on the metric and you can use the PHQ-9 or the
20	CESD or the PROMIS depression. It doesn't
21	matter because you are reporting the metric.
22	DR. ADAMS: Thank you, Ted.

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1	DR. GANIATS: This is Ted and I
2	have a corollary or a slightly different take.
3	I think it depends on if it is a process
4	measure or an outcome measure. And so I co-
5	chaired a heart failure performance measure
6	panel. We recommended two or three process
7	measures. You should check for function.
8	But to be able to compare those,
9	there is just absolutely no way because the
10	theoretical constructs behind the three we
11	chose were so different you couldn't crosswalk
12	them.
13	And so if it was a process
14	measure, I like a thousand flowers. If it is
15	an outcome measure, I want to have one flower.
16	And I have an exceedingly high bar for
17	crosswalk. If it has a R square of 0.8, I
18	don't care. That is not good enough. Because
19	if it is an accountability measure and it is
20	only a 0.8, I think that is too much
21	variability.
22	I want one flower and I want the

	Page 173
1	one flower to have one bloom. And if you have
2	two instruments that aren't I mean the VA
3	version of the SF-36 and the RAND version of
4	the SF-36 and the quality metric version of
5	the SF-36, they are probably close enough.
6	But almost anything else, you are not going to
7	be able to do a close enough crosswalk for
8	accountability.
9	DR. ADAMS: Any response from our
10	panel? Gene do you want to or yes. I was
11	going to say, Lewis, with that thread, did you
12	have a comment? I saw your hand go up.
13	DR. KAZIS: Thank you. I just
14	want to indicate that David Cella is really on
15	the right track here. A common metric I think
16	is what we are after. It may take some time
17	but there is a body of literature out there I
18	think that began a number of years with Danny
19	Fryback who had an NIH funded grant to begin
20	to develop bridges across a number of
21	different assessments. Many of them were
22	generic in those days.

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1	But I think that the objective
2	here is the metric. You know, that is what we
3	are looking at, a common metric. And the
4	methodology, I think, is there. It is just a
5	question of application of that methodology
6	across these many instruments.
7	DR. ADAMS: Please respond and
8	then we will go to Gene. Thank you.
9	DR. GANIATS: Denny and I, along
10	with a few others with the HUI, EQ-5D, SF-36,
11	and the QWB did simultaneous administration of
12	all of those in random digit dialing across
13	the country and disease-specific over time.
14	It is crap. Okay? It is really
15	sad. You can crosswalk all day long between
16	those instruments and their responsiveness to
17	change in two different conditions are
18	completely different; where sometimes the SF-
19	36 will show a change, sometimes it won't
20	depending on the condition. Sometimes the
21	QWB, sometimes not. So the fact that you can
22	crosswalk doesn't make them equivalent. And

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1	so you have to be incredibly careful.
2	So there is one thing to be able
3	to do the arithmetic, the arithmetic of a
4	crosswalk. It is another thing for it to be
5	good enough for an accountability measure.
6	And I mean it is published out
7	there. I just think we have to be incredibly
8	careful.
9	DR. ADAMS: So Gene, I am going to
10	ask you. I know you have been waiting. And
11	then we have an audience comment and then I
12	will wrap us up. Gene? And anyone from our
13	panel? Sure, of course.
14	DR. NELSON: So this is just very
15	brief. The flow chart, once it gets revised
16	a bit will be really helpful. And that would
17	be really helpful to actually test it with a
18	measure coming through and there is some
19	opportunities with the ONC meaningful use PRO
20	measures, et cetera that we should really take
21	the flowchart as revised and try it out.
22	DR. ADAMS: Thank you, Gene. I

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1	think that as you are raising here do we have
2	a few use cases that we want to put through
3	here would be very helpful.
4	And you mentioned you had a
5	comment from the panel in regards no?
6	Okay.
7	So there was someone from the
8	audience that wanted to comment on this, too.
9	And then Al, I'm going to give you the
10	pleasure of wrapping us up.
11	MS. POTTER: I'm D.E.B. Potter
12	from AHRQ. There are several of the PRO
13	measures that are included in our national
14	surveys. And so you have a benchmark of the
15	non-institutionalized civilian population.
16	And a lot of times you can cut them by various
17	sub-populations.
18	So I guess I urge people to think
19	about the use of that data. And should we
20	start to think about that as a way to build a
21	national benchmark? Because we are not going
22	to have the resources to build a benchmark

Page 177 1 database for every single one of the PROs in 2 use. Thank you. 3 DR. ADAMS: San Keller, American 4 DR. KELLER: 5 Institutes for Research. And I wanted to 6 merge the two positions of the common metric 7 and the implications of using something that 8 you have shown statistically to be similar. You know that there should be sensitivity 9 10 analysis to the effect of the differences and whether or not they make a difference in the 11 12 application of the measure. 13 And I am reminded of Dana Safran's 14 work on the six response versus the four 15 response and how it orders doctors and so on. 16 So you can do that and those hypotheses should 17 be stated up-front when you are making those translations to address that potential 18 19 criticism. 20 DR. ADAMS: Albert, I think it is 21 you. Yes, great. Thank you. 22 DR. WU: So I have a question

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1	about I think that coming up with some use
2	cases is absolutely the smartest thing to do.
3	And to really specify the heck out of the
4	first use cases, so that we are really, really
5	focused on whatever it is we are focused on.
6	I sort of then became a little
7	unsure about how this is sort of going to get
8	rolled out because the first use case will
9	then be generalized somewhat if we are looking
10	at hypertension in African American men
11	between the ages of 50 and 55, what is the
12	next case what is the next use case going
13	to be? Or how are we then going to move from
14	that to all hypertension in all men,
15	hypertension in genders, hypertension in all
16	ethnicities, in primary care, in long-term
17	care, in acute care, in rural, in urban, and
18	so on and so forth.
19	So we wind up in a way do we
20	wind up with a family of related flow charts
21	for hypertension measures? Because in some
22	cases, the evidence is going to be there for

	70
Page 1	. 19

1 African Americans but not for some other 2 ethnicity. How is it going to -- how are the 3 family of flowcharts going to relate to each 4 other?

5 DR. PERFETTO: Our point was just rather than just start with the outcome, the 6 7 hypertension outcome, it is thinking through 8 the context, as we were talking about earlier, 9 what is the problem. So maybe there is only 10 one population of hypertensives that you want to improve care for and zero in on them and 11 12 the others you may not need to because you don't have any indicator that there is an 13 14 issue there. Or you start with the one and 15 then you go to others. But you start with the 16 one where the problem is most significant. Ιt 17 is really articulating the problem.

DR. ADAMS: Okay, so one other comment and then we will wrap it up. But Al, thank you, because I think the flowchart is already serving its purpose. Because you are already seeing how it could be used in various

	Page 180
1	ways with implementation. So thank you.
2	And Ted you want to wrap it up for
3	us, please?
4	DR. GANIATS: Yes, I just have a
5	question. I would think of a PRO as an
6	outcome. I would think of blood pressure as
7	an intermediate outcome. I don't care about -
8	- I mean from a PRO point of view, I don't
9	care about blood pressure. I care about
10	stroke, heart attack, et cetera.
11	So the PRO is conceptually much
12	closer to what we are interested in it is
13	what we are interested than essentially all
14	the other performance measures.
15	DR. ADAMS: So on that closing
16	remark, I would like to once again thank our
17	reactor panel. And shall we give you a round
18	of applause? Yes.
19	(Applause.)
20	DR. ADAMS: Okay, so we are going
21	to move on to lunch. And then there have been
22	several topics that have percolated in

	Page 181
1	addition to our future direction. So when we
2	come back from lunch, we will be discussing
3	that and Patti will be leading that off.
4	And we will be coming back from
5	lunch at 1:00, so in 45 minutes.
6	(Whereupon, at 12:13 p.m., a lunch
7	recess was taken.)
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	Page 182
1	A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N
2	(1:03 p.m.)
3	DR. BRENNAN: Well, good afternoon
4	and welcome back to the last session.
5	So I have learned that as you go
6	through your career, in the beginning of your
7	career they ask you talk about the future of
8	a discipline. In the middle of your career,
9	they suddenly start asking you to give
10	retrospectives on your work. And when you are
11	at the end of your career, they put you back
12	into giving future perspectives again. So I
13	guess this is a sign that either I am at the
14	beginning of my career in quality out of
15	informatics or I am at the end of my career in
16	informatics, I'm not sure which.
17	I want to begin our last session
18	here today by actually doing a lot of the
19	things that we do often in the very last
20	minute and don't have a moment to reflect on
21	them, and that is to thank the staff and the
22	participants and the audience for the work

Page 183
that they have done to make this Patient-
Reported Outcomes Workshop so successful.
Please join me in a round of applause for
everyone here.
(Applause.)
DR. BRENNAN: Thank you everyone.
The double Karen or whatever we have been led
by have just been inspirational.
But I also want to thank each of
you who have given up time from work, each of
you who has children at home starting school
this week, giving up time from big family
events, to be here to work through this.
In our last hour, we have one last
piece of work to get done today and then I am
going to give you a brief overview of what to
expect. Over the next couple of days, if you
begin reflecting on a conversation you had
here and you have an inspiration or a
clarification, please send it to Karen Pace or
Karen Adams. They will be pulling together a
draft report based on our conversations, the

Page 184 1 background reports that were provided to the 2 meeting and the two workshops. That report will be written within the next month. 3 But if you have thoughts in the next couple of days, 4 5 please send them on. 6 There is also you received for 7 this particular meeting a background document 8 that was prepared by RTI. If you have any comments on this document, it would be 9 10 critical to get those here within the next couple of days to early -- at the latest 11 12 Monday or Tuesday because the authors of that 13 document will be taking that feedback and 14 making a final copy of that report. 15 There will be a call with the 16 expert panel, those of you who are in this 17 room, sometime before October 26th. That will 18 be before the report goes out for public 19 So you can expect to be hearing from comment. 20 Gene and the scheduling folks. 21 The comment period begins October 22 26th. Please, as you know, encourage your

1 constituencies to review the report and make 2 comments on it.

There will be a meeting with the 3 entire expert panel via a webinar after the 4 5 comment period closes. That webinar will be open to people, to the general public. 6 So 7 those of you who are in the audience and would 8 like to listen in to that presentation, you 9 will be able to hear that probably before 10 Thanksgiving it is likely that will happen. And then the final recommendations 11 12 are going to go to the CSAC on December the So there will be lots of work going on 13 10th. 14 in the background, lots of opportunity for 15 interaction. Your primary contact points are We need to leave them with 16 Karen and Karen. 17 some quidance and some instruction. 18 So I am going to ask everyone to 19 please pull out our colorful guide and box 20 here and we are going to review the

21 recommendations that were made in the previous 22 hour. If you have a pencil nearby, you might

	Page 186
1	actually want to update and mark up your
2	document. There will be a new document
3	circulated.
4	And then we will have a time for
5	discussion until about ten until two and then
6	we will start wrapping up the session. I
7	guarantee we have a hard stop at two o'clock
8	because I have a phone call, as well as some
9	of you.
10	So, thank you very much for the
11	panel right before lunch really gave us a
12	great deal of content to work with, as well as
13	commentary to work on. And we have several
14	adjustments. And so I want you take oh, I
15	can move these, can't I? I can't.
16	Please go to the next page. At
17	the very top of this diagram I want you to put
18	a black just a box that says box zero. Box
19	zero is what we are using as a placeholder
20	proposed to be the space where we would invite
21	the proposers of a new PRO-PM to explain the
22	motivation for it. Why is this happening now?

	Page 187
1	Is it opportunity? Is it clinical care
2	problem? Is it a sense of an absence of a
3	metric in the system?
4	So box zero is the first change
5	that we heard. You are not committed, even if
6	you are writing in ink. This is just I want
7	to bring you up to date to where we are with
8	our thinking about this. Next slide, please.
9	On the next slide, you will see in
10	box five that we have redlined the phrase
11	clinical practice and, instead, changed that
12	to be real world. What this means is to
13	clarify that we want before a PROM can
14	actually go through the evaluation process and
15	be applied to the criteria, someone has to use
16	it in the real world, where it is supposed to
17	be used. And if it is supposed to be used in
18	the clinical care setting, fine, then clinical
19	practice is fine but it might be a plan that
20	is using it. It might be a community that is
21	using it. It might be a large integrated
22	system. So it is not meant to imply that you

	Page 188
1	must use every prompt in a clinical care
2	service experience with a patient to have it
3	reviewed. It is meant to say you must have
4	real world experience with this, which then
5	leads us to what I am calling box five prime.
б	Next slide, please.
7	Just below box five, you should
8	make a small box called five prime and call
9	that fit for purpose. And I think that was
10	Rob's suggestion that we made sure we had a
11	point there where we figured out was this PROM
12	actually doing what we thought it would do?
13	Does it fit the purpose it was intended to do?
14	The last major change we heard in
15	the morning, if you go to the next slide,
16	please, is it goes at the very bottom of the
17	page, box 14. We are placing in there a
18	feedback, a box for feedback that probably is
19	going to have tentacles and arrows coming out
20	of it, going back into going back into
21	different parts of the process.
22	So now you see on your screen and

	Page 189
1	you see in front of you. And if the audience
2	at home is following, on your papers you
3	should see a slightly revised pathway that
4	will help the NQF create a systematic way to
5	start examining PROS and taking into the
6	process of PROMs and get up to the PRO-PM.
7	Our responsibilities in the next
8	half hour, 40 minutes are to look hard and
9	think hard and talk actively about this
10	document. We would like to get, if possible,
11	to a point of consensus for the staff, not
12	specific to individual words, maybe a box
13	would be bigger or smaller, but a conceptual
14	consensus that this is a pathway that we
15	believe as a group will be useful for going
16	from a PRO to a PRO-PM.
17	And so it will take a few minutes
18	of conversation. Now you had two sets of
19	conversations already to talk about whether
20	the current criteria for approval need to be
21	modified for the PRO-PM process. And the
22	sense that I got there was a lot of interest

1	
	Page 190
1	in making clear the importance criteria number
2	one wasn't as much consensus around other of
3	the three criteria what changes need to be
4	made for the PRO.
5	But I would like you to reflect
6	for a moment about the discussions you sat in
7	and about the idea of what must be or should
8	be considered for modification to ensure that
9	the criteria the NQF uses to approve the PMs
10	is not going to present an unusual or
11	insurmountable barrier for the patient-
12	reported outcome.
13	And I will take comments and I see
14	that Dave is ready for a comment. Okay, Dave.
15	DR. CELLA: Well, this comes back
16	to the first thing I said this morning. So it
17	is kind of like repeating myself but in the
18	context of this flowchart.
19	I think it is great. It is great
20	to put all these things down on paper. But
21	then to me the question is how will it be
22	used. How will it be applied? If it gets

	Page 191
1	applied strictly, nothing will ever pass. You
2	can always find a way to say something is not
3	ready. So there are several points along this
4	continuum where a reviewer could say this
5	doesn't make it. This doesn't make it.
6	So it is possible to use this
7	diagram to reject everything.
8	DR. BRENNAN: So we would like
9	this diagram to be an enabler. So based on
10	Dave's comments, would you take a look through
11	here and just right now circle or place a
12	checkmark about where you think this pathway
13	might be particularly vulnerable to a
14	capricious or perhaps non-supportive response
15	by reviewers so that no PRO ever gets through.
16	Because I am going to take some time in a few
17	minutes to ask you what is missing. And it
18	might be what is missing is where the judgment
19	calls. Where is the point that we need to
20	have risks. So I think your point is very
21	well taken.
22	So take a look through here and

	Page 192
1	just mark off on the box or jot some notes for
2	yourself about do you see a point of risk
3	where in too rigid or inappropriate
4	application of one of these boxes or of the
5	commentary, remember that is on the second
6	page that might help you understand that might
7	make a PRO particularly vulnerable.
8	Other opening comments for now?
9	Yes.
10	MS. TORDA: It just strikes me
11	that for broader use really being more
12	explicit about the criteria for a PROM and the
13	criteria for a PRO-PM and how they relate
14	would be useful. Because I think we were
15	continually have to explain it to ourselves.
16	And if we had to explain it to ourselves,
17	being more explicit about it would be a good
18	idea.
19	DR. BRENNAN: So that would be
20	occurring in boxes 10, 11, and 12 or 10 and
21	11, I guess.
22	MS. TORDA: Well or even when you

Page 193 are selecting --1 2 DR. BRENNAN: Oh, no. I see. 3 MS. TORDA: -- the PROM that you 4 are looking for and then how you are using the 5 PROM and then how you are turning the use of the PROM into a performance measure. 6 7 DR. BRENNAN: Yes, Karen? 8 DR. PACE: I was just going to say 9 the second note page unfortunately the number 10 boxes that those notes go with got left off. But we can do more work there to make that 11 12 distinction to clarify what characteristics go with selecting the PROM versus the PRO-PM if 13 14 that is useful. 15 DR. BRENNAN: Would it be possible 16 for someone to state what the PRO-PM might 17 look like so we are all on the same page with 18 that? So we have heard about PROMs. We know 19 that here is various phases to depression or 20 hypertension. But a performance measure, does 21 somebody feel energized by lunch? 22 MS. PITZEN: Hi, it's Collette

Page 194 from Minnesota. 1 2 A performance measure would be depression remission at six months. 3 So the outcome is having that remission event 4 5 occurring at a certain point in point and the 6 PROM is the PHQ-9. 7 DR. BRENNAN: Okay. Would you put 8 like a threshold like 100 percent of the 9 patients demonstrate depression remission at six months? 10 MS. PITZEN: No. 11 12 DR. BRENNAN: Isn't the measure 13 the percentage of patients? 14 MS. PITZEN: Correct, it is the 15 percentage of patients that achieve remission at six months. 16 17 DR. BRENNAN: So no threshold, 18 just the statement of the percentage. Okay. 19 MS. PITZEN: Correct. 20 DR. BRENNAN: Okay. All right so 21 22 MS. PITZEN: Could I back up and

	Page 195
1	add a comment of just something that would be
2	prohibitive, especially in this measure but
3	maybe for measures going forward?
4	The requirement to have a process
5	measure endorsed before you are going to that
6	outcome measure. I think it is very important
7	to have those processes in place but it is
8	almost like it is supportive of having the
9	outcome that you desire.
10	DR. BRENNAN: So I think that what
11	Karen is saying is that under box five prime
12	that we added, you really should have, those
13	are two pathways that could occur
14	simultaneously. But what you are recommending
15	is that they be made explicitly simultaneously
16	so there is not a dependency from one to the
17	other.
18	MS. PITZEN: I missed part of a
19	discussion this morning. So my apologies.
20	DR. BRENNAN: That's fine. And
21	someone had also suggested that we actually
22	might want to you might want to even invert

	Page 196
1	the green and orange box so that you do one
2	first and then the other. But the issue
3	clearly this diagram was not meant to imply
4	that you must go through the process before
5	the outcome.
6	Yes?
7	MS. DUBOW: Are we saying or
8	Collette did you say we have to have a process
9	measure before we can have an outcome measure?
10	DR. BRENNAN: No, she wanted to be
11	sure we didn't have to.
12	MS. DUBOW: Oh. Oh, that's fine.
13	I'm sorry. I misunderstood. Thank you.
14	DR. BRENNAN: Yes.
15	DR. PACE: I just want to clarify.
16	That was not the intention and we can fix the
17	diagram but the idea was that you could go
18	directly to an outcome measure but in some
19	cases you may want to consider the process
20	measure.
21	So we obviously need to make that
22	very clear on the diagram and we will work on

	Page 197
1	that. But I don't think the intention was
2	that it has to go through that pathway.
3	DR. BRENNAN: Right. And once
4	things get immortalized on a website, though,
5	they can be complicated.
6	Jack, yes please.
7	DR. FOWLER: This, I guess, has to
8	do with box 11. And we talked a little bit
9	about, I mean we talked off and on what
10	validation of this performance measure looks
11	like. And when Anne Deutsch was talking
12	yesterday afternoon, I think she was the one
13	that put up an example of saying if you had
14	some practices that you thought were exemplary
15	and then some practices that were usual care
16	and you could demonstrate a difference but
17	that would be an example of validity
18	information.
19	But I think it should be clear.
20	And again I can't see how you could get
21	evidence of validity without at least having
22	practices that varied in what they did in some

	Page 198
1	ways that you thought were credible that in
2	fact had different outcomes on your measure.
3	You know, we have talked around
4	about whether that was really essential or
5	not. And I just find it hard to believe that
6	if you have got an outcome that you want
7	practice to change, that you don't need an
8	example of several practices that behave
9	differently, that get different outcomes.
10	Because that is all I could believe would
11	constitute valid evidence that the way you
12	practice medicine could affect the outcome
13	that you are after.
14	And maybe you don't need to
15	elaborate on what that means but
16	DR. BRENNAN: So let me just
17	restate it. We are taking all comments right
18	now. And so I think that if I am
19	understanding you correctly, what you are
20	saying is for box 11 where there is the
21	performance measure should be tested for
22	reliability and validity, you are suggesting
	Page 199
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1	that that be made explicit on the level of
2	practices that we show variability across
3	practices and variability in what they do as
4	well as the outcomes they achieve.
5	DR. FOWLER: That's right.
6	DR. BRENNAN: Okay. And so that
7	is it. That is an example of how one might
8	demonstrate that kind of a test. That is
9	helpful.
10	Yes, John?
11	DR. WASSON: Two comments; first
12	is on Jack's comment.
13	What we also heard though earlier
14	today is that in some cases that would be the
15	highest level, I guess. And then there might
16	be a lower level, which is this is something
17	that is so important to measure for patient
18	reasons, et cetera, that although we need a
19	lot of validity and reliability criteria, so
20	to speak, we may not have an intervention that
21	is going to show an effect yet.
22	So I don't know if we want to

Page 200 1 throw those out but at least they might be at 2 a different level. DR. BRENNAN: 3 If I can say that 4 back to you, what you are suggesting is that 5 there may be PROs, there may be concepts that we want to assess the performance of a 6 7 practice on, that we don't have any way of 8 intervening with right now. And someone brought up the idea of fatigue and chemo. 9 And 10 those of you who are really good a fatigue and chemo, I am sorry if I underspecified that 11 12 one. And so it may be appropriate to include as another kind of validity evidence the fact 13 14 that practices or groups of patients or plans vary in terms of this PRO, in terms of this 15 16 phenomenon, not that the care leads to changes in the phenomenon. 17 18 At this time. DR. WASSON: 19 DR. BRENNAN: Okay. So you are 20 arguing in a broader sense to a higher level -21 - I'm sorry -- various approaches to validity 22 evidence.

Page 201 1 DR. WASSON: Yes, and 2 intermediate. And then because Helen didn't 3 4 laugh at me for this last comment, I feel free 5 to bring it out. DR. BRENNAN: 6 Okay. 7 DR. WASSON: And you can blame 8 Helen for doing it. 9 DR. BRENNAN: All right. 10 DR. WASSON: Number 14, your feedback. 11 12 DR. BRENNAN: Number 14, yes. 13 DR. WASSON: Yes, I was suggesting 14 to Helen, she didn't laugh, that I really 15 think it shouldn't be just feedback. Ιt 16 actually should be sunset. That every measure 17 at the end of a three-year cycle automatically will sunset unless there is positive evidence 18 19 that it is the best of the current measures or 20 that it has good evidence that it should be 21 continued. Because otherwise, we are going to 22 proliferate ourselves to death or kill our

	Page 202
1	patients.
2	DR. BRENNAN: We are going to have
3	a million measures.
4	DR. WASSON: yes.
5	DR. BRENNAN: Yes. Helen is not
6	really laughing just yet but she is into a
7	work mode up here.
8	So I heard a friendly amendment to
9	box 14 that we expand the concept of feedback
10	to include such things as earlier today there
11	was a mention of post-market surveillance and
12	now John is suggesting that we actually have
13	a hard stop on all measures over a set period
14	of time, or at least a reevaluation of the
15	continued value of the measures. I think that
16	is reasonable.
17	I would like to ask you, is that
18	unique to PROs or is that for all of the NQF
19	indicators and PMs?
20	DR. WASSON: I don't think anyone
21	should be automatically exempt.
22	DR. BRENNAN: Okay. You can tell

Page 203 1 you are in this business. 2 DR. WASSON: Yes, because the 3 market is going to -- I mean we really are going to change in our knowledge over the next 4 5 X number of years. 6 DR. BRENNAN: Okay. I mean I 7 think that will come for consideration and we will see when it comes out of the staff mixer 8 what it looks like at the end but I think we 9 10 have got a pretty clear documentation of it. And I personally actually like it very much 11 12 because we are, at the university, overassessed right now to the point if one more 13 14 person puts a yardstick up next to me, I will 15 spit on them. 16 Yes, Kathy? 17 MS. PITZEN: This is Collette. Ι 18 am probably oversimplifying but part of the 19 maintenance endorsement for the NQF measure is 20 you have to demonstrate that your measure is 21 still valuable and that there is variability 22 among the people that you are measuring and

	Page 204
1	that there is still opportunity to improve.
2	So I am a little bit opposed to the automatic
3	sunset setting. And I know Phyllis had a
4	comment as well.
5	DR. BRENNAN: And it sounds like
6	you have some knowledge about the process that
7	I don't that says there might be a mechanism
8	built into that already.
9	We are all not accepting John's
10	idea of no tenure. We are just including it
11	as part of the comment.
12	Kathy. Oh dear, you need longer
13	arms. There is a quality performance measure
14	going on up here; stretch the guest.
15	DR. LOHR: On the sort of box 14,
16	I don't know if you could take a page from
17	what the National Guidelines Clearinghouse
18	does but guidelines are essentially dropped if
19	they are not updated and otherwise some step
20	done to ensure that they are still, if you
21	will, valid and all up to date every five
22	years.

	Page 205
1	So I think three years and
2	sunsetting might be too soon.
3	DR. BRENNAN: Okay.
4	DR. LOHR: But a five- or six-year
5	window particularly because you are looking
6	for you are giving PROs at least or PRO-PMs
7	up to six years to be used in accountability
8	applications and so forth.
9	So conceptually, I think the
10	sunsetting idea might be a good one. Three
11	years I think is too short a term. And there
12	are models out there for what one might do to
13	sort of help with, if not sunsetting, at least
14	updating.
15	My other question, though, is your
16	bottom 10 through 13 or 14 are all orange or
17	will be orange. But I thought that everything
18	up through 12 is essentially the
19	submitter/developer's responsibility and that
20	13 and perhaps 14 will be NQF's responsibility
21	and the developer sort of disappears.
22	So should 13 and 14 be a different

Page 206 1 color or a different part of the whole thing? 2 DR. BRENNAN: I think that would 3 actually just make the display useful. it may be as the staff is redoing the display. 4 5 Because remember, this started with Eleanor's 6 doodle. So we have come a long way from 7 Eleanor's doodle. But I think what Kathy is 8 saying is that actually box 9 and 13 --9 DR. LOHR: Yes, and nine. 10 DR. BRENNAN: -- are part of the 11 NQF internal process. 12 DR. LOHR: Yes, and everything else belongs external to NQF because it is the 13 14 developer people and current users and so forth who are going through this whole process 15 and then finally submitting something and then 16 17 NOF does its thing. 18 DR. BRENNAN: Right. That is 19 really very helpful. 20 Other comments at this point? 21 Okay, now we are going to come to the 22 interesting part of the conversation. Look

1	
	Page 207
1	carefully at either your modifications or the
2	boxes here having heard the kind of changes
3	likely to come, so lines will move and there
4	may be 12 boxes instead of 14, but essentially
5	we are looking at a process.
6	And let us know if there is
7	anything that you absolutely cannot live with.
8	And this is the point in time to go back to
9	thinking about where are the trickster spots
10	that could actually capriciously kill
11	basically good measures because they have got
12	some weird performance.
13	Kathy and then the back table with
14	
15	DR. LOHR: This is just really a
16	question. But is there a possibility of
17	having list A and list B of a lot of these
18	criteria such that some would be utterly
19	mandatory and others more desirable
20	DR. BRENNAN: Okay.
21	DR. LOHR: and might move a
22	measure along more quickly or something like

	Page 208
1	that. But to me, this is a lot of criteria
2	that have to be met simultaneously with a lot
3	of data and maybe a lot of landmines, given
4	ten or 15 or 18 or so criteria. And there
5	might be some way of trying to say some are
6	just absolutely utterly required and others
7	might let us discriminate among or across
8	similar PROs or PROMs or so forth, instead of
9	having absolutely everything be completely
10	required.
11	DR. BRENNAN: Okay.
12	DR. LOHR: And it is a question.
13	DR. BRENNAN: That is really a
14	helpful question. Let me ask Karen or Karen.
15	It seems to me that that is consistent with
16	the evaluation criteria already. Yes, you
17	want to just comment on that for a minute?
18	DR. ADAMS: I mean, Karen, you can
19	speak to it. But what came to mind to me was
20	the NQF criteria around importance. It is a
21	must pass.
22	So if the measure is not deemed

Page 209 1 important and a lot of this tied into our 2 meaningfulness and naturally scientific, et cetera evidence, that you don't get pass go 3 for that. So I think it is looking through. 4 5 Some of the comments that came back from the survey when we were looking at 6 7 the characteristics mentioned this and I think 8 it builds on what David said that nothing 9 could beat every criteria. So we want to be 10 careful. So which one of these, when I was 11 12 thinking about this, some of these are very 13 helpful guidepost, and it is what we hold true 14 and where we want to go and other things are 15 hard and stern as I think you are saying and 16 additional guidance there would be helpful. 17 DR. BRENNAN: Additional quidance 18 like you would like some recommendations for 19 that now or over the next couple of months you 20 would like people to be thinking about it? 21 DR. PACE: Right, I think there is 22 more flexibility in those characteristics of

	Page 210
1	choosing the PROM and this pathway. But in
2	terms of NQF criteria, as Karen Adams was
3	saying, you know, measures have to meet our
4	criteria for importance to measure and report
5	for scientific acceptability and measure
6	properties. Usability or feasibility and
7	usability in use are more judgment calls to a
8	certain extent.
9	So I don't think we want to say
10	that. I mean we have heard a lot of
11	indication that maybe we want to be stricter,
12	I don't know that we would want to eliminate
13	NQF criteria. But I think there is definitely
14	flexibility in this pathway and also in
15	choosing those PROMs.
16	DR. BRENNAN: There is a comment
17	in the back. Is your comment directly related
18	to the Karen conversation? yes, go ahead
19	please and then Ted.
20	MS. DUBOW: I just wanted to make
21	the observation that this pathway provides
22	useful technical assistance, as opposed to

	Page 211
1	being a set of an NQF requirements. The way
2	the evaluation criteria are, for example,
3	where those are criteria that need to be
4	addressed.
5	This pathway to me suggests to
6	developers, measure developers and to
7	everybody else in the process what we think
8	needs to be wrapped into this process and it
9	provides it's useful. And I'm concerned
10	about eliminating anything in order to come up
11	with something that looks more palatable if we
12	don't bless it with the notion that this is a
13	mandatory set of must do every item kind of
14	thing but rather to suggest that indeed it is
15	a pathway. I just don't want to lose the
16	useful guidance that we have spent so much
17	time thinking about.
18	DR. BRENNAN: So if I can
19	summarize what Joyce is saying. Your hope is
20	that the pathway serve as a model for
21	proposers to know how to go through the
22	process and that we not mandate or become

Page 1 rigid about the many pieces of it but simply 2 say this is a pathway. You need to follow 3 this. If you have got to make a change, you	ge 212
<ol> <li>rigid about the many pieces of it but simply</li> <li>say this is a pathway. You need to follow</li> <li>this. If you have got to make a change, you</li> </ol>	
<ul> <li>2 say this is a pathway. You need to follow</li> <li>3 this. If you have got to make a change, you</li> </ul>	
3 this. If you have got to make a change, you	
4 need to explain why you are skipping	
5 something.	
6 Okay, actually both of you can	
7 speak, that's fine. And then we will come up	þ
8 to Ted here.	
9 DR. PAWLSON: On this point.	
10 DR. BRENNAN: Greg is speaking.	
11 Sorry.	
12 DR. PAWLSON: Greg Pawlson. On	
13 this point, I think the issue that we are ki	nd
14 of grappling with here is not whether I don'	t
15 think whether these criteria are the right	
16 criteria but providing, especially in a new	
17 area like this, more guidance than usual on	
18 precisely what each of these mean and how fa	r
19 we expect the review panel to go.	
20 Because in the scars that I have	
21 accumulated from the NQF review process, whi	ch
22 I have to say have gotten much more refined	as

	Page 213
1	time has gone on. So I really want to
2	acknowledge that but this is a new area. And
3	what we don't want is somebody coming in and
4	saying oh, well that means you have got to
5	have absolutely everything in the reliability
6	thing absolutely nailed, you have got to have
7	I already used in 500 different practices,
8	because that will never happen because it
9	often takes NQF endorsement to get some people
10	to use the measure widely enough.
11	Now that doesn't mean you can't
12	test it in a couple of sites but I think
13	really making sure that the review panels
14	understand these are going to be new, they
15	haven't been broadly most of them have not
16	been broadly used as yet, at least in this
17	country. If we are going to take evidence
18	from Britain and Sweden we might do better.
19	But I think it is the degree to
20	which these and I would see especially
21	number five and number 11 as being potential
22	huge stumbling blocks if they are

Page 214 1 misinterpreted or over-interpreted. And it 2 doesn't mean that those criteria shouldn't be in there but it does mean that I think the 3 review panel is going to need some very clear 4 5 instruction on how to balance. And it always I mean everybody who is in the room who 6 is. 7 has been on a review panel knows that good a 8 review panel is always balancing off how 9 important is this, how critical is this to get 10 forward, and can we come back. And I don't know whether you are planning to have 11 12 provisional approval of this or at least the option of saying we passed this but we are 13 14 going to actually review it in a year and you need to come back with additional evidence. 15 16 DR. BRENNAN: So Greg is calling 17 for some judgment throughout but actually 18 raised a brand new point which I am going to 19 ask Helen to address. Which is, in the 20 process after box 14 -- or rather maybe I 21 guess it is in box 13 when NQF makes the 22 endorsement -- is it feasible, is it possible

	Page 215
1	to consider a provisional endorsement. Like
2	we will endorse this for a year and then you
3	have got to come back?
4	DR. BURSTIN: This is a complex
5	issue.
6	DR. BRENNAN: Sorry about that
7	Helen.
8	DR. BURSTIN: So essentially we
9	have a very, very limited applicability for
10	untested measures coming through our process
11	which might be what people think of as
12	provisional. We don't allow it for outcomes
13	actually because I think outcomes are
14	something, frankly, that need to be tested
15	before they come in.
16	However, one of the things we have
17	been experimenting with, we have a pilot right
18	now, is actually trying to create a two-stage
19	endorsement process. So for some newer areas,
20	we probably may need to consider bringing in
21	the measure concept first, understand a
22	measure concept, the importance around the

	Page 216
1	concept and then allowing the measure to go
2	back out and get fully tested and blessed.
3	So I think there are different
4	approaches here. And again, just as an
5	interesting point, on the Minnesota measure
б	around PHQ-9, there were a lot of concerns
7	about the lack of risk adjustment, for
8	example, that there was no risk adjustment as
9	part of that measure. And there was an
10	understanding this was important enough. Put
11	it out there. We will learn. We will add
12	that in as it goes forward. So I think it is
13	important to also note that measures are
14	iterative and we recognize that and we are
15	happy to take updates to measures as they go
16	out in the field and we learn. It is really
17	through implementation that we gain a lot more
18	understanding of these measures.
19	DR. BRENNAN: So one of the things
20	that Helen has introduced is a possible
21	intermediate step, which I might call three
22	prime that would happen before a lot of work

	Page 217
1	went on the field, which is getting to
2	understand the concept early on. So there
3	might actually be yet another box added in.
4	Did you have another comment to
5	make, I'm sorry, Barb?
б	DR. GAGE: Yes, I was just going
7	to raise the concern, and I think it has been
8	hit upon in solutions in different forms, is
9	that it is an iterative process in getting
10	anything through. You don't want to make it
11	too tight or you won't be able to get to the
12	final points.
13	DR. BRENNAN: Excellent. Ted, you
14	have been patient.
15	MR. ROONEY: I pretty much want to
16	amplify what Greg said because the number
17	five, I mean if you want to do a new measure
18	on clinical data or hemoglobin A1Cs or BPs or
19	cost of care, there is a wealth of existing
20	data that you can get access to the model but
21	there doesn't exist a lot of the data that we
22	want to test with outcomes. So as long as

	Page 218
1	five is seeing that you are not going to have
2	all the data, testing validity and
3	reliability, and all these different
4	population segments because you don't do it,
5	it doesn't exist. So that is where I think
6	you get really tripped up if someone starts
7	comparing this.
8	The other quick comment was that
9	again I live in the world of both improvement
10	and accountability and Gene came over, Gene
11	Nelson came over to us a year ago to really
12	talk of PROMIS. We had huge excitement for it.
13	We cannot get one PCP practice to even test it
14	because they are so overwhelmed right now.
15	But whereas if you told me if I
16	can go back and say, look, this is going to be
17	an accountability measure in a year, I have
18	more practices that I could handle to do it.
19	So that is the thing, if it makes
20	it too hard to get to an accountability
21	measure, it will never happen or I would be
22	afraid it would never happen.

Page 219 1 DR. BRENNAN: So I heard two 2 things in what you are saying and I want to make sure I got them correctly. The first one 3 was there is a great absence of test data. 4 And so maybe one corollary activity might be 5 6 to think about how a test bed of data could be 7 developed that would allow people to begin to 8 test measures. And the second is that in the 9 absence of a mandate for action and in the 10 test bed, the clinical engagement is really tough. Did I get that? 11 12 MR. ROONEY: Yes, and that is only a problem then if you need the clinical 13 14 engagement to then approve it. 15 DR. BRENNAN: Right. 16 MR. ROONEY: So it becomes circular. 17 18 Yes, I got it. DR. BRENNAN: 19 This gentleman and then over here. 20 I'm going to call you Mike. Yes, sir? I know 21 it is not Mike you just look like a Mike to 22 Jim. me.

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1	DR. BELLOWS: Hi, this is probably
2	such a simplistic observation that it is not
3	worth saying. But to me the boxes in green
4	and the boxes in orange are incredibly
5	similar. And actually the more we talk about
6	it, it seems like they are almost the same.
7	There is stuff in green about it has to be
8	well-specified and there is stuff in orange
9	about case-mix adjustment and so forth. But
10	actually both of those things go in both of
11	those boxes. So I wonder if we might want to
12	just simplify it all by not repeating the
13	green boxes and the oranges boxes.
14	And then for people who are just
15	scared by the number of boxes on the page,
16	there wouldn't be as many boxes.
17	DR. BRENNAN: One of the things
18	that I have learned that is really important
19	when you read an NQF document is to read the
20	notes. So this might be arguing for fewer
21	boxes, more notes, maybe. That is good. That
22	is very helpful. Yes?

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1	MS. TORDA: To go back to the
2	kinds of other tests or the data that you
3	threw out, I think we need to be clear. It
4	needs to be data that was collected for non-
5	research purposes.
6	DR. BRENNAN: Yes.
7	MS. TORDA: And what might be even
8	more useful is somehow to identify sites that
9	are actually using the PROM so that we would
10	know where to go for testing, as opposed to a
11	test bed of data.
12	DR. BRENNAN: I see. I see. So
13	one of the things that you would find helpful
14	is during the process of building up through
15	box one, two, three, four, five, it would be
16	useful to have some public list that you could
17	refer to. So if a site in Maine is working on
18	something you might collaborate with them.
19	The second thing I heard is that
20	data collected from real world people in a
21	real world activity is really scarce and
22	important.

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1	MS. TORDA: Yes.
2	DR. BRENNAN: Okay, I am going to
3	go to the phone for just a moment, please. I
4	understand we have a comment or a question.
5	OPERATOR: At this time, in order
6	to ask a question press * then the number one
7	on your telephone keypad.
8	Again, to ask a question, press *
9	then the number one on your telephone keypad.
10	DR. BRENNAN: Well, all right.
11	OPERATOR: At this time, there are
12	no questions.
13	DR. BRENNAN: Thank you so much.
14	Okay, we are going to come back to
15	the room here. We have been talking about
16	what you can't live with. And what I am
17	hearing in the tenor of the conversation is
18	people can't live with rigidity. There needs
19	to be judgment, maybe there needs to be some
20	use cases that demonstrate various types of
21	PRO-PMs that come through and where their
22	evidence will be presented and how they would

Page 223 1 be treated in this model. 2 Anything else -- and somebody doesn't like the green and orange being 3 4 separated. I got that. 5 Anything else? It's a show stopper. It is just going to be not a good 6 7 thing. Yes, Ted? 8 DR. GANIATS: I think this is sort of obvious, at least to me, but I haven't 9 10 heard it explicitly stated. Most, if not all, performance measures come from a guideline. 11 12 There is a quideline that states X should be done. We are de novo creating criteria for a 13 14 performance measure and have nowhere stated 15 that it should be from a guideline or that there should be evidence that it should be --16 there is evidence that it makes life better. 17 18 And I just think it is a little 19 late to work through all of that but it is 20 something for NOF to think about. You know, 21 just because it is a patient-reported outcome 22 doesn't, by itself, mean it is good fodder for

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1	performance measurement.
2	DR. BRENNAN: Very, very important
3	point, Ted. And Karen is going to respond to
4	that. Karen Pace.
5	DR. PACE: Just a clarification.
6	NQF does not require that for endorsement that
7	something be identified in a guideline. Our
8	criteria is about evidence. Many guidelines
9	are evidence-based but what we are really
10	interested in is the evidence behind a
11	guideline a recommendation and that evidence
12	doesn't have to be connected to a guideline
13	recommendation.
14	I think the whole discussion we
15	had here about actionability really relates to
16	that evidence. What you are saying and many,
17	that we have right now in our criteria that
18	health outcomes don't have to present a whole
19	body of evidence because they are kind of
20	evident on our face that we should measure
21	those. I think what we have heard here is we
22	want some evidence of actionability, which

	Page 225
1	really gets that again, is there is evidence
2	that there are interventions that affect the
3	PRO.
4	And again I think in this
5	discussion someone brought up again some
6	flexibility because there may be PROs just as
7	health outcomes that by measuring it we will
8	hopefully stimulate improvements. But I think
9	that is a judgment call.
10	But I think we have heard pretty
11	loudly about looking this actionability,
12	especially at the start of this endeavor.
13	DR. BRENNAN: Yes, Kathy and then
14	Ted.
15	DR. LOHR: Another question back
16	to the pathway. If I were a developer or
17	wanting to do something to develop a PRO that
18	would be a PROM that would eventually get
19	submitted, is the implication here that
20	somehow or other I have to start de novo with
21	boxes one and two? Or is there a possibility
22	that I can take something that I have been

	Page 226
1	working on for the past ten years, has a lot
2	of information behind it, I can pull together,
3	if you will, proof that I did the things that
4	I was supposed to do in box zeros, one and
5	two, and short circuit both in time and effort
б	some of what this implies would otherwise
7	would need to be spent? And can people start
8	with three?
9	DR. BRENNAN: I understand what
10	you are saying. I think what you are asking
11	for is to have boxes one, two, and three, be
12	able to be operationalized in any order. And
13	so I think that is a very interesting, very
14	reasonable suggestion because there may be
15	really, really good PROMs that haven't had
16	enough patient input that get some patient
17	input. There might be things that have had a
18	lot of patient input but are fairly long down
19	the track.
20	DR. LOHR: Right. And if I can
21	prove to you that I have done a decent job
22	with one and two, maybe then I can just go

Page 227 1 ahead with three. 2 DR. BRENNAN: This speaks well, though, to what one would consider proof or 3 evidence, whether it is done de novo or it is 4 5 historical. And I think that is very 6 important guidance. Ted? 7 DR. GANIATS: Yes, just in 8 response to Karen. Thank you for making me 9 relax and feel better and for causing me to 10 get quite nervous. 11 (Laughter.) 12 Boy, is she a DR. BRENNAN: 13 powerful woman. 14 DR. GANIATS: The first part regarding evidence I am just ecstatic and you 15 can see me dancing with excitement. 16 17 On the other hand, I really don't like the other statement. I think that the 18 19 performance measure or a measure that is 20 supposed to go through the NQF should be a 21 measure that is supposed to assure quality or 22 assess performance or something like that.

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1	For an NQF measure's purpose to be to be an
2	intervention that is going to improve quality
3	is something that I think we would have to
4	talk long and hard about because I mean you
5	said, gee whiz, maybe this measure would get
6	people to do things better. I think that is
7	an intervention in the practice and,
8	personally, I didn't know that was part of
9	NQF's charge.
10	DR. BRENNAN: Helen?
11	DR. BURSTIN: It's not part of our
12	charge, per se, Ted. I think it is just as we
13	have gone through, particularly the issues
14	around evidence, with our Board. And this is
15	a multi-stakeholder group. We get a lot of
16	different perspectives. It is what makes NQF
17	very special.
18	You know we have heard clearly
19	from consumers and purchasers in particular
20	that there are clear instances where outcomes
21	have been put out there. We don't always know
22	what the right intervention is. And that by

	Page 229
1	putting it out there, publicly reporting on
2	it, interventions begin to emerge.
3	So I think it is circular. It is
4	not something linear. I think there is
5	something about the process of public
6	reporting, the process of learning about an
7	income that then leads to interventions, that
8	leads to I mean the classic example people
9	give is the public reporting on central line-
10	associated blood stream infections, which
11	actually in fact preceded a lot of the actual
12	interventions of what to do.
13	There are other examples like
14	that. It is not part of our charge but I
15	think we have to recognize that quality
16	measurement and improvement is iterative. And
17	we hope it is. And in fact, if putting some
18	of those outcomes out there drives some of
19	that improvement, I think that is a reasonable
20	hypothesis.
21	DR. GANIATS: Quality improvement
22	might be iterative but accountability, it just

Page 230 1 makes me nervous to have an accountability 2 measure whose role it is to --3 DR. BRENNAN: Albert is going to fix this for us. Right? 4 DR. WU: Okay, Ted, I'm going to 5 fix you. 6 7 DR. BRENNAN: Uh-oh. 8 DR. WU: No. It does seem to me 9 that there are a number of sort of 10 aspirational outcomes. Okay, I'm worried 11 DR. BRENNAN: 12 about those already at other tables in this 13 place. So, yes. 14 DR. WU: No but I think that 15 insisting on accountability in three years or 16 five years or whatever for those measures, 17 particularly if all the processes aren't 18 specified is overreaching. But if there were 19 sort of a different -- since outcomes are 20 different, if the goal were simply to reduce 21 pain in cancer or whatever it winds up being, 22 to relieve dyspnea in chronic obstructive lung

1	
	Page 231
1	disease, I wouldn't insist that that be an
2	accountability measure in the immediate
3	future. Maybe you get a longer time period.
4	This is the sort of thing that would drive
5	innovation, as opposed to pull people up to
6	speed.
7	DR. BRENNAN: That is helpful.
8	Well we have gone through the
9	things you can't live with and we have moved
10	a little bit into the things that you would
11	like to see added to at least the
12	interpretation and application of this
13	pathway. I want you to take one last look
14	through it and see if there is anything that
15	is unspecified or under-specified that you
16	believe would be important to include in this
17	pathway and our guidance about it to the NQF
18	staff.
19	Yes, is that Lewis?
20	DR. KAZIS: Hi.
21	DR. BRENNAN: He looks like a
22	Harry to me but I didn't want to say that.

Page 232 1 Go ahead, Lewis. 2 DR. KAZIS: Sorry? 3 DR. BRENNAN: I re-baptized you. 4 DR. KAZIS: Oh. So this goes 5 along the lines of a box 14 again. And in 6 addition to the concept of sort of a continued 7 endorsement or recertification after a couple 8 of years, perhaps to have something along the 9 lines of on an annual basis to provide an 10 annual update. DR. BRENNAN: Yes, I think that is 11 12 part of the process now. 13 DR. KAZIS: Okay. 14 DR. BRENNAN: So users of the PMs 15 have to state what they are doing. 16 DR. KAZIS: Right and then maybe a recertification beyond that. 17 18 DR. BRENNAN: Yes, okay. 19 Excellent. But making it explicit that there 20 is a public trail. That's good. 21 Anything else under specified/ 22 unspecified? Yes, Mike -- no it's Jim, I

Page 233 1 know. 2 Well I made this DR. BELLOWS: point earlier but I would love to see the word 3 harmonization somewhere on the second page. 4 5 And I know it exists elsewhere in the NOF stuff but with respect to it being 6 7 particularly important for stuff that we 8 introduced into the system, I would love to 9 see that word stuck in in some appropriate 10 place and there is many appropriate places but we could figure it out. 11 12 We spend too much DR. BRENNAN: time at ONC harmonizing standards for me to 13 14 really want to see that word ever again in my But what I would like you to be a 15 life. little bit more specific and say if what you 16 are meaning is that apropos of the discussion 17 18 earlier of one measure/multiple measures, you 19 are suggesting that we make explicit the need 20 for if there are multiple measures that there 21 be harmonization of some type. 22 DR. BELLOWS: That is correct or

	Page 234
1	maybe it also relates back to box zero, which
2	is what is the reason we are doing this. And
3	if we are just doing it because there is
4	another measure out there somebody wants, then
5	you could write that in box zero but whoever
б	is reviewing then measure might say is that an
7	adequate. But then if there is multiple
8	measures, then the harmonization kicks in.
9	DR. BRENNAN: So harmonization
10	explicitly. That's great. That's good.
11	Anything else underspecified/unspecified,
12	translated into three languages? Kathy.
13	DR. LOHR: I am not sure whether
14	folks would agree but to me it is still a
15	little unclear whether you are expecting
16	developers, when they have submitted a PROM to
17	have not only indicated whether risk
18	adjustment is needed for X, Y, or Z
19	applications but also specify anything about
20	the method for risk adjustment. I am not sure
21	that that is clear in here that all those
22	sorts of pieces of information would be needed
	Page 235
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1	as well.
2	And I have some question in my
3	mind as to whether PRO developers would
4	necessarily have all the right information to
5	say do your risk adjustment this way rather
6	than that way. Or whether just saying the use
7	of this across for accountability maybe not
8	so much for internal quality improvement but
9	across sites or across plans, you are going to
10	have to risk adjust and leave it unspecified
11	as to how. That is a question.
12	DR. BRENNAN: Okay, so the
13	question is do we need to require that the
14	proposer make explicit whether risk adjustment
15	is needed and how to do it.
16	DR. LOHR: And how, yes.
17	DR. BRENNAN: Or is it acceptable
18	for them to give a nod to it must be there but
19	no specific plan. And Karen is going to make
20	a comment about that.
21	
22	DR. LOHR: And then I have one

Page 236 1 other quick question. 2 Okay, I just want to DR. PACE: In order to be a 3 answer that question. specified performance measure, that includes 4 5 the risk model that goes with it. Because 6 remember measures that are endorsed for NOF 7 are endorsed to be suitable for accountability 8 purposes. And so people couldn't implement an 9 outcome measure that needs risk adjustment 10 without having that risk model already specified with the measure. 11 12 DR. LOHR: Do they get more than 13 one way of doing it? I mean Anne's paper has 14 several risk adjustment models. Are you saying the developer has got to pick one or they can 15 16 say you can do this, or this, or this? 17 DR. PACE: Pick one. 18 DR. LOHR: Oh, pick one, okay. 19 I think I would think that might 20 be tough but if that is an understood 21 requirement, fine. 22 The other thing, and it is not

	Page 23
1	another box exactly but maybe it falls into
2	the same kind of bucket as harmonization and
3	that is whether in all of this process NQF is
4	in a position to say there is a research
5	agenda here and turn some of these kinds of
6	methods or application kinds of question,
7	whether technical or more political, back to
8	sort of point to some research funders it
9	might be PCORI, it might be AHRQ, it might be
10	others and say there is a substantial
11	research agenda here that somebody else has
12	got to follow through with. Because I think
13	this is another generation's worth of research
14	here.
15	DR. BRENNAN: But I certainly
16	think that what we have learned at least this
17	particular part of the NQF process is that
18	there is a lot of intersections with a lot of
19	different communities and the unique
20	perspective that NQF has to offer in offering
21	up new agendas is really quite important.
22	I am going to actually we are

7

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1	at five of and I want to make sure that the
2	staff feel like we have got enough of a sense
3	of where to go and then I am going to let you
4	all have the last six minutes for comments;
5	two minutes apiece.
б	So Helen you can go and Karen and
7	Karen you can come and say your goodbyes.
8	You're fine? You're fine?
9	All right, then let me be the one
10	to say to the group speak now or it is going
11	into stone on the internet and it will be
12	there forever. Anything else you want to add?
13	If you think on the plane on the way home oh
14	gosh, they should have, make sure you let the
15	Karens know.
16	I hope to see you in a colorful
17	future and I thank you all very much for all
18	that you have done to get us to this point in
19	time. And thank you again to the staff. Safe
20	travels everyone.
21	(Whereupon, at 1:55 p.m., the
22	foregoing proceeding was adjourned.)

			l	l
A	accountable 26:6,7	143:18 148:12	adjourn 4:25 24:2	Affordable 54:4
<b>AARP</b> 1:13	accreditation 61:2	151:8,14 153:18	adjourned 238:22	afraid 22:11
ability 12:15 59:21	accumulated	156:2 158:22	<b>adjust</b> 36:16 55:21	218:22
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161:21	accurate 43:21	168:10,19 170:14	adjusted 27:8 34:8	179:1
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## CERTIFICATE

This is to certify that the foregoing transcript

In the matter of: Patient Reported Outcomes Workshop 2

Before: NQF

Date: 09-12-12

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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Court Reporter

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