

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

WHAT SHOULD PCORI STUDY? A CALL FOR TOPICS FROM
PATIENTS AND STAKEHOLDERS

Tuesday,
December 4, 2012

Hilton Alexandria Mark Center
5000 Seminary Road, Alexandria, VA

[Transcribed from PCORI Webcast.]

B&B REPORTERS
701 Copley Lane
Silver Spring, MD 20904
[301] 384-2005

AGENDA

	<u>Page</u>
Introduction to PCORI	
Joe Selby, MD, MPH, Executive Director, PCORI	5
Susan Hildebrandt, MA, Director, Stakeholder Engagement, PCORI	22
Workshop Orientation	
Jonathan Peck, President, Institute for Alternative Futures	28
Marty Hatlie, JD, CEO, Project Patient Care	30
Engagement and Patient-Centeredness: Sharing Perspectives with PCORI	
Sue Sheridan, MBA, MIM, Director, Patient Engagement, PCORI, Moderator	32
Helen Haskell, Mothers Against Medical Errors	33
Greg Biggers, Invoke Health/Genomera/Genetic Alliance	37
Pat Quigley, PhD, ARNP, American Nurses Association	41

AGENDA [CONTINUED]

	<u>Page</u>
Engagement and Patient-Centeredness: Sharing Perspectives with PCORI [continued]	
Dan Leonard, President, National Pharmaceutical Council	46
Ardis Hoven, MD, President-Elect, American Medical Association	55
Rebecca J. Culyba, PhD, Alliance of Community Health Plans	59
Recess	121
Facilitated Small Group Sessions	121
Soliciting Research Topics: What Have We Learned?	
Greg Martin, PCORI	122
Assessment of Diagnosis, Prevention and Treatment Options	
David Hickam, MD, MPH, PCORI	122

AGENDA [CONTINUED]

	<u>Page</u>
Soliciting Research Topics: What Have We Learned? [continued]	
Improving Health Systems	
Chad Boulton, MD, MPH, MBA, PCORI	125
Addressing Disparities	
Anne Beal, MD, MPH, PCORI	130
Communications and Dissemination Research	
Bill Silberg, PCORI	135
How to Prioritize: A Real World Example	
Kara Odom Walker, MD, MPH, MSHS, Scientist, PCORI	166
Closing Remarks	
Anne Beal, MD, MPH, Deputy Executive Director and Chief Operating Officer, PCORI	202

P R O C E E D I N G S

[8:14 AM]

1
2
3 DR. SELBY: Good morning, everyone. How
4 are you this morning? You look fantastic. You
5 look marvelous. Welcome to PCORI's Patient and
6 Stakeholder Workshop that's entitled "What Should
7 PCORI Study? Call for Topics from Patients and
8 Stakeholders."

9 So, imagine that two years ago this month,
10 two years ago last month, you were called by the
11 GAO and asked to serve on the board of a new
12 research institute created by the Affordable Care
13 Act and charged with conducting research that
14 answered questions that patients, their caregivers,
15 and their clinicians needed answered. That was
16 about it. And, by the way, your institute was
17 called the Patient-Centered Outcomes Research
18 Institute.

19 That's what our 21-person Board of
20 Governors ran into in November of 2010, when they
21 convened for the first time. And today is really
22 in many ways the culmination of an amazing amount

1 of thinking and amazing amount of work that has
2 gone on since that time. Much of it done already
3 in coloration with people in this room and other
4 stakeholders representing patients, people who care
5 for patients, their caregivers, clinicians, health
6 care delivery systems, payers; that is insurers,
7 employers, the research community, and
8 policymakers. All of those folks have met with
9 PCORI's board, with PCORI's staff, with PCORI's
10 Methodology Committee over the last two years
11 beginning to wrestle with this notion of how do we
12 identify the questions most critical to patients as
13 they make decisions, most critical to their
14 caregivers as they assist in making those
15 decisions, most critical to clinicians as they face
16 the fact that oftentimes today, we practice
17 medicine with an amazing, shocking degree of
18 uncertainty as to what works best. And if we know
19 what works best, we're at still at a bit of a
20 disadvantage because we don't necessarily know what
21 works best for whom.

22 That's our mandate. What we need to now

1 is decide exactly what research PCORI will fund.
2 PCORI has a substantial amount of money after you
3 take out the portion that goes to HHS and AHRQ,
4 we'll likely have by 2014 approximately \$400
5 million to spend on research. It sounds like a
6 lot, it is a lot. There are an awful lot of
7 questions out there and the legislation really gave
8 us amazingly little guidance on what in fact would
9 be most important to research.

10 So, I'm going to show you kind of what our
11 board did in the intervening time that brings us to
12 this date and that addresses that very question.
13 So, this is a picture of the Board. It's a very
14 handsome group of people, very prestigious group of
15 people. I say that because five of them are in the
16 room and I talk like that. And you're going to
17 hear from the vice chair of the Board in just a
18 minute.

19 But these folks have done a remarkable
20 amount of thinking and a remarkable amount of work
21 and one of the first things they did and they did
22 it just about the time that I arrived in July of

1 2011, they crafted this mission statement and the
2 mission statement says "PCORI helps people make
3 informed health care decisions and improves health
4 care delivery and outcomes by producing and
5 promoting high integrity, evidence-based
6 information," and this is the key part here "that
7 comes from research guided by patients, caregivers,
8 and the broader health care community." So, that's
9 driving us.

10 It's an inspired statement and you ask
11 what's in a name? The Patient-Centered Outcomes
12 Research Institute is the name we got and I think
13 that has an amazing amount to do with how the
14 mission came to be worded the way it is and how our
15 activities and our strategic plan come to look the
16 way that they do.

17 And it all comes down to stakeholders.
18 The research that we conduct is not aimed at
19 explaining some hidden mechanism of what causes
20 disease. It is not aimed at pursuing the personal
21 interests of a researcher or a research group.
22 It's not based on the last piece of research

1 someone did which makes the next piece of research
2 more fundable. It has only one aim and that aim is
3 to ask questions like what do patients need to
4 know? What's most important for this condition?
5 What's most important for these patients? What
6 research is most likely to change practice, change
7 behaviors, and improve outcomes? That's a tough
8 question. These are stakeholders. You're in
9 there, whether you are a patient or a caregiver,
10 clinician, delivery system, payer, employer,
11 policymaker, or researcher. You're in this picture
12 and you're in our hearts and minds.

13 This is what we've come up with and I hope
14 that shows up. We have two different ways of
15 getting to this research and I'll explain both
16 ways.

17 This first way is in many ways more
18 traditional. Some people would call it the
19 investigator-initiated track for research. We're
20 not interested in investigator-initiated, we're
21 interested in research that's initiated by
22 investigators partnered with patients and other

1 stakeholders. But here, the idea is that PCORI
2 issues broad funding announcements and we've done
3 that. We did that last May. We're actually deep
4 into our second cycle of these announcements so we
5 issue broad solicitation. Send us your best ideas,
6 they must be patient-centered, they must be likely
7 to change practice, you must be partnered with
8 patients and other stakeholders.

9 So, we issue the broad announcements.
10 Researchers partner with stakeholders and generate
11 the research questions. They pay attention to our
12 review criteria and they tell us why this research
13 question is critical to patients and why it's
14 likely to change practice. It comes to our study
15 sections, our review panels. On those review
16 panels, 30 percent of the members are either
17 patients or other non-technical stakeholders. So,
18 unlike a review section at NIH or AHRQ, where
19 either 95 or 100 percent of the reviewers are
20 scientists, in PCORI's study sections, 30 percent
21 of the reviewers are either patients or
22 stakeholders.

1 The study sections, the review sections
2 pay attention to our criteria, they pay attention
3 to the applications, and they select those
4 applications they believe are most patient-centered
5 and most likely to change practice. We wind up
6 with a diverse portfolio of highly specific, high
7 priority research. That's method number one.
8 That's going on and we're not really here to talk
9 about that much today. We're here to talk about
10 method number two.

11 In method number two, and we're here to
12 talk about this in part because when we launched
13 method number one, people said this is the same old
14 same old. This is the way that research has been
15 done for many years and it's not likely to change
16 things. We do feel, as I said, that we made a
17 number of changes in that process to make it more
18 patient-centered and to make sure that we'll get to
19 high priority research.

20 But in process number two, we start by
21 simply sitting down and talking to patients and
22 other stakeholders and that's what today is all

1 about, sitting down and talking about what are the
2 questions that are most important to you, whether
3 you represent patients or another one of our
4 stakeholder groups. This is not the only way we
5 intend to get this information, but it's certainly
6 probably one of the richest and most human ways and
7 one of the most compelling ways to really sit
8 together and talk about what questions are most
9 critical. We don't intend to sit and talk to
10 patients one day, clinicians the next day. We
11 think it's much richer to bring all the
12 stakeholders together as we're doing today and in
13 the name of patients and in decision-making by
14 patients, we find the questions that are most
15 critical and the questions that are most
16 answerable.

17 So, we start by identifying questions.
18 That's today, generating topics. We then move onto
19 prioritizing those topics. So, together with
20 patients, together with other stakeholders, we
21 decide, given that we've got limited funds which
22 are the topics that are most compelling, most

1 likely to change practice, most important to
2 patients? You're going to hear about that
3 prioritization process today at noon from Dr.
4 Rachael Fleurence.

5 Once we determine what are the most
6 important questions, PCORI staff put together
7 funding announcements, very targeted funding
8 announcements, and they go out rather than those
9 broad announcements, we have a set of targeted
10 funding announcements. They go out, researchers
11 get together with patients again and other
12 stakeholders, create their proposals, and send them
13 in, and, again, the review process is the same and
14 in this case, we also get very high priority
15 research this time targeted to the questions that
16 patients and stakeholders have told us are the most
17 important. That's what we're going to do today,
18 start that process.

19 We're interested not only in your
20 questions today, but we're also interested in
21 talking about how we maintain communications with
22 all of you. What works best for you?

1 One way that we've already put into place
2 and gotten about 500 questions. Imagine that we
3 have 500 questions on day 1, is one the PCORI Web
4 site, we have a place where you can go and simply
5 state your question. It's quite straightforward,
6 it's not real structured, it's inviting of everyone
7 including patients to put their questions in.
8 Those questions will be among the questions that we
9 will ultimately prioritize and some of them will
10 wind up turning into funding announcements. But,
11 as I said, there are other ways and today is one of
12 those other ways.

13 I want to just mention briefly that we are
14 anxious to move toward having some of our research
15 be targeted research. The Board recognized that
16 even before PCORI existed, a number of stakeholder
17 groups had come together, one of them being the OIM
18 and fielded questions from across the country and
19 prioritized them.

20 So, we went through a process, the Board
21 instructed us to go through a process and we went
22 through a process to look for research that was

1 patient-centered, research that had been
2 recommended by other stakeholder groups, research
3 that wasn't already funded, that the answers hadn't
4 become apparent in the time since the OIM report.
5 We looked at agendas of NIH and AHRQ and other non-
6 governmental patient organizations and funding
7 organizations, and we ultimately came up with three
8 topics and these are the first three topics. We
9 have not issued these funding announcements yet,
10 but we will after we convene an expert stakeholder
11 advisory group to talk about each one, we will
12 release our first targeted funding announcements
13 and they will be in these three areas.

14 Options women face when they are suffering
15 from symptomatic uterine fibroid, so, a very common
16 condition in women as they approach menopausal
17 years, causes a lot of pain, causes a lot of missed
18 time from work, interferes with family life and
19 social functioning, and there are a number of
20 treatment options, including some new high-tech
21 treatment options and the answers are not yet in on
22 what works best given a particular woman's personal

1 situation. So, that's topic number one.

2 Number two, the safety and benefits of the
3 treatment options for African-American and minority
4 patients with severe chronic asthma. So, again,
5 asthma is a very prevalent disease. It leads to a
6 lot of morbidity, it leads to mortality. It
7 particularly leads to mortality in African-American
8 and other minority populations and there are some
9 treatments that look like they may, in fact,
10 although they work in majority populations, may
11 have some particular adverse consequences. So, the
12 safety and benefits of various approaches to
13 treating severe asthma is topic number two.

14 And falls prevention in the elderly, a
15 very common event, often the event that signals the
16 end of an independent and productive life. Much
17 work to be done in figuring out what can a health
18 care system do to prevent falls in the elderly and
19 who is the target population among people 65 and
20 above? Who's the target population?

21 So, there I have given you the first three
22 targeted topics that PCORI is going to release

1 funding announcements on, but your job, our job
2 today is to come up with the next 10 or 15 of
3 those.

4 So, I'm going to stop and before I
5 introduce Susan Hildebrandt, our director of
6 Stakeholder Engagement and the mastermind behind
7 today, I have the pleasure of introducing the vice
8 chair of the PCORI Board of Governors, Mr. Steve
9 Lipstein. Steve is from St. Louis, and he is the
10 CEO of BJC Hospitals. That includes the Washington
11 University Hospital complex and hospitals scattered
12 throughout the Midwest and south and Steve is a
13 real force on the Board and a good friend and he's
14 come from St. Louis to add the welcome of the Board
15 this morning.

16 [Applause.]

17 MR. LIPSTEIN: Good morning. Just
18 curious, how many others of you have come from west
19 of the Mississippi River? You're all on that side
20 of the room, okay.

21 [Laughter.]

22 MR. LIPSTEIN: Good, welcome. Well, I'm

1 glad you're here this morning and on behalf of our
2 Board of Governors, I wanted to just say a few
3 words and welcome you. I also would like to share
4 with you that, as Joe pointed out, we are in the
5 second year of our journey with PCORI and this is a
6 very exciting time for us and this is a very
7 important meeting that we're having today. And so,
8 what we're asking you to do in participating with
9 us to identify some of these key areas of
10 investigation and research is really important and
11 I'll talk a little bit more about that in a minute.

12 But, first, let me introduce -- as you
13 know, we are a stakeholder board and we came
14 together. Many of us hadn't met each other for the
15 first when we got together two years ago, and so,
16 if I can, just because we are representatives,
17 where is Larry Becker? Larry. Larry is an
18 executive with Xerox Corporation, and so, Larry is
19 representing many of the employer stakeholders who
20 are interested in patient-centered outcomes
21 research.

22 Debra Barksdale is right in front of me.

1 Debra is a professor of nursing. I always have to
2 point this out -- at the University of North
3 Carolina at Chapel Hill. I went to Duke, so, this
4 is a challenge.

5 [Laughter.]

6 MR. LIPSTEIN: But Debra's a professor of
7 nursing. I saw Harlan Weisman. Harlan is a
8 physician, cardiologist. He and I actually started
9 out in our youth together at Johns Hopkins Hospital
10 many years ago, but Harlan was formerly of Johnson
11 & Johnson and brings both a scientific and a
12 pharmaceutical perspective to our work.

13 Gail Hunt. Is Gail here yet? Gail in the
14 back is the CEO of the National Alliance for
15 Caregiving and represents caregivers as a
16 stakeholder group within our board as well as one
17 of what the statute refers to as our consumer
18 representative.

19 And then Ellen Sigal will be here later
20 this morning. She's not here right now, but Ellen
21 is the founder and CEO of Friends of Cancer
22 Research. And so, we have some other perspectives

1 on the Board that are more disease-focused.

2 So, we are a stakeholder board. As Joe
3 mentioned, I come from BJC Health Care in St.
4 Louis, which many of you may recognize names like
5 Barnes-Jewish Hospital or St. Louis Children's
6 Hospital and at the place where I work, in our
7 organization, we admit about 3,000 patients a week
8 to our hospitals and we see about 20,00 patients in
9 our outpatient environments. And so, when we talk
10 about getting specific with the research agenda for
11 PCORI, I always think about the who, not just the
12 what, were the topics. So, who are the people that
13 are going to benefit from our research agenda? Who
14 are the people that are going to be included as we
15 get more specific and we identify key areas of
16 investigation?

17 So, as Joe mentioned a minute ago, many
18 women patients who suffer from uterine fibroids
19 will be among the first beneficiaries of our work.
20 Many of our more vulnerable patient populations and
21 our minority populations who suffer from asthma may
22 be the first beneficiaries of our work, but one of

1 the things we're asking you to help us with today
2 is to really focus in on our research agenda and
3 our priorities as we get more and more specific in
4 the coming timeframe.

5 So, I welcome you, I can't overemphasize
6 enough the important role that you play today. We
7 are going to work you hard. We have had workshops
8 like this before and I can tell you it's a long and
9 exhausting day, but I hope at the end of it, you
10 will find it as meaningful as we do in securing
11 important stakeholder input into the work of PCORI.
12 So, again, thank you, all, for being here today.
13 We look forward to working with you.

14 [Applause.]

15 DR. SELBY: Thanks, Steve, and I'll just
16 say in closing that whenever we have one of these
17 events, it always turns out that at least five
18 board members show up. They drop what they're
19 doing in their jobs. I guess, Steve, you don't
20 have a boss, really, so, I don't know what their
21 bosses say back home, but they're here and we're
22 most appreciative. It makes the board meetings

1 that much more interesting because they've actually
2 been here and seen this happening.

3 Okay, I'm going to now turn it over to
4 Susan Hildebrandt, who, as I said, is our director
5 of Stakeholder Engagement. She came to PCORI from
6 the American Academy of Family Physicians and she
7 has the very interesting job of developing and
8 growing and maintaining relationships with every
9 group of stakeholders except patients and
10 caregivers and that's Sue Sheridan's job.

11 Where's Sue Sheridan? So, many of you
12 have met Sue Sheridan. Sue sort of manages our
13 connections to patients and patient advocacy
14 organizations, caregiver organizations, and Susan
15 gets all the rest of you.

16 So, without further ado, here is Susan
17 Hildebrandt and thank you, Susan.

18 [Applause.]

19 MS. HILDEBRANDT: Welcome and good
20 morning. I'm absolutely delighted to see all of
21 you here today for this workshop and also enjoy
22 meeting and speaking to a number of you last night,

1 hearing your stories, what brought you here, that
2 sort of thing. We really appreciate it.

3 I just wanted to quickly mention three
4 things, tell you how else you can get involved in
5 PCORI outside of this workshop. We are really
6 seeking to build a PCORI community, and so, I'll
7 talk to you in a bit about that.

8 Second, let me just kind of reemphasize
9 the purpose of today's workshop for you and then,
10 third, also want to thank the Planning Committee
11 members who really also were the other masterminds
12 behind this workshop.

13 So, PCORI really has been involving
14 stakeholders in four key ways. As Joe indicated as
15 well as Steve, we think of stakeholders as really
16 anybody who is interested in PCORI or could
17 potentially be affected by our results and that's
18 all of you in this room. So, we're delighted to
19 have you.

20 So, we've been getting stakeholders
21 involved in topic generation, what should we study?
22 Of course, that's why you're here today. Secondly,

1 actually reviewing our funding proposals, helping
2 us share our findings and, again, always telling us
3 what we're doing.

4 Let me just talk a bit about those in a
5 little more detail. So, you are here and the first
6 way that we involve stakeholders is, again, getting
7 your research topics, and, of course, that is
8 really the purpose of the workshop today. And so,
9 your involvement is absolutely key. We hope that
10 with your topics, we can put them into our
11 prioritization process and then ultimately make
12 them into some sort of PCORI-targeted funding
13 announcements.

14 Second way you all can get involved is
15 review our funding proposals. That means sitting
16 around a table with other scientists, stakeholders,
17 patients, and others and looking at the impact and
18 what I mean by that really is does this research
19 proposal make sense? Would it make a difference to
20 me as a patient? Would it make a difference to me
21 as a clinician? And that's what we are trying to
22 do which is different about PCORI.

1 I actually attended the stakeholder review
2 of the proposals a few weeks ago and was really
3 struck by the fact that the scientists, the
4 patients, caregivers, and others really sat around
5 the table and discussed the proposals on equal
6 footing. There was a real sense of community and a
7 real shared vision. And it was a tremendously
8 exciting experience. So, I thank those of you who
9 have already signed up to be reviewers and I urge
10 the rest of you in the room to do so, as well.

11 Similarly, you all can get involved in
12 forming research partnerships and we really want to
13 answer your questions, your research questions. We
14 want to answer questions that are relevant to
15 patients, clinicians, and others, and the way we'd
16 like to do this is involve you at all steps of the
17 process. So, that means things like determining
18 the research questions, as we have indicated today,
19 but also really helping us define the key
20 characteristics of the individuals that should
21 actually participate in the study.

22 A third way to get involved is helping us

1 get the word out, dissemination, and I think
2 everybody in this room would agree that we want to
3 shrink the gap, shrink the 17-year bench to
4 practice gap. And we are deeply interested in this
5 issue. How do you communicate? How do you
6 disseminate? How do you get uptake of your
7 results? And, as you know, one of our funding
8 announcements is actually on that very subject.
9 And we think that stakeholders like you would
10 actually be very interested and excited about doing
11 that if we can produce information that is relevant
12 to patients.

13 So, really, the fourth way to get involved
14 is to give us feedback. We are continually seeking
15 information and input. We really pride ourselves on
16 being a learning organization, and so, we are
17 always evaluating our activities. So, after this
18 workshop, probably the moment you are walking out
19 the door and breathing a sigh of relief, you'll get
20 an e-mail from us asking you to tell us what you
21 thought. Did you learn something? What did you
22 like, what didn't you like? What can we change?

1 And we really urge you to take this very, very
2 seriously because we will. We will take your
3 information and input and that will help us improve
4 or change future events at PCORI.

5 So, as both Joe and Steve have said,
6 you're here today to give us research topics. We
7 would also like to get your thoughts on engagement
8 with PCORI and then we're going to give you kind of
9 a sneak peek about our draft prioritization process
10 and that really answers the question of what are we
11 going to do with all these topics that you give us
12 with all this information that you generate? Well,
13 we're going to put them into our prioritization
14 process, so, we'll explain what that is, actually
15 do kind of a mock walkthrough in terms of how that
16 works, and then, of course, invite your feedback.

17 So, I need to conclude by thanking all of
18 the other masterminds on the Planning Committee.
19 I'm going to embarrass all of you and ask you to
20 stand when I read your name.

21 So, I'm going to start with Andrew Baskin,
22 Ann Caldwell, Lynne Cuppernull, Maureen Dailey,

1 Nancy Foster, Andrea Garcia, Jennifer Graff, Helen
2 Haskell, Dan Leonard, Jennifer Meeks, Jennifer
3 Phillips, and Sylvia Trujillo. Thanks to all of
4 you and I really deeply appreciate all of your
5 assistance.

6 [Applause.]

7 MS. HILDEBRANDT: I am now going to turn
8 the meeting over to Jonathan Peck and Marty Hatlie,
9 who will give you more details about how we will be
10 handling the rest of the day. Thanks.

11 MR. PECK: Thank you, Susan.

12 So, Marty and I are going to be playing a
13 role of co-facilitators throughout this session and
14 first, I want to get you oriented to what we're
15 going to be doing. We'll be in the plenary session
16 until 10:30. We've got to break then and then
17 we're going to go into the small group sessions.

18 So, each of you have signed up for two
19 small group sessions, and they're going to be
20 facilitated by PCORI teams and we'll have those go
21 through noon and we'll have lunch with a talk from
22 Dr. Fleurence. And then we'll go back into the

1 second small group session after the break. And
2 we'll have another break along the way. Then we'll
3 go and we're going to hear feedback at 3:00 from
4 the small group sessions.

5 So, the session leaders will present kind
6 of an overview of what we've learned from you
7 through the day and that's when we'll move towards
8 a final how do you prioritize? So, Dr. Kara Odom
9 Walker will go through the PCORI priority process
10 and then Dr. Anne Beal will give our closing
11 remarks. So, that's the overview of the day.

12 This morning, after you're sort of
13 oriented to how we're going to work together, we'll
14 have a panel come up of different stakeholders and
15 Sue Sheridan and Marty and I will be co-moderating.
16 You're going to hear what does success look like?
17 If you go to the seven years that PCORI's been
18 funded for, at the end of those seven years, what
19 does success look like from the perspective of the
20 different stakeholders? So, we're going to have
21 about a 45-minute panel centered on that and then a
22 45-minute discussion with you so we can get your

1 views of what does success look like for PCORI?
2 And then from there, we'll move into the small
3 group sessions.

4 MR. HATLIE: And, Jonathan, we noticed
5 last night that there are a handful of people here
6 from our first workshop, too. So, they'll be kind
7 of a bridge in that panel between that workshop
8 which was about a month ago and this workshop. So,
9 it'll be great.

10 My job now is to cover the roles, which
11 are pretty basic and we do want to hear from as
12 many people in this room today as we can hear from.
13 So, please don't kill the messengers if we are not
14 picking the person whose hand is always up first.
15 We really want to hear from you, but we also want
16 to hear from the people who are a little less
17 likely to jump in first. And don't worry about
18 that, that will be our job to kind of keep the
19 conversation flowing. But all of your input is
20 important.

21 We do have to stay on time. I mean,
22 that's our main job. So, we're going to ask for

1 your help in helping everyone stay on time and
2 then, of course, if you could turn off anything
3 that makes noise. So, all electronic
4 communications, all of those things that keep us in
5 touch with the real world, if you can kind of
6 distance yourself from that a little bit today and
7 just kind of turn that off during our session so we
8 don't distract others. And those are the basic
9 rules, Jonathan.

10 MR. PECK: Great. Thank you, Marty. And
11 so, we're going to have lots of breaks where you
12 can turn those little devices back on.

13 Just so you're prepared for the small
14 groups sessions, which is where each of you really
15 get the most airtime, if you will, that there,
16 you're going to get quickly oriented, teams of
17 facilitators. You've got assigned rooms. The key
18 here is your recommendations for research topics
19 and that's the key to success for today's meeting,
20 that we get to hear your thoughts about what PCORI
21 should be looking at for research topics. Then we
22 also want to find out from you how you see your

1 organizations using comparative effectiveness
2 research. And then we also want to learn from you
3 what are the best practices, what's worked best.
4 So, this is our opportunity for PCORI to learn from
5 you and that's the key through those.

6 So, without further ado, let's bring Sue
7 Sheridan up and we'll bring our panel up. Helen
8 Haskell, if you would come join us. Thank you.
9 Greg Biggers and Pat Quigley. Dan Leonard. Ardis
10 Hoven and Rebecca Culyba.

11 [Pause.]

12 MS. SHERIDAN: Like Jonathan mentioned, I
13 am Sue Sheridan. I am the director of Patient
14 Engagement at PCORI.

15 I'd like to welcome the panel to the
16 stage. I have, like Joe Selby said, the pleasure
17 of working with patients and patient organizations,
18 caregiver, caregiver organizations to bring their
19 voice, their collective wisdom into the research
20 enterprise and it's actually a really exciting
21 opportunity. I've had the privilege of witnessing
22 the power of partnership between patients and

1 researchers and the nursing organizations and
2 physicians and industry to really drive change.
3 And so, I can say I have seen it work.

4 So, as we welcome this panel, actually, if
5 you look in your bio books and realize where they
6 are all coming from, this is really a dream team.
7 I mean, just imagine what we can do as a research
8 organization and as a group of stakeholders,
9 imagine what we can do in the research enterprise.
10 I think it's very powerful.

11 So, I'm thrilled to be here and I'm eager
12 to hear about the vision that this panel has on
13 what is success in Patient-Centered Research and
14 Patient-Centered Outcomes Research and comparative
15 effectiveness working as partners.

16 So, I'm going to start with I believe
17 Helen Haskell, is our first to share her vision.
18 Helen is a mom and she is a nationally renowned
19 patient advocate. She and I have grown up together
20 in the patient safety world. So, I welcome Helen.

21 MS. HASKELL: Thank you, Sue. Well, as
22 Sue said, I am here as a mom. I have an

1 organization called Mothers Against Medical Error
2 and I am also here as a representative of CUE,
3 which is the consumer arm of the Cochrane
4 Collaboration which has training for patients,
5 education, and learning to interpret scientific
6 studies which is an indispensable part of this that
7 we should not forget about.

8 So, I want to start with thinking about
9 the PCORI mission statement because I think that's
10 actually one of the best mission statements I've
11 ever seen. Helping people make informed decisions
12 and improve their outcome delivery and outcomes to
13 evidence-based information derived from research
14 guided by patients, caregivers, and the health care
15 community. This is the foundation of good health
16 care. And I think what we're trying to do here is
17 to transform health care from the inside out by
18 going right to the most fundamental aspect of
19 health care, which is what we do and why we do it.

20 I've been in patient safety and quality
21 for about 12 years now. I've worked with a lot of
22 medical error victims and with providers and what I

1 have concluded over all those years is that it
2 really all comes down to the research.

3 My son died from complications to the
4 procedure that he should not have had. And in many
5 areas, including that procedure, research doesn't
6 address the important issues. It doesn't ask the
7 right questions. It is not correctly interpreted
8 and it's not property disseminated. And the result
9 all too often is expensive, fragmented, ineffective
10 care that's serving the aims of someone other than
11 the patient and patients are often left bewildered
12 as to what is best and safest for them to do. So,
13 that's what PCORI is all about, asking the right
14 questions for the right reasons, and only patients
15 can make that happen because patients are the
16 reason for research.

17 So, what will PCORI do if it works as it's
18 supposed to? The first thing is it will change the
19 power gradient. Paternalism, which is the
20 dangerous idea that patients don't know enough
21 about their own health to really say what they
22 think or what they think should be done will be

1 affected, hopefully will be turned on its head.

2 Overtreatment, overuse, overpayment, if we
3 focus on outcomes that patients want, we can take
4 on the big challenges that are facing health care
5 today. We can only have good health care if we
6 have solid Patient-Centered Research. And once
7 we've mastered the patient-centered aspects of
8 research, Patient-Centered Outcomes Research has
9 the power to change the way that health care is
10 delivered. We should not take our eyes off that
11 goal. Research must have a point. It shouldn't
12 just be knowledge for its own sake. It is not
13 enough to find the truth; it needs to be a real
14 truth. It needs to have real benefits that get to
15 real people who need them and that's where PCORI
16 can take us. Thank you.

17 [Applause.]

18 MS. SHERIDAN: Thank you, Helen.

19 I'd like to invite Greg Biggers to the
20 podium. I met Greg at the Patient Engagement
21 Workshop a month ago and his spirit, his energy,
22 and his vision of partnership was compelling, so,

1 we wanted to bring him here to share his message
2 with you.

3 MR. BIGGERS: Thank you, Sue. So, in
4 addition to the three organizations named in the
5 biography, which you can just peruse it at your own
6 leisure, in addition to representing these
7 organizations, I'm also a patient with vitiligo,
8 thyroid disease, back pain, and possibly some other
9 kind of autoimmune mysteries that we're still
10 investigating. I'm a caregiver in areas including
11 stroke, spinocerebellar ataxia, mental illness, and
12 child development. I'm a parent. I'm also an
13 advocate. I love helping others be heard and I
14 often try to represent many others, but I think
15 today at a time when many of us are trying to
16 represent larger groups, it's helpful for us to
17 remember that none of us can ever do that truly and
18 completely, that even when we are our best
19 advocating selves, there will always be voices that
20 are not being heard. And I think that should give
21 us pause and that should be a context for
22 everything that we do today.

1 So, what does it look like when PCORI is
2 successful? What does it look like when we get
3 Patient-Centered Research right? We think of four
4 things.

5 The first one is all involved parties
6 self-identify as we. We think that we are doing
7 it, not you are doing it, not me doing it, not them
8 doing it, but it is we. When I stand at the
9 sidelines as a patient and refer to some of you as
10 you, when we other one another, that undermines
11 sustainability of what we're doing.

12 So, language and roles really matter and
13 we're seeing a continuum of enlarging roles of the
14 patient in research. We're seeing a continuum that
15 stretches from unwitting subject to willing subject
16 to participant to collaborator to shareholder in
17 the research endeavor. So, language and roles
18 matter and when you think about how we're going to
19 refer to one another as patients, well, you refer
20 to as subjects, patients, participants, or how
21 about partners, collaborators, shareholders, maybe
22 even investigators. That's how we express it is we

1 doing this research. So, that's number one.

2 Two, patients are and feel like
3 collaborators at every step in the research
4 project, so, not just occasional advisors, not just
5 boxes to check, but actually involved. So, we want
6 to see less of we have designed a study for
7 question X and now we're looking for some patients
8 who sign off on it and much more we have a group of
9 people including patients who are designing a study
10 about question X and let's go do this. That's
11 number two, collaborators.

12 Three, patients are spreading the word.
13 Because we had ownership at every step along the
14 way, patients are spreading the word about the
15 results of studies with vigor and sometimes maybe
16 even often, patients are authors or even
17 investigators in published studies. That's three,
18 patients are spreading the word.

19 And then four, we have a sustainable
20 culture of deep collaboration in this culture is
21 spreading, replicating, affecting all of health
22 research, even outside of PCORI and PCORI-funded

1 projects because we believe we're at an inflection
2 point in the history of human health research. And
3 if the PCORI community, if we seize this moment of
4 opportunity, we will have dramatic effect on the
5 future of research for years and years to come.

6 So, those four things: the involved
7 parties self-identify as we, patients are and feel
8 like collaborators at every step, patients are
9 spreading the word, and, four, we have a
10 sustainable culture of deep collaboration. So, we
11 think that those four things can be, we hope they
12 will be PCORI's gift to the world not just getting
13 great research done, but also a sustainable way to
14 do research because patients are at the center. A
15 few things to think about.

16 [Applause.]

17 MS. SHERIDAN: Thank you, Greg. I'd like
18 to invite Pat Quigley who is representing the
19 American Nurses' Association. I'd like to let you
20 know that in your bio book, there was an incorrect
21 reference to the organization that she's with and I
22 just want to say, Pat, thank you and I've also had

1 the opportunity and privilege of witnessing the
2 power of nursing in research and you're a bold and
3 energetic profession that we need more of.

4 MS. QUIGLEY: Thank you. Thank you so
5 much. Thank you. And thank you for having us be
6 part of this dream team. Really, this dream team.
7 What a great day to be in this nation's capital to
8 really address patient outcomes. And thank you for
9 correcting in the program that I am not with the
10 Mothers Against Medical Errors, but certainly
11 patient safety is indeed our world.

12 So, on behalf of that to bring you
13 greetings on behalf of the American Nurses'
14 Association and Dr. President Karen Daley, Dr.
15 Maureen Daley, as well, who's here, a senior policy
16 fellow on ANA. We thank you so much for this
17 opportunity to be able to participate in this
18 dialogue. Rich in our ability to be able to really
19 inform the research that is being directed to help
20 with patient and caregiver, patient-centered
21 outcomes.

22 The American Nurses' Association is the

1 only full service professional organization
2 representing the interests of the nation's nurses,
3 the single largest group of health care
4 professionals in the United States. Our membership
5 includes direct care nurses, advanced practice
6 registered nurses, nurse educators, nurse
7 administrators, nurses across all settings,
8 military, civilian.

9 In a patient-centered system, it is
10 essential that the information and communication
11 techniques are leveraged to engage the patient's
12 ability to make thoughtful, informed decisions
13 about approaches to diagnosis, to treatment, to
14 stay well, to manage chronic illnesses, and to
15 experience optimal end-of-life care. The ANA's
16 vision for patient-centered care is a health care
17 system in which teams embrace empowered patients
18 who identify the care goals to own and manage their
19 own care. Patient-Centered Research is needed in
20 interrelated areas of care coordination, patient
21 engagement, and safety to identify the team's best
22 practices in a learning health care system.

1 First, care coordination. A priority area
2 of research to inform pathways to Patient-Centered
3 Outcomes to improve care coordination is essential.
4 The ANA has identified key care coordination
5 competencies as well as gaps in research and
6 effective quality measures such as in primary care
7 and preventive care and the care of those with
8 multiple chronic conditions as well as functional
9 changes that occur with aging. Nurses view there
10 are patients as deep and full partners in only
11 their own care.

12 An example is daily care planning that is
13 being done in the Department of Veterans' Affairs,
14 where patients and caregivers come together to talk
15 about what are our goals, what's our plan today,
16 how can we achieve these goals together? And,
17 beyond that, we need to ensure that there are
18 processes to support critical paths that are really
19 guided towards effective and Patient-Centered Care
20 using Electronic Medical Records. How can we best
21 utilize Electronic Medical Records to really fully
22 engage patients as owners in their care? And this

1 needs to be an interactive engagement of patients
2 throughout all of their care settings and the
3 continuum of care.

4 So, the ANA's vision for the design
5 implementation, evaluation, and dissemination of
6 Patient-Centered Outcomes Research really needs to
7 address a reducing of disparities, improving care
8 and access across all settings, self-care
9 management, and patient safety. Patients and
10 caregivers can inform and be needed and really
11 drive the research that's needed to help us best
12 team communication practices so that we can empower
13 our patients to truly own their care. And this
14 will require that we address fully health care
15 literacy. In addition, how to be able to address
16 socio and economic and cultural barriers, as well
17 as removal of the power gradient that exists
18 between patients and caregivers and health care
19 team members. So, the American Nurses' Association
20 believes that this research must address really
21 prioritized areas throughout the entire episode of
22 care.

1 In addition, our secondary that we'd like
2 to help really draw this patient engagement.
3 Nurses are uniquely positioned as proximal
4 caregivers at the point of care in all settings of
5 care to engage patients and Patient-Centered
6 Outcomes, another key area, patient engagement.
7 Nurses as interdisciplinary team members can engage
8 patients to accurately access their own symptoms.
9 Patients can be involved in reporting their own
10 outcomes, their own symptoms related to pain,
11 fatigue, maybe conditions, functional status,
12 aging, urinary incontinence, and patients conduct
13 kind of reporting with reliable and valid tools to
14 be able to really be engaged as a full partner in
15 their fall prevention program.

16 And then as well as safety, to really help
17 patients be able to be totally engaged in their
18 patient care environment, advocating for our health
19 care providers to wash their hands, safely dispense
20 medications, and to learn how to be able to prevent
21 falls not only in hospitals, but after discharge.
22 What are the best practices to be able to help

1 this?

2 So, the American Nurses' Association is so
3 honored to be part of this and our vision is,
4 indeed, Patient-Centered Health Care System where
5 patients are full partners in their care, that
6 patients own their care, patients value health, not
7 just the health of today, but to have a healthier
8 tomorrow, and that we all understand our roles in
9 being able to help this be achieved for all those
10 that we serve. So, thank you on behalf of the
11 American Nurses' Association.

12 [Applause.]

13 MS. SHERIDAN: Thank you, Pat.

14 I'd like to welcome Dan Leonard, the
15 president of the National Pharmaceutical Council.
16 A part of our health care system that helps people
17 in chronic pain, with disease management, we
18 welcome you. You are an important stakeholder here
19 to share your vision in Patient-Centered Outcomes
20 Research.

21 MR. LEONARD: Thank you, Sue. And, yes,
22 indeed, it is nice to be here. Thanks, everyone,

1 for coming and Sue mentioned just a couple of areas
2 in which our member companies are the primary
3 pharmaceutical companies in the world, they're
4 involved in every disease state that's represented
5 here in the room and beyond, and so, we're going to
6 be relatively agnostic as to what PCORI should
7 study, but we'll be exuberant cheerleaders when it
8 comes to saying yes, get out there and study these
9 questions and we'll be very involved in talking
10 about how the research is done.

11 So, my organization represents, yes, the
12 pharmaceutical industry, but more specifically, the
13 scientific side of the industry and the health
14 outcomes research organizations and our companies
15 play a big role. So, how the research is done and
16 conducted is very important to us.

17 And in any setting like this, there are
18 challenges and opportunities that are in front of
19 us and you can say that really about anything in
20 our society, but if you think about an aging
21 population, that's a great thing to have, the fact
22 that people are living longer. This is a victory,

1 but it creates challenges and it generates
2 challenges in caring for those older Americans.

3 And we have this great technological boom.
4 We've talked already about Electronic Medical
5 Records and the importance that they will play, the
6 human genome being understood more robustly. All
7 of these technological breakthroughs are great and
8 will create much more information. But more
9 information isn't always better information. So, a
10 key will be harnessing that information and
11 understanding and using it for good.

12 PCORI specifically can have an important
13 role and will play an important part in ensuring
14 that we are equipped for this environment of
15 tomorrow and that we can improve the quality of
16 health and health care that's delivered and
17 probably most importantly, improving the health
18 care decision-making that takes place between the
19 physician and the patient because that's really at
20 the end of the day what this is all about.

21 As I mentioned, my organization is very
22 involved in the health outcomes side of the

1 pharmaceutical business and we are ready and
2 willing, there are folks in our companies that do
3 outcomes research and study the promising medicines
4 of tomorrow every day. So, we want to be a willing
5 partner with PCORI going forward, and so far, the
6 relationship has been just terrific.

7 So, three things that I really want to
8 stress, and in a previous call with Jonathan, he
9 said paint a picture of the land flowing with milk
10 and honey, right? So, in the 7 to 10 years out,
11 what is the ideal situation that PCORI could find
12 itself in and what positive developments will we
13 see? So, I took him up on that.

14 So, in the land of milk and honey from
15 where we stand, first, health care decisions are
16 more about the individual than about the masses.
17 It's more individually focused. It's very easy for
18 research to devolve to answering questions about
19 large populations or about averages and none of us
20 in the room are average, we're all above average,
21 of course, right?

22 This is Lake Wobegon, of course. But

1 getting beyond averages and finding out what really
2 works to the individual patient.

3 Now, we had a meeting just a couple of
4 days ago and one of the things I learned at that
5 meeting because it was on this topic of "The Myth
6 of Average" and Joe Selby was there and he made a
7 very good point, which is that to get to the
8 individual, sometimes you have to find out what
9 works for the population first. So, it's not a bad
10 thing to be asking questions that work for the
11 larger hole or the average, but it's going to take
12 that and then drilling deeper and drilling deeper
13 until you find answers for the specific individual,
14 what works for that individual. And that's what
15 patient-centeredness is all about. So, I applaud
16 PCORI for putting patients in the process at the
17 beginning and the middle and the end during this
18 whole exercise. Because what works best for the
19 average will not always be what works best for the
20 individual.

21 I think the key, and what I've referenced
22 it up top, is where we are now with technology, and

1 to get to treatments for the individual, it's going
2 to take an understanding of the whole. So, big
3 data, the larger that we can utilize in the
4 research, the Electronic Medical Records, records
5 from CMS and from large databases. It's going to
6 take big data to answer small questions, to be able
7 to get down into those individual questions and
8 what works best for whom. Its' going to take the
9 robust technology that's becoming available to us.
10 So, that's point one on treatment for the
11 individual.

12 Point two would be related to that, but
13 it's real-world evidence in how different types of
14 research can be used to answer these questions.
15 And the pharmaceutical industry for many, many
16 years, it's been all about randomized controlled
17 trials; you take one population and pit it against
18 another to find out what works. That is not going
19 to be a practical solution for much of PCORI's
20 work. It may be for some, that's yet to be
21 answered, I think, but for much of the work that
22 PCORI will be doing, it'll be in different types of

1 research, observational research, registries,
2 database studies.

3 So, understanding, having a clear set of
4 standards as to what is good when it comes to that
5 type of research will be important. Particularly
6 when it comes to observational studies, there are
7 many out there. Many are good, many are not so
8 good. So, getting a clear set of standards or
9 rules of the road when it comes to this type of
10 research will be important to making sure that when
11 that research is done that is recognized and
12 accepted by the research community as solid
13 research and it'll get the buy-in from the
14 physician community going forward. So, that's
15 point number two.

16 Point number three is on the communication
17 and the dissemination aspect of things. At the end
18 of the day, it could be the best research on the
19 planet, but if it's not getting into the hands of
20 the clinician who needs it at that moment when he
21 or she is talking to their patient, then it's of no
22 use. So, how can PCORI take this robust

1 information and get it to the right place at the
2 right time and making sure it's easily accessible,
3 breaking down that 17-year gap that Susan
4 referenced between bench to bedside, shrinking
5 that, but also shrinking the chasm in the language?
6 So, if the research is written for an academic
7 audience, a clinical audience, it may not make any
8 sense to the patient who really needs it. So,
9 there's also a chasm in the language that needs to
10 be used when you're disseminating this information.

11 So, and the third part with regard to
12 communication is the sort of the who, what, when,
13 and where. Who can speak about this research and
14 when is it appropriate? With all of this new
15 technology and information and the Internet,
16 anything you can search is up there, but how will
17 PCORI's work stand out from the din on the
18 Internet? And, also, will PCORI's research stand
19 on top of the shoulders of research that has come
20 before it so that it's building on the already
21 existing evidence base. That's an important part.

22 So, those are really the three points that

1 I wanted to make and as we look forward to the land
2 of milk and honey is that the research that's
3 relevant to the individual, that new types of
4 research, real-world evidence as we call it, is
5 utilized in an appropriate fashion and standards
6 are set so we can all salute it when it comes out,
7 and, three, that the communication that takes place
8 is appropriate and gets to the physician and the
9 patient in a timely and efficient way.

10 So, thank you very much for having me.

11 [Applause.]

12 MS. SHERIDAN: Thank you, Dan. The land
13 of milk and honey, wow.

14 I would like to welcome Ardis Hoven up
15 from the American Medical Association who
16 represents the clinicians who are those making
17 important, sometimes difficult decisions with their
18 patients. This is a really important partnership
19 that PCORI recognizes. This is why we're doing
20 research to provide this critical information to
21 the clinicians and the patients and caregivers and
22 other stakeholders to make these tough decisions.

1 I recall Ardis at our very first
2 stakeholder engagement event. She talked about the
3 importance of partnership in the dissemination to
4 make sure that we disseminate our findings from the
5 clinician throughout the whole system, including
6 the patient. So, I welcome Ardis to share your
7 vision on the future.

8 DR. HOVEN: Thank you and good morning.
9 I'm delighted to be here and participate in this
10 very good activity.

11 The AMA has been a consistent and vocal
12 advocate and supporter of comparative effectiveness
13 research. Our support has been rooted in the
14 belief that comparative effectiveness research
15 should build the clinical evidence base of medicine
16 and inform clinical decision-making so that
17 physicians are better equipped to provide patients
18 with recommendations on the best diagnostic and
19 treatment options and by extension, support
20 patient-informed decision-making. I, we, all the
21 members of the health care team need reliable
22 evidence-based clinical information that is readily

1 available at the point of care and relevant to the
2 specific needs, preferences, and insurance coverage
3 options of our patients.

4 In this setting, one size does not fit all
5 and it is something we must consider. In our view,
6 a surprising success of PCORI would not be simply
7 the identification, but rather the widespread
8 adoption of the best in class infrastructure that
9 facilitates the uptake of the highest quality and
10 up-to-date clinical information to inform and
11 support physician decision-making at the point of
12 care during a physician-patient interaction.
13 Physicians need information that is intelligently
14 and intuitively organized that is part of their
15 regular workflow, and most obviously relevant to
16 the specific health needs of the patients that they
17 are seeing.

18 The most pressing challenge for PCORI is
19 not identifying the relevant and important research
20 priorities and conducting such research, this is
21 being done in lots of areas, which was mentioned
22 earlier. But their work needs to continue and we

1 do support PCORI's work in areas where there is
2 significant health burdens such as chronic
3 conditions. We've already seen the first level
4 that is going to be discussed. This is very
5 important. But the greatest achievement of PCORI
6 would be providing research findings rapidly and
7 I'm talking about diagnostics, therapeutics,
8 prevention strategies, and even health care
9 delivery methods to physicians and others in ways
10 that are relevant at the point of care, in my
11 office with a patient, real time, intuitive, and
12 part of my workflow.

13 We strongly support the use of clinical
14 registries, which not only provide information in a
15 rapid cycle to practicing and treating physicians,
16 but enable rapid feedback on pressing research
17 needs relevant to practicing physicians. We
18 support efforts by PCORI to develop a viable and
19 ambitious strategy to scale up infrastructure, to
20 support uptake and application of comparative
21 clinical evidence. These efforts should be
22 integrated into infrastructure that would

1 facilitate access to information that promotes a
2 learning health care environment at the point of
3 care across a broad spectrum of areas, including
4 genomics, quality measurement, combatting
5 prescription drug abuse, prevention screening, for
6 example, and many, many others.

7 PCORI needs a thorough and creative view
8 of the role of new technologies, which has been
9 mentioned, that could simplify and enrich the
10 quality of information at the point of care in
11 addition to building on the evidence generation
12 that can be used to inform clinical decision-
13 making. Physicians want to support their patients
14 and their decision-making and to promote the best
15 outcomes. We believe that equipping physicians
16 with the tools to serve as navigators and learned
17 intermediaries would be a surprising and much
18 allotted success for PCORI. The questions are:
19 How do we do this and what are the tools that we
20 are going to need? Thank you very much.

21 [Applause.]

22 MS. SHERIDAN: Thank you, Ardis.

1 I'd like to now welcome Rebecca Culyba to
2 the stage and I want to point out that you received
3 a new bio that's on your tables. We referenced her
4 being with a different organization. So, Rebecca,
5 please join us.

6 MS. CULYBA: Thank you. My name is
7 Rebecca Culyba and thank you to PCORI and to the
8 Alliance of Community Health Plans for inviting us
9 to be here from the UPMC Center for High Value
10 Health Care.

11 Our center was established in 2011 as a
12 non-profit within the UPMC Insurance Services
13 Division. We're just a subsidiary of UPMC located
14 in Pittsburgh, Pennsylvania. It's one of the
15 nation's largest integrated health care delivery
16 and financing systems. The Insurance Services
17 Division has a range of products: Medicaid,
18 Medicare, commercial, children's health, behavioral
19 health, employee assistance. Their products and
20 services reach nearly 1.4 million members and as
21 such, as a regional, integrated service delivery
22 financing system, have had a long relationship with

1 ACHP and really have strived to be a role model to
2 other regional and community health plans and being
3 on the cutting edge of innovation to transforming
4 health care and addressing the triple aim.

5 So, our center, founded very recently,
6 really aligns ourselves with that mission, to be on
7 the leading edge, and we really believe actually
8 that engaging patients and other stakeholders in
9 our community is a requirement of that, and so, we
10 appreciate PCORI because it supports our work and
11 it supports our work currently because it's not
12 always -- well, our mission is to integrate
13 research practice and policy and we collaborate
14 with the university, with our provider network with
15 the hospitals, and so, Jonathan asked us to look
16 ahead for 5 to 10 years and what would success look
17 like? And, to us, we think that it will be
18 successful because we aspire that to reach high-
19 value health care that's not defined just by
20 economics, but is also through the engagement of
21 patients, local and state governments, community-
22 based service providers, and clinical practices so

1 we can focus on technology, therapeutic approaches,
2 and system level change. And as we do this and as
3 our analytics and program evaluation that's coming
4 from a payer becomes more sophisticated,
5 disparities rise to the surface, it shines the
6 light on addressing disparities. And so, we
7 believe that in 5 to 10 years, that will also be
8 something that we're successful on.

9 And we know that PCORI is not mandated to
10 address cost-effectiveness, but as we partner with
11 payers, we know that the results of comparative
12 effectiveness research can be integrated into the
13 marketplace which can increase the pace of
14 translation. So, I just want to thank you for
15 having us here today and look forward to the
16 discussion.

17 [Applause.]

18 MS. SHERIDAN: Thank you, Rebecca, and
19 when I introduced you, I failed to give you your
20 correct institution of the University of Pittsburgh
21 Medical Center. So, thank you, and I just wanted
22 to make that reference.

1 So, we are now done with the dream team
2 vision and we're going to move into just some
3 dialogue to look at where maybe there are some
4 overlap and some topics that we might want to
5 highlight. And something that really stuck out to
6 me was when Greg introduced the new we and PCORI is
7 now trying to develop this new we, and so, I would
8 like to ask the panel if you could address how does
9 PCORI develop the infrastructure and support to
10 create this new we in Patient-Centered Outcomes
11 Research? Any volunteers?

12 DR. HOVEN: Do you want me to turn my --

13 MS. SHERIDAN: Yes, do we have --

14 DR. HOVEN: Am I on?

15 PARTICIPANT: You're on.

16 DR. HOVEN: I've been called wired before,
17 but this is the actual literal translation.

18 I think the whole -- and I sort of touched
19 on it a little bit as I started talking about I,
20 we, and all the members of the health care team is
21 a first bridge, if you will, to beginning to have
22 this conversation. And from the provider side, the

1 clinician side, this is a big shift, I think, to
2 the first step in the "we." The next step in the
3 "we," obviously, is the bridge to the patients,
4 their families, their supporters, and care, and I
5 think we have to be very careful as we talk about
6 patients, we can currently address the issue of the
7 family member, the health care surrogate, the
8 whomever is involved in the decision-making for
9 that particular patient so that it's not just a
10 patient, it is that team care. So, I think that's
11 a logical first step as we begin to talk about it
12 and that we include this in our dialogue in every
13 venue we're in.

14 MS. SHERIDAN: And can the panel address
15 maybe how PCORI can help facilitate some of this?
16 How can we help create this new "we" as a research
17 organization?

18 MS. QUIGLEY: May I?

19 MS. SHERIDAN: You may.

20 MS. QUIGLEY: I think one other suggestion
21 is to really, really examine how to engage --

22 MS. SHERIDAN: Do you want to come up to

1 the --

2 MR. PECK: I think the rest of us need to
3 turn our mikes on. There's a little switch on the
4 console here.

5 MS. QUIGLEY: Thank you so very much for
6 that help.

7 [Laughter.]

8 MS. QUIGLEY: I'd like to suggest that I
9 think one of the strategies is to really look at
10 what is interactive patient engagement? I hope
11 everyone can hear me now.

12 PARTICIPANTS: Yes.

13 MS. QUIGLEY: Traditionally, care planning
14 processes really have been owned by a team. For
15 example, in nurses, we have nurses' process,
16 nurses' care planning, but how do we really, really
17 transform that into patients' goal-setting and we
18 look at how do we really merge and make sure that
19 the patients' goals are really considered what's
20 important to them based on their preferences and
21 how to really have that be a driver and then how to
22 help them integrate.

1 So, I think really getting into based on
2 socioeconomic status, cultural preferences, the
3 whole spectrum that you have addressed is how do
4 you really transform the interactive engagement of
5 patients that it is that we do ask what's important
6 to them? What are their goals? What do they want
7 to accomplish while they're here? And then we can
8 always talk about the disease issues, the health
9 care management issues, the functional status
10 issues to improve their safety, but what's really
11 important to people? How can that be the first
12 question that we ask patients when they come into
13 our care? What is it that you want to be able to
14 achieve to be as independent as you can be and as
15 self-sufficient and as productive within your
16 family and your society as you can be?

17 And I think that that would be really
18 transforming is to put that question first before
19 we do other kinds of initiatives. So, I think if
20 you could help as PCORI to really help patient-
21 centered and patient preferences become one of the
22 top priorities, certainly beyond someone who's

1 really acutely ill, but really when we're dealing
2 with preventive health primary care, how can we
3 help that be one of the top priorities? What's
4 important to you?

5 I know in the world of rehabilitation,
6 fall prevention, and even in health literacy,
7 patients prefer to be involved, patients prefer to
8 have a team sit down with them and talk with them,
9 to spend time with them, and to really engage them.
10 So, I would like to suggest that that really
11 emerged to a top priority is how to really make
12 them full partners and ask them what's important to
13 them.

14 MS. SHERIDAN: Thank you, Pat.

15 Greg, did you have anything to add?

16 MR. BIGGERS: As you know from my brief
17 opening remarks, we think that part of the PCORI
18 opportunity is about the culture of research. And
19 so, we think there's a concrete opportunity in
20 PCORI facilitating this new kind of "we" about
21 investing in some cultural context setting and even
22 focused training. And this is true we think for

1 the whole ecosystem.

2 So, researchers probably could use some
3 actual cultural training about what is it like to
4 partner with somebody that you used to call a
5 subject? A likewise on the patient side, many of
6 us need some help, need some guidelines about how
7 do we get in the trenches in something from which
8 we felt outsider for so long?

9 MS. SHERIDAN: That's a great point, and
10 PCORI is looking at opportunities to do training in
11 the future, to look at the cultural environment.

12 MR. BIGGERS: Yes, right.

13 MS. SHERIDAN: I know there are
14 researchers out in the audience who have partnered
15 with patients and I think if we reach out to that
16 population, we could learn a lot and bring that
17 wisdom and knowledge into PCORI.

18 Any other comments on the --

19 MR. LEONARD: Well, quickly, if I could,
20 because you asked Sue what PCORI could be doing in
21 space. I think we are already at one level and Joe
22 outlined a little bit this morning.

1 So, traditionally, research has often been
2 top-down, it's been investigator-initiated. So, an
3 academic is sitting in their institution and they
4 think up what they think is a cool question and
5 then they go find money to fund it. Well, that
6 works to an extent, but I know PCORI really wants
7 to hear from the grassroots up, from the patient
8 up, which is the purpose of today. So, you don't
9 really get to "we" until those two triangles come
10 together in the middle where you have investigator-
11 initiated questions that are important, they are
12 coming down toward the patient, and the patient
13 ideas that are coming up. You get to the we when
14 those are both kind of synced up and moving forward
15 together.

16 MS. SHERIDAN: And PCORI hopes to create
17 that space.

18 MR. LEONARD: Right.

19 MS. SHERIDAN: That space to create that
20 dialogue and bring these voices together and in the
21 Patient Engagement Workshop, it was actually
22 brought up by patient groups to consider flipping

1 the funding and making funding available to patient
2 organizations through micro contracts, small seed
3 money to start creating this dialogue in
4 partnership and also looking at really facilitating
5 this culture change that would be so very
6 beneficial.

7 I'm going to move onto another question
8 that as you all talked, you talked a lot about the
9 electronic health care record, and, of course,
10 PCORI's very interested in data and data networks
11 and the future of the electronic health care
12 record. I think Pat and Dan, you both brought that
13 up, and if anybody has any comment. I think you
14 all probably have thoughts about this. How can we
15 as a collective we address this issue?

16 DR. HOVEN: Okay, here I go again.

17 [Laughter.]

18 DR. HOVEN: I'll take a first crack at it
19 because I think this is one of the biggest
20 challenges we've got in many arenas right now with
21 Electronic Medical Records and various platforms
22 for information sharing that are not really out

1 there and I think maybe one of the parallel works
2 that PCORI needs to be thinking about is how, in
3 fact, an ideal platform would look for us, in fact,
4 to share and have this information.

5 And when I talk about this platform, I'm
6 talking about the science piece coming in, coming
7 in on the clinician side of it so we can see the
8 data and the science that's out there. The
9 platform then being able to allow me as a physician
10 to share relevant and important information with my
11 patient in a way that's translatable to what they
12 need and understand and concurrently, that
13 information is then send out other members of the
14 team because at the end of the day, it's not going
15 to be just me, it's going to be the nurse, the
16 secretary, the administrator, a lot of other folks
17 engaged in the process. So, we're talking about a
18 platform that looks and smells differently from
19 what we're used to doing in the traditional
20 Electronic Medical Record. It's an expanded type
21 of a thing and it's not just purely documenting
22 what's interesting the medical record.

1 MS. QUIGLEY: And I'd like to add, too,
2 that I think that there's still so much more work
3 to get Electronic Medical Records operational. In
4 2012, moving into 2013, we still have hospitals
5 that are using paper records. We have to move that
6 forward. But, nonetheless, with Electronic Medical
7 Records, I think that the patient perception is
8 changing.

9 There were a lot of concerns at first that
10 clinicians, providers were spending more time
11 looking at the computer than they were really
12 engaged with the patients, and I think some of that
13 is shifting again as we really help patients to see
14 how -- to be able to follow their own lab values,
15 to be able to see the improvement in their health
16 care, to be able to follow their functional status,
17 to be able to report on their measurement of
18 fatigue and pain. I think that there are ways to
19 be able to really engage patients with that not
20 only when they're in our care, but when they go
21 home. I mean, it's a transition of care.

22 As a rehab nurse and all the nurses at

1 American Nurses, it's how we work with patients
2 throughout their entire continuum of care in their
3 lifetime, so, how do we move this beyond just the
4 episode of care and into their own real health care
5 management and really own their own care planning.
6 So, I think that there are ways to even be able to
7 do that, to know their plan of care after discharge
8 and be able to communicate back to us how they're
9 doing and the progress that they're making.

10 So, I think that that are some really
11 great opportunities. It's not just managing the
12 acute disease episode, but really their whole
13 health care and be able to move Electronic Medical
14 Records in a different way and electronic
15 communication.

16 MS. SHERIDAN: And you kind of are leaping
17 to another question that I had about the Patient-
18 Reported Outcomes, the PROs.

19 MS. QUIGLEY: Yes.

20 MS. SHERIDAN: And this is a new area even
21 for the patient community to recognize the power of
22 Patient-Reported Outcomes. Several of you brought

1 that up.

2 Would some of you like to comment on the
3 future of Patient-Reported Outcomes and how that
4 can help drive improvements and outcomes and how we
5 use that data?

6 MR. BIGGERS: Can I throw in one more
7 short comment about the EMR?

8 MS. SHERIDAN: Absolutely.

9 MR. BIGGERS: So, I think everyone
10 realizes that researchers would love to have all of
11 that data that are going into Electronic Medical
12 Records and it seems to me there are two approaches
13 that we can use in research to harness that data
14 and one of them is already beginning to happen
15 where people are consenting patients at the point
16 they enter a system so that that data in an
17 identified way can be used in the VA and the U.S.
18 has done a lot of work in this.

19 But I think specific to PCORI's context,
20 we have an opportunity to help patients actualize
21 their own locus of control regarding that data and
22 take potentially a different or additional approach

1 by enabling patients to become the control point
2 for contributing their data to research and that
3 carries with it a few other benefits around the
4 consenting process and crossing the HIPAA and
5 HITECH Act firewall and all that kind of stuff.

6 MS. SHERIDAN: Yes, very good points, and
7 there are many patient organizations that are also
8 very supportive of this concept.

9 Helen?

10 MS. HASKELL: In terms of Patient-Reported
11 Outcomes, I think, first of all, we need to start
12 at the individual level, interactive medical
13 records so that patients can input their symptoms
14 and concerns, make corrections in the record. I
15 think this is really essential for safety in
16 addition to just sort of moving things forward, and
17 I think one of the things that we found which is
18 something that patients have known for a long time
19 is that there are a lot of complications, symptoms,
20 outcomes, sequels that patients are well aware of
21 that are somehow not in the medical literature and
22 you can capture that in the medical record if the

1 medical record is interactive and you can use it to
2 do further research, to refine treatments. And so,
3 I think this is a big area for research and for
4 [inaudible].

5 MS. SHERIDAN: Thanks, Helen, and that
6 supports what many organizations have been talking
7 about recently about interactive health care
8 records as well as open notes, and it looks like
9 the future is going to be this sharing and giving
10 and taking of information and packaging the data
11 for research.

12 Thank you, all -- oh.

13 MR. PECK: I can say [off microphone] --

14 MS. SHERIDAN: Yes.

15 MR. PECK: In a good way.

16 MS. SHERIDAN: Yes.

17 MR. PECK: And I think we can bring people
18 into the dialogue with the panel.

19 So, Marty's got a microphone there and if
20 you would like to speak and ask a question or make
21 a point to the panel, a brief point, please raise
22 your hand and Marty and I will -- he's got that

1 half, I've got this half.

2 MS. QUIGLEY: And I think while they're
3 travelling, I'd just like to add that in
4 relationship to Patient-Reported Outcomes, that
5 there are valid and reliable instruments out there.
6 For some of them, outcomes to measure, but they
7 still need to look at cultural preferences, gender
8 preference, and gender considerations. I think
9 that there's still more opportunity for enhancing
10 those measures and those tools that are out there.

11 MS. SHERIDAN: Great. Thank you.

12 MS. QUIGLEY: Thank you.

13 MS. FRIEDMAN: Good morning. I'm Susan
14 Friedman with the American Osteopathic Association
15 and I have a question for Dr. Hoven.

16 As you talk about the team-based care
17 approach, can you address how this is going down to
18 the medical school level to sort of change the
19 culture to enhance that?

20 DR. HOVEN: Great question. I didn't pay
21 her to ask this question.

22 [Laughter.]

1 DR. HOVEN: As we're moving forward at the
2 American Medical Association, one of the first
3 important legs of our new strategic plan is
4 actually changing medical education. It has been
5 what it's been for 100 years; it hasn't really
6 evolved to meet the demands of the 21st Century.

7 So, in fact, our medical students will now
8 be taught team care, how to work with others, how
9 to play in the sandbox appropriately, how to get
10 the work done by a team and involving team members
11 to their highest level of function so that they can
12 get the work done. So, I think you're touching on
13 something which is very important and what I kind
14 of alluded to earlier because I think to do what
15 we're talking about, it's more than just the doctor
16 and the patient because there are many other moving
17 parts to the system of care and they've all got to
18 be on the same pathway. But thank you for the
19 question.

20 MS. WISE: Hi, I'm Leslie Wise and I'm
21 from Biomet Orthopedics. And, actually, my
22 question had to do with the Patient-Reported

1 Outcomes.

2 Last week, I was in Boston at an industry
3 meeting on real-world data and how we're going to
4 be able to make it actionable and impactful and
5 take clinical research from random control trials,
6 which is the very homogenous population to
7 population health, which is what real-world data
8 should help us with. But one of the things that
9 have been identified is that the traditional tools
10 that we used for PROs have maybe 100 measures on
11 them, right? So much information that it doesn't
12 become enough to really be impactful.

13 How do we begin, and you kind of spoke to
14 that, to develop tools in this area for Patient-
15 Reported Outcomes that really matter to patients?
16 Because it may not be 100 things and that's a lot
17 of things in 1 area. How do we hone it down to
18 those four or five things per disease state, per
19 research area that can really impact their lives
20 rather than sort of collecting a lot of things that
21 researchers maybe want to know that patients don't
22 necessarily find important?

1 MR. LEONARD: I'll take a cut at that. I
2 think, again, that bringing the patient in earlier
3 in the process is an important step in that
4 direction. I think PCORI certainly gets that and
5 is taking those steps, but asking patients or a
6 patient what are their preferences before you go
7 into a study? So, it may not be what the academic
8 or what the researcher is looking for or
9 traditionally put in a questionnaire, but it's
10 questions around side effects, it's questions
11 around does this therapy make me drowsy or inhibit
12 me when I'm at work, whatever those questions that
13 really are germane to the individual patient. So,
14 getting the patient involved in designing the
15 research or designing the questions that'll go into
16 the study on the frontend clearly is the first
17 step.

18 MS. CULYBA: I would echo that and also
19 just from a real-world data perspective, we're
20 challenged by this in our work by partnering with a
21 health plan or a hospital system with existing
22 data.

1 MR. HATLIE: Rebecca, we can't hear you
2 well. Can you -- there you go.

3 MS. CULYBA: Can you hear me now?

4 MR. HATLIE: It's on your battery pack.

5 MS. CULYBA: Can you hear me better now?

6 MS. SHERIDAN: Use your big voice.

7 MS. CULYBA: So, we're challenged by this
8 in our work because we do partner with health plan
9 analytics and hospital system analytics and I think
10 just coming together of multiple systems can be a
11 challenge, but to have those folks at the table,
12 too, from the beginning alongside patients so that
13 there's this reconfiguration of the "we" and to
14 also have our scientific partners who can speak to
15 the best statistical methods is important, too.
16 So, that's part of what we've been trying to do in
17 Pittsburgh at our center.

18 MS. QUIGLEY: And maybe one of the
19 strategies with PCORI is to really narrow down and
20 specific any of the reported outcomes related to
21 your three top priorities now and to really look at
22 what can we address and what is really of value and

1 a priority to patients and caregivers related to
2 those three top priorities that are going to be
3 your funding priorities in 2014. That might be a
4 strategy to help narrow and focus.

5 MR. BIGGERS: I thought that was a really
6 insightful question because it highlights the
7 complexity of the problem that we're trying to
8 solve, and so, I just had it back to culture again,
9 that we have the opportunity finally to let
10 patients be the experts in some of these things.
11 And I think that has great power, but we have to
12 become comfortable with the emergent nature of
13 letting things like that bubble up from the bottom
14 versus a top-down ontology and I think that's a
15 major culture shift.

16 MS. SHERIDAN: Good point, Greg.

17 MR. HATLIE: [Off microphone.]

18 DR. WILLIAMS: Good morning. I'm Dr.
19 Pamela Williams. I'm a nurse scientist from the
20 Medical University of South Carolina, and I wanted
21 to respond to the representative from big pharm and
22 you're saying that you come here "agnostic" and

1 trying to understand what you mean by that.

2 And in addition, thinking about that
3 agnosticism that may be out there beyond just your
4 identifying yourself as that, here we are and we're
5 talking about culture change and culture change
6 takes time. We're trying to develop a space and
7 it's a very fine space that we're talking about
8 developing, but those cultural changes will take
9 time.

10 So, what can we do now to start
11 instigating the culture change? And I believe that
12 as a scientist, we can even in these traditional
13 top-down type of formats like clinical trials,
14 pharmaceutical clinical trials, we can start
15 collecting patient perceptions, Patient-Reported
16 Outcomes should be included in clinical trials, not
17 just Physician-Reported Outcomes.

18 So, I'm trying to say a couple of things
19 mixed together in that those scientists that are
20 married to and grew up in the historical culture of
21 a top-down research design, if we can start
22 stimulating change by even provoking Patient-

1 Centered Outcomes collected even in the most
2 traditional study design.

3 MR. LEONARD: Well, what I meant by
4 agnostic was with regard to what should we study in
5 the disease states specific. So, should PCORI
6 spend its money in cancer or diabetes or heart
7 disease? That's where we're agnostic. We're very
8 engaged when it comes to how it should be studied
9 and the types of research and the models of the
10 research and the standards around observational
11 studies or whatever you're going to do, but when it
12 comes to what should be studied, what specific
13 disease states, I think PCORI's onto that and
14 they've got a process in place, but that's not
15 where we're going to have an opinion specifically.

16 MS. TRAN: Yes, my name is Ho Tran and I'm
17 with the National Council of Asian Pacific Islander
18 Physicians and I just want to go back into the
19 issue of the we, very innovative, and also a
20 comment because for our organization, we also look
21 at the concept perspective of changing the health
22 care system, especially for the workforce. So, we

1 call it the 21st Century Medicine.

2 So, going back to Dr. Hoven, it is kind of
3 a paradigm shift. So, what I would like to ask,
4 especially for PCORI, it is that when we talk about
5 the we, we talk about the public education, about
6 involving the residents, the people. So, for us,
7 we look at it should be a shared responsibility and
8 that someone is missing in the panel. It is the
9 legislature, the one who makes the law. Because
10 when we talk about that, physicians say that we
11 would like to be a partner with patients, but we
12 also are very much liable. So, how can we have
13 that discussion, education that the patients are
14 also responsible for their behavior?

15 MS. QUIGLEY: I would like to comment on
16 that, as well, because I think wouldn't it be
17 wonderful if we knew what is the best practice
18 model of the family that values and owns their
19 health today for tomorrow and how can all of health
20 care industry be able to help them be able to
21 achieve that? I mean, do any of us know what that
22 best practice model is where family members really

1 and all of us are really taking responsibility? If
2 PCORI could be able to help create, pull families
3 and caregivers together to find the best practice
4 model where people really do value and their own
5 their health and, again, not just for today, but
6 for tomorrow and how can we as a health care
7 industry and all the analytics and all the support
8 system really be able to help people achieve that?
9 Wouldn't that be wonderful?

10 MS. SHERIDAN: The land of milk and honey.

11 [Laughter.]

12 PARTICIPANT: Yes.

13 MR. MAILMAN: Good morning. I'm John
14 Mailman. I'm a patient advocate. I represent a
15 rare disease, neuroendocrine tumors. I'm also an
16 executive board member of the Society of
17 Integrative Oncology. I'm also a patient
18 stakeholder at BraveNET.

19 And I wanted to come back a little bit to
20 a conversation about Patient-Reported Outcomes and
21 do we need to develop new tools? And I also happen
22 to sit on the NCI Taskforce for Neuroendocrine

1 Carcinoma, so, I see a lot of questions on quality
2 of life and Patient-Reported Outcomes and what I
3 see across a bunch of studies is different
4 methodologies for reporting patient outcomes and
5 when clinicians are looking across different
6 methodologies, they can't compare these apples-to-
7 apples. And so, what I've seen recently and
8 certainly I've had some training on and I think
9 building the bridge, using the same methodology
10 across multiple studies, there is, of course, the
11 PROMIS, the studies that the NIH is doing to help
12 promote Patient-Reported Outcomes so there's a
13 consistent tool, but the same types of questions
14 can be asked across all sorts of studies with
15 certain disease-specific questions that can get at,
16 but so there's consistency so that when we see
17 Patient-Reported Outcomes, they're consistent
18 across studies. So, they're not treated
19 differently so commissions can actually have some
20 idea that they have the same relevance and using
21 the same measurement.

22 So, I heard kind of an idea we need to

1 create new things and one of the challenges, we
2 need to use things that consistently across a broad
3 spectrum of research, creating new things will only
4 add some more confusion to that. I just wanted to
5 add that as a point.

6 DR. HOVEN: Can I jump in here?

7 MS. SHERIDAN: Yes, absolutely.

8 DR. HOVEN: Because I want to make a
9 comment and because I think what he's saying is
10 very important, number one. Number two, I also
11 think that we have to look at the balance, the
12 appropriate balance between the scientific outcomes
13 in terms of disease management and at the same time
14 the issue of the Patient-Reported Outcomes, which I
15 think it's easy to talk about, but it's really
16 going to be hard to try to narrow some of that down
17 specifically when you get into certain illness
18 types or you get into cultural issues. You've got
19 to be able to address that across a spectrum of
20 entities and I think we've got to do a better job
21 of doing that, but I caution here that we have to
22 concurrently not only talk about Patient-Reported

1 Outcomes, but we at the same time as givers of care
2 have to talk about what the outcomes are in terms
3 of the science and it's a very, very difficult
4 balance sometimes to get us to the right place and
5 I think that also goes to the question over here
6 about the liability pieces of this, that these are
7 significant. And so, therein comes the balance
8 between the science and the patient needs and
9 reported outcomes. So, there's a lot of work that
10 I think PCORI may need to do in this particular
11 area, as well.

12 MS. SHERIDAN: Thank you, Ardis.

13 MS. LINKOV: Hi, can you hear me well?
14 So, I'm Faina Linkov from the University of
15 Pittsburgh and I'm a cancer epidemiologist and a
16 researcher so I represent sort of the rare breed in
17 this room.

18 My question is about the culture that most
19 of you mentioned, the changing culture of research
20 involving patients and development of research. I
21 have to admit that as researchers, we are very much
22 puzzled as to how exactly to do it. Like, for

1 example, if in my research I need to involve
2 diabetes person or like breast cancer person, I
3 know that they can go for the leader in the field
4 and have like this one person and that would be
5 enough for my grant to represent expertise in this
6 area.

7 When it comes to patients, one patient
8 would not necessarily represent all the issues
9 involved in designing a study or basically giving
10 us a better idea as to what a patient would be
11 looking for. So, when we develop our teams, how
12 many patients do you think should be involved? How
13 many patients is enough? Especially those of you
14 who are involved like as patient advocates. So,
15 like basically with research, we know what the
16 sample sizes are, like we have the methodologies.
17 For something like this, I feel like methodology is
18 not there. So, my question is to the entire panel:
19 Do you envision some kind of methodologies for
20 identifying the magic number of patients?

21 MR. BIGGERS: And when you say "the magic
22 number of patients," you mean in helping design

1 this study, right? You don't mean the "n" that is
2 actually being studied?

3 MS. LINKOV: No.

4 MR. BIGGERS: Okay.

5 MS. QUIGLEY: Well, I know in PCORI, one
6 of your entities within PCORI is to address that
7 very issue about research methodologies and what
8 are the best research methodologies to really move
9 forward to be able to help answer the questions
10 that are coming forward and how to be able to
11 engage patients and families. So, I don't know if
12 we have the actual answer for you, but I know that
13 you have one of the organizational infrastructures
14 that you have is to really, really help guide
15 research methodologies surrounding this area.

16 Go ahead.

17 MS. CULYBA: I would just say as well that
18 I think that the opportunity that PCORI provides us
19 is to start to just experiment with this, with this
20 whole notion of the "we" and how patients can be
21 involved from being participants in a study all the
22 way to being full collaborators, and we've really

1 tried to do that. We've tried to really just throw
2 ourselves in there by applying for PCORI's and
3 we've gone all the way to identifying
4 collaborators, so, which I have up here patient
5 investigator on the team, which is a really new
6 thing and we don't really know the best way to do
7 it, I would say.

8 So, we also try to get input like I think
9 a lot of people who are writing grants may do,
10 focus groups and things like that. So, we've tried
11 to kind of get a broad range from fully
12 collaborative to just informing the questions and
13 vetting our questions and then the challenge that I
14 think PCORI gives us is how do you demonstrate in
15 your proposal that you've done that? And they ask
16 you to do that. And so, it forces us, I think,
17 eventually to have best practices for that.

18 MS. SHERIDAN: And just to add to what you
19 said, PCORI does in our funding announcements
20 require that there are patient collaborators or
21 stakeholder collaborators to partner with the
22 research design team and we are pioneering new

1 territory. Now, there are some examples of
2 patient-stakeholder partnerships out there with
3 researchers and they have been more on an ad hoc
4 basis if PCORI wants to create this by design. And
5 so, we through our 50 pilot projects and current
6 announcements we're going to make about some
7 awardees, we hope to provide to the community
8 examples of what we find is the best kind of
9 partnership. I don't think it will necessarily
10 fall on a specific number, but what's the richest
11 kind of contribution that the patient stakeholder
12 partners can make to the outcomes of the research?
13 So, we call ourselves a learning organization. We
14 are learning and we are sharing, and as we learn
15 and grow, we encourage your input to help us
16 identify what are the best practices.

17 MR. BIGGERS: So, I have to weigh in on
18 this one, but it'll be brief. So, I agree with Sue
19 that this is an absolute frontier and I'll skip out
20 on a small limb of presumption to say I'm one of
21 the people in the world who has a lot of experience
22 in this area, but that's only because there aren't

1 very many of us with any experience. And so, this
2 is the first time I've even heard that question
3 asked, like what is the right number? So, I think
4 the answer today is more.

5 [Laughter.]

6 MR. BIGGERS: And we're going to find out
7 what the parameters as we go.

8 MR. HATLIE: We also just got a lot of
9 offers at the last workshop from patient advocates
10 about ways in which they'd be willing to help us
11 count the numbers or figure out the right numbers.
12 So, just rich feedback there.

13 MR. LEONARD: A thought on that maybe is
14 for PCORI to set up some network or to connect the
15 patients with the research community so you have a
16 question, but where are these patients that I
17 should bring in, and PCORI can play that role.

18 MS. SHERIDAN: And, actually, we announced
19 at our last workshop kind of a soft launch of a
20 challenge that we will be announcing shortly on
21 we're calling it finally the Match-Making concept,
22 and this came up, this was a very robust discussion

1 at the Patient Engagement Workshop because the
2 message was we patients are eager, we're here,
3 we're ready to partner. How do we find our
4 researchers? And on the flipside, the researchers
5 understand the value of incorporating the patient
6 stakeholder wisdom in the research, but the
7 researchers also say to us how do we find the
8 patients? So, through a challenge that we'll be
9 announcing, we hope to create some creative
10 thinking and possibly applications or systems that
11 will actually help facilitate researchers finding
12 patients and vice versa.

13 MS. QUIGLEY: And if I just may add, I
14 know that there are people waiting, but always to
15 be conducting mixed method research where you are
16 doing the qualitative part where you have focus
17 groups and you get patient preferences. And then
18 there are organizations that are research in the
19 effectiveness of patient advisory councils, too,
20 and health care systems. So, I know that there's
21 movement in that area.

22 MR. BIGGERS: So, you can teach us what

1 the right number is.

2 MS. QUIGLEY: Yes.

3 [Laughter.]

4 MS. SHERIDAN: Thank you.

5 MS. SALY: Hi, my name is Martha Saly.

6 I'm the executive director of the National Viral
7 Hepatitis Roundtable.

8 I am hearing a lot about the new we and I
9 appreciate the comments, some really great ideas
10 coming from this stage. I'd like to ask the
11 panelists if you could talk about additionally
12 besides engaging the patients, how in your programs
13 and in your work are you engaging both the
14 caregivers and the family and wider support network
15 of patients, especially among very vulnerable
16 populations of patients? Sometimes, it's difficult
17 for the patient themselves to engage and also if
18 you would talk about how or if you are engaging
19 your wider community, meaning the community-based
20 organizations addressing the issues that are
21 important to you in your practice, the
22 policymakers, and other areas within your

1 communities.

2 DR. HOVEN: Well, I'll jump in on this
3 one. I'm an infectious disease specialist. So, I
4 hear what you're saying. I think it is very clear
5 in various populations, particularly vulnerable
6 populations, and I alluded to this earlier, is that
7 it's not just the patient sitting in there, it is
8 the health care surrogate, it's the family member,
9 it's the life partner, it's whomever it is helping
10 that individual navigate through all the pieces
11 that have to be dealt with. Built on top of that
12 is part of the health care team, which is the care
13 coordinator, the case manager, whomever it is
14 that's necessary to help us, again, navigate the
15 various challenges and portals that have to be met.

16 I think that's an inherent issue in this
17 whole discussion and it cannot be left out in any
18 way, shape, or form. It also goes to the issue of
19 the community-based entities because I firmly
20 believe that much of this health care, all of this
21 health care is local and our engagement with
22 community groups, be they the health department,

1 whatever it is in our community's hospital-based
2 systems, teaching institutions, integrated
3 practices, church groups, whatever it is, we have
4 not done the best job necessarily at linking all of
5 these together.

6 So, I think part of what we're going to
7 have to do, and, again, it's another thing on the
8 to-do list for PCORI, but for all of us who are
9 engaged in this is that we're responsible for
10 providing the leadership in our grassroots level
11 that gets that accomplished, but I think this is a
12 huge issue and it's going to bear watching and
13 deliberation as we go forward. Thank you.

14 MS. SHERIDAN: And let me just add that
15 when PCORI, and I'm just speaking on behalf of
16 PCORI, but when we talk about the "new we," I mean,
17 we're seeing a global "we" when we might speak of
18 patient engagement and we mean patient community
19 caregiver and the broader health care community.
20 We don't see us moving forward individually in
21 silos, but, collectively, we believe that. So,
22 we're going to find the power.

1 MR. HATLIE: Sue, Jonathan, we have a
2 number of comments, people that have asked to get
3 in line. So, we're about 20 minutes away. We'll
4 try to get to as many comments as we can. But
5 thanks.

6 Jonathan, you've got something teed up?

7 DR. ANDREAE: My name is Michael Andrae,
8 Albert Einstein College of Medicine, New York.

9 As a critical care physician, I've seen a
10 lot of patients pass away in the ICU. That's where
11 a lot of health care dollars are spent in the last
12 weeks and days of our lives. And let's face it,
13 everybody of us eventually will have to pass and we
14 would all like to do that at home in our gardens,
15 surrounded by a lot of family and friends, but
16 that's not what's happening at the moment.

17 And so, my question is: How can we get
18 the most bang out of the buck in the later years of
19 life? How can we add life to years instead of
20 years to life and how can we -- yes, that's my
21 question for you.

22 DR. HOVEN: I'm sorry to be talking so

1 much --

2 MS. SHERIDAN: No, go for it.

3 DR. HOVEN: But these people are hitting
4 all of my --

5 MR. SHERIDAN: Your buttons.

6 DR. HOVEN: My flags and I'm excited about
7 it.

8 The whole issue about elder care, end-of-
9 life care, end-of-life decision-making, again, I
10 think is another thing that PCORI needs to be
11 talking about. I had a conversation at dinner last
12 night with some of my new friends about this whole
13 issue of self-determination, value recognition,
14 what's important to that patient, what's important
15 to that patient's family, and getting that laid out
16 there, and I think to your point, many, many
17 seniors don't want to die in the ICU, which is
18 exactly where they're dying. We've got to do a
19 better job in this country of allowing them to tell
20 us and we are responsible for initiating
21 conversation and we are responsible, all of us in
22 the health care team, for making sure we value what

1 that patient and their family needs and wants so
2 that that transition and the ultimate death can be
3 made at the right place, at the right time, and the
4 right way in a care model that isn't an
5 institution-based model; it is, in fact, a home
6 model or some other model that allows these folks
7 to get what they need and deserve as Americans.
8 So, thank you for that question.

9 MR. PECK: Sue, we have questions not only
10 in the room, but a Twitter question. One for the
11 panel is: How can PCORI best support translational
12 research?

13 MR. BIGGERS: So, maybe we have to ask the
14 statute to that question.

15 MS. SHERIDAN: What's that?

16 MR. BIGGERS: Maybe we have to ask the
17 statute that created PCORI.

18 PARTICIPANT: Ask the statute.

19 MR. BIGGERS: There are some boundaries
20 there, I think.

21 MS. SHERIDAN: Are there any comments on
22 that from the panel?

1 DR. HOVEN: I don't have an answer to it -
2 -

3 MS. SHERIDAN: Yes.

4 DR. HOVEN: But we've got to answer it.

5 MS. SHERIDAN: Right, I don't have --

6 DR. HOVEN: Because it goes to the very
7 issue we've been talking about that transparent
8 platform of doing translation and passing
9 information on includes that translational
10 research, as well.

11 MR. BIGGERS: And one of the frontiers is
12 the boundary between translational and clinical
13 seems to be blurring. It's so much more of what
14 happens in the clinical setting is actually a
15 little bit experimental and we don't have the rules
16 for doing that.

17 MR. LEONARD: PCORI does have the
18 translation table exercise underway, as well.

19 MS. SHERIDAN: Right.

20 MR. HATLIE: Okay, we've got another
21 comment here.

22 MR. SPERLING: I'm Andrew Sperling with

1 the National Alliance on Mental Illness.

2 Another layer of complication on this, and
3 not only a public health burden, but also
4 scientific opportunity and tie it to where I think
5 the health care system needs this work the most and
6 that is with the cost of the highest and that's
7 with chronic disease management.

8 Particularly for individuals with multiple
9 chronic conditions and it's certainly an issue with
10 the population I represent of individuals that have
11 disorders such as bipolar disorder, schizophrenia,
12 major depression, but the real high cost associated
13 with the care is not their psychiatric disorder but
14 the fact that they have two, three, and sometimes
15 four multiple chronic conditions: diabetes, heart
16 disease, COPD, and how we deal with these complex
17 situations in real-world treatment settings where
18 largely they're excluded from other types of
19 industry and other types of government-funded
20 research because they have all these multiple
21 chronic conditions. It makes it difficult to
22 isolate the particular condition that a particular

1 institute at NIH or a particular target that a
2 private sector drug company is looking at.

3 I think there's an enormous opportunity
4 for PCORI to move the health care system forward to
5 deal with what -- we're a part of a group called
6 the Partnership to Fight Chronic Disease. I think
7 their estimate is 75 percent of the health care
8 cost in this country, dealing with chronic disease
9 management and I think this is an enormous
10 opportunity for PCORI to look at populations in
11 real-world treatment settings where physicians are
12 interacting and dealing with not just one
13 condition, but three or four conditions at the same
14 time.

15 MR. BIGGERS: Yes, ironically, comorbidity
16 is kind of a novelty in research. I mean, isn't
17 that strange because that's real life?

18 So, perhaps, there's an opportunity as
19 PCORI starts to develop some priorities to earmark
20 within topic areas that PCORI would like to see
21 some number of studies explicitly include
22 comorbidities even though that might not always be

1 true.

2 MS. HASKELL: I'd like to add to that. I
3 think that PCORI needs to be sure that it is
4 addressing the big questions, and I don't think
5 there's one bigger than mental health. The really
6 big issues, how effective are these treatments?
7 What can we do this fragmented, dysfunctional
8 system that deals with mental patients? How many
9 of these comorbidities are caused by the treatments
10 and is there anything we can do to prevent that, to
11 change the treatments to help people? So, a big
12 comparison is mental health. Other big issues like
13 infection, chronic disease, all of those things I
14 think we need to not be afraid to tackle.

15 MS. SHERIDAN: And some -- okay.

16 MR. LEONARD: I alluded to it in my
17 opening remarks. Andrew mentioned "real-world
18 evidence," and isn't that what this is all about,
19 is finding out what happens in the real world and
20 not the clinical world? And the irony is that
21 research done on a traditional clinical randomized
22 trial would disqualify the people that Andrew is

1 talking about right now because they have a
2 condition outside of what investigators are looking
3 at. So, expanding the scope of real-world
4 evidence, but then making sure that there are
5 standards that are set. So that when the research
6 is complete, it's appreciated, understood, and
7 recognized as high-quality.

8 MS. SHERIDAN: And part of PCORI's mandate
9 is to address multiple chronic conditions, and so,
10 that is definitely on our radar and it's something
11 that we appreciate very much and address in our
12 funding announcements.

13 MS. QUIGLEY: And I'd just like to add,
14 too, I know there are so many in line, but
15 certainly underfunded is what are the best
16 effective patient and family education strategies
17 so that people really do learn to the point that
18 they're able to take what they learn and change
19 their practices, to change their behavior? What
20 does it take to change behavior? So, I think that
21 really getting into the best effective patient and
22 family education strategies is such an important

1 priority.

2 MS. SHERIDAN: Very much, and some of our
3 Pilot Projects address kind of the doctor-patient
4 communication and the best, most effective methods
5 and way to communicate and educate patients.

6 DR. UNDERWOOD: Hello. I'm Willie
7 Underwood. I'm a surgeon, neurologist. I do
8 health services research, I do health policy, I do
9 disparities research, and I'm also African-
10 American.

11 Now, I'm going to tell a story and I'm
12 going to talk about this in a way that I hope we
13 get to the point. So, when I was young, I
14 remembered learning to make phone calls. I would
15 take a pencil, you had that big circle to dial,
16 right, and if you started at zero, sometimes you
17 never made it all the way around. Today, look at
18 us today. We have telephones that are computers.
19 We call long distance for free. We interact with
20 each other in ways that we never have before.
21 However, the phone company didn't do that. So, at
22 the time when I was a child, if I talked about,

1 hey, one day, we're going to be able to look at
2 each other on the telephone and talk to each other,
3 my grandmother would have said yes, maybe, highly
4 unlikely.

5 Okay, now, PCORI has the opportunity to do
6 the same thing for the health and health care in
7 this country. How do we focus on improving the
8 health of America? How do we step out of we are as
9 researchers, as scientists, as nurses and doctors
10 and say yes, I understand this little piece right
11 here, but how do we come together and say listen,
12 if we put our intellectual and experiences and
13 things together as individuals into the "we" as we
14 call it and create something that we can even
15 imagine today existing because that's our goal, is
16 to do something that we cannot imagine and that is
17 truly making America and the world a healthier
18 place. How do we do that? And that's the question
19 I have for PCORI and that's what I thought we were
20 going to do when I came here because I believe we
21 can do it.

22 MS. SHERIDAN: Thank you.

1 [Applause.]

2 MR. WHITE: Hi, I'm John White. I'm a
3 rehabilitation researcher in Philadelphia.

4 My question has to do with the "we" of the
5 many stakeholders and the fact that, right now,
6 we're all together because there's no actual
7 evidence being weighed, but, historically, when
8 evidence gets weighed, not everyone sees eye to eye
9 and it's not cut and dry and we still have large
10 portions of our health care industry that are in
11 corporate culture whose primary mission is not the
12 patient-centered outcome.

13 So, I guess what I'm interested in how
14 PCORI imagines navigating the political landscape
15 given that we will likely face situations where by
16 some people's eyes, the evidence is in favor of
17 something that is very much not in the financial
18 interests of another stakeholder. Thanks.

19 MS. SHERIDAN: Any thoughts? I thought
20 maybe you'd respond to that.

21 DR. HOVEN: Well, let me jump in --

22 MS. SHERIDAN: Yes.

1 DR. HOVEN: If I may.

2 MS. SHERIDAN: Go ahead.

3 DR. HOVEN: Because I think we are going
4 to have to develop very tightly-knit collaborative
5 work and relationships with all of the moving parts
6 that deliver health care and that interact with
7 patients in any venue. Now, what I'm getting at
8 is, for example, speaking as a physician and the
9 American Medical Association, utilizing our
10 relationships with specialty societies, with state
11 medical associations, leveraging that information,
12 getting it out there down to a grassroots level and
13 getting the buy in from my physician colleagues so
14 that they can begin to work on the ground with this
15 information. I think the ANA doing the same kind
16 of thing. I think physical therapists, everybody
17 engaged in this dissemination of information. This
18 isn't going to be something PCORI is going to be
19 able to flip a switch on at the top. I think this
20 is going to have to be driven really down deep and
21 it's going to take some collaborative effort. But
22 we, back to Willie's comments, have to do this

1 because we're capable of doing this.

2 MR. BIGGERS: Well, it's unfruitful to
3 have a conversation about costs if we don't any
4 evidence. So, let's generate a lot of evidence and
5 let somebody else figure out what that means about
6 cost.

7 MS. CULYBA: Well, and I would just say
8 from our perspective, I mean, this is a real
9 challenge in the work that we do working with
10 hospitals and providers and we really try to have
11 the goal of collaborating knowing that we're not
12 really going to come to consensus all of the time.

13 So, if we're leveraging, for instance, a
14 quality initiative that's a payer provider
15 initiative and then we bring patients and other
16 community stakeholders to the table, it kind of
17 changes the landscape of what we're trying to do.
18 So, when we were putting proposals together and
19 asking questions, I think sort of the smaller scale
20 of these PCORI announcements, it suits us because
21 it doesn't ask for huge, huge change which is
22 ultimately, I think, what everybody wants, but

1 maybe to start on smaller scales and really try to
2 get everybody at the table at the beginning, but
3 it's a real challenge.

4 MR. LEONARD: So, the question is around
5 what happens at the end when research comes out?
6 There may be dissent in the community or political
7 dissent. I think the answer is actually at the
8 beginning and a lot of the work that PCORI is doing
9 with the methods upfront and making sure that the
10 methods of the research going in are pure and are
11 accepted so that when the research comes out, it's
12 more bulletproof to the politics of the day.

13 MS. SHERIDAN: Yes?

14 MR. LIPSTEIN: [Off microphone.]

15 This is really an important point and I'll
16 speak loudly about it. It's important for
17 everybody to know that PCORI is not [off
18 microphone] except by statute independent of
19 government. And so, really, there really aren't
20 political considerations in our board room at all.
21 And so, the research that we're doing is really
22 being guided by what we believe is in the best

1 interest of patients and their caregivers and their
2 clinicians.

3 And so, I just wanted to reemphasize that
4 point really because the founding fathers and
5 mothers of PCORI went to great lengths to ensure
6 this was set out outside of the political
7 infrastructure. And so, just keep that in mind
8 because that also prevents us from a very great,
9 unique opportunity to do research and produce
10 information that is completely unbiased and then we
11 think will help inform federal decision-making
12 without [off microphone] somebody referred to as
13 corporate or financial interests.

14 DR. WEISMAN: [Off microphone.]

15 MS. SHERIDAN: Here, come on up.

16 DR. WEISMAN: When the Board started, we
17 came from all different places and different
18 backgrounds, different jobs, different
19 representation of stakeholders, and what you find
20 is what we found is that all stakeholders, whether
21 it's from medical product industry, insurance
22 industry, hospital industry, whether they're

1 physicians or nurses, chiropractors or patients, we
2 all want the same thing, it's just that we don't
3 trust anybody else and their intent. And so, one
4 of the things, one of the rules is you've got to
5 assume good intent when you start and you can't
6 start with the assumption that my intent is good,
7 but I don't trust the other person. And that
8 allows you to move forward.

9 Everyone has conflicts of interest in
10 this, everyone does. If you're a doctor and
11 specialist, you believe your specialty ought to be
12 performing a procedure rather than the other guy's
13 procedure. You don't trust the hospital; you don't
14 trust the insurance companies. Everyone's making
15 your life miserable. Nobody takes the patient at
16 the center and the patients are totally lost in all
17 this.

18 If we all come to the table at the
19 beginning and agree on a fair way of going forward
20 by methods and other things, I think the most
21 important thing is transparency and openness in the
22 process. That cures everything. And if everybody

1 agrees at the beginning what we want is as close to
2 truth and relevance that informs decisions, the
3 best will come out. From an industry perspective,
4 they'll be winners and they'll be losers. But
5 that's the nature of capitalism, right?

6 All we're saying is the information flow
7 will be more open and that's to the betterment of
8 everyone. Overuses of technology is a big problem,
9 but so is underuse. There are a lot of patients
10 who don't get treatments that they ought to be
11 getting. So, hopefully, it'll be a flat --
12 everyone holding hands. That's what the Board has
13 done. Everyone holds hands and we're in it
14 together, it's for the good of all of us to get
15 this right.

16 MR. HATLIE: Jonathan, Joe wants to jump
17 in here and then Carol and Venus.

18 DR. SELBY: I really apologize for
19 hijacking the sequence of questions, but Jon did
20 ask kind of perhaps the elephant in the room
21 question, and since we have all stakeholders here,
22 it's a good time to say two things.

1 Number one, the genius of the name, the
2 Patient-Centered Outcomes Research Institute, it is
3 an amazing field leveler, if you will, to say that
4 as we convene from our various perspectives, we all
5 are here to ask and answer questions in the
6 interest of patients. We've seen that happen and
7 we saw that happen at our stakeholder forum in
8 February of this year, about 900 people convened
9 and it was striking to hear everyone subscribe to
10 the notion that this research is done in the name
11 of patients. So, that really levels the table.

12 The second thing is, as Steve said, this
13 is not a federal entity. We are not told what to
14 do from somewhere inside government. It means we
15 are much more of a democracy. Democracies, as you
16 know, can get hijacked. So, it really speaks to
17 the essential requirement that all stakeholders
18 embrace the opportunity that we have as a country.

19 I mean, this is an experiment at the
20 national level. Embrace the opportunity to do
21 research differently, stay at the table. We, as
22 PCORI, are passionate about keeping everyone at the

1 table. We think that's the way to get the best
2 research done. We couldn't do it without
3 researchers, we couldn't do it without industry,
4 couldn't do it without payers, clinicians, or
5 patients.

6 MS. PRICE: I'm Carol Price from Ohio, and
7 I have to say that I was a nurse for 40 years and I
8 retired from nursing because of the state of health
9 care and have focused on advocacy work to try and
10 improve health care.

11 I've heard a lot of discussion about how
12 do you get the patient, the caregivers involved in
13 their health care to want to improve their health.
14 Ms. Quigley bought up the patient care plans and
15 patient conferences. I feel that health care
16 workers have been the cause of a lot of the
17 problems within the health care system because they
18 run the show and a lot of the patients will back
19 down, figure the doctor knows best, the nurse knows
20 best, they're afraid to speak up. It's very
21 evident a lot of times in those care plans and care
22 conferences.

1 I want to put a challenge forth to the ANA
2 and the AMA to follow PCORI's mission and flip the
3 paradigm and have the patients run those care
4 conferences.

5 MS. QUIGLEY: Thank you so much for
6 sharing. Your passion, your drive, and for all of
7 your service as a professional nurse in this great
8 country. And I would like to say that that is,
9 indeed, the heartbeat of our entire code of ethics
10 and our standards of care is that everything is
11 patient-centered and everything is patient and
12 family-centered.

13 So, thank you so much for your remarks
14 and, indeed, it is a journey to engage people and I
15 think even when you think about PCORI, I think that
16 there's real opportunity to look at how do we help
17 patients really to become their own advocates? How
18 do we really help patients and families exercise
19 autonomy? And what does autonomy mean? I think
20 that there is some opportunity to really be able to
21 help bring that to a higher level of importance in
22 all of this effort that we're doing for patient-

1 centered care. But thank you so much for your
2 comments.

3 MS. GINES: Okay. My name is Venus Gines.
4 I am a 20-year breast cancer survivor and a Latina
5 applicant, and I don't know how many Latinas are in
6 this room, but one of the things I want to talk
7 about is I heard a lot of the "we" and I heard
8 about culture. One of the biggest cultural
9 barriers within our Latinos and African-Americans
10 and Asian Americans is mistrust and unless we see
11 us reflected in panels such as this or on the
12 boards or on major committees and planning
13 committees that are putting together the protocols,
14 we will not trust the research.

15 [Applause.]

16 MS. GINES: And I am frustrated because I
17 was here for the October -- I was one of the
18 reviewers and I looked around the room and in my
19 hand I can count the five Latinas in the whole
20 review process and even worse with the African-
21 Americans. And that's unacceptable. So, I think
22 PCORI really has to make a commitment to diversity

1 from top down and then that's where we really are
2 going to get the patients, those of us who are the
3 vulnerable patients.

4 African-Americans are dying in bigger
5 numbers of breast cancer. Latinas and Asian
6 American women are dying in big numbers of cervical
7 cancer and we can go on and on, but all the
8 research is always top, and then they invite us.
9 After they get their money, they invite us and they
10 give us gift cards for us to do 200 surveys to get
11 data. You got to understand that that's not going
12 to work anymore. Latinos and African-American
13 community folks are tired of being used for
14 research when all of the research dollars goes to
15 the major institutions and nothing comes back to
16 the community.

17 So, thank you, and I'm celebrating my 20-
18 year breast cancer survivor last week, so, I had to
19 say this.

20 [Applause.]

21 MS. SHERIDAN: I'd like just to respond to
22 that. Thank you very much for that comment, and

1 something that PCORI is going to be focusing on
2 next year is going to where the patients are and we
3 celebrate and we invite you to help us develop
4 strategies to partner with communities that are
5 well-represented within us. So, I will reach out
6 to you and that is definitely something that is a
7 priority of ours, to address health care
8 disparities, hard-to-reach populations, the
9 vulnerable populations. So, with that, I thank
10 you.

11 I think we're headed to a break. So, I
12 just want to wrap this up and just reflect on what
13 we have discussed today. I mean, we've discussed
14 on our panel the "new we," we've discussed culture
15 change, we've discussed Patient-Reported Outcomes,
16 new data structures. We've been challenged to
17 address cultures that are under-represented. And
18 we were challenged about the political environment.
19 And so, this is not going to be easy, but PCORI has
20 made a commitment and I think that people on this
21 stage have shared their commitment in what this
22 will take going forward. And change requires

1 passion. As Joe mentioned, passion, and it also
2 takes courage. So, I encourage us to go forward
3 this afternoon with passion and courage trying to
4 develop the collective "we," and let's ask
5 ourselves dare we embrace this opportunity to go
6 forward in partnership and help create PCORI in a
7 successful way that will improve outcomes for all
8 of us, our family members, and our communities?

9 So, with that, I close this session and I
10 invite you to, I think, refreshments and then we
11 will continue in our breakouts on developing this
12 new vision. Thank you very much and thank you to
13 the panel.

14 [Applause.]

15 [Recess.]

16 [Whereupon, at 10:22 A.M., the workshop
17 went into Facilitated Small Group Sessions.]

18

19

20

21

22

1 sessions both this morning and this afternoon that
2 examined research topics for the program area of
3 the assessment of options for prevention diagnosis
4 and treatment and I was very impressed with the
5 amount of energy and enthusiasm that the people who
6 came to the sessions brought to the discussion.

7 In terms of thinking about the really
8 broad sort of overarching themes, I think the major
9 theme that I heard was stressing the importance of
10 understanding the way that research results can be
11 applied to decision-making by patients particularly
12 and patient provider dyad.

13 And one of the individuals in our
14 afternoon session had a great comment in which she
15 said that she likes to think of outcomes based upon
16 whether they are relevant to and resonant with the
17 interests of individual patients. And so, I think
18 that sort of captures the idea that we've got to
19 think hard about outcomes. There's the
20 understanding that the important outcomes vary
21 across patients and that we need to understand risk
22 groups and how comparative interventions may differ

1 across those different groups.

2 There was really quite a range of clinical
3 areas that were identified in the discussions.
4 There was a lot of interest in chronic diseases
5 affecting adults. Issues such as chronic
6 obstructive lung disease, depression, arthritis,
7 diabetes, kind of generic chronic pain, and the
8 multiple possible interventions that are available
9 for those diseases, try to understand how
10 comparative information results from comparative
11 studies can be brought to bear to the decisions of
12 those individuals make and in the realm of ongoing
13 chronic care.

14 There also though were many pediatric
15 topics that were brought up. There were a lot of
16 interests in disabilities and rehab-oriented
17 interventions. There was interest in lifestyle,
18 obesity, substance abuse, the kinds of clinical
19 problems in which behavioral interventions may be
20 quite important. There was interest in some acute
21 decision-making that runs the range from
22 postoperative pain, chemotherapy for cancer, end-

1 of-life decision-making in settings in which
2 patients may be hospitalized close to the end of
3 life.

4 So, there was, I think, quite a range of
5 topics that resonate with people, but I think it
6 all comes back to really trying to understand how
7 the results from comparative studies can really
8 help people participate more effectively in the
9 decisions that are important to them. Thanks very
10 much.

11 MR. MARTIN: And thank you to Dr. David
12 Hickam. And next up is Dr. Chad Bould, the
13 director of Our Improving Health Systems Program.

14 DR. BOULT: Good afternoon. I came to
15 PCORI about a month ago, then kind of getting
16 acquainted with people and procedures and computer
17 systems and so on. This is my first foray into
18 interacting with stakeholders since I've arrived
19 and if I had any doubts about the value and the
20 commitment to our incorporating stakeholders into
21 the PCORI, they rapidly dissipated as I had a
22 chance to co-lead with Sue Sheridan our two groups

1 today. This was truly fantastic. I think honestly
2 we can say we had two dream teams, meaning the
3 members in the room. They were very different from
4 each other. We had every conceivable perspective
5 represented and our discussions were very rich.

6 I want to just very briefly summarize some
7 of the main points that came out of this. This was
8 the sessions on how PCORI can help discover new
9 information that will lead to improved performance
10 by health care systems leading to improved outcomes
11 for patients.

12 Before we could even get into defining
13 questions, however, we had to deal with some
14 infrastructure issues like what is a system? It
15 isn't just the usual payers and providers and so
16 on, but it was clear that it's also family
17 caregivers, it's also community agencies, and we
18 have to expand our thinking to incorporate these
19 essential elements of care, especially for people
20 with chronic illnesses.

21 It was also brought up that we need to
22 think about our lexicon, the words we use. No

1 one's ever aware of it, but we tend to use jargon
2 and we fall into jargon and we use words that don't
3 mean the same things and we have to be very careful
4 about that.

5 Some more infrastructures, tools. In
6 order to do the kind of research that we're talking
7 about doing, we need tools that measure certain
8 things like Patient-Centered Outcomes, particularly
9 that are non-disease-specific, but they're just
10 common across all patients. What do they need,
11 what do they want, and how well are our systems
12 meeting those needs?

13 And a third infrastructural element has to
14 do with design. In other words, we have to make
15 sure that our designs for studies of systems
16 incorporate a variety of populations, including
17 underserved ethnic and racial minorities and rural
18 areas as well as urban cities.

19 So, that's all just to get started, and
20 then here, I'm just going to give you a quick list
21 of some of the specific issues that came up and if
22 I didn't incorporate your suggestion, throw

1 something, but it's not intentional. We only had a
2 minute to put this together.

3 So, a lot of questions about what is the
4 effect of information technology on a variety of
5 things like patients' decision-making, clinicians'
6 decision-making, monitoring, and sharing of data?

7 Next, how should we best deploy our
8 professional personnel so that everyone is working
9 at the tops of their licenses and we're maximizing
10 efficiency and minimizing waste? What kind of
11 coordination programs can we create within systems
12 coordinating across hospitals, across specialist
13 and primary care and weaving it all together,
14 especially important for people with multiple
15 chronic conditions.

16 How can we enhance patient self-management
17 or engagement in one's own health through behaviors
18 like taking medicines and eating and exercising and
19 variety of other things? How can we enhance
20 support for family caregivers, the unsung heroes of
21 the health care delivery system?

22 How about using databases that are already

1 out there? Some have yet to be linked; others are
2 already linked, but we're not using them yet.

3 How about systems for improving quality?
4 There are a variety of different types of creating
5 learning communities where different systems share
6 learning with each other and share best practices?
7 For instance, do advisory councils involving
8 patients and caregivers and so on really make a
9 difference in system performance?

10 Incorporating patients' values and
11 preferences, the core of patient-centeredness. We
12 don't really know how to do it. We need to fund
13 research that shows us.

14 Providing access to the right care at the
15 right time and the right place for patients in all
16 different phases of their illness. And, finally,
17 and not least is collaboration. We need to find
18 ways to collaborate effectively with other funding
19 agencies so that we're filling each other's gaps
20 and ultimately creating a continuum of research
21 that ranges on the NIH end from the discovery of
22 basic biologic processes to the PCORI and which

1 focuses on application of new knowledge to
2 producing actual better outcomes for patients.
3 Thanks.

4 MR. MARTIN: And thank you to Dr. Chad
5 Boulton.

6 Next up is Dr. Anne Beal, our chief
7 operating officer to discuss the addressing
8 disparities sessions.

9 DR. BEAL: Great. Okay, so, as you heard
10 from Greg, my task was to synthesize the work that
11 we were focused on in disparities and it was
12 actually a very interesting and energized group of
13 people who we had to try to corral.

14 One of things that's very nice in terms of
15 how PCORI's thinking about disparities is that
16 we're definitely clear that we want to move beyond
17 simply describing disparities and really understand
18 what are the interventions that are available to
19 address disparities. And so, this was a group that
20 was really quickly able to move in that direction.
21 I think, historically, there's been a lot of work
22 which has really gone onto really study and

1 research whether or not disparities exist, but I'm
2 a believer in the fact that they do exist and I
3 think the people who were in the room also believed
4 that they do exist and we were able to just jump
5 forward and start to have a discussion around what
6 are potential topics that we can study?

7 So, one of the first things that struck me
8 was actually because I was tasked with trying to
9 identify some of the themes that came about from
10 this discussion was the absolute lack of themes,
11 particularly in the first group that we had. That
12 there were 21 people in the room, then we had 21
13 different and distinct ideas that I thought all had
14 merit in and of themselves. But, actually, over
15 then the course of two sessions, there were then
16 some themes that we started to hear that were able
17 to start to emerge.

18 So, one, and many of them actually are
19 somewhat similar to what we heard in the health
20 systems group, was thinking about opportunities to
21 leverage technology and think about the role of
22 technology to reach different populations, but also

1 to think about delivering care in new and different
2 ways in order to address the issues around health
3 disparities.

4 There was also a very robust conversation
5 around the role of policy and particularly payment
6 policies and payment policies within the safety net
7 and what role does that play in terms of access to
8 care, in terms of providing high-quality care, and
9 also thinking about the current opportunities that
10 exist as a result of the Affordable Care Act
11 related to both payment policies particularly in
12 Medicaid as well as policies related to collecting
13 race and ethnicity data to looking at clinical
14 performance measures and to providers to have to
15 hold themselves accountable for specific outcomes.

16 And so, one of the things that emerged was
17 that we talked about the fact that policy matters
18 in terms of really affecting the population health
19 and I will say the research question that then
20 emerges is so then how do we look at the impact of
21 these policies on populations that experience
22 disparities in care?

1 There was a lot of discussion around
2 disabilities and the disabilities community, but
3 also not only looking at disparities within
4 disabilities, but then disparities as a result of
5 having a disability. And so, looking at how people
6 with disabilities are sometimes treated differently
7 within the health care system.

8 There was also a lot of discussion around
9 geographic disparities and the fact that
10 particularly as we have primary care providers and
11 safety net providers closing down across the
12 country, what does this mean then in terms of
13 geographic availability of different providers to
14 different populations and then what is the
15 subsequent impact of that on different populations?

16 A lot of discussions around the need for
17 integrated care, and this actually came up in both
18 sessions where people were talking about the fact
19 that we need to think about bringing together
20 different types of providers. So, whether it's
21 school-based, clinically-based, or whether it's the
22 Department of Health based, community health

1 workers, we're really thinking much more
2 holistically about bringing together the different
3 types of providers that can touch on different
4 populations. And in both sessions, we had this
5 discussion around hard-to-reach populations and had
6 this discussion about we really need to understand
7 exactly what does that mean? Is this a term that
8 we want to use? And do we challenge ourselves to
9 not necessarily say that they are hard to reach,
10 but we are not reaching out appropriately to
11 different populations that are thought of as hard
12 to reach.

13 In addition, we had a lot of discussions
14 around mental health and behavioral health, and,
15 again, thinking about it both in terms of
16 disparities and accessing care for people who have
17 those conditions, but then also disparities as a
18 result of having particularly serious mental health
19 conditions.

20 And so, overall, I would say that there
21 was a lot of energy and enthusiasm, a lot of
22 interest. And then also one of our sessions was

1 quite interesting because then we were able to
2 devolve into a conversation as to what is the role
3 of CER in terms of your own work and how would you
4 use the kind of work that PCORI is trying to
5 develop? So, there were a lot of interests in
6 terms of training as well as a lot of discussion
7 around the fact that people are already observing
8 changes in terms of -- researchers in particular in
9 trying to engage patients in the work that they're
10 doing because of the requirements that we have for
11 PCORI to engage patients and other stakeholders in
12 a substantive way. So, I'm glad to hear already
13 that we're starting to see some preliminary impacts
14 as a result.

15 Okay, thank you.

16 MR. MARTIN: All right. Thank you, Dr.
17 Beal.

18 And next up is PCORI's Director of
19 Communications, Bill Silberg, to talk about the
20 communications and dissemination research sessions.

21 MR. SILBERG: Welcome to the non-clinician
22 portion of your program. I had the great privilege

1 of co-facilitating two sessions today and I think
2 as you've heard from my colleagues here, the level
3 of engagement, and not to make a pun, but the level
4 of engagement and enthusiasm that I experienced
5 that the rest of them experienced really was quite
6 special and quite important.

7 The two sessions had somewhat different
8 personalities, if you will, but I think we got at a
9 lot of the same issues and very effectively. Two
10 very robust discussions, and what I found most
11 interesting about both of them is we spend a lot of
12 time talking through the recognized importance
13 value and criticality, if you will, of
14 communication and dissemination as a core component
15 of what it is we were all trying to do,
16 understanding that the dissemination and
17 communication and implementation use of actionable
18 evidence is really what we were all about with an
19 end goal of affecting outcomes. So, we spent a
20 fair amount of time talking about some of the
21 critical core questions related to that,
22 acknowledging that there's been a lot of work in

1 this area that has recognized and elucidated the
2 barriers, if you will, the challenges, the bars to
3 the effective communication dissemination uptake of
4 actionable evidence, but that didn't stop us from
5 trying to figure out how we might in this context
6 with PCORI as an engine and a catalyst building on
7 the work of others, try to do a better job.

8 So, we talked about such things as the
9 important nature of message development, issues of
10 trust, who does one trust in delivering and
11 receiving the message? How do various parties in
12 the communication process which by definition we
13 thought was a two-way process. How do folks on the
14 receiving end wish to receive that information?
15 That varies depending on who that person or that
16 group is. We talked about the importance of
17 customization of messaging and information, that
18 the value of the information, the likelihood that
19 it will be heard, listened to, utilized, followed,
20 and applied broadly really depends on the meaning,
21 the context within which it is delivered and the
22 meaning that it has for the person receiving the

1 information.

2 We talked about, as I think you've heard a
3 little bit, issues of tools, channels, technology,
4 what role do new communications technologies play
5 in giving us new opportunities to perhaps get
6 around or get over some of the barriers that we
7 know traditionally face us in the communication and
8 dissemination process.

9 We spent a fair amount of time talking
10 about the different kinds of evidence and how
11 different audiences weigh different kinds of
12 evidence differently, and this was not a detailed
13 discussion about classes or categories of evidence,
14 it was really much more a matter of how meaningful
15 and real-world the evidence that was being
16 presented was to the person hearing about it and
17 how it was presented to them. So, we really
18 touched on some very basic areas of communication
19 practice and implementation science, if you will.

20 I don't think we came to any conclusions
21 on what is perhaps most important, but there was a
22 great deal of discussion of how we might generate

1 research questions based on some of those key
2 points, and these tended to focus, in my view, in
3 three broad areas. There was the notion of intra
4 and inter-professional communication dissemination
5 and implementation. How do professionals talk to
6 and work with each other within and across groups?
7 What might we learn from both the research and the
8 clinical world in terms of how best practices are
9 shared and new evidence is promulgated within and
10 across groups? That was a very interesting
11 discussion.

12 We also talked about the interaction in a
13 similar context between professionals and
14 consumers, patients, caregivers, advocates. How do
15 those processes work? What can we learn from best
16 practices and what appears to be some successful
17 models? How might we apply them broadly? Much of
18 this occurs in sort of a vertical context. One if
19 talking about a particular problem or a particular
20 condition. Might we learn from effective
21 communication in a particular context and apply
22 that more broadly?

1 And then the final grouping was patient-
2 patient, patient-consumer, consumer-caregiver. I
3 won't call it the nonprofessional side; it's an
4 expert side. But the question of how consumers and
5 patients and advocates and other stakeholders talk
6 to and amongst each other. And, again, much of
7 this, as we took from the discussion, occurs in a
8 vertical sense by condition, by disease, but,
9 surely, there are ways that we can learn from what
10 seems to be working in these vertical slices and
11 perhaps applying through PCORI's special sauce, try
12 to help folks talk to each other and amongst each
13 other and perhaps push best practices out more
14 broadly.

15 So, I want to thank the folks who
16 participated in my two groups. I learned much more
17 from you than you learned from me, I assure you,
18 and we have quite a bit of follow-up information to
19 take back to the office and start working on.

20 MR. MARTIN: Okay, thank you, Bill, and
21 thank you to the panel and please remember, folks,
22 the six o'clock show is entirely different from the

1 three o'clock show. So, we encourage you to come
2 back from the buffet. Right now, it's looking like
3 the midafternoon Diet Cokes are probably wearing
4 off a little bit. I'm seeing some faces kind of
5 sag a little bit and maybe you're dragging just a
6 little bit.

7 So, let's do one of my favorite things,
8 which is really these sessions overall because I
9 like to hear what folks have learned because I've
10 learned a lot today. Oprah has her favorite
11 things, and, unfortunately, we couldn't find 76
12 Rancheros to put keys for new cars under your
13 seats. So, instead, we're just going to have to
14 make do with each other's company.

15 So, let's do a quick show of hands. Have
16 you learned something today?

17 [Hands raised.]

18 MR. MARTIN: That's incredible. That's
19 what we were really hoping for out of this was that
20 folks would learn and that we would learn
21 something, too.

22 So, now is the time when I would actually

1 love to turn this back over you, the folks, the
2 stakeholders, the patients, the caregivers who have
3 taken time out of your busy schedules to come to
4 Alexandria, Virginia, on a Tuesday to help us
5 understand how we can achieve our mission.

6 So, Jonathan and Marty are out in the
7 audience with microphones, so, we'd like to hear
8 from you. What have you learned? What are the
9 topics that we should be studying? What have we
10 not covered up here and the summation of the day's
11 discussions? What are extra things that might have
12 occurred to you since then? So, we're ready and we
13 want to hear from you.

14 PARTICIPANT: One of the first things that
15 I thought of [off microphone] you mentioned
16 depression and diabetes [off microphone.]

17 MR. MARTIN: Thank you. And if anybody on
18 the panel has thoughts that they'd like to add to
19 any of the responses from the audience, feel free
20 to jump in.

21 DR. BEAL: I'm a pediatrician, and I
22 agree.

1 DR. BOULT: I'm a geriatrician, and I
2 agree.

3 [Laughter.]

4 DR. HICKAM: I have one thought about
5 that. I think it's a really important point that
6 you made, and, again, we're always sort of getting
7 back to Patient-Centered Outcomes and part of your
8 thought there to think about outcomes in kind of a
9 long-term sense, yes, I think that's a really good
10 point.

11 PARTICIPANT: Hi, thank you. Actually, I
12 have a question. Originally, options to choose
13 from included rare diseases and I see that we
14 didn't have that today. I'm just wondering if you
15 could speak to the reason that had been eliminated.

16 MR. MARTIN: Well, actually, we were
17 really disappointed that we removed those
18 breakouts. We were really hoping that we could use
19 those as an opportunity to learn more about rare
20 diseases as an institute.

21 Unfortunately, we did not have a large
22 enough response and we asked folks to indicate

1 their primary and secondary areas of interest in
2 discussing today. And so, we are examining
3 different ways that we can do some outreach and
4 engagement on rare diseases and it's something that
5 we're really looking forward to and I would
6 encourage you to keep an eye out for early next
7 year and we'll have some more activities based
8 around rare disease.

9 DR. BEAL: The only thing I would add to
10 that is that there were a couple of comments that
11 did emerge in the disparities session related to
12 rare diseases, particularly about uncertainty
13 around time of diagnosis and making sure that
14 people had information.

15 MR. HATLIE: Anne, you're hard to hear.

16 DR. BEAL: So, there were a couple of
17 things that did emerge in the disparities session
18 related to rare diseases and specifically there
19 were three themes that I heard related to the rare
20 diseases.

21 So, one was issues around diagnosis and
22 uncertainty around the time of diagnosis and people

1 describing that there were often challenges in
2 terms of getting an appropriate and timely
3 diagnosis. Secondly was around creating measures
4 so that as we think about outcomes and Patient-
5 Centered Outcomes Research that we have the
6 appropriate outcomes. And then the third was
7 actually then having the appropriate data
8 associated with really looking at some of the rare
9 conditions so that we can study them over time.

10 So, we did get some of that information,
11 although, as Greg said, we weren't able to have a
12 session devoted just to that.

13 MR. SILBERG: And I would just add in the
14 communications sessions, there was actually a fair
15 amount of discussion of rare diseases from two or
16 three points of view. One, we were privileged to
17 have one of our Pilot Project awardees who is a
18 rare disease investigator.

19 So, we talked a little bit about
20 communications issues related to professional
21 patient communication about a rare disease. From
22 the patient point of view, it was this issue of

1 uncertainty about what the problem is and how they
2 could be better served by having professionals more
3 readily armed and equipped to deal with their
4 questions in a way that wouldn't send them to 12
5 other physicians before they finally get a
6 diagnosis that can give their lives some certainty.
7 That was one.

8 A second one was the whole notion of how
9 professionals across different rare diseases,
10 because there are something like 6,000, I guess,
11 how professionals across those different rare
12 disease states might be able to share best
13 practices more effectively because even though the
14 diseases are quite different, this notion of how
15 one communicates evidence within one's field about
16 a rare disease professionally as well as with
17 patients seem to be quite an important point.

18 And the third was there was some
19 discussion of -- and you get into this a little bit
20 -- how we might leverage data networks and
21 registries as repositories of information that
22 could allow both on the input side and the output

1 side some new types of communication dissemination
2 research.

3 So, we actually had a fairly robust and
4 rich discussion with several folks from the rare
5 disease community. It was quite helpful.

6 MR. WHITE: Hi, John White from
7 Philadelphia.

8 I wanted to ask about -- well, I applaud
9 PCORI's focus on Patient-Centered Research and
10 research that will make a practical difference, but
11 I'm quite interested in the developmental process
12 of clinical research and the fact that it typically
13 involves stages of development and I guess what I'm
14 wondering about is that in some agencies that have
15 been pressed to fund the practical, it's my
16 observation that sometimes they prematurely fund
17 studies that are intended to answer a practical
18 question, but where the tools have not been
19 adequately developed or the background research has
20 not been done.

21 So, in the prioritization that we heard
22 about earlier, I don't think there was any filter

1 that asked sort of what's the scientific readiness
2 to be answering this question and I'm just
3 wondering sort of how PCORI will facilitate in
4 making sure that these practical questions are
5 asked at a point where we have the tools and the
6 preliminary work to make the money go well?

7 Thanks.

8 PARTICIPANT: Yes, I could answer if I had
9 a mike.

10 DR. BOULT: So, I'll try to answer.

11 PARTICIPANT: Okay, go ahead.

12 DR. BOULT: So, to get back to this issue
13 of trying to really think about how the results of
14 the research project may be useful to decision
15 makers, do you think that that may be a strategy
16 for trying to get at the issue about the readiness
17 that you're mentioning?

18 MR. WHITE: Well, I mean, I guess the
19 concern I would have is supposed the answer is this
20 study as it could be proposed today won't answer
21 that question. Is there a step back that gets
22 supported to get us to the point or if it turns out

1 that the tools aren't there today, oops, drop that
2 from the priority list and let's move on.

3 DR. BEAL: So, what I would add is that if
4 you look many of the Pilot Projects that we've
5 funded, many of them are designed to answer just
6 those questions. So, what are some of the best
7 tools that we have to capture some of this
8 information?

9 So, the first answer is that we've already
10 done some work, but then the follow-on answer is,
11 clearly, there will be more work that needs to be
12 done and it's certainly one of the things that we
13 are considering as we're looking at potential
14 questions that are out there, if there's really
15 just not this fundamental baseline work that has
16 been done that allows us then to answer these
17 questions. It's certainly something that would be
18 considered.

19 PARTICIPANT: I know you've put it onto
20 us, but I would put it back to you just for a
21 second just to thank you for the opportunity to be
22 here and be part of this. I'm pretty overwhelmed

1 by the kind of openness to different perspectives
2 and the emphasis on the patients' voice and the
3 caregivers' voice, things that I don't hear or see
4 that often, unfortunately, outside of this arena.
5 So, we used the word "we" this morning. I would
6 reiterate I wish we have great luck in the future.

7 I do have a more practical question, too.
8 Working in academic medicine, I'm curious where
9 does medical education fall within your research
10 priorities and so on? Because I've heard it's
11 easier to teach new dogs old tricks, something like
12 that. I don't want to be ageist. I work in
13 geriatrics, but if you get trainees at a younger
14 point in their career, you might reap better
15 benefits.

16 DR. BOULT: I'm not really knowledgeable
17 enough to fully answer that question, but I
18 certainly resonate with the theme of it. In other
19 words, to be training the next generation of people
20 who are going to be doing research, they have to be
21 viewed with these kinds of principles that
22 otherwise we're just going to keep on doing the

1 same old same old. So, I'm just not sure what
2 PCORI has done so far or plans to do with regard to
3 training the next generation.

4 DR. HICKAM: Well, I think that's a couple
5 though of kind of natural applications of your
6 question and one is the communication and
7 dissemination work. I think there is opportunity
8 there for projects that are applicable to trainees.
9 The other thing is PCORI just recently came out
10 with a broad announcement about infrastructure and
11 it's worth examining that because it's got some
12 workforce components in there.

13 MR. SILBERG: Yes, following-up on the
14 communication dissemination piece, we talked about
15 that in our group a little bit in two specific
16 contexts. One was research projects that would
17 look at how communication dissemination can be
18 better incorporated into training. So, what might
19 best practices be that docs on and other clinicians
20 on their way up through training might be taught
21 that might be more effective than whatever training
22 and communication is there now, which depending on

1 where you come from, may or may not be adequate.

2 There was also quite a bit of discussion
3 in that context, but even more broadly about this
4 whole notion of the new communications landscape
5 with regard to tools. So, you were in the session,
6 so, I know you will recall some of this. This gets
7 to not just clinical and scientific training,
8 whether you're a physician in training or a nurse
9 or some other clinician, but this whole notion of
10 the technical environment in which all of this is
11 happening and because the tools are changing so
12 dramatically and many of those tools either were
13 designed for or have very specific communications
14 functions of the way scientific information is
15 assessed, the way that information is provided, the
16 way research is happening, much of this technology
17 could potentially be an evening out, a leveler of
18 the playing field in a way, if you will.

19 So, there may be some opportunities there
20 that even as we look at how these tools might apply
21 in general communications in dissemination
22 research, the training aspect might work naturally.

1 DR. BEAL: Right, and then the only other
2 thing I would add is, so, Steve earlier today
3 mentioned that we are not a federal agency, but
4 that doesn't mean we don't pay attention to what
5 other federal agencies do and our board is a very
6 active and engaged board and we're actually very
7 fortunate to have Carolyn Clancy from AHRQ as well
8 as Francis Collins from the NIH on our board. And
9 so, one of the things that we pay attention to is
10 to not do efforts that would replicate the work of
11 others. So, in fact, AHRQ is actually doing a lot
12 of work in this space to support training and
13 development for the conduct of people or Patient-
14 Centered Outcomes Research. So, we pay attention
15 to that to make sure that although as an
16 independent entity, we are not lapping and
17 duplicating the work of others.

18 PARTICIPANT: To follow-up briefly on
19 John's question on the tools and also as someone
20 who's only a quasi-researcher and half the time is
21 more an advocate trying to clear up some things in
22 my mind about PCORI maybe you could help me with.

1 So, one of the tools that we would want is
2 we would want patient health status measures,
3 right? So, we've known for a while we have things
4 like the SF-36 and how is my hip implant doing and
5 all the rest, but some of these have been in not a
6 very well-developed state because, frankly, there
7 hasn't a demand for them. The demand the payment
8 system rewards, new tools for orthopedic surgeons,
9 not new tools for orthopedic surgeons to know how
10 their patients are doing. Just to pick one aspect
11 of medicine.

12 Now, if you all were something like DARPA,
13 the defense research people who are probably on
14 this side of the river, you would have a goal that
15 says we want to advance America's defense
16 capabilities, so, we will reach out and fund
17 certain kinds of things so that they can be
18 implemented to help us. Will you all reach out and
19 say you know what, if we want to transform the
20 health care system, we need to go and, in fact,
21 proactively fund better measurements of patient
22 health status. We need to proactively make sure

1 that some of the technology that Bill's talking
2 about is able to be integrated from off the grid
3 into the grid. I mean, that kind of sort of with
4 purposeful kinds of transformational research that
5 you will actively seek or you're more well, we want
6 to go disease by disease and things like that.
7 That's kind of swirling around in my head.

8 DR. HICKAM: So, I would direct you,
9 again, to the recently-released announcement, the
10 broad funding announcement for methodology and
11 infrastructure because I think it does give some
12 room for development of better measurement methods,
13 which is what I think I heard you say was a goal,
14 that it would be important.

15 PARTICIPANT: There's a larger question
16 there [off microphone]. That's a terrific health
17 services research answer. I'm trying to get beyond
18 that to see whether you guys are trying to
19 transform the health care system and, therefore,
20 the strategic way will fund certain kinds of
21 research or are an enormous academic funding
22 mechanism.

1 DR. BEAL: Right. So, our first stab at
2 this has been actually very explicit language in
3 all of our funding announcements that the kind of
4 outcomes that we're interested are the sorts of
5 outcomes that matter to patients.

6 So, if I'm a working mother with condition
7 X, I'm interested in can I take care of my
8 children? I'm interested in can I go back to work
9 to maintain my health insurance. I'm interested in
10 my level of fatigue. And so, one of the things
11 that we've demanded in all of our funding
12 announcements are that the outcomes that we ask and
13 that the investigators ask are the kinds of
14 outcomes that matter to patients. So, it's not
15 just about morbidity and mortality, it's about what
16 matters most.

17 And is that ideal? No. And is it the
18 total comprehensive way of looking at it? No. But
19 it is a very first important step and one of the
20 things particularly in some of our areas related to
21 communications and health systems were people who
22 have asked us well, really what is a PCORI-like

1 project? The PCORI-like project is the one where
2 the outcomes are the ones that my aunt, my mother,
3 my father would recognize as being important
4 because they matter to patients, not just to me as
5 a clinician.

6 DR. ANDREAE: Traditionally, researchers
7 in the United States have been trained with
8 mentored research training grounds and there's a
9 whole generation of researchers like me who would
10 like to learn how to research patient-centered and
11 I wondered will you put out some K08 awards,
12 mentored research training grounds, or do I need to
13 turn back to the old-fashioned kind of NIH
14 institutes?

15 DR. BEAL: So, we're currently not
16 planning, which is not to say that we never would,
17 but we are exploring different ways to think about
18 this. If you've ever done training programs and
19 training grants, they actually take years to
20 develop and then maintained in order to do them
21 well. So, it gets back to the question that was
22 asked earlier about training around this area.

1 And so, one of the strategies that we're
2 taking is thinking about outreach particularly to
3 different types of medical centers to think about
4 how do you do this research and what are some of
5 the different types of training opportunities that
6 we can make available to different types of medical
7 schools or to make people aware of the sort of
8 training that we do for our reviewers with
9 immediate training that we can do for researchers.

10 And so, we are thinking about training and
11 helping to develop and refine the field, although
12 not right now within the context of a classic K
13 award.

14 PARTICIPANT: I'd like to build on some of
15 the workforce comments that I've heard throughout
16 the day and Dr. Quigley brought up in health
17 systems improvement, that we really need the teams
18 in order to engage patients, we really need the
19 teams to function to the top of the scope of their
20 practices and license in line with the OIM Future
21 of Nursing Report.

22 So, we could certainly involve patients

1 and caregivers and research, how can we get that to
2 happen? The drivers in the Readmission Action Team
3 convened by the National Quality Forums National
4 Priorities Partnership, the Readmission Action Team
5 for the Partnership for Patients was patient
6 engagement and the real crux of the way to get that
7 to happen is to get the team functioning as a team
8 with the right mix, with the right staffing, with
9 the right certification, knowledge, and skills all
10 practicing at a high level to the scope of their
11 practice and their license.

12 MR. PECK: I couldn't agree more.

13 [Laughter.]

14 MR. MARTIN: Any final questions or
15 comments? One more.

16 PARTICIPANT: Sorry, I just can't help
17 myself. I need to follow-up on that and just
18 suggest that we need all of that, but we also need
19 a mechanism for patients and families to learn how
20 to be a team member, to accept the roles and
21 responsibilities, or for us to understand if they
22 have limitations that they can't accept those rules

1 and responsibilities that we understand how we
2 manage that. So, team-based care has to, as we
3 know, include the patient and family, but it has to
4 do it differently than we've done it in the past.
5 We have to start giving them some better
6 understanding. It's almost like illnesses doesn't
7 come with an owner's manual, as I said recently,
8 so, I think we need to figure out a way of being
9 able to help them understand what their roles and
10 responsibilities will be so that we actually do
11 have a full participatory team.

12 MS. WILLIAMS: Okay, so, I'm Pam Williams
13 and I'm one of the Pilot awardees and I have now
14 heard the last two comments, the physician up at
15 the front as well as the lady that just spoke
16 asking about training to do community-engaged
17 research and to have community partnerships.
18 Getting the partners trained as well as getting the
19 academic scientists trained.

20 And I'll just share what my success story
21 was, was going to my CTSA, their community
22 engagement core. And CTSA's are parked all around

1 the country. Most of them should have a community
2 engagement core, a community member should be able
3 to go to that CTSA office and say I want to be
4 trained. That's what happened at my academic
5 institution, that's how I got my matchmaker. PCORI
6 wants to have a matchmaker initiative. Sometimes
7 they're already out there, these models are already
8 out there and I just want to urge people to look to
9 their local CTSA's.

10 Oh, okay, CTSA's are funded, I believe,
11 through NIH and they are Clinical Translational
12 Science Awards and they are at local -- across the
13 country -- academic institutions. Duke had one.
14 UNC Chapel Hill has one. They're all over the
15 country and they call themselves by different
16 names. So, afterwards, anybody that's interested,
17 I'll be here for the rest of the day and I'll try
18 to get you hooked up with that.

19 But there are so many different research
20 institutes out there on the horizon for community
21 members to try to interface with and it is alphabet
22 soup. So, but just remember not one institute's

1 going to meet all your needs. Sometimes, you have
2 to think about diversifying the different
3 institutes to get all your needs met.

4 MR. PECK: So, we have a question that's
5 come from Twitter. How can imaging be used as part
6 of Patient-Centered Research to maximize
7 efficiencies around diagnostics?

8 MR. MARTIN: A question from the Twitter-
9 verse.

10 DR. HICKAM: Well, that's a comparative
11 diagnosis question, I think. So, I think that is
12 open to creative research ideas.

13 MR. MARTIN: Okay.

14 MR. BIGGERS: I just wanted to add, going
15 off of the comment over here, as well as the
16 earlier comments about the rare disease
17 communities, I think connecting with the rare
18 disease communities will be helpful to the PCORI
19 effort to the "new we" both because PCORI has been
20 mandated to help serve that community, but also
21 because in our view, that's the best place where we
22 find the highest concentration of success stories

1 and case studies about how to do patient-
2 collaborated health research. And, in fact, when
3 we set out to build this online platform for doing
4 participant-driven health research, we went and
5 studied a bunch of the rare disease communities
6 because that's where it's happening now.

7 So, I've already offered to Sue and Susan
8 to help convene more of the rare disease community.
9 I think there are other people here, too. But if
10 you have an urgent need in addition to the CTSA's,
11 which it sounds like she's connected to a better-
12 than-average CTSA. That's another place to go to
13 find some lessons.

14 MR. HATLIE: Did we get an answer to the
15 Twitter question? I'm not sure. I guess we did.

16 One more hand over here. Greg, do we
17 still have time for questions?

18 MR. MARTIN: We can take one more. This
19 will be the last train to Clarksville.

20 MR. HATLIE: Okay.

21 PARTICIPANT: So, you said the rare
22 disease communities, and I wanted to actually

1 second that, but not just the rare disease
2 communities; also very common disease communities.
3 So, the Michael J. Fox Foundation Parkinson's
4 Disease Research, Parkinson's Disease Foundation, a
5 number of epilepsy disease communities, CURE, et
6 cetera. So, that was my comment about that.

7 But the one question that I wanted to ask
8 that I didn't get a chance to ask earlier today is:
9 Where is this research going to be done?
10 Academicians, in my experience, haven't been really
11 good at this Patient-Centered Outcomes Research,
12 although, we're trying to foster an environment
13 where they can do more of this, but it's an uphill
14 battle and sometimes I feel like Sisyphus at the
15 bottom of the hill every Monday morning, but where
16 is this research going to be done if community
17 providers don't have the infrastructure to do
18 research? Does PCORI plan on providing enough
19 funding to provide that infrastructure for those
20 community providers to do some of that research?

21 MR. HATLIE: Dr. Beal? Chad?

22 DR. BEAL: So, one of the things that was

1 very exciting when I came onboard was to actually
2 read the legislation and the legislation was clear
3 that they wanted the research to be done in places
4 that do research, not necessarily in places that
5 are academic medical centers or schools or public
6 health or schools of business or whatever, but in
7 places that do research. Combine that with the
8 essentially directive that we're received from our
9 board to think differently and think out of the
10 box, I think actually that there's a lot of
11 opportunity for us to not do it among the usual
12 suspects, and, in fact, I will say with a lot of
13 certainty that our board is really pushing us to
14 think very creatively and not necessarily have all
15 of our grants go to the usual suspects.

16 We have to make sure that that is balanced
17 with making sure that the research is rigorous and
18 extremely well done because patients are going to
19 be making decisions based upon the results of what
20 we're going to be sending out. But it is actually
21 very exciting to not only see it written into the
22 legislation, but then hear the directives from our

1 board to say do this differently and think about
2 research differently, which means, obviously, doing
3 it in places that are not where we usually do
4 research.

5 MR. MARTIN: Okay. Thank you. And thank
6 you to everyone on the panel and now actually,
7 because everyone was so wonderful, we have a great
8 treat for you now. We're going to turn it over to
9 our resident rocker, Dr. Kara Walker.

10 I've spent the last five minutes trying to
11 think of a clever way to introduce her. She's
12 going to give you a real-world example of how to
13 prioritize. So, basically, this is going to help
14 bring it back from the framework that Rachael
15 Fleurence discussed earlier and how we can take
16 these wonderful topics that you've been giving us
17 today and prioritize them.

18 So, with that, I will get off the stage
19 and hand it over to Kara.

20 DR. WALKER: So, I have a set of slides
21 that should pop up. So, good afternoon, everyone.
22 This is almost the last session of the day and it's

1 really meant to wrap up everything that we've done
2 from the breakout sessions to hearing about
3 research prioritization.

4 I want to walk you through a real-world
5 example of what may happen to one of your questions
6 that you came up with today and use that as an
7 example of a way to walk you through the process.
8 So, I might call on you, and so, if you don't want
9 to get called on, you should volunteer.

10 So, this is the example question. So, I'm
11 a family physician and I'm a researcher, but one of
12 the things I know is that patients come to you with
13 questions and they come to you with questions when
14 they're really making decisions. So, this is an
15 example. Mr. Jones is a 77-year-old man who has
16 several medical conditions. He has diabetes,
17 congestive heart failure. His doctors say we need
18 to keep an eye on your kidneys and make sure
19 everything's okay with your blood pressure. But
20 over the Thanksgiving holiday, he had a great time
21 with his family, probably had a little too much
22 salt in his diet from that great gravy and had some

1 chest pain and his family was very worried.
2 They've rushed to the hospital and the doctor said
3 well, we think you're having a heart attack and we
4 need to figure out what's going on. So, his wife
5 was there with them and they were trying to think
6 through along with the doctors what they should do
7 in this case. It was pretty severe and we
8 definitely needed to think about it. So he's
9 listening to the doctors, he's really stressed
10 about making the right health decision, and his
11 wife is trying to help him along, but he doesn't
12 necessarily have the information at the tip of his
13 fingers.

14 So, this is an example of a research
15 question that could come into PCORI. They go home,
16 they've decided what may happen, but we're going to
17 sort of go through this process. So, Ms. Jones
18 goes home and says I'm going to send in this
19 question to PCORI's Web site because I think I need
20 better information at the point of care when I'm
21 making these decisions along with my doctor about
22 what to do for my husband given all these medical

1 conditions, his age, his other comorbidities. And
2 so, this is an example of what could come into
3 PCORI.

4 So, now I'm going to put some of you on
5 the spot. How many nurses are in the room? Great,
6 I'm so excited that you're in the room. How many
7 cardiologists? Do we have any? I know there's
8 one. How many internal medicine docs? Great.
9 Wonderful. How many payers? Employers count.
10 Absolutely, wonderful. I can't wait to engage you
11 in this next step.

12 So, as you heard from Rachael, we're
13 planning to generate a series of questions from our
14 topic generation process. The question about what
15 to do in the treatment of coronary artery disease
16 is one of those questions. But just as you heard,
17 we're planning to have a wide range of questions
18 that come in in a variety of clinical areas. And
19 some of them will be about health systems
20 questions, some of them will be about comparative
21 treatment options. And so, this will just be one
22 of those topics that come in through this process.

1 So, the next step that we'll have to go
2 through for this question that Ms. Jones presented
3 us is figuring out what evidence exists. What
4 evidence exists for the treatment of coronary
5 artery disease for this particular situation? So,
6 PCORI will think about it and we'll think about it
7 for a range of topics, including what systematic
8 reviews are out there and exists? What systematic
9 evidence has been compiled to date to answer these
10 specific questions given Mr. Jones' specific heart
11 condition and his specific medical decision-making
12 that he's going through right now?

13 So, as a high level, some of the
14 cardiologists in the room and internists may know
15 the evidence at a much more detailed level, but
16 right now, what we do know is that there's a lot of
17 information about whether it's better to have open
18 heart surgery, so, CABG, Coronary Artery Bypass
19 Surgery, or percutaneous angioplasty, where they
20 use a balloon to go in and open up a vessel,
21 depending on how many arteries are blocked. That
22 could involve stents, but for some people who are

1 really sick and can't necessarily go through a
2 surgical option, it might be that medical
3 management is the best option for them given their
4 risks and benefits and all of those type of
5 questions that are out there. So, for this
6 particular question, there's more research that's
7 needed and PCORI says this is something that should
8 go into our research prioritization process.

9 So, as you can see, we this list of
10 questions that's coming in. We've eliminated a few
11 that maybe, as Rachael Fleurence said, already has
12 evidence and what we need to do is a better job of
13 disseminating the information at the point of care
14 so that people can implement existing evidence.
15 But this is one of those questions where we
16 actually may need to gather more evidence and
17 research.

18 So, we're thinking about all these
19 different factors about which topic should be
20 highly prioritized and funded in a targeted way and
21 these are some of the criteria that we're trying to
22 think through. So, what we're going to do is this

1 group today is going to be a virtual advisory panel
2 where we're going to talk through how we evaluate
3 one topic. It could be a topic one of you
4 submitted, but we're going to talk through this
5 coronary artery disease example and think about all
6 the different tradeoffs as we go along.

7 So, okay, I'm going to take a poll. So,
8 in terms of patient-centeredness, is this question
9 that Mr. and Mrs. Jones have patient-centered in
10 your mind? Is it something that patients and
11 clinicians are asking for? Is it something that
12 may make a difference in Mr. Jones' life as he
13 makes this decision? I'll just take a show of
14 hands for this one.

15 [Hands raised.]

16 DR. WALKER: Oh, wonderful. So, we all
17 agree that it's patient-centered.

18 Would anyone like to volunteer an argument
19 to say why it's so patient-centered? I know
20 someone out there is dying to tell us. Anyone,
21 anyone?

22 [No response.]

1 DR. WALKER: There are lots of volunteers.
2 You need more caffeine. It's the end of the day.

3 Well, I'll say while you think about your
4 argument that this is obviously a question that
5 many people face and that has to do with specific
6 decision-making and it's something that's not that
7 uncommon and we'll get to that, as well. But there
8 are probably other issues that we could talk about
9 in terms of this specific question. It's not yet a
10 research question. So, maybe some of you in the
11 audience might say well, to make it even more
12 patient-centered, we need to think about how we
13 incorporate Mr. Jones' preferences to make this a
14 really patient-centered research question. Maybe
15 there are other questions about quality of life and
16 how he can interact with his grandchildren that we
17 need to account for when he's making decisions
18 about whether to have a risky surgical option or go
19 with some other lower-risk option for his
20 condition.

21 So, I'm going to ask one more time: Any
22 other arguments about why this is patient-centered

1 or not? Maybe somebody says this isn't so
2 important. Great.

3 PARTICIPANT: There is a flaw in your
4 story and that is that the patient you presented to
5 us is in an acute care situation. We don't know
6 whether they've had a heart attack, and so, we do
7 know what to do in that situation. So, I think
8 it's premature to say that we would go to all those
9 other options.

10 DR. WALKER: Great, thank you. Thank you.
11 You're right; we don't have enough clinical
12 information to say what the true decision factors
13 are.

14 Please.

15 DR. WEISMAN: There are a couple things
16 besides -- let's say he had a heart attack and we
17 do know what best practice might be in an academic
18 medical center or a tertiary care center with those
19 options available, but if Mr. Jones lives in a
20 rural setting where some of these are not
21 immediately available, but could be available by
22 some type of transportation, that also is going to

1 go into personal preferences and what's practical.
2 It may be that being very close to his family and
3 having them around him are far more important than
4 being at a hospital three hours away where people
5 can't be around.

6 So, there are a number of factors that
7 will go into both his immediate care and his
8 ultimate outcomes that matter to him that must be
9 individualized.

10 Another one that I think is really
11 important is that it sounds like he's retired by
12 his age, but driving may be something that's very
13 vital for some reason in his life. You can't drive
14 for two to three months or longer after coronary
15 artery bypass surgery. So, there are lots of
16 things that go into choices that go beyond what we
17 know from randomized clinical trials that have
18 given us very clear algorithms on what to do.

19 DR. WALKER: Great, thank you.

20 PARTICIPANT: Okay, yes, I guess I do want
21 to comment also now because as you're right, it's a
22 very complicated situation and even if we know that

1 he has acute coronary syndrome or he's just had an
2 MI, we don't know if he's already been on Plavix,
3 has he been taking warfarin? You can't go right to
4 CABG if the person has already had too much of a
5 blood-thinner. So, there are definitely decisions
6 that will have to be encountered and is he a
7 candidate for stenting? Everybody is not a
8 candidate for stenting. Stents close on people. I
9 mean, there are definite real questions that need
10 to be -- did he end up a center where they have
11 standards in place when the patient comes into the
12 emergency room? Because I used to work for
13 Bristol-Myers Squibb and was part of the team that
14 helped get a lot of those admission orders in
15 place, but there are still lots of hospitals around
16 that don't have standard operating procedures when
17 somebody comes in with an MI.

18 So, it's a lot of pieces that are floating
19 around and it's not just that clear just because
20 you know that he's had an MI. So, you're right,
21 there are a lot of things that have to be
22 considered.

1 DR. WALKER: Absolutely. So, we'll go to
2 the next slide and -- oh, please, one more comment.

3 MR. WHITE: Yes, well, I'm not sure
4 exactly how this maps onto patient-centeredness,
5 but this is one of many examples where the
6 different interventions are offered by different
7 specialties which I think makes it harder for
8 patients to weight and pros and cons because
9 they're not getting the information from a
10 particular professional who weighs them, but
11 potentially from people who have vested interests.

12 DR. WALKER: Yes.

13 PARTICIPANT: And just one more comment
14 before you go to your next slide.

15 DR. WALKER: Okay.

16 PARTICIPANT: Your example should have
17 been a woman and it should have been stable angina,
18 and the reason I say that is that I was on the
19 evidence review that just published this summer on
20 the treatment options for women with heart disease
21 and the evidence gap is truly in women and the
22 evidence gap for whether you should get bypass

1 surgery, PCI medical therapy is probably the
2 largest gap for gender-based outcomes. So, next
3 time when you do the example, she's a woman.

4 DR. WALKER: Thanks.

5 [Laughter.]

6 [Applause.]

7 DR. WALKER: I like that suggestion.

8 So, we've already kind of touched on this
9 next factor that should be considered by all of our
10 panels, although we are interested in highly
11 prevalent diseases, we also are interested in rare
12 disease or understudied populations, as you just
13 mentioned. And so, as we think about this
14 question, I think the questions that come up around
15 are we studying a common disease, I think most
16 people in the room would say yes. We know 1 in 6
17 have the chance of having coronary heart disease in
18 their lifetime, but we also know that there are
19 subsets of the population that are understudied and
20 those that are older, over 75, are not often
21 included in randomized controlled trials, those who
22 are women and those who have multiple chronic

1 conditions because they're high risk, and so,
2 sometimes they get weeded out of these kinds of
3 studies.

4 So, would anyone else like to make the
5 case for why this disease topic area should be
6 studied from the perspective of thinking about
7 individual suffering and loss of productivity?

8 [No response.]

9 DR. WALKER: Go heart disease. Everyone
10 thinks it's a great topic, sounds like. Great.
11 We'll go to the next slide.

12 So, this gets to this question of where is
13 the evidence? So, the difference in benefits and
14 harms and reduction and uncertainty is something
15 that PCORI wants to make sure we're addressing. We
16 want to find those research and evidence gaps that
17 we can fill and do that through comparative work.
18 So, how do we look at this question that Mr. Jones
19 and his wife have brought to PCORI? How do we
20 think about what are the needs in terms of new
21 research? And I think we just heard that we need
22 more research in cardiovascular disease in women

1 and particularly for unstable angina.

2 Are there other issues that we should
3 bring up? And maybe that makes us change the
4 research question slightly, depending on where
5 those gaps in evidence are. Anyone else want to
6 add to that, build on the last thought?

7 [No response.]

8 DR. WALKER: Do you think there's
9 sufficient uncertainty for those of you may have
10 heard about these kind of decision-makings?
11 Sufficient uncertainty, raise your hands. Hands,
12 hands. Maybe. There's a couple of maybes.

13 [Hands raised.]

14 DR. WALKER: There is a lot of research
15 that's out there right now about whether you choose
16 open heart surgery, CABG, or stents or others and
17 who has been adequately studied?

18 So, okay, well, how many people think we
19 know the evidence, we don't need to pursue this as
20 a topic? It's been over studied. Anyone want to
21 make that case?

22 PARTICIPANT: [Off microphone] case for

1 that --

2 DR. WALKER: But you think it's over-
3 studied. Great. There are other topics that
4 should be placed at higher priority potentially?

5 PARTICIPANT: Yes, I think it would be
6 difficult for PCORI now to say well, we had some
7 input from the patients and the stakeholders, so,
8 we are shifting gears and Mr. Jones has now become
9 Ms. Jones and we also are interested in
10 incorporating more stakeholder comments like, for
11 example, location costs and you mentioned conflict
12 of interest and how they can impact that. So, I
13 would say we should change the research question in
14 that direction and then yes, indeed, there is
15 enough uncertainty.

16 DR. WALKER: Great. Excellent. And what
17 you don't have in front of you is the range of
18 other topics and other research gaps that we're
19 considering across. So, right now, our agenda item
20 is to talk about this particular question, and so,
21 I think that's great input. Wonderful.

22 MR. HATLIE: We have a comment over here.

1 DR. WALKER: Oh, we have one more. Gail,
2 please.

3 MS. HUNT: Yes, this is kind of small, but
4 my understanding of open heart surgery is that one
5 of the harms that's not often discussed is the
6 possibility of having stroke subsequent to it. And
7 I think I saw a paper on that once and I know that
8 there are people who've gone and had open heart
9 surgery and no one ever said there are a such and
10 such percentage of people who have stroke post-
11 surgery.

12 DR. WALKER: Thank you. Thank you. And
13 those are personal choices that need to be made and
14 weighed when you're thinking about how you make
15 these treatment options and treatment decisions.

16 So, this next one is really a question
17 about how do we choose research topics that are
18 likely to be implemented and practiced in a
19 relatively short timeframe? How do you find those
20 research questions that if we knew what to do in
21 women, with Ms. Jones in particular, how likely
22 would that change practice? And if we had that

1 answer, would we know what to do next? So, I
2 wonder if anyone would like to make the case that
3 this is really important now that we're studying
4 Ms. Jones and it's something that will be used and
5 picked up by clinicians and something that will add
6 to improving the health care for this population.
7 Anyone? Please. Microphone is coming.

8 MS. LINKOV: I have a comment and a
9 question. So, the answer to your question is I
10 think that if this, whatever it is that's being
11 developed, if it helps with patients like this
12 couple, it will get picked up. But, unfortunately,
13 doctors tend to be busy. So, depending on what's
14 involved, there are many decision supports out
15 there that doctors are not willing to use.

16 So, when we, the researchers, developed
17 our grants, how do we know what PCORI or reviewers
18 will view as something that might or might not be
19 implemented? Because, to me, it seems like
20 depending on how long of a physician time this
21 intervention or whatever it is will take place, it
22 will determine whether or not it will be uptaken or

1 I don't know what reviewers or whoever will be
2 using. So, I would appreciate your response to
3 that.

4 DR. WALKER: That's exactly right. And
5 so, as we develop the information that will guide
6 these advisory panels and the research
7 prioritization process, part of it is asking for
8 the views of those who are at the table to decide
9 whether this is something that's implementable
10 without having a study in front of them, without
11 having necessarily the research protocol in front
12 of them. It's really looking at a topic and a
13 research question.

14 So, I think that's challenging. It's
15 challenging to figure out which things will be
16 easily implementable and I saw some other hands up
17 about this particular factor and criterion as we
18 evaluate research topics. I'd love to hear some
19 other thoughts about this one.

20 PARTICIPANT: One of the things that we
21 know in industry is that if whatever doctors train
22 on -- now I'm giving away the Dark Empire secrets,

1 but we know that whatever physicians train on, that
2 is generally what they will do when carry on
3 through their lives. It's what you learn early.

4 The VA system is a big place that they do
5 the majority of training of residents. And so, if
6 you have your intervention, the VA system
7 physicians will train on it, but that's one reason
8 why with respect to women. Now, that's changing in
9 the VA system, but for many years, there were very
10 few women in that system and most clinicians train
11 in that system. And so, they learn their practice
12 habits there. So, I think that as we have more and
13 more women in the VA system, you'll start to see a
14 lot of the practice patterns become broader.

15 But speaking to cardiovascular disease,
16 like for instance we know today that it's not the
17 site -- for instance, we'll tell people oh, you
18 have a 70 percent blockage, you have an 80 percent
19 blockage, and it's like oh my God because that
20 makes sense to the common mind, right? But it's
21 really the less than 50 percent on stable Plex that
22 are more dangerous than the 80 percent stable Plex.

1 They don't understand that variance. Nobody takes
2 the time and sometimes people get surgery or
3 interventions that they don't need and it's that
4 kind of detail that I think she's speaking to where
5 we sit down and explain those differences. I think
6 it's easier, as he said; it depends on the
7 specialty talking to them.

8 So, if it's interventional radiologist,
9 he's like yes, we can take you to the cath lab
10 right now and stent you and you can go home
11 tomorrow. We have to begin to communicate the
12 level of information down to the patient so they
13 can understand when and when they should not, but
14 you're right, they don't have that today.

15 PARTICIPANT: And I think my comment kind
16 of jobs tops onto that in terms of sorry to be a
17 little bit cynical, but at least there are some
18 people who would say that depending upon which
19 center you go to and what specialty is strong at
20 that center, they will find that the best therapy
21 is whatever is their strength. And so, I think
22 what's relevant here is that a study which brings

1 all of those stakeholders to the table and involves
2 surgeons and involves cardiologists and involves
3 minimally interventional vascular folks is probably
4 stronger than one that is only representing one
5 point of view.

6 MR. LIPSTEIN: Kara, one of the things,
7 you haven't read our Methodology Report. It's a
8 real page-turner.

9 [Laughter.]

10 MR. LIPSTEIN: But there's a section on
11 there on what they call value of information
12 research which I didn't really know what that was
13 until I became a member of the PCORI Board, and it
14 turns out that there's this whole area of
15 investigation where you actually say if I had this
16 information, would it have changed what I did
17 anyway?

18 And so, in Mr. Jones' situation, I'm
19 thinking okay, here's a man, he's in the emergency
20 room, he's got bad chest pain. He and his wife and
21 probably at heightened levels of stress, anxiety,
22 fear, and they may have actually looked into this

1 ahead of time, but if they didn't, is there any
2 information that would be available that would
3 actually change the decision-making at the point of
4 care? And if it wouldn't change the decision, then
5 according to this methodology logic, it has a low
6 value of information even if it would be good to
7 know.

8 And so, part of what I would encourage as
9 we think about this is where are those
10 circumstances in a land where we have 800,000
11 physicians, many times more nurses than other
12 health care professionals at 320 million people,
13 where is the real value going to take place when we
14 add in information into the mix?

15 PARTICIPANT: And I'll bring up one more
16 point around this evidence stuff. So, at the
17 American Heart Association meeting, they brought up
18 the fact that diabetics do better with bypass and
19 so does your patient diabetes. So, as we talk
20 about patient-centeredness and making decisions
21 around individuals, already in the cardiovascular
22 society, and I'm a general internist, but I follow

1 the heart.org. They did say that diabetics have an
2 advantage with bypass surgery. So, if you told me
3 this patient's a diabetic, I might have a more
4 serious conversation around the surgery than if
5 knew that they didn't have that risk factor and I
6 might think about stenting that person or medical
7 therapy. So, just something to bring it up that
8 there is some uncertainty in this topic of
9 treatment options.

10 DR. WALKER: Absolutely. Particularly
11 because some of those studies weren't conducted in
12 those who are older than 75 and have other
13 comorbidities. And so, it is challenging, but it
14 is also a question about how do we find things that
15 will be implemented because, as you said, if
16 guidelines are already out saying diabetics do
17 better with open heart surgery, then maybe
18 physicians won't be likely to listen to a new study
19 that's much smaller in size. So, it's an ongoing
20 discussion and question.

21 Are there any other hands that I missed?

22 [No response.]

1 DR. WALKER: That's a great discussion.

2 So the next criterion that we are going to
3 talk about is if we conduct this study to answer
4 some of these research gaps, how long will evidence
5 exist? Are there going to be new technologies that
6 emerge that will cause us to have to revisits the
7 research gaps all over again? Are there going to
8 be new types of drug-eluting stents that need to be
9 now evaluated against CABG?

10 And so, I wonder if anyone in the room
11 would be willing to chat about whether these
12 research findings will be still valid or whether
13 there's going to be some new technology, some new
14 intervention, some new procedure that will take the
15 place of these other strategies that have been
16 tested and would be tested through this existing
17 study. Anyone? And I guess part of it is it's a
18 little unknown. We're not sure what may emerge.
19 Maybe someone in the pharmaceutical industry or the
20 device industry knows some advanced knowledge, but
21 as part of the advisory panel process, we're going
22 to be asking these types of questions. Some of

1 it's a little bit of fortunetelling to see what the
2 case is and using your own judgment and experience
3 to make those assessments.

4 Please.

5 PARTICIPANT: I think one of the research
6 that PCORI could fund that would have longest
7 impact would be methodological research. So, in
8 fact, we're trying to do off-pump CABGs and we're
9 going to have many more blood-thinners in the next
10 couple of years and those will be strongly
11 impacting the results of the comparison study,
12 particularly with Patient-Centered Outcomes like
13 stroke incident or patient is different afterwards
14 and not quite as sharp anymore as before, which
15 will be important for me personally, for example,
16 when I make that choice.

17 So, with that regard, we are concerned
18 about the lack of validity after a short period of
19 time and having to repeat the study, but if we
20 develop a new way of doing a study, a new way of
21 taking the patient's outcome interest into account,
22 then future studies could be modeled on that study.

1 So, I think mythological improvements and a sense
2 of patient-centeredness will be where this study
3 would gain its validity beyond the short time
4 period it's followed.

5 DR. WALKER: Great, thank you. Wonderful.

6 We'll go to the next slide. So, what
7 we've just done is talk through all the criterion
8 for one particular question. You can imagine that
9 the advisory panels in reality will actually go
10 through multiple questions in this way. The
11 evidence may be different, the level of the
12 questions and research gaps may vary across these
13 topic areas, but we're going to ask a wide range of
14 people and views just as you did today.

15 And as you could see from our draft
16 process, there are a range of people who are going
17 to be involved in this process, as we talked about
18 in our pilot process, which Rachael led. We had
19 patients, but we also had caregivers and family
20 members and clinicians and patient advocacy
21 organizations represented and that's what we
22 envision happening with these advisory panels, that

1 people will get some background knowledge about the
2 evidence and the gaps that we know. But we also
3 expect the variety of opinions and experiences will
4 add contextual information to these kinds of
5 prioritization processes as we go forward moving
6 forward with the value of information analyses, you
7 do have the ability to characterize and numerically
8 assess between topics. But some of it still is
9 about how do people come to the table and bring
10 their input and views into finding the right
11 research questions that will have high impact?

12 So, now everyone is in the process of
13 voting. So, everyone has decided which topic
14 should be highly-ranked on certain criterion, as we
15 just walked through. You're going through this
16 process and you're thinking about it with the
17 information in front of you. And so, the next step
18 will actually be to vote using a software tool.
19 So, we right now have used some decision analysis
20 software to walk through how we'll characterize and
21 rank all of these topics. What we've found is that
22 using different types of software does generate

1 some variance in the answers.

2 So, interestingly, for one of the groups
3 that we went through in our pilot process, this
4 very question about how do you treat coronary
5 artery disease ranked very highly. And as Rachael
6 emphasized earlier, some of the other topics were
7 sorted differently, but what we found is that there
8 were a few voices that said this issue was very
9 important and they brought in their own experience
10 to say why we should think about this duration of
11 information and the implementation likelihood more
12 highly for certain topics over others.

13 And then in another group, there were
14 other questions that came up and the treatment of
15 coronary artery disease was the second-ranked
16 topic. And it was still highly-ranked and thought
17 of as something that needed additional research
18 dollars and investment, but we also saw other
19 topics sort differently. And so, we're learning
20 from this process and we're learning from even
21 these conversations we're having today about what
22 topics to study and how we consider and evaluate

1 each of these topics, one against another.

2 And so, what you'll imagine is that as we
3 take this question and we've gone through this
4 ranking process which you have seen our draft
5 process to date, we do plan to have this fully-
6 ranked list that will then go to our board. Our
7 Board of Governors will go through and see this
8 ranked list and then they will finally approve the
9 topics and the research questions that'll move
10 forward for targeted funding opportunities for the
11 research community, stakeholders, patients to apply
12 for.

13 So, we're still learning. I would like to
14 emphasize that all of these conversations and your
15 thoughts about this are truly being taken into
16 account as we move forward with the process. We're
17 really interested in figuring out how we capture
18 this patient-centeredness through research topics
19 and research prioritization, how do we emphasize
20 the patient's voice? How do we clarify the
21 criterion, how we describe them, whether it's
22 talking about the duration of technology, the

1 ability to implement the research, or how do we
2 think about finding the right level of supporting
3 information? People have a variety of inputs.
4 Some people have clinical stories that can add to
5 the systematic evidence that is out there and that
6 we present to our advisory panels, but some of it
7 is about having the right tools to facilitate a
8 conversation and to collect consensus around all of
9 these different topics.

10 So, we're looking forward to moving
11 forward with this process. As we talked about
12 today in our small groups, we're looking forward to
13 getting a long list of questions and I'm sure
14 Rachael, you and I will have a long list of
15 questions to think about as we leave today's
16 meeting. We're really looking forward to figuring
17 out where they fall and some may overlap with our
18 different priority areas, but we're looking forward
19 to moving forward with this research prioritization
20 process in this coming year and welcome any of your
21 feedback, welcome your questions, and welcome the
22 opportunity to think about how we create high

1 impact research moving forward.

2 So, back to Mr. Jones, which we are now
3 replacing with Ms. Jones. So, as we talked about,
4 he had a huge team of physicians and
5 interventionists come to him and talk to him about
6 options and he really thought about what he should
7 do given his issues. And we're not really sure,
8 but in the future, he'll have information available
9 to him that's in a lay summary that he can
10 understand and apply, he can talk to his wife about
11 it, and he can talk through the decision-making
12 with his physician and care team in a way that
13 allows him to make these tradeoffs between having
14 the fewest risks and the greatest long-term
15 benefits for his health, taking into account his
16 own preferences and his own expectations for his
17 health.

18 So, we're looking forward to being able to
19 guide patients in this decision-making process,
20 whatever the clinical situation, and making sure
21 that we are able to make a difference in moving
22 forward with generating evidence that makes a

1 difference.

2 We have to say thank you again to all the
3 people who have helped us think through how you do
4 research prioritization, how we collect the
5 questions that you've generated today, how we're
6 going to move forward with putting those questions
7 in the public domain so that others can learn from
8 the questions and then move forward with generating
9 new evidence together. So, thank you so much for
10 this opportunity. I'm open to taking questions.
11 I'm sure the other members of the PCORI staff would
12 also be very interested in your thoughts and
13 comments on this process. Thank you.

14 MR. HATLIE: Okay, thank you.

15 [Applause.]

16 DR. WALKER: Are there any comments,
17 questions?

18 MR. HATLIE: Are there any comments or
19 questions for Kara before she steps down?

20 MS. HUNT: Yes, yes, me. I'm interested
21 in and maybe you could clarify what do you envision
22 as the level of detail that the research questions

1 that are coming out might be? Because it makes a
2 big difference. I mean, people could have lots of
3 different ways that they would bid on this, which I
4 think is great. So, could you just talk about it?
5 Is it going to be kind of like Mr. Smith or
6 whatever his name was and then --

7 DR. WALKER: From the questions that have
8 come in through the Web site, we've seen a wide
9 range. I mean, there are questions that are about
10 how did I get this condition? What is the
11 etiology? And we're really looking forward to
12 those comparative questions that address Patient-
13 Centered Outcomes Research. And so, how do we
14 collect those questions in the right way? As many
15 of you heard during the small group sessions,
16 sometimes those questions come into us like
17 stories.

18 People talk about a scenario such as Mr.
19 Jones' scenario and we can think about how to
20 partner them with a researcher who can create that
21 specific research question that we need answers to.
22 But we could also imagine that some of the

1 questions may come in and not have a specific
2 design in mind or specific outcomes in mind and
3 then we might present that as a portfolio of
4 topics.

5 Many people in one of my breakouts today
6 talked about the importance of care coordination
7 and you can imagine that that as a thematic area
8 could involve studies of a wide range of conditions
9 and scenarios. And so, it may be that we need to
10 think about how we're going to prioritize within
11 that thematic area and not necessarily on specific
12 questions.

13 Does that -- yes, we're definitely working
14 hard on thinking about how to do that thoughtfully.
15 So, wonderful. Wonderful. So, this was wonderful,
16 thank you.

17 MR. HATLIE: No, I was just going to say
18 if there are any more questions for you, Kara.

19 DR. WALKER: Yes, any more questions.
20 Great. It looks like there's maybe a question
21 here.

22 MR. HATLIE: There's a comment here.

1 DR. WALKER: Or comments.

2 PARTICIPANT: Yes, not really a question,
3 a comment. Thank you very much for having me. I
4 thought this was one of the most interesting
5 conferences I've been to in a long, long time, and
6 it was amazing to see the diversity of stakeholders
7 and that every single one had something for me
8 meaningful to say and it certainly changed my
9 perspective and it was exciting to be part of the
10 future because this clearly is the future.

11 DR. WALKER: Thank you.

12 MR. HATLIE: Great. Thank you very much.

13 DR. WALKER: Thank you.

14 MR. HATLIE: Okay, Kara, I think --

15 DR. WALKER: Great, thank you, everyone.

16 And I think we're inviting --

17 MR. HATLIE: I think we're inviting Anne
18 to close, yes.

19 DR. WALKER: Yes, come up.

20 MR. HATLIE: Thanks very much. Kara,
21 thank you.

22 [Applause.]

1 DR. BEAL: Great, so, it has been quite a
2 day and actually I was just thinking nice closing
3 comments, Michael. Maybe next time I'll have you
4 come up and say them. But really first of all,
5 it's just thank you because I know that we actually
6 ask a lot from all of the participants who came
7 today and we're really asking for a lot of input
8 from the field.

9 And so, first of all, we want to thank you
10 all for the time, the energy, the enthusiasm that
11 you brought to today's meeting. I also want to
12 thank the PCORI staff who spends a lot of time
13 pulling this together and it was really great to
14 see us just all work together to be able to have a
15 vision and really execute it.

16 One of the things that I wanted to make
17 clear though is how does this fit? Today's
18 session, how does it fit? Because one of the
19 questions that we often get is: All right, we've
20 all come together, but then what's next? So, many
21 of you who are here, particularly those who come
22 from patient advocacy or patient backgrounds

1 actually know that we also had about six weeks ago
2 a Patient Engagement Workshop where we wanted to
3 hear from patients around best practices for
4 engagement. We also have plans to engage in these
5 types of activities to hear from the field around
6 the country to hear from different interest groups,
7 to hear from different perspectives. I actually
8 received a lot of comments in terms of making sure
9 that we really engage in making sure that we have
10 inclusive elements to really bring the voice of
11 diverse patient populations into this discourse.
12 And so, we're definitely working on those
13 activities, so, look for more in terms of 2013.

14 So, today, I heard a lot of great ideas
15 and everything that you all shared with us today is
16 going into the process that Rachael described
17 earlier today, but I heard actually a lot of
18 comments around training. And so, I think that we
19 need to think a bit more in terms of what are our
20 plans around training. I don't think that we're
21 going to do the classic type of K awards, but that
22 doesn't preclude us from thinking about other

1 opportunities for training and I hear that there's
2 a lot of hunger for that kind of work.

3 I also heard a lot around mental health
4 and mental health issues and integrating mental
5 health into physical health. And so, what does
6 that mean in terms of some of the future research
7 questions that we had? And heard a lot around
8 disabilities and the disabilities community. And
9 so, I know that this is an area that we've been
10 doing a lot of thinking around and actually we've
11 had roundtables specifically seeking input from the
12 disabilities community on our work. And definitely
13 heard loud and clear on the need for us to really
14 think about rare diseases. We're not only hearing
15 about it from the rare disease community, but,
16 frankly, it included in our legislation. So, we're
17 definitely going to be doing a lot of thinking to
18 provide specificity for that.

19 So, what I would say as a follow-up, stay
20 tuned. There's going to be a lot of work that
21 you're going to hear about coming from PCORI. You
22 heard Joe mention this morning that we're going to

1 be releasing targeted funding announcements early
2 in 2013, and those are going to relate to uterine
3 fibroids, treatment of asthma, and prevention of
4 falls in the elderly. And so, when you think about
5 the process that Kara just described and think
6 about so, what are some of the criteria that we
7 would apply, in many ways it becomes, I think,
8 increasingly evident why we would pick these kinds
9 of topics where there is not a lot of certainty,
10 where there is a real impact on patients, where the
11 outcomes are really Patient-Centered Outcomes. And
12 so, look more for those types of announcements.

13 In addition, and you've heard a couple of
14 people talk about advisory panels, and so, we are
15 actually going to be forming advisory panels that
16 will be created to help advise us in terms of our
17 research programs, as well as some advisory groups
18 that are going to help us with some of the
19 development and refinement of these funding
20 announcements. So, there's going to be a lot of
21 opportunity for engagement in those.

22 What I would say is for those of you who

1 are not already signed up to receive announcements
2 from PCORI on our Web page, please go to PCORI.org
3 and subscribe in order to sign up to receive
4 announcements because whenever we do have a call
5 for advisory panel members or a call for a meeting,
6 we use that list in order to send out
7 announcements. So, definitely sign up as well as
8 encourage the people from the organizations that
9 you represent to sign up, as well.

10 And then one of the things that I'm very
11 excited about is in the new few weeks, our board is
12 going to be voting on the first round of projects
13 that are coming out of the broad funding
14 announcements that we released in May. And so,
15 some of you actually participated as reviewers in
16 that process and we thank you for your time and
17 attention to that activity, as well. And so, we
18 now have the final high-scoring proposals and will
19 be developing in the final slate, which is going to
20 go to our board in the next few weeks. So, look
21 for announcements on those to be coming out
22 shortly.

1 So, lastly, I want to thank you for your
2 time and thank you for your interest in PCORI, but
3 really recognize that when we talk about we are
4 trying to do research differently, we want you to
5 own PCORI. One of the things that came out of the
6 Patient Engagement Workshop was that people raised
7 their hands and said we want to be PCORI
8 ambassadors.

9 We also are starting to talk about welcome
10 to the PCORI family when people come to our events
11 or when they become award recipients from PCORI.
12 And so, as part of owning this, we want you to
13 challenge us and to help us make this better
14 because part of what we're doing and you're hearing
15 this a lot is that this is a new paradigm, a new
16 way of thinking about research, a new way of
17 evaluating the value of information that is coming
18 out of the research. And so, as we're trying to
19 create this, we're really eager to hear from the
20 field to make sure that we're doing the right thing
21 and that the work is truly relevant to yourselves
22 and to the nation, honestly.

1 So, thank you again and have a good trip
2 home. Bye.

3 [Applause.]

4 [Whereupon, at 4:47 PM, the workshop
5 was adjourned.]

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22