

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
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1767 King Street
Alexandria, VA 22314

[Transcribed from PCORI webcast.]

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P R O C E E D I N G S

[10:17 a.m.]

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2
3 CHAIRMAN NORQUIST: Good morning. I'm Dr.
4 Gray Norquist, Chair of the PCORI Board of
5 Governors. I want to welcome you to today's Board
6 meeting, which we are holding in Alexandria,
7 Virginia.

8 Let me extend a special welcome to those
9 joining us today via webinar and teleconference.
10 Instructions for registering to join us online or
11 by phone are available on our website at
12 PCORI.org/events. All materials presented to the
13 Board today will be available during the webinar
14 and after will be posted on our website, PCORI.org.

15 The webinar is being recorded and the
16 archive will be posted within the next week.

17 As with all of our in-person Board
18 meetings, there is a public comment period later
19 today from 4:30 p.m. to 5:00 p.m. Eastern daylight
20 time, and we welcome comments from members of the
21 public here with us in the room as well as those

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1 joining us by webinar and teleconference.

2 Information about how to offer public
3 comment is on our website at PCORI.org/events, and
4 of course we welcome feedback any time by email to
5 info@PCORI.org or through PCORI.org. We're live-
6 Tweeting today's activities on Twitter. Join the
7 conversation at #PCORI.

8 I did realize I said teleconference, but
9 we're not teleconferencing today. This is a change
10 for us. We're only doing audio webinar, so you
11 will not be able to see us, but if you want to see
12 our pictures you can always go to our website and
13 see who we are. That means -- yeah, and you can
14 get rid of the makeup people. That's a joke. We
15 don't actually hire makeup people, just don't want
16 anyone to get that impression.

17 But that makes it even more important that
18 when you talk, please say who you are so people
19 will know who's talking.

20 So, I'm going to introduce now Joe Selby.
21 Oh, I'm sorry. Joe reminded me -- since you can't

1 see, three of our Board members will not be with us
2 today, Arnie Epstein, Leah Hole-Marshal and Steve
3 Lipstein, and Rick Kuntz is at a meeting. He had
4 to leave and will be back at some point. There may
5 be -- I think, Harlan, are you going off for a
6 little while? Yeah, later, so we may have a few
7 dropping in and out also. Thanks.

8 Joe Selby.

9 DR. SELBY: Thanks, Gray, and good
10 morning, everyone. Let's see if I can advance the
11 slides.

12 Okay, so good morning and welcome to
13 Alexandria. I'm going to speak briefly on several
14 big items that won't get discussed much otherwise
15 in the day and those include a brief update on
16 PCORNet, a brief update on our Pragmatic Clinical
17 Studies Initiative, reports back from two advisory
18 panels, the Clinical Trials Advisory Panel and the
19 Rare Diseases Advisory Panel, which just met last
20 week for the first time. We have a welcome of a
21 new executive team member, Jean Slutsky, and then a

1 brief review of today's agenda.

2 So, PCORNet is undoubtedly PCORI's largest
3 investment to date and it is a genuinely exciting
4 opportunity to transform the way that research gets
5 done in this country, to make it more patient-
6 centered, to make it more involving of all the end
7 users of research, not only patients, but the
8 clinicians who care for them and the healthcare
9 systems where they get their care. It brings
10 together 11 clinical data research networks of a
11 million persons a piece or more, and 18 patient
12 powered networks, which are activated patient
13 groups who are dedicated to participating in
14 research and who will grow and cooperate with the
15 CDRN, the Clinical Data Research Networks, over
16 time.

17 We're in an 18-month startup phase right
18 now. I want to point out that we have a steering
19 committee that has a number of potential future
20 funders of PCORNet research including the NIH, the
21 FDA, AHRQ, the CDC. We also have CMS, the Office

1 of the National Coordinator, ONC, and the Assistant
2 Secretary for Planning and Evaluation, ASPE,
3 because these three represent federal entities that
4 can support PCORNet, and particularly can help us
5 access data that is needed to complete the cohorts
6 that have been built and identify the outcomes that
7 matter to patients and to us.

8 On the steering committee also are
9 representatives of the medical product, that is
10 pharmaceutical and device industries, because we
11 want to build a network that will support research
12 that's of interest to them as well as to the
13 federal funders of research.

14 That's the steering committee and it also
15 includes PIs from every one of the 29 networks,
16 held together by a coordinating center housed at
17 Harvard, Pilgrim, and Duke, that is very
18 experienced at building and supporting these kinds
19 of networks and charged with 11 major tasks. This
20 is a transformative effort, it's also a daunting
21 effort, and I will just mention briefly three areas

1 that we've been working on particularly in the
2 early going.

3 The first is the -- and I noticed that now
4 this is working, good -- the first is data
5 standards and security. To build a network, we
6 don't transfer data between sites in the network,
7 but we do have to arrange the data within each one
8 of the participating networks in the same standard
9 way, so that we can write programs and codes to do
10 queries and to do analyses. We then pool the
11 analyses. So, this protects data security and
12 patient privacy.

13 But it's a lot of work and we have been
14 working hard with our 29 participating networks to
15 agree on early, pretty simple data standards so
16 that we can begin looking at data across these
17 networks without transferring any data.

18 I want to say too that it's pretty
19 inspiring, the passion and the commitment that
20 these 29 networks bring. To a network, they
21 appreciate the transformative nature of what we're

1 trying to do and they're tolerant of us in the
2 complexities that we're running into jointly.

3 One critical area that we've addressed in
4 the last couple weeks with a very successful
5 meeting at the IOM is the notion of how health
6 systems get involved. I mean, we asked them to
7 grant permission for research to be done within
8 their systems, we ask them to eliminate barriers to
9 accessing data, and we will be asking in phase two
10 for their support, their -- hopefully for some
11 financial support for the network to continue.

12 We held a meeting at the IOM where we
13 heard from -- in discussing many of these issues,
14 and I think it's fair to say that there was a lot
15 of enthusiasm from the CMOs, the CQOs, and other
16 high level executives within a number of
17 organizations inside and outside of PCORNet, but
18 the message was also clear, that this research
19 needs -- for them to be genuinely interested, this
20 research needs to be rapid and it needs to be
21 research that serves the interests of health

1 systems struggling to survive, so it really proves
2 the point that if you want support, you've got to
3 be meeting the needs of those who would support it,
4 the end users.

5 So, very hearty meeting and we will follow
6 it up with a meeting with CEOs at the IOM in June.

7 The third area, which has received some
8 attention in the last couple weeks, is the critical
9 area of data privacy, and I will say that PCORNet
10 has a number of aspects of it that are already
11 designed to provide additional protections toward
12 securing data privacy, but I think there's a
13 dialogue to be held with patients, with patients in
14 our Patient Powered Networks, patients in our
15 CDRNs, with the health systems that are
16 participating, and with the community, about what
17 data privacy means and how we optimally balance the
18 great opportunities of these data with the real
19 risks to patient data privacy, how we include
20 patients in the decision making about policies, and
21 also about the particular projects that we'll

1 undertake together and in the decisions about when
2 informed consent -- when individual informed
3 consent is needed and when other forms of
4 communication between health systems and the
5 patients are needed.

6 So, these are three huge areas, not to say
7 that all of these other areas on the right aren't
8 also going to be big areas to work on during these
9 18 months.

10 This is the timeline, and I mainly want to
11 show that we expect to have the first query from
12 the Common Data Model, the Standardized Data Model,
13 September of this year followed by governance
14 policies, but a really big issue is in December of
15 this year we will release an announcement for phase
16 two.

17 Phase one is only 18 months long. Some
18 sense of continuity is needed by the investigators,
19 by the networks, and by the healthcare systems that
20 host them, and that announcement will come out in
21 phase two. It will be competitive. It will be

1 awarded at the end of phase one, at the end of
2 September 2015, and it will be open -- our view at
3 this point is that it will be open to additional
4 competitors as well, so others who want to join
5 PCORNet will be able to compete at this time and
6 there will be continued infrastructure funding, but
7 we hope that phase two also is advanced by funding
8 for real research as well as continued building of
9 infrastructure. We expect that.

10 Okay, that's all I'm going to say on
11 PCORNet. I want to say a few words now about the
12 pragmatic clinical studies and stop for a minute
13 for --

14 CHAIRMAN NORQUIST: Hang on, Sharon has a
15 question.

16 DR. LEVINE: You've got a very large
17 steering committee, just looking at that, so I
18 assume that it's in the -- you know, more than 20
19 people and I'm just wondering how the work of the
20 steering committee and the executive committee, how
21 that's divided up.

1 DR. SELBY: Well, it's a good question and
2 the executive committee clearly does a lot of the
3 initial thinking, the agenda setting, for example,
4 and then a lot of the work is actually done in the
5 taskforces.

6 The model is that the taskforces do the
7 work; they generate draft policy. Most of these
8 taskforces have representation from just about all
9 the networks, so that's how much work is going on,
10 and the policies come up through the taskforces to
11 the steering committee for consideration,
12 modification, and votes.

13 So, now I'm moving on to a second topic,
14 the pragmatic clinical studies. As you know, we
15 issued our first pragmatic studies announcement in
16 February of this year and received around 270
17 applications. A number now have been reviewed and
18 invited to submit full applications, which will be
19 reviewed in November, and the first six to nine
20 pragmatic clinical studies, I will tell you that it
21 looks like most of them will be clinical trials,

1 will be funded in January -- awarded in January of
2 2015.

3 But I just put up here, and I'm not going
4 to read through them, but there's two slides that
5 anyone listening online can -- will be able to see
6 posted on the PCORI website later today, of the
7 topics just to give you a sense of the yield from
8 this announcement. We were very excited by the
9 letters of intent that came in, really looking
10 forward to the reviews and to identifying the
11 projects going forward.

12 Again, here is the second set. Another
13 announcement for the next round of pragmatic
14 clinical studies goes out later in May, and so
15 those listening should be on the lookout for that
16 if there's interest.

17 We've really emphasized in these not only
18 that it must be a high priority topic, but also
19 that the applicants must bring along organizations
20 that represent the patients and the clinicians,
21 maybe the policy makers or payers, who would

1 implement the financials. So, this is really
2 engagement at a very high level and consequently
3 the funding award is large, and so these, I think,
4 will be among the studies that we point to within a
5 year as being emblematic of the way that we do
6 research and the ways that we do it differently.

7 I've already gone through this. The
8 awards will be announced in January and probably
9 the earliest start date would be April of 2015.

10 So, as I said, the advisory panel on rare
11 diseases met for the first time -- we had actually
12 two remarkable meetings this week, probably more
13 than two last week, but two of them that I attended
14 were the rare diseases and the clinical trials
15 panels.

16 So, this multi-stakeholder panel with a
17 lot of expertise from various sectors of the rare
18 disease community from federal funders, NIH, to
19 patient organizations, the National Organization of
20 Rare Diseases, industry was well represented, and
21 patients -- there's a tie to PCORNet and PPRNs on

1 this panel, but the initial focus was very clearly
2 that they wished to help us on foundational issues
3 like issues related to the data standards for rare
4 disease registries, for issues -- really serious
5 issues that you talk to the owners of these
6 registries about early on about policy questions o
7 who owns the data. What happens to the data if the
8 funding should run out? How do you sustain a
9 registry such as this? Policies about access to
10 the data and issues related to institutional review
11 boards.

12 So, there's expertise on this panel that
13 will help us both -- with all of those questions.
14 They want to commission a landscape review on the
15 set of issues that are uniquely related to rare
16 diseases. They're particularly interested in
17 addressing IRB issues, interestingly as is PCORNet
18 and their interest is particularly related to rare
19 disease research, and they want to advise on how we
20 take the CER framework and use it in rare disease
21 research.

1 They will coordinate closely with our
2 advisory panels. This panel does not make
3 decisions about topics to research, but they will
4 interact with our advisory panels to give them the
5 perspective of the rare disease community and they
6 will certainly coordinate with PCORNet's taskforce
7 on rare diseases. Very successful launch of this
8 committee, very dedicated people on it.

9 And the very next day we held our first
10 meeting at a clinical trials advisory panel and I
11 think we found also there just a very well suited
12 group of people, a complementary group, a lot of
13 expertise across the range of issues, and they set
14 out -- their mission will be to keep -- remember
15 that the Methodology Committee is closely linked
16 with this committee because they both have a lot of
17 methodological interests and responsibilities.

18 So, one of their first tasks will be to
19 work with the Methodology Committee to review the
20 standards that are related to clinical trials and
21 keep an eye out for either the need for updates or

1 for additional standards.

2 So, I suspect that recommendations for
3 some new standards will come out of this panel.
4 They want to provide guidance for applicants on
5 some of the innovative methods around comparative
6 effectiveness and pragmatic trials, particularly
7 adaptive trials using Bayesian methods.

8 Also in collaboration with the Methodology
9 Committee, they will work to give PCORI
10 methodologic consultation at the point where
11 letters of intent are being considered, at the
12 point where we actually solicit targeted funding
13 announcements and pragmatic clinical studies.

14 So, they will work with us on refining the
15 solicitations and the letter of intent review, the
16 process of that, to make it fit better with optimal
17 clinical trials methods when research is funded.

18 They will also provide methodologic
19 consultation along with the Methodology Committee
20 to reviewing applications, to reviewing the details
21 of methodologic issues in applications to enhance

1 the rigor and the pragmatic utility of proposed
2 studies.

3 They will advise PCORI on developing
4 policies for DSMBs, Data Safety Monitoring Boards,
5 that's a critical issue that we face particularly
6 as the pragmatic clinical studies come online. And
7 they will work with us on the ethical assessment of
8 low-risk pragmatic trials, particularly issues
9 related to IRB oversight and the need for informed
10 consent.

11 So, those are the issues that they're
12 going to help us with and we're just delighted at
13 the first meeting and very glad to have that
14 assistance.

15 Okay, now we're moving into other news.
16 As you know, the legislation called for a five-year
17 review of PCORI by the Government Accountability
18 Office and that process has begun. We received a
19 letter from the GAO in March. He's identified two
20 primary objectives for the review. The first is,
21 what has PCORI done to establish research

1 priorities and get research underway, and how does
2 that align with the legislative mandate? So, that
3 was the first broad question they'll be asking us
4 many details about.

5 And the second is, to what extent has
6 PCORI established plans and undertaken efforts to
7 evaluate the effectiveness of its work? So, the
8 GAO is very motivated, very oriented towards
9 strategic planning and careful evaluation in light
10 of a strategic plan, and I think we are well served
11 by having our strategic plan in place and by having
12 our PCORI evaluation group in place.

13 We held our first conference with the team
14 in April and they will be returning for a series of
15 meetings over the next several months, and in terms
16 of a timeline, the final public comment vetted
17 report will go to Congress in March of 2015.

18 I want to celebrate the arrival of Jean
19 Slutsky. I think, actually, because we haven't had
20 a public meeting since November, this is one more
21 opportunity to let the community know that our

1 previous chief officer for engagement, Anne Beal,
2 notified us in February that she would be resigning
3 as of March 1st and moving on to a critical job
4 with Sanofi Pharmaceuticals as vice-president for
5 patient engagement. So, patient engagement is
6 rapidly making its way into industry. That's good.
7 And we will look forward to a lot of opportunities
8 to work with Anne in her new role.

9 Jean Slutsky was coming on as the program
10 director for communications and dissemination
11 research about that time and we subsequently
12 determined that she -- it would be ideal for Jean
13 to take on the role that Anne had held and lead
14 engagement. Her title is chief engagement and
15 dissemination officer. Everyone knows Jean,
16 everyone on the Board and the Methodology Committee
17 knows Jean because she's been with us since the
18 very beginning in her role at the Agency for
19 Healthcare Research and Quality.

20 Everyone in the comparative effectiveness
21 and patient-centered outcomes research community

1 knows Jean because she's been at AHRQ for 12 or 13
2 or 20 years -- I'm sorry, Jean, I can't quite
3 remember -- quite a while, and she's really been
4 the face of comparative effectiveness research and
5 the brains behind it. So, we are very fortunate to
6 have Jean and you will hear from her later today
7 with her eight-week assessment of engagement and
8 how it fits into PCORI's agenda, and I just want to
9 say that we are heartened and strengthened by her
10 addition and it's really a pleasure to have her on
11 the team.

12 And lastly, I just want to preview today's
13 agenda. Most people know that we have, through a
14 governance review process, we've reorganized the
15 Board into three strategy committees aligned with
16 our three strategic goals, to produce useful
17 research, that's the Scientific Oversight
18 Committee, or SOC, to speed implementation, that is
19 the Engagement, Dissemination and Implementation
20 Committee, or EDIC, and to influence research by
21 others to become more patient-centered, to

1 basically transform research funded by us and
2 others to be more patient-centered, and that is the
3 work of the Research Transformation Committee, RTC.

4 And so, we will move forward with a lot of
5 work being done in these committees and coming to
6 the Board in the service of our strategic plan.

7 Today we're going to see an agenda that is
8 a bit of an evolution, just a transition in a
9 direction that the governance report felt we should
10 go, and that is that the Board, among other things,
11 should become -- perform more of a monitoring
12 function, to monitor the performance, how we're
13 doing with respect to our strategic plan and with
14 respect to the directions we want to go.

15 So, you will hear for the first time
16 today, our new dashboard, the dashboard that we
17 think we'll be living with for months and years to
18 come, which I do have a lot of suggestions for
19 changes, additions, subtractions from the
20 dashboard, but this dashboard begins to show a
21 longitudinal picture of our progress over time.

1 You will also hear a report from Dr.
2 Romana Hasnain-Wynia on our research portfolio.
3 The Board has asked, on a number of occasions, for
4 more detail on what we funded, and we have been
5 busy synthesizing what we've funded and Romana is
6 going to show you the results of that effort in one
7 program and then at all subsequent Board meetings,
8 telephone calls, and face-to-face meetings, we will
9 be presenting parts of our research portfolio for
10 your suggestions and input. That's a good way to
11 begin identifying gaps in what we're funding and
12 also to get to know what we're funding and to
13 celebrate some of the projects that we're
14 particularly pleased with.

15 Also in the area of monitoring
16 performance, we're going to hear a report from
17 Regina Yan on our five-month into 2014 financial
18 review.

19 There's also a lot of areas in which the
20 Board has asked us about how we're doing something
21 or asked us to produce documentation on aspects of

1 our process. So, you're going to hear three
2 reports today from Bryan Luce, our chief science
3 officer, on ensuring adherence to methodology
4 standards, an issue brought up as early as last
5 December. How do we make sure that our funded
6 research follows the methodology standards? How do
7 we select awards? Following the merit review and
8 the presentation to PCORI's board of ranked
9 results, how do we select the actual awards that
10 will be funded? And do we ever deviate from the
11 ranked scores? So, you'll hear a report on that
12 procedure.

13 And the third is, how do we select
14 research topics that come from stakeholders, that
15 pass reviews by our advisory panels, and ultimately
16 either get selected for targeted funding
17 announcements, perhaps get put on the list for
18 pragmatic -- large pragmatic studies, and what are
19 the details of that process -- that most important
20 process of how we set our agenda?

21 We'll also hear from the Methodology

1 Committee on the really rather large body of work
2 that they've taken up in the last few months, 2014
3 going forward.

4 And lastly, in terms of strategy, you're
5 going to hear a report from Michele Orza on our
6 evaluation plan worked out in collaboration with
7 our evaluation group. This is really our
8 opportunity to make sure that we've got markers
9 that assure us and the outside world that we are
10 moving forward toward our strategic goals. And you
11 will also hear the engagement update from Jean.

12 So, that is it, Gray, and I'll ask you if
13 there are comments from the Board.

14 CHAIRMAN NORQUIST: When I introduced you,
15 you were supposed to make some initial comments and
16 you went running on, so we didn't get a chance to
17 approve the minutes.

18 [Laughter.]

19 CHAIRMAN NORQUIST: I just let you go.
20 You were so excited with your presentation --

21 DR. SELBY: I was really keyed up.

1 CHAIRMAN NORQUIST: -- I just let you go.
2 So, unfortunately, I need to just -- but we need to
3 back up just a second. Joe went tearing into this.
4 I need to get the minutes from the last meeting
5 approved. So, I need a motion and a second.

6 UNIDENTIFIED: So moved.

7 UNIDENTIFIED: Second [off microphone].

8 CHAIRMAN NORQUIST: Okay. All in favor?

9 [Chorus of ayes.]

10 CHAIRMAN NORQUIST: Anybody opposed?

11 [No response.]

12 CHAIRMAN NORQUIST: Okay, now.

13 DR. SELBY: Sorry about that. So, do we
14 have some time for comments? Good. I presented a
15 lot, everything from PCORNet and the pragmatic
16 clinical studies to --

17 CHAIRMAN NORQUIST: According to our
18 schedule we have 15 minutes for discussion here.
19 Yes, Harlan.

20 MR. KRUMHOLZ: Joe, I just --

21 CHAIRMAN NORQUIST: Sorry, you need to say

1 your name so people will know --

2 MR. KRUMHOLZ: Sorry about that. Harlan
3 Krumholz. Joe, it's a breathtaking amount of work
4 you did for a very short period of time. For
5 people who are listening and are very interested in
6 what's going on with PCORNet, which I know many of
7 us on the Board feel is one of our most important
8 initiatives with respect to something that might
9 have a long legacy, what do you think people can
10 expect to see in the next six months from PCORNet
11 as they are sort of tracking this? And for those
12 who are listening and are interested in PCORNet but
13 are not part of the PCORNet network, how can they
14 best keep up with the kind of discussions and
15 decisions and issues that are coming up for PCORNet
16 so that there can be some opting for alignment? And
17 if they're not in PCORNet, the final thing is, will
18 there be an opportunity in the future for them
19 perhaps to be able to interact with this network?

20 DR. SELBY: Thanks, Harlan. I think the
21 best way to track PCORNet is through our website.

1 You saw all those taskforces on the right, and
2 those are charged with developing white papers and
3 policies that will go to the steering committee,
4 and I think all of this will be done very much in
5 the open.

6 A lot of this is transformative work,
7 crucial questions about how a network like this
8 actually governs itself and makes decisions with
9 patient and clinician and health system input. So,
10 a lot of excitement on that front.

11 I think there's nothing as important as
12 the issue of privacy and I think you'll be seeing -
13 - in the next week you'll be seeing new material on
14 our website related to privacy.

15 And I think -- I predict that you will see
16 quite a bit on privacy including possibly even
17 convening a meeting of stakeholders to discuss this
18 issue.

19 The challenge -- the opportunity, I'll
20 call it, actually, of having this discussion about
21 the value of the research, the issues related to

1 data security and patient privacy, and how best to
2 engage the millions of patients whose data are
3 available to be used, how to engage them into -- in
4 the discussion about the uses of those data and
5 privacy is -- internationally it's a huge issue and
6 it's certainly an issue here.

7 In terms of the last part of your question
8 about others, I did say that phase two is going to
9 be open competitively to others who would like to
10 join and one of our taskforces is actually charged
11 with creating a data model that's easy to interact,
12 interface with and so I think that, you know, the
13 message is we would love to expand PCORNet, larger
14 than it is.

15 This is the only network that's dedicated
16 broadly to a broad range of research. This is not
17 a disease-specific network, that is. So, we would
18 love to become the national network at that level
19 and that creates, then, a foundation, I think, for
20 registries and a wide range of other applications.

21 CHAIRMAN NORQUIST: Francis.

1 DR. COLLINS: Francis Collins, Board
2 member. I share Harlan's enthusiasm for what
3 PCORNet can be and how important it is to make sure
4 we're hearing from as many different quarters as
5 possible in designing this and implementing it in a
6 way that both respects patient privacy and allows
7 research to go forward that would potentially not
8 be possible in any other way and the power of this
9 to be able to carry out observational studies in a
10 relatively short term at relatively low cost is one
11 of the things that we are particularly compelled
12 by. But ultimately, of course, interventional
13 studies as the gold standard, must also be a major
14 part of the plan.

15 I actually wanted to raise a question
16 about the pragmatic trials which I'm also very
17 excited about seeing emerge out of PCORI's
18 portfolio and the topics that you have shared with
19 us all look to be extremely interesting ones.

20 One of the challenges, though, of course,
21 is to look at the whole landscape and try to figure

1 out what's already going on in terms of other
2 studies on similar or identical problems, and
3 that's always been a bit of a challenge for PCORI
4 in trying to make decisions about where to invest
5 dollars.

6 So, can you say something about how that
7 part of the process might work as these pragmatic
8 clinical trial proposals are being reviewed?
9 What's the arm of the review that is going to
10 survey what's already happening in terms of other
11 related research enterprises to make sure that
12 PCORI's investments are going to fill a niche and
13 not pile on top of something that's already going
14 on?

15 DR. SELBY: Thanks, Francis. So, this is
16 a process that we've had to put in place several
17 times before for the targeted funding
18 announcements, and we turn first to our Board
19 partners, NIH and AHRQ, because they have a good
20 handle on what's going on.

21 I think there's probably more work to do.

1 One of the things I think that we're going to rely
2 on is the inclusion of key groups that are actually
3 knowledgeable about this on the research teams of
4 the winners. In other words, applicants must bring
5 along -- if this is an orthopedics question, let's
6 just say, for example, it's a question about back
7 pain, we would expect that a national organization
8 representing orthopedists would be in sight and
9 would be saying, look, this is the question that
10 needs to be answered.

11 So, we think we've helped our cause a bit
12 by requiring that people who are already in the
13 know say this is the important question, this is
14 the one that would help change practice, but I
15 think, you know, a part that we probably need to
16 work on during that same period that we're
17 consulting with NIH and AHRQ is consulting with
18 industry sponsors, at least in some of the
19 instances.

20 DR. JESSE: So back to --

21 CHAIRMAN NORQUIST: You need to say who

1 you are.

2 DR. JESSE: Bob Jesse. Board. Back to
3 PCORNet. You know, one of the real issues here is,
4 of course, all the privacy things that center
5 around enrollment and the like and apropos to some
6 discussions I've been having about the rewriting of
7 the common rule, I would think that as we are
8 setting this up, we would be able to learn an awful
9 lot about how that might be better handled in the
10 way that we can both ensure patients' privacy, but
11 also liberate the ability to do the kind of
12 research we want to do. And we had talked earlier
13 about PCORI as a convening force. I think there's
14 a real opportunity to learn a lot as PCORNet rolls
15 out and to use that to drive those discussions
16 about how we can fix, if you will, research in this
17 country.

18 DR. SELBY: Yeah, I think that's an
19 excellent point and I hear it. We will definitely
20 take that back to our coordinating center and to
21 staff, and I think you can expect to see something

1 in that line soon.

2 CHAIRMAN NORQUIST: Yeah, Allen.

3 DR. DOUMA: Again, I'm a very strong
4 supporter --

5 CHAIRMAN NORQUIST: And you are?

6 DR. DOUMA: Allen Douma. I'm a very
7 strong supporter of PCORNet and all of its
8 potential, but it's because it is so broad and
9 diverse and it's taking on challenges that others
10 have been attempting to deal with for decades,
11 literally, in particular the last decade, the HIEs
12 have been enmeshed in this throughout the country.
13 We need to be really clever and quick and so I
14 think it's just important that we have an
15 organizational or governance structure for PCORNet
16 that draws on the talents of the rest of PCORI and
17 the people we don't know that the RTC will be
18 taking this up in a big way tomorrow afternoon. I
19 look forward to the movement along those lines.

20 DR. SELBY: It just gives me the
21 opportunity to say, yes, one of our three strategy

1 committees, the Research Transformation Committee
2 chaired by Dr. Lewis-Hall, had this as really one
3 of its central foci and they already have been very
4 helpful in these discussions about PCORNet and will
5 be working with us closely, especially on this
6 issue of phase two -- the phase two funding
7 announcement.

8 CHAIRMAN NORQUIST: Okay, so, why don't we
9 go ahead -- we're about five minutes early, but we
10 can -- Bryan, if you want to come on up.

11 Bryan Luce is the chief science officer.
12 He's going to give us an update on science
13 processes. It's not just -- so, it's going to be -
14 - I can't see now -- implementing the methodology
15 standards, the award selection, and the topic
16 selection.

17 And, Christine, this is primarily coming
18 out of SOC, so we'll allow Christine to have input
19 also if she needs to.

20 MR. LUCE: Well, thank you very much. I'm
21 delighted to be here this morning. I'm going to be

1 talking about the three issues that have been of
2 deep interest and concern of the Board in terms of
3 the process in which we develop topics and that we
4 monitor the research, the methodological assurance,
5 and so forth.

6 So, I'll get right to it. I'll start off
7 with the entire process of implementing the
8 methodological standards, then move to the process
9 of award selections, and then finally go to the
10 topic selection process itself.

11 The methodology standards processes start
12 quite a ways back in terms of the Board's
13 recommendations as to how that should go about. I
14 will give you a sense of that timeline. We put in
15 place a processes to ensure that our awardees
16 adhere to the standards, I will talk about that.
17 And then speak about the training program that we
18 have just instituted that we'll be rolling out over
19 the next few months.

20 Going over -- back down to the period
21 prior to July 2013, you may remember that the

1 methodology standards were recommended for all
2 projects in cycles one through three. These
3 recommendations were embedded in the application
4 guidelines and the funding announcements as well as
5 the merit review guidance.

6 During part of this time, of course, the
7 methodological standards were in a draft report.
8 In August of 2013 cycle, the adherence was required
9 for all projects, again, that requirement was
10 embedded in the application guidelines and the
11 funding announcements as well as the contract
12 language itself.

13 This last December we instituted a process
14 for award adherence monitoring, both pre-award and
15 post-award, which I will go into in a little bit
16 more depth, and just last month we developed a
17 pre/post-award adherence process for staff. It was
18 more systematic.

19 In terms of the pre-award process, the
20 adherence for methodological standards are reviewed
21 on a case-by-case basis for every project and it's

1 required for -- adherence is required prior to
2 contract activation. We have developed a checklist
3 that staff uses to track adherence. I'm going to
4 show you a screenshot of that. That checklist is
5 available for your review in its entirety.

6 We also have established a research
7 template for applicants to highlight standards
8 through the application process, to sort of map the
9 actual standard with the actual part in the
10 application. I have a screenshot for that as well
11 for you to look at.

12 In terms of post-award, adherence is
13 monitored through the active portfolio management
14 process we've put in place. We have -- we require
15 milestones at either six months or one year,
16 interim reports depending on the nature of the
17 study, and of course the final report includes
18 progress and the adherence to the methodological
19 standards.

20 So, here is a screenshot of the
21 methodology standards checklist that staff uses at

1 the point at which the contract is literally
2 negotiated. You can see on the left hand side the
3 very first standards of formulating research
4 questions. I draw your attention to that very
5 first item, RQ1, identify gaps in the evidence.
6 When we look at the screenshot for the research
7 strategy template that the applicants actually use,
8 you can see RQ1 and all of the other standards
9 circled there to give you an indication that when
10 the applicant goes through the process of
11 developing proposals that -- each section of the
12 application is identified exactly which standard
13 they are to review and ensure adherence.

14 Also want to note that in August -- for
15 the August 2014 cycle that were awarded and -- the
16 projects were awarded this last December, all 53
17 projects were reviewed by staff using the adherence
18 review process and all methodological issues
19 required modification were dealt with, successfully
20 resolved and added to the milestone schedules.
21 That was, if you recall, during our last in-person

1 meeting. There was a specific concern and we've
2 put that into place.

3 In terms of next steps, we are moving back
4 toward looking at the projects that were funded
5 prior to the August cycle when the standards were
6 recommended but not required and we're going to
7 systematically go back and check those projects for
8 adherence, and we've instituted a training program
9 that I'll talk about next.

10 So, the -- we've been -- last year we
11 engaged a scientific expert to help us develop a
12 curriculum and that is in place, in part, we've
13 already begun training patients and stakeholder
14 reviewers. That started in March. The staff will
15 be trained starting this month and then, as you can
16 see, we'll be rolling out the training. All this
17 training is very consistent with the one slightly
18 tailored to the students or the folks that we're
19 training. In July we'll be training the technical
20 reviewers, in September the prospective applicants,
21 and then for more the general public we're planning

1 a future in-person training conferences.

2 So, that's fairly well developed and on
3 the way.

4 So, with that -- so, that's the
5 methodology standards. Before we open up for
6 questions and comments, Robin, do you have anything
7 that you may want to add?

8 MS. NEWHOUSE: No, except that on behalf
9 of the Methodology Committee, we thank you for all
10 of your work and I know Stanley [unintelligible]
11 has briefed us and presented us with some of the
12 implementation strategies and we're all very
13 appreciative of your work and support.

14 CHAIRMAN NORQUIST: Okay, so, let's --
15 we'll open it up now for discussion. Did you have
16 anybody else you wanted to recognize?

17 MR. LUCE: No.

18 CHAIRMAN NORQUIST: Okay. Well, let me
19 just ask one question. Sharon is first, then Kerry
20 and we'll go around. When you're saying that
21 you're requiring them to hold to the methodology

1 standards, and one of the things, Robin, we had had
2 -- by the way, this is Gray Norquist talking -- if
3 we -- if someone -- there's some methods that you
4 guys are proposing, but obviously there may be some
5 disagreement in the field about what method to use.
6 So, if someone makes a very strong case for some
7 other method than what might be recommended by the
8 methodology standard, that of course would be, I
9 assume, taken into consideration, we wouldn't be
10 rigid about it right?

11 MS. NEWHOUSE: From our perspective,
12 innovative methods should not be discouraged, but
13 there has to be some rationale for the methods that
14 are proposed.

15 MR. LUCE: Yes. That is how staff is
16 handling it.

17 CHAIRMAN NORQUIST: But let me -- I just -
18 - I'm sorry, to be a little bit more concrete about
19 this, but on the process, then, someone proposes
20 "an innovative method". How is that adjudicated,
21 whether it is indeed? I mean, who's making that

1 decision that that's okay? Does that go to the
2 peer review? Are we having a separate group make
3 that?

4 MS. NEWHOUSE: This is Robin Newhouse.
5 The Methodology Committee has not adjudicated any
6 disagreements, so I'm going to defer to Bryan.

7 MR. LUCE: There's a whole series of
8 processes, of course, here. Obviously, we go
9 through the merit review process itself and these
10 standards are reviewed at that point and then staff
11 follow up with that. And part of the answer,
12 certainly with respect to clinical trials, will
13 reside with the Clinical Trial Advisory Panel that
14 we just convened this past week that will get
15 directly involved with both, as I think Joe
16 mentioned earlier, the LOI process all the way
17 through the merit review and ultimately the
18 implementation of the beginning of the study
19 itself.

20 So, the other comment I'd make is that as
21 Robin would attest to, I think you all know, these

1 standards are minimal standards to begin with.
2 They're really not anywhere near ceiling standards
3 and we encourage experimentation and pushing the
4 envelope with respect to the standards.

5 CHAIRMAN NORQUIST: Yeah, my main thing is
6 -- I'm assuming I'm an investigator coming in, I
7 get dinged, I don't get my grant now, and I mean,
8 so obviously we let them come back and I think we
9 just need to be very clear about what was not right
10 in that particular application and give them some
11 instruction so that when they come back they might
12 be more successful. They may miss it the first
13 time if they don't get it.

14 Okay. Sharon, let me stop talking. Is
15 that your question? Okay. I think, Kerry, you were
16 up, if I remember, first.

17 MR. BARNETT: Just briefly. Do we require
18 in the award contract itself that they follow the
19 methodological standards?

20 MR. LUCE: That's correct.

21 MR. BARNETT: And so then if we were to do

1 our review a year or two later, during the research
2 trial itself, and find that they've strayed from
3 those standards, that would provide some very
4 specific recourse for us. Is that the idea?

5 MR. LUCE: That would legally be the case,
6 that's exactly right. The staff have really put in
7 place a fairly rigorous monitoring process, so, you
8 know, presumably that will be picked up as things
9 go along, but, you know, research goes astray and
10 so I expect there will be issues coming from time-
11 to-time.

12 CHAIRMAN NORQUIST: Harlan and then I
13 think it's Francis and then Harlan Krumholz.

14 DR. WEISMAN: You know, one question I
15 have tying this back to PCORNet and the
16 availability of vast amounts of clinical
17 information, Francis talked about the ability to do
18 outcomes research outside the setting of an RCT.
19 Now, methods are available for doing this. These
20 are often controversial in terms of those methods,
21 and I think one of the bullets talked about

1 Bayesian methods.

2 How much of this is coming up and are we -
3 - maybe this is more of a question for Robin --
4 what -- all these things are brought up and it's
5 contrary to the methodologic standards, which set a
6 base of providing information about the methods
7 being used, but how much are we exploring, either
8 through the grants that are being sent to us or by
9 solicitation of grants to look at methods of
10 outcomes research outside the setting of -- you
11 know, more in the setting of real world
12 observational data?

13 MR. LUCE: Well, in the course of the
14 actual applications up to now, we haven't
15 specifically faced that although a lot of these
16 projects, of course, are being conducted in real
17 world settings. I mean, that's sort of the nature
18 of what PCORI has put in place requiring
19 stakeholders to be part of the process and part of
20 the project and the project team as well as
21 patients and patient advocates and so forth.

1 You raise a really important point. It's
2 actually the subject of a session we're going to
3 have at academy health, specifically focused around
4 the application of pragmatic clinical trials within
5 a learning healthcare system like PCORNet and we're
6 literally going to tee all of that up and start
7 thinking through how it really works in that kind
8 of setting.

9 I think there's a long way to go and a lot
10 of methodological issues that will be grappled with
11 as real world research is done within a real world
12 operating system that needs information to make
13 decisions about healthcare as well as, you know,
14 the research findings themselves.

15 DR. WEISMAN: You know, I asked Joe, it
16 seems at least until now, almost all, if not all,
17 the pragmatic trials that we will be -- that we're
18 looking at are RCTs, and nothing wrong with that,
19 and I think everybody supports that, but there is
20 the limitation on how many questions can be asked
21 by RCTs from a funding -- just from a pragmatic

1 standpoint, just how many pragmatic trials --

2 MR. LUCE: Right.

3 DR. WEISMAN: -- you can do, but
4 observational studies are much less constrained in
5 that way and I think a lot of times they're written
6 off as mere anecdotal information when, in fact,
7 looking at them and looking at them in some
8 systematic fashion allows you to use information
9 that is sitting there otherwise and not being
10 utilized.

11 MR. LUCE: Well, that is absolutely in our
12 plans and even the list that Joe showed of the
13 topics that we're expecting, that we've invited to
14 be -- to come in for this particular solicitation,
15 that will include, and I'm sure it does include,
16 observational studies.

17 So, we're trying to point toward
18 randomized trials in real world settings, that is
19 sort of pragmatic, different degrees, of course,
20 depending on the issue, but it also includes
21 observational studies and certainly I see, I know

1 as staff sees, I'm sure you all see, that the
2 decisions that need to be based on evidence will
3 include all evidence, that coming out of non-
4 randomized observational data as well -- some of it
5 more systematic than others and others being from
6 randomized trials that may be very, very well
7 controlled and others much less so controlled
8 depending on the issue.

9 There's an awful lot of room to move here,
10 which provides a lot of opportunity and a lot of
11 challenges as well.

12 CHAIRMAN NORQUIST: Harlan Krumholz.

13 MR. KRUMHOLZ: I wanted to raise two
14 questions, one easier and one a little bit harder.
15 I'll do the easier one first.

16 What a tremendous advance, a great tribute
17 to the Methodology Committee and the way in which
18 the staff have worked together with them to
19 implement these policies. I think they're
20 tremendous. They ought to be quite visible in
21 terms of how grants are conforming with this

1 because part of this is around the spread and the
2 changing culture and the normative thinking about
3 that. In that line I totally salute the
4 curriculum. You know, we talked about this in a
5 prior meeting and it's wonderful to see that moving
6 forward.

7 I was looking on the site, saw the
8 wonderful video of Robin prominently displayed on
9 the methodology page, but what I really would love
10 to see now, not when we get the curriculum, but
11 now, is a toolkit because I'd love to use this in
12 my curriculum tomorrow.

13 Like, when I'm teaching people how to do
14 grants or thinking about projects, when I'm telling
15 them to make proposals to us, talking about
16 anything from medical students on up, I'd like to
17 hand them this toolkit and say, I want to crosswalk
18 what you just gave me to the standards that the
19 Methodology Committee has put out.

20 And I think far in advance of having any
21 sort of sophisticated curriculum, the tools that

1 you've already created, by which you're already
2 evaluating the grants, can be -- I can use them
3 tomorrow and they'd be so beneficial to me. And
4 not only that, I'm doing work in other countries,
5 as many of you know, and many people are at much
6 earlier stages of their scientific development, and
7 to be able to give them these documents,
8 translating them into their languages and helping
9 them to see the kind of construct and framework by
10 which these sort of proposals are put together
11 would be tremendous. It would also spread the word
12 of the work that has been done and pay honor to it.

13 So, that's the first thing. That's the
14 easy one. Do you want --

15 MR. LUCE: Yes. We are highly supportive
16 of that and I think the training modules will help.

17 MR. KRUMHOLZ: I'm even saying, even
18 before you get to the -- finish the final versions,
19 I want an alpha version that I can just take
20 tomorrow.

21 MS. NEWHOUSE: Well, and I would just say,

1 many inter-professional colleagues are asking for
2 the same thing, just cases, exercises, how to apply
3 the methodology report, just some suggestions for
4 how to incorporate it into their teaching. So,
5 I've seen an exponential increase in the request or
6 they ask me if I have anything like that that I'm
7 using.

8 So, I will second that.

9 MR. KRUMHOLZ: In the spirit of that, just
10 on the website, make it really easy for me to find
11 it. So, if it could be like a little box there
12 that says "go here for Methodology Committee tools"
13 or toolkit or something like that, because
14 sometimes when I get to the site it's so packed
15 with information. You guys have done a great job
16 filling it with so much knowledge, but things like
17 this people just want to be able to, bang, get to.
18 It's good advertisement for us. It should be
19 really easy. And there might even be a shortcut
20 URL, just PCORI toolkit.

21 MR. LUCE: Harlan, we actually developed a

1 checklist for the field, which is very similar to
2 the checklist, I showed you that one screenshot,
3 but the feeling of the staff was that we weren't
4 ready to roll that out, we didn't want to confuse -
5 - we thought it was too confusing until we went to
6 a training program.

7 But we're pretty close to where I think
8 you want to go and I'm certainly supportive of
9 that.

10 MR. KRUMHOLZ: And be glad to call it
11 version 1.0, because, I mean, I think this is going
12 to iteratively evolve anyway and, you know, so
13 then, just don't let perfect be the enemy of the
14 good, that's all, because what I'm seeing here, I
15 could use, and I think a lot of other people could
16 too.

17 The second thing I just wanted to jump
18 into was this issue about the pragmatic trials and,
19 again, salute you at the pace with which you were
20 able to take what were ideas that were floating
21 around here and elsewhere and get them into a call

1 and evaluation. So, I think that's terrific.

2 I just want to add one other dimension
3 here that I think is really important, which is,
4 our goal is not only to produce great science and
5 science that can be used, but we also want to try
6 to improve the research enterprise. And in that
7 spirit, you know, we're trying to figure out how to
8 do research faster, better, cheaper and PCORNet's
9 part of that, but in every aspect of these
10 pragmatic trials, we ought to also be evaluating,
11 you know, what's the price-per-subject? How is
12 that price benchmark?

13 And are there innovative aspects to this
14 that would allow us to generalize it? Is it going
15 to be sustainable or is it going to be built up and
16 then dismantled? I mean, all of these particular
17 pieces -- it may be too late for the first call
18 because we don't want to change the rules for
19 people who have applied, but as we think forward, I
20 think what we're trying to figure out is how does
21 this fit in.

1 And in alignment with that I wanted to ask
2 you the question, which is, if we thought there was
3 a great question but that the way in which it's
4 being proposed is overpriced for what it could be
5 done, would we be willing to say, we want to do
6 that project, but we want to see if we can do it
7 for half the price? And so we'd like you to lead
8 it, but we want to now go out and competitively bid
9 because you guys are quoting us a price \$1,000-per-
10 patient.

11 We want to see if it can be done for \$250.
12 We want to see if it can be done for \$150. And we
13 want to see what kind of creative ways either
14 leveraging PCORNet or others. And so then we are a
15 catalyst for not only just saying, we want the
16 great ideas, but we want the innovative solutions
17 to how the research is conducted and we want to
18 figure out whether we can change the way that
19 people have assumed it must be done in the past in
20 order to get it done.

21 When I heard Harlan Weisman say, well, you

1 know, the trials, they're just too expensive and
2 you just can't do to many of them, I want to
3 challenge us to say, well, let's think about how we
4 can do experiments.

5 What I'm seeing in industries outside of
6 medicine are people saying, we need an experimental
7 culture. We need to be able to build this into the
8 way that we do our work everyday. We need to
9 recognize that there are questions for which we're
10 not sure and we're bound by limited resources, so
11 we have to do phase-ins with regard to how we're
12 doing our work. Well, set it up as an experiment.
13 Now we've got to work on the privacy, consent,
14 there's lots of issues here to deal with, but I
15 think we should be challenging people who are
16 applying to us to get that price point down so
17 that, you know, and this makes a big difference
18 because we may be able to do twice as many studies
19 if we can get the price point down on each of the
20 trials that we are doing.

21 So, this has tangible impact on every

1 patient around the country because if we can only -
2 - you know, we want to expand the capacity with
3 what we can do with the money that we have on hand
4 as much as possible.

5 So, I'm just curious of your thoughts
6 about that.

7 MR. LUCE: Well, we've thought about it
8 methodologically a little bit and that is this
9 methodological consultation service that we spoke
10 to the Clinical Trial Advisory Panel just last
11 Wednesday and I know the Methodology Committee has
12 done some speaking about it and we haven't put it
13 into place yet, but the thinking definitely is, you
14 know, from just the methodological standpoint, how
15 we can intervene in a very positive way to improve
16 designs. You're getting into a whole new
17 dimension, obviously, and actually if you don't
18 mind, Francis, I'd love to turn to you because the
19 NIH has just gone out, what, about three, four
20 months ago, with a pragmatic trial announcement
21 that drastically lowered the price-per-trial, at

1 least in the announcement, and it will be very
2 interesting to see whether, in fact, trials can be
3 done at that -- good trials can be done at that
4 price, in essence.

5 How you put that into play, I don't know
6 exactly in terms of revising a study and
7 negotiating with particular study applicants in
8 terms of totally changing the nature and how they
9 go about doing it from an economic standpoint, to
10 the point you're talking about, but I think there's
11 a lot to learn that we will learn ourselves and I
12 think that the NIH will learn and help us move
13 forward on that.

14 DR. COLLINS: So, if possible I would like
15 to call on Mike Lauer to answer that question
16 because he can do so with greater specificity than
17 I can.

18 DR. LAUER: Thanks, Bryan. This is music
19 to our ears. So, a couple things, one is a
20 collaboratory -- the Common Fund Collaboratory has
21 already been working on this and we're already

1 funding a number of trials at less than a million
2 dollars a year in direct costs and what they're
3 doing is they're leveraging existing resources and
4 through the same folks who are helping to work on
5 PCORNet, we're converting this into a learning
6 experience, so this will help us further on down
7 the line.

8 Secondly, we're doing this, and I'll tell
9 one real quick, 30-second story. I had a group of
10 investigators come in with a trial, an interesting
11 CER trial where they wanted \$10,000 per patient and
12 we pointed out to them that they had access to
13 resources that would make it possible for them to
14 collect 90 percent of the data that they needed,
15 high quality, at essentially no cost. It was right
16 under their noses and they hadn't even thought
17 about that.

18 So, then they circled around and came back
19 with a proposal, which was about 25 percent the
20 cost of the original one.

21 So, this is -- the realities of the

1 current budget are creating great opportunities for
2 us to, in a way, force people to become
3 resourceful.

4 DR. COLLINS: Okay, thanks.

5 MR. LUCE: -- how we can use our
6 colleagues and collaborators to -- kind of a
7 learning healthcare system, a learning research
8 system, and presumably, this is what PCORNet will
9 allow us.

10 CHAIRMAN NORQUIST: Okay. We're going to
11 need to move on. Go ahead, Harlan.

12 MR. KRUMHOLZ: And just one other thing I
13 would ask is in the spirit of transparency, why
14 don't we take our trials and show what the price-
15 per-subject is and publicly report it so that
16 people can see what it is. I think that will put
17 pressure on us and also show the world sort of what
18 we're investing in and give a -- it will put focus
19 on the value of information that's been gained from
20 that.

21 CHAIRMAN NORQUIST: Freda, did you have a

1 comment?

2 DR. LEWIS-HALL: Um --

3 MR. KRUMHOLZ: You're not going to say yes
4 on that, Gray? You're the chair.

5 CHAIRMAN NORQUIST: It's the Board's
6 decision, not mine alone. I'm waiting for
7 everybody else to vote.

8 UNIDENTIFIED: So moved.

9 CHAIRMAN NORQUIST: Allen -- two people --
10 We wouldn't take a vote. I think Mary wouldn't
11 allow us to take a vote on that at this point. I
12 know we're just kidding. We're having a good --
13 but as a general idea, I don't -- look, let me just
14 say, when I was at NIH, we had the same kind of
15 struggles and we pointed out to people quite often,
16 look, the game, if you're sitting on the other side
17 sometimes is you want more money because that looks
18 very prestigious, all this stuff, you know.

19 I think, Harlan, you're absolutely on
20 point here because it may be that we start to
21 develop a cadre of people who are kind of the

1 operations arm for trials and you have other people
2 who sit, so if we had this, so then we can have our
3 own infrastructure in which we can operate these
4 and the ideas come into play on that. That's the
5 whole idea of infrastructure, but I think it's
6 pretty clear the price points are vastly different
7 and not always for rational reasons.

8 So, I'll say that publicly. Okay, Freda.

9 DR. LEWIS-HALL: So, my quick question
10 goes back to an earlier point that Harlan made and
11 that is, do we have any ability to capture how the
12 methodology is changing not only through our
13 assessments or PCORI-related grants, but is there a
14 way to kind of take some kind of assessments or
15 metrics around how we're shape shifting the more
16 general research community with the methodology
17 report?

18 MS. NEWHOUSE: I would say Michele will be
19 presenting the evaluation plan and I think we'll
20 address some of those answers. Yes, there are ways
21 to understand are these standards being, first of

1 all, endorsed, second of all, adopted, and third,
2 used.

3 CHAIRMAN NORQUIST: So, is this going to
4 be quick? Because he's got two more topics and we
5 need to move.

6 DR. DOUMA: Allen Douma. I'd also like to
7 add to that list that we need to begin tracking now
8 what are the outcomes that are improved as a result
9 of adopting the methodology report?

10 CHAIRMAN NORQUIST: Yeah, okay. And I do
11 want to pick up on Harlan Krumholz's earlier point
12 about the training stuff, because we're all being
13 asked -- I'm being asked this all the time, I'd
14 love to have these. And there's no reason -- and
15 I'd like to see us not just say it's a good idea,
16 but let's pick a deadline and let's do something
17 here and get it out, okay? So, you don't have to
18 answer right now, but let's just have that as a
19 process.

20 MR. LUCE: Agreed.

21 CHAIRMAN NORQUIST: Thanks. All right.

1 What's your next topic here? Award Selection?

2 MR. LUCE: Award Selection process. This
3 is pretty well established, I think. Now, you've
4 all seen this circle, we've re-titled it a little
5 bit, but this just goes from upper left, PFA
6 development through letter of intent all the way
7 through the application process and the merit
8 review to the final Board of Governors funding
9 slate review. So, I won't dwell on this by any
10 means, but I wanted to talk through and just make
11 it very clear to you and to the public how we go
12 about establishing this funding slate.

13 The top scoring applications that come out
14 of the merit review process are reviewed by the
15 program directors. The initial funding line is set
16 based on the available program funding and
17 application budgets. That's been true all along.
18 The applications are reviewed for any budget
19 adjustments that are required. This goes, in some
20 ways, to what Harlan was just talking about.

21 Staff recommends a slate based on merit

1 scores and exception criteria. The default is
2 always on the merit scores. There are specific
3 issues that staff may bring up on a given project
4 relative to exceptions, and I'll get to that in a
5 minute.

6 A slate has been submitted to the
7 selection committee for review and approval and the
8 selection committee brings it to the Board for
9 final approval. You're all aware of that.

10 The exceptions criteria has been put in
11 place that are outlined as before you. There has
12 to be a fit with programmatic vision as outlined in
13 each strategic framework, for each program. The
14 potential synergy within the portfolio, avoiding
15 duplication in project aims within the portfolio
16 and possible adjustments to address between panel
17 scoring differences.

18 So, these are the types of exceptions that
19 can occur where staff would recommend changing the
20 mix in terms of what would be considered for
21 funding.

1 The guidelines for recommending the
2 projects are as follows: in addition to the merit
3 review scores, which again are the defaults -- I
4 mean, if the staff agrees with the merit review
5 scores, that goes directly for consideration for
6 funding.

7 But the projects that are discussed based
8 on the exception criteria I just talked about,
9 those applications go to the Selection Committee
10 members who will review both the abstract and the
11 summary statements of all such recommended projects
12 that are exceptions based on the considerations
13 other than the merit review scores and in selected
14 cases the selection committee may request the
15 entire application process. You recall that the
16 selection committee is made up of Board members
17 mainly and Methodology Committee members.

18 And I just want to make note that the
19 award selection process was reviewed by the Science
20 Oversight Committee and all of their
21 recommendations were incorporated.

1 So, that is just quickly where we are on
2 that. I think we're ready to -- I think this is
3 pretty much put to bed. Christine, you may have
4 comments.

5 CHAIRMAN NORQUIST: So, let's let
6 Christine as chair of that committee have some
7 comments here.

8 MS. GOERTZ: Thank you. Christine Goertz.
9 Thank you, Bryan. Just a reminder that this is one
10 of the topics that we discussed during our retreat
11 in February and the SOC has been working with staff
12 in order to finalize this SOP and it's sort of, you
13 know, hot off the press, actually, the final
14 version, and so we can make sure that Board members
15 have an opportunity to take a look at that before
16 it gets, you know, posted publicly or however it is
17 we're going to handle this particular SOP. But I
18 just want to thank Bryan and the staff for putting
19 this together because it's been -- it's always an
20 interesting process when you have a process in
21 place but then when you go and try to write down

1 the criteria and try to figure out how to
2 standardize a process that does not easily fall --
3 it's not easily standardized, it can be complicated
4 and they've just done a great job.

5 CHAIRMAN NORQUIST: So, can we come to an
6 agreement on when this will be finalized, when it
7 will be ready and stuff so that we can --

8 MS. GOERTZ: I think the SOC will be
9 looking at it for a final time tomorrow. Is that
10 correct, Bryan?

11 MR. LUCE: Absolutely.

12 MS. GOERTZ: So, it will be tomorrow
13 afternoon at 3:00.

14 CHAIRMAN NORQUIST: So, by the next Board
15 conference call we could probably have this ready
16 to vote on, is that right?

17 MR. LUCE: We're not --

18 CHAIRMAN NORQUIST: It doesn't need a
19 vote, but agreement. Agreement that this is the
20 process. Is that the plan? I mean, you're saying
21 -- what is the plan at this moment?

1 MS. GOERTZ: Yeah, I think, the SOC is
2 working with staff to develop SOPs in several
3 critical areas related to our science portfolio, so
4 our plan is to post the SOPs somewhere so that --
5 and to let Board members know that they're
6 available so that instead of having the -- because
7 we will spend all of our time looking at SOPs if we
8 start bringing them to the Board.

9 CHAIRMAN NORQUIST: Okay, so, that's what
10 I wanted to get at is the process here. So, what
11 you would like, basically, for us to agree on,
12 which we could just basically agree on, is that the
13 SOC will do the majority of the work. We will kind
14 of empower you to develop these SOPs and then we're
15 certainly free, as Board members, to look at those
16 and have input or something, but we don't need to
17 formally bring them back all the time to move it
18 forward, is what you're saying?

19 MS. GOERTZ: Right. As SOPs are
20 developed, we will let the Board know that they
21 have been developed and how to access those so that

1 the Board has an opportunity to take a look at them
2 and make further comments.

3 CHAIRMAN NORQUIST: Okay, so I just --

4 MS. GOERTZ: But there won't be a formal
5 approval process.

6 CHAIRMAN NORQUIST: Great. So, I then we
7 just all agree on that is what -- I just want to
8 come to that decision. All right --

9 MS. GOERTZ: That's what the SOC is
10 recommending to the Board.

11 CHAIRMAN NORQUIST: Okay, so, does anybody
12 have a disagreement or not like that process, I
13 guess is the question, right?

14 [No response.]

15 CHAIRMAN NORQUIST: Good. Okay, so you're
16 empowered to do this but you do need to -- you guys
17 need to put it up so that we can all see and be
18 very transparent about what that is, okay? But I
19 would ask that -- the only thing I would say is, do
20 these, do them quickly so you have a process,
21 because the worst thing is that if you're an

1 investigator coming in and the selection process
2 changes every time or we're unsure what it is,
3 that's not what you want. Okay?

4 All right, yes, it looks like, Alicia, you
5 want to say something, but our little thing is we
6 put our cards -- we turn our cards. All right,
7 thank you.

8 DR. FERNANDEZ: Thank you. This is Alicia
9 Fernandez. I just wanted to be sure that I
10 understood whether you were suggesting that these
11 be posted as is in terms of the boarding cycle.
12 Let me just tell you, perhaps it will be more
13 helpful if I explain my concern, which is that
14 obviously the scientific community which has
15 concerns about exceptions because of the
16 difficulties as it is of navigating a rigorous --
17 appropriately rigorous peer review process and I
18 wonder whether there should be some language in
19 there around -- and perhaps this is something that
20 is best discussed in committee, but I'm wondering
21 whether there should be some language in there

1 around the limitations of exceptions or around how
2 exceptions, around which -- under which criteria,
3 for example, an exception is made, for example,
4 duplicative of an existing study or so on and so
5 forth.

6 Only, again, to be reassuring to the
7 scientific community that exceptions are rare, they
8 are important, they highlight the work of the
9 entire scientific community and the research
10 agenda, and so on.

11 But again, this is something that may be
12 best considered in a committee discussion as I'm
13 sure there are lots of nuances that I've failed to
14 consider.

15 CHAIRMAN NORQUIST: I think it's critical
16 and I think it's part of what we always want to say
17 in an award criteria that, you know, we have the
18 authority to not pick because of certain things
19 like this is duplicative or something, but I think,
20 Christine, you might want to --

21 MS. GOERTZ: Thank you for that comment

1 and now that you're coming on board and will be a
2 member of the Scientific Oversight Committee,
3 you'll definitely have a lot of opportunity to be a
4 part of that process and, you know, Bryan and I
5 have been in a lot of discussion about this and
6 this is one of those SOPs that we feel absolutely
7 needs to be, you know, made public and that our
8 investigators need to be very aware of how the
9 selection process occurs and when exceptions might
10 happen and what those will look like.

11 So, again, once this SOP is finalized,
12 we'll be looking at ways to make sure that people
13 are educated about it so that they're able to know
14 how the process works.

15 DR. DOUMA: Allen Douma. Just to
16 reinforce what we just heard, also would be
17 helpful, and maybe you can quickly do that now, to
18 re-acquaint me with how is -- what is the selection
19 committee? How is it chosen? Whom do we try to
20 put on that committee in order to be able to
21 maximize their ability to make exceptions?

1 MR. LUCE: That's a Board decision and I'm
2 not -- Joe or --

3 CHAIRMAN NORQUIST: No, there's a
4 selection committee. We don't just --

5 DR. SELBY: I think up to this point we
6 have solicited interest. We're working carefully,
7 particularly now as the selection process begins to
8 look at more of the information about particular
9 studies to place a conflict of interest review at
10 the beginning of it and the other principle that
11 has been held to since the beginning is that we
12 rotate that responsibility over time so that all
13 Board members ultimately participate in the
14 selection committees.

15 MS. GOERTZ: One of the things that we've
16 been in discussion with is trying to balance, you
17 know, rotating people through with consistency and
18 making sure that, you know, decisions that are made
19 in one round are consistent with the other. So,
20 that's something that we're continuing to work on.

21 CHAIRMAN NORQUIST: And of course

1 ultimately the decision about the funding comes to
2 the full Board. This is the recommendation from
3 the selection committee, so just keep that in mind
4 also. Okay.

5 Bob. I'm sorry. I missed your card.

6 DR. ZWOLAK: Bob Zwolak, Board. Bryan,
7 earlier today Joe pointed out that the GAO in their
8 initial letter had asked us to what extent PCORI is
9 establishing the research priorities and then
10 funding research in accordance with the priorities
11 and for the pragmatic trials I think that most of
12 them are either consistent with the IOMs list or
13 PCORI's list or sometimes both lists and although
14 there's a small number, I think, that may not have
15 been on either list.

16 So, having made it through the threshold
17 from letter of intent to invitation to submit a
18 full application, does that mean that the ones that
19 are on neither list have shown enough value that we
20 would still fund them? And will they be considered
21 equally from this point on until the ones that are

1 on, say, one, or potentially more than one list?

2 MR. LUCE: The present policy is
3 absolutely that, that proposals that come in are
4 based strictly on the merit, not just technical
5 merit, but merit relative to their likelihood of
6 making a difference and importance to the field,
7 but there's no preconceived screen or special gate
8 that a proposal has to go through that's relative
9 to what is already on an established list. But it
10 is a very strong message to the field that paying
11 attention to the topics that we've keyed up that we
12 think are important is what we tend to get most of.

13 But there's no special screening.

14 CHAIRMAN NORQUIST: Okay. Your last
15 topic.

16 MR. LUCE: Moving on to my last topic.
17 Dear to the hearts of many here and to us is the
18 topic selection update. This, just to tee it up a
19 little bit, this is -- we really went back to
20 ground zero after the Board retreat to review the
21 entire topic selection process and we are ready to

1 put this to bed with the Science Oversight
2 Committee, hopefully tomorrow. We'll, of course,
3 see how that works out, but I think we've come to
4 the point where we have -- we're in basic
5 agreement.

6 To just give you a brief background, the
7 Board indicated an interest in reviewing the topic
8 selection process and its role, probably all along,
9 but in particular I think it reached a head at the
10 Board retreat last December. The Science Oversight
11 committee asked us specifically to engage a process
12 improvement expert to help us with this process,
13 which we did do. It took a little bit longer to
14 put in place than we had hoped, but we worked the
15 contract folks as fast as they possibly could and
16 the experts really moved very quickly.

17 The process was completed in April. The
18 SOC has been fully briefed at their process itself
19 and their findings and then over the past several
20 weeks, staff has, across scientific staff and
21 engagement staff, have vetted these recommendations

1 through really a formal process of a survey and
2 reviewed the processes and now made recommendations
3 that have gone to the Science Oversight Committee
4 literally as we speak, right now. I've been in
5 close contact with Christine, as she knows well.

6 So, we have both a set of recommendations
7 and a revised SOP that will be discussed tomorrow.

8 Just to give you a sense as to what this
9 expert consultant group did, it reviewed all of our
10 existing policies. We had, really, a draft SOP of
11 the entire topic selection process that's been
12 unfolding since really the beginning of PCORI, or
13 at least the scientific staff and the advisory
14 panels and so forth, that you're all pretty
15 familiar with. So, they reviewed all of the
16 existing policies and procedures in great detail.
17 They interviewed selected Board members and
18 selected science staff. They depicted a detailed
19 map of the entire topic capture and prioritization
20 process, which turns out to be quite complex that
21 I'll mention in a minute.

1 They paid special consideration about the
2 Board role in their process, which is really what
3 really generated a lot of the interest in December
4 here and then they recommended improvements.

5 To give you a sense of the scope of the
6 topic capture and research prioritization process,
7 there's a specific SOP for each one of these, for
8 engaging stakeholders, for monitoring, for new
9 opportunities such as the gap analysis and
10 discussion with other funders such as NIH or AHRQ,
11 developing individual program strategic frameworks,
12 which is in the process right now. You'll actually
13 -- you'll get a flavor for that one when Romana
14 speaks to you later on today, a process for
15 capturing topics and database management that's in
16 process right now, a process of vetting and
17 prioritizing topics, developing topic briefs and
18 landscape reviews as indicated, prioritizing topics
19 by the program advisory panels that you all are
20 very familiar with, and refining the research
21 questions ultimately for PCORI funding

1 announcements.

2 So, each one of these processes have
3 multiple steps. I think there was something like
4 156 individual steps. It was all put together in a
5 very complex diagram that I won't show you. So,
6 there are two basic issues that really come out of
7 this, I think, that are of key interest to the
8 Board and to the Strategic Oversight Committee, one
9 is the timing and the nature of Board involvement
10 probably through, in many cases, through the
11 Strategic Oversight Committee.

12 So, precisely where the Board intervenes
13 adds input to that topic generation and
14 prioritization process. And the other is, which
15 also needs to get worked out, probably has to be
16 flexible, is the extent of information that
17 especially Board members need, but all of us need,
18 and the advisory panel themselves need, in terms of
19 the topic brief are full landscape reviews, are
20 systematic evidence reviews appropriate for the
21 actual process. There's just a lot of scope here

1 because a full landscape review can take five, six
2 or more months, cost a great deal of money, and
3 what we're trying to do is titrate the amount of
4 information that's really required for the decision
5 to go or no go. And to whether to go into a full
6 targeted funding announcement versus a list for
7 pragmatic trials or in general announcements.

8 So, that's what we're doing and that's
9 what we'll be talking to the SOC tomorrow about.
10 I'll be happy to answer any questions.

11 CHAIRMAN NORQUIST: Okay, let's let --

12 MR. LUCE: Christine may want to --

13 CHAIRMAN NORQUIST: -- Christine make some
14 comments and then the one thing that's also missing
15 here is the third point about the criteria for what
16 we will use to select the topic that becomes a
17 targeted funding announcement as to ones that are
18 perhaps a different category.

19 MR. LUCE: That's right.

20 CHAIRMAN NORQUIST: Christine.

21 MS. GOERTZ: Right. Thank you, Bryan.

1 Christine Goertz. As Bryan has indicated, this is
2 a very complex process and as we all know from the
3 discussion that we had at our retreat, there are a
4 lot of parts to it and a lot of steps in each of
5 those parts and so we had originally hoped that we
6 could get this -- and this particular SOP we are
7 going to be coming back to the Board with because
8 we do think it's so key to what we're doing and we
9 are trying as hard as we can to move quickly
10 through this process.

11 And so, as Bryan mentioned, our hope is
12 that we either finalize it or get close to
13 finalizing it at the SOC meeting tomorrow and that
14 this would come back to the Board meeting in June
15 so that you are able to take a look at that and
16 have input actually looking at it in a little bit
17 more detail with particular emphasis on those touch
18 points where the Board, through the SOC, would get
19 involved in the process.

20 CHAIRMAN NORQUIST: Yes. This is an
21 important issue because it gets to the point of

1 getting these topics out, getting them funded, and
2 the key issues are: what are the touch points for
3 the Board, primarily, we're hoping, through the
4 SOC, to be kind of empowered to do that, this issue
5 of when we need full landscape reviews and stuff?
6 The other thing that we agreed on is to move
7 earlier into the process, which I think is to get
8 more feedback from the funders so that we get more
9 experts early on in the process and certainly the
10 advocacy groups that are in that area so we don't
11 try to push something through a process where it's
12 pretty clear it's just not going to go or it's been
13 tried before. And third point is, what criteria
14 are we going to use to decide whether something's
15 our big trial, basically, you know, a targeted
16 funding announcement where we put specific
17 resources into a specific question, versus some
18 other kind of mechanism we may use to cover a
19 topic.

20 So, please pay attention to this as this
21 comes out because we want to finalize this and get

1 this done because we need to get moving to get the
2 topics through so we can get this done.

3 So, Larry I'm going to start and we're
4 going to go down around, because I don't see
5 anybody on this side yet, so Larry and then Sharon
6 and then Ellen and then Allen.

7 MR. BECKER: So, I just wanted to thank
8 you for --

9 CHAIRMAN NORQUIST: And this is Larry
10 Becker talking.

11 MR. BECKER: I'm sorry. Larry Becker. I
12 just wanted to thank you for taking the time to
13 walk the process. We know from LeanSixSigma kind
14 of work that we do, when you put that process out
15 and you put those 150, 160 steps around the room,
16 you learn a lot, your partners learn a lot, the
17 stakeholders learn a lot, and at the end, you get a
18 much more efficient and effective process. So,
19 thank you for doing that.

20 MR. LUCE: You're welcome.

21 CHAIRMAN NORQUIST: Sharon.

1 DR. LEVINE: So, two comments, the first
2 is just a small process thing, but it would be
3 helpful when you're putting information together,
4 rather than referring to a generic scientific
5 science expert or process improvement expert, that
6 you actually put the name of the individual or
7 group that you're using, just for informational
8 purposes, I think it would be helpful.

9 MR. LUCE: Yeah. I actually agree with
10 that.

11 DR. LEVINE: The second thing is, as a
12 non-researcher in the room, I think it would be
13 very helpful to clinicians, patients, and members
14 of the public if somewhere on the PCORI website
15 there was a brief description in lay terms of the
16 different kinds of trials that PCORI funds and what
17 the terms mean -- pragmatic clinical trials,
18 targeted funding announcements, randomized control
19 trials -- just a glossary of terms around different
20 kinds of research that PCORI funds and why or what
21 the intent is, perhaps then go into the methodology

1 standards for anyone who's interested, but some way
2 to demystify the inside baseball talk.

3 CHAIRMAN NORQUIST: We're laughing because
4 we were having this very discussion last night
5 about the need to define these things. So,
6 absolutely, it's critical. We need to define what
7 the game is we're playing, right?

8 MS. SIGAL: Ellen Sigal, Board. So, Bryan,
9 thank you. I know that the outcome will be
10 significantly better, but, you know, the feelings
11 were that it's taken a long time and we often
12 didn't get to results that we could have or should
13 have had we engaged the Board or content experts
14 earlier in the process in really some landscape
15 reviews.

16 I know that we're still voting on this and
17 looking at it, but can you, perhaps, summarize the
18 significant changes that will occur with the new
19 process? Because, again, the intent is to really
20 not spend a huge amount of time and find out that
21 we're off on a tangent of work that's already

1 duplicated or is not a high priority to priority or
2 perhaps subject matter experts.

3 MR. LUCE: I certainly can. Is it -- so,
4 I'm turning to Christine as well because I don't
5 want to preempt the SOC, but --

6 CHAIRMAN NORQUIST: We'll let Christine
7 get this and then, Bryan, you can chime in if
8 there's something that you missed.

9 MR. LUCE: Yeah.

10 MS. GOERTZ: Yes, thanks, Ellen.
11 Christine Goertz. I think that's an excellent
12 question and, yes, we're definitely planning to
13 insert the SOC and several layers of experts
14 earlier on. So, for instance, now the plan is what
15 has been happening is that the Board and the SOC
16 didn't get involved until fairly late in the
17 process, as you know. What we're planning to do is
18 have the SOC involved actually before it goes to --
19 any of the topics go to the advisory panel.

20 So, not only to have the SOC, but also
21 have it vetted by experts in NIH and AHRQ and other

1 -- and stakeholder groups as well so that when the
2 advisory panel actually looks at the topics that
3 are queued up, those are pieces of information that
4 they'll have -- what did the stakeholder groups
5 say?

6 What's happening at NIH and AHRQ or other
7 agencies related to this? What are the comments of
8 the SOC? So, that goes into the mix and then
9 trying to -- and, again, shortening the process
10 instead of having these lengthy and very expensive
11 landscape reviews, I think that would be much more
12 the exception than the rule.

13 And then the other touch point for the
14 Board through the SOC would be at some point you
15 have to decide -- you have, you know, 50 topics or
16 40 topics that have gone through the process and
17 trying to figure out what you do with all of these.
18 You can't write targeted program funding
19 announcements for all of them, so trying to sort
20 them into buckets, you know, the buckets are a
21 targeted funding announcement, which my

1 recommendation is that that would be when we know
2 exactly what the specific question is.

3 And so, it's a very finite question, we're
4 going to do a targeted PFA or there may be times
5 when we say, you know, we're just going to list
6 this as a general area of interest within our
7 general funding announcements or we may decide to
8 put it on the pragmatic clinical trials list or
9 maybe some other kind of trial that wouldn't fall
10 under our definition of pragmatic trial. But just
11 helping to sort out which of those buckets it goes
12 into and then what -- is there a financial set-
13 aside or not, because with all of those options you
14 can either have a set-aside or not, so trying to
15 decide, do we want this to compete -- that topic to
16 compete against all other topics or do we want to
17 say this is such an important topic to us that we
18 want only -- we want to be asking people to compete
19 within that general topic area for dollars that
20 have been set aside?

21 DR. LEVINE: I think that's really

1 important and of course, as we start to analyze our
2 portfolio for gaps, this will also inform us too,
3 this will be very much part of that.

4 MS. GOERTZ: And as you know, that's one
5 of our goals for the SOC over this year is to
6 really do that kind of gap and opportunity analysis
7 within the portfolio.

8 CHAIRMAN NORQUIST: And the other reason
9 that we're asking for at every Board meeting to
10 have an update on a part of the portfolio so that
11 we all know the portfolio, which I think is
12 critical too.

13 DR. DOUMA: Allen Douma. Thank you for
14 all the work you've been doing, particularly having
15 to slog through the data diagram that you're
16 referring to. Having been an engineer in my past,
17 I actually love them, so I look forward to seeing
18 it sometime in the future.

19 MR. LUCE: I'd be delighted to send it to
20 you.

21 DR. DOUMA: Please do. Please do. In the

1 spirit of what we're hearing -- talking about
2 before, and Harlan Krumholz in particular having
3 toolkits for both external as well as internal
4 transparency, it'd be great to these significant
5 things, two of which we talked about today are
6 landscape review versus something else --
7 literature, systemic evidence, review. And the
8 second being determining how much research is -- if
9 there's as much ongoing research we don't want to
10 duplicate. What we need to have are tools that
11 basically use or have a set of criteria to
12 determine when enough other research is being done
13 and to determine when we do a landscape review.
14 So, it can be more consistent and methodological
15 with our methodology as we move forward.

16 MS. HUNT: Gail Hunt, Board. I listened
17 to what you said Christine and I'm saying to
18 myself, okay, so we're saying that the SOC will
19 have prepared or will have done a lot of review in
20 advance before this goes to the advisory committee.
21 But I guess the question I have is, that's great.

1 Is the advisory committee the last stop before the
2 Board? Or is it the SOC, the advisory committee,
3 back to the SOC and then the Board?

4 MS. GOERTZ: Correct.

5 MS. HUNT: Okay, great.

6 MR. LUCE: Gail, what we're trying to do
7 is to eliminate the process by which topics get
8 through all of the advisory panel and then get
9 derailed because it's clear that there wasn't any
10 question that could be answered appropriately or
11 that there was really not consensus among key
12 stakeholders and so forth. We're simply trying to
13 make this process more efficient and to provide the
14 Board, through -- especially through the SOC, more
15 touch points earlier in the process. But we think
16 it is going to be a much more efficient process.

17 CHAIRMAN NORQUIST: Okay, I don't see any
18 other cards up. I think, Sharon, yours was left up.
19 So, thanks. So, we are five minutes early. Let me
20 just -- I'll recap from the methods thing. I think
21 the key thing there, we got an issue about getting

1 these training or at least getting out some of
2 these checklists as soon as possible, I think,
3 quickly, we have a plan hopefully soon to do that.
4 This issue about what's the price of our clinical
5 trials and how to operate them, what's the most
6 cost effective way is something that we really need
7 to focus on and to think about.

8 On the selection process we're going to
9 allow the SOC to basically make it approve the SOP
10 for this, but we'll put it up for Board
11 information. And then on the topic selection,
12 because of the importance of this one we're going
13 to bring it back to the June Board meeting so that
14 the Board can finalize it, but there will be a lot
15 of work, obviously, the SOC will do in the
16 meantime. Did I miss something? No. Okay.

17 Thank you all and for those listening on
18 the phone, we're now going to take a break for
19 lunch and we'll be back at 1:00 p.m. Eastern
20 Daylight Time. Thanks.

21 [Whereupon, at 11:66 a.m., a luncheon

1 recess was taken.]

2

3

4

5 A F T E R N O O N S E S S I O N

6

[1:00 p.m.]

7

CHAIRMAN NORQUIST: We are going to be
8 starting back here because we are supposed to start
9 at 1:00. So, if people could get into their seats.

10

DR. SELBY: Good afternoon, everyone, if
11 you're in the room and on the line. This is Joe
12 Selby, Executive Director of PCORI and we're going
13 to have a presentation right now from Dr. Romana
14 Hasnain-Wynia, a synthesis of the disparities
15 portfolio of projects that we've funded.

16

The Board has asked, and we as staff agree
17 wholeheartedly, that we need, as an organization,
18 to heighten our awareness of the projects that
19 we've funded so that we can, among other things,
20 identify gaps in what we've funded, identify
21 consistent trends that might need to be emphasized

1 or supported more, and, frankly, have projects that
2 we can talk about even as they are ongoing.

3 So, under Bryan Luce the Science Program
4 has developed an active portfolio management. Now
5 I think it's called the Strategic Portfolio
6 Initiative, which was first suggested by Arnie
7 Epstein about a year ago at a board meeting. We
8 have been very actively looking at the projects we
9 funded, getting familiar with them and looking for
10 patterns and overlap.

11 And so, Dr. Hasnain-Wynia is going to go
12 first, as she often does, and we appreciate that
13 and I think you'll find this a very thoughtful
14 presentation. We look forward to your comments.

15 MS. HASNAIN-WYNIA: Great. Thank you very
16 much, Joe, and I also want to thank the Board for
17 the opportunity to present you with an update of
18 the Addressing Disparities Program at PCORI.

19 So, what I'm going to do is give you a
20 little bit of background information. I'd like to
21 set the presentation in this context, so just a

1 brief review of the program's mission and goals.
2 I'll review the program's progress to date and then
3 spend a little bit of time talking about a
4 conceptual framework that we've adopted to guide
5 the program, and then a driver model that is really
6 being used by us as a tool to help us understand
7 where we are and where we may need to go. We'll
8 have a few slides on next steps and I would really
9 welcome your comments and your questions.

10 So, I do have to acknowledge the
11 Addressing Disparities team. The team is a
12 dedicated, hard-working, fun, smart team and the
13 work really could not be done without them, so I'm
14 referring to -- not myself -- to my program
15 officers, Cathy Gurgol and Ayodola Anise as well as
16 our program associates, Katie Lewis, who's in the
17 back of the room today, and Mychal Weinert.

18 And then Tomica Singleton, who is our
19 senior administrative assistant, who is represented
20 by the flowers versus her picture, and I should
21 also let you know that we are going to be bringing

1 on an additional program officer towards the end of
2 this month and we're really looking forward to
3 that.

4 So, I don't think I have to tell the Board
5 that PCORI has a broad and complex mandate and
6 within that mandate one of the priorities is to
7 address disparities.

8 As I said, it is one of our five national
9 priorities for research. The legislation
10 specifically calls it out. And the reason that I'm
11 bringing this up is because sometimes I do get
12 asked, why a focus on addressing disparities, and I
13 think it's important to note that a focus on
14 reducing disparities, particularly through
15 comparative effectiveness studies that focus on
16 populations that have, for a very, very long time,
17 been at risk for experiencing disparities can
18 actually provide us with lessons from multiple
19 groups.

20 We know that vulnerabilities are not uni-
21 dimensional, they're not mutually exclusive. I

1 know that all of you keep up to date with the news.
2 We keep hearing about increasing income inequality
3 and we know that low SES is a driver of disparities
4 as well. So, the studies that we are funding at
5 PCORI through the program, I think, have
6 implications across a broad population.

7 Also, just from a foundational standpoint,
8 persistent disparities in healthcare, which, you
9 know, many of the people on the Board have
10 contributed to the vast literature that has
11 identified the existence of disparities, but
12 persistent disparities in health and healthcare
13 really does violate a widely held societal norm
14 within the United States around equality of
15 opportunity and the dignity of each person to be
16 able to live their life at the highest level of
17 productivity.

18 So, it's an important focus for PCORI,
19 it's clearly a very important focus of the program.

20 So, I want to anchor the Board and those
21 listening to our program's mission statement, which

1 really aligns with PCORI's vision, which is for
2 patients and the public to have the information
3 that they can use to make informed healthcare
4 decisions about healthcare outcomes that are
5 important to them.

6 So, PCORI's mission is to reduce
7 disparities in healthcare outcomes and to advance
8 equity in health and healthcare, and I think it's
9 important to recognize that intersection between
10 health and healthcare. We all know that health
11 outcomes are not determined solely by what happens
12 within the four walls of the clinic or a hospital.
13 Community context, neighborhood context is
14 incredibly important, where people eat, play, pray,
15 go to school, et cetera, is an incredibly important
16 context in terms of improving healthcare outcomes
17 and improving health overall.

18 So, as I talk about some of our specific
19 projects, you'll see some of that intersection
20 highlighted.

21 Our program's guiding principle is to

1 support comparative effectiveness research that
2 will identify the best options for eliminating
3 disparities. And I have been asked and have been
4 questioned about having such a lofty goal, and I
5 would say that goals should, in fact, be lofty and
6 I don't think that this is a lofty goal. We have
7 had some evidence of actual elimination of
8 disparities despite the fact that they remain quite
9 pervasive.

10 So, for example, David Williams, who's at
11 the Harvard School of Public Health, has pointed
12 out that pneumonia and flu, which is the seventh
13 leading cause of death with about 65,000 deaths per
14 year, the disparities between blacks and whites in
15 1950 were huge, 70 percent mortality for blacks
16 compared to whites. That disparity has pretty much
17 been eliminated. So, I do think that we should
18 have goals that are REACH goals, but have realistic
19 measures of success that are more proximal along
20 the way.

21 I also want to emphasize that one guiding

1 principle of the program, which is really not
2 stated here, is that we want to also fund
3 comparative effectiveness research with a focus on
4 patient-centered outcomes to actively eliminate
5 disparities, not just describe the problem. We've
6 had just, you know, a very, very rich evidence base
7 that has described the problem for many, many
8 years. In the last ten years we've begun to
9 understand some of the drivers of disparities. We
10 recognize that they're multidimensional. There's
11 not just one driver, there are many, many drivers.
12 So, the interventions that we fund and that we
13 support through the program tend to be
14 multidimensional.

15 On this slide you can see kind of the high
16 level programmatic goals to identify high priority
17 research questions relevant to reducing and
18 eliminating disparities and healthcare outcomes to
19 fund comparative effectiveness research with the
20 highest potential to reduce and eliminate
21 disparities and then to disseminate and facilitate

1 the option of promising practices, which hopefully
2 can become best practices, but again, realistic
3 measures to reduce and eliminate healthcare
4 disparities.

5 So, this just gives you, again, a pretty
6 high level overview of where we are to date in
7 terms of what we have funded. So, through our
8 broad PCORI funding announcements, which are our
9 investigator-initiated projects, through the four
10 cycles that we have funded to date, and at the end
11 of this week we will be reviewing our fifth cycle,
12 so we'll have more projects in the portfolio, but
13 we have funded a total of 31 comparative
14 effectiveness research projects totaling almost \$53
15 million.

16 The Addressing Disparities Program is also
17 the first program to release a targeted funding
18 announcement focusing on uncontrolled -- treatment
19 options for uncontrolled asthma in African-American
20 and Hispanic/Latino populations. We have funded
21 eight comparative effectiveness research projects

1 totaling over \$23 million. So, to date, the
2 investment that PCORI has made in projects that
3 very specifically target disparities and
4 disparities populations is \$76 million.

5 What we have in the pipeline, you can see
6 the three bullets here, are projects at different
7 stages. So, let me highlight the first one, which
8 is obesity treatment options in primary care. This
9 is focused on diverse populations. This was the
10 second targeted funding announcement that the
11 addressing disparities program released in February
12 of this year.

13 We will be reviewing applications in
14 August and we'll be making awards. This year we
15 expect to fund up to two pragmatic trials with an
16 investment of up to \$20 million in this area. I
17 should tell you that we instituted a competitive
18 LOI for this process. We received 48 LOIs and we
19 invited 11 --

20 [Audio drops for three minutes.]

21 MS. HASNAIN-WYNIA: A substantial part of

1 our portfolio also focuses on mental health
2 projects. I should say that 19 percent in the
3 Addressing Disparities Program, but if you look
4 across all of PCORI's portfolio, about 32 percent
5 or 33 percent -- we're still really looking through
6 this information -- focuses on mental health. So,
7 it's a topic that cuts across all the funding
8 priorities.

9 MR. BARNETT: Romana, is this by dollars
10 or by numbers of projects?

11 MS. HASNAIN-WYNIA: These are by numbers
12 of projects.

13 I also want to highlight the target
14 populations. So, what you see here are the target
15 populations for the disparities program, but what
16 I've provided for you here is a chart that shows
17 you, again, by number of projects, the target
18 populations. So, the blue bar gives you the number
19 of disparities projects that target specific
20 populations. These are not mutually exclusive, so
21 individuals can be from rural areas and low-income,

1 for example, but we also give you the numbers for
2 the entire portfolio for the four cycles so far.

3 So, the denominator here is 190 projects.
4 What you can see is that for a third of the
5 projects, or a third of the projects that focus on
6 racial and ethnic disparities come out in the
7 Addressing Disparities Program. It's a total of
8 109 projects total across all the programs, but the
9 important point that I want to highlight here is
10 that the Addressing Disparities Program targets
11 projects with a focus on reducing disparities.
12 That's the intent of the interventions and the
13 studies that we're funding within the program.

14 For the other programs, it may be that for
15 some of the populations, it is a target, but for
16 others there may be subpopulation analysis, but we
17 don't know if the studies are actually powered to
18 actually make definitive conclusions.

19 So, just to kind of highlight the balance
20 here in terms of what the target of the disparities
21 program is, which is to target a disparity, and we

1 expect the applications that come to us to really
2 motivate the rationale for the proposal in terms of
3 the impact of the condition, the burden of the
4 condition, and so forth, and particularly for the
5 specific populations that you see highlighted here.

6 DR. DOUMA: Could I ask a question on
7 that? Quick clarification. I just heard you say,
8 correct me if I'm wrong, that we have 109 research
9 projects in the AD arena?

10 MS. HASNAIN-WYNIA: No. We have a total
11 of 39 projects in the AD arena.

12 DR. DOUMA: Thirty-nine.

13 MS. HASNAIN-WYNIA: What you see here are,
14 if you look at the X-axis, it gives the target
15 populations. So, the target populations for the
16 program are racial ethnic minorities, low-income
17 populations, rural populations, individuals with no
18 literacy or numeracy, individuals with
19 disabilities, and LGBT.

20 DR. DOUMA: Right, and these numbers have
21 added up higher because of the overlap you already

1 mentioned?

2 MS. HASNAIN-WYNIA: Exactly

3 DR. DOUMA: Are there any other
4 disparities groups that are not there?

5 MS. HASNAIN-WYNIA: So PCORI has a much
6 longer list of what we call priority populations.
7 So, within the priority populations, so for
8 example, the elderly are included in PCORI's
9 priority populations, so they're a priority for
10 PCORI, and clearly we have projects within the
11 Addressing Disparities Program which address the
12 elderly population, but often with a cross-section
13 to another -- to a target population for the
14 Disparities Program, so, racial and ethnic
15 minorities who are elderly, for example.

16 So, this is the target population for the
17 program itself.

18 DR. DOUMA: But you're saying some
19 programs or projects here, there's already -- there
20 are some of the ones that are low income who are
21 also racial and ethnic?

1 MS. HASNAIN-WYNIA: That's right.

2 DR. DOUMA: So then why wouldn't elderly
3 show up, which are also racial and ethnic?

4 MS. HASNAIN-WYNIA: They would, but we're
5 not categorizing them in terms of the bar graph
6 here. So, they're embedded in here, but we're not
7 highlighting them within the bar graph.

8 DR. DOUMA: Okay.

9 MR. KUNTZ: Just a quick clarification.
10 I'm still a little bit confused about the PCORI
11 projects addressing disparities. If you culled
12 them out of the overall PCORI projects about
13 addressing disparities but then said that they
14 weren't necessarily powered to define those --

15 MS. HASNAIN-WYNIA: Yes, so the title
16 should probably be changed and I apologize for
17 that. So, these are -- so, what we have here is --
18 so, initially what I had was just the Addressing
19 Disparities portfolio, which showed the 31 projects
20 that focus on racial and ethnic minorities, the 25
21 that focus within the program on low-income, and so

1 forth, and then we also were -- are very interested
2 in seeing whether there are cross-cutting projects
3 to cross all the programs.

4 So, one of the things that we started to
5 look at was what other programs within PCORI
6 address target populations that are at risk for
7 disparities. So, the projects in the red -- so,
8 78, 59, 53, so on and so forth, are projects in the
9 other programs where the investigators have
10 identified these as either target populations or in
11 their sub-population analysis, but we don't know at
12 this point because we haven't had time to really
13 dig deeply into all of the other projects in the
14 different portfolios to see whether all of these
15 projects are powered sufficiently for the sub group
16 analysis.

17 So, I can't speak to that - -

18 MR. KUNTZ: I'm just being a little
19 nitpicky. I think that if somebody has an
20 objective to address something that has to be
21 powered, we can't just say that --

1 MS. HASNAIN-WYNIA: Right, I mean, I think
2 you raise an important point. So, the title for
3 this should be basically a focus on which projects
4 include underserved populations, not necessarily
5 that they're addressing disparities.

6 MR. KUNTZ: And then the question is
7 different. The question is, within the group, what
8 works, which is actually very valid. You're not
9 making your contrast and you're not contrasting
10 those individuals with the control group, which
11 would be non-disparity people, right?

12 MS. HASNAIN-WYNIA: Right.

13 So, we also wanted to highlight the
14 research methodology. So, again, 39 projects
15 within the disparities program total that we have
16 funded to date. So, of those 39 projects, 33 of
17 them incorporate a randomized control trial. Many
18 of them are mixed methods, which have a randomized
19 control trial component.

20 There are a small number of studies that
21 are not randomized control trials, they're quasi-

1 experimental or observational. They are
2 comparative. They have comparative components.
3 One of the things to highlight here, however, is
4 that, again, reflecting back on the disparities
5 populations, for many of the populations, for low
6 SES, for racial and ethnic groups, we have a great
7 deal of evidence about disparities. For some of
8 the other populations, we just don't have that much
9 evidence, so individuals with disabilities, the
10 LGBT population, so some of the work that's coming
11 forward that targets these groups are not
12 necessarily randomized control trials, they're
13 quasi-experimental or they're observational,
14 they're providing an important contribution and
15 laying an important foundation, but they're frankly
16 not ready to move straight into a randomized
17 control trial at this point.

18 Again, they're a very small number.
19 Eighty-five percent of the portfolio focuses on
20 randomized control trials. Yes?

21 DR. WEISMAN: The thing about what you're

1 saying and also the fact that -- this is Harlan
2 Weisman -- of the other studies that may not
3 specifically be looking at disparities but have
4 these populations included, do we have any kind of
5 standardization on the kinds of data that's being
6 collected that go to this? You know, we bemoan
7 often that other studies that have happened,
8 whether they're registries or randomized trials,
9 use different definitions, different lexicon, and
10 therefore it's hard to aggregate or look at things
11 and the same question in different places, but
12 among our own studies, there might -- you know, it
13 seems to me there would be virtue in ensuring
14 across certain variables that we're defining things
15 a certain way. Do we do that?

16 MS. HASNAIN-WYNIA: Yes. We do to a
17 certain extent. So, in terms of looking across the
18 entire portfolio, are we looking at how we define
19 rural populations?

20 DR. WEISMAN: Well, I meant more or less
21 replicating findings in one study, whether you

1 would see it if you looked at -- it may not have
2 been the primary intent of another study, yet those
3 people were there and those variables were there so
4 you could look at --

5 MS. HASNAIN-WYNIA: Yeah, so that's -- so,
6 in terms of looking across the entire portfolio,
7 yes, and part of what we're actively working on
8 right now is a lot of cross collaboration across
9 the programs as we're each really digging deeply
10 into our portfolios to see what we have
11 individually and also where there's overlap, and I
12 think, you know, that really does present the
13 opportunity to do exactly what you're suggesting.

14 DR. ZWOLAK: This is very nice, 39 studies
15 --

16 CHAIRMAN NORQUIST: Bob, can you say who
17 you are?

18 DR. ZWOLAK: Bob Zwolak, Board. Sorry.
19 Thirty-nine studies, \$76 million, are they meeting
20 milestones? And when are the results going to
21 start rolling in?

1 MS. HASNAIN-WYNIA: Yes --

2 CHAIRMAN NORQUIST: Why don't we -- so,
3 let's let her finish. If we have clarification
4 questions, I suspect that's going to be coming up,
5 is that correct?

6 MS. HASNAIN-WYNIA: Yes.

7 CHAIRMAN NORQUIST: So, why don't you go
8 ahead and if we have clarification questions --

9 MS. HASNAIN-WYNIA: Okay. So, I want to
10 highlight a couple of studies and I can go ahead
11 and actually answer the question about milestones,
12 yes, we've begun to get our first set of milestones
13 from the first set of projects that we have funded
14 and they are all meeting their milestones so far.

15 Many of them are underway and we're
16 expecting reports in the next couple of months, but
17 for the reports that we have been getting, all of
18 the projects, actually, within the Addressing
19 Disparities Program, have been meeting their
20 milestones.

21 I should also say in terms of assessing

1 milestones, we have been working very closely with
2 the engagement team. As many of you know,
3 engagement officers have been working with the
4 science staff in terms of really not just
5 monitoring the scientific milestones, but also the
6 engagement milestones for each of the projects and
7 those are integrated throughout all of the
8 milestones for all of the projects.

9 So, we really hope to have some very
10 robust information about not just the scientific
11 milestones that are being achieved, but also
12 really, you know, very robust information around
13 the engagement milestones as well.

14 So, there are a couple of projects --
15 again, you know, there are 39, so I'm just going to
16 be highlighting a couple of these to give you a
17 flavor. We're really excited about this project,
18 which is led by Ken Wells at UCLA. It's a project
19 that looks at long-term outcomes of community
20 engagement to address depression outcome
21 disparities. This takes place in South Los

1 Angeles, which there's basically a population of
2 about two million people, which is six times the
3 size of New Orleans.

4 It's important to note that there is no
5 public hospital, there are very, very few primary
6 care practices, so this is a project that has
7 really focused on engagement of the community and
8 really building off the assets that the community
9 currently has.

10 So, it's a mixed method study. The long-
11 term outcomes focus on three-year outcomes, again,
12 focusing on depression. There is a randomized
13 control trial component, so 95 service providers
14 are being randomized to either a technical
15 assistance arm where the clinicians are being
16 trained, the sites are being trained around
17 medication management, webinars around cognitive
18 behavioral therapy for depression, et cetera, and
19 then the active intervention arm is also providing
20 technical assistance, but with a very strong
21 community engagement component, so really helping

1 these providers and these organizations network
2 with each other and network with community-based
3 organizations.

4 This has really been a great model in
5 terms of PCORI's vision around engagement. The
6 community engagement component collaborating with a
7 large academic medical center has really played out
8 on kind of equal footing. Loretta Jones is the CEO
9 of Health African-Americans and sits as a co-
10 investigator. They present together at national
11 conferences. There's just a very positive view of
12 this project within the community as well and
13 really does offer very strong lessons in terms of
14 the importance of engagement and collaboration.

15 The other piece that I think I really
16 would like to highlight here is that there is a
17 clear focus here on both a healthcare system
18 intervention working within the context of the
19 community, so again, there's more information about
20 this project than I can obviously share with you,
21 but I wanted to highlight this partially because

1 the methods follow many of the -- the model follows
2 many of the projects within our portfolio which are
3 mix-methods, again with a -- sometimes a strong
4 qualitative component or a quasi-experimental
5 design coupled with a randomized control trial.

6 So, the second project I'd really like to
7 highlight, because this does focus on one of our
8 high-priority areas, which is reducing health
9 disparities in Appalachians with multiple
10 cardiovascular disease risk factors, again, this
11 project takes place in Kentucky, the study is based
12 at the University of Kentucky, very, very high risk
13 disparities population in the 1 percent for
14 cardiovascular risk, very low-income.

15 This study focuses on a randomized control
16 trial. Again, very strong engagement, patient
17 engagement and stakeholder engagement, it compares
18 two approaches to reducing cardiovascular disease
19 risks among at-risk individuals in Appalachian
20 Kentucky.

21 The goal is really to develop a model and

1 a tool of engagement so people can be very self-
2 directed and have the tools to be able to address
3 some of the CVD risk factors that they experience
4 in this community.

5 This project is, I think, a fascinating
6 project because it focuses on the Frontier county.
7 It's based at University of Montana. There's very
8 little data available on Frontier counties. So,
9 Frontier counties are focused on areas that are
10 pretty under-resourced because of the wide kind of
11 geographic spread, very, very low population
12 density, we're talking about maybe six people per
13 square mile, so clearly there's a real challenge in
14 terms of the services that are offered.

15 So, this is a non-randomized control
16 trial. They use a quasi-experimental, mix-methods
17 design to compare this model that they're
18 developing called the Roadmap against standard
19 practice to improve outcomes post-discharge for
20 people with chronic conditions.

21 And then the last project for now that I'd

1 like to highlight is this project that focuses on
2 improving the quality of care for individuals with
3 disabilities. This focuses on Medicare
4 beneficiaries with disabilities within the primary
5 care setting. Again, very little data available in
6 this area, so this study is based at the University
7 of Pennsylvania under Margaret Stineman's
8 leadership. Again, very strong patient engagement
9 and we really think that this will provide an
10 important tool setting the groundwork for maybe a
11 future randomized control trial, but it focuses on
12 both provider education, primary care clinicians,
13 as well as patient education to advance quality of
14 care in the primary care setting for individuals
15 with disabilities.

16 So, I'm being very mindful of time so I'd
17 like to move quickly, if you don't mind, into kind
18 of a larger snapshot of our project and where we
19 are to date.

20 So, one of the things that we started to
21 really think about in the program was to ensure

1 that we had some kind of a conceptual grounding for
2 the work that we're funding and to be able to map
3 that to a conceptual framework that's been vetted
4 and accepted.

5 We looked through a number of different
6 models, there are many out there. Amy Kilburn
7 [phonetic] has a great model that focuses on
8 improving health outcomes and reducing disparities
9 within the context of the healthcare system. We
10 have adopted Lisa Cooper's model, which was
11 published in JGIM, the Journal of General Internal
12 Medicine in 2002. Part of the reason that we've
13 adopted this model as a conceptual framework for
14 guiding our work is because the inputs are multi-
15 dimensional, as you can see, but the outcomes are
16 very patient-centered in terms of morbidity, well-
17 being, functioning, the patient's experience of
18 care.

19 So, again, this is kind of the
20 underpinning or the guidepost for the program.

21 What we've done is we've taken this and

1 then we've put an overlay of what we call a driver
2 model. This is very program specific. This
3 doesn't fit within the larger world. It really is
4 just program specific within the context of the
5 Disparities Program.

6 I know that many of you who use driver
7 models are used to seeing them going from the right
8 to the left. This goes from the left to the right
9 partially so it maps to the conceptual model, also
10 because of how we're defining these drivers. So, I
11 just want to very quickly -- you should have this
12 in your Board book, but I just want to quickly
13 describe what we mean by drivers.

14 So, we know that disparities are
15 multidimensional. We're all aware of this, and so
16 we're looking at what we consider the primary
17 drivers, which are the higher level factors that
18 may influence our main outcome here, which is to
19 reduce and eliminate disparities, so policy level
20 factors, organizational point of care.

21 The secondary drivers are elements or

1 concepts that can influence policy, that can
2 influence the organizations or the healthcare
3 system, or what happens at the point of care. And
4 then within the context of the tertiary drivers,
5 these are actually the interventions that are
6 embedded within the projects that we're funding.
7 So, we're going from very granular to a higher
8 level.

9 I didn't draw arrows here because the
10 arrows can go in multiple directions, so if you'll
11 just bear with me, I'll show you how we're
12 beginning to use this.

13 So, this is an evolving tool. It's
14 something that is dynamic, that will change, we'd
15 appreciate your input, but part of what we're doing
16 is trying to map all the projects that we have
17 funded to get a sense of what we currently have in
18 our portfolio.

19 So, we have, you know, a broad array of
20 projects, as you know, that address a wide variety
21 of conditions, that address different patient

1 populations across a number of settings. So, I'm
2 going to use one of our asthma projects to kind of
3 highlight how we're using the driver model.

4 So, this is a project that was funded
5 through our asthma-targeted funding announcement.
6 It takes place in Seattle, has three different
7 arms, it's focused on guidelines to practice,
8 reducing asthma health disparities through
9 guideline implementation. The three arms, you can
10 see, focus on a health plan intervention plus
11 provider education. Another arm focuses on
12 community health worker home visits and self-
13 management support, and the third arm focuses on
14 enhanced clinic care with decision support.

15 There's a high level of partnership in
16 this project. Allina Healthcare, which is a
17 Medicaid health plan, is engaged. The Seattle and
18 King County Public Health Departments health
19 system, so we have a lot of cross collaboration,
20 very strong patient engagement as well.

21 So, one of the interventions focuses --

1 one arm focuses on community health workers. So,
2 we're interested in where use of community health
3 workers may have an impact on secondary drivers
4 such as enhancing or expanding the workforce or
5 working within the context of the community or the
6 home environment.

7 Another aspect of this study focuses on
8 team-based care and self-management, so again, we
9 can map these to the secondary drivers.

10 What I can say is that, as far as the
11 outcomes that are measured within this project,
12 which are incredibly focused on clinical outcomes
13 and patient experience of care, functionality,
14 provider-patient communication, are all point of
15 care interventions with a component of
16 organizational or system-level focus as well. But
17 if you look at all of our programs in terms of all
18 of our projects, what we have funded to date, the
19 red flags basically show you the number of projects
20 and what drivers they align to. And you can see
21 here that -- I'll highlight -- the top three

1 drivers that we have funded so far within the
2 program focus on self-management, working with
3 community health workers, and the tailoring of
4 tools and resources around culture and language.

5 In terms of the secondary drivers, what
6 the program has funded to date focuses on access to
7 care, high quality care, training and education,
8 and patient empowerment.

9 Most of the projects that we have funded
10 really, in terms of the primary driver, focus on
11 point of care or communication interventions. A
12 small number focus on organizational level
13 interventions. We do not have any projects that
14 primarily focus on policy level comparing different
15 policy level interventions.

16 Again, I want to emphasize that this is
17 program-specific, so when we're looking at primary
18 drivers, we're really looking to see, are there
19 outcomes within the projects that we're funding
20 that may focus on policy-level comparators? We
21 don't have those within our portfolio, and in some

1 ways that makes sense given PCORI's mandate, but
2 this might also tell us where we may need to
3 collaborate with other funders, with others who may
4 be focusing on policy level interventions to maybe
5 focus on patient-centered outcomes.

6 It also tells us where we've already made
7 a great deal of investment in a given area. So,
8 again, we're really trying to take a great deal of
9 data, reduce it to a level that we can understand
10 where our investment is going so far, and where we
11 may want to make an investment in the future.

12 We know that even with point of care
13 interventions, we would hope that it would affect
14 policy, that it would affect what happens at the
15 system or at the organizational level, but again,
16 the focus here is on what the program has currently
17 funded to date.

18 So, I should have brought this up earlier,
19 but this is basically, again, these are the number
20 of projects that include underserved populations in
21 PCORI's portfolio. And, again, all the projects

1 within the Disparities Program clearly focus on
2 underserved populations.

3 We're beginning to really move forward
4 with developing learning communities among PCORI-
5 funded projects, so we hope to start to host
6 learning communities this fall. We're excited
7 about working with the engagement team under Jean's
8 leadership to really develop mechanisms to foster
9 cross learning among project teams, but also, even
10 more important, to really bring together the
11 research community in a given area, so we're going
12 to start off with asthma with end users, so
13 bringing together patients and payers and employers
14 to really interact with the research community to
15 inform what it is that they're looking for as well
16 as to allow some facilitation of dissemination
17 early on versus waiting for the projects to be
18 completed before we actually move forward with
19 dissemination activity. So, we'd like that to
20 happen a little bit more organically at the
21 beginning of our cycles rather than after the fact.

1 So, we'll continue to hopefully develop a
2 more sophisticated understanding. We would really
3 appreciate your input in terms of how we monitor
4 our program and how we can also go about
5 disseminating the best and promising practices and
6 partnerships with our key stakeholders.

7 CHAIRMAN NORQUIST: Okay, so let's --
8 we'll go around the room. We'll start -- Larry had
9 his card up first there. We'll just go around this
10 way.

11 MR. BECKER: This is wonderful.

12 CHAIRMAN NORQUIST: Larry, your name.

13 MR. BECKER: It's Larry Becker. Sorry. I
14 think this is wonderful and I think that it's
15 beginning to show sort of how we're bringing
16 everything together. And I think we know that if
17 patients are intrinsically motivated, that's the
18 best way to get them to change.

19 So, here's sort of a rhetorical question
20 and how do we know that the things that you have up
21 here are driven by what patients really want? And

1 I ask that question to say, as we begin to
2 communicate this stuff, if we could show the
3 linkage, all the hours and months of work we've
4 done to link those two things together, I think
5 this is amazingly powerful.

6 MS. HASNAIN-WYNIA: Yeah, and we can
7 definitely do that. I mean, that's part of why I
8 brought up the fact that we're really actively
9 monitoring the milestones, not just on the
10 scientific side, but on the engagement side. So, I
11 think that we can really start to develop a very
12 comprehensive framework in collaboration with the
13 engagement team.

14 So, part of our goal is not just to look
15 at whether the outcomes are improving on the
16 clinical side or the systems level, but is this
17 really driven by what patients want, what family
18 members want, what caregivers want. So, that is
19 part of our, you know, kind of active, strategic
20 portfolio management to get a comprehensive picture
21 of that.

1 So, what I provided here was, again, just
2 a snapshot.

3 CHAIRMAN NORQUIST: Okay. Rick, I think I
4 see your card there.

5 MR. KUNTZ: First of all, congratulations
6 for really putting together a fantastic --

7 CHAIRMAN NORQUIST: Your name, please?

8 MR. KUNTZ: Sorry. Rick Kuntz, Board
9 member. Congratulations on putting together a
10 really nice portfolio and I think that this is a
11 really important part of the PCORI. My question
12 is, while there's a methodology process to review
13 these grants, one of the grants you showed was
14 quite complicated with the matrix, three arms, I
15 wasn't quite sure what the control arm was. Could
16 we have the Methodology Committee review a few of
17 these just to make sure? Because CER is probably
18 the most complicated of the methods we're going to
19 develop. I, frankly, couldn't find how you were
20 going to be able to tell what the winner was, in
21 that one study, but none of us had a chance to

1 really review that.

2 But I think that the Methodology Committee
3 could really help calibrate grants as we go along
4 to look at certain examples of this and potentially
5 provide a report back to the Board with respect to
6 whether or not the methods that they espoused are
7 actually being incorporated into the [inaudible].

8 MS. HASNAIN-WYNIA: I think that's a great
9 idea. And I'm sorry, yes, the comparator arm was
10 the health plan intervention. Everybody is getting
11 that. So, I should have identified that.

12 CHAIRMAN NORQUIST: Okay and now Sharon
13 Levine, who's a Board member, will be speaking.
14 I've decided this is the way to do it instead of --

15 DR. LEVINE: No trust, no trust. Sharon
16 Levine, Board member. So, looking at disparities
17 in health outcomes versus healthcare outcomes, the
18 latter has an awful lot to do with the design
19 elements in the delivery system, and it's not clear
20 to me from what you put up there. I looked at that
21 page full of -- the one right before the drivers

1 and there's nothing in there about design elements
2 of the delivery system or the site of care where
3 patients actually get their care, and I'm wondering
4 how you're accounting for that and looking --
5 because part of our portfolio is health system
6 improvement.

7 MS. HASNAIN-WYNIA: Right. So, part of
8 what we have put into the broad funding
9 announcement, and that's a great point, and a lot
10 of the work that I did before I came to PCORI was
11 I'm looking at point of care and site of care and
12 whether that's a driver of disparities and how and
13 so forth.

14 So, part of what we've done is really
15 start to focus, partially also by -- through advice
16 from our advisory panel, is to embed within our
17 funding announcements that we are interested in the
18 studies that focus on disparities taking place in
19 settings where these populations get their care, so
20 within the context of community health centers,
21 public hospitals, more under-resourced providers,

1 so we can embed kind of the evaluation component of
2 the design within that.

3 So, many of our studies focus on that.
4 Not all of them. So, hopefully we have the ability
5 to do some comparisons at the design systems level,
6 but many of them do take place within the context
7 of safety net settings.

8 DR. LEVINE: So, I would argue that with -
9 - in a post-ACA world, it is going to be much more
10 important to compare traditional care delivery
11 settings with safety net providers because more
12 patients in Medicaid and more low income patients
13 are going to be accessing the traditional sites of
14 care delivery and the ability to understand what
15 that means is going to be increasingly important.

16 MS. HASNAIN-WYNIA: I agree. Thank you.

17 CHAIRMAN NORQUIST: Harlan Weisman.

18 DR. WEISMAN: Harlan Weisman, Board
19 member. You know, I really liked what you were
20 presenting and the kinds of questions that are
21 being asked and probably what made me think about

1 it more -- these might be naïve questions -- but I
2 was wondering, at the end of all this, what does
3 success look like? Is it that disparities go away
4 or the disparities get less? And how do we
5 actually measure that? And from population to
6 population, because we're not looking at that --
7 let me just give you -- and then the question was
8 how general -- you talked about changing practice -
9 - this has the potential of changing practice -- to
10 one of the things you presented, and I was
11 wondering, practice where? You know, how
12 generalizable is the findings from one study to --
13 across the nation or across different populations?
14 And I'm just curious about what you were thinking
15 about in terms of generalized ability, you know,
16 whether it's in systems geography or whatever.
17 I'll stop there.

18 MS. HASNAIN-WYNIA: So, I think these are
19 great questions. So, in terms of measures of
20 success, I think that part of the reason that I
21 wanted to focus on having kind of a very lofty goal

1 of eliminating disparities, we realize that is
2 maybe a generation or two away, but we really do
3 think that we can move the needle in terms of
4 reducing disparities within specific areas.

5 So, part of this is going to really be
6 derived also through how we strategically focus on
7 our Targeted Funding Announcements and what we
8 focus on. So, as Joe said earlier, ensuring that,
9 you know, we're bringing the right stakeholders to
10 the table very early on so the adoption -- the
11 dissemination, implementation, adoption of these
12 practices can start to happen early. So, I think
13 that is going to be one measure of our success is a
14 level of uptake, even if we are only seeing small
15 progress in terms of actually reducing disparities.
16 And it's going to depend on the conditions that
17 we're targeting as well. So, we have to be mindful
18 that a one-size-fits-all approach is not going to
19 lead to a reduction.

20 So, I think it's really important for us
21 to keep that in mind as we start to measure the

1 impact of our program, especially as we approach
2 2019, because that's a pretty short timeframe to
3 focus on closing the gap as well as improving
4 outcomes for everyone.

5 Your second question, in terms of the
6 generalizability, I think that's -- you know, many
7 studies face challenges around generalizability,
8 but one thing that I think, in a very simplistic
9 way, is that if we can show that something works in
10 a really resource-constraint environment, we would
11 hope that some of these practices can be adopted in
12 broader environments as well, because if it works
13 in very under-resourced -- and that was part of our
14 focus strategically around paying attention to
15 safety net providers and under-resourced providers,
16 so we're hoping that we can have an impact on
17 generalizability through that pathway.

18 CHAIRMAN NORQUIST: Thanks. I have to
19 make an announcement here. Unfortunately, there
20 were some technical issues, so for people who are
21 listening, you can't see the slides, you have to

1 log back in in order to see the slides. You have
2 to go to pcori.org/event and log back in so you can
3 see the slides.

4 Okay, Ellen, you snuck in there. Ellen
5 Siegel is now speaking.

6 MS. SIGAL: Sorry. Ellen Siegel, thank
7 you. It's very important work. The issue, really,
8 will be in terms of implementation, the economic
9 feasibility, so it's what we learn is going to be
10 important, so the issue is when the study goes
11 away, the economic ability to implement this is
12 really -- without the resources, is an issue years
13 ago I worked on clinical trials in community
14 settings and we came up with some really
15 interesting models to get underserved populations
16 involved in these trials, but unfortunately, the
17 economic model didn't work, it was too expensive.

18 So, speak a little bit to how this all
19 works. Obviously, this is important, but the
20 ability to have the resources to implement is going
21 to be important.

1 MS. HASNAIN-WYNIA: Yeah, so, I completely
2 agree and, you know, part of -- you know, sometimes
3 we act before we study, so I'm reflecting back on
4 pay-for-performance programs that were -- that have
5 been implemented over the last, you know, ten years
6 or so and quite a bit has been written about, you
7 know, whether the pay-for-performance programs may,
8 in fact, exacerbate disparities. But we are
9 functioning on a model of kind of value-based
10 purchasing. We're moving forward with value-based
11 purchasing in terms of the ACA. I think that there
12 is, you know, a real focus right now in terms of
13 how organizations are delivering care and being
14 accountable not just for what takes place within
15 the context of the healthcare system, but also
16 within the context of the community.

17 So, when we look at accountable care
18 organizations, patient-centered medical homes, I
19 think that there are going to be natural economic
20 drivers, especially when we start to link some of
21 the work around -- if we use hospitals -- around

1 community benefit and such to what providers get
2 paid for, that there will be natural drivers that
3 may, in fact, support the integration of some of
4 the findings that we derive from the evidence base
5 that we developed to actually improve those
6 outcomes.

7 So, I think that there is an opportunity
8 here with the roll out of the ACA with new payment
9 models, with new delivery models, to really begin
10 to integrate a focus on disparities reduction
11 versus, you know, just paying for overall quantity
12 of care.

13 And it's much more complex than that,
14 clearly, but it is one component that we have
15 talked about quite a bit in terms of kind of a
16 natural influx, in terms of a focus on, you know,
17 what could be an economic driver to really focus on
18 reducing variations and disparities and practice.

19 CHAIRMAN NORQUIST: Allen Douma.

20 DR. DOUMA: I'm Allen Douma. Let me just
21 say that this is one of the most important

1 presentations I've heard since I've been on the
2 PCORI board. I think it's taking us a dramatic
3 step forward in understanding what we're doing and
4 after we understand what we're doing, we have a
5 much better idea of how we can do it better.

6 I would love to see the approach you take
7 in your conceptual framework be applied to every
8 study that we've funded and to use that as a guide
9 to what we -- what is, where are the gaps, so we
10 can fund better in the future, and hopefully
11 they're learning from your excellent work in how to
12 apply it to everything else, including a searchable
13 database across all the parameters you talked
14 about.

15 Within the conceptual framework I'm
16 particularly pleased to see the emphasis on things
17 like self-management, a little bit of over-
18 emphasis, in my mind, on self-management within a
19 clinical setting, because so much -- most of self-
20 care, for example, goes on outside of clinical
21 settings, but you're in that direction, in that

1 ballpark, and I love it. Compared to the rest of
2 our research, I think we're too far away from it.

3 The only thing that I would like to bring
4 up, for a lot of good reasons, including I'm an
5 emissary from AARP, is I would love to see more of
6 a reporting and emphasis on the elderly.

7 And I do have one question. How do you
8 prioritize, in your own mind, and how does that
9 prioritization influence our decision-making with
10 regard to which disparities or which groups that we
11 want to focus on in the future?

12 MS. HASNAIN-WYNIA: So, in terms of
13 prioritizing, we have used the process that many of
14 the other programs have been using, so we rely on
15 the IOM-100. We started to do that early on even
16 before the formation of the advisory panels.

17 Our advisory panel clearly provides us
18 with some guidance in terms of topics and target
19 populations. We do this through a pretty diligent
20 process of looking at where, you know, a number of
21 stakeholders have come together, such as the IOM-

1 100, some of AHRQ's future research needs, what's
2 being funded at the NIH, we spend a lot of time
3 talking to our colleagues at NIH, at AHRQ, and at
4 CDC to really understand where some of the gaps are
5 where PCORI can make a contribution.

6 And through that mechanism we then go
7 through our advisory panels, prioritize, and then
8 come forward to the Board and the respective
9 committees to hopefully motivate and really hone in
10 on a target topic as well as target populations.

11 CHAIRMAN NORQUIST: Okay. Debra and then
12 Gail and then we need to wrap up because we're
13 behind.

14 MS. BARKSDALE: Debra Barksdale, Board.
15 Could you go back to slide 67, please?

16 MS. HASNAIN-WYNIA: Sixty-seven?

17 MS. BARKSDALE: Sixty-seven. Yes.

18 CHAIRMAN NORQUIST: You passed it. You're
19 going the wrong way.

20 MS. HASNAIN-WYNIA: Sorry.

21 MS. BARKSDALE: That's it. Given that

1 there is a significant amount of work on
2 disparities going on throughout PCORI, how do we
3 leverage all of the potential knowledge that might
4 be gained?

5 MS. HASNAIN-WYNIA: So, part of the
6 leveraging is -- you know, part of this is a call
7 from Bryan Luce, who's our chief science officer,
8 as you all know, is to really start working across
9 the programs and looking at specific clusters of
10 projects in a given area, and look at the focal
11 points in terms of our national priorities. So,
12 you know, which projects really focus on addressing
13 disparities across the portfolio? Which projects,
14 within the Addressing Disparities Portfolio, have a
15 strong emphasis on improving health systems or on
16 clinical CER? Which projects within the
17 communication and dissemination portfolio cross
18 over with the disparities portfolio? So, that's
19 the work that we have really actively just started
20 and we really hope to be able to bring you a more
21 comprehensive picture of that at a future board

1 meeting, but it's something that we're very mindful
2 of. We recognize that, you know, our success is
3 not going to be measured just by what happens
4 within different programs, but across PCORI in its
5 totality.

6 So, we've really been working as a team to
7 really begin to understand that and develop those
8 crosswalks.

9 CHAIRMAN NORQUIST: Okay. And that was
10 Debra Barksdale asking the question. Okay, Gail
11 Hunt will now speak.

12 MS. HUNT: Gail Hunt, Board member. I
13 notice that in one of the three studies that you
14 gave us as an example, I know that family care
15 giving was an important component. I would just
16 suggest that particularly in this area of
17 disparities, although not exclusively, that you are
18 absolutely sure that the researchers include family
19 caregivers, because they're such an important
20 component in being able to do the -- to actually
21 roll something out.

1 MS. HASNAIN-WYNIA: Absolutely agree with
2 you 100 percent.

3 CHAIRMAN NORQUIST: Rick Kronick.

4 MR. KRONICK: Rick Kronick, Board member.
5 One question, Romana, for you, and then one for my
6 fellow Board members.

7 For you, following up on Ellen's comment
8 and actually also Allen's, it does seem that for
9 some of the tertiary drivers particularly self-
10 management, the economic case may not be very hard
11 to make and if you can show how self-management
12 works, a lot of people will jump on that.

13 Community health workers, totally
14 opposite, and I imagine that we ask when applicants
15 are applying, but just -- the question, do we ask
16 them, you know, what is the sustainability model?
17 And, you know, how do you -- you know, if we show
18 this works, how do you get from here to there?

19 Before you answer, then I will ask my
20 fellow Board members, you know, this was an
21 extremely useful presentation. It responded, I

1 think, at least in some part, to the question that
2 Harlan asked at the end of the retreat, which was,
3 were we able if asked to say what was it that we
4 were doing in PCORI, that we're funding, that we're
5 really excited to see the answers and we're really
6 looking forward, and I would ask my fellow Board
7 members, having seen this now, are we better
8 positioned at the next cocktail party when somebody
9 says, okay, what's PCORI funding that you're really
10 excited to see the results of, are we better
11 positioned to do that?

12 CHAIRMAN NORQUIST: So, we'll ask you
13 first, though, what is your answer?

14 MR. KRONICK: I would say for myself, a
15 little bit, but not too much. I would probably
16 talk about the Ken Wells study and say might be
17 some pretty cool things coming out of there, but I
18 feel like I don't really know enough about it and
19 I'm not sure how excited I am about it.

20 CHAIRMAN NORQUIST: Yeah. So, what would
21 make it more helpful, I guess, at this point?

1 MR. KRONICK: Probably a little more
2 information -- I know it's tough because there's
3 not much time.

4 CHAIRMAN NORQUIST: Right. We clearly did
5 not set aside enough time and I think you're
6 absolutely right. I have the same feeling. I know
7 about Ken's stuff because I know Ken personally and
8 I know he just won an award for this, but I think
9 it's true, we don't know the -- and my answer to
10 you would be, I feel somewhat the same. And so,
11 there is an opportunity to learn from this
12 experience, I think. Harlan?

13 MR. KRUMHOLZ: I just want to thank you
14 very much, and Rick, thanks for remembering. There
15 were some sticky messages from the discussion in
16 San Francisco.

17 I just want to go back to at least the
18 proposal that I've been making before and if we
19 don't do it on grants, maybe we can do it on
20 presentations, which is -- and I want to give
21 credit to John Eisenberg for this idea because I

1 remember having heard it at AHRQ, which is, give me
2 the newspaper headline that comes out when this
3 paper is first published or give me the abstract in
4 the *New England Journal of Medicine* or whatever
5 paper, the *Journal of Community Medicine*, I don't
6 care, that's going to come out when this paper is
7 done. Let me judge -- give me the most optimistic
8 view that you have of what people are going to
9 report on this, give me the most optimistic view of
10 what that front page of the paper looks like.

11 I'm not criticizing --

12 MS. HASNAIN-WYNIA: No, no. I understand.

13 MR. KRUMHOLZ: But I'm trying to get us to
14 focus on the value of the information by thinking
15 about the end product. If the outcome of research
16 is keeping the end results in mind, I'm trying to
17 bring that mentality to the PCORI Board, and when
18 we're -- every single project, I want to see what
19 that paper looks like in the most optimistic of
20 worlds and what the headline in the newspaper looks
21 like and the press release looks like in the most

1 optimistic of worlds. And don't worry that you're
2 making assumptions about everything going right and
3 the findings being, you know, as best as they
4 possibly can, because I want to know what that is.

5 Now, ideally when we're doing the
6 evaluation of the grants, I would like to see a
7 mock paper without -- or even with optimistic
8 results, what they would expect to see, a press
9 release, and then I want some estimate of the
10 likelihood of getting those results, because any
11 good investigator will tell you, here's what I
12 would hope to see and there's -- you know, either
13 at equipoise or they could be a little more
14 enthusiastic, but I want to know how high risk it
15 is. But that may be before the committee.

16 But for us, when we're being presented --
17 I think Rick's bringing up a really good point --
18 for us to be good ambassadors and for this Board
19 meeting to be able to communicate broadly to the
20 people listening and for the audiences here with us
21 today, the technical parts, and even the conceptual

1 model is less important -- many of us are deeply
2 interested in this, but for many people this is
3 inside baseball, is give us the headline. What's
4 the headline? If this is successful these are the
5 three headlines you'll see in three to five years.
6 And that, I think, will help get us to the value of
7 information. Was that headline worth \$23 million
8 or \$10 million or \$500,000? And that's where I
9 think we in the public will be able to take it in.

10 You happen to be up, but I'm saying this
11 broadly because I think that we need to find better
12 ways to communicate this. Maybe the engagement
13 group can help think about this too, but we need to
14 find better ways to communicate this so that it's
15 sticky and people leave there thinking, I heard
16 three studies that, wow, I can't wait for those to
17 come out.

18 And I would have the same trouble you're
19 having right now. I'm impressed, but I don't -- I
20 couldn't do a teach back with me in the hallway and
21 I can't repeat to you, you know, the three things.

1 I could say asthma, but I don't know what it is. I
2 can say something going on in Montana, in Kentucky,
3 that Mozer's [phonetic] doing a great study or Ken
4 in LA, but I can't go beyond that.

5 CHAIRMAN NORQUIST: Yeah, so we have some
6 work to do to get the message right and I think
7 there's another piece of the message here, which is
8 not only the headline -- so, if you were writing
9 this for *The Washington Post*, since we're in
10 Washington, or if you're writing for *The New York*
11 *Times* and it would get their attention, get the
12 editor's attention, and when I have this published,
13 what would you say, basically. That would also
14 help me understand these instead of I think
15 sometimes we get lost in the trees here and miss
16 the big point.

17 The other thing, I think, that's also
18 missing in this is what's unique about it for
19 PCORI, because there are a lot of other places that
20 are funding. I mean, Dr. Collins has a lot of this
21 going on at NIH and Rick does too, and I mean, the

1 question is, what's unique for us? Because we can
2 all sit here and say, this is wonderful to do, but
3 really, what particularly also is it about what
4 we're doing that's unique? What's unique about
5 your portfolio, our portfolio that I think would
6 also be very helpful as part of the message also?
7 Okay?

8 Thank you very much. I know you've done a
9 wonderful job --

10 [Applause.]

11 MS. HASNAIN-WYNIA: Thank you. And thank
12 you for the comments and the questions. They're
13 actually incredibly helpful for us.

14 CHAIRMAN NORQUIST: Yes, and I appreciate
15 -- it's all done in a collegial manner. We hope
16 everybody understands that, right, we're all trying
17 to move forward in the same way.

18 And, Robin, we have taken out 15 minutes
19 of your time. I don't know if it's going to still
20 take you 30. We'll have to try to make it up if
21 you want to. You don't have to, but I guess you're

1 going to. Okay.

2 While Robin is moving up, make it real
3 quick, Joe, because you're going to use up some
4 time.

5 DR. SELBY: Yep. I just have to say that
6 for the record, Romana asked for an hour and I only
7 gave her 45 minutes.

8 CHAIRMAN NORQUIST: Ah-ha. So, it's your
9 fault?

10 UNIDENTIFIED: She took the hour.

11 CHAIRMAN NORQUIST: She took the hour.
12 That's right. The heck with Joe. She just took
13 it. That's your staff.

14 Okay, so next, Robin Newhouse, who is the
15 chair of our Methodology Committee will be giving
16 us an update on the Methodology Committee, correct?

17 MS. NEWHOUSE: All right. So, I'm going
18 to try to do something innovative. Harlan's
19 inspired me. Methodology Standards Transform
20 Science. PCORI Methods Task Force Identify Ways to
21 Harmonize Data. Open Science Group Develops

1 Reproducible Research Standard. Decision Science:
2 Improve Decisions for Clinicians, Patients, and
3 Health Systems. And a little bit about an update
4 with new Methodology Committee members. So, there
5 you go, Harlan. We'll give it a start there for
6 your challenge.

7 Okay, so in terms of, first of all, the
8 methodology standards, we are working on two sets
9 of new standards that are important for PCORI. The
10 first is around designs that use clusters and the
11 second is around complex interventions. These are
12 two areas where PCORI has invested in research
13 studies, and they're both important.

14 Complex interventions are those
15 interventions that involve multiple components.
16 They're very difficult to disentangle. So, the
17 idea that is we are approaching the development of
18 these methodology standards in a little different
19 way in that they are starting with a landscape
20 review, moving toward working with experts that
21 have already started work in this area, and will

1 result in workshops before standards are developed.

2 So, we will be able to update you at the
3 next public Board meeting about where we are with
4 those standards. We expect that there will be a
5 workshop in the fall related to the research
6 designs using clusters. We don't have a date
7 identified for the complex intervention standards.

8 The second thing I'd like to update you on
9 is many of us have received a number of inquiries
10 related to new standards or recommendations for new
11 standards. We've now developed a public forum for
12 solicitation of ideas for standards. You see it --
13 this is just a snapshot of the PCORI website. So,
14 now those that have a recommendation for new
15 standards development can go right to the website.

16 Second of all, the Methodology Committee
17 has identified a need to develop a task force
18 related to identifying innovative methods that have
19 evolved as gaps as PCORNet grows and is launched.
20 So, that effort is led by Sebastian Schneeweiss and
21 it is just getting started. The members of this

1 task force include Methodology Committee members,
2 the PCORNet coordinating center as well as PCORI
3 staff.

4 The third agenda item, and Harlan, I might
5 call on you. I know Steve is on the phone and if
6 you have any additional comments to make, the open
7 science workgroup has begun its work led by Harlan
8 Krumholz and Steve Goodman, who is on the phone.
9 This group is under the oversight of the Research
10 Transformation Committee. And they've had one
11 meeting so far and have developed at least a draft
12 of direction. And, Harlan, do you want to say
13 anything about that work?

14 CHAIRMAN NORQUIST: Could you say
15 something, Harlan, about where we are at this
16 point? Is Steve Goodman on the phone? I didn't
17 realize he was on the phone. Steve, are you there?

18 MR. GOODMAN: Yes.

19 CHAIRMAN NORQUIST: Okay, good.

20 MR. KRUMHOLZ: Steve, do you want to go
21 ahead and start?

1 MR. GOODMAN: Sure. I'll just say briefly,
2 we developed a draft proposal that we discussed
3 with the working group. Then Harlan and I have
4 honed it down to a more concrete proposal that
5 we'll be representing to that same workgroup and we
6 expect to have that to the RTC within the next few
7 weeks or months.

8 MR. KRUMHOLZ: Yeah, and I just want to
9 add to what Steve's saying is that we've channeled
10 forward a lot of the comments that we've heard over
11 the course of the last several years, both from the
12 Board and from external stakeholders and CS is
13 being uniquely positioned to help push these
14 forward both with regard to our actions and
15 policies as well as our ability to create more
16 normative behaviors. We're, to be honest, riding
17 the waves of a lot of other activity that's going
18 on in this area, but we want PCORI to be seen as
19 progressive and as a catalyst for these kind of
20 activities.

21 Steve is at an IOM meeting. Rick went

1 over this morning, I'm going to go over now.
2 There's kind of resonance back and forth with a lot
3 of other efforts that are happening here and we
4 appreciate the Board's support and Methodology
5 Committee's support of the idea that PCORI can play
6 a critical role in helping to push forward some of
7 these very important areas of ethics within
8 science.

9 MR. GOODMAN: Yes, I'll just add to that.
10 While we are sort of riding the wave, one of the
11 reasons there had to be such a wave is because most
12 of the agencies and entities who could move this
13 [unintelligible] forward, have constraints that
14 maybe PCORI won't have, and I think we can really
15 be leaders in this space even though some of the
16 technical challenges are actually somewhat
17 daunting.

18 But I think there's a potential for us to
19 set the standard going forward. So, this is really
20 quite an exciting area and you'll hear from us in
21 the near future.

1 DR. COLLINS: Francis Collins. I think
2 this is great that there is a workgroup focused on
3 this. Thank you, Harlan. Thank you, Steve.

4 Just remind us, though, what's the process
5 for bringing forward the output of your workgroup
6 to the Board given that this is sort of an unusual
7 group that's partly connected with Methodology
8 Committee and partly with the RTC. How is that all
9 going to emerge?

10 MR. GOODMAN: Well, the current thought is
11 the group itself will consider the proposal that we
12 currently have on the table, perhaps modify it, and
13 then that proposal will be brought into the RTC.

14 There are some elements of it that will
15 absolutely require serious discussion and
16 potentially commitment of resources or effort by
17 PCORI, so this is the kind of thing that the
18 recommending joint committee can't decide by
19 themselves but we can put the issues forward for
20 the Board. And we expect to have that, as I said,
21 probably in the next month or two at the very

1 latest.

2 MR. KRUMHOLZ: It would be ironic if a
3 committee on transparency were to keep its
4 intentions secret until the final moments. So, I
5 think --

6 CHAIRMAN NORQUIST: I'm not worried about
7 secrecy at all.

8 MR. KRUMHOLZ: So in seriousness, it's our
9 challenge to both make progress, do refinements,
10 and then share at appropriate junctures where we
11 can keep moving forward, but certainly this is
12 going to be far too important for us to move
13 forward at all without the full Board's consent and
14 enthusiastic endorsement as well as the Methodology
15 Committee. I mean, I think if one group or the
16 other is not completely 100 percent supportive of
17 this, we're going to have an issue.

18 So, we're going to try to take steps
19 forward, keep people in the loop, and then come
20 back to the Board, maybe for the next meeting be
21 able to present some of these ideas in a little

1 more detail.

2 CHAIRMAN NORQUIST: But it sounds like the
3 primary process -- I'm sorry, Steve, go ahead.

4 MR. GOODMAN: I was just going to say,
5 this will be the subject of an hour-long discussion
6 at the Methodology Committee meeting on Wednesday.

7 CHAIRMAN NORQUIST: Yeah, and this is Gray
8 Norquist, but my sense is that this will come back
9 through the RTC for the most discussion and then it
10 will come to the full Board, correct?

11 MR. GOODMAN: Correct. That is the plan.
12 Yes.

13 CHAIRMAN NORQUIST: Thanks. Do you want
14 to move on now?

15 MS. NEWHOUSE: Yes. Thank you. So, the
16 last and additional exciting focus for the
17 Methodology Committee in coordination with PCORI
18 Board members and staff is the excitement around
19 some of the decision science conversations that
20 we've had.

21 The Methodology Committee workgroup has

1 worked on a framework for decision sciences and
2 they're moving forward with several activities,
3 including a draft of a sort of framework and
4 they're in the planning stages now of a workshop
5 again for the fall. They're gathering more
6 information.

7 So, the framework just includes items such
8 as improving decision making for patients and for
9 health systems. Some of the others, decision
10 making when a patient isn't able to participate in
11 meaningful -- participate meaningfully, how people
12 decide the factors other than evidence that affect
13 medical decisions, facilitating shared decision
14 making, so they've spent some time developing this
15 framework that can then be a basis for a workshop
16 to help advance some of our thinking about the
17 science, our decision sciences.

18 So, that's a very quick update of some of
19 the activities that the Methodology Committee has
20 been involved in.

21 The last thing that we wanted to recognize

1 is that we've had four members of the Methodology
2 Committee that have left, Sherine Gabriel, Sharon-
3 Lise Normand, as well as John Ioannidis and Al
4 Berg. Al Berg, we're very sad that he is rotating
5 off of the committee. He's made major
6 contributions from the beginning of developing the
7 charter for the Methodology Committee when we were
8 formed right to our current discussion about how we
9 can work best as a Methodology Committee to serve
10 the PCORI Board, and we will greatly miss him.

11 John rotated off a little earlier this
12 year, but Al will be serving through June with us
13 until we have replacements announced.

14 The Government Accountability Office did
15 open a request for nominations for the Methodology
16 Committee, which closed on April 11th, so we're
17 looking forward to embracing new members of the
18 Methodology Committee to help us carry our work
19 forward.

20 So, just to summarize, we've done quite a
21 bit of work in terms of developing new standards,

1 particularly around areas that PCORI is investing
2 in research. We have developed a taskforce, the
3 PCORI Methods Taskforce, to identify gaps that are
4 apparent through the PCORI network and Sebastian is
5 leading that.

6 The open science work has begun to advance
7 and you'll hear more as that work evolves, as well
8 as the decision science initiative that we've been
9 heavily engaged in.

10 So, I'll close with that summary and
11 invite any questions that you may have about the
12 Methodology Committee work to date.

13 CHAIRMAN NORQUIST: Thanks, Robin. These
14 cards, I think, are from the last -- do I have
15 anybody that has questions at this point? Or
16 comments?

17 [No response.]

18 CHAIRMAN NORQUIST: Okay, thanks for that
19 nice -- one thing I would ask, Robin, when do you
20 expect kind of this -- we just heard about for the
21 open science from the decision science. When do

1 you think you're going to come to some conclusion,
2 because that will inform kind of what we're doing
3 as far as what we're funding and it might be nice
4 to have that sooner rather than later.

5 MS. NEWHOUSE: We have our Methodology
6 Committee meeting on Wednesday, so we will come to
7 some conclusions about deliverables and dates so
8 those dates have not been scheduled yet. So, we'll
9 get back to you after Wednesday.

10 CHAIRMAN NORQUIST: Yeah, so that will be
11 important because we'll need to let the field know
12 about what our interests are, what they're not, so
13 that we don't lead people into submitting
14 applications in the future and stuff if it's not
15 something we're going to think we're going to fund
16 or something, correct?

17 MS. NEWHOUSE: Yes.

18 CHAIRMAN NORQUIST: Okay. Harlan Weisman.

19 DR. WEISMAN: Harlan Weisman. Robin, in
20 the past, there were concerns on the Methodology
21 Committee, I think on the Board and maybe the

1 Institute about effective integration of the
2 Methodology Committee in PCORI processes and
3 utilization of the talents and capabilities of the
4 Methodology Committee. And a number of actions
5 were taken, I guess, over the last six months to a
6 year. Can you give us a view of how you think --
7 how the Methodology Committee thinks things are
8 going? Have there been improvements? Are the
9 committee members feeling better about the
10 integration?

11 MS. NEWHOUSE: I would say that the work
12 and engagement of the Methodology Committee
13 throughout the PCORI initiative has grown
14 exponentially, not only as a result of many of the
15 efforts that are undertaken by the PCORI Board and
16 PCORI staff, but also in terms of the governance
17 structure and embedding the Methodology Committee
18 members in the different taskforce and in the
19 groups -- the initiatives driven by the PCORI
20 mission.

21 So, I think that we all are heavily

1 involved and I would say that I haven't heard one
2 person say they would like to be more engaged. We
3 certainly have been actively engaged in anything
4 that PCORI has done.

5 CHAIRMAN NORQUIST: So, thanks for asking
6 that, Harlan. That's an incredibly important point
7 and I'm glad to hear that that's the movement we've
8 made, some success there.

9 Next, while we're setting up here, Jean
10 Slutsky, who we've introduced earlier and we're
11 very pleased to have join us, who was on the
12 Methodology Committee and at AHRQ, is now our chief
13 Engagement and Dissemination officer and Jean is
14 going to give us a brief update on Engagement
15 activities.

16 MS. SLUTSKY: So, Romana wanted an hour
17 and I wanted five minutes. So --

18 CHAIRMAN NORQUIST: And I made her take
19 15.

20 MS. SLUTSKY: We both got what we wanted,
21 okay. I can't tell you how happy I am there's no

1 cameras here so my evil double chin doesn't show
2 up.

3 Anyway, enough levity. First of all it's,
4 you know, an honor to be here. It's great to be on
5 this side of the curtain, so to speak. I've worked
6 with many of you for a lot of years.

7 So, I became the chief Engagement and
8 Dissemination officer on March 17th. On February
9 18th I became the program director for
10 Communication and Dissemination Research. So, this
11 is actually a nice diad. It allows PCORI to bring
12 together two streams that are in the same
13 organization but get much closer together. So,
14 bringing communication, engagement, and science
15 much, much closer together. And as many of you
16 know how well things get identified as important
17 topics and how we engage stakeholders throughout
18 the research process has a great deal to do with
19 how things get implemented in the end, and that's
20 something that obviously has been a lot of topic of
21 discussion in this meeting and before this meeting

1 and will continue to.

2 So, I don't have a lot of new program
3 direction to tell you. It's a little early. I
4 will say that I'm watching very closely this space
5 with the Methodology Committee and their work in
6 decision sciences because clearly, as we revise the
7 PCORI funding announcement for communication and
8 decision -- dissemination and communication
9 research, we'll be looking very closely at what the
10 Methodology Committee comes up with.

11 So, I wanted to give you just some
12 staffing updates. First of all, I have to say that
13 the staff that I've worked with, both on the
14 engagement side and the science side, although I
15 will say the CDR portfolio that I lead is just me
16 right now, but there's been wonderful contributions
17 from project officers from all the other national
18 priority areas to pick up the slack, and it's just
19 been amazing to see how many of those people worked
20 to develop projects that they're not really
21 responsible for.

1 So, the first engagement officer has been
2 hired and we've made an offer, and I have to say
3 now that offer has been accepted, for the director
4 of the Eugene Washington PCORI Engagement Awards
5 Program, and that individual starts May 19th. And
6 I -- also new breaking news -- I made two offers
7 for a senior and junior program officer for the CDR
8 portfolio. So, hopefully they will accept and I'll
9 be an n of three for that portfolio, which, I think
10 is exciting.

11 And we're also developing under the
12 engagement awards directions on how PCORI will fund
13 large and small conference grants, which up until
14 now has been somewhat ad hoc, and so this is really
15 signaling to the field how -- what's of interest to
16 PCORI and how we'll fund them.

17 And then kudos to the Engagement team.
18 The edict, which put a great deal of effort into
19 this, the patient and family engagement group has
20 been completed and plans are underway to
21 incorporate it into future funding announcements

1 and to provide training to merit reviewers and
2 potential PCORI applicants.

3 And my last comment is that training is
4 now part of Engagement and we're working very, very
5 diligently to provide continuing education and
6 continuing medical education training for many of
7 the training modules that have been given to merit
8 reviewers, the Methodology Committee standards, and
9 other activities we've done, not only as an
10 inducement for people to take part in these
11 activities, but to influence behavior in taking up
12 these training activities and standards.

13 So, you'll be happy to know, or maybe not
14 so happy, that I have one slide -- well, two
15 actually with the title slide.

16 So, Gray, I can take some questions, but I
17 think I might have gotten you back on track.

18 CHAIRMAN NORQUIST: Oh, no, we're going to
19 give you a lot of questions. Wait a minute. I
20 want to let Debra Barksdale say something if she
21 wants to since she's chair of our Edict Committee,

1 which is the relevant Board strategy committee.

2 MS. BARKSDALE: Thank you. Debra
3 Barksdale, Board. Well, first of all, I'd just
4 like to give my appreciation to Jean and Orlando
5 and others who -- I'm sorry if I missed someone,
6 but those are the ones I've worked with most
7 closely and I really appreciate the support that
8 they have provided in helping us to develop the
9 work of this committee and also to members of the
10 committee as well that are around the table.

11 I think, as Jean has indicated, stay
12 tuned, there is more to come.

13 CHAIRMAN NORQUIST: So, the other thing --
14 a couple things I wanted to say is, particularly on
15 the last bullet, I think this is critical because
16 we talk about how to train investigators in the
17 methods and all this other stuff, but we also need
18 to train them in what we mean by engagement.
19 That's really a critical issue and the more we can
20 do on that to get that out is really critical,
21 because every place I go now, particularly

1 academia, is like, what does this mean? What am I
2 supposed to do? Can I just send a letter? No, you
3 can't send a letter. You know what I mean?

4 So, I think that's really important and
5 the more we can do on that.

6 The other thing that's not in here because
7 it's not finished and it's always a topic that
8 comes up is, what are we going to do in
9 implementation a la an interface with AHRQ? And
10 that will come in September or some other time
11 we'll have that discussion, but we do have this
12 contract out, correct, that we are looking at
13 that's supposed to inform us on that, but that's
14 where we are with that particular process now.

15 MS. SLUTSKY: Yeah, so, just a quick
16 comment on that. The edict committee has been
17 briefed and the Board was briefed, I believe, at
18 the last committee meeting about the framework
19 contract and AHRQ and PCORI have been meeting. The
20 last time we met, I think, was a couple weeks ago,
21 three weeks ago, perhaps, and we are setting up a

1 leadership committee between PCORI and AHRQ to meet
2 once a month or bimonthly to set out a strategy for
3 how we can coordinate our activities in this area.

4 CHAIRMAN NORQUIST: Okay, great. And then
5 the other thing I would ask is, at some point we
6 need kind of an update on what's happening with the
7 Eugene Washington Engagement Awards, I mean, as far
8 as like where we are with those awards, kind of
9 what's in that portfolio also, I think.

10 MS. SLUTSKY: Yeah, so I'm really glad you
11 brought that up because, you know, the person that
12 -- in fact, this morning I spoke to the person
13 who's joining us as the director of the Eugene
14 Washington Awards, so it's a little premature to
15 tell you about what we're doing, but it is going to
16 be a focus of trying to dissect if we're sending a
17 clear message to the field, how this fits in with
18 the other engagement awards. And so, I guess, I
19 hate to say stay tuned, but that's definitely high
20 priority on my agenda.

21 CHAIRMAN NORQUIST: Thanks. Freda.

1 DR. LEWIS-HALL: Freda Lewis-Hall. Jean,
2 I am sure you have answered this question for me
3 before, but the FDA is having kind of a fairly
4 large and expansive set of activities to engage
5 around drug development and safe and effective use,
6 and I'm wondering if we have any plans or have
7 initiated any interface with them or if you believe
8 that's appropriate.

9 MS. SLUTSKY: We actually had a rather
10 large meeting with our FDA colleagues about two
11 weeks ago talking about how we can share best
12 practices. It actually was supposed to be an hour
13 meeting and Sue, you can correct me if I'm wrong,
14 but I think it lasted almost two and a half hours
15 where they were very interested in what we were
16 doing; we were very interested in what they were
17 doing, but they came away saying that they'd
18 learned a lot from our engagement activities at
19 PCORI.

20 CHAIRMAN NORQUIST: Others?

21 MS. SLUTSKY: Joe, you can't ask any

1 questions.

2 CHAIRMAN NORQUIST: You can't ask a
3 question.

4 DR. SELBY: So, thank you, Mr. Chair. Joe
5 Selby. Jean, you moved pretty quickly over the
6 engagement officer and I'm not sure we've ever
7 really discussed engagement officers with the Board
8 and I thought you also mentioned the rubric and I
9 thought a little bit more information on what these
10 engagement officers are going to be doing and how
11 the rubric might fit in would be good.

12 MS. SLUTSKY: I apologize. I didn't know
13 that the Board hadn't necessarily been briefed on
14 this.

15 The engagement officers, it's a new
16 concept where we pair individuals who work with the
17 different portfolios and the investigators on
18 developing and monitoring the engagement plans and
19 ongoing funded projects. And, for example, we have
20 an intern who's working closely with the Patient-
21 Powered Research Networks. Just hired someone

1 who's working with other portfolios on their funded
2 projects. So, it's to really draw someone in to
3 help monitor the engagement plans as well as how
4 we'll they're doing.

5 The rubric is -- and Sue could probably
6 give a much more detailed discussion of that, but
7 it's really a framework and discussion about how to
8 develop an engagement plan, how to engage patients
9 and families in developing your research study and
10 monitoring your research study, and it allows
11 people -- it shows people actually how to develop
12 an engagement plan as part of their research
13 application.

14 CHAIRMAN NORQUIST: Sharon.

15 DR. LEVINE: Yeah, that is a really
16 terrific --

17 CHAIRMAN NORQUIST: Sharon Levine talking
18 now.

19 DR. LEVINE: Sharon Levine, Board member.
20 Sorry. One out of two isn't bad. This is a really
21 important piece of work because I think one of the

1 most confusing things about PCORI's out of the gate
2 request for proposals has been, well, what the heck
3 do they mean by engagement, what are we supposed to
4 do, how are we supposed to represent this, and our
5 own concern about people putting words on paper and
6 not actually knowing what to do with the words
7 they've put on the paper. So, this is fabulous.

8 MS. SLUTSKY: Well, I can't take any
9 responsibility for it, so kudos to the engagement
10 team for pulling it together, but I'm happy to take
11 your gratitude on their part.

12 CHAIRMAN NORQUIST: You know, I think
13 we're all very appreciative of that. You can take
14 credit for keeping it moving forward. At least it
15 didn't come to a screeching halt when you came,
16 right?

17 Okay, good. Thank you, Jean, very much.
18 You're off the hook this time. Just wait until
19 next time.

20 And next, before our break, Michele Orza -
21 - where's Michele? Oh, good. Okay. So, Michele,

1 who is the senior advisor to our executive
2 director, Dr. Selby, is going to present the
3 Evaluation Framework and Plan and we gave her 30
4 minutes. I expect we'll have more discussion on
5 this one.

6 MS. ORZA: Thank you. So, it's often said
7 that everyone thinks that evaluation is a good idea
8 but nobody likes to be evaluated. But at PCORI we
9 are different in all things and we are actually
10 extremely excited by the opportunity created for us
11 by our leadership to evaluate the heck out of
12 ourselves and welcome evaluation by others as well.

13 The work I'm going to discuss with you
14 today comes from a large and enthusiastic and truly
15 cross-cutting team of staff from every department,
16 the core of which is led by Laurie Frank in our
17 Research Integration and Evaluation Unit, and we
18 are extremely grateful for the assistance of our
19 evaluation task force, which is composed of three
20 Board members, Gail Hunt, Bob Jesse, and Bob
21 Zwolak; three Methodology Committee members, Robin

1 Newhouse, Mike Lauer, and Naomi Aronson and several
2 external experts as well. So, I'm pleased to have
3 the Board and MC members here with me today so that
4 when my allergies cause me to lose my voice, you
5 can chime in and fill in the rest of the story.

6 So, because we have committed at PCORI to
7 functioning as a learning organization, when it
8 comes to evaluation, the joint is really jumping,
9 and I'm only going to be able to give you really
10 just a flavor of all the things that are going on
11 under the heading of evaluation.

12 I have some modest objectives for this
13 presentation, to give you an introduction to some
14 of the things we're doing with evaluation, to give
15 you a progress report on some of the core
16 activities, and at the end, to give you a guide for
17 how you can follow up and dive in and help us with
18 making this progress further.

19 I'm pressing the wrong thing here.

20 So, currently we're focused on three main
21 sets of tasks, the first is to build our evaluation

1 framework, that is to delineate and prioritize and
2 flesh out all the questions that we and our
3 stakeholders have about patient-centered outcomes
4 research in general and about PCORI specifically,
5 determining how we can measure some of the key
6 things that we need to measure, namely our goals --
7 our three goals that we established, and engagement
8 in research, the discussion earlier about what
9 exactly is engagement, what do we mean by that, how
10 does one do it, and what effect is it having.

11 And then, finally, we have a lot of
12 evaluation activities that have been underway and
13 are being initiated on things that we already know
14 are high priority such as surveying certain
15 audiences and starting to attempt to assess the
16 impact that engagement is having on our work.

17 So, what is an evaluation framework? It,
18 very simply and straightforwardly, is the
19 organization of all of our questions and the
20 explanation of how we're going to go about
21 answering them.

1 So, at the end of the day, it's a giant
2 table that has these fields, the first column lays
3 out what the question is, the second column lays
4 out the metrics or the measures that you need in
5 order to answer it, the third column describes the
6 method by which you're going to go about trying to
7 answer the question, and the fourth column
8 describes the sources of the data that you will
9 need in order to answer that question. And at the
10 end I'll show you what this looks like for one
11 specific question.

12 So, our evaluation framework is all
13 encompassing, it's everything that's going on with
14 the entire organization and so it's very large and
15 kind of overwhelming, but we break it down into
16 three sets of questions. The first set is -- are
17 the questions about our day-to-day work. So, what
18 are we doing? How effectively are we doing it?
19 Are we on track? And most of these questions wind
20 up being reflected on our dashboard. I'm not going
21 to say too much about this bucket because Joe is

1 going to go next and talk you through our dashboard
2 except to say that there's a lot of interesting
3 stuff in here and even though we're just at the
4 stage of kind of describing what's going on and
5 counting things and laying things out, you really
6 learn a lot in that process.

7 Fred Mosteller always used to say that the
8 first three rules of data analysis were, look at
9 your data, look at your data, look at your data,
10 and in doing that we learn a lot, we gain a lot of
11 insight, and we develop a whole lot more questions.

12 So, Joe will be going over -- I think
13 there's almost three dozen metrics on this one
14 page, he'll be going over that with you next.

15 The second set of questions are the
16 questions about our three goals. Are we on track?
17 And are we, in fact, accomplishing those goals?
18 And what I'd like to tell you is just a little bit
19 about how we're going about tracking and measuring
20 the attainment of each of our goals.

21 So, the first goal, as you all know, is to

1 produce useful information. So, every word in this
2 statement of our goal is important. We are, for
3 example, we have a whole set of methodology
4 standards that go toward ensuring that the
5 information that results from our studies is of the
6 highest quality and is trustworthy, but what we're
7 really focused on in terms of developing metrics
8 and in terms of defining success on this goal is
9 producing useful information.

10 And so, we've been focusing a lot of
11 attention on how do we define and how do we measure
12 useful information.

13 We set about doing this by asking the
14 users or the people who -- the would-be users of
15 the information, what would make it useful for
16 them. So, we looked at the literature on this. We
17 partnered with the National Health Council on an
18 effort that they had to define these criteria, and
19 we've been consulting with our advisory panels and
20 our patient engagement advisory panel and a variety
21 of stakeholders to ask them what would make

1 information useful to you so that we can then
2 translate those into criteria that we would try to
3 bake into our processes so that the information
4 that results at the end is useful.

5 This is a draft set of criteria and what
6 we're doing with these now is pilot testing them on
7 some of our applications and cross-walking them
8 with the criteria that we already do have, such as
9 for topic selection or for merit review and the
10 methodology standards to see to what extent we've
11 already captured a lot of these things in our other
12 criteria and to what extent do we actually have to
13 develop new ones.

14 So, we can't say anything much about the
15 actual usefulness of our information until the
16 studies are done, but what we can say now is to
17 what extent does it look like these studies that
18 we're funding have the potential to yield useful
19 information. And so the first thing we're planning
20 to do is, once we refine these criteria, actually
21 apply them to our portfolio in the spirit of

1 saying, well, does it look like these at least have
2 the potential, if they are successfully completed,
3 to yield information that people will find useful.

4 And the other thing that we can do is we
5 can actually talk to our stakeholders about -- and
6 have them take a look at what's in our portfolio
7 and let us know whether they think it has potential
8 to be useful to them when it's completed.

9 But that's just what we're able to do now.
10 But ultimately, the test of whether or not we're
11 producing useful information is going to be whether
12 or not people are actually using it, and so we're
13 not letting ourselves off the hook for that. We
14 ultimately are going to be looking at that as well,
15 it's just this is what we're doing on the short-
16 term to be able to say something about usefulness.

17 So, for our second goal, we really have to
18 wait on this one, we can't tell whether anybody's
19 using our information until the information is
20 actually created for them to use. So, what we've
21 been doing here is focusing on once we have it, how

1 will we determine whether or not it's being used
2 and implemented.

3 So, we've been developing a set of
4 indicators or metrics here. They start on the left
5 hand side with very modest measures that initially
6 are more about how effectively we're disseminating
7 than whether or not anybody's actually taking the
8 information up, and they -- toward the middle they
9 become more and more reflective of whether
10 anybody's actually taking up the information and
11 using it, and then at the far right, it really
12 becomes a question of is this information actually
13 being implemented and actually having an impact on
14 decision making, on healthcare, and on health
15 outcomes.

16 On the left hand side, these are all
17 things that can readily be measured. There are
18 some existing systems and data sources and ways of
19 measuring this that we can take advantage of and it
20 gets harder and harder. Some of these things we
21 actually have to create and they will be resources

1 intensive for us to track, and then when we get to
2 the far right, really looking at impact. Those are
3 going to be very challenging kinds of metrics to
4 track and so we're thinking that we try to do
5 everything on the left hand side for every study,
6 but maybe we focus in on a smaller set of studies
7 as we move toward the right.

8 And then finally our third goal, to
9 influence research, we had initially thought that
10 we would have to wait until we had something to
11 show for ourselves before we started influencing
12 people, but we're already detecting that that's not
13 true, that people are very excited about patient-
14 centeredness, they're very excited about
15 engagement, and we're already starting to detect
16 some influence.

17 So, these turn out to be things that we
18 actually can start to measure now and we are trying
19 to put the systems and the means in place to track
20 some of these things.

21 We're able to look at, for example, and

1 this was said earlier too, the extent to which
2 people are being influenced by our methodology
3 standards and things like whether or not they're
4 using the guidance that we put out about engagement
5 or about patient-centeredness.

6 So, we think we will be able to tell you
7 something about influence probably in the next
8 quarter or two, definitely by the end of the year.

9 Finally, the third set of questions in the
10 framework, the kind of all-embracing, all-
11 encompassing set of questions go to the questions
12 about our approach, the PCORI way. Does research
13 done differently in fact make a difference, or what
14 difference does it make? And these are some of the
15 toughest and the most ambitious, but also the most
16 important questions for us to be able to answer.

17 So, what we've done here, and it's on the
18 web, we didn't put it in your binder or attempt to
19 show it here because it's 26 oversize pages long,
20 but what it basically does is sort of -- for each
21 ingredient in the PCORI recipe, it lays out a

1 diagram, for those of us who are visual, that kind
2 of shows what our theory is about how that
3 ingredient contributes to the total recipe, and
4 then after that comes a table, like I showed you
5 initially, that lays out what all the questions
6 are. And it's all -- it's just questions, it's all
7 plain English, it's straight forward questions
8 about, you know, if we do this, will it result in
9 that. If we take this approach, will it lead to
10 that?

11 So, these are the sections in it. There
12 is an entire section that focuses on engagement in
13 research, but what you will find, because it's such
14 a key ingredient for PCORI, is that questions about
15 engagement are also in all of the other sections.

16 So, what would really be helpful from you
17 all is if you would adopt a section of the
18 framework that particularly interests you and
19 actually take a look at it and let us know whether
20 or not you see your questions reflected in it so
21 that we can be sure that we're really capturing

1 what's important.

2 This is the first draft that we've posted.
3 We've had a lot of input but we'd like to be sure
4 that we're capturing all the questions and
5 prioritizing them before we move on to tackling
6 them.

7 So, on the really big question of what
8 difference does engagement make, we actually have
9 had quite a bit of activity underway, especially
10 with respect to merit review. We've been looking
11 at what difference engaging patients and other
12 stakeholders in merit review had been making to
13 that process and that work is ongoing and I believe
14 that Joe presented it at a previous meeting and
15 that we have a paper that was accepted and will be
16 coming out soon on this.

17 We also are attempting to study what is
18 the effect -- what are the early effects of
19 engagement in research. And in order to do that,
20 we really needed to have a way to capture and
21 describe exactly what is going on with engagement

1 in our studies, and so we have developed this tool,
2 we're calling it the ENACT, which is a self-
3 reported tool to measure and describe in very great
4 detail what is actually going on with engagement in
5 our funded projects, and we've developed slightly
6 different versions of this tool for the pilot
7 projects, the CER studies, and the PCORNet
8 projects, because they have slightly different
9 needs.

10 This tool has been in development for
11 quite a while and it's been pretty thoroughly
12 tested and vetted and we think we're ready to give
13 it a try. So, it started off as something that we
14 developed in the context of the Pilot Project
15 Learning Network and it has been developed in close
16 coordination with the Patient and Family Engagement
17 Rubric.

18 So, it captures a lot, as I said, about
19 engagement, who's engaged, who are they, how are
20 they forming these partnerships, to what degree or
21 at what level are they being engaged, what are they

1 being engaged in, exactly, what are the effects
2 perceived by different members of the team on the
3 different aspects of the research process, what are
4 people to finding to be the challenges in the
5 facilitators, and what are people learning, and how
6 are they finding the PCOR principles to be
7 implemented or not.

8 So, what we're hoping to do with this is
9 assess all of the studies that have -- when they
10 reach their 12-month point, and we have a bunch of
11 those now. And we think that at this phase we can
12 tell something about what the impact of engagement
13 has been on the formation of the research
14 questions, on the study design, on the functioning
15 of the study team, and perhaps on the earliest
16 phases of recruitment, and we hope to be able to
17 report that to you by the fourth quarter for this
18 first batch.

19 So, as I said, this is the blank table
20 that I showed you at the beginning, just filled in
21 for one of these engagement questions. So, what is

1 the effect of patient and stakeholder engagement on
2 the functioning of the study team and on the study
3 design? To figure this out, we need to be able to
4 measure with some precision what we mean by
5 engagement and what exactly is going on in the
6 studies.

7 And so, we've developed the ENACT. The
8 methods that we'll be using will be a combination
9 of qualitative and quantitative ones and the
10 sources for this will be what we learn from
11 applying the ENACT tool, the progress reports that
12 the studies are required to submit every six
13 months, and the conversations that are had with the
14 study teams by both project and engagement
15 officers.

16 And we would love it if you would like to
17 know more and if you would like to help us out,
18 these are some of the things that you can check
19 into if you're interested. One, we are blogging
20 about this as often as we can and we post the
21 materials that go with the PEG meetings also along

1 with these blogs. We have, as I said, now posted
2 the evaluation framework so you can take a look at
3 that.

4 We had also earlier posted the usefulness
5 criteria if you would like to comment on those and,
6 as always, you can comment on anything and
7 everything through the info@PCORI.org.

8 And I think that's all she wrote.

9 CHAIRMAN NORQUIST: All right. Thanks,
10 Michele, and Joe will present the dashboard after
11 the break.

12 MS. ORZA: Correct

13 CHAIRMAN NORQUIST: So, we have time to
14 talk about just evaluation now. We'll go
15 clockwise. Let's start with Ellen.

16 MS. SIGAL: Do we have time for questions
17 now?

18 CHAIRMAN NORQUIST: Yeah. We're doing
19 this now and then we take a break and then we come
20 back and Joe does the dashboard, so we just want to
21 have comments on what Michele --

1 MS. SIGAL: So, thank you. It's really
2 useful. I like your evaluation criteria. I think
3 it's important because we really need to understand
4 what engagement really does yield and what is
5 different. But I'm a little perplexed about where
6 you started from in terms of usefulness and impact.
7 I mean, isn't that really our criteria? Aren't we
8 funding everything based on its utility and its
9 impact? Isn't that a core value that we have?

10 So, I'm kind of confused. I'm not
11 confused on the back end on how you're going to
12 evaluate and, you know, understanding the utility
13 of the methodology and on the -- the patient-
14 centered aspect, but isn't that just core that
15 everything that we fund should have -- should be
16 useful and should have impact?

17 MS. ORZA: Absolutely, and I think that's
18 what we think -- we hope that we have captured
19 through our topic prioritization process, through
20 our merit criteria, through our methodology
21 criteria. We hope that we have a process which

1 identifies and funds only studies that are likely
2 to yield useful information.

3 What we're trying to figure out through
4 these usefulness criteria is whether we've missed
5 anything. So, in what other people are telling us
6 would be a useful study, is there some distinct --
7 something distinct there that isn't already
8 captured in one of our merit review criteria or our
9 methodology criteria? And we're kind of in the
10 middle of that analysis, so we're not sure yet.

11 In other words, usefulness is maybe a
12 little bit different than impact or significance.

13 MS. SIGAL: We're hoping to re-analyze our
14 criteria for funding on usefulness and impact,
15 because, again, those are core values, those are
16 core criteria, I would think, of anything that we
17 fund. So, we want to see if we missed it or we're
18 not evaluating it or capturing it, is that it?

19 MS. ORZA: Yep.

20 DR. WEISMAN: One is intent and the other
21 one is what happened.

1 MS. SIGAL: For funding that would be -- I
2 mean, if we go through the criteria of peer review
3 and we're funding something, theoretically we --
4 the potential for it to be useful in impact would
5 have been there in the criteria?

6 It would be disappointing if we missed it.

7 CHAIRMAN NORQUIST: That's a very good
8 point. It will be very disappointing.

9 MS. ORZA: We will be very disappointed.

10 CHAIRMAN NORQUIST: Yeah, we'd better
11 hope. Yeah. Okay, Harlan Weisman.

12 DR. WEISMAN: Harlan Weisman. Michele,
13 thanks. It's a great undertaking and I just in
14 general really like the framework that you
15 outlined.

16 I have two major comments. One is about
17 not just developing the framework, which the
18 working team has done, which as I understand it is
19 internal except for two external people we've
20 appointed to participate. But it's largely a self-
21 evaluation and I think the most useful information

1 often comes when you ask not only self-evaluation,
2 but ask others on the outside to participate in the
3 evaluation, you know, 360 type thing, and I'm
4 wondering whether that's been considered.

5 We talked about it at the Board about 18
6 months ago and one thing that externally people
7 have commented on historically about PCORI is the
8 question of whether we're going too slow.

9 So, you mentioned, for example, that a lot
10 of our studies -- you know, it's premature for us
11 to look at usefulness because we don't have the
12 results yet, but should we have the results?
13 Should we have funded things that -- where we would
14 have the results? And, in fact, if we looked at
15 our portfolio, my guess is that many of the
16 studies, and certainly when you look at that chart
17 of dissemination, uptake, and impact -- many of
18 these things will maybe not only outlive PCORI, but
19 maybe PCORI Board members in terms of when those
20 things can be measured.

21 That's not bad. We should have something

1 -- an annuity of ongoing influence, but shouldn't
2 we also have things in which we have influence, you
3 know, sometime in the next year or two? And that's
4 something I wonder about because I don't know the
5 answer to that question.

6 So, timeliness, to me, is a big deal and
7 the idea of should we be getting external review as
8 well as internal self-evaluation before the general
9 -- the GAO does their thing?

10 And then one last -- more minor -- is we
11 used to talk about -- I remember conversations with
12 Joe about this. Usefulness is important, but so is
13 usability. You know, if I find -- just as a
14 trivial example -- I find often when I buy
15 something and I look at the instruction manual,
16 there's probably a lot of useful information in
17 there, but I can't discern it, it's not very
18 usable, so I think both of those criteria are
19 important.

20 MR. KUNTZ: Rick Kuntz, Board member. I
21 want to essentially echo Harlan's comment. I think

1 that what you have is a really good operation plan,
2 it's really good, but we probably ought to invest
3 in having external review just basically re-gage,
4 and I would probably recommend that what we do is
5 just set the objectives of what you want to have
6 them evaluate and let them figure out the methods
7 to evaluate them, and the idea that Harlan said,
8 the 360, I think it's not what you want to do in
9 your operational stage, you know, you were going to
10 gauge your projects by what you're doing by exactly
11 what you've laid out here, but it would be good to
12 get a biopsy from the outside.

13 CHAIRMAN NORQUIST: Alicia.

14 DR. FERNANDEZ: Thank you. Alicia
15 Fernandez, Board member. This is a very lucid and
16 such a thoughtful approach to laying out what the
17 evaluation questions should be and how one could
18 begin to approach them.

19 I wanted to come back to the evaluation of
20 this question number three around patient
21 engagement, which may be the most novel component

1 that PCORI has to date added to the large
2 scientific research work. And it may simply be
3 that I did not follow it completely, but I wanted
4 to go back to the slide where you talk about the
5 methods and the sources -- sorry, the slide number
6 -- you got it -- and the reason I want to come back
7 to this is, and I think it may be hidden in here,
8 is we are asking the patients, right, and we are
9 asking the stakeholders in the sources, not just
10 the project and engagement officers, right? And I
11 wonder whether there may be -- and I assume part of
12 that is through this ENACT tool, but the reason I
13 make this comment now is that the window may close
14 on learning about all of the things that do not
15 work as we go through them in real time, and I
16 wonder, because this is such a novel component that
17 PCORI is bringing and because there should be many
18 ways that people are approaching this, I wonder
19 whether the evaluation group has considered
20 investing in a qualitative evaluation that is
21 fairly granular in terms of following along some of

1 these projects, and doing so from not the
2 perspective of the project officer of the
3 scientific research team, but from an outside
4 perspective that can really interview all three
5 proximal stakeholders? I hope that was clear.

6 DR. FERNANDEZ: Helpful. Thank you.

7 CHAIRMAN NORQUIST: Joe, it's your turn.

8 DR. SELBY: Joe Selby. So, I just wanted
9 to reemphasize this notion of -- two things, one,
10 the notion of usefulness. That's a word that we
11 actually didn't invent. I mean, patient-centered
12 we didn't invent either, but patient-centeredness
13 with respect to research, we were just about the
14 first to talk about it, and now it's -- everyone is
15 talking about patient-centeredness in research as
16 well as in care.

17 And I think usefulness we did not invent,
18 actually, the first place that I heard it was
19 developing a concept of usefulness. It came from
20 the National Health Council, Mark Boutin and others
21 at the National Health Council. We have been

1 working with them and I think Michele showed you a
2 pretty advanced definition.

3 One of the characteristics of usefulness
4 is it's something you can assess at the level of
5 the funded awards before the research is done, in
6 one way, and then you assess it again when it's
7 completed, but I think we are -- this framework
8 stakes quite a bit on a definition of usefulness
9 that started externally, that actually we have
10 compared notes with them and I think they feel like
11 we have a very good handle on measuring usefulness,
12 but it's a metric that we would be well served, I
13 think, to promote as well as to apply, and engage
14 in debate and get perfected, because I think it's
15 going to become a byword and it would be nice if we
16 were in the lead.

17 And I think that until you can show that
18 you've got useful results, it's better to be able
19 to say that you've got useful research. I take
20 Ellen's point that everything we do should be
21 useful by definition, but I think -- I really think

1 that the criterion that we've come up with is
2 probably even a little bigger than what we asked
3 applicants to come up with.

4 So, I do think it will be worth our
5 measuring and it will be helpful to us,
6 particularly until we get the results.

7 The second thing is this notion of an
8 external evaluation. I don't have any problem with
9 that and I think we could commission one or
10 encourage somebody else to just undertake one, but
11 if we are a learning health system, we're also
12 going to be evaluating ourselves regularly and
13 especially if we say that we're at the cutting
14 edge, I think we're going to perhaps trust our own
15 evaluations rather than those of others for a
16 while. So, I think we really -- and the last thing
17 to be said about that is that the engagement group
18 really does bring in external expertise to go with
19 the Board and Methodology Committee and staff. So,
20 I think there's -- probably we're going to get more
21 out of this internally than we would from most

1 external evaluations today.

2 CHAIRMAN NORQUIST: Okay. Bob Jesse?

3 DR. JESSE: Bob Jesse, Board. So, in the
4 end, knowledge is information put to productive
5 use. And as a final measure, that's really what it
6 comes down to, but I think everything else, and
7 particularly process measures are informing, and in
8 many respects, they're going to be informing about
9 both the fidelity of the work that we are doing or
10 we are awarding contracts to do, meaning, are
11 people doing what they said they were going to do
12 and in the way they said, and also informing, I
13 think, about the process of research, which then
14 speaks to efficiency and value.

15 And so, there's a lot of measures in here,
16 but I think they all have a role, all are
17 important, all will keep us well grounded, well
18 poised, but in the end, the external evaluation is
19 going to come around knowledge. Have we generated
20 the knowledge that changes how healthcare is
21 delivered in this country?

1 CHAIRMAN NORQUIST: Deb?

2 MS. BARKSDALE: Debra Barksdale, Board.

3 Since Joe brought up about the usefulness criteria,
4 I did have a question about that particular slide.
5 I was going to let it pass, but now I think it will
6 -- I am curious about the use of the word "would"
7 as a criteria, as opposed to "should" or "could".
8 Can you explain a little bit about -- I know it's
9 semantics, but words matter, so what -- and under
10 the first bullet, "People who would use the
11 information have been identified. People who would
12 use the information are asking the right
13 questions." What does that mean?

14 MS. ORZA: This formulation of the
15 criteria is to apply them to assess potential for
16 usefulness. I'm not sure I understand the --

17 MS. BARKSDALE: Understand the question?

18 MS. ORZA: Yeah.

19 MS. BARKSDALE: People -- so, you have
20 "People who would use the information have been
21 identified." So, I guess I don't understand -- so,

1 you're identifying people who would use the
2 information as opposed to people who should use the
3 information or could use the information?

4 MS. ORZA: So, the first three criteria
5 relate to trying to establish whether or not the
6 extent to which the idea for this study or the
7 question underlying this study is user-driven. So,
8 does it come from the people who would want this
9 information or who need this information or who
10 would use it if they had it? That's the sense in
11 which we --

12 DR. LEWIS-HALL: Can I take a run at this?
13 I think I know where you're going, which is, let's
14 take a group of primary care physicians that treat
15 a certain population. These are people that should
16 be applying this information. And your question is
17 whether or not the ratio would be right if we only
18 measure "would" use it. So, there are 100
19 physicians that should be applying this information
20 in order to improve the outcomes of their patients.
21 How can we measure, right, but only 20 would

1 according to this measurement. I think we want to
2 close that gap. We want to say -- we want to
3 measure who would against who should, not just who
4 would.

5 I think I just made it worse.

6 [Laughter.]

7 MS. ORZA: It's kind of the -- sorry.

8 DR. LEVINE: Sharon Levine, Board member
9 using thing microphone. I think to some extent I
10 think the difference is that in some ways the way
11 this is formulated, and by the way, I think this is
12 right, is people who in an ideal world, because of
13 the nature of their practice, would use this
14 information, is what you're trying to get at. The
15 question of closing the gap between those who would
16 and those who should is a different set of
17 activities. It's around dissemination, it's around
18 education, it's around engagement of the
19 clinicians.

20 But starting with identifying that
21 population of either clinicians or patients who in

1 an ideal world would use that information, because
2 it should be of high utility to them based on our
3 best ability to estimate that, then we get to ask
4 the question later of, okay, now that we've done
5 that, how do we close the gap between those who
6 should use it and those who are using it. Does
7 that help?

8 CHAIRMAN NORQUIST: Maybe we have some
9 more discussion to do on this one. For now --

10 DR. SELBY: Could I --

11 CHAIRMAN NORQUIST: -- I think a concrete
12 example of where you have this might be much more
13 helpful than the hypotheticals or something where
14 you'd put this into place if we had an example of
15 where you actually did an evaluation using this
16 might be very helpful to make sure we're addressing
17 what the concerns are here.

18 DR. LEVINE: But to some extent you're not
19 going to -- I mean, the goal isn't to have the
20 universe of users drive this, it's those whom you
21 can identify who are situated in a way that they

1 would, should, could, and ought to need to use the
2 information in order to get beyond that first
3 question.

4 DR. DOUMA: I agree with Freda, a concrete
5 example of how you would measure who would versus
6 who should and what's the difference, and just give
7 us an example.

8 MS. ORZA: This first set of three, which
9 is trying to get at the notion of whether this, you
10 know, this question is being asked by the end users
11 or whether this study is being sort of driven by
12 the people who would want and who would use the
13 results is a little bit different than the other
14 two sets because it's almost like it's a scale,
15 right? I mean, at a minimum, if you're looking at
16 an application, you would want the investigators to
17 have clearly identified the users, the end users of
18 this information.

19 And the third criteria we really think is
20 the ideal, that this question, this study is really
21 coming from the end users. So, that's kind of the

1 sense in which we -- you know, you're looking at an
2 application and you're trying to gauge how well
3 they've convinced you that this is really a user-
4 driven, that there's a set of end users out there
5 who are really wanting and waiting for this study,
6 which will increase the likelihood that it gets
7 used. That's kind of what they're driving at.

8 CHAIRMAN NORQUIST: So, yeah.

9 DR. DOUMA: While we're on semantics, the
10 real word -- the clear answer, I think it's
11 important that we have the concept of oftentimes we
12 won't ever have a clear answer in our lifetimes and
13 that decision making is based on unclear
14 information but it still may be useful, and we
15 don't want to throw out the baby with the
16 bathwater.

17 CHAIRMAN NORQUIST: So now that we've had
18 all our semantic games, I think it's time for a
19 break. My brain is gone at this point. So, let's
20 do this, let's take a break. I'm sorry, Francis,
21 did you want to say -- did you have your card up?

1 Yes, it's now up. Okay, go ahead.

2 DR. COLLINS: I'm just thinking, anybody
3 who is listening to this discussion on the phone
4 must have wondered what they'd walked into if they
5 just tuned in the last ten minutes and we got into
6 "coulda, woulda, shoulda," in a way that I've never
7 quite heard debated before. It's really
8 fascinating.

9 I just wanted to enter the colloquy
10 between Rick and Joe about who does the evaluation
11 on the side of both, and, instead of either/or, and
12 maybe that's what you're both saying.

13 I do think PCORI is in a great position to
14 be able to do its own evaluation and must do so.
15 If I have any concerns about the plan that's put
16 forward here it may be that it's even a little
17 over-engineered and you have to be careful not to
18 lose the forest for all the trees that you're going
19 to be cataloguing.

20 But I do think for credibility on the
21 outside, and for other reasons of getting a fresh

1 perspective from people who don't have some
2 particular reason to want it to look good and we
3 all probably have some of that, if we're honest
4 with ourselves, you need to have that outside look
5 as well.

6 And GAO will do some of that, but you
7 don't want to depend on GAO to be your only outside
8 evaluator.

9 CHAIRMAN NORQUIST: I think you're
10 absolutely right and we should think about what
11 that -- certainly not as comprehensive as what
12 we're doing or something like this.

13 So, we'll revisit this, I'm sure, some
14 more, and as we get more concrete examples, it will
15 help us do the semantics, I think, to some degree.

16 So, let's take -- we have a 15- minute
17 break, which brings us back -- well, probably at
18 3:30 is the way we usually operate. So, we'll be
19 back at 3:30.

20 [Recess.]

21 DR. NORQUIST: Okay, we are getting ready

1 to start back up again. We will now restart our
2 afternoon session and we're going to pick up with
3 Dr. Selby who is going to present the actual
4 dashboard. So, those slides should be coming up.
5 Are you going to sit here and do it?

6 DR. SELBY: That's right.

7 CHAIRMAN NORQUIST: I'm fine. Yes.

8 DR. SELBY: So, thanks, Gray. This is Joe
9 Selby and I'm just going to put this up just so you
10 can feast your eyes on it and make some
11 introductory comments.

12 This is the first time we've shown a
13 dashboard like this to you. Up until this point
14 we've shown you a dashboard of one-offs, things
15 that have to happen and have they happened, so that
16 was the 2013 dashboard.

17 If you notice on this, you see a lot of
18 arrows moving from left to right, you see some
19 trends over time, so the dashboard from now on is
20 going to be a longitudinal instrument to show you
21 changes over time and hopefully progress.

1 I don't have any doubt that after I get
2 finished with this presentation you're going to
3 suggest that some items on this dashboard are
4 really not very informational and don't need to be
5 continued, you can save the real estate. And I
6 hope that you'll also, working with us today and as
7 we go forward every quarter looking at this updated
8 report that you'll -- that we together will come up
9 with other metrics that better reflect what we
10 think is meaningful progress. And so that after
11 two or three quarters of looking at this, this will
12 become a document that we all know and if we don't
13 love it, at least we'll understand it and be able
14 to spot changes as they happen over time.

15 The last thing to say is that there are
16 several items on here that are still in development
17 and I'll point those out as we get to them.

18 And then I also have some slides behind
19 these that back this up, but I will try, starting
20 in the upper left, to introduce you to this
21 dashboard and what's on it and I have a better

1 slide than this one. The upper left most graphic
2 shows you it's all in percents so by cycle three,
3 there are four vertical bars and they are from left
4 to right. The applications, as a percent of LOIs,
5 so you'll recall that we always get about 40
6 percent of our LOIs turn into applications, and
7 that's pretty steady over time. Maybe it's going
8 up a little bit in the most recent -- the August
9 and then winter 2013 applications.

10 The next bar is the awards as a percent of
11 applications, so that's basically the pay line, and
12 you'll recall that it was down around 5 percent in
13 the very first cycle, but after that it's been
14 between 10 and 11 percent and that's where it has
15 stayed as far as we can see, which is through the
16 August 2013 award cycle. The others, we don't have
17 the awards yet.

18 So, the pay line remains about 10 percent.
19 The third bar, and it only kicks in in cycle three,
20 is resubmissions. So, the light blue is
21 resubmissions as a percent of the total number of

1 applications and you'll see that each time that
2 looks like it was about 10 to 15 percent of the
3 applications were resubmits. And the fourth bar,
4 the bright purple bar, shows that both times the
5 resubmissions did much better than the overall pool
6 of applications.

7 Moving down then, and I hope you can see
8 this better than I can, it seems like the focus is
9 off or else my glasses are, the next one, and I
10 don't think we have a slide that shows this, the
11 next one is the priority topics. So, these are
12 targeted PFAs and other high priority items that
13 are sent to the pragmatic clinical studies
14 announcement.

15 So, a total of 40+ high priority topics
16 have been processed and identified, either by the
17 Board initially, or subsequently by the advisory
18 panels. Fifteen of those made their way onto the
19 list of the pragmatic clinical studies and I showed
20 you the results of the first solicitation from
21 that, and under the column called "funded", none of

1 those have been funded. The first funding will be
2 in January of 2015 after the reviews in November.

3 Then the targeted PFAs, we have three
4 targeted PFAs that have been funded and those are
5 the prevention of falls in the elderly -- and when
6 we say funded we mean the funding has been
7 transferred to NIA, and by the way, we're just
8 about to announce the awardee of that and we will
9 certainly let you know with great detail when that
10 is announced -- and the second one are the asthma
11 awards that Romana reviewed a little bit ago. And
12 third -- under the asthma targeted PFA -- and the
13 third is the uterine fibroids targeted PFA, and
14 that announcement is still a bit away. The reviews
15 have been done, but the announcement is not quite
16 ready.

17 And then the three others that Romana also
18 told you about that I think at least two of those,
19 the treatment of obesity in high-risk populations,
20 there's one for improving health systems on
21 transitions in care, and the third one that has

1 been approved, I believe, is the -- yes, the blood
2 pressure control in minority populations. So,
3 those are the other three targeted PFAs that have
4 been approved by the Board and are in development.

5 DR. DOUMA: Joe?

6 DR. SELBY: Yes.

7 DR. DOUMA: I've got a clarification.

8 There you have posted under targeted PFAs three --
9 funded three of six? Do you mean posted as six and
10 we've funded three of them?

11 DR. SELBY: And I should have said at the
12 beginning that I've got Michele right behind me and
13 sometimes I'm going to have to lean on Michele a
14 little bit for some of these details. So, Michele,
15 could you just address exactly the posted? I think
16 you're behind me, aren't you?

17 MS. ORZA: [Off microphone.]

18 DR. SELBY: Okay, so that would be obesity

19 --

20 DR. DOUMA: So, I'm just clarifying --
21 once something that is posted as funded, it comes

1 off the posted --

2 MS. ORZA: Correct.

3 DR. SELBY: What's the third one? I

4 mentioned transitions in care --

5 MS. ORZA: Promise.

6 DR. SELBY: Pardon?

7 MS. ORZA: Promise.

8 DR. SELBY: Oh. Okay, the Promise Awards.

9 Below that is a measure that we've just discussed
10 in detail, the usefulness, so by quarter four of
11 this year, so by the end of September this year, we
12 will report to you on the usefulness using the
13 criteria that we're developing in our portfolio.

14 We will also have early measures of
15 engagement impact by that time. So, those two need
16 some more development and then they particularly
17 need measurement within the awards.

18 DR. WEISMAN: What would that be, though,
19 because I thought Michele said it was very
20 difficult to do these before we actually have the
21 research?

1 DR. SELBY: No. We have, as I meant to
2 say earlier, usefulness is a concept that we feel
3 we can assess at the application level or at the
4 award level, so I think -- at the award level, so
5 this would be usefulness among projects that we've
6 awarded. So, you know, we have usefulness built
7 into the merit review process and we would hope, as
8 Ellen said, we would hope that what we wind up
9 funding does indeed meet usefulness criteria.
10 These criteria, as I said, were contributed to by
11 people including ourselves, so others have weighed
12 in too, we need to really promote the meaning and
13 measurement of usefulness and then apply it to our
14 portfolio just to give us a better sense that we're
15 on the way to useful results.

16 Engagement impact is the same, and then
17 beneath that is the first of several arrows that
18 you'll need to get a little bit use to seeing.
19 This is our commitment of research funding thus
20 far. So, the far right, you'll recall that in
21 lengthy discussions in, I think it was September,

1 when we were contemplating the 2014 budget, we
2 talked about committing \$528 million this year and
3 we converted that to committing a billion dollars
4 over two years at Dr. Goertz's advice.

5 The news is that if you look on a quarter-
6 by-quarter projection, we're currently at or very
7 slightly ahead of where we aimed to be at this
8 point, but the big news is that by the end of the
9 fourth quarter, we will not be at \$528 million.
10 So, Christine was absolutely right, and those who
11 agreed with her, and so you will see that next
12 quarter, and particularly at the end of the fourth
13 quarter, we will have funded a lot -- we will have
14 committed to funding a lot of research. We don't
15 think, at this point, it's going to come to \$528
16 million, but it will be in the \$400+ million range
17 for this year.

18 Okay, so that's -- I'm going to go to the
19 middle column now, the top bar, and this is a
20 question that the Board is asked a lot and I put it
21 up to you whether this is something you want to

1 continue monitoring over time or possibly do
2 something about.

3 So, this shows you the proportion of our
4 awards subtracting out the methods awards, the
5 proportion that are prevention, that's on the
6 bottom, the light green, diagnosis, that's the dark
7 blue and that's a very slender sliver of the total,
8 the light blue, which is treatment, so most of what
9 we evaluate is treatment -- most of what we've
10 funded is treatment, the green is screening and
11 then the other is kind of a composite, I think.

12 So, it really does not show much change
13 over time, perhaps a little bit of a drift up in
14 topics other than treatment, but I'm not sure that
15 it's at all meaningful, and I would just invite the
16 Board to -- now having seen it for five cycles --
17 oh, I'm sorry, the last one is the total, so
18 there's really only four cycles there -- having
19 seen it for four cycles, it does look like there's
20 a little bit of a drifting up, and whether this is
21 something worth following over time or worth doing

1 something about, either one of those, I think, is a
2 legitimate response. I mean, are we underfunding
3 in some area in way that you'd like to see us
4 change?

5 The next is the progress of projects from
6 the first -- from quarters one, two, and three, so
7 we have evaluated --

8 UNIDENTIFIED: [Off microphone.]

9 DR. SELBY: Let's see if I do here. Okay,
10 so this is what we've just been talking about. So,
11 you see the light blue is treatment, the dark blue
12 is diagnosis, the light green is prevention -- this
13 is an "all" column here, so these are the ones you
14 want to look at, this is if you want to look for a
15 trend, and if anything, this light blue is
16 shrinking a little bit over time, but I don't know
17 at all that's an important change.

18 This next one is progress of projects,
19 shows the results of our program officers
20 monitoring the projects to see if they're hitting
21 their milestones, and I have a slide later on about

1 this, but you'll see that at the -- for research,
2 so this is -- all the projects that are at six
3 months, and there may be a few that are at 12
4 months, and Michele, correct me if I'm wrong, but
5 this is the proportion that -- oh, I see, this is
6 two quarters, I guess -- quarter one and quarter
7 two of the research projects, of their life. So,
8 67 percent of projects were in compliance at the
9 end of quarter one and 63 at the end of quarter
10 two, and we do have a detailed slide coming up on
11 that and this is obviously something we'll want to
12 follow closely over time.

13 I'm going to move over to this little
14 table up here in the upper right. So, there's only
15 one number on here, and this is a learning
16 experience that these just don't project very well.
17 The application adherence to the methodology
18 standards. So, this is specifically adherence to
19 the methodology standards. And as Bryan explained
20 this morning, we've really only looked at one
21 quarter's worth of one round, the most recent round

1 where they were really expected to adhere, and we
2 found that 74 percent overall, at the initial
3 assessment, these were corrected before they were
4 funded, but at the initial assessment, 74 percent
5 adhered to the methodology standards using our
6 template, and I've got a slide on that.

7 UNIDENTIFIED: Quick question.

8 DR. SELBY: Yes.

9 UNIDENTIFIED: [Off microphone.]

10 DR. SELBY: Good. This is the new fiscal
11 year. So, the second quarter ended in the end of
12 March.

13 Okay, so the next is from our engagement
14 program, how we're doing with respect to the
15 Pipeline to Proposals awards. And this shows that
16 our planning called for us to be at this point here
17 and we're just a little bit ahead in terms of the
18 amount of funding we've awarded, but the planning
19 also says that by quarter three we'll be much
20 further than we are now.

21 So, this is about 31 projects funded and

1 we're proposing to fund 65 within the fiscal year,
2 and they should be funded by the end of the third
3 quarter, so we will see the next time we report
4 whether we stay -- whether we've actually got this
5 green dot moved out to here, whether we are up to
6 staying up with our plan. But for the moment we're
7 on schedule there. Yes?

8 MS. HUNT: Gail Hunt. Is that the awards
9 -- so, that's the Tiers 1, 2 and 3 --

10 DR. SELBY: Yes.

11 MS. HUNT: Is that just the awards or are
12 those the ones that have done well enough to now be
13 putting in a real proposal, which would be there's
14 the point, it's not just how many awards you gave
15 out, but are they -- did they move on to be able to
16 apply?

17 DR. SELBY: Right, and I think that's a
18 metric that we will have -- that's a metric that we
19 will have but we don't have it yet. This is just
20 the number, but it's a very good point.

21 MS. HUNT: I would say that would be more

1 valuable to have in -- sooner.

2 DR. SELBY: Yes. Okay. The next is the
3 result of surveys from four events, and I think
4 over time we're going to need a better way of
5 presenting this and, in fact, I believe I have
6 another slide that gives you -- so, the key point
7 to remember about this, too, is when you get this
8 packet -- when you get this report, you always get
9 a set of slides that back it up and there is a
10 slide that will detail this, but 86 percent of
11 participants in any of, I believe, it's four
12 engagement events say that they have done something
13 new with patient-centered outcomes research since
14 they participated in the workshop.

15 This is the ambassador training, and
16 that's actually -- you see that by quarter three
17 we're supposed to have 50 percent and 50
18 ambassadors trained. We were not supposed to have
19 any trained yet by the end of quarter two and
20 that's where we are. I think that we will -- I
21 think we're planning to hit that mark. I'm not 100

1 percent sure, but you'll see at the end of the
2 third quarter if we have.

3 So, just moving right below, the
4 completion of phase one of PCORNet looks like it is
5 a little bit behind and that is only because --
6 remember, PCORNet just started in quarter two of
7 2014 and our goal for the end of quarter one was to
8 have all the contracts signed. We fell just a
9 little bit short of that. All the contracts are
10 now signed and that's because these contracts were
11 extraordinarily complex and they were new, they
12 were new to us and they were new to the awardees,
13 so it took an amazing amount of work on the part of
14 our general counsel Mary Regina and our contracts
15 group, especially Scott Solomon.

16 So, they worked night and day, as, I think
17 it's fair to say that folks in program offices
18 around the country who were the awardees worked
19 hard too, but I know that we bent over backwards to
20 make this happen, and refined the contracts
21 somewhat in the process, learn from it, but that

1 was a lot of work. We have caught up, but that was
2 a lag and you'll see it reflected below, but that's
3 also why that's got a yellow title there, yellow
4 heading. Yellow means that we are off track to
5 some extent.

6 Just for the moment going down right below
7 that to speak to staffing, and Regina is going to
8 speak in the next presentation to both staffing and
9 expenditures, but you will see that we are actually
10 behind even our quarter one projection. So, we had
11 extraordinarily ambitious projections to be at 165
12 by the end of the year and nearly there by the end
13 of the first quarter.

14 So, we were at 118 at the end of second
15 quarter and we are now up in the 120-some where we
16 are hiring at a pretty steady pace and we've talked
17 a lot this morning about -- in the -- where was
18 that -- I can't remember exactly where we were
19 having this discussion, but doing a lot to orient
20 these folks and to get them plugged into the PCORI
21 system.

1 But we are behind, more behind the second
2 quarter, and I think we will still be behind at the
3 third quarter, but I predict -- and it looks for
4 all the world like we will be at 165 by the end of
5 the year.

6 Partly as a consequence of the delays in
7 staffing and partly as a consequence of delays in
8 submission by awardees of invoices, we are well
9 behind in spending too, but Regina will go into
10 much detail with you on that.

11 So, I just want to point over here.
12 Communications, I've got a slide a little bit later
13 on that shows that we are continuing to be well
14 above our expected goals in various aspects of
15 communications. Journal articles by and about --
16 and seriously about PCORI are accumulating. And
17 media mentions certainly are there.

18 The red one, the award to contract time,
19 last time we were very pleased to announce that we
20 had gone from 16 percent of contracts awarded
21 within 90 days to 80 percent. We've dropped to 37

1 percent but I'll show you some data in a minute
2 that nearly all of this is because of those 29
3 CDRN and PPRN contracts, which just took much
4 longer because they were first time and they were
5 very distinctive.

6 Contracts response time remains
7 remarkable, in fact, it's a little better even and
8 99 percent are answered within two business days.
9 And the science response time on the very bottom
10 has risen from 54 percent two quarters ago to 81
11 percent answered within three days, and this is, I
12 think, due to diligence on the part of staff but
13 also, it must be said, some growth in the staff, so
14 the capacity has improved.

15 DR. DOUMA: Joe?

16 DR. SELBY: Yes.

17 DR. DOUMA: On the communications side,
18 you're talking about the industry click-through
19 rate?

20 DR. SELBY: Yes.

21 DR. DOUMA: I saw this earlier and so

1 maybe I'm misreading it now. Is that saying it's
2 like 140 and 130 and 140? Those are the three
3 numbers? Anybody else can see --

4 DR. SELBY: Yes, it's 140 percent of the
5 target or the reference.

6 DR. DOUMA: Oh.

7 DR. SELBY: And on the first one, the
8 unique web visitors, the target was the same
9 quarter a year ago, so we are 50 percent ahead.
10 We've grown by 50 percent from last year.

11 The next one, though, the target is the
12 industry standard for the click-through rate and we
13 are 143 percent of that.

14 DR. DOUMA: Okay. Yeah, I was reading
15 that as your click-through rate was 140 percent and
16 I thought that was really ingenious --

17 DR. SELBY: That's right.

18 MR. KUNTZ: Joe. I'm a little bit
19 bothered by the one in expenditures, and I think
20 that's an indicator of are we doing our job, and I
21 just wonder why you're not using the accrual

1 system, meaning you've got outstanding invoices, we
2 should probably put the expenses accrued rather
3 than --

4 DR. SELBY: Can we defer that to Regina's
5 presentation? She's -- and she'll have Pam right
6 behind her, to respond to that. I appreciate the
7 comment.

8 Now I'm going to go kind of quickly
9 through -- this is basically the same information.
10 Now it's presented in numbers instead of percent,
11 so the percents don't quite let you know that the
12 number of LOIs is pretty steady. It's gone up a
13 little bit but in part because we're sometimes
14 tucking additional opportunities into the number of
15 applications received. But there's nothing else
16 new on here I don't think, a little bit new -- the
17 details on the asthma and the infrastructure awards
18 over there.

19 And this is, again, the composition of the
20 portfolio in terms of -- this is 169 applications,
21 the methods are excluded, this is the first four

1 cycles, and you see that 74 percent of our awards
2 are in the area of treatment, two percent in the
3 area of diagnostics, so I welcome any comment and
4 also the comment on whether we should keep
5 following this.

6 DR. COLLINS: So, what should it be?

7 DR. SELBY: That's for you to answer.

8 MR. KUNTZ: But we should have objectives
9 on these, right, so we can actually measure whether
10 we're meeting objectives.

11 DR. SELBY: It would be -- again, I'm
12 putting it out there as a matter of discussion. I
13 would be very interested on the Board's opinion on,
14 you know, I think that's the same question, metrics
15 on it or having --

16 MR. KUNTZ: And the slide before as well.
17 I mean, I think it would be great to know whether
18 or not we are --

19 DR. SELBY: You mean this one?

20 MR. KUNTZ: Yeah, what's our target --

21 DR. WEISMAN: The whole issue of

1 diagnostics is a tough -- being somebody who was in
2 the diagnostics business once. It's said that they
3 contribute up to about 70 percent of all medical
4 decisions and account for 2 percent of expenditures
5 and so it's by coincidence, that's what we're
6 spending too on research. It's tough because they
7 contribute a lot, but nobody wants to pay for them
8 and how we figure that out and their use and
9 appropriateness has always been a challenge.

10 DR. SELBY: I mean, it's interesting to
11 think about the possibility of a targeted funding
12 announcement in that area. Diagnostics.

13 DR. DOUMA: Also, self-care and self-
14 management, the parameters that we looked at
15 earlier in the disparities arena cut across those
16 things.

17 DR. SELBY: Yes.

18 DR. DOUMA: So, I think we need another
19 circle somewhere.

20 DR. SELBY: Maybe not too much in
21 diagnosis.

1 DR. LEVINE: Just a clarifying question.
2 Sharon Levine. When you say -- I assumed diagnosis
3 was different than diagnostics?

4 DR. SELBY: Well, diagnosis means, in this
5 case, studies of how to make diagnoses,
6 diagnostics, so I'm quite sure that this is
7 diagnostic testing. I don't know what diagnosis
8 would be as a --

9 DR. LEVINE: Okay, but --

10 DR. SELBY: -- as a counterpart to
11 prevention and treatment.

12 DR. LEVINE: So, diagnostic testing is --
13 diagnostics, at this point, is a term of art
14 referring to a specific --

15 CHAIRMAN NORQUIST: Wait, Bryan Luce can
16 tell us back here. What is it?

17 MR. LUCE: It's definitely diagnostic.

18 DR. SELBY: Meaning comparative
19 effectiveness evaluations of diagnostics.

20 CHAIRMAN NORQUIST: Okay, processes or
21 technologies.

1 DR. LEVINE: But not just technologies?

2 Okay.

3 CHAIRMAN NORQUIST: Not just technologies.

4 That's correct.

5 DR. WEISMAN: Just for clarification, and

6 I missed -- what I was taking about was in vitro

7 diagnostics, not the imaging and --

8 DR. SELBY: I'm sure most of this is --

9 very little of it is in vitro. There might be one

10 or two genetic testing studies, at the most --

11 CHAIRMAN NORQUIST: But we can dance

12 around this one, I think we can go back to the

13 question that Francis raised earlier, which is what

14 is the percentage -- who cares what --

15 DR. SELBY: Please.

16 CHAIRMAN NORQUIST: I mean, the issue is

17 we haven't had that discussion about what is the

18 right number here. I don't know what the right

19 number is, quite honestly.

20 UNIDENTIFIED: There are certainly

21 arguments to be made that we're under-supporting

1 prevention when we all would agree that the
2 healthcare system in general has been poor in
3 defining effective means of prevention and we have
4 a sick care system instead of a healthcare system.
5 This seems not to be making a big change in that
6 emphasis.

7 CHAIRMAN NORQUIST: Yeah, I would agree
8 with you. I think the prevention field would look
9 at this and say, you're way under where you need to
10 be on that.

11 DR. WEISMAN: It does reflect -- the
12 overall pie reflects an emphasizes on disease
13 management as opposed to health and, you know, we
14 always talk about healthcare but we're really
15 talking about disease management and that looks
16 like what we're doing as well.

17 CHAIRMAN NORQUIST: But to me this is
18 informative in the sense that it means that if
19 we're going to start targeting certain areas or we
20 want to -- maybe prevention topics are ones that we
21 should really look at as rising to a high priority

1 or something.

2 DR. SELBY: Okay. Just wanted to show you
3 the comparison of the funding level announced with
4 the funding level awarded, and so that's -- after
5 the first cycle, where we announced, I think --
6 well, it looks like we announced up to 120 million
7 and only funded 40 million, you recall that first
8 round we only funded about 5 percent of awards and
9 really the judgment was that that was about the
10 percentage that we're ready for funding and part of
11 the fall down was around engagement and patient-
12 centeredness, and our judgment was that that
13 improved every cycle since.

14 And so we funded about as much as we said
15 or even in the case of asthma and infrastructure we
16 funded significantly more than we put on the table
17 because, again, we were very impressed by the
18 quality of the applications. Can't say it for
19 those others yet.

20 UNIDENTIFIED: Joe, on the last slide,
21 what's the difference between prevention and

1 screening?

2 DR. SELBY: Well, to get technical,
3 screening is looking for early disease often time,
4 so it's preventing bad disease. But, for example,
5 in colorectal cancer or mammography, the cancer, or
6 at least a precursor, has to be there and you find
7 it with prevention -- with screening. Prevention
8 would try to make sure that that cancer never
9 develops in the first place, so that would be
10 exercise or diet or vitamin or something along
11 those lines.

12 DR. WEISMAN: So, what you're saying is
13 normally primary prevention --

14 DR. SELBY: Pardon?

15 DR. WEISMAN: It's only primary prevention
16 you're saying because there's the secondary
17 prevention certainly flips over into what they were
18 talking about.

19 DR. SELBY: I don't know -- I do not know
20 where secondary prevention came in, but even in the
21 secondary case, you can still talk about screening

1 in the secondary case. Surveillance is a big part
2 of that.

3 DR. WEISMAN: You're right.

4 DR. SELBY: So, I do not know if -- I
5 don't know if you know, Bryan or Michele, whether
6 secondary prevention made it into the prevention
7 slice?

8 MR. LUCE: I can't tell you that. I don't
9 know.

10 DR. SELBY: Okay, so -- and this just
11 makes the point about the slowness, the decline
12 from 80 percent of contracts signed within three
13 months to 37 percent, so included in the 82 awards
14 the most recent time where the 39 from the CRNs and
15 the PPRNs, these were novel and complex and big.
16 We executed 41 percent of them within 90 days and
17 to date all but one, which is pending signature,
18 have been executed. So, we really got them done in
19 a surprisingly short time compared to the
20 experiences, you know, in other large studies from
21 other funders thanks, again, I'll say this, to the

1 hard work of Mary and the contracts people. Just,
2 you know, it was hard.

3 But once we started working on the other
4 awards, that is the eight targeted asthma PFAs,
5 asthma studies from the PFA and the 45 from the
6 broad announcement, 70 percent of them were,
7 nonetheless, executed within 90 days, so I think
8 part of the drop from 80 to 70 was a diversion of
9 effort to the CDRNs and PPRNs. But I think we have
10 every reason to think that this high rate of 80
11 percent is what we'll see going forward.

12 Science response time. Just thanks to the
13 science team, congratulations, and yes, there's
14 still a little ways to go, but this is --
15 particularly the target is response within three
16 business days and this response is usually by way
17 of a nice conversation.

18 This is adherence to methodology
19 standards, more information on adherence to
20 methodology standards. Our judgment was that --
21 so, this is the cycle three awards, so this is

1 based on 53 most recent awards, those awards who
2 really had to be accountable to methodology
3 standards before they could be contracted, so there
4 were four sets of standards, which are sort of
5 applicable to every single application that we
6 have, at least nearly all of them at the time of
7 application, so we just present data on these four
8 sets of standards. Overall the adherence to these
9 four were 74 percent. Formulating the research
10 questions, almost everybody got that right. Being
11 patient-centered, not surprising that of those that
12 were scored well by the merit review process, they
13 got it right. Data integrity and rigorous
14 analysis, so, this is really the analytic methods,
15 a little bit of a fall off. And then dealing with
16 this issue of the heterogeneity of treatment
17 effect, which we tell everybody that they should
18 do, and we have methodology standards for how to do
19 it, less than half of them have met that one. So,
20 that's one that really needs some work.

21 But I want to hasten to add that before

1 these contracts were signed, and I think they're
2 all signed now, these deficiencies were remedied.

3 MR. KUNTZ: You know, this is a really
4 important metric we're following and obviously I
5 think that it probably is one of the most important
6 contributions we can make is to improve the rigor.
7 Do you think the binary scale of whether they
8 adhere or not is too overly simplistic and that
9 maybe it should be a more scaled approach? Because
10 I'd have a hard time trying to figure out who's
11 figuring out if we're, in fact, adhering or not
12 adhering to patient-centeredness, for example, and
13 it just might be easier to gauge progress?

14 DR. SELBY: Yes. To create a score of
15 some kind?

16 MR. KUNTZ: Yeah, I just think that they'd
17 be tough to do as a binary.

18 DR. SELBY: Let's take that under
19 advisement. I know Michele is getting notes and
20 it's a good question, especially as we talk about
21 this ENACT tool and I think, you know, we don't

1 want to stray beyond the standards in the methods.
2 We do stray in what we talk to them about when we
3 talk about engagement, for example, and we actually
4 probably go further than the methods when we talk
5 to them about what we mean by patient-centeredness,
6 but --

7 MR. KUNTZ: [Unintelligible] is that you
8 might have to resolve it to something simple like
9 do they mention that they're going to use a method
10 and then that's a yes, but really it should be
11 something like do they mention it as a method and
12 did they actually describe their method.

13 DR. SELBY: Yep.

14 MR. KUNTZ: I mean, there might be
15 something -- there may be something that's a little
16 bit more granular than just yes or no on something
17 so important like are we basically driving methods
18 into research.

19 DR. SELBY: That's a very -- we will get
20 back to the Board on that because I think that's a
21 nice example of the Board improving the metric and

1 understanding the score that results as well.

2 Thanks, Rick. Larry?

3 MR. BECKER: So, Larry Becker. So, is
4 there any evidence or process that says, so we've
5 created these methodology standards that anybody
6 else is considering them or using them beyond the
7 things that we are funding?

8 DR. SELBY: Michele, if you can help me
9 out here. I think we are on the lookout for that,
10 but it's not on the dashboard yet. Is that right?

11 MS. ORZA: That's correct.

12 DR. SELBY: Okay, so, Larry, we will
13 continue developing an approach to -- I know we are
14 -- we do want to measure that and it will make it
15 onto the dashboard at some point soon.

16 Okay, Ellen, it sounds like you're in
17 response to Larry's question, otherwise --

18 MS. SIGAL: I think Larry brings up
19 something really important --

20 CHAIRMAN NORQUIST: Ellen Sigal.

21 MS. SIGAL: -- I mean, yes, Ellen Sigal.

1 I'm sorry. If we pay for it, they'll do it, but we
2 want them to do it because it's important
3 ultimately and that the methods and the outcome is
4 really important.

5 I know I struggle a lot with patient-
6 reported outcomes and some issues that we don't see
7 nearly enough in clinical trials, but what we find
8 is if you don't require it, it doesn't happen. So,
9 I mean, I think hopefully our value is going to be
10 that it happens not just because we're paying for
11 it and because it's important to us, but because
12 it's important research and we get better results.

13 DR. SELBY: Bob? I think we're done with
14 the slides. Go ahead, Bob.

15 DR. ZWOLAK: Bob Zwolak, Board. So, my
16 question goes back to your original dashboard and I
17 was just looking back here and we announced the
18 pilot projects late in 2011 and I think funded them
19 in 2012, and so I see journal articles way down
20 there in the bottom left and I assume those are
21 articles about PCORI or authored by PCORI of

1 primary folks but not the results of our pilot
2 projects. And my question is, when -- is 2014 too
3 soon to start adding a metric of research reports,
4 journal articles, written by authors funded by
5 PCORI grants, because it seems to me that's a huge
6 metric of funding research and is it time to put
7 that up there yet?

8 DR. SELBY: I think the answer is yes. We
9 are aware of -- at that meeting that I called the
10 sort of clandestine first annual meeting of PCORI,
11 we became aware of several papers that were just
12 about to be published. We also have two papers
13 that were recently in the Annals of Internal
14 Medicine that came from basically topic briefs or
15 landscape reviews that we commissioned for the
16 advisory panels. So, from Duke came a very nice
17 summary of the evidence around ductal carcinoma in
18 situ and a second topic, which I'm not going to
19 remember right now. Bill might remember.

20 So, yes, there are some, excellent point,
21 and we can definitely call out a category.

1 DR. ZWOLAK: I mean, I just think that's
2 hugely important and shouldn't be buried down there
3 with clicks on the website and emails and those
4 sorts of things.

5 DR. SELBY: Good. Good point. Okay, I'm
6 going to --

7 MS. NEWHOUSE: Can I just ask a question
8 about --

9 CHAIRMAN NORQUIST: Robin.

10 MS. NEWHOUSE: Robin Newhouse. Is there a
11 requirement for those funded by PCORI to publish
12 within six months after --

13 DR. SELBY: That is -- you can't require
14 somebody to publish within six months because, as
15 you know, sometimes it takes longer than that to
16 convince the peers that it deserves publishing and
17 get it into print, but we are working very hard and
18 we owe you, in short order, a process, actually,
19 for posting reports on completed work within 90
20 days of the completion.

21 So, you will get that -- we have a pretty

1 -- we need to discuss it first with the SOC and
2 then bring it to the Board, but we've been working
3 -- we've involved Hal Sox in the work coming up
4 with a plan that we think will meet two
5 requirements, the one is for a peer review process
6 for everything that we fund to make sure that it
7 adheres to the methodology standards, and the other
8 is to get it published within 90 days. So, it's
9 complex to do both, it's hard to do both a peer
10 review and published in 90 days, but we've got a --
11 we have a plan that we will be presenting shortly.
12 And, in fact, this has to go out for public
13 comment, so this will be happening in the next
14 month or two.

15 How much time do I have, Gray?

16 CHAIRMAN NORQUIST: Well, you're over by
17 five minutes.

18 DR. SELBY: I think I should just -- I
19 don't even know that I really need to -- I don't
20 think I need to say anything about that. It looks
21 like we're not going to have anymore Pipelines to

1 Proposals -- nothing expected from Pipeline in
2 fiscal year 2014.

3 CHAIRMAN NORQUIST: Incorrect slide, move
4 on.

5 DR. SELBY: So, never mind. So, this is
6 the engagement event survey details. So,
7 interviewing people after four events, and you see
8 the events down there, their response rate's in the
9 middle, and the summary question was -- where's the
10 question? -- since attending the workshop have you
11 done anything new to conduct, promote, or use
12 patient-centered research? And you see that the
13 vast majority of people at each point in time said
14 yes, and it shows the example up there in the
15 italics but I'm going to move on.

16 Engagement events survey results -- so,
17 this just shows two ways, either acted as a patient
18 or stakeholder partner on a research team or acted
19 as a primary or co-investigator on a research team
20 and actually the higher percentages are acted as a
21 primary or co-investigator on a research team.

1 And then this is the last slide, I think,
2 and it's on communications, and this shows unique
3 traffic and there it is in numbers on the left, the
4 target in green, the blue is actual, and on the
5 right is three years -- those three squiggly lines
6 are 2012, '13 and '14 -- '14 is very short -- and
7 it just shows that year-on-year we've had a big
8 increase in traffic.

9 This is the Twitter follower group. This
10 is email open rate compared to last year. So,
11 you'll see that we're ahead of last year each time.
12 And then this is the click-through rate, and this
13 is compared to the industry standard, so we're well
14 ahead of that. And this is the media coverage that
15 we've discussed.

16 So, that's it and I thank you for your
17 attention.

18 CHAIRMAN NORQUIST: Gail is first.

19 MS. HUNT: Gail Hunt, Board. You know, if
20 we could go back to the dashboard? I would suggest
21 that right now, progress of projects, needing

1 [inaudible]. I think that's really not useful.
2 You were looking for things that might be taken
3 off, because -- the one right in the middle --
4 because at this point we don't have any idea, like,
5 what that means. What is it, like they met the --
6 you know, it's just so vague and so un-revealing, I
7 guess, of what we're trying to figure out and we've
8 only got that one, you know, the research side.
9 What does it mean that -- I just think that it
10 would be -- you're looking for gearing up things, I
11 would take that off.

12 DR. SELBY: Okay, so that's a good point
13 and if we do leave it on, we better give you a very
14 detailed explanation on what it means.

15 CHAIRMAN NORQUIST: Yeah. Harlan Weisman?
16 We'll go to Robin, okay. Robin Newhouse.

17 MS. NEWHOUSE: I just wanted to respond to
18 Gail. This is Robin Newhouse. The progress of
19 research, I actually -- my eye went there first
20 because a third of our projects aren't on track, so
21 figuring out what the issues are is really

1 important for us to help other investigators that
2 are being funded, whether it's IRB approval or
3 whether it's the contract negotiations, it tells us
4 there's a problem in the process or there's a
5 problem with the implementation of the study.

6 If we can discover what the major issues
7 are, and I know that people get to the end of their
8 projects and they will be asking for a no-cost
9 extension, which I'm not sure if we do or not, but
10 to keep people on track, and a third are behind, is
11 really important. So, defining that metric is an
12 important one for us.

13 CHAIRMAN NORQUIST: Agreed, yes. So, I
14 think the key issue is what does it mean and it
15 could mean that they're not even getting any
16 subjects, which is a huge issue and then you really
17 have to address that issue or it could just be the
18 contract, I mean, so it does -- but if you
19 aggregate it, what does it mean? Right? Okay.

20 DR. WEISMAN: Yeah, I wanted to go back to
21 the comments on publications, which, you know, we

1 have this whole thing on open science and
2 transparency, we also have an obligation of public
3 reporting within a certain period after completion
4 of the research, and then the investigators
5 certainly want to write the publication.

6 But what I'm wondering is, what is PCORI's
7 responsibility on the publication of results that
8 in the traditional sense an investigator feels they
9 own it, they interpret -- analyze, interpret,
10 report, and their emphasis or their findings may be
11 different -- I'm not saying wrong, but may be
12 different than what PCORI's is as it relates to
13 what PCORI's mission is in terms of providing the
14 information that enhances the ability of patients
15 and clinicians and consumers to make decisions.

16 So, I'm not sure whether the standards --
17 how the standard approach works in conjunction with
18 our obligations.

19 DR. SELBY: You know, that's an excellent
20 question and one we're worried about with respect
21 to this peer review requirement and the publishing

1 of results within 90 days, so we have talked about
2 it a lot. I think it will come up when we present
3 this plan to the Board -- to the SOC and then the
4 Board, I think the short answer is that early on
5 while we're still close to the funding period, we
6 will have some leverage over the investigators to
7 show us their draft manuscripts or at least their
8 final report and we'll be able to peer review it.

9 Further out it's going to be more
10 difficult and I think other funding agencies also
11 have a harder time following things once the
12 funding has ended, but as the stream of
13 publications keeps coming in we will have to find
14 ways to do that and to register objections if we
15 object.

16 CHAIRMAN NORQUIST: Larry, is your card up
17 new or is that left over? Okay. Others?

18 One thing I would say is that one of the
19 ways you can get people to publish quickly is to
20 give a deadline on when their data or their
21 priority and then when they become public, so if

1 you're very clear that the data are publicly
2 available at some point in time that others can
3 analyze, they'll quickly get their papers out.
4 Trust me. I mean, that's the lesson that's already
5 been learned.

6 DR. SELBY: And that is part of the plan.

7 CHAIRMAN NORQUIST: Okay, yeah, and that's
8 part of our open science issue, I hope, is the part
9 of that discussion.

10 Okay, thanks. Any other questions? All
11 right, thanks very much, and as usual, we're asking
12 for continued feedback on how to improve this
13 dashboard and I think we've had a number of
14 suggestions today that could be very helpful.

15 Okay, Regina? I hope we're going to be
16 able to move because we are coming up against our
17 public comment period. So, what do you want to
18 present first, this resolution for a cash-secured
19 letter of credit, I mean, which is a big issue but
20 relatively minor for the Board, but we have to vote
21 on it. Do you want to do that first?

1 MS. YAN: Yes.

2 CHAIRMAN NORQUIST: Okay, so let's skip
3 through that one pretty quick. And everyone should
4 have some --

5 MS. YAN: Yes. You have the hard copy in
6 front of you. It was also sent ahead of time
7 electronically.

8 We have funds in our 2014 approved budget
9 to lease additional office space to accommodate the
10 additional new employees we're bringing on board.
11 We have already signed a lease on M Street for
12 additional office space, which is only one block
13 away from our current office on L Street and the
14 lease requires a Letter of Credit of \$150,000 as a
15 form of security deposit and the Letter of Credit
16 will require the Board's approval.

17 CHAIRMAN NORQUIST: So, we just need a
18 motion to approve --

19 UNIDENTIFIED: I so move.

20 CHAIRMAN NORQUIST: Thank you.

21 UNIDENTIFIED: Second.

1 CHAIRMAN NORQUIST: Second. We have a
2 second. Okay. Any discussion now about this?
3 Yes, Ellen?

4 MS. SIGAL: I have a question, it's not
5 about the Letter of Credit, but it's about the
6 moving costs, the set up costs for the new space.
7 We looked -- you know, because we're only going to
8 be there, what, four or five years, how long did we
9 take this space for?

10 MS. YAN: We signed the lease through the
11 end of 2018, it's a sublet space, so at pretty deep
12 discounts, and we also signed a year and four
13 months of prime lease with the landlord so that we
14 would have the lease co-terminate with the lease we
15 have on L Street.

16 MS. SIGAL: Great.

17 MS. YAN: So, we did not plan to sign any
18 lease that would go beyond the current lease period
19 of our office space right now.

20 MS. SIGAL: Great. And what about the
21 moving costs? Do we have a lot of renovation to

1 do? Are we taking it as is?

2 MS. YAN: We are doing some renovation.

3 However, because the rental rate is so low, so we
4 are able to offset that and we are not going beyond
5 what we have in our budget already.

6 MS. SIGAL: The issue is what you have in
7 the budgets?

8 MS. YAN: We have factored into our budget
9 additional office space at the current rental rate
10 at our office on L Street.

11 MS. SIGAL: Thank you.

12 CHAIRMAN NORQUIST: Thanks, Ellen. Okay,
13 any other discussion? Okay, all those in favor?

14 [Chorus of ayes.]

15 CHAIRMAN NORQUIST: Anybody oppose?

16 [No response.]

17 CHAIRMAN NORQUIST: Now, what was it you
18 said we had to sign this or something?

19 MS. YAN: You would have to sign it.

20 CHAIRMAN NORQUIST: My name? My name?

21 It's got Steve --

1 MS. YAN: No, I have another piece of
2 paper, an appendix of this, that I will have you
3 sign. Yeah.

4 MR. LIPSTEIN: This is Steve.

5 CHAIRMAN NORQUIST: Yeah. I can hear you,
6 go ahead.

7 UNIDENTIFIED: [Inaudible.]

8 CHAIRMAN NORQUIST: You need to add yours
9 too. I didn't hear the first part of it.

10 UNIDENTIFIED: [Inaudible.]

11 MS. YAN: So, we'll take care of the
12 collection of signatures.

13 CHAIRMAN NORQUIST: Okay. All right.
14 Thank you. Is that it? Okay, Regina, you want to
15 do the financial?

16 MS. YAN: I would like to give you a
17 review of our financial. This is a five-month
18 financial. Ideally, we would like to give you a
19 six-month, which is mid-year, but at the time when
20 we prepared the materials in April, the financials
21 available was from February.

1 I'll go over some of the key
2 accomplishments for the period, and not repeat what
3 you have heard today in many of the presentations,
4 and then we will go over the revenue, cash balance,
5 funding commitment, and our cumulative obligations
6 as well as a budget versus actual through the
7 period of February.

8 I will not repeat some of the things that
9 you have heard today, but this year we -- in
10 December you have approved \$191 million of projects
11 and you probably wonder when you are going to see
12 the next slate actually a winter cycle, the
13 proposals will be going through merit review
14 actually this week, on Thursday, and we hope to, in
15 July, bring a slate of projects to you for your
16 approval, and also spring cycle applications
17 including the pragmatic trials and others that were
18 issued, and we do have merit review that's
19 scheduled for August and we hope before the end of
20 fiscal year in September we will be bringing to you
21 the spring cycle projects for your approval. So,

1 we do have two cycles of award that we plan to
2 bring to you for your approval before the end of
3 the fiscal year.

4 And also this fiscal year we have on board
5 38 employees so far and I know that a lot of Board
6 members are concerned about how we will absorb the
7 new employees at this rapid pace, so we do have
8 developed on-boarding programs, we have also now to
9 implement our first annual performance review for
10 our employees.

11 For our revenue this year as of February,
12 we have received revenue of \$206 million, which
13 includes the appropriation of \$120 million and also
14 the CMS funds for \$86 million and we have a cash
15 balance of \$488 million, which includes the funds
16 we have in the trust funds as well as the money we
17 have in the bank.

18 And for 2014, we have an approved funding
19 commitment of \$528 million. You approved \$191 in
20 December. At this moment we are projecting to a
21 little over \$400 million by the end of this fiscal

1 year and our plan for 2015 is about \$600 million
2 that make up the two years of \$1 billion of funding
3 commitment plan.

4 And cumulatively, since inception, we have
5 awarded \$525 million. This includes all our funded
6 contracts including PCORNet contracts awards as
7 well as the coordinating center. And out of the
8 \$525 million, we have an obligation of \$468 million
9 that represents the payments that we still have to
10 make.

11 DR. WEISMAN: For clarification, maybe
12 this touches on what Rick asked earlier, but what
13 form of accounting do we do? Do we do cash -- cash
14 basis, accrual basis, management commitment basis?
15 Because some of the judgments on how to view some
16 of these things depends, I guess, on the exact
17 accounting mechanism.

18 MS. YAN: Okay, let me address that later
19 after --

20 DR. WEISMAN: Okay.

21 MS. YAN: -- I finish this.

1 If we look at our 2014 budget versus
2 actual, 2014 budget is \$182 million that you have
3 approved, all of which actually includes about \$100
4 million in research spending. Research spending
5 refers to actually the actual research spending
6 reported back to us by our awardees. And our
7 budget through February, \$68 million, and our
8 actual spending is only \$26.5 million, and I will
9 go over the variants with you.

10 Here's a summary of the budget versus
11 actual in categories, which also represents the
12 broad categories in the approved budgets. So, if
13 you look at this, our approved budget is \$182,
14 budget through February \$68, spending is \$26, and
15 so we have a \$42 million of variance, out of which
16 about 70 percent of it is in the research spending,
17 and I will go over later in the detail of what that
18 is and why.

19 And after that, about 10 percent of that
20 variance is in science, another 10 percent in
21 management in general, about 7 percent in contracts

1 management.

2 MR. KUNTZ: Your first column is your
3 fiscal year budget and then the spends are year-to-
4 date?

5 MS. YAN: Yes. The second one is budget
6 year-to-date through February.

7 And there are two major causes to the
8 difference between our budget and our actual, one
9 is some cost savings and the other one is delayed
10 expenses. And I'll go over the details of what the
11 delayed expenses are.

12 We have several areas of delayed expenses,
13 number one is, as we are projecting our research
14 spending, how much we think that we will receive
15 from our awardees in their reported spending, we
16 developed that forecast using the model that we
17 will have contracts executed within 90 days after
18 the Board approved them, and then 90 days after
19 execution, we expect to see invoices coming in
20 because right now we're issuing cost reimbursable
21 contracts. So, that was the forecast model that we

1 used.

2 But right now we are seeing these invoices
3 coming in pretty slowly, so we are now analyzing
4 some of the patterns to see whether that model
5 needs to be reviewed and then our forecast needs to
6 be adjusted because one thing is sometimes with
7 universities, the majority of our awardees are
8 universities, sometimes the pace is probably slower
9 than we would hope even though we use a very
10 aggressive forecast as our model, because we do
11 really want to see all those expenses coming in.

12 DR. WEISMAN: Could I please ask you to
13 maybe -- because it looks like you're using a cash
14 basis of accounting here?

15 MS. YAN: Yeah, because what we issue,
16 they are contracts, they are not grants, so we can
17 only recognize the expenses as they report back to
18 us. But what we do, as soon as we receive those
19 invoices, we recognize it.

20 DR. WEISMAN: As I understand, I'm not an
21 accountant, but as I understand it, in order to

1 make sense of under-spending, because that's what
2 it looks like, in fact, if we were accruing -- and
3 I think under accrual it's the services rendered,
4 in other words, they're actually doing the research
5 but they're not billing us yet?

6 MS. YAN: Well, but we don't know how
7 much.

8 DR. WEISMAN: So, we don't have a way of -
9 -

10 MS. YAN: Exactly, so the only way that we
11 know is when they send in the cost proposals or
12 they send in the invoice.

13 DR. WEISMAN: And then the other -- I
14 mean, typical of government is that they would do a
15 --

16 MS. YAN: They would do the obligations --

17 DR. WEISMAN: At the time --

18 MS. YAN: Of the payables. Right.

19 DR. WEISMAN: Because it makes it hard as
20 Board to know why we're so far behind if on an
21 accrual basis or on a --

1 MS. YAN: Well, there is one thing I know
2 that --

3 DR. WEISMAN: In that case we would know
4 that actually the money is being spent.

5 MS. YAN: Yeah, I know that, you know, a
6 lot of times we tend to look at here to see whether
7 research has been done, you know, so what we're
8 looking at now is that is not the place that is
9 going to give us the answer, and I want to go back
10 to an earlier question about meeting milestones,
11 whether that is a useful metric. For us right now
12 we go back to that one because for us to see --
13 since we can't look at the invoices coming in, the
14 measurement of whether the research has been done,
15 so now we are looking into our science staff as we
16 talk to our awardees, as we're tracking their
17 milestones, and to get assurance that research is
18 actually being done and they are actually making
19 progress.

20 MR. KUNTZ: I think I'll press you on this
21 a little as well. It's really hard to manage if

1 you're just looking at the pure cash price and you
2 should have -- we should have a budget outlined for
3 each grant. There should be expected fixed
4 expense, right, that the grants laid out, there's
5 some variable expenses too, which you might not
6 know until you get your invoices, but we should be
7 able to have some projection accrual of expenses so
8 that we can actually look at whether or not we're
9 spending correctly.

10 I think we also should have a metric that
11 looks at outstanding invoices just like you would
12 do DSO and other things like that as well. So, I
13 mean, I just think that it's a better way for us to
14 manage if we can project what the actual expenses
15 are as opposed to waiting for the mail to show up
16 and see how turns in an invoice, especially for
17 academic institutions, which you already
18 acknowledge, you know, don't actually keep up to
19 pace.

20 So, I don't know how difficult that is to
21 do it, but I mean, my guess is a projected budget

1 for each of these grants, at least we can track to
2 what's projected expenses were, right?

3 DR. WEISMAN: This is sort of arcane, but
4 this would be very unusual for an organization like
5 this to use cash basis accounting. You know,
6 governments usually use the commitment and
7 businesses usually use the accrual method, and only
8 small businesses use what we're doing because it's
9 so hard to do it.

10 MS. YAN: I'm going to have Pam Goodnow.

11 [Discussion off microphone.]

12 MS. YAN: Yeah.

13 MS. GOODNOW: We are using accrual basis
14 accounting so expenses are about one month behind
15 as they would be with anybody. If someone fails to
16 invoice us, we are accruing for them. So, it's
17 just that there's a very slow start to the expense
18 and it is a concern.

19 MR. KUNTZ: Just for a little bit of
20 clarity. If you -- on the previous schedules that
21 you showed, you showed a pretty big gap, so I'm a

1 little bit concerned about that. If you think that
2 that's on track, then we should have an indication
3 to suggest that that gap is on track, right?

4 MS. GOODNOW: Yeah, and so, what we're
5 finding is that people just are not starting the
6 research. When we get an invoice, it's for the
7 previous month, it's just that it took some number
8 of months to get either work together -- a lot of
9 people have to rent space, hire, so --

10 MR. KUNTZ: I guess the thing is that the
11 actions we can take are that if someone's not
12 starting the research, then we should take action
13 on that, because that's -- we have to compel people
14 to do research. They're not turning in their
15 invoices, we're not going to compel -- I mean,
16 that's not going to be something we can fix. And
17 the question is, how do we figure out which is
18 which? And when you had the variances, you had
19 variances to year-to-date, which I wouldn't call a
20 variance, I would call the variances the year-to-
21 date expenses expected. So, it just seems like if

1 you're starting in January you'd have a big
2 variance, right, because you're looking at fiscal
3 budgets versus the actual spend.

4 MS. GOODNOW: Actually the way that the
5 budgets are done by the awardees is it's just, they
6 give us a year, so year one, two, and three, so we
7 didn't know -- we don't know what to expect on
8 month one, two, and three. What we do know is when
9 we're getting our invoices they are for the
10 previous month, so if work is being done, it's in a
11 contemporary way.

12 MR. KUNTZ: I just want to make a general
13 statement. We just have to know what levers to
14 pull. And so, if some of the lack of spending is
15 lack of activity, then it's the Board's obligation
16 to make sure it gets moving.

17 MS. GOODNOW: And we've been having those
18 discussions -- science to science has been having
19 those discussions on a regular basis, so we meet
20 weekly. We make sure that people understand who's
21 behind and if there are problems, what they are,

1 and that they're being addressed, and that they
2 have a comfort level that we're moving forward.

3 CHAIRMAN NORQUIST: So, look, I think that
4 the problem here is it's not on track. And there
5 is concern and, Kerry, you've expressed some
6 concern about the spending too, and so that -- and
7 so, see, we really do need to look at this, and I
8 agree with Rick, I mean, there may be some levers
9 we can pull and some we can't if people are just
10 delaying and we need to rethink what they're doing.
11 They may not be able to get into the field for some
12 reason or something and that's a serious science
13 issue, perhaps, or maybe it's some other issue

14 But it is a concern that that difference
15 in what we would have expected to have spent,
16 regardless of how we account for it, and not being
17 there, I think regardless of how we account for it,
18 we're behind. Let's be clear about that, right?
19 Okay.

20 So, we do need to figure out where those
21 points are about what it is and see what we can do.

1 I mean, it's not, obviously, the accountant's
2 problem. It's a problem just internally that we
3 need to figure out, right, Kerry? You may want to
4 say something about this since you're --

5 MR. BARNETT: Well, we're going to hear
6 some other instances from Regina here. I mean, I
7 think you put your finger on it. The concern is
8 that we as an organization want to, as much as we
9 can, consistent with our strategic plan and
10 consistent with our goals and objectives, we want
11 to rev up the activity, you know, kind of
12 recognizing that it's -- as an organization, we're
13 on potentially a limited timeline and we want to be
14 able to demonstrate to the GAO and Congress and all
15 of our stakeholders the impact of the great work
16 that we're doing, and that means kind of revving
17 things up.

18 And, you know, some of the issue that
19 Regina's presenting to us is, I think, you know,
20 our eyes were bigger than our stomach and we were
21 predicting that we could get more done in general -

1 - and I'm speaking generally to the issue as
2 opposed to just to the research piece. We had
3 hoped and intended to, I think, rev things up more
4 quickly than we were able to.

5 Clearly, you know, all the discussions
6 that we've had at the meeting here today shows a
7 huge amount of very impressive work being done and
8 if you compare kind of quarter over quarter and
9 year over year, where we were a year ago, it's
10 really very impressive, you know, the significant
11 advancements that we've made.

12 Still, I think, you know, as the budget
13 spend shows, we're substantially behind what we
14 originally thought we were going to be at. Now,
15 when I say substantially, as Regina said, it's
16 about, what, 60, 61 percent behind where we thought
17 we were going to be and I think that gives us all
18 some level of concern. We've had some very direct
19 conversations at the FAC level with Regina, with
20 Pam, and with Joe and others, and I think they've
21 certainly heard our concerns and are being very

1 responsive to those concerns.

2 But ultimately, at the end of the day,
3 this is about making sure that we're able to
4 accomplish what we set out to accomplish.

5 One of the variances that Regina, I know,
6 is going to talk about is on the staffing side. If
7 you remember, there were some very ambitious
8 intentions in terms of staffing up for these
9 activities and that staffing has occurred more
10 slowly than anticipated.

11 If we're bringing the people on more
12 slowly than we had thought, that means they're not
13 engaged yet and they're not doing all the work that
14 we thought.

15 Some of the variances that you're going to
16 hear about are due to efficiencies. And hey,
17 that's great. That's exactly what we want. Being
18 under budget is always better than being over
19 budget, except when being under budget is because
20 we're doing less or accomplishing less, and they've
21 very much heard our concerns and we're sort of

1 revving up our activities, but that's really the
2 issue that I think is on the table here today.

3 CHAIRMAN NORQUIST: I'm sorry, just one
4 second, I need you to just kind of sit here for a
5 minute and think about this because we've gone into
6 the public session and we need to respect the
7 peoples' time. We have a person here and then
8 somebody's on the phone, so if it's all right,
9 Regina, I'm sorry, but we'll have a hold here for
10 just a second on this and I'll give us a chance to
11 have our mathematical minds working here or
12 something.

13 So, I'm going to ask Sue Sheridan, who is
14 the director of Patient Engagement, to come up to
15 the front or wherever you want to be, and we have
16 one -- I think you told me we have one person here
17 in person who wants to say something and then
18 someone on the phone. And then if we don't have
19 anyone else, we'll use the rest of this time for
20 this discussion. If not, we'll use the next
21 period. Thanks, Pam and Regina, for just a minute,

1 thank you.

2 Okay, Sue?

3 MS. SHERIDAN: Great, thank you, Dr.
4 Norquist. I believe we only have one person on the
5 phone but there may be others that may have called
6 in during the afternoon, but I just want to share
7 kind of our process. You're familiar with the
8 process, but for those on the phone I want to share
9 this. We'll take comments from the people here in
10 the audience first and after that we'll ask the --
11 our operator -- I understand our operator is
12 Michael. Michael, are you on the phone?

13 OPERATOR: Actually, [unintelligible].

14 MS. SHERIDAN: Oh, I'm sorry. Hi.
15 Welcome. And then we're asking that for those who
16 may be listening but are not going to offer
17 testimony that you can send comments into email
18 info@pcori.org as well. And then all testimony and
19 everything -- all materials submitted to us will go
20 to the Board or the Methodology Committee or staff
21 or whoever's appropriate for us to consider in the

1 work that we do.

2 So, at this time I'd like to introduce
3 Sarah Van Geertruyden who is with PIPC. Sarah's
4 also a member of the Patient Engagement Advisory
5 Panel that's been meeting twice a year. So, we're
6 going to ask that Sarah keep her comments to three
7 minutes and then we will open it up to the phone
8 lines.

9 MS. VAN GEERTRUYDEN: Great. Thank you.
10 I'm Sarah Van Geertruyden, executive director of
11 the Partnership to Improve Patient Care, which you
12 probably know as PIPC.

13 Thank you for the opportunity to provide
14 comments. I want to first thank Sue for her great
15 leadership. We had, I think, one of the most
16 productive engagement panel meetings that we've
17 ever had in our last session last week. I thought
18 it went very well.

19 I also wanted to thank Jean Slutsky.
20 We're excited to be working with her in the future
21 and hope to have many more round tables. As I'm

1 sure you're aware, we've been doing a series of
2 roundtables over the last couple of years.

3 So, my comments today are actually going
4 to be centered around a recent roundtable that PIPC
5 held related to PCORI's development of an
6 evaluation roundtable, which included members of
7 our steering committee and members of the patient
8 engagement panel to discuss how PCORI can and
9 should be measuring their success.

10 So, I very much appreciated the
11 participation of Kristen Konopka and Suzanne
12 Schrandt in that meeting.

13 The summary and recommendations that came
14 from that roundtable are available on the PIPC
15 website. To summarize, the roundtable group
16 identified that PCORI has a dual role being both a
17 mission-oriented, nonprofit, the mission being
18 patient-centered research and it is research
19 funder.

20 It was the view of the roundtable group
21 that PCORI's mission should be a core component of

1 its evaluation framework to support the brand that
2 PCORI is trying to develop and that brand is
3 "research done differently". An important step in
4 developing this brand is to better define, through
5 its evaluation metrics, what makes PCORI truly
6 different from other research organizations,
7 patient engagement, the use of advisory panels to
8 prioritize research, and the application of
9 patient-centered criteria that must be included in
10 all of PCORI funded research. This will get
11 PCORI's brand "research done differently"
12 credibility.

13 We also agree that PCORI should be using
14 best qualitative and quantitative metrics in its
15 evaluation framework. So, if "research done
16 differently" is the brand, it is the qualitative
17 measures that will immediately distinguish PCORI
18 from other research organizations. Although it's
19 vital for PCORI to conduct rigorous research to
20 ensure it has a high quality product that leads to
21 an enduring high quality brand, it is the mission

1 of patient engagement and research that makes PCORI
2 immediately different.

3 For example, quality measures could
4 identify standing innovations for PCORI's work,
5 which include things like the use and replication
6 of PCORI's engagement practices and patient-
7 centered programs.

8 Our roundtable concluded that the aspect
9 of the evaluation framework focused on PCORI's
10 patient-centered mission should have a three-year
11 timeline and many of the measures being used would
12 immediately identify PCORI's commitment to its
13 patient-centered mission.

14 Although we're pleased that the draft
15 evaluation framework recognizes the value of
16 patient engagement and usefulness of information,
17 we do hope that the final evaluation framework will
18 capture whether there was adequate patient and
19 stakeholder involvement in topic generation and
20 research prioritization on the broad funding
21 announcement process as compared to the targeted

1 process that uses advisory panels.

2 I was interested to hear Dr. Krumholz's
3 comment about identifying the headline for research
4 at the early stages of developing the research
5 question as a means to determining its usefulness
6 in very practical terms. This is a view very
7 consistent with our roundtable discussions. I
8 would argue that the headline to which he refers is
9 really driven by the patients and providers that
10 will either use or not use the research findings at
11 the point of care.

12 Therefore, this point underscores even
13 more the importance of engaging patients and
14 providers in determining the usefulness of
15 potential research questions early in the process
16 of topic development and research design. Related
17 to dissemination, it also concerns me that I often
18 encounter patient and provider groups that are not
19 aware of the research PCORI is already funding that
20 targets populations they serve simply because
21 they're not stakeholder partners in that individual

1 project.

2 Although this is a natural consequence of
3 a broad funding announcement process, we hope that
4 the dissemination and implementation action plan
5 provides PCORI with guidance to address this issue.

6 PIPC has consistently recommended that
7 PCORI engage those groups that will be integral to
8 dissemination of specific projects at the front end
9 of research so that there is an eagerness and
10 demand for the research upon completion. Their
11 engagement in the dissemination strategy will
12 assure that the research is disseminated in a
13 manner that is useful and is therefore more likely
14 to be actually used. This all gets to the
15 should/would/could gap, which you were talking
16 about earlier.

17 In closing, PIPC is pleased to see the
18 transition to targeted funding announcements and
19 meaningful engagement of advisory panels and we
20 thank you for considering our recommendations and
21 for this opportunity to comment.

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1 CHAIRMAN NORQUIST: Thank you very much.

2 MS. SHERIDAN: At this time, we can open
3 the telephone lines. Do we have somebody who would
4 like to offer some comments?

5 OPERATOR: [Unintelligible] press the
6 number 7 on your telephone keypad. Our operator
7 will ask for your name and organization and place
8 you in the queue. When it is your turn to speak, I
9 will announce your name noting that your line is
10 now open. Please hold while we wait for the first
11 question.

12 DR. DOUMA: Sue, while we're waiting,
13 could you tell us how many people are on the line?

14 MS. SHERIDAN: [Inaudible] that I know of.
15 I believe we have a Ms. Cadwallader?

16 DR. DOUMA: You'll scare her away.

17 CHAIRMAN NORQUIST: I think your question
18 was the number of people listening, is that
19 correct? Do you know the total number just
20 listening? Twenty.

21 OPERATOR: The first question comes from

1 Danny Cleary [phonetic]. Please go ahead.

2 MR. CLEARY: Good afternoon. I just had a
3 question. I am a patient that was on a clinical
4 trial -- I was on the call earlier today and I
5 heard the gentleman talk about reducing costs by
6 collaborating. One of my questions is, I suffer
7 with Hepatitis C and I have cirrhosis of the liver,
8 and I was on the clinical trial in 2010.
9 Fortunately, the staff guided me through the
10 process, but as an African-American, what I wanted
11 to know, will PCORI be having trials that will look
12 at the different things that impact people who are
13 taking medications on clinical trials for Hepatitis
14 C?

15 DR. SELBY: Well, this is Joe Selby. You
16 might have noticed in the presentation this morning
17 under the listing of pragmatic clinical studies,
18 one of the high priority topics that was invited to
19 go forward was in fact a comparative effectiveness
20 study of newer treatments for Hepatitis C, so that
21 has not been funded, but we're expecting an

1 application.

2 I agree with you, it's a very important
3 area with a lot of questions both about
4 effectiveness and the tremendous costs because of
5 the very, very large number of people in the
6 population who are infected with Hepatitis C. So,
7 I agree with you completely. It's a very good
8 topic for comparative effectiveness research.
9 There's a lot we need to know about the relative
10 benefits and possible harms and the effectiveness
11 of different treatments.

12 OPERATOR: If you have a question, please
13 press the number Q or the number 7 on your
14 telephone keypad.

15 [Discussion Off microphone.]

16 DR. SELBY: -- range of outcomes that are
17 important to patients, so I think certainly --
18 first of all, you said recovery and so I think
19 recovery is pretty much aligned with ability to
20 function again. So, functional status is a very
21 important outcome and I think in most conditions

1 we're going to expect to see something other than
2 simply the number of readmissions, although in some
3 conditions, and with appropriate patient
4 engagement, I think we could be convinced that
5 having to go back to the hospital and be readmitted
6 again and go through that whole routine is a real
7 concern to patients.

8 So, I think readmissions is an interesting
9 one because it sounds a lot like it's a health
10 system worrying about costs, but it's also, I
11 think, a patient and a patient's family worrying
12 about really having to go through this again.

13 So, I would say that readmissions has some
14 real interest of patients, but you usually see it -
15 - in a PCORI study you usually see it coupled with
16 reports on how patients are functioning. You
17 probably wouldn't see it alone in a PCORI-funded
18 study.

19 MS. SHERIDAN: Thanks, Joe. Operator, do
20 we have any other people on the line who would like
21 to submit a comment?

1 OPERATOR: We do not.

2 MS. SHERIDAN: Okay, thank you very much.
3 If there's anybody else that's listening, you can
4 submit it electronically and we will respond to
5 that.

6 Does the panel have any -- the Board have
7 any other questions?

8 [No response.]

9 CHAIRMAN NORQUIST: Okay, thanks, Sue.
10 And thanks to everyone. So, we'll go back to our
11 discussion that we were having before and we'll
12 lead off with Bob Zwolak. You had the last --

13 DR. ZWOLAK: Bob Zwolak, Board. My only
14 comment was I think in this biggest category that
15 Regina is describing as behind budget, it's not
16 PCORI or PCORI staff that's behind, it's the
17 scientists that we're funding who are behind on
18 their spending. Isn't that correct?

19 MS. YAN: That is correct. We are doing
20 two things here, number one is we're evaluating our
21 original model to see whether it's too aggressive

1 and not realistic based on the pace that they're
2 sending us the invoice. Secondly, most
3 importantly, is to monitor the milestones and make
4 sure that the project itself is progressing,
5 meeting the satisfaction of our fine staff.

6 CHAIRMAN NORQUIST: But I would say that -
7 - I mean, Kerry, some of the discussions I thought
8 we had had, part of the issue has also been not
9 enough program officers sometimes to do some of the
10 work too. I mean, I think it's the staffing also.
11 So, on some, I mean, I think it's both sides. I
12 mean, yes, the scientists are not getting in, but I
13 think it's also the amount of effort that we're
14 able to do to help them, you know, with some of the
15 project staff and stuff.

16 So, hopefully as we hire more people, have
17 them in, this will move ahead quicker too.

18 MS. YAN: Maybe one thing we can do more
19 is really follow up with our awardees as we are not
20 seeing the costs coming in.

21 Another factor we talked earlier about is

1 the hiring. We set a very aggressive goal for
2 ourselves to fill -- to have 142 head count by the
3 end of second quarter. But we were at about 115 at
4 the end of February. But I do want to give you the
5 latest data because the head counting is every day
6 -- a new employee arriving every day. As of today,
7 we have 122 employees. We have six employees that
8 are waiting to start. They're not on payroll yet,
9 they're scheduled to start, and we have five offers
10 ready to be made, so we are looking at 133.

11 So, what that means is that in the seven
12 months since the beginning of the fiscal year, we
13 have recruited and filled about 56 positions.

14 We have five months ago, until the end of
15 fiscal year to meet our 165 target. That means
16 that in the next five months we have about 32 more
17 positions to fill.

18 In the last seven months we have filled
19 about 56.

20 And obviously, we are not filling the
21 positions as quickly as we can, we have under

1 spending in personnel and other related expenses.

2 We have several areas that we have real
3 cost savings. We did a lot of workgroup meetings
4 and landscape reviews for the targeted PFAs that we
5 developed in previous years, so as a result, we
6 include all the funds in our budget for this year.
7 For that, you know, if we need it we have it, but
8 the thing is, as we decide to have the pragmatic
9 trial PFAs going out, and that does not require
10 workgroup meetings or landscape reviews, so as a
11 result of that, the funds that we have budgeted for
12 PFA development we did not need to utilize it.

13 In addition, because we do have a few more
14 staff this year than last year, you know, our staff
15 have also done some of the work that previously was
16 done by contractors.

17 In addition, in contract management, which
18 runs the merit review process, we also have
19 included some efficiencies and we have some cost
20 savings there. Now we are using a standing panel
21 with the reviewers. We also have some of our PFAs

1 use competitive LOIs so that also changed the cost
2 element for us with our streamlined contract
3 template, that's been improved. We also have
4 reduced cost and timing.

5 I think as we move forward we will
6 continue to have some cost efficiency there.

7 MR. KUNTZ: So, if we're starting to make
8 the conclusion that this very ambitious process
9 here might have been a little bit too ambitious but
10 everybody's moving the right direction and you're
11 staffing up and some of these sites are potentially
12 trying to get coordinated, we want the good science
13 to be committed and we want it to be completed. Do
14 we need to alter our expectations of a three-year
15 project to go to four years? Should we start
16 thinking about that?

17 Because I think these are \$500,000 a year
18 for three years plus the projects, and if we're
19 recognizing that actually there are some things
20 that we didn't account for, but we're seeing really
21 good activity, but it's a little delayed, should we

1 start to actually change the structure of those
2 grants so they will be completed?

3 MS. YAN: I think that's a science
4 question.

5 MS. GOERTZ: Yeah, Christine Goertz. I
6 just want to echo Rick's concerns that the odds
7 that all of our projects are going to end, you
8 know, right on time within the amount of time that
9 we actually had originally anticipated just doesn't
10 exist. I'm trying to think if I've ever finished a
11 randomized clinical trial on time, quite frankly,
12 and my guess is the answer is no. And it's just a
13 very complex process.

14 It takes longer than you can ever imagine
15 that it's going to and because there were some --
16 particularly when you're starting a new program
17 like this, I think, and bringing in new
18 stakeholders and a different type of investigative
19 team, I think it's realistic to imagine that it's
20 going to take longer and that as we're looking at -
21 - you know, I'm not quite sure what criteria to use

1 for trying to decide whether people are on target
2 with their goals or deadlines, but I think we need
3 to be thinking about is there data that we can
4 capture early on that will actually help us get a
5 more realistic estimate of when we're actually
6 going to be spending money, because my guess is
7 that the funding -- that will be more common than
8 not that the funding gets pushed into some sort of
9 a no-cost extension.

10 CHAIRMAN NORQUIST: Yeah, so, one of the
11 key indicators is recruitment of subjects. I mean
12 having done this for many years and then we got
13 into this issue when I was at NIH to start
14 requiring at a certain endpoint if you didn't have
15 this percentage of subjects, then we were going to
16 cut it. I mean, basically, at some point you know
17 somebody's not probably going to be able to recruit
18 the number of subjects and you have to deal with
19 that or you have to keep pouring money into it to
20 keep it going.

21 So, that's an early indicator, but I've

1 never in all the 15 years I did all these, I never
2 saw maybe one or two trials finish on time. I
3 mean, and they were pretty small trials too. And
4 we're doing some larger trials with some
5 complicated settings and stuff, but non -- I mean,
6 when you're in the real world it takes even more
7 time.

8 MR. KUNTZ: [Unintelligible] accounting
9 structure, if we do see legitimate reasons why
10 they're a little bit slow for the uptake, and
11 again, we want to get good research, do we have a
12 request -- a requirement that they spend the money
13 at the end of each fiscal year? Is there a method
14 for us to carry dollars over? This is something I
15 think we --

16 CHAIRMAN NORQUIST: So, do we, Regina? I
17 mean, that's a good question. This is Gray.

18 MS. YAN: Well, one thing is we are new
19 and we are under significant pressure to show
20 results. So, we have not spent a lot of time
21 thinking about how we let people have more time and

1 delay it. So, we're focusing more energy on how we
2 get people -- get their work done as quickly as
3 they can.

4 CHAIRMAN NORQUIST: No, I know. But the
5 problem is that if we commit money and we get up
6 front where we tell a bunch of people that we're
7 going to give them -- I'm just making this up now -
8 - \$10 million and only \$5 of that is spent and then
9 we're putting more, we better keep up with the \$10
10 we already committed and we may have to push that
11 down the line or something as they get into it.

12 And we should have a plan at some point to
13 say, you know, you're a year and a half behind,
14 you've only spent ten bucks. I think it's time to
15 call it quits. We're not going to keep letting it
16 go. I mean, I'm exaggerating, but I ran into these
17 very situations and we got -- it got very
18 difficult. And you had to just say, you know, it's
19 not worth it now. We've put some investment in,
20 but we're not going forward. We'll put it into
21 something else.

1 MS. YAN: We definitely need to add that -
2 -

3 CHAIRMAN NORQUIST: Well, this is
4 something we have to have a conversation -- we're
5 not going to solve it here, but we do need to have
6 this conversation and come up with a plan.

7 UNIDENTIFIED: We need to have a carry
8 over and no cost --

9 CHAIRMAN NORQUIST: Absolutely, we need to
10 have a policy on that. Yes, Harlan Weisman?

11 DR. WEISMAN: Yeah, Harlan Weisman.
12 Couple points. One, in terms of, Kerry, what you
13 were saying, you spoke very knowledgably about
14 what's accounting for the variance. Putting aside
15 the discussion on how do we account for things,
16 what would be very helpful for me as a Board member
17 is to understand the sources of variance with a
18 little more detail.

19 For example, how much of the \$27 million
20 or approximately first quarter gap is due to
21 slowness of a program? How much of it is due to

1 slowness of an invoice? How much of it is due to
2 improved efficiencies, which as you said, it's a
3 good thing, because I don't know how much worry I
4 should have, although it sounds like from what you
5 were saying, a lot of it may be slowness to launch.

6 The other thing is, just in terms of
7 running a research enterprise, at least in the
8 private sector, which I have a lot of experience
9 on, I would agree that this is not uncommon for
10 research organizations to over budget and under
11 deliver, and in fact, they'll do it perennially.
12 But on any given -- and I'm not saying that's a
13 good thing, on any given project, the expectation
14 should be that you're delivering when you say
15 you're going to deliver and you measure it's
16 performance.

17 But from a budgeting the enterprise
18 standpoint, I don't know what the right numbers are
19 for this one, is I went to managing what I called a
20 probablized likelihood, and I basically took
21 everybody, what they said they were going to do,

1 and then budgeted 70 percent of it. I held
2 everybody accountable to deliver, but I knew at
3 least 30 percent wasn't going to be on time and
4 that kept -- because it's bad for an organization
5 to over budget as much as it is to under budget,
6 because that money could be used for other things
7 and I think we need to make sure that, at least in
8 high priority areas, we may have to do tighter
9 management of our sites. All research,
10 particularly clinical trials, have inertia. It's
11 very hard to get them going. On the other hand, I
12 know that if you focus attention when you're
13 managing them, managing investigators, you can get
14 them going. You've got to figure out what their
15 particular issues are and pound the pavement, so to
16 speak.

17 So, these are all levers that we have.

18 CHAIRMAN NORQUIST: Yeah. Kerry, and then
19 Debra.

20 MR. BARNETT: Kerry Barnett. If I could
21 just respond. First of all, it'd be great to set a

1 time with both Pam and Regina, with you, Harlan, to
2 go over some of those details in the specific
3 budget variance reports. There's a lot of data
4 there and so it can be spelled out with great
5 granularity.

6 You know, our focus right now in this
7 discussion is talking about the budget, and I guess
8 what I would really stress is that I think the real
9 issue for the Board is not focusing on budget under
10 spend or over spend, but to go back to the last
11 presentation about the score card, because I think
12 what our focus should really be on is, what are the
13 goals of the organization, what are the activities
14 that we've laid out and committed to, and how are
15 we tracking along those commitments, that that's
16 really what we should be focusing on. It's far
17 more important than kind of what the specific
18 budget variance report may be telling us.

19 At the end of the day --

20 DR. WEISMAN: But that's fundamental to
21 our Board, is looking at the finances.

1 MR. BARNETT: But I guess that's really
2 what I'm saying is that if there's an issue on the
3 table here -- I don't think there's anything wrong
4 with the finances, I'm very confident of that. If
5 there's an issue, it's around the pacing of the
6 organization, which is exactly what Joe is
7 addressing when he lays out the scorecard. Should
8 we be doing different things? Should we be going
9 faster? Should we -- are we accomplishing what we
10 set out to accomplish?

11 I would just say that that, I think, is
12 what the real focus of the Board should be on.

13 CHAIRMAN NORQUIST: It's Debra's turn
14 unless you want to just follow up on this
15 particular --

16 DR. SELBY: Okay, I'll be really quick.
17 And I think that sometimes looking at the finances
18 can give you a window into what's going on in the
19 organization, so at least just these kind of
20 questions. I'm sitting here furiously emailing
21 people behind me to try to figure out why I told

1 you -- why I told you that -- I'm so lazy. This is
2 Joe Selby, by the way -- I just reported to you
3 that 67 percent of the projects were on target,
4 right, meeting their milestones at one and two
5 quarters, and then Pam's explanation for why we're
6 under spending is that they haven't gotten started
7 on their work.

8 And so the dashboard forced me to try to
9 ask that question that I might not have otherwise
10 asked. So, that's it.

11 CHAIRMAN NORQUIST: Debra Barksdale.

12 MS. BARKSDALE: I'm changing the subject.
13 This is Debra Barksdale and this is an easy one.
14 You've talked about staff growing and needing to
15 grow even more, and I know previously there were a
16 few contract employees and I think on the previous
17 slide you said that had been reduced. What is the
18 current number of contract employees?

19 MS. YAN: Well, as we are staffing up, we
20 still have some -- there's some work done by
21 contractor because they are not meant to be there

1 for a long time. So, we keep those. We have some
2 contract staff on site. We have probably about a
3 dozen of them right now and some of them will be
4 rolled off as the staff comes on board.

5 I want to talk about --

6 CHAIRMAN NORQUIST: I think -- no, we have
7 another question up here, and I think the big
8 question is, have we reduced the percentage of
9 contractors -- I mean, because that was always the
10 question that we had and how much have we reduced
11 that and brought more in-house, right?

12 MS. YAN: Well, we had about 20-some
13 contractors just supporting contracts management
14 last year and right now, you know, we probably have
15 half a dozen. So, that has significantly reduced.

16 CHAIRMAN NORQUIST: Okay. Allan, you have
17 a question?

18 DR. DOUMA: This is sort of, I guess, a
19 little bit of a change. I'm not sure whether
20 you're done or not, but just -- one of the
21 variables that is easy for outside people to track

1 and therefore important for us to track as well is
2 what percentage of our budget is spent on research
3 and is that -- we added some numbers, you know, a
4 year ago. Are we tracking that on an annual and/or
5 quarterly basis? And what do they look like?

6 MS. YAN: Yes, we are tracking them. In
7 the approved budget, our administrative rate was at
8 16.5 percent and then as of February, you just look
9 at the February actuals, our administrative rate
10 was at 25 percent, that's year-to-date.

11 DR. DOUMA: The administrative rate is a
12 funny term. It depends on what you want to put in
13 administration. That's why it's, I think, more
14 useful to have what percentage of your budget is
15 research and are you saying that that's 84 percent
16 or is it a -- is it in the research? The numbers
17 that show this --

18 CHAIRMAN NORQUIST: That would be 75
19 percent.

20 MR. BARNETT: Are you saying research or
21 program? Because obviously program is a broader

1 term than research.

2 DR. DOUMA: Right, I was saying research
3 in particular.

4 CHAIRMAN NORQUIST: Remember, we also have
5 engagement. I don't know how engagement gets --

6 DR. DOUMA: And I think engagement can be
7 thrown into research because of who we are, but if
8 you combine research and engagement, what
9 percentage --

10 MS. YAN: Are you talking about just the
11 awards or are you talking about the programmatic
12 works?

13 DR. DOUMA: What I'm talking about is what
14 anybody on the outside will think goes into
15 research so we can communicate.

16 DR. WEISMAN: We made a commitment, or you
17 made a commitment to us, that our administrative
18 fees were high as a percent of total budget because
19 of our size, but that as our spending increased,
20 our administrative versus operating would go down.
21 In fact, it's going the other way.

1 MS. YAN: Well, the spending depends on
2 when the spending comes in.

3 CHAIRMAN NORQUIST: Yeah, part of the
4 problem is, she's giving you a percentage of -- we
5 got the problem the research dollars run out, so
6 the percentage that's administrative, but what we
7 have now is going to be high. What is it in the
8 budget, basically, is the question?

9 MR. KUNTZ: The question is, do we have an
10 operating statement? I mean, that's generally what
11 the Board should see, and the operating statement
12 will lay out what the operating overhead is, what
13 the programmatic costs are. It would be just
14 answered by one schedule.

15 CHAIRMAN NORQUIST: So while they're
16 looking at that I think Alicia has a question.

17 DR. FERNANDEZ: I actually had a comment
18 more than a question.

19 CHAIRMAN NORQUIST: Okay.

20 DR. FERNANDEZ: I hope it's helpful. As
21 you know, I'm newly on the Board and I'm even more

1 newly on the administrative committee. I believe
2 they wanted someone who would play the role of the
3 Village Idiot and say, oh, how --

4 CHAIRMAN NORQUIST: Come on, Alicia,
5 you're not the Village Idiot.

6 DR. FERNANDEZ: After all, I'm a physician
7 and almost by definition a poor administrator. But
8 this is a relevant introduction because I don't
9 want to feel, even though I've only been to one
10 meeting or two meetings, that the administrative
11 committee has failed the staff in anticipating what
12 the Board would want. And I wonder whether instead
13 of pursuing sort of ad hoc questions, we could take
14 a little bit of time to reflect either -- perhaps
15 not in this session, perhaps in another session --
16 to reflect on how one would want -- what would be
17 the right dashboard that the Board would like to
18 see on the financials? What are the right metrics?
19 What would the rest of the Board like? Is it the -
20 - do we always want to know the current
21 administrative to expenditure section or whatever

1 the right metric is?

2 And then, if we had that from the rest of
3 the Board, then perhaps as an administrative
4 committee we could do our job better of backing up
5 the staff to make sure that when they present, they
6 have -- they're presenting what we want and are in
7 a full position to be able to answer the question.

8 Anyway, just a thought, and feel free to
9 always come to me because there is no question that
10 is too silly for me to ask in that committee.

11 CHAIRMAN NORQUIST: So, Alicia, you have
12 proven that you're not the Village Idiot. So, and
13 she has a good sense of humor, which -- and
14 actually this committee is meeting tomorrow
15 morning, early, for West Coast people. I just
16 don't understand why you torture yourself that way.

17 So, but I agree, I think that's one of the
18 issues that the FAC is supposed to be responsible
19 as the Board committee to do this, and I think we
20 could give them some input. And I think you've
21 heard a fair amount and I think -- about some of

1 the concern about the way the information is
2 presented so that it does make some sense.

3 I think what you're also hearing is just
4 concern that we're behind in our spending. We do
5 not want to have a public image of our
6 administrative fee being too high if it's not. I
7 mean, if it really is not in the budget or the
8 commitments or whatever, you know, it's not. If it
9 is, then we need to address why it is high and is
10 that where we want it to be and what is high. I
11 mean, if it's 50 percent, it's obviously high.

12 Okay, Regina, what else did you guys want
13 to do at this point?

14 MS. YAN: I just want to quickly go over
15 the next steps that we plan to do. Right now, we
16 will be doing a reforecast of our spending for this
17 year, looking at the actual spending so far and
18 also looking at the latest cost assumption and our
19 program timelines, so we do plan to come back to
20 you and present to you our reforecast for this
21 fiscal year sometime in June.

1 CHAIRMAN NORQUIST: And this would be done
2 in conjunction, obviously, with Alicia, Kerry, and
3 the rest of the folks on the FAC, right, so that we
4 will, as a Board, know that this is the kind of
5 input --

6 MS. YAN: Actually, all the presentation
7 reviews have been reviewed with the FAC.

8 CHAIRMAN NORQUIST: Okay, so the input for
9 our questions, we will make sure that we get to the
10 group. Okay? All right, thanks. Other questions?
11 Comments? Allen, did we get you? Are you still --
12 okay. I think that's it, right? Everybody's
13 enough now?

14 MS. YAN: So, if you have any further
15 comments about our plan to reforecast, you're
16 welcome to send me your comments. Thanks.

17 CHAIRMAN NORQUIST: Thank you. So, that's
18 the wrap-up, I think, and I can't -- I have to put
19 my glasses on. I can't read the closing comments
20 here. So, I want to thank everyone who was on the
21 call. All of the information that you saw today,

1 the slides and the recording of this Board meeting
2 will be on our website at PCORI.org and we always
3 welcome feedback at info@PCORI.org.

4 So, Joe, any final comments you want to
5 make? I'll let you.

6 DR. SELBY: Well, I thought this meeting
7 today was really good in helping us both think
8 through the evaluation and just suggestions. I'll
9 just mention these briefly in case I've got
10 something wrong or in case I've overlooked critical
11 points.

12 I don't have --

13 CHAIRMAN NORQUIST: We have tomorrow
14 morning also.

15 DR. SELBY: Just for our public audience.
16 So, one of the encouragements I heard from the
17 Board, and this was new to me, was this notion that
18 we should not only be proactive about this issue of
19 privacy, but we should really be conveners in this
20 world. This is really our role, to convene the
21 sides, if you will, in this discussion about

1 weighing the benefits, the great potential of big
2 data type research, with the serious, legitimate
3 concerns about privacy and data security, that in
4 the area of clinical trials PCORI may be able to
5 play a role in pushing the price point for trials
6 down. This is linked to PCORNet, but also to our
7 pragmatic clinical studies initiative, and even
8 consider, and I think this really can go back to
9 the SOC for some serious discussion, consider the
10 idea, when we clearly know the research question
11 that we need contracting directly with a PI or
12 seeing a PI with a good idea and contracting with
13 them to do the research, perhaps even in another
14 population or other infrastructure; that we need to
15 get a version of our standard operating procedures
16 that's suitable for public -- for the public, into
17 the public eye; that we need to get our methods
18 checklist and other materials as quickly as
19 possible into the public so people can use them, so
20 people can use them for teaching and be familiar
21 with PCORI's -- with the methods, standards, and

1 the tools to teach them; that we have some work to
2 do in presenting our expenses -- Rick and Harlan
3 both had some good ideas there that I think we need
4 to follow up on in the line of projecting expenses
5 for individual contracts, trying not to be
6 completely handcuffed, if you will, by being
7 limited to what funds have actually gone out the
8 door, but also investigating further this issue of
9 outlying and slow invoices.

10 I still want to get further into the
11 question of whether the delayed invoices reflect
12 delayed billing or delayed research activities. I
13 think it's not an answered question yet.

14 Several suggestions for the dashboard,
15 that we should definitely have a separate item on
16 the number of PCORI-funded publications separate
17 from those studies -- those that are written by
18 PCORI or about PCORI; that we need to have a clear
19 understanding of -- explanation of what it means to
20 be -- for projects to be up to date and meeting
21 their milestones or not meeting them. We really

1 need to flesh that out with some background
2 information. And then a metric that we can, again,
3 probably work out with Harlan, Rick, and the FAC on
4 what metric on the dashboard gives us a look, over
5 time, at the proportion of our expenditures that
6 are going for research versus administration.

7 Did I miss -- I bet I missed a few
8 important topics, I usually do.

9 CHAIRMAN NORQUIST: We can talk about it
10 more, but I think that's good.

11 DR. SELBY: I thought Dr. Levine had her
12 hand raised.

13 DR. LEVINE: Just a clarification. I
14 don't think it was research versus administration,
15 it was administrative expenses versus programs
16 research and the content related work of PCORI.

17 CHAIRMAN NORQUIST: Yeah, it's
18 administrative expenses overall versus the content
19 stuff that we do.

20 DR. LEVINE: Right.

21 DR. SELBY: And it was noted that

1 engagement should be combined -- programmatic
2 expenses for research and engagement should be
3 combined with the external expenditures supporting
4 research and contrasted with the administrative
5 expenses.

6 DR. LEVINE: Right. Right.

7 CHAIRMAN NORQUIST: Correct. Okay.

8 Alicia? That was from earlier. Thanks, everybody,
9 and then we have -- Debra, are you having your
10 publications committee or something?

11 MS. BARKSDALE: Yes. The scientific
12 publications committee is meeting now in the
13 Potomac Room.

14 CHAIRMAN NORQUIST: Well, 5:30 is what --
15 5:30 to 6:30, I think, and then there's a dinner at
16 7:00 and then we will reconvene tomorrow at 9:00
17 for our closed session and you guys have your FAC
18 early.

19 [Whereupon, at 5:17 p.m., the PCORI Board
20 of Governors meeting was concluded.]

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