PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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The Westin Georgetown

Washington, D.C.

[Transcribed from PCORI webcast.]

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Steven Lipstein, MHA (Vice Chair)
Grayson Norquist, MD, MSPH (Incoming Chair)
Ellen Sigal, PhD
Eugene Washington, MD, MSc (Chair)
Harlan Weisman, MD
Robert Zwolak, MD, PhD

AGENDA

AGENDA [Continued]

AGENDA [Continued]

P R O C E E D I N G S

[8:07 a.m.]

CHAIRMAN WASHINGTON: Good morning everyone. Welcome to the Board of Governors of the Patient-Centered Outcomes Research Institute, PCORI. It's always an honor for us to invite our guests, who are gathered in the room, as well as those who are participating via webcast and teleconference on any occasion when we're meeting, but it's a particular honor today because we're celebrating our third anniversary, which is our third birthday. And so it's not rehearsed and I'm concerned about the voices of our members, otherwise I would ask you all to sing "Happy Birthday" this morning to ourselves.

This is not just the 3rd anniversary, this would be our 14th in person meeting and we've had 7 webinars that represented official Board meetings, so this is really our 21st Board meeting in the last three years, and so --

[Applause.]

CHAIRMAN WASHINGTON: Congratulations to

us and thanks to all of you here in the room, as well as those of you who have been in the room in the past and are on teleconferences and participating through webcasts. Just a reminder that, in fact, all of the material that you're going to see today will be available on our website during the webcast and will be posted later this week on www.pcori.org.

We will have a public comment period later on this afternoon, approximately at 2:15, lasting for half an hour and so if you have an interest in signing up for that period and you have not to date, you still have some time. You can see Bill -- where's Bill Silberg. He raised his hand. And, please, as always, provide us with feedback regarding what's happening with this meeting, I mean, live today or subsequent to the meeting by e-mailing us at info@pcori.org.

And then, finally, being the very progressive organization that we are, we're live Tweeting today's activity on Twitter. Did I get that right, Steve? Join the conversation at

#pcori, okay?

And with those opening announcements I'm going to turn to the business at hand for today. And the first official piece of business would to be to welcome our new Board member, Dr. Richard Kronick. Richard, welcome.

[Applause.]

CHAIRMAN WASHINGTON: Many of you saw the announcement regarding Dr. Kronick and his distinguished background and also note that he is now the head of the agency for Healthcare Quality and Research. And congratulations on that appointment.

DR. KRONICK: Thank you, it's a great pleasure to be here.

CHAIRMAN WASHINGTON: We are going to turn to the minutes and we have minutes from our face-to-face meeting in May, and plus we've had two open Board meeting calls since then. And you should have seen the minutes by now, and so why don't I take the face-to-face meeting first, the May meeting, and ask if there are any comments? Any

corrections?

UNIDENTIFIED BOARD MEMBER: Move to approve.

CHAIRMAN WASHINGTON: Motion moved and second, all in favor?

[Chorus of yeas.]

CHAIRMAN WASHINGTON: All opposed? Any abstentions?

[No response.]

CHAIRMAN WASHINGTON: Okay, motion carries.

And, Joe, I think it's okay to take both of our two open Board meetings minutes together. Any comments? Questions? Motion to approve?

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

CHAIRMAN WASHINGTON: So moved.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

CHAIRMAN WASHINGTON: Second. It's been moved and second. Any comments?

[No response.]

CHAIRMAN WASHINGTON: All in favor?

[Chorus of yeas.]

CHAIRMAN WASHINGTON: All opposed? Any abstentions?

[No response.]

CHAIRMAN WASHINGTON: Okay, great.

Now it's my pleasure to turn the program over to our illustrious executive director, Dr. Joe Selby.

DR. SELBY: Thank you, Gene, and good morning, everyone. First things first. As Gene said, this is the third anniversary of the date that the GAO notified each of you that you'd been appointed to PCORI's Board. You didn't actually meet for two months, although I learned last night that you did meet by telephone sometimes in between. I wish I had been there, but I wasn't.

One of the bad things about the three-year mark is that it does mark the end of a term of a Board chair and vice chair. And Gene announced about eight weeks ago that he would be stepping down from the chairmanship and from the Board at

the end of this three years. We have a new chair, Dr. Gray Norquist, and we are extremely excited.

[Applause.]

DR. SELBY: One thing that I think this meeting is going to demonstrate is that in many ways PCORI is entering the next era and that we begin it with a new chair and with a returning stellar vice chair --

[Laughter.]

DR. SELBY: -- returning? -- reappointed vice chair is great news for us and we are indeed in good shape. But, Gene, you're not quite done yet. I know that you're going to lead us through the day with an iron hand, as always, and we're going to really thoroughly enjoy being led by you once more.

I need to say, and I suspect a few other people are going to need to say, a couple things about you this morning, your thinking and your energy, but even more than that, the personality of the man that you are has really influenced us all. I would say that from here forward it will inhabit

the Board, inhabit PCORI.

[Phone rings.]

DR. SELBY: You've shaped us to be an organization that emphasizes turning your phones off before the meeting starts --

[Laughter.]

DR. SELBY: -- and engaging patients and those who care for them, personally and professionally. Many of us joined you last night to celebrate your tenure, your career, your contributions, but I thought we should take a brief time this morning to acknowledge it again in front of the full Board, more of the staff and the public, how much you've meant to PCORI.

From a personal point of view, I just want to say thank you for your mentoring and your support and, most of all, your friendship. It has been wonderful.

[Applause.]

DR. SELBY: I think Mr. Lipstein may have something to say.

VICE CHAIRMAN LIPSTEIN: I'm hoping

everyone can hear me if I stand up a little bit. But, Gene, what's remarkable is if we had this Board meeting three years and one day ago, there'd be nobody in the room. And when you look around the room and you see the assemblage of our Board, the Methodology Committee is seated here this morning and our staff is here, none of this was here three years and one day ago. Actually, the staff didn't show up until about two years ago. And the fact that you were our founding chair in helping us to establish this organization, put it together, launch it, and we've accomplished as much as we have in such a short period of time, it's just a testimony to your leadership.

And while we are very excited to carry on the work of PCORI under Dr. Norquist for the next several years, we can't let this moment pass without acknowledging the wonderful contribution you have made, not only to the research community, but also to our country and to advancing the engagement of stakeholders and patients in the research enterprise.

So we have a little collage of pictures that demonstrate your leadership over the last three years. And while it would always be a little bit risky for me to speak on behalf of the entire Board, I don't think there is one among us wouldn't acknowledge that because of you, we are where we are today. Thank you very, very much for everything.

[Presentation off microphone.]

[Applause.]

DR. SELBY: Okay. In so many ways this meeting marks the beginning of the next era and it does definitely mark -- and we've talked about this a lot -- the beginning of an era in which the Board moves to more of a governing role and that is reflected substantially in this dashboard, which you've seen before, which discussed before. This identifies a large number of priority activities that come from our strategic planning activities and that tell us what's most critical for us to take on in 2013 and moving into 2014.

And the agenda today and from henceforth

is going to be organized around these key priority activities. You're going to hear from Bryan Luce, our chief science officer, about our efforts in establishing advisory panels, particularly the Clinical Trials Advisory Panel, and a bit from me about the Rare Diseases Advisory Panel. You'll also hear from Bryan about a key activity in developing portfolios -- PCORI's active portfolio management process.

You'll hear from Dr. Anne Beal about our engagement awards, efforts to support bringing members of the healthcare community, including patients and clinicians, more actively into the research process. You'll also hear from Anne about progress in developing PCORI's plan for dissemination of research findings in collaboration with the Agency for Healthcare Research and Quality.

You will hear from Robin Newhouse and Steve Goodman about our progress in disseminating the methodology standards. And you will hear from Chief Operating Officer Regina Yan about one of our

metrics which we're watching closely and that's our ability to shorten the time from awarding a contract to getting that contract signed and in place. So, in every presentation, you can reflect back to one of our strategic priority activities.

You have in your book, and you also have in front of you, a set of strategic questions that we think it would be valuable for the Board to weigh in on with Staff Methodology Committee in the room. We don't claim that these are all the strategic questions or that they are necessarily the most strategic questions. They're our first effort and in working with you we'd like to move in this direction of identifying key questions for each topic that needs discussing, and questions that are indeed at the level of strategy.

So that's the agenda for today and you can follow along in front of each of you on the annotated agenda that has these questions.

This afternoon, in celebration of our third anniversary, we're actually going to feature three of the studies that we funded. So three

principle investigators, three patient co-investigators, will be here and we think a responding stakeholder group from each of the three -- certainly for two, and we hope for all three -- will be there to demonstrate both engagement within a research team and engagement of a research team with the larger stakeholder community. So that's a preview of the strategically oriented agenda for today.

We really are moving full speed ahead. That's the way it feels at PCORI and it wouldn't feel that way if we hadn't added, just at the time of the last Board meeting, two key people to join Dr. Beal and myself: Bryan Luce as chief science officer and Regina Yan as chief operating officer. And with them in place it feels substantially different, substantially better, and substantially more like we're able to move ahead with our plans and with your guidance.

So we are funding a lot of research. It takes the form of broad funding announcements, where we've funded approximately two-thirds of the

amount we've planned to commit in 2013, and we have one more round that we funded in December. You know about our targeted funding announcements and their commitments, one involving NIH and one involving AHRQ. The infrastructure awards, very exciting. We announced the coordinating center about 10 days ago and those awards, the CDRNs and PBRNs, will be announced again in December. So, you see, we solicited a name to spend about $427 million in research funding this year, to commit it, and we are on track to do that.

But this is really a time, also, of refinement. And, in fact, if 2012 was the year of engagement and 2013 was the year of strategic research investment, 2014, I think, in many ways, is going to be a year of refining what we do. In the area of merit review, Dr. Lori Frank from the science team has taken over and integrated science much more closely into the merit review process. We're moving quickly towards establishing standing review panels as opposed to the ad hoc panels for each round. We have revised, simplified, and

clarified the review criteria, and we've enhanced the training of reviewers, both patients and other stakeholders and scientists.

In the contracting process, as I said, you'll hear from Regina about progress in streamlining the awarding documents and the time it takes to get an award into a signed contract.

In the area of topic generation, we continue to work with our advisory panels. We had two meetings in the last two days. Friday we met with our Patient Engagement Advisory Panel and again on Saturday. That panel jumped into the process of breaking engagement down into its components. What does engagement mean? What are our awardees doing in the name of engagement?

And this is a first step toward evaluating what engagement actually works and whether engagement, the way we do it at PCORI, makes a difference in terms of the research we fund and the results we get. A very exciting panel.

Saturday we had the second face-to-face meeting of the Clinical Effectiveness Advisory

Panel and that panel focused on further steps in identifying and refining high priority questions. Another very exciting day. Both panels were excited and staff who were there really got the clear sense that these panels are an integral part of who PCORI is and an integral part of us getting to the targeted research we want to find.

This is a preview of discussions we'll have this afternoon with the committee, COEC, PDC, and the FAAC over the next two months as we head into the budget for Fiscal Year 2014. The message is that for a number of reasons, we're going to have to grow. This is simply the growth we anticipate by the end of calendar year 2013. So we are currently at 80 employees; we targeted 88. At this time we're at 80 and postings are up for the other eight and for additional people. So we anticipate by the end of this year we'll be at 118. And in negotiations with committees over these next two months, I think we'll agree that actually that's an inadequate number to have by the end of 2014, but that's obviously a process that the Board

is going to engage intensely with us on.

Reasons for staff growth, there really are a number of reasons. I want to get them on the table. The portfolios are growing rapidly in size. By the end of this year we'll have on the order of 200 to 250 active projects.

We made a strategic decision earlier this year to employ active portfolio management, both pre- and post-awards, so we now talk by phone with interested applicants. We work very closely with applicants once awarded, more intensively perhaps than we planned, more intensively than some other funding agencies routinely do, for a host of reasons that are related to making sure that this research is done as well as it can be and that it has an impact.

We made a strategic decision to commit more funding in the early years and although we have more discussions to be had -- and that is a very strategic question -- we did commit more funding this year than we originally anticipated. And that increases demand for staff, both in

preparing the announcements, in adjudicating and running the review process, and in overseeing and managing the research.

We also made a strategic decision in about February of this year to develop and fund the National Clinical Research Network, our infrastructure program. This is a program that was not on the radar at the time we budgeted last fall.

And lastly, we've decided that we need to replace the consultants in a gradual process. We need to replace our scientific review officers, who are consultants, with staff, just to improve further the merit review process. So, for all those reasons, they all contribute to a need for staff growth in 2014.

I'm very delighted to introduce to you the newest member of our executive team, Mary Hennessy. Mary, are you here?

MS. HENNESSY: I'm right here.

DR. SELBY: I'd like to say welcome to Mary, our new general counsel, and, as I said, a member of the executive team. Mary comes to us

from ASCO, the American Society of Clinical Oncologists. Before that she spent a number of years in regulatory science and legal counsel at the FDA, and before that she was in a private sector law firm that served health plans and health institutions. So, a very diverse background, very steeped in conflict of interest. A graduate of Harvard, an undergraduate at Harvard Law School. And she will do a number of things, including overseeing our compliance effort, working closely with the Board, with me, and with our executive team on legal issues, overseeing all aspects of contracts. And, in general, within hours of Mary's arrival it was very clear to all of us that her arrival was overdue and it's really a great pleasure to have her on the team.

It's been four months since we met and PCORI has grown some. These are 21 individuals, scientists, contract people, communications people who were not with us when we met in Chicago, who have joined us since.

Just a word about the progress on the

infrastructure awards. We're not going to talk about this much this meeting just because there are a number of other strategic issues we need to cover, but, as I mentioned, we have named the coordinating center, a very seasoned coordinating center, with all the expertise we need to build a national infrastructure. People who've been working on different aspects of this for many years, it's led by Harvard pilgrim, Dr. Richard Platt, co-led by Duke, by Dr. Rob Califf and really the lineup of co-investigators on this coordinating center is really impressive.

The application deadline for CDRNs and PBRNs is the 27th, that's this Friday. We have a meeting that's in the works, in planning, that will be held in collaboration with the IOM. It will be held on October 31st and November 1st, and it's on the technical issue of common data models. How in the world do we take data from eight disparate healthcare systems and actually get it into a shape where it can be shared, one way or the other, so that we can do multicenter research, both

observational research and clinical trials research?

The application reviews will take place in mid-November and the applications will be awarded in a telephone Board call on December 17th. We also have a second IOM meeting in the planning stages and that will take place sometime in the spring of 2014. And this meeting will have a completely different focus. It will be focused on how one actually brings the systems that are contributing the data to the network, how one brings those systems into the governance and use of this network. So we want the systems to think of this network as a place they can go to ask and answer questions.

And, most importantly, we want these systems to recognize that in a number of instances that doing a comparative effectiveness research question, a patient-centered CER study, appropriately requires randomization. So this complex notion of randomization within healthcare is something we want to talk about with the leaders

of healthcare systems, both those who have joined us and others who are interested.

And I just want to say a word to you. We won't say too much about this today, but we committed in May, in Chicago, to also getting started on a Rare Diseases Advisory Panel. As I mentioned, Bryan will tell you in some detail about the progress on the Clinical Trials Advisory Panel, but I'm happy to report that we held a roundtable about two weeks ago -- in fact, on September 11th, I believe -- with multi-stakeholder participation. Included in the group were patients representing rare disease communities, clinicians who do clinical care and research in those communities, industry who produces new agents and therapies for those communities, payers, the FDA, the Office of Rare Disease Research at the NIH, and researchers. And one of the tasks there was to discuss the way that comparative effectiveness research and PCORI could find its place in this complex area of supporting research on rare diseases, given that NIH and FDA and industry are already there. So

that was very fruitful.

The other thing we did was work on a charter. That charter -- excellent suggestions for that charter -- it's being revised and you'll be hearing about that between now and the November meeting, so we will submit a charter to you, probably in early November. We hope that that charter will then be able to be approved at the November Board meeting and we anticipate that we will be able to open applications for membership on this advisory panel early in January, at the same time we reopen applications for our other advisory panels.

So I'll close just with these questions, which are also on your annotated agenda, questions about aspects of the merit review process. I know that many of you wind up being exposed to comments about the merit review process. This would be a good time to surface them. Ask us questions. Make suggestions in that area.

Having a general counsel and having a relationship between the general counsel and this

body leads me to invite you to make any comments you'd like on tasks or issues that we need to work on together with Mary. And, also, I'd love to answer any questions or issues you want to raise about the National Patient-Centered Clinical Research Network.

DR. KRUMHOLZ: Thanks, Joe. I just want to key on the first question for a second. Harlan Krumholz, Board member.

I've heard from a lot of people in the research community some questions about the review process. I don't think this is unusual, certainly for those of us who have applied. We always have questions when we don't get funded, but what is the way that the research community can funnel their questions and talk to someone and get feedback? And what kind of feedback can we let people know that they can expect to get because managing expectations is always important. But I believe that this is a very critical issue for us, the engagement of the best scientists in the country, and giving people strong, good feedback about their

applications in ways that both help them strengthen it.

Everyone should know that those who resubmitted their applications in the last round had a much higher success rate, so we do want people to persist in their applications. We have evidence that those who do persist do well, but for those who really want to be able to talk to someone and understand the comments and parse their way through it, what can they expect and how does it work exactly?

DR. SELBY: Thanks, Harlan. Well, let me just reemphasize one thing you said, which was that the success rate for resubmissions was 29 percent. The overall success rate was 12.7 percent and that was pulled up by the 29 percent for resubmissions. So I wanted to just reinforce what you said.

Our scientific staff has recently, as it's grown a bit, has taken on the challenge of being able to address in telephone conversations questions of applicants before they submit applications. We held a webinar last week that was

attended by -- I'm not sure, if somebody can help me out -- I think it was somewhere between 200 and 400 attendees on what we are thinking and what we've observed to be best practices in engagement. Because a lot of the questions have been about what do you actually mean by engagement?

So when applicants begin the application process, they now find a way that they can submit questions and then get telephone feedback. This is something that we aim to continue improving and I think it is very predictable that we will, particularly as the staff continues to grow.

DR. KRUMHOLZ: And the phone number is on the website.

DR. SELBY: The phone number is on the application.

DR. KRUMHOLZ: On the application, yeah. So where can -- just if anyone's listening or we want to put this out, the phone number is --

UNIDENTIFIED SPEAKER: 202-627-1884.

DR. KRUMHOLZ: 202-627-1884. Can we get an easier number for people to remember, like 1-

800-PCORI?

[Laughter.]

DR. SELBY: Yes.

DR. KRUMHOLZ: But it would be really good, I think, to spread that around. And maybe, Robin, we're thinking about, with the Methodology Committee, how we can ensure that people get that and then managing it. Because if we do get a lot of requests, which is always a challenge, it's just going to be a question of how to manage it best.

DR. NORQUIST: Gray Norquist. I want to second what Harlan is saying because I've been getting a lot of concern about this. And having worked at NIH for 15 years, one of the big things there and what really helps is to have an individual you can talk to. And I think the webinars and all these things are very good, but what it boils down to is if I have an individual application that doesn't make it, I want to know exactly what did I not do right, or something? And having program officers basically sit in those reviews and come back and say, here's kind of what

-- because if the summary statements, or what we used to call the pink sheets, don't always reflect what actually happens and that's some of the concern that I'm hearing about.

You know, the scores are divergent and they're like, well, what happened? And having a program officer who sits in the reviews and can come back and tell you this is where you went wrong and this what's going on, I think, would be incredibly helpful. So I like the idea of seeing the staff numbers picking up because that's what it's going to boil down to is actually having people who will be able to do that.

The other thing I've heard from some folks, and I think it's something at some point that we need to think about, is the actual review process in and of itself. I've had some reviewers who have said that it's very tedious in some ways in what they're filling out. And I think that another thing perhaps at some point we might want to look at is what's actually going on. And, you know, earlier the Methodology Committee, I thought,

was going to do a study. Actually, I think Michael and some others were looking at this, at actually what was going on, and I think we should think about that in the future, about maybe improving actually what goes on in that merit review process.

DR. SELBY: Yes. A couple of things. We do have a paper that is just about to be circulated to everyone and then submitted on what goes on in the review process, and it is quite interesting. And members of the Methodology Committee have helped us with that a lot.

VICE CHAIRMAN LIPSTEIN: Steve Lipstein, member of the Board. One of the things that PCORI does that, for those of us who don't live in the research community every day, that we believe is unique, but maybe it would help to -- is our review process includes, and Gray referred to this as -- it's a little bit tedious, but it reviews a lot of measure of the extensiveness of end user engagement, whether the end user is the patient or the caregiver or other stakeholders. And so one of the things that I guess I've heard, and we're all

reporting a little bit anecdotally, is that it's possible to submit an outstanding application to say, the NIH, and get a really good score, but not get funded. I think that's possible, right?

And then you could take that same application and submit it to AHRQ and it's really good and it gets a really good score, but it doesn't get funded. And then you submit it to PCORI and because of our additional criteria or our different criteria -- I don't even want to say additional -- our different criteria with regard to stakeholder and patient engagement, it doesn't even get a good score. And then that's very frustrating because here there was a great peer review process at one nationally known agency and a great peer review process at another and then you come to us and I have found -- and this has happened at my home university -- that people are just now beginning to read the RFAs and look at the criteria and the merit review criteria and outlining how it's different from other agencies.

And I think, I guess, I'd like to hear

from people who live in the research community, but I think that we're on a learning journey where people are realizing that an application to PCORI needs to be significantly different from what they're accustomed to. And that's been a source of frustration because if one organization gives you an A and another organization gives you A and a third organization gives you a C, it just doesn't feel like it's a fair review process, but the criteria is different and I think everybody's learning that. But for those of you who have done this before, it would be interesting to hear your perspectives.

DR. WEISMAN: Harlan Weisman. Just picking up on a theme, maybe a comment, question, and suggestion embedded in all of it. Likewise, I've certainly received individual feedback and it's always hard to know how much help to give. You know, we're not supposed to help individuals randomly, but I've tried to give them general guidance.

Steve said something about this being a

learning process and we began the peer review and I know we've gone through some iterations, but with the idea originally that it was interim. That we were adopting an NIH-like study section system because it was expedient, and then we would grow and evolve from that. And I know there have been changes, but basically it seems like it's pretty much the same.

And what I was wondering is, we can all speculate and we have a lot of anecdotal information, but there are a lot of people who are applying. There are people who write letters of intent and don't apply, somewhat because they do find it mysterious and sometimes onerous to figure out what it is that we want.

And then there are the people who apply and don't get grants and those who apply and do get grants. Have we surveyed these people? It seems like it's a tremendous amount of data out there where, as a learning organization, we could learn a lot about the effectiveness of what we're trying to do. I've gone through the application and read it

and everything is there. It makes sense to me, but I'm an insider and what do we do to find out from our customers, so to speak, the researchers, about our process? What do they think about what we're doing? And I don't mean bitterness because somebody didn't get an award, but I mean in terms of the overall process.

DR. SELBY: We are launching surveys of both the applicants and the awardees. In fact, some results from them will very likely be on the 2014 Dashboard because we agree with you, it's critical to know what the research community is saying. So we will have survey results by the end of the year to show you on a baseline of what applicants are saying.

CHAIRMAN WASHINGTON: Gail? And then Ellen.

MS. HUNT: Gail Hunt, a Board member. Now, on the flip side, I just came off the day and a half Patient Engagement Advisory Panel and I can say that there is interest on that side of the issue, which is perhaps the reverse or a different

one than the research side. There is really an interest in pushing this patient engagement and outcomes.

What are the outcomes in terms of patients and caregivers, for example, and other stakeholders? Really pushing that, making it an even greater part of PCORI's merit review and a greater part of PCORI's eventual evaluation and concern about implementation and dissemination of our research. So that's something to take into account as well.

CHAIRMAN WASHINGTON: Ellen?

MS. SIGAL: Sorry. Ellen Sigal, Board member. So peer review is not perfect. It's not perfect anyplace. It's not perfect at the NIH, it's not perfect at AHRQ, and it won't be perfect at PCORI. However, we should be different. We should be different because if we're doing exactly the same thing, then we're not doing it right. Our research is about the patient and it seeks a different way.

I think the issue is clarity. What is it

we want? Why is it different? What are the expectations, up front? If it's just recycled grants from NIH to AHRQ, it's not going to help us because we're asking different questions.

And the biggest issue that I hear from the community is the lack of ability to understand what we want and to have a person to speak to, to guide them through. I do a lot of work with the FDA and I do a lot of work with the NIH and when you can talk to people and they can understand what you want and they understand what the rules are up front, you get it right.

So that's what we have to do. But, again, I'm not at all worried about disgruntled researchers who don't get grants. I'm just worried about are we getting what we want?

CHAIRMAN WASHINGTON: Okay, thanks, everyone. Steve, I think we answered your question. Yeah, and Ellen just summarized it quite effectively.

DR. SELBY: I think that's it. I just want to say that I really appreciate your ongoing

inquiry into this question of merit review. I loved what Ellen said, but we take everything that each of you said seriously and I'd say we agree with it. And over these next couple of months we will talk with you on several occasions about assessing from the point of view of these applicants, successful and unsuccessful, about how we're doing.

And I would just echo again that I think this move towards standing panels, people who review every four months with us and get to know the ways that we're thinking and the evolution of our thinking from one cycle to another, will make a huge difference in terms of consistency and clarity. Harlan?

DR. WEISMAN: Just since you opened up on the questions and one of them is about the Patient-Centered Clinical Research Network. I know we're going to talk more about it, but I just want to take the moment to say that I thought that the initial application process was spectacular. And I don't have a question except to just comment and

commend the staff and the team and to note for people listening that I think this is going to be a remarkable initiative. I think it has the potential to be one of the most transformational things that PCORI does.

In the selection of the group, the Coordinating Center, is I think a landmark moment in PCORI's continuing life cycle. And I just wanted to say it out loud to people who are listening that this was just done really, really well and we've got a wonderful group to get us started. And I'm looking forward to the continuing news about applications as we go through the rest of the year.

DR. SELBY: Thank you, Harlan. Joe, I think on that note we're going to shift topics, okay? Why don't you go and introduce the next -- oh, I'm sorry. Dr. Zwolak, you've got to end on a high note.

DR. ZWOLAK: Two seconds. Bob Zwolak of Governor. The meeting announcement that you described about IOM and the common data models, I

think, is an absolutely crucial next step. Is that information available in terms of date, meeting site, agenda, and so forth?

DR. SELBY: The date is October 31st, Halloween, and the first half of November 1st. It will be here in D.C. I'm not quite sure of the venue here in D.C., but definitely here in town.

The agenda is not entirely shaped yet. There is a planning committee that's working very diligently on it.

Okay, so we're going to move now to Dr. Bryan Luce and he's got actually two topics lined up, the first of which has to do with the charter for the Clinical Trials Advisory Panel. As you know, the legislation calls upon us to have a Clinical Trials Advisory Panel and among its responsibilities is looking after the clinical trials that we fund. We've made a lot of progress in getting a charter put together. It's not quite ready to submit to the Board for approval, but a revised version is in front of you. So you have a revised Clinical Trials Advisory Panel charter in

front of you.

We recognize along with the Methodology Committee that there is a lot of overlap between what the Clinical Trial Advisory Panel is charged with doing and what the Methodology Committee is responsible for. And so we spent a lot of time with the Methodology Committee and improved the charter, I think, substantially in the process by clarifying the relationship between the Methodology Committee, the Board, and the staff in this advisory panel.

So I'll turn it over to Dr. Luce.

MR. LUCE: Thank you, Joe.

CHAIRMAN WASHINGTON: Just before Bryan starts -- I'm sorry, Bryan -- but I would remind the Board members that we do have a set of strategic questions before you and Bryan is expecting that he will receive some feedback on these questions.

MR. LUCE: No, I have -- yeah.

CHAIRMAN WASHINGTON: Okay, sorry, Bryan.

MR. LUCE: Well, good morning, everyone.

It's a pleasure to be before you. I'd just like to start my remarks -- again, I'm Bryan Luce, the chief science officer -- to reinforce what Joe said and the concern that I heard around the table about the review process.

It is the highest priority in the Science Office and we're putting all efforts into improving the process from the very beginning of matching our reviewers to proposals, to the review process itself, to improve the summary statements more professionally and scientifically, and in the standing panels. So there's nothing more important on my desk than that.

So I'll walk you quickly through the Clinical Trials Advisory Panel. It's in quite good shape. As you know, the panels review key information regarding the role and establishment of PCORI's advisory panel on clinical trials. You have the charter in front of you. It was the product of a very close relationship and coordination with the Methodology Committee and you will have -- I would think it's in pretty good

shape and you'll have it probably for the next Board meeting for a decision.

Also, likely know that the authorizing legislation mandates that we have at Clinical Trials Advisory Panel that will assure high methodological standards and design and conduct of trials to advise the Methodology Committee and the Board in priority areas for the development of clinical trial methodology and to advise PCORI on their readiness of trial results for dissemination or implementation.

The specific duties from the legislation are to review proposed trials, to provide oversight and analysis of funded trials, provide guidance on designs and protocols, and provide strategies for recruiting key patient groups.

The proposed charter is just a couple of pages in length, so it's easy for you to review, and probably already have. The panel will advise PCORI, its Board of Governors, Methodology Committee -- you can read this in multiple aspects pertaining to the selection, design, and

implementation of trials for patient centered outcome research conducted in typical community settings. PCORI advisory panels do not serve, as you know, in an official decision making capacity, but their recommendations and advice are carefully taken into consideration by the institute.

We're proposing two staggered terms for a maximum of two terms. In terms of composition, we're proposing 10 to 14 members, at least two of who are members or caregiver representatives of the Patient Advocacy Organization and at least half will have technical expertise in the conduct of clinical trials. Up to two Methodology Committee members can serve, in addition to appointed members ex officio. The chair of the advisory panel we're proposing to be the chief science officer, which, of course, at this stage is me.

So we have worked very closely with the Methodology Committee in crafting this charter. The concern was and certainly is that this particular advisory panel is highly focused on methodology and we didn't want competing entities

with respect to providing methodological guidance in this area, so that we've really interwoven the Methodology Committee as well as this charter for the advisory panel.

So I'm pleased to open up for any comments or ideas or suggestions for the guidance from the committee -- from the Board.

CHAIRMAN WASHINGTON: Why don't we start with Gray and then Ellen and then Allen?

DR. NORQUIST: So Bryan -- Gray Norquist -- I was looking at this and it seems like we have a Methodology Committee that's a lot of this expertise and I'm just curious how of you see it. It seems to me that to me, personally, it would make more sense for this group to report to them perhaps and come through instead of thinking directly to the Board. But, I mean, I don't know what the thinking is. You just mentioned that there may be some mingling or something, but I'm a little confused because it sounds like to me that we have a stellar group of people on this Methodology Committee who have a lot of this

expertise.

So I'm just wondering how you see that as working. And instead of coming directly to the Board, it seems to make a lot more sense to me for them to go directly to the Methodology Committee, but maybe I'm missing something here.

MR. LUCE: It's possible we need to be more clear in the charter, but the full intent is that from an operational standpoint it will advise directly both the Methodology Committee and staff in the conduct of trials than more indirectly to the Board. But the charter itself was literally staffed and massaged with the Methodology Committee. They're very comfortable with this. They were as concerned as you are expressing your concern right now that not only to make use of the expertise within the committee but, in point of fact, a real concern that there was sort of a competing, really confusing aspect to it. So we do not intend that to happen and I think that's one of the other reasons that there was a decision to ask me to chair the committee.

MS. SIGAL: So I know that -- Ellen Sigal, Board -- so know that the legislation called for this and I understand the need for it, but I'm confused about the silos we may be creating and content expertise we may need because clinical trial design is very complex and it depends on the questions you're asking and the disease setting. And I'm wondering how we're going to get the experts because they're just not generic. The way you do a trial for cancer outcome or quality of life is going to be very different from what you're doing for falls.

So I don't know how exactly this will work, not only in working with the Methodology Committee, but how will it work when we are actually putting out NRFP or RFAs, so I don't know. So will you get the right content experts to ask the right questions and advise and work with the methodology and work with the PDC on it? So how does it work in the ecosystem, I guess I'm asking?

MR. LUCE: I'm not sure we're prepared to understand exactly how it will unfold and I

certainly agree with you that a clinical trial is not a clinical trial. It's not a clinical trial, especially as we think in terms of moving into more real world, comparative learning healthcare system trials, like we are. So it is a brave new world and, of course, there's a lot of clinical issues that separate different trials from different trials.

We certainly envision adding ad hoc members to specific trial guidances that we need beyond the more general issue of clinical trial methodology. So I presume that that's how we will handle that over time. But we will look for continued guidance all the way through, specifically with the Methodology Committee as to how to handle this.

And, I don't know, Robin may want to add to this because you and the committee have been very much involved with this sort of thinking.

MS. NEWHOUSE: Yeah, I would just add that we are very thankful for all of the interaction and work on this Clinical Trials Advisory Panel from

Bryan and the Methodology Committee. There were multiple points of interaction as well as interaction with the PDC, and I think working through the charter language, the composition, the roles and function, we're comfortable with the draft as it stands. We did discuss whether the Clinical Trials Advisory Panel should report to the Methodology Committee.

MR. LUCE: Right.

MS. NEWHOUSE: And we also are very mindful that they have a role in advising PCORI staff, too. And, operationally, how would that work if it came through the Methodology Committee? So we would be fine with it reporting to the Methodology Committee, that was one of the suggestions, but we also are comfortable with Bryan leading as the scientific review officer and with Methodology Committee members being on the advisory panel.

So I would say that in the dialogue between the three groups, we're comfortable with the panel as it stands, but we also would be open

to the Methodology Committee being the reporting structure as well, as we discussed.

CHAIRMAN WASHINGTON: Allen Douma?

DR. DOUMA: Allen Douma, Board. I have several things, actually. One is, it says in our enabling legislation there will be panels, plural.

CHAIRMAN WASHINGTON: Yeah.

DR. DOUMA: Are we conceiving that this is going to be an evolution and some addressing perhaps what Allen is talking about, the need for different expertise, or are we going to try to do it under one forever? Is that our attempt?

MR. LUCE: I wouldn't argue that we're going to do it under one forever.

DR. DOUMA: Okay.

MR. LUCE: Dave, you had a comment? Go ahead.

DR. HICKAM: So there's a provision for subcommittees of the Clinical Trial Advisory Panel, which I think would capture the multiple and specific needs.

DR. DOUMA: Okay. The second question is,

in the write-up in the material that we have -- and I don't know if we actually came across in our slides. It talks about this group being active. One of the major things they do is actually advising us in the dissemination of clinical trials. It seems like that's kind of an expertise which is different than what you would want in somebody who is designing clinical trials, so I'm not sure why that's thrown in. There's a lot of work that's being done across the organization on dissemination in general and we may be careful and not getting too confused about roles and responsibilities.

MR. LUCE: Okay. Thank you.

DR. DOUMA: And just minor things. With regard to the appointment of people for two years, staggering roles. If you do that, the easiest way to do that is you appoint somebody for one year.

MR. LUCE: Right.

DR. DOUMA: I would suggest one year is too short in a start-up situation. By the time anything is happening, anybody has any

understanding, they're gone. So maybe, in the beginning, you can think in terms of having three-year/two-year, and reappointments are only two? It's just an idea.

MR. LUCE: Yeah, we went through that process. The first iteration was just one-year terms and that obviously didn't work at all. But that's a good point.

DR. DOUMA: Yeah. And finally, as we will talk about later on tomorrow perhaps, about the governance report that's coming out, it talks about the amount of time prior to a committee meeting when materials should be available. I'm just suggesting the advisory panels have the same timeframe, just so we're consistent.

MR. LUCE: Yeah, okay.

CHAIRMAN WASHINGTON: Harlan and then Michael, Freda, and Christine.

DR. WEISMAN: Harlan Weisman, Board member. Like the others who have commented, it's a little confusing still to me, though I'm reassured by Robin's comment of the close working

relationship. The rationale, I guess, to begin with is that it is explicitly stated in the legislation that created us, but, like Allen, to me when I read the paragraph on expert advisory panels for clinical trials, it seems to suggest that rather than working on conceptual and generic issues of conducting clinical trials, that it is to advise the institute on conducting the research on the research question involved, and the research design or protocol, including important patient subgroups and/or other parameters of the research. "Such panels shall be available as a resource for technical questions that may arise during the conduct of such research."

So, to me it sounds like almost a consulting advisory group that's available for very specific research questions and specific areas of research, either ones that we want to fund in a specific area to give us some ideas, maybe in terms of evaluating research proposals, or, in fact -- by the way, it reads "advising specifics of the research design in question." Maybe after an award

rather than the way I see the Methodology Committee which is to lay out the general principles of conducting various types of outcomes research.

Am I --

MR. LUCE: No, you're absolutely correct as I read the legislation as well. I think we all do. It doesn't bar us from broadening the charter. And we felt as the staff and the Methodology Committee that we wanted a more standing panel that provided overall guidance as well as to be able to be the central point by which we would put together ad hoc or subcommittees for specific panels. But we --

DR. WEISMAN: I'm sorry. The latter, to me, presents no confusion of roles and responsibilities because we don't really have that type of specific advice. And, in fact, it seems to be somewhat like what Harlan Krumholz and perhaps Gray were asking for, which is to give more help in specific items.

MR. LUCE: Right.

DR. WEISMAN: On specific research

questions, when you then broaden it the way you're suggesting and -- you know, look, if the Methodology Committee finds this useful for their charter, I'm fine with it. But it does seem that once you broaden it, you're then going into Methodology Committee territory and hence my confusion.

So let me give you an example. What if -- and I know you have Methodology Committee members on there. You're proposing up to two. There was a divergence of opinion between this committee and something more broad in methods and our Methodology Committee as a whole. How does that get adjudicated?

And I almost feel that broader function -- and maybe it is two different roles -- has to go through the Methodology Committee whereas the more narrow one is an advisory role in which you tap into Methodology Committee experts and external experts to help on specific questions following the general principles that have been outlined by the Methodology Committee. It sounds like we're

creating something in that broader role that maybe we don't need, but I could be wrong.

MR. LUCE: Well, we will be learning as we go along in the universe, especially a learning healthcare system and we certainly will be learning it. I certainly agree that all of those issues will come up. Okay?

DR. LAUER: Thank you. Mike Lauer, NIH designee. I want to echo Ellen's point about the importance of assuring appropriate expertise for this. And I know that a number of people have brought that up. The other point I wanted to raise, this is something we have talked about within the Methodology Committee and we've been reassured that this is being addressed, there's a lot going on in this sphere of clinical trials. I don't have to tell you this, Bryan.

And in particular, there is a group which is being overseen by the FDA, the Clinical Trials Transformation Initiative, which has brought in a whole lot of stakeholders. And we want to make sure that there is appropriate interdigitation and

communication between this group and the CTTI, in particular, as well as other high level, multi-stakeholder groups that are concerned about the future of clinical trials in the United States.

CHAIRMAN WASHINGTON: Thank you. Freda and then Christine and Harlan.

DR. LEWIS-HALL: Freda Lewis-Hall, Board. Actually, Michael covered one point, but I'll reiterate. I sit on the Executive Committee of the CTTI and we just completed a landscaping and it is a pretty crowded space. That's a good thing because of the level of interest, but it also means that there is a lot of perhaps redundancy and lack of communication and integration for findings. So there's no language in here around how this committee works with other areas of specialty in this area and I think that that might be helpful.

The second thing is I, too, am a little bit concerned. I'm reassured with the words that you say, but I'm not sure that it's reflected in the document the way in which responsibilities and activities are parsed out appropriately between the

Methodology Committee and this advisory panel. We may want to be clearer, so that as it evolves, it doesn't evolve directionally incorrectly.

And the third thing is we may be able to reduce redundancy or conflict between the work of the Methodology Committee through the appointments of unique or specialized expertise that would allow some of that additional more visionary work in evolving this space. So, to pull people onto this that are not kind of mirror images of who's on the Methodology Committee from an expertise standpoint, but instead to find folks who have unique or special or a wildly different areas of expertise to provide greater separation.

MR. LUCE: Thank you. Just in quick reply, if you consider the fact that the Board will actually be appointing the members of the panel, so members such that could be cutting across with CTTI and others, you'll have an opportunity to help shape that. And that will probably be critical in that we do create a panel that doesn't stand all by itself and that is part of the national move

towards the transformation of clinical trials in this country.

MS. GOERTZ: I just wanted to reiterate the point that Freda made in regards to tightening up the language here. I mean, I agree that it sounds like there's a gentlemen's agreement about how we're going to operate here, but as things evolve and as people change, that can get lost. And if it's the intent of this group now to establish a charter where essentially this would report to the Methodology Committee, I think we should explicitly state that and make that more clear in the charter. That would be my recommendation.

MR. LUCE: Thank you.

CHAIRMAN WASHINGTON: Harlan and Debra?

DR. KRUMHOLZ: Thank you, Gene. Harlan Krumholz, Board member. I just have a couple of quick questions. One is that Joe told us that there are 250 projects that are currently underway and under the auspices of PCORI. How many of those project are clinical trials?

MR. LUCE: My understanding is that there are 30 that at least have been approved. I don't know, I can't tell you how many are actually up and running. Probably not anywhere near 30.

DR. KRUMHOLZ: And I ask just because I think that we're talking about advisory group. I think it's important for us at this juncture to really focus on what we think the proper balance of clinical trials in our portfolio is and in our responsibility as performing CER. Where do we think experimental designs fit in here?

And there is a big question that, I think, for the Methodology Committee, for this group, for us, is many small or few big? I mean, this is the time we have to decide because if we've got six years to go, so mounting large trials take time, we've talked about the possibility of trying to focus on trial with patient-centered approaches and PROMs as outcomes, so they could cycle faster. We've talked about studying things like Tamiflu, but I really feel an urgent need for us to define what is our aspiration in this kind of work because

it takes time to ramp up and perform, even in the best, most efficient designs.

And so, at the same time, I have this sense of discomfort that we're talking a lot about this charter for this group that's going to be charged and is finally going to get to meet and then, ultimately, going to get us recommendations. And I just wonder, it will take time for us to get those, but meanwhile, I'm feeling discomfort that we aren't clear. How many trials do we want to do? When do we want to mount them? And you have to start yesterday if you really want to get them to deliver in a short period of time.

So I just want to make sure that we're also focused on this bigger question. And I would like us to articulate a clear aspiration since 50 percent of our portfolio ought to be in this kind of approach. Again, it depends on whether the good questions have been raised, but I'm worried in our principle charges, the CER group, that we are still not quite clear on our approach in that way.

Thank you.

MR. LUCE: That's a great segue into my next presentation because explicitly we want to engage the Board about guidance going forward. As you'll see, the questions we've teed up for you, we didn't specifically focus on clinical trials, non-clinical trials, but we did focus on larger, longer studies, which is a surrogate in many ways for clinical trials.

MS. BARKSDALE: I'm struck by the very first bullet that his panel will assure high methodological standards in the design and conduct in clinical trials supported by PCORI. In my mind this seems very much beyond the role of advisory and actually seems like something either staff should be doing or the Methodology Committee should be doing, but it seems to give them something to as way out of the realm of being advisory.

CHAIRMAN WASHINGTON: Comments?

MR. LUCE: Well, actually, I would agree with that. I would actually appeal to the legislation. Does the legislation use the word "assured," does anyone know? I actually don't have

it in front of me, but I agree we're talking about advice.

CHAIRMAN WASHINGTON: Well, Bryan and Joe, there have been some concerns raised that I know you will take on to consideration as we move forward. I share many of them. I think we're all somewhat reassured knowing that there has been a dialogue with Methodology Committee staff and with other members of the Board. But the points that are being made about being clearer I think are right on target. And we seem to maybe have not completely gained clarity about this balance, and I agree with you, it is advisory.

So at the end, because we're not too sure, we're going to have you chair the group and having you chair raises a question for me about independence. If we're going to go through this to get a group together, advisory be they may, we still want them to be independent. We want them to be able --

MR. LUCE: Yeah.

CHAIRMAN WASHINGTON: -- to objectively

give us their opinion and their thoughts. And so, why have you chair this group? And it seemed like isn't that somewhat atypical?

MR. LUCE: Well, it's certainly atypical in my experience, in general, when I've got an outside advisory group and then have a staff member chair it. That's one.

But, two, on our other advisory groups, are we chairing any of them?

UNIDENTIFIED BOARD MEMBER: No, no.

CHAIRMAN WASHINGTON: So in that regard it also really stands out as atypical.

MR. LUCE: You know, I didn't volunteer for this job.

[Laughter.]

CHAIRMAN WASHINGTON: I'm trying to get out of it.

[Laughter.]

MR. LUCE: And I was surprised as well. I think it was a -- if I can speak for my colleagues in the Methodology Committee. I think it was a sense of recognition that this is a very important

committee to furthering our mission and that we're going to have many -- to go back to Harlan's comments about the number of important trials we may be getting into. But I would love to hear some comments and guidance from the Board with respect to chairing.

MS. NEWHOUSE: I guess the other difference in this panel was it's specifically design-related, so it's not an overall portfolio. It's around design.

CHAIRMAN WASHINGTON: Right.

MS. NEWHOUSE: So having Bryan pose and frame the right questions and interact, understand the advisement from this council, seemed to make sense to us.

CHAIRMAN WASHINGTON: But Robin, Bryan can do that and not chair. In fact, we would have that expectation for any advisory panel where someone on the staff is the point person who is posting, clarifying, framing, and managing, and guiding, but it just seems like a line that's not usually crossed in this kind of governance setting. So if

I'm the only one that feels that way, let's move on.

UNIDENTIFIED SPEAKER: As long as you don't recognize --

CHAIRMAN WASHINGTON: A cause that supports my view right now.

[Laughter.]

CHAIRMAN WASHINGTON: Okay, Dr. Zwolak?

DR. ZWOLAK: Bob Zwolak. I, in fact, in reviewing this information, had written a note to myself on a PDF, "Is it appropriate that PCORI chief of science chairs the CTAP?" And I agree with your concern. I think that they should be independent and I think that Bryan can provide information for them to focus on without the chair.

CHAIRMAN WASHINGTON: Richard?

DR. KRONICK: Rick Kronick, Board member. I agree as well.

CHAIRMAN WASHINGTON: Just thoughts for you to take back.

MR. LUCE: Yes.

VICE CHAIRMAN LIPSTEIN: Steve Lipstein.

I realize we're trying to comply with the statute, but I don't know how descriptive the statute was in terms of independence. And so -- pardon, Joe?

DR. SELBY: It does not say -- it says "advisory." It does not say anything about independence.

VICE CHAIRMAN LIPSTEIN: Mary, this is where you're going to come in handy. Would it be out of line for the Board to say, rather than constituting an independent -- yet another advisory panel, we delegate this advisory capacity to our Methodology Committee? In other words, my concern -- and, Gene, I guess, while I appreciate we want another independent advisory panel, if we already have the expertise to do this in our Methodology Committee couldn't we assign this role to the Methodology Committee to serve as our advisory panel on clinical trials and avoid all of the duplication cost effort and time delay of having an independent advisory panel on clinical trials?

MR. LUCE: We actually debated that.

MS. HENNESSEY: I actually think when the

statute mentions specifically two different bodies and I think there were prior discussions by the Board of this overall framework, the Methodology Committee primarily having a significant role ahead of time in the structure of research and guiding it.

And then the research projects are identified and the concept that, as we read the language of the statute, this expert advisory panel primarily from playing a role in that regard, I think if you begin to collapse these two different visions, I think, in a way that may not really match what the statute intended. That's not to say that there isn't a role at this beginning stage to create a Clinical Advisory Panel to get going and then, with some experience, there is this opportunity with specific projects to form such committees that are very targeted with the right expertise. You could even pull in from the Methodology Committee at that point to advise on that specific project.

But in order for these small, targeted

advisory panels, clinical trial advisory panels, to be developed for a project, I do think it helps to have some kind of parent body that can kind of give it structure. I think some of the overlap is somewhat inevitable, but I do think with a targeted agenda and the like, it can serve both independently, but, you know, not [off microphone].

CHAIRMAN WASHINGTON: Okay, you used the word "multiple clients" [off microphone] and I think that that's what we were asking for. A little bit more specification, that's what I took from the comments in general, starting with Harlan Weisman raising the question about the overarching versus a more targeted.

MR. LUCE: Right.

CHAIRMAN WASHINGTON: And just, again, take these comments back really to the Methodology Committee as well as with Robin and Steve, and I understand that PDC is involved, and then decide how you want to move forward.

MR. LUCE: Leah also had a --

CHAIRMAN WASHINGTON: Oh, Leah?

MS. HOLE-MARSHALL: Leah Hole-Marshall, Board. I think I was just going to echo what you said. I think what you're hearing from us is that while we respect what's in the statute, I have heard all of us say, from a strategic perspective, the Board thinks that we ought to minimize additional duplication where possible and really hone down what it is we want from an advisory panel and then seek only that. And where possible use Methodology Committee members to fill some of those roles or filter them or be a primary resource for us--or where those advisory panels come back to.

And I had the same question as Steve, so--or even delegating it to--if there are other bodies that already do this, as Freda and Mike Lauer were saying. Maybe we should consider when the questions come up, working with our Methodology Committee, do we need to engage an advisory for this particular question, and then working with one of those groups for the panel for that trial or set of trials.

MR. LUCE: Thank you, well stated. Okay?

CHAIRMAN WASHINGTON: Thanks, everyone, for a robust discussion.

MR. LUCE: All right, moving right along to something more complex. I want to walk you through PCORI's research portfolio and planning and investment strategy, and I'm sure you'll have lots of comments and guidance here as well.

In this slide we depict an overview of what we've committed to date in 2013, through our broad funding program, from Cycles 2 and 3, recalling that Cycle 1 actually occurred in 2012. We have committed for funding 122 projects, totaling nearly $203,000.

We anticipate committing another $80 million--

DR. SELBY: [Off microphone.]

MR. LUCE: Pardon? Did I say thousand? We anticipate committing another $80 million in Cycle 4 before the end of 2013 for an estimated total of $283 million. Again, this is only addressing the three cycles of broad announcements. It does not include commitments associated with

targeted announcements nor the infrastructure awards.

So, here we depict the total projected funding by year through 2015, thus we see what you of course know, a huge jump from 2012 to 2013 where we estimate the total committed spend will be $425 --I think earlier Joe put up $427 million, this total includes the $283 million we just talked about in broad funding, the three targeted projects previously approved by the Board, which is preventing injuries from falls in the elderly, treatment options for severe asthma in African-Americans and Hispanics and Latinos, and treatment options for uterine fibroids registry that we're doing in collaboration with AHRQ, and it also includes the $68 million approved for the data infrastructure initiative that Joe mentioned.

We further anticipate that funding will level off in 2014 and 2015 at about the $500 million annual level.

DR. KRUMHOLZ: Just a point of clarification. So, that is money going straight to

research, not overhead or anything, that's just--

MR. LUCE: That's correct.

DR. KRUMHOLZ: -- that's money --

MR. LUCE: That's out the door. That's correct.

DR. DOUMA: Allen Douma, Board. Would you reconcile the difference between the bar graph, which shows 2013 at $425 million and the slide before that that shows our committed research at $283 million?

MR. LUCE: Yes.

DR. DOUMA: That $425 versus --

MR. LUCE: That $425 includes the targeted projects as well as the infrastructure projects.

DR. DOUMA: And the $283 does not?

MR. LUCE: Right, the $283 is the broad cycles.

DR. DOUMA: Just the -- just the broad cycles.

MR. LUCE: That's correct.

DR. DOUMA: Okay. I see the title. Thank you.

CHAIRMAN WASHINGTON: We have a frowned face across the way.

DR. BARNETT: So, clarify the bar charts, the $500 million, because 20 percent goes to AHRQ, right --

MR. LUCE: No, not out of that, no, this is what we're proposing funding from our own net of AHRQ.

DR. BARNETT: These are funding commitments. The dollars won't actually go out the door --

MR. LUCE: That's correct. That's correct.

DR. BARNETT: -- until at some point over the next two, three, four years.

MR. LUCE: Yeah, there's a major lag as there is right now. Yeah.

So, here in this slide we're depicting our thinking about modifying the funding mix, and this, I am sure, will engender comments and hopefully guidance. For the purposes of having a greater impact and being more responsive to patient-

stakeholder guidance, I'm hoping to obtain your guidance in our thinking and I will come back to this issue at the close of my presentation.

Specifically, whereas we will continue to fund research through both the broad and targeted mechanisms. We propose to emphasize a more targeted approach that is shifting funds from the broad category to the targeted category. I'll provide specifics of our thinking at a later slide.

Further, we are considering allocating a significant portion within the remaining broad category for larger, longer studies, some of which may transcend 2019, and that would get to the point that I discussed briefly with Harlan, as well, but to be depicted on the next slide, we are planning to identify areas or categories of special PCORI interests within the broad announcements, possibly even carving out categories for funding.

For example, announcing with any broad announcement that we intend to allocate some specified amount such as the $5 million for obesity projects as an example.

In this way, we believe we can more efficiently address a number of priority topics, identify buyer advisory panels rather than waiting the many months it takes for developing an improved targeted announcement for every single one of these priority topics.

There's really quite a backlog and it's hard to get through it all efficiently.

So, in essence, this is graphically trying to depict what we're trying to do. We're trying to spread our funding in a little bit more sensible way across the spectrum.

The graphics of the slide are intended to demonstrate the mix of funding consistent with what I just discussed. We will still have the broad announcements to stimulate, investigate, initiate ideas, which we continue to think is important, of course. We will include focused areas of interest and highly specific targeted announcements. In essence, this is a gradation from broad to targeted funding.

We want to inform you that we're in

discussions with the PDC about ways to be more efficient in developing approved PFAs. As I'm certain you're aware, the process is much too long, extending from a year to up to as long as 19 months, which is clearly not acceptable. Some of this time will hopefully collapse as we continue to hire sufficient scientific and project staff, but we will still need other improvements.

For example, we're exploring the use of fast track Board approvals for selected, clearly high priority topics and separately concept approvals, by which the Board would approve going forward pending further due diligence efforts by staff in close consultation with the PDC. We're going to be very interested -- I'm going to be very interested in your feedback on these or any other ideas that you may have to speed up this process.

I think you've seen this slide many times, or a number of times, but I wanted to put it up to give you a sense of the research prioritization process before I move on to the later phase. So, we think it's helpful to remind the Board on the

process where we begin topic generation from multiple sources followed by a gap confirmation process, such as reaching out to AHRQ and others for selected topic briefs, followed by submission to and discussion by our standing advisory panels that occurred this last weekend and the clinical effectiveness panel, leading to a manageable list of high priority topics.

So, going back to this post prioritization process, we're depicting here that the developing framework that we're discussing with the PDC, it concerns the process that extends from a prioritized topic to a Board-approved PFA. For instance, we're imagining three tracks, a fast track process for "no brainers" that doesn't need, at least at this level, for your approval to have all the i's dotted and t's crossed. These could go directly to the drafting of a PFA. A second track could be approved early on as an approved concept pending appropriate due diligence efforts of staff working with the PDC, and a third track would be a fully developed PDC having dotted all i's and

crossed all t's, blessed by the PDC before being presented to the Board for approval.

And we'd be happy to entertain any comments you have on this or other ideas along these lines.

VICE CHAIRMAN LIPSTEIN: At the risk of interrupting you, could you go back to those previous two slides, because I think they're very important for our Board and for the people listening in, 26 and 27?

MR. LUCE: Which one?

VICE CHAIRMAN LIPSTEIN: At our Board meetings, both the ones we have telephonically and the ones we have in person, a number of Board members will come up with specific research questions that could be viewed as high priority, and for folks listening in it may appear that if a Board member asks a research question, it's going to become high priority.

And so what this does is it says that while we have -- we, on our Board, are made up of expert panelists, advisory panelists, and a number

of researchers on the Board, that that top box in the first column is where you take in those ideas --

MR. LUCE: Right.

VICE CHAIRMAN LIPSTEIN: -- because they come from multiple sources, so they just don't come from us, they're just not coming from the Board, they're coming from the workshops, the roundtables, other stakeholders, and then you're going to vet them through a process of gap confirmation, research prioritization -- hit the next slide -- and then they will be vetted with our advisory panels --

MR. LUCE: That's correct.

VICE CHAIRMAN LIPSTEIN: -- and then they will go through landscape review before they come back to the Board. Now, that's a fairly lengthy vigorous process and there is time delay involved, but I think it's important to assure the public that the Board isn't trying to dominate or monopolize the research agenda here, that it is going to be broad-based with a lot of stakeholder

input, which isn't to say that the Board doesn't come up with very good targeted research questions, it's just they can't be the only source and they can't have preferential treatment just by virtue of the fact that a particular stakeholder, me representing hospitals, happens to sit on this Board.

And so, I think these two pages are really key and hopefully will come back and have some discussion about that.

MR. LUCE: I do too, and my remarks were not focused on a fast track from a Board idea to a PFA, it was, once the idea is vetted, sufficiently, how much more do we need to, as I said, dot the i's and cross the t's and make absolutely certain that the exact question is perfect before the Board says to go ahead.

CHAIRMAN WASHINGTON: Brian, can we just let Joe also comment on the point?

DR. SELBY: Thanks. I just wanted to add just a bit to what Brian said and that is that in our view, this is one of the most strategic

questions we face. We need to remain nimble and fast moving, even while we have a process that's describable, that's recognizable, and that's adhered to, and so we've even been talking with the advisory panels about this specter of the high priority topic that hits us in the face. It may be very time limited, the opportunity to jump in and do the study may be very time limited, so we want to work in that flexibility to a process that still no one will question.

VICE CHAIRMAN LIPSTEIN: Yeah, Joe, I think the balance here is as we go for speed and nimbleness and agility, the integrity of our process -- we're not allocating just a million dollars here. When we allocate $30 million to a top priority, that's a lot of money and it's not our money, we're stewards of that money, and we have to assure the people who provide it that our process has lots of integrity.

And when we go fast, we sometimes need to just remind people that even as we go fast, we haven't given up on our standards for rigor, for

validity, for reliability, for everything that you've taught us.

CHAIRMAN WASHINGTON: Including transparency.

MR. LUCE: We have a lot of other -- do you want me to continue to the end?

UNIDENTIFIED BOARD MEMBER: Well, yes. I mean, I don't know how much --

MR. LUCE: I'm almost done.

UNIDENTIFIED BOARD MEMBER: Okay.

MR. LUCE: I just have a few more things and then we're opening up for discussion.

So, turning back to the 2014 funding mix, because this is the other issue on the table that we'd like to discuss with you, we're envisioning a future funding mix as depicted here where on average 54 percent of the funds allocated to the targeted category versus only, as I calculated, 33 percent in 2013. It's a significant funding mix toward more targeted.

In terms of targeted topics, the Board, as you know, has already full approved only three --

the falls, asthma, and uterine fibroids that I mentioned earlier, and has approved in concept two more, the treatment options for back pain and treatment options for obesity in diverse populations. And this is the pipeline that we're facing right now in the three programs -- three CER programs -- addressing disparities, clinical effectiveness research, and improving healthcare systems, and we're actively working in there on all of them.

As Joe mentioned, the advisory panel -- the clinical effectiveness research advisory panel met on Saturday. They had -- it was evidently an extremely productive panel and my understanding is they honed in on the actual questions that they recommended we address for the management strategies for ductal carcinoma in situ and medication treatment options for bipolar disorder, and you will hear more about that very shortly in the next -- certainly in the next Board meeting or two.

So this -- we've already started to

address some of these questions, but the questions that we're teeing up and we're opening for many more are, first of all, the general issue of shifting from broad to targeted, and then maybe the more specific guidance as to the degree to which we may want to do that. Allocating within the broad category whatever is left in the broad category, that may be a smaller piece of the pie, but reallocating a larger -- some portion to larger, longer studies that could transcend 2019, by the way, which is, I think, another strategic issue that I'd like comments about. Presently to remind you that in our broad category "solicitations" our general limits of $500 thousand per year for three years and we're proposing something along the line -- like 50 percent of that broad category could be on the order of possibly $1 million per year over three to five years as an example. Nothing is in stone there by any means, we're just teeing this up from our discussion and where the staff thinks we should go.

And then, finally, within the broad

announcements we're identifying -- we think it's smart to identify areas of specific PCORI interest to address some of these targeted areas that have been surfaced through our advisory panels, and with possible carve outs where we would literally indicate that we were carving out a certain portion of the funds for certain areas.

So, with that, I'm more than interested in hearing comments and guidance.

CHAIRMAN WASHINGTON: Let's start with Gail and then Allen and Ellen.

MS. HUNT: Gail Hunt, Board member. Bryan, if we can go back to gradations of targeted funding approaches, which is the one that's got the three circles --

MR. LUCE: The three bubbles?

MS. HUNT: -- across the top? Yep. Okay, I guess I'm having some difficulty with the concept that there is something between the broad and focused and targeted -- between broad and targeted, and it's now focused, but it's actually taking funding from broad, and in your example you're

saying, okay, maybe we'll do asthma as essentially moving into the broad area, but making the broad area more targeted as well as having the typical targeted ones that we've talked about, uterine fibroids, blah, blah, blah, asthma in African-Americans. Well, actually, that's an interesting question because asthma in African-Americans was to be a targeted --

DR. LUCE: And it is, yeah.

MS. HUNT: So, here we've got it as a focused area, so it's sort of in the middle between the two. And I guess I think that there is some advantage to just having research-initiated projects and taking the money from broad and then creating this new middle category, which is focused, which actually sounds a lot like targeted to me when it's described, is -- you know, can you explain that in a better way?

MR. LUCE: Gail, the graphic is, of course, incomplete. It's meant to convey a concept.

MS. HUNT: I understand that. If you

could --

MR. LUCE: I'm sure you do. The difference between the way we're doing targeted funding now is we develop precise questions to be answered. A focused area would not do that. It would indicate areas of general interest for the investigator to propose questions of interest to be investigated within some parameters. In point of fact, this is a little bit misleading, this particular graphic, because the asthma example that we are going out with a targeted PFA, is truly a targeted PFA. So, that's one way you may have been misled by this particular graphic.

DR. EPSTEIN: [Off microphone.]

MR. LUCE: Right.

DR. EPSTEIN: [Off microphone.]

MR. LUCE: It is.

DR. EPSTEIN: [Off microphone.]

MR. LUCE: That is true. It was presented to you as a targeted PFA, but --

DR. EPSTEIN: [Off microphone.]

MR. LUCE: Well, I wasn't here at the

time, but --

DR. EPSTEIN: [Off microphone.]

MR. LUCE: That's right.

DR. EPSTEIN: [Off microphone.]

MR. LUCE: That was a family of studies -- go ahead, Romana, please step up and grab a hold of a mic, why don't you?

MS. HASNAIN-WYNIA: So, the asthma funding announcement fell under the category of targeted funding announcements, was not as specific as the fall study, so what was presented to the Board was a narrowed down topic, after we had convened an ad hoc workgroup, to focus on improving the [off microphone] to put the clinician [off microphone]. So, that was the target. However, the interventions that we were seeking may differ, so it wasn't a [off microphone] study the way that [off microphone] was.

The focus of the outcome was very targeted. We want to see improvements in [off microphone] and the patient side, but what we said in the funding announcement, to motivate the

funding announcement, particularly in the [off microphone] where there's not a lot of evidence, was give us your best interventions to get us there, and they may be multidimensional, and by necessity they will be multidimensional.

So, just by definition, it is not as targeted as the falls prevention.

CHAIRMAN WASHINGTON: Thanks, Romana. And in your strategic questions, you have two categories, broad and targeted, 79 and 21. Where is focused in your mind? I think that would help clarify.

MR. LUCE: Well, first of all, it's in the middle, and secondly --

CHAIRMAN WASHINGTON: If it's in the middle, you've got two categories, that's part of the problem, and at the end you want our input on two categories, so --

MR. LUCE: It comes from both directions, actually. The way I presented it here, we were sort of pulling from broad to focus some of the requests in our PFAs in certain areas. Listening

to Romana just now about the way in which the staff recommended and the Board approved, it was considered a targeted area that was, in essence, a more focused announcement.

So, it can come from either direction. I personally think that the point here is first of all the direction, should we be doing more focused and targeted than the mix we have now, and secondly, then how to carve it up and how much, what was the level.

CHAIRMAN WASHINGTON: Right, but it may seem like subtle but it's actually important to us.

MR. LUCE: Okay.

CHAIRMAN WASHINGTON: Because I'm having problems. I'll confess. So, if we go back to Romana's point, as we think about your question -- because you're giving us two categories, you're giving us the category of broad and targeted, and if you go back to Romana's examples, we understand falls, that's clearly targeted, but the way that I would interpret what she said was that I would put asthma in targeted also.

MR. LUCE: That's --

CHAIRMAN WASHINGTON: Is it targeted? And if it's not targeted, Brian, you've got to explain this to us before we can --

DR. EPSTEIN: [Off microphone] that's not the way to go. I want to start out with the notion -- I'm going to use the words on the slide so we can start to develop a common vocabulary for some simple, but pretty important concepts.

If you start at the left-hand side, what we call broad, I think of it as the R01 approach, a thousand points of light, submit really important projects that are going to move us toward greater knowledge.

One step down, we choose an area that we think fits our particular priorities, we have some in the legislation or otherwise, about disadvantaged groups and so forth, where we think there's been progress in the state of the art, usually exogenous, that makes it a particularly propitious time where we can make progress, and that might be care for minorities in the asthma,

and in this slide we're calling that focused. We could call it something else.

Then there may be cases -- we've got one in falls prevention, but only one to date, another one would be the NIH example we discussed at a previous Board meeting, the NLST screening, where we think not only do we have an area, but we have a specific project, well-defined research that we ought to be supporting, and in most cases it's going to be with big dollars, and in that context, falls -- we've talked about it's features, and we're using the word targeting.

CHAIRMAN WASHINGTON: But you're saying this is a specific project.

DR. EPSTEIN: Specific project. Now let me -- with that rubric, if you track that, the way I interpret the funding flow here -- and Joe and Bryan, correct me -- is you're using broad to mean the stuff on the left, which is stuff that comes --

MR. LUCE: That's right, that's correct.

DR. EPSTEIN: -- through an RO1 there, and anything that is well focused or targeted, you're

using for targeted. I think that's really the first important idea. Second important idea is, as you move to what I've called the targeted, you've got to get really clear that you're going to hit the jackpot. You're going to put big money in a single study --

MR. LUCE: Right.

DR. EPSTEIN: -- you've got to vet it very closely, and go ahead, second idea. Third idea, I'm a little less sure about what Steve said, which is I don't see the kind of vetting needed for a focused area as quite at that level. We're really saying something different. It's important, there's been a lot of change, doctors and patients don't know what to do, we think we can move ahead, and the reason to have focus instead of or RO1 is that we think -- I think that knowledge rarely advances by a single study. It's usually a confluent of three or five or seven pieces of information and all of the sudden we think we've got a little more light on the area and we can get that out of what is being called the focused area

there, but we won't get it so clearly out of an RO1.

CHAIRMAN WASHINGTON: All right, just if we pay out what you're proposing, and again, just to clarify, since we only have two categories under strategic question and we might label this last category "specific projects" just for the sake -- then both focused areas and specific projects come under the broader rubric of targeted funding.

DR. EPSTEIN: Exactly. But internally -- and the reason why I go through this, which it's not picayune, is by having three different areas, it will force us to think clearly about the advice and consent process that we want to put these through, because I think the may be quite different.

One further complication -- not a complication, I think it's a good idea but makes it a little more complicated to think about it, is what I hear Bryan proposing, is to take some focused areas and for purposes that have to do with procedurals, to shorten the process he wants to

nest them in the broad advisory, but keep an eye -- the de facto, they will still be focused, and I get where he's going and it makes sense, it's just a little harder to think about it.

MR. LUCE: Thank you.

CHAIRMAN WASHINGTON: Bryan, again, just [off microphone]. At the end, with the question regarding resource allocation -- because even within now the targeted funding categories, there's a question of distribution.

DR. EPSTEIN: There's a real question of distribution --

CHAIRMAN WASHINGTON: I'm talking resources, because you could decide you're going to have 90 in specific projects and 10, and there are going to be some who feel, no, that's not --

DR. EPSTEIN: So, let me break it down. One question is what you're calling specific projects used to be called targeted versus focused, got that. Second issue is, what happens if there's a wealth of really important work that comes in on the minority asthma RFA or a dearth, and can we

find some way to build into our process that we can assign roughly $15 million or $12 million or whatever that number is, but if, at the end of the day, we get $4 million worth of good projects, we don't automatically push the money out, and you can see on the other side the same sort of thing.

I'm just trying to -- I don't have the answer to that one, but it strikes me as for good management purposes, that's what we want to have to go.

CHAIRMAN WASHINGTON: Now we have unequivocal clarity on this.

MR. LUCE: So, one particular guidance we definitely want is, we're recommending shifting from left to right here, and the question is, is it the sense of the Board that we should do that? And the second question along those lines is, to what extent should we do that? And then we can then talk about more specifics about how to do that.

CHAIRMAN WASHINGTON: [Off microphone.]

DR. DOUMA: Allen Douma, Board. Slightly different topic, but you were talking a little bit

earlier, having to do with topic selection generation. We talk about high priority, and you even use the term "no brainer".

MR. LUCE: Yes.

DR. DOUMA: My question is, what metrics do we use and process do we use to apply those metrics, perhaps even an algorithm to make topic selection?

MR. LUCE: I don't know if I could really address that particularly well. It's sort of -- the thinking was that certain topics may rise to the point with the gestalt of the staff and ultimately the Board, there's so much confidence that this is the right issue to go after that you're ready to give approval to move forward without really specifying exactly what to do.

I don't have anything on the top of my mind as an example, nor a particular criteria. It would be a gestalt of, aha.

DR. DOUMA: But even below the A-Ha topic, the high priority topic, or just topic selection in general, the question -- my question is still the

same -- what kind of metrics do you use to select a topic? What outcomes of the research are you looking for that makes this topic so much more important than somebody else or something else?

MR. LUCE: Well, that's even -- there was a topic of discussion yesterday at some length, actually, using the value of information analysis, a more formal process, which we have not gone through. Up until now much of our process has been more organic of ideas coming in and then vetted by the advisory panels rather than a formal process of determining how many people are affected, how much morbidity is involved, the costs involved, the likelihood of making a difference, and so forth.

I mean, you can do that formally and we have an advocate on the Methodology Committee, David Meltzer, who spent 45 minutes on a passionate plea that we go through a much more formal process. That will -- in my opinion, that will compete with other processes we're using, which is the more organic advisory panel process. So, I don't know if that helps you, but we --

DR. DOUMA: No, it helps me better understand the process that we use. And I don't have enough experience to know how difficult it would be to have what you were just describing in the discussion is. I think it's important that we talk about it so that others can understand our topic selection better from the outside.

MR. LUCE: I agree with that.

MS. GOERTZ: Thank you. Christine Goertz, member of the Board and chair of the Program Development Committee. So, you know, Bryan and I have had numerous discussions about this whole process and I think there are two issues, one is the conceptual issue of to what extent do we want to be more targeted than broad. The other is just to some extent it's more pragmatic. When we're looking at how to sort these things -- so, let's call this three buckets. So, let's just say that the pipeline for our research ideas are coming from our advisory committees, and so we now have 15 ideas -- and we do have around 15 ideas right now -- potentially for targeted funding announcements.

Well, just from a feasibility standpoint, we can't possibly -- we don't have the bandwidth, we don't have the staff to come up with 15 targeted funding announcements before the next batch of advisory committee ideas are presented to us.

So, how do we sort the -- and so, some of these ideas may be really important, maybe not -- we may decide when we do our evaluation, you know, that's really not PCORI, or it's a great idea but we just don't -- we're just not going to do it for some reason, but then once we decide we are interested in something the question is, how do we move that forward? And right now we have gotten bogged down in trying to create some targeted funding announcements because it's difficult to come up with a specific question.

So, for instance, let's look at low back pain and obesity. Those have been on our plate as targeted funding announcements now for about a year, probably over a year, and in that time, we've had three targeted funding announcements that have actually gone out on the street where we're

starting to look at getting applications, but we haven't been able to -- in spite of a lot of time and a lot of work and a lot of effort -- come up with what is that targeted question.

And so, in those cases, instead of putting so much time and effort and never getting anything out the door, it make a lot more sense to say, you know what, this is a focused area that we're really interested in, but the investigator community probably knows better than we do what the questions are because we've been struggling with what the questions are and just are not able to come up with it.

So, I look at not only from a, you know, what is our priority, but really just, what are we actually able to do? And I think the targeted funding announcements really need to be focused on areas where we really are clear on what the question is. We actually can come up with the question better than the investigator community can, and we have the expertise and the bandwidth to actually make that happen. And in cases where

that's not the case, then we would be looking at more of these focused areas, you know, either with a set aside or without a set aside that would be sort of built in.

CHAIRMAN WASHINGTON: It's very helpful, Christine. Thank you. Gail?

MS. HUNT: Yeah, I guess what I was really concerned about before was where the money was going to come from, and what I think you've said is, yes, we are taking money from the broad to put it into focused.

MR. LUCE: And targeted.

MS. HUNT: Well --

MR. LUCE: Shifting it --

MS. HUNT: Shifting it -- okay, all right. Shifting -- so, taking money out of broad and putting it in focused and targeted, and I guess I was thinking that more money was coming out of broad in order to be able to have it go into this new category, which is called focused.

MR. LUCE: Yes, that's --

MS. HUNT: Okay.

MR. LUCE: -- what we're thinking about.

MS. HUNT: That's what is on the table.

MR. LUCE: Absolutely. That's correct.

MS. HUNT: Gotcha. Okay.

MR. KRONICK: Rick Kronick, Board member. Bryan, would you go to the last slide that you used please? Just in answer to the question that you posed of -- you know, are we in support of shifting towards the right here, I would be. I mean, I think, you know, as a new Board member and seeing PCORI kind of from the outside until two weeks ago, that the challenge of being able to say what the impact is of the work that we are doing is a significant challenge in moving towards a more focused or targeted solicitations would, I think, be helpful. I meant the last slide that's got words on it, I think, you had a slide with questions coming up.

MR. LUCE: Ah, this one.

MR. KRONICK: Sure. So, here, and just to be clear in my mind, when you have the proposed 45-55, it sounded to me that the 45 was including what

we are -- what you've called focused, but in the subsequent discussions we are talking about it as being closer to targeted. Is that correct that your 45 is including --

MR. LUCE: Yeah, that's not totally clear, even in my own mind. The -- because it's a gradation is what we're proposing, and yet that is not a gradation, that's --

MR. KRONICK: That's two things.

MR. LUCE: That's a toggle switch here. But I think the gestalt in there is that 45 percent would remain -- let's put it this way, 55 percent would be quite targeted and within the 45 percent, two things would be the case, one would be there would be a -- sort of a carve out for focused areas of interest, maybe even a true carve out, and then secondly, that has not been discussed yet but I don't want to lose it, is that we're talking about whatever is in the broad category to make them larger and longer studies, or at least a portion of them, than we are presently doing.

MR. KRONICK: So, then I think, to

Christine's last point, a question would be for you and your colleagues and then for us is whether we think, you know, the 55 percent that's targeted is -- do we have ideas for targeted studies that we think we can actually get out in 2014.

MR. LUCE: Right.

MR. KRONICK: And, if so, you know, it sounds like focused and targeted together might well be 75 or 80 percent. Is that what you're thinking?

MR. LUCE: Probably in that direction, probably not quite that high.

CHAIRMAN WASHINGTON: Ellen and then Harlan W.

MS. SIGAL: So, I don't want to get hung up between focused and targeted. I think it's the strong sense of the Board that we want outcome-driven research and we want things that will help patients, and I think that goes in the targeted or specific.

Where I'm having a hard time is really understanding what our process is going to be and

how we're going to get there and do we know enough now to take those five or ten meaningful projects and do that within the next year or two in a process that's streamlined but rigorous That's where I'm really struggling because I think there's a lot that is in our plate now, but there's a lot that could be in our plate that may be even more meaningful, and that process is where I'm really having a hard time figuring out how we can get there, because there's a lot of things that are on our list that perhaps may not have answers or may not be meaningful and there may be things that we could do that would really have substantive outcome.

And that, until we define what that is, what the metrics are, what the criteria is, and how -- and are these questions we can answer, is really where, frankly, I'm struggling.

MR. LUCE: Yeah, we are as well. That's a struggle. We've had -- it's difficult, as Joe says, to come up with the right questions that -- do you want to continue? Please.

MS. SIGAL: I'm sorry. It's not the questions. When you understand the issues that we can weigh in on, we can get experts to answer the questions. That's not the issue. The issue is the topic selection and how -- what we think is most important that we can really get an answer to. The questions you can get the right experts in the room and broad based community and do that, the issue is, is what do you want to question, what do you want to do, what are those issues, or what are those diseases or conditions or very specific targeted areas of research that we think really will be landscape changing. That's really, I think, the issue.

Asking the questions is easy once you figure out what you want to do, the five or ten disease settings or questions you want to ask, and that's, I think, a little bit, in my opinion, more muddled in terms of where we are.

MR. LUCE: Okay. Thank you.

CHAIRMAN WASHINGTON: Harlan W. next.

DR. WEISMAN: Harlan Weisman, Board

member. To me it's very difficult to even answer these questions because you say they're strategic questions, I think they are -- to answer them you must know your strategy and what your goal is. And in an oversimplified way, the job of the Board is to understand what the ultimate goal is, what's our timeframe, and to spend the money and resources wisely to achieve that goal.

As I understand it, our goal was set in the legislation to be eight years after the legislation created us, and we set a goal. You know, and that goal was our vision, it was a little vague but, you know, basically it was to allow patients at the point of care, more broadly, Allen's -- you know, the public people, whatever questions they have, have the information to make decisions reflecting their desired outcomes in working with the clinicians and others who are providing them with advice.

How do we do that? Now, one method would be to get -- we all agreed up front we can't do that for all aspects of healthcare. It's

impossible. So, we could do it, as Ellen is suggesting now, through specific targeted or focused, whatever the right term is, programs to answer just a couple questions, the other way was to go broad, but in either way we were going to do it it was as if we were saying, we're going to create some archetypes of what Patient-Centered Outcomes Research is, that if followed, will allow this vision to eventually take place. It would be one of influence as much as it would be by producing primary results.

MR. LUCE: Right.

DR. WEISMAN: We also said that we wanted to emphasize areas of infrastructure, training, you know, systems, processes, that would enable that, and we also said that -- and the legislation said -- that dissemination is an important part of this.

I know Larry and others have at various times argued that there's a lot of low-hanging fruit out there that perhaps would allow us to achieve some of these things earlier, like we do know, at least under some settings, that you can

hit in a large population hemoglobin A1c targets, yet we know that most diabetics don't hit hemoglobin A1c targets. Is that a failure of knowing what to do or is that a failure of getting it done in a way that works? And, you know, I was talking to Harlan Krumholz about this last night, we are very paternalistic in the healthcare system about how we talk about patients.

You know, if the patients would just listen to us, they would get better, and you do not blame your customers for failure to buy your product. We need to understand that stuff. There's a lot of things we could do, I think, on the march. Whether this idea of shifting is a good idea, I can only judge that by whether it is an effective way, given where we are, of midcourse correction that makes it more likely that we will achieve our goal.

And in this discussion, I have heard nothing about the rationale from a strategic standpoint that tells me this is what we ought to do. I am all for it if it increases the

probability of our meeting our eight-year goal, but then we need to paint that picture.

You know, when you create an orchestra you start with individual virtuosos, all of whom can play wonderful music apart, and you put them in sections, all of which -- strings and so forth -- that can play music apart, but the key is turning it into a group, an orchestra that can align and get you to the goal of making the music.

And I do not see -- we are doing lots of activity, we're doing lots of things, but I do not see how it aligns and integrates in a way that achieves our goal. If this does it, I'm all for it, but you've got to tell me how it does it.

MR. LUCE: Just as a quick response, Harlan, what is a major reason that's -- major issue -- major reason we're proposing this is specifically to be more impactful. There's a clear sense on the staff that we need to focus our funding on key issues more than we have in the past, and to be more efficient at getting the funds out.

So, that's on the topic here as well as whether you agree with that, but that is clearly a major reason that the major issue that's driving this proposal.

DR. WEISMAN: You know, research studies seldom have the kind of impact that we're talking about, which is definitive, unambiguous direction. It's usually a family of studies over a period of many years, which requires that to happen. So, the question is, what is the likelihood that any given -- focused or broad -- any given piece of research we do will have the kind of impact that we want it to have? If we can do that magically, which nobody else has seemed to be able to do, most research ends with as many questions as it started with.

So, to me, you know, it makes sense to let's pick areas where there already is a lot of information but we haven't figured out how to make it useful in a way that it gets used and is accepted by the ultimate people who need it, which are patients. But there may be other ways. Maybe this is the way. I am not seeing it.

CHAIRMAN WASHINGTON: Freda.

DR. LEWIS-HALL: Freda Lewis-Hall, Board. Actually, I'm excited about the notion of shifting from broad to more specific. To Harlan's point, I think as we continue to refine our strategy and start to leverage some of the tools that we've already developed, like the ones that we use to characterize the targeted programs that we currently have agreed to, you know, I think that is directionally correct because I underscore, again Harlan's point, to have an investigator-initiated trial that happens to come in that will truly be shape-shifting is really a shot in the dark.

But really focusing in on areas of high need, ones that our work is particularly focused on and would be unique to, allows us this, you know, as a tool to put a family of studies together or create a body of work that would finally inform us in these areas.

Having said that, and even though I am a psychiatrist, I am not happy about the idea of gestalt. You know, I think we need to use evidence

to inform the areas that we work in. The NPC put out an article a couple of years ago when we first got started that talked about how to synthesize areas of high need. We've got some tools that we rehearsed with when we did our targeted funding.

I think that there is data and evidence around us that can help inform our decisions and that we could create an algorithm that defined the need that we believe exists, the need that we think we're uniquely suited to address, and then to use that along with the work of our advisory Boards, our Board, the PDC, and others to then finally come into them.

So, yes to the first one, yes to the second one, but I really think that we have to come up with a well-refined, evidence or data-based way of driving ourselves to what those priorities are.

MR. LUCE: That's the value of information analysis.

CHAIRMAN WASHINGTON: Gray and then Leah and then Bob Zwolak.

DR. NORQUIST: So, let me add -- I don't

want to just repeat -- I mean, I think that's clear, but one of the things I can tell you is, we've got to move quicker about trying to come up with the topics because quite honestly, if we're going to do large, targeted, very specific trials, that day is over to get there by 2019. I can tell you that, having done four of them, launched four of them within a year and a half at the NIMH and it took us seven years at the end of that to actually finally get the data out, get it analyzed, all that stuff.

So, there are two issues we're going to have to decide at some point is if we really want to do that, we have to act like we're going to go past 2019, and I think at some point we have to act that way because if we forever say, oh, 2019 is there and we're always working that way, then we're way behind, and I think we just have to say, look, you know what, at some point we just have to put it out there, we have to do it -- if 2019 comes and whoever decides we don't exist, then that happens, but at least we made an effort at it.

So, I mean, personally I think we'll never get to the far end now because -- and, by the way, a million dollars a year for three -- that's going to cost you -- we spent $20 million on one small -- we said relatively small trial in adolescent anti-depressants. So, it is quite possible to simply put a topic out and let the field tell you, and then that's exactly what we did. We picked the four big, large areas in mental health at that time, we vetted it with our communities, they all said, yep, let's do these four, put it out to the field as a contract, let them come in to tell you exactly how to design the trial and get it going and you can do it that way.

But we need to move quickly on that and we need to decide how much money, and without knowing the topics, it's very hard to say how much money, but we've got to come up with a more streamlined process to get that going.

MR. LUCE: I agree.

CHAIRMAN WASHINGTON: We have Leah then we have Robert Zwolak and Harlan.

MS. HOLE-MARSHALL: Not reiterating too much of what Gray and Freda said, I think I agree with those very much, so I'll just focus on a few things.

I think the concept of shifting from broad to targeted is not what concerns me. So, underneath the allocations and the exact numbers, I don't think that's a strategic question, I actually think that's a staff question about how to do that to meet the goals, reflecting what Harlan said earlier.

So, my question really comes back to -- it becomes really important if we're moving to targeted how we select the target, so that was Freda's point, I think. You know, we've talked about this idea of portfolio management and the thing that I've heard about how we might be able to be more meaningful and reach our goals is that when you cluster a set of studies, you're more likely to get a result that would be impactful than not.

So, I'm okay with that as our working theory, but then when I look at what we've done so

far with targeted, I don't see that we've clustered around someplace where we've said, gee, if we do these six studies or these six areas, that gives us a body of knowledge that we'll do X. I see that we've picked things primarily by partnering with NIH and AHRQ. I'm not saying that's a bad strategy either, but that doesn't necessarily get us to what we're talking about in terms of impactful or meaningful.

So, talking about, well, we'll just throw more money at a smaller number of projects, I'm not sure how impactful that is, but I'm not disagreeing with the concept, but it just becomes more important then, that we all know what we think is meaningful versus -- because I think what it means really is we're substituting not just a researcher initiative, but if we're doing it right in PCORI, the researcher and their stakeholder community who has already told them what was right, right, we're substituting our judgment for the stakeholder community that the researcher engaged in to come up with a topic that was important to that community.

So, I would suggest, even in our broads, that we continue our progression about ensuring that researchers know how to reach out to their community, because I'm still not convinced that that isn't a good approach to getting meaningful research.

So, this balance doesn't bother me more than just figuring out how we get there.

MR. LUCE: Thank you.

CHAIRMAN WASHINGTON: Zwolak and then Harlan K.

DR. ZWOLAK: Bob Zwolak, Board. Like many others, I have the intuition that it's appropriate to shift from broad targeted, but after that it certainly does get pretty muddled, especially this parsing of the money between two buckets rather than three, and I think if we're going to be asked how much to parse, then we need to know some more details about that.

I am -- I am fully in agreement with the concept that we have to move faster, and then I worry a little bit about the phrase "no brainer"

and I think that we need to be very careful, no matter what project seems so totally obvious that we should fund it that it gets due process and appropriate objective consideration, and I would caution, I think, a little bit against even the use of the phrase "no brainer".

And finally, I agree that we need to make some assumptions about life beyond 2019 because if we're going to fund big projects, in order to get them off the ground and running and near completion despite how fast we can possibly work today or tomorrow, it's still likely to extend beyond 2019.

MR. LUCE: Thank you.

CHAIRMAN WASHINGTON: Okay. Next is Harlan K.

DR. KRUMHOLZ: First, I just want to say how much I appreciate this discussion because I think it's been much needed and this kind of open mic and I'm worried a little bit Bryan that we're giving you enough direction and clarity because, you know, at the end of the day it's going to be exactly what's going to happen. We're all

expressing a lot of discomfort, and you are too, around exactly how this is going to proceed, but this is so important and we're at such an important juncture.

I felt that one of the principle issues for the Board to define for the staff better and for the public is what success looks like. What does success look like for us? And I feel that we can't just say we've got funding and we're just looking for meritorious grants and we're just hoping to get some good articles that we can then figure out how to translate into action and hope that people are going to be benefitted.

We are liberated without having to come up to Congress every year for reauthorization. We are in the position to be creative and thoughtful about trying new things, to take some risks. I think, in fact, that's why we were created in this way in order to give us that sort of independence to try to break through and develop new paradigms by which this can happen, but it starts by saying, what does success look like.

And what I've been advocating too around both our funding opportunities and as we develop them is not going forward, we've got money, let's pull in ideas, let's fund them, and let's hope they turn out well, but start at the other side. What does the end result look like? And for me, even when I was talking about the grant applications, I know I've pitched this to all of you, but when a grant comes in, I want to know, what does the paper look like? And that paper's not enough, but it's got to be the scientific contribution. Tell me what the bottom line is.

And, I agree with you, it often takes more than one, but let me know what piece is this. If things turn out well, knowing that if we have a real big portfolio, not everything will take risk, not everything will turn out the way they think, but what will it look like?

If we're going to spend $30 million with NIA, if someone walked in that door today with a satchel and said, I can save you five years, in this satchel I have the results. PCORI, all you've

got to do is write me a $30 million check -- I'm asking you around the table, what's in that satchel that would make you guys today write a $30 million check to that person who walked in the door and said, I've got the results of what you just funded and I'm saving you five years.

And if we can't answer that, if we're saying, no, you know, this issue of falls is important and we're hoping something good comes of it, and god bless it, you know, I just want to see what that's going to look like, but I've got no friggin' idea what it would be -- we've got a problem, because we've got to be able to see, when you're doing some of these trials and experiments, I know what it's going to be.

When you're doing a CORT [phonetic] and you're saying, I want to know, are patients benefitted by tight control or not, and you get an answer, no, you actually kill people with tight control in a CORT and maybe at the end of the day it's not actually hazardous to people, but it doesn't look like it's beneficial, particularly for

macro vascular benefit. That is a fundamental advance for patients in informing decision-making about diabetes, and I hold that up -- it was a $300 million trial, it answered questions about lowering blood pressure, it answered questions about tight control, it answered questions about Fenofibrate, a $2 billion a year drug that was failed to show that it had any benefit. And at that price it was a bargain and it answered a clear and explicit question, and when they started, they knew what the end result would look like, that is, they didn't know what the result was going to be, but they could show you a mock article and you would say, wow, that would be a blockbuster article.

I suggest that we need to start looking at the end and look back, funneling in all this input, but I think it's going to be important to try to really have in mind what the end result is. By the way, that's the definition of outcomes research; it's the end result of healthcare. What is it that we're evaluating?

And my final point here is just that with

regard to the specificity, whether it's targeted or not, I mean, I think that there's a mistake here not to think it's all targeted in some sense, and what we fail to do, I think, is articulate clearly enough the type of research we want. From the beginning, at least, when I was advocating opening this up to the investigators and communities around the country to come up with ideas, I wasn't saying, just throw out anything, it was, we had parameters that we were going to try to do, and the more specific we can be about what we're looking for, what would a win look like, I just don't know what the best low hanging fruit is, but I know what it looks like, it's a comparative effectiveness study, and I would say, chockfull with experiments and trials, that has outcomes that people care about that are answering questions that people face every day that have immense consequences that's poised for translation into practice.

And I can have as many committees as possible meeting as many times, as many places, but how about doing like an X prize? Give me the idea

and then let's do it together, but I think that we need -- the specificity needs to come on. What are the properties of a successful application? And what does it have to have to get us excited? And then, when I was arguing for opening it, it was because I don't know where the best ones are going to come from. Sure, I'd love to do things in asthma and in obesity and all these things, but I really want to do the ones that are going to be impactful, consequential, that are going to be good bargains for the money, that people care about, that's going to be meaningful in patients' lives, and somehow the question is, how do we get from here to there ASAP?

But I think defining those properties and saying what success looks like, and helping you -- you guys are doing great work, we have the most talented PCORI staff in the world, we've got to be able to, as a Board, provide the strategy and then just let you do it. And that's what concerns me, is that we're not defining that clear enough and not helping you to do that.

[Off microphone discussion.]

DR. LAUER: I want to extend on what Harlan just said. So, this is an impossible question to answer, because if it were a possible question to answer, we would have answered it by now and ideally we'd do a randomized trial, we can't do that, and I have to say, at NIH we've gone back and forth. I've seen within my own institute where we've gone from a great focus on investigator initiated studies, less targeted, to more targeted, and now we're going back the other way.

You're at an advantage here, and we talked about this yesterday in the Methodology Committee, in that we have an opportunity to look at this prospectively and we have expertise within PCORI on value of information, if you want to call it that, but prospective assessment of impact, and we can do this. We can look at -- the nice thing is, you almost have a randomized trial right now because you're talking about a 50-50 balance or something close to that, so you could look at -- make prospective judgments about the applications that

come in, about the projects that actually get funded, and in some kind of systematic way, make some kind of an assessment as to what the likely impact of the specific projects are going to be, and in this way, assess the data -- put together a database.

You already have 122 projects that aren't finished yet, so you don't have the results yet, so you could probably go ahead and start with those, and that might give you a sense as to whether or not the broad approach is bringing in studies that are more likely to be impactful as opposed to the targeted approach. And these are data that you could probably put together within a matter of a few months and we could look at it and this way have a more informed conversation.

And I hate to do this, but I'd actually volunteer to help with that because I think it would be a very interesting thing to do and would help make this policy decision, which is a critical policy decision, to be more of a data driven one as opposed to an opinion driven one.

The other thing is, is that the networks are presenting a unique opportunity because the network itself -- the development of the network, obviously, is a targeted project, but the networks present an opportunity to look at -- to spawn both targeted as well as non-targeted projects, and that might be another opportunity to look at, although it will be 18 months or so before we'll be able to start doing that.

So, I think that, you know, the message that Harlan gives, which is that you want to be able to say before a project is done that I'm interested in the results. I once sat on a manuscript review committee that looked at manuscripts for a journal and we used to say, well, one way of knowing whether or not we're interested in the paper is before anybody tells us what the results are, now that you've heard the background and the methods, do you care? Are you at the edge of your seat to find out what the study showed? If the answer is yes, then we are potentially interested in that. And I think that's very much

what Harlan is talking about here.

So, we could do this in a semi-quantitative, systematic, prospective way taking advantage of the expertise that we have here within PCORI and potentially develop a whole new paradigm for driving this kind of policy, not only for PCORI but for all government -- for all funding agencies. Thank you.

CHAIRMAN WASHINGTON: Last comment, Larry Becker.

MR. BECKER: So, I wanted to link the two conversations of the two Harlans, and I wanted to talk about impact and implementation. And what I want to know is more about -- so, targeted, broad, but I want to understand when we put money out there for people to do research is, how are they going to implement that and what impact are they going to have.

You know, Harlan Weisman said, you know, we try -- if it weren't for the patients, you know, they don't want to follow orders. In my experience working in the community, it's not because people

don't want to, it's because there are barriers, there are barriers -- I'll give you one example is, as maybe hard as this is to believe, but we go into the inner city and we talk about diet, you know, for high blood pressure people or people with diabetes, and we say, you know, there are certain fruits and vegetables you should think about eating, you say, well, broccoli, and they say, I've never seen broccoli, how do you cook broccoli, and we have our community health workers literally take them to the store and show them what it is and show them how to cook it.

So, I mean, it's well and good to put all the research out there and to have this information, but we've got a whole wealth of information that's out there and we're not implementing it and people aren't taking it up, not because they don't want to, but because there are barriers.

And so as we start to think about the kind of research that we're going to do, I think we also need to think about, you know, is this practically

implementable and what kind of impact can that have on us? So, that would be my contribution to the conversation.

CHAIRMAN WASHINGTON: Well, thank you all for quite a bit of input, Joe and Bryan, which I know you will take it. Let me just see if I can summarize from my perspective.

MR. LUCE: Please.

CHAIRMAN WASHINGTON: I think you have heard general support for the notion of shifting from broad to targeted, however you end up categorizing those last two groups, and certainly, based on what I picked up, these percentages would be in line with the sentiment, I think, that was just expressed. That's point one. Point two is, there's unanimity that we need to move more quickly and we've got to find some way to move projects on in any of these categories and move ideas from implementation in a more efficient manner.

But point three, in doing that, we still want to pay careful attention to process, rigorous process, all the elements that Steve mentioned,

including being transparent about that.

MR. LUCE: Sure.

CHAIRMAN WASHINGTON: And there is a sense that we can do all that and we've got some experience.

Probably the biggest challenge for all of us as we move forward is this question of defining success and this question of impact that we've talked about before. We do have a mission statement, but the question then becomes, yes, this is what we want to achieve, but a universe of ideas out there, how do we cast the net to ensure that we're sensitive but efficient about getting them and getting the ones that are going to be the most impactful?

And so part of what I'm hearing again and again, today wouldn't be the first day that we've heard it, is what is that group of studies -- because we're talking about how we get to them, that's really what this is about one way or the other, which way gets us there quicker -- but I do understand the sense that we have a mission, but

we've not made that big leap of saying, this is the set of questions over the next eight years they're going to get there.

To some degree we suffer from having too much freedom. You know, if we had been given the resources and said, you're going to spend the next eight years working on falls, then we'd have the same discussion but at least we were going to be working on falls.

We have a problem with choice and we can be anywhere, but part of what we keep saying is, we've got to decide what that big family, someone said, a portfolio of studies look like that we feel are going to ultimately get us --

MR. LUCE: I didn't speak to that and I'm not prepared to in any depth here, but that's what -- we are going through that process right now that will, I think, help you.

CHAIRMAN WASHINGTON: Right, and as part of that, I mean, that would be very helpful when we get there --

MR. LUCE: Yeah.

CHAIRMAN WASHINGTON: -- and that's what I interpret Harlan W. was saying, I interpret the other Harlan saying, you know, in the meantime, whatever the study is, we need to be -- they need to be explicit about what the impact is going to be, how this is in fact going to explicitly change patient experience, patient outcomes in ways that add to our portfolio of successes and contributions that ultimately give us, in aggregate, the impact that we think we can have with this amount of money.

That's what we're all in agreement about what we want to get to, so that's what I believe you're picking up on.

MR. LUCE: So, just one last thing and then I'll leave. This conversation converges beautifully with the discussion we had yesterday with the Methodology Committee about value of information analysis, which is essentially exactly what I think Harlan and several of you have talked about in terms of really getting a picture and developing a model of success for specific, focused

work, in areas or in specific diseases, and I think that's what you're going to hear next time when I'm sitting here.

CHAIRMAN WASHINGTON: Fantastic. Well, Joe, you're going to wrap this up and then we're going to break.

DR. SELBY: So, I just -- I want to thank the Board for a really rich discussion. I think we purposely raised some of the critical strategic questions and your summary, I think, was really helpful, Gene, and it does give us a broad direction forward, but I guaranty you that we will be bringing these exact questions back to you in a more fleshed out form and that process actually starts tomorrow with the PDC meeting. A number of these topics are on both the clinical trials advisory panel and this idea of streamlining the topic identification process are on our agenda for tomorrow.

The last thing I'd say is, I think it would be good to bring to the Board the process that we do have in place that is used by the

advisory panels, because while it's not formal VOI, I think that the advisory panel works hard at looking at some of the key elements of the value of information, none more critically -- I mean, it is the paramount question with them after patient-centeredness, and that is, is a study in this area or a group of studies in this area likely to change practice? So, they are wrestling with that and when they send a prioritized list out, that's one of the main drivers of what gets something to the top.

CHAIRMAN WASHINGTON: Okay. Thanks again, everyone.

MR. LUCE: Thank you very much. This was very helpful for me.

CHAIRMAN WASHINGTON: Thank you, Bryan. We're ten minutes behind, so we're still going to take our 15 minute break and reconvene at 10:55.

Thank you.

[Recess.]

CHAIRMAN WASHINGTON: I'm looking for one more Board member to have a quorum and I see Dr.

Krumholz coming in.

DR. KRUMHOLZ: I like to be useful.

CHAIRMAN WASHINGTON: Welcome back, everyone, to this Board of Governors meeting for the Patient-Centered Outcomes Research Institute. We're now going to shift into another area of focus for PCORI and I'm going to ask our Executive Director, Dr. Joe Selby, to introduce this next topic and team.

DR. SELBY: Thanks, Gene. As everyone knows, PCORI's purpose in the legislation is to conduct research that provides answers to questions that patients and clinicians, caregivers, and other shave, but just as importantly, in the purpose statement of the legislation is, to disseminate these research findings.

There is clear language in the legislation that we do that in collaboration with AHRQ, which has dissemination capacity, and it's one of our strategic priorities for 2013 to develop this plan, this thorough going plan for moving research findings when they come to us, and that will start

in 2014, out making them available in useable format so that there will be a chance that the findings can be taken up and implemented and that's how we change decisions and health outcomes.

So, Dr. Anne Beal, who is Deputy Executive Director and Chief Officer for Engagement is going to talk to us about both a roundtable that we held on dissemination and implementation and also a follow up plan to get to a set of processes that we will implement quickly so that dissemination happens.

The next topic is about engagement awards and Anne will describe these engagement awards, but the secret here is that engagement is really the first prerequisite for dissemination. If you are not engaged with the end users of the research, it has no chance of being disseminated.

So, engagement is a way to pull those end users, the stakeholders, into our activities at very early stages -- at the earliest stages, and again, there is this strong connection between engagement and dissemination. So, thank you, Anne.

I'll turn it over to you.

DR. BEAL: Thank you, Joe. So, as Joe mentioned, our first topic for discussion today will be the update on our plans in terms of dissemination and implementation. As you all will recall from the early days of PCORI, we actually had a workgroup that was formed out of members of the Board for focus on dissemination and implementation, and so earlier this year decided very much to resurrect our activities in that space, primarily because, as Joe mentioned, we're going to have our first results coming out in 2014. And so, it's now time to really start to think about what is our plan for dissemination and implementation in this space.

So, for today's presentation we're going to just provide, very briefly, and overview of our plans in terms of what it is that we're trying to accomplish with dissemination for implementation of comparative effectiveness research. In addition, we're going to talk about the results and lessons learned from a roundtable that we held recently to

focus on best and promising practices related to dissemination and implementation and to talk about next steps.

This is actually a very robust activity currently going on within the organization and so you actually have an appendix, which is filled with the details of the roundtable as well as all of the participants and the RFP, which we issued on August 30th.

So, a big chunk of the information that we have to share is actually included in the appendix for your overview.

So, the big question that we want to address today is really the question about what is the appropriate relationship between dissemination activities and implementation activities. Very specifically, if you've been watching our work closely you know that early on we started to talk about dissemination and implementation and internally we've started to have the discussions that maybe we as an organization need to scale back a little bit from that and to really focus just on

making sure that our efforts are targeting dissemination with a view towards supporting implementation, but really our efforts are really focused on dissemination.

And so, from a strategic perspective we're asking for guidance from the Board in terms of really what is the cut off in terms of these activities. Should we focus on dissemination? Should we focus on dissemination and implementation? And also underscoring this, as in the second question is really asking, are we on the right path in thinking that we should emphasize dissemination and making information available as a path towards implementation as compared to a very active role towards implementation in and of itself.

So, the first thing that we wanted to do is to really just remind us what it is that we're trying to achieve with this work and one of the things that we've started to talk about a lot internally is that a major part of the effort that we're trying to achieve through our patient and

stakeholder engagement is really with a view towards supporting our efforts towards dissemination, and so we have talked about the efforts to try to create demand for this work, to try to make sure that patients and stakeholders are involved with the creation of research questions so that when we get to the point of having then the results, we are actually answering questions that have been identified by the field.

As you all know, we have requirements for involvement in engagement of stakeholders and patients, in our research, in our peer review process, and ultimately as we're doing this plan, we want to involve them in our dissemination and ultimately the implementation as well as, then, in the assessment of the impact of this work to determine are we making the right steps.

But what we wanted to do and to convey with this particular slide, though, is that we really do think about the overlay of engagement and dissemination as being one and the same, that we're thinking about engagement as a mechanism to promote

and support our efforts towards dissemination and ultimately towards implementation and impact.

So, the reason why this is an important part of the work of PCORI is we've mapped this out as saying, okay, in this country we have optimal healthcare practice and we know the fact is is that we are not yet there as a nation, and so part of the gap that is -- that we're trying to address, there's the current knowledge and practice, which we know has been put into place, and as an organization, part of what PCORI is trying to do is to make new investments in that knowledge, but we all know that knowledge is not enough, it is not enough to get published in JAMA or the New England Journal, but we also need to focus on when you take that knowledge, how do you then disseminate it to promote implementation efforts.

And so, when we're thinking about trying to really expand the impact of PCORI's effectiveness, it is definitely that we're making these investments to generate new knowledge, but also what we're trying to do is to say when you

have this new knowledge, how do you put it into practice ultimately with a view towards trying to get us towards optimal healthcare practice and giving people the information that they need to make informed healthcare decisions?

So, as we've thought about our work, as I mentioned, it really is with a view towards supporting dissemination, but ultimately with a view towards putting that knowledge into place and so it's dissemination for implementation.

As we've thought about our work we've said that, yes, we are going to develop a plan around dissemination, but ultimately, the way that we will know how it is that we're having an effect is that, is this work on dissemination actually helping to speed implementation, and then also, what is our role in terms of evaluating the effectiveness of these efforts?

So, one of the things that I wanted to share with you is some of the early work that we've done, and so many of you are familiar with the work that we did related to the in-crowd survey, and I

know that Freda was involved with this, I know Harlan was involved, I think Gail was involved with this survey, but it was one of the earlier surveys that we had done, which was reaching out to patients and to providers to just try to develop an understanding of where do they go for information.

And so, as you can see here, when we ask, well, where do you go for your information, providers said that they actually utilize the Internet.

Historically, when one thinks about dissemination of research information, we often have talked about trying to generate data and putting it into the peer-reviewed literature, but as you can see here, when we talk about different mechanisms that clinicians report that they use, the peer-review literature is well below online subscription services, access to colleagues, and as I said earlier, using the Internet.

In addition, we've thought about not only what is it that clinicians do, but we're also very interested in patients and their caregivers and

where do they go for information. And so, not surprisingly what we've found when we ask people, where do you go for health information, we found that the Internet is a very common source, but what is intriguing about the results here is that we actually differentiated between patients who have chronic medical conditions versus those who have rare diseases, and one of the things that we've found here is that actually patients with rare diseases use a variety of different factors and are less likely to go to the Internet than our patients with chronic diseases.

So, it tells us, again, from a dissemination perspective, as we're trying to reach out to different populations, not all patients are the same, that different patients utilize different resources when they go to try to identify information.

And then in looking at where do people go when they're on the Internet, what we've found is that then patients use a variety of sources, and so they often will report using online communities,

they use websites from their health plans, they use websites from government agencies, and again, what we saw was that there was significant variation between patients with chronic conditions versus those with rare diseases.

So, the big take-home message, really, is that one size does not fit all and that as we're thinking about getting information out to providers, to patients, to patients with chronic conditions versus those with rare conditions, that we actually really need to very much take on a multi-pronged approach.

The other thing, though, that we wanted to know is not only where do people go, but then who do they trust and who do they utilize and what information do they value when they try to get that information? And so, one of the questions that we asked is then, when you get information, how much do you trust that information from your different sources? And not surprisingly, and thankfully our patients reported that they in fact very much trust the information that they receive from doctors as

well as from disease-focused groups.

And so, again, the take-home message for this is that what we're trying to do is make sure that as we think about our plans for dissemination and implementation, we need to know, one, who are the targeted audiences that we're trying to get to? Two, where are the places where they go to try to get that information so we can make sure that we have information available to them where they need it? But then, three, what are the trusted sources so that when they get that information they feel that they can rely on that information?

I think the bottom line take-home message is that one size does not fit all and while we definitely saw that the Internet was something that people reported that they go to, you could see it's actually relatively low in terms of their sense of trust of the Internet as a source of information. So, this tells us, actually, that there's a lot of work to be done and that this is a very nuanced approach in terms of thinking about how we're going to get information into the hands of people who

need it.

So, as we've started to think about this, we're taking a multi-pronged approach right now, and so part of the work of engagement is to start to think about outreach to different organizations to try to really lay the foundation for the work that we're trying to do in terms of dissemination, and so, as many of you know, our work in engagement includes engaging major patient organizations, we are establishing partnerships with specialty organizations, and so many of us who are clinicians know that we often rely on our medical specialty societies for information about best practices for healthcare, we're building working relationships with the health plans and identifying their mechanisms for reaching out to both clinicians as well as to patients, we're developing partnerships with health systems, and actually we plan to do a lot of work through the Patient-Centered Clinical Research Network, which Joe talked about earlier today.

In addition, we're working through

communications and the work of Bill Silberg and others, is to really work on establishing good relationships with key journals, as well as to talk about opportunities for open access of information that could be available through key journals. And we're also very much interested in the utilization of web services and really thinking about applications and social media as another mechanism for trying to do this.

So, this is really very much still a laundry list of some of our preliminary thinking in terms of dissemination and implementation, but I think it's a very good starting point.

So, with that said, I wanted to then just remind us that PCORI is not doing this alone, and in fact, PCORI is very much reliant on the work of AHRQ and its efforts to try to disseminate this work. As you all will recall, written into the legislation is language that there are significant funds coming from the PCORI trust to AHRQ to really focus on dissemination of CER results, and so while the legislation also talks about the work that we

have to do in terms of dissemination of research findings, the lion's share of this effort really is being conducted by AHRQ.

And so, as we're thinking about then what is our plan for carrying on this work, we need to be very mindful of the work that is going on at AHRQ because we want to make sure that we are not duplicating services and that we're not replicating the efforts that they have in order to focus on dissemination of research and dissemination of CER that comes out of not only PCORI but out of a number of different funding entities.

So, with that said, as we then launched into our thinking about developing a plan, what we decided that we wanted to do first was to really approach it, frankly, with a sense of humility and to hear from others what it is that they're doing, and so there are a lot of people who are interested in this. There's the work of the VA and what they're doing around dissemination and implementation, there are researchers who are working in this area, there are quality improvement

organizations, there are patient groups that are trying to reach out and get to their constituents and so, what we wanted to do as we thought about, so what is the PCORI way of doing this, we wanted to hear from others to not only understand what is it that we can learn from their experience, but then also to get guidance from them to help us in developing our own efforts.

And so, one of the first things that we did was a major roundtable, to just hear from multiple stakeholders and learn about best practices around dissemination for implementation.

So, what this slide maps out is actually the overview of the project that we are now working on, and so we actually started by conducting a series of phone calls with different experts from around the country to hear from them and to have them engage in a series of conversations with us around what is their experience around dissemination and implementation as well as their recommendations for us.

We then held the roundtable discussion

where we revisited those questions and asked them to provide us with feedback as well as it was an opportunity for them to engage with one another. And then based upon that roundtable, we then issued the RFP, which actually went out on August 30th of this year, and we plan to issue the results of that in November, and I'll talk about the timeline for that.

Then, as a result of that RFP, the recipient or recipients of that award are going to then do the work of really doing the landscape reviews to identify what are the current frameworks that are out there around dissemination and implementation, to determine what is the work that AHRQ is doing, to determine what is the work that others are doing, and then to really make recommendations for what is it that PCORI should do in terms of their plans for dissemination and implementation.

We're then going to bring that forward in February and have a workshop in the early part of the winter to, again, bring together experts, but

also to then provide this background information and then based upon that background information, combined with the feedback that we're going to get from experts at the workshop, we'll then deliver our action plan for dissemination and implementation about 30 days after the February workshop.

So, this is just the agenda from the roundtable that we had and what's important about the agenda is not how we spent the day, but it's the fact that we actually very much relied on participation from key members of the Methodology Committee. So, you see here a picture from Brian Mittman. As we all know, Brian is a national expert in the science of dissemination and implementation, and he was actually very good in helping to lay a foundation for our thinking about a framework for this type of work.

One of his reminders to us is the fact that there actually are about 60 frameworks for dissemination and implementation out there, and so we should not think about trying to recreate the

wheel, but in fact should identify what is the best practice from what already exists and then incorporate that into our work.

In addition, Jean Slutsky gave an overview of the work that AHRQ is currently doing in this effort, which then again provides us with some guidance as to some of the areas where we should and should not work, so I want to thank them in particular for their efforts and the foundation that they laid that day to really help set the course for the conversation.

So, on this particular day we had 28 panelists from around the country including the active participation from our Board members, so Gail Hunt was involved, Bob Jesse was involved, both as a Board member as well as a representative from the VA, Sharon Levine was there as were Brian and Jean.

We also had over 300 webinar participants because we wanted this to be open to the public and to really provide an opportunity for people to provide us with feedback, and we actually also

engaged not only the people who were there at the roundtable itself, but also the organizations that they represented, and so actually had a very active Twitter outreach on that particular day.

And so, we had a Twitter reach of that event of 3.4 million individuals because of the activities that we were able to Tweet at the time of the meeting as well as our participation of the different organizations.

And so, this webinar consisted of nearly six hours of conversation what was webcast and I know that there were several people who, as I said, did participate and log in.

So, the multi-stakeholders that were represented, we had clinicians, providers, we had patients, caregivers, we had a variety of different types of perspectives, but the underlying theme that we were trying to get as we brought together different people are those who are involved with getting information out to different entities.

What actually is not listed here, but we did include, were even people who are involved with

the web, and so folks from WedMD were there, and as we were trying to think about who actually gets out to get messages around health and healthcare, that's who we were trying to have at the table.

So, this is our picture of the participants, and one of the things that we were quite appreciative of was essentially their level of engagement and involvement. It was a very, very robust discussion and they gave us a lot of really great insights.

So, there were essentially six question that we dealt with on that day and the first set of questions, the first three, we're really trying to get from them their experiences and to really understand what is it that they currently understand around dissemination and implementation, and to make sure that, are there lessons, are there watch outs, are there things that they would advise us to do as we're thinking about a plan.

The second set of questions were really more focused and targeted towards help us with our plan and developing our plan as well as with the

RFP, and so we asked them a lot about the concepts of developing a frame. We asked them about the recommendations in terms of what should be the skill set for the recipient of this particular RFP.

And so, it was a very, very robust conversation, and essentially there were six lessons that we really pulled from that day. The first was a very, very strong recommendation for us to develop a consortia or a consortium or consortia of people who can help us with this work. One of the things that we heard loud and clear is people said, well, you know, I might work in the VA and have a good sense of health systems, but I'm not necessarily going to have the outreach and impact into the physician groups or the patient groups.

And so, as PCORI is really thinking about the way that we want to do this, we want to reach out to so many different populations that it is very unlikely that one organization will be able to do that, and so what they recommend, as we think about this RFP, is that we actually pull together someone who can actually tap into all of those

different constituencies.

The other thing that they said is, do not recreate a framework, but build on what already exists so that we're not recreating the field, that the major contribution will not necessarily be in a new framework to add to the 60 that are already out there, but it's really in the application and utilization of what already has been developed.

In addition, as we're thinking about then reaching out to different organizations, is to really develop an understanding of what we can think of as different stages of readiness.

So, some organizations say that our patient focus might be more grass roots, might have fewer networks and capability to reach out as compared to, say, other organizations like, say, AARP, which has a very robust capacity for outreach into different organizations. And so that we as PCORI, as we're thinking about our plans for dissemination, we might need to think about not only the stages of readiness of different target organizations and target groups, but then what

might be some of the wrap-around that we might need to provide in order to help different organizations with their different stages of readiness.

In addition, we need to tailor the messages, and this was particularly emphasized as we talked about outreach to underserved populations, but to understand that we need to really work through trusted channels, we need to tailor the message so that people can understand it for what are their needs. So, the same healthcare outcome or the same treatment options that you might have available as a result of our research, the way that we would message that to the clinical community might be somewhat different from, say, the patient community.

Fifth is to leverage partnerships, and again this gets back to what I was saying earlier in terms of the work that we're doing for engagement. Right now, we are developing relationships with patient groups, with clinician groups, with hospital groups, with others, so that when we have the results that go out there, it's

not just that PCORI is disseminating this information, but many of these groups can disseminate this information on our behalf, and so, thinking about involving these organizations and individuals early on so that we can try to leverage those partnerships.

And then, lastly, is to make use of new media. We received a lot of support and a lot of guidance to be innovative, to think differently, to go to not the usual suspects. As you can see from the survey that we did, the peer-reviewed literature is maybe the first step, but is definitely not the last step, and so they said to think about social media and to use the non-usual suspects, such as magazines and journals and others.

So, I want to then just take a moment to thank the members of the Board who have been involved with this process. It's been actually very helpful to get their participation and I think also was very useful at the roundtable itself for them to hear that this activity actually has the

highest level of oversight and interest from our Board members.

Obviously, our participation from the members of the Methodology Committee was very important and we definitely plan to continue this model going forward.

So, our next steps for this are to really then work towards the development of the action plan, and so as I mapped out here, this is where we currently are. We actually have issued the RFP and we have scheduled, actually, the final list will be coming to Atlanta in November for the final interviews, and so for any Board members who are interested in participating in that, please let me know as soon as possible, but we actually scheduled the interviews to occur, as I said, in Atlanta in the days after the Board meeting.

So, if anyone here is interested in participating, you are more than welcome to participate in that. And as I mentioned, we're going to then have the workshop in February and so, again, any Board members who are interested are

more than welcome to participate.

So, this is just the timetable for this RFP. And what I want to do now is just get us to the discussion. As I mentioned, the big question that we now have on the table is really -- our current focus, and this is actually going to be important as we issue the RFP and really make clear to the award recipients the scope of work, is really this dichotomy between are we working on dissemination for implementation or are we working on dissemination and implementation.

As you all can well imagine, it has implications in terms of staffing, the scope of our work, there's a significant implication as a result of this, but I think it's the kind of strategic question that is very appropriate for this Board and is the kind of direction that we're seeking.

CHAIRMAN WASHINGTON: Before we start the question and answer period, I want to remind everyone to please turn your mic on. The recorders were having difficulty completing the recordings and recognizing different individuals.

DR. BEAL: And as I mentioned, this is a project that we've been working and talking a lot to the COEC, so I don't know if any members of the COEC, or Gray, if you had any comments that you wanted to make before we opened it up to discussion.

DR. WEISMAN: [Off microphone.]

CHAIRMAN WASHINGTON: Okay. Harlan? Dr. Krumholz.

DR. KRUMHOLZ: Harlan Krumholz, Board member. Thanks. It's really great to see all the wonderful activities going forward and it's a rich discussion.

Here's one thing that I struggle with regard to dissemination, which is that often it's understood as, we've got to get the message out, we've got to tell people the answers, but the truth is that informing decisions is a matter of helping people understand the trade-offs and helping then to personalize the decisions according to their own preferences, values, and goals.

It's a nuanced approach that isn't one

that, wow, we just have this answer and now we just have to tell people, take this med or do this thing, it's more about saying, wow, we've now learned how to -- you know, what the balance of risks and benefits are and then how they might be understood with regard to your personal context.

And when you've gotten these groups together, how have you -- or has that come out in the discussion? Because I think sometimes it's -- we think too simply about what's truly a very complex communication challenge, which is how do we get people -- how do we get the information in people's hands that they need at the time that they're facing important decisions in a way that they can use? Because it's not just a matter of saying, we just did a study and Drug A is better than Drug B.

And we've said that from the beginning, I mean, in fact, our charge was to think about the heterogeneity and the individual tailoring for people's needs and wishes.

And so, how have you -- has your group

provided any help there? And that's where I think we could provide some advance, because I think normally we just think, get this out on the airwaves and get this into people's things, but it's not yes/no at all, and so what do you think?

DR. BEAL: So, I alluded to it a little bit when I talked about one of the principles that came out of that roundtable was the need to tailor the message and while I talked about it within the context of thinking about specifically targeting underserved patient populations, these other issues that you're raising are exactly what came up.

So, a PCOR agenda is patient-centered and is understanding the patient's needs and the patient's priorities, and so part of that tailoring is not just based upon race, ethnicity, primary language, things like that, it's also based upon tailoring it to understand what the patient's priorities are and so that even if we know Drug A versus Drug B, but to understand then, what are the risks, what are the draw backs, as well as what are the outcomes that are most important to patients.

So, it was something that has been alluded to. I think one of the challenges in terms of specificity is we need to have the actual results to really think then through who are the different populations and how do we tailor that.

DR. KRUMHOLZ: And just quick follow up, in the course of doing this, are we envisioning the development of tools that people can use? Because I think it's also hard to give people information when they don't need it, it just kind of goes over their head, there's so much information out there. But what the real issue is, is when I need it, I'm facing this decision, how do I get what I need? And do you envision these calls being for the production of tools? I know you've got implementation, which is great, so not just dissemination. For anyone listening, it's a really important thing that you said dissemination and implementation. So, how are you thinking about that?

DR. BEAL: So, in terms of tools, as it currently stands -- and we're going to talk about

this when we talk about the engagement awards -- but there's a component of the engagement awards which is around dissemination efforts and dissemination projects, and so the development of tools would be exactly the kinds of things that we're thinking about developing. And so we'll talk a bit more about that.

DR. WEISMAN: [Off microphone.]

CHAIRMAN WASHINGTON: Harlan, would you state your name?

DR. WEISMAN: Yeah, Harlan Weisman. And I'm a member of the COEC and we've been discussion, Harlan, some of the things you were asking questions about. I think we all believe it's not just telling people something or throwing it out there, it's -- and it goes back to the vision statement of making sure that patients, their families, clinicians, people have the information they need that's relevant to their decision making about the kinds of outcomes that would be important to them.

And that means -- and we had an

interesting discussion, Allen Douma brought it up and maybe Allen can talk more about it, but the distinction between useful and usable. In other words, we could produce useful information but it wouldn't be very usable at the point of care because of translation issues, lack of tools, lack of translation of findings, but Harlan, you brought up another point that I think is important. A single piece of work and research finding in isolation does not help make a decision when there's -- when it has to occur within a framework of other information to know about the applicability of a finding on a very personal level, if you can do that.

So, and that's both in terms of what is known by a research finding with certainty and what may not be known, what may not be directly applicable, and giving people a sense of how they can weigh advantages and disadvantages and the probabilities of different outcomes, and that, to me, is a lot more work than simple dissemination. We have to provide context that can be

personalized.

DR. DOUMA: Thank you. Allen Douma, Board. Before I express my concern about what I'm hearing, I think it's really important, based on what Harlan was saying as well, is that we need to look at the issue of the end user and the end user's demand for CER, not just information, but CER. And without that demand we can't cram stuff down anybody's throat. And we are -- what I'm seeing here is we're supply oriented rather than demand based, and as we all, I think, would agree, without implementation, dissemination is of little to no value.

And to see this disjuncture between the two that is fairly new in our thinking is of concern. It's also, we need to just bear in mind, that the whole roundtable and discussion that we had, and most of the discussion in the COEC has been the D&I, not the D4I, and so the conclusions may not be quite appropriate.

It's also, if you look at on slide six, and I'll read it so you don't have to go to it --

by the way, in slide six in our material it says, "PCORI's action plan for dissemination and implementation", you've changed it to "for" here, but it says it targets the gap between information and its use in decision-making.

Well, that gap is the implementation gap. So, I'm not -- I'm confused about what we're actually hearing is that where do we draw the line, where does dissemination stop, where does the implementation start, and what are we -- and I was talking to Joe earlier today and the question is, are we going to be tracking all of that and seeing the impact of our information, how we disseminate it, which is step one. Step two is, are we going to do research into making the implementation better? Because we know that's the key issue in almost everything.

And I would suggest there is nobody out there, and maybe AHRQ is going to be doing this, I hope so, but there's nobody out there who's looking at the demand side. There's very few people, including clinicians, who think CER is the best

thing since sliced bread, and perhaps we need -- pardon me -- a PR campaign just to make that point clear.

So, I think we ought to be careful the substituting "for" for "and".

CHAIRMAN WASHINGTON: Thank you, Allen. Gail?

MS. HUNT: Yeah, Gail Hunt, Board member. I want to second both Harlan's and Allen. I think we have to include implementation as part of the dissemination and implementation side of things because all along we've talked about getting down to the level of decision making of the patient, the caregiver, and the primary care doc, and if we're just talking about dissemination, it's sort of just sending the stuff out there, it's not saying, okay, we're actually going to expect that there is usable information, that it's useful, and that it's actually used, and that we are evaluating whether or not the research results that we've funded are going to take people down to that path and allow them to make those decisions, whatever they are.

CHAIRMAN WASHINGTON: Okay.

MR. BECKER: So, in our business we use a sales model called ACH, awareness, consideration, and hit-rate. So, in this context, making people aware of the information that we've generated, getting them to consider whether they should use that information, and then understanding how often they actually use that, and it would seem to me that with all of this information, we should be thinking about, where are the teachable moments so that at that moment somebody, if they're aware of it, will actually consider using it, and we have a higher rate of actually implementing the information.

So, I think each of these pieces of knowledge that we generate, we should think very carefully about where is the right place in the process and that will give us keys to how we should communicate that and when we should communicate that.

CHAIRMAN WASHINGTON: Thank you.

MS. HOLE-MARSHALL: Leah Hole-Marshall,

Board member. So, I appreciate the significant work and the roundtable discussion and summary of that, so thanks for that information. And I think this is really key. So, my comments are actually just going to focus in a slightly different place -- I agree with many of the comments already made -- and that's kind of trying to focus in on what problem PCORI staff, PCORI, us, and staff, are trying to solve, because when I look at the statute and the funding steam, more importantly, we have one place where PCORI is charged with dissemination, and that's in our general purpose. So, one three-sentence phrase, then there is an entire page about the dissemination activities that will occur through AHRQ.

So, the question that I always have around this is, when we don't know what those activities are, I feel like PCORI should be focused on the gaps that we think are still left and because we're not briefed on those, I don't know what those are.

So, I'm not saying any of this is not important, because I do think it's critical that

part of why we want to do research differently is that there is uptake, that there is usability, and that people know about it, but I still -- the problem I think we, as PCORI, should be trying to solve is, what is not happening at AHRQ that we would like to extend, or, you know, maybe not even not happening, but how can we help extend that?

And the same thing with the researchers, so, I think these presentations should be focused around, here's where 15 percent of our dollars are already going and what that's purchased, and how we'd like to extend it, and here's where we have already charged every single researcher with an implementation or dissemination plan, and here is what they're not doing and what we should be adding to it or what we should fund.

Maybe we have extenders on our research studies where that we actually pay the researcher to do the dissemination. I think that would be fine.

So, I really feel that this is really a place where PCORI does not lead, but they extend or

fill in gaps where other people are already charged with doing this work.

[Off microphone discussion.]

MR. KRONICK: Rick Kronick, Board member. I'll pull the new guy card. I mean, I've been on the job for about two weeks and you ask a very good question, to which I'm not able to give you an answer right now, but I will comment in response to Allen's earlier comment and on this general question of dissemination or implementation, dissemination and implementation, an observation that I know, you know, you're all aware of. We have a $3 trillion healthcare system, 200,000 primary care physicians, you know, 650,000 or more physicians in active practice, you know, with the resources that AHRQ has from the PCOR trust fund or whatever part of the resources that PCORI might choose to devote to implementation, it would be a very, very small implementation effort per se, we need colleagues that we have in the federal government at CMS, at HRSA, at CDC, other operating divisions, and in the private sector, to be

involved in any implementation effort that will matter, it does make sense to me, as Allen was suggesting, that we should be working on trying to develop the science of implementation, figure out what implementation may actually be successful that then, if applied more broadly by our various partners, would lead to the kinds of changes in patient outcomes that we're all looking for.

So, you know, I apologize for not being able to give a more definite answer at this point about AHRQ's plans here, but look forward to that conversation as we move forward.

CHAIRMAN WASHINGTON: Thanks, Rick. Steve?

VICE CHAIRMAN LIPSTEIN: I think --

CHAIRMAN WASHINGTON: Your name for the record.

VICE CHAIRMAN LIPSTEIN: For the record, you're handsome.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: My name is Steve Lipstein. And the perplexing part about this, and

I'm glad we're devoting so much of our agenda this morning to this topic because, you know, when you presented those slides and said, you know, here are the places people go to to get information. As you know, that's very age/education specific, but the who is really important. Who are we disseminating to and who are we implementing for? And Kerry once came up with an idea that was really kind of interesting. He said, you know, one of the things we need to first do is come up with a list of CER's greatest hits. In other words, we haven't yet made a compelling case to the American people or whoever the who is that CER is really, really important, and here's what I can do for you because here's the great accomplishment it's produced in the past.

And Allen used a different phrase, he said, how do you create demand for a CER? Well, you know, if we can show that CER is wonderful, what I worry a little bit about, and I'll just give you an example, is we're spending as a country billions, mega billions on implementing electronic health information technology.

And somebody in Washington decided there was huge demand for this out there, huge demand for this, and that everybody would love it, the uptake would be just enormous, and actually five companies are really benefitting nicely from this right now.

But if you were to listen to the rhetoric, which is, 50 million Americans now have access to a patient portal or their own electronic medical record, if you actually get down into that and look at how many people actually use their portals, and then what we tend to count is not how many individual users, but how many time the same person hit their portal 50,000 times.

And so, the technology, while it's there, doesn't seem to be the solution. In this discussion where PCORI needs to make, I think, it's unique contribution is identifying how we make CER more relevant in the lives of real people, and today it's not relevant, and so to form a consortium of all the people who have -- I mean, maybe what we'll learn is why the current dissemination/implementation strategies are not

working, because if they were working, because if they were working, we would just deploy them more fully.

But we have to get to the who, and if the who is 320 million people, I think we need to think differently. If the who is just the 800,000 physicians in America, you would think differently. If the who is just the people who have Disease A, B, or C, where, as Ellen once said, if the who is just the 10 million cancer survivors who are now in their post active therapy phase, it's a different who.

But how do we make CER relevant to each of those segments is, I think, what Kerry's idea was about, what Allen's idea was about -- correct me if I'm wrong -- and it's where PCORI really needs to find its unique space.

DR. ZWOLAK: Bob Zwolak, Board. To the focused question of dissemination versus implementation, I really favor dissemination because I think effective dissemination will result in implementation. So, it's got to be

dissemination to the level of the provider and the patient and the pathway by which implementation occurs, I think, is going to be different based on many factors of circumstance.

ACOs, I think ACOs will begin to influence appropriate use of CER information by all of their caregivers, and to some extent, of course, Medicare now impacts implementation by coverage policies on say the prohibitive side and quality measures on the positive side, as do some Medicaid programs, certainly as does the VA with hundreds of process measures trying to impact implementation of care. So, I really think that effective dissemination is where we need to be and we can measure implementation, if it's measurable, or help try to figure out how to measure it, if it's measureable, but if we disseminate the information effectively, I think we will positively impact implementation.

CHAIRMAN WASHINGTON: Bob.

DR. JESSE: Other Bob, Bob Jesse, Board. There's a couple things that I struggle with here. First is one of language because we've really spent

a lot of time over the past couple of years with the mantra that we want to provide answers to questions that patients want answers to, and when we do that, we need to make sure that those answers that we discover are communicated not in the language that we understand, but in the language that patients understand.

And so, I still sense a real absence of understanding of health literacy -- we talk about this a lot, but I think frankly it's probably more often or not, we're the illiterate ones, not the patients, because when they get together, they clearly understand each other and we don't and they don't understand us.

So, part of any discovery and then its dissemination as implementation is ensuring that that happens in a way that actually ends up doing what we really want to do, and toward that end, as we're putting out all these grants and proposals, how are we closing those loops? So, do we just put out a grant for discovery or do we put out a grant for discovery that also includes a subsequent plan

for at least testing the impact of whatever is discovered in a way that actually meets the one mission that we truly, truly agree on is impacting on how we are able to work with patients, caregivers, stakeholders to fundamentally change the dynamic of the healthcare system.

So, you know, I think all these important -- you know, we've taken our health services research for ten years has focused on implementation science. It's a very difficult topic and it's not going to be solved in a couple years by PCORI, but what we can do is provide, I think, substantive answers to a lot of questions that patients have and communicate those findings in ways that patients understand them and I think that really needs to be one of our main foci.

CHAIRMAN WASHINGTON: Thank you. Dr. Kuntz, you've been quiet this morning. You want to continue to be quiet. That's okay.

DR. KUNTZ: I'm not quite sure what that comment means, Gene. In listening to the conversation I tend to be more on the dissemination

rather than implementation side as well and I don't know if I can add a whole lot more to the conversations, but I do think that getting the message correctly, giving the formula for how to make decisions, and then allowing the various different providers to do the implementation as they see fit in their own local environments is, to me, the emphasis. So, I'll stop there.

CHAIRMAN WASHINGTON: How can we help you at this point, Anne? I mean, what I wrote to myself was "we can't do everything".

DR. BEAL: Right.

CHAIRMAN WASHINGTON: And I really think that that's one of the questions that you're raising, that in the dissemination sort of arena, how broad we want to be versus how deep do we want to go in some very limited areas.

DR. BEAL: Right and what I'm definitely hearing is that the Board is not of one mind, so I was sitting here thinking, I think that this is a conversation then that we need to take back to the COEC for us to essentially make a determination and

particularly because the Board is not of one mind, so I think we have to have a more focused and targeted conversation. And then what I would suggest is after that conversation, we can bring it back to the full Board.

DR. WEISMAN: I actually -- as a COEC member and part of the Board -- the greater Board -- I'm uncomfortable with that and I'll tell you why. I think this is a strategic issue for us, a philosophical issue, because it really depends. I mean, dissemination and implementation are basically how are you communicating and who are you communicating to and what do you want as an outcome from that and that's sort of the basis of what we say we're doing, which is providing high quality information.

If you take a paternalistic view and we just want to get people to do what we want them to do because we know what's good for them, then that's one way of doing it, you just communicate to whoever the authority person is who is going to tell them what to do and then the patients won't do

it anyway and we'll blame them.

Or you take a participatory view of patients participating in their care and being the ultimate decision makers with the people giving them the information, they're doing that not just based on a scientific finding, they're doing it based on other considerations of their social situation, their particular medical or family situation, which adds complexity, and, you know, how we measure our effectiveness in terms of implementation, to me it is not -- implementing -- if implementing we mean they do what we want them to do, we may be disappointed.

If we give them the information that they can weigh in deciding their options, in making their decisions, that, to me, is success. If all we do is throw the information and disseminate it, I don't think we've made a difference, really, in the broad base of healthcare in this country because we know most things aren't done.

You know, so, to me it's about effective communication in a way that people find the

information valuable in their decision making no matter what they decide ultimately because it is a personal choice.

But for me, obviously I'm exposing my own bias. I think we -- by its very nature of saying that we're patient-centered means we don't take a paternalistic approach, but we take an approach in which there's a partnership between the healthcare delivery and the people to whom it's being delivered. I think most people will behave rationally and make reasonable decisions if given the appropriate information that allows them to make those decisions, even though their decision may not be the decision I would make or all PCORI Board members would make.

What's the measuring tool of success, I think, is very important, but to me -- I don't see how we dissociate implementation in the sense of the information being part of the equation at the point of care, because that's not done very well. And then one final statement, this is done effectively in some places in the United States and

in the workshop, I was just wondering whether you had people there where they are in places where they've moved the needle in healthcare delivery in which good information is there and both clinicians -- and I'm purposely -- I told Debra I'm purposely saying clinicians -- my experience is that where implementation is done well, it's often because nurses, pharmacists, educators, and others are participating in the effective communication. So, I disagree, but I also had a question.

CHAIRMAN WASHINGTON: Okay, can I --

DR. BEAL: So, the short answer to your question is yes and we can talk about it offline, but I wanted to get back to where Dr. Washington had us in terms of a path forward because from my perspective, I do not hear us as being of one mind and so I think then there's a need for some further discussion, and obviously bringing it back to the full Board.

So, I would just propose that we bring it back to the COEC. I think all the COEC members have heard the differing views and it's clear that

wherever we land, someone's going to be unhappy, but at least then we've had a chance to deliberate, view all the perspectives, and then we bring it back to the full Board.

DR. WEISMAN: Maybe we can provide the information they need to make a high quality decision based on the Board's needs.

CHAIRMAN WASHINGTON: In either case I think that that is the next best step forward. I'm looking at the Chair who won't be the Chair after tomorrow.

DR. NORQUIST: Well, no, the COEC chair.

CHAIRMAN WASHINGTON: But you won't be the COEC chair after tomorrow.

DR. NORQUIST: I'm looking at Richard Kronick too because I think there's this input we also need from AHRQ and to be very clear about where we stand together with you guys also.

MR. KRONICK: We certainly look forward to working together on this. But I think it also might be helpful, even in just framing this discussion, I'm not sure that we all have a clear

and shared understanding of what dissemination and implementation actually are, so maybe we should have started with that, but if we're trying to decide is this and/or or, kind of getting a clearer definition on that would probably be helpful for the next discussion.

CHAIRMAN WASHINGTON: Again --

DR. DOUMA: Gene, quickly, also, the first question you have for us, what is the appropriate relationship between dissemination activities and implementation activities, I think that increased clarity that Richard's talking about will help even understand what that question means, and it would be really helpful to have a flow diagram from A to the end point of people's health being improved because of implementation, and start by example showing where one thing cuts off and one thing starts.

CHAIRMAN WASHINGTON: Okay, this conversation -- what a high level asset manager told me once and that was, all strategic questions boil down to a question of resource allocation --

asset allocation, and that's really what we're talking about, whether you realize it or not, at the end of the day, that's what we're talking about, so we'll come back to that. Freda?

DR. LEWIS-HALL: I just had a clarifying question. Leah started, I think, at the beginning of this, asking the question if what we're really supposed to do is back up into the AHRQ work and, you know, perhaps work ourselves around that, filling gaps, amplifying, whatever it is we want to do, how will we actually, as a full Board, get that information and when? As you do the next step planning, how will that actually get to us and in what form?

DR. BEAL: We will ask Jean.

MS. SLUTSKY: I feel kind of bad because Richard's only been with us for two weeks, so he's kind of at a disadvantage because we've been briefing him on a lot of things, but at the meeting that Anne and her colleagues held, we actually did present all of our investments and investments that had pre-notifications, so there is a slide deck

that actually talks about all the investments that we've made under the PCOR Trust Fund and those that have been announced, plus a framework that we used in making those investments.

Now, obviously, we're under new leadership and, you know, I think we need to give Rick some time to understand the lay of the agency and where he personally wants to take the agency, but up until August or the end of July, there is a slide deck that's publicly available, that's on the PCORI website, which is a very long slide deck, plus we've briefed the PCORI staff on numerous occasions in an even longer slide deck. We spent two hours with them about two weeks before that.

So, there is a pretty detailed discussion going on.

DR. BEAL: And I would add that part of what we wrote into the RFP was that there needs to be an absolute understanding of the work of AHRQ so that the plan that we're developing is just as you described it, this wrap around plan, so as not to replicate efforts.

CHAIRMAN WASHINGTON: I will remind the group that this discussion and this topic falls under the big rock category. This is a big rock and this is a very important strategic question that we have to answer. And so, Anne, I like your proposal. We're going to ask that the committee continues the deliberation and bring it back to the Board with this set of questions reframed, but take it a step further with a couple of options that might call the question, which will prompt us to answer the question of how far beyond just getting the information do we want to get into decision making, context of decision making, whatever we're calling implementation, and the question about how deep we want to get beyond just whatever AHRQ is already doing, filling in the gaps. My sense is, we don't have much of an appetite as a Board in general for going too far beyond filling some gaps that might add something, but it would be up for the Board to decide.

Another great discussion. Thank you.

DR. BEAL: Thank you.

CHAIRMAN WASHINGTON: Okay. Do you want to jump into the next one or do you want to introduce it, Joe?

DR. SELBY: No, I think -- Anne, are you ready?

DR. BEAL: So, I'm very pleased and proud, actually, to introduce the next topic, which is really our proposal for the development of what we're calling the Eugene Washington PCORI Engagement Awards.

CHAIRMAN WASHINGTON: I should leave. I've got a conflict of interest here.

[Laughter.]

[Off microphone discussion.]

VICE CHAIRMAN LIPSTEIN: Anne, after you make your presentation, we'll explain why the Board feels it's appropriate to name these Engagement Awards in Gene's honor for his service as our founding Board Chair, but I think it would be really important for everybody to know what the awards are before we explain.

DR. BEAL: Yes.

VICE CHAIRMAN LIPSTEIN: But I will remind the Board, if you vote down these awards, it isn't going to -- so, but I think it's important to know what the awards are about.

DR. BEAL: Absolutely. Thank you, Steve. So, actually, today's conversation is actually more for the concept of the --

CHAIRMAN WASHINGTON: Can I just say, I'm not sure I realize -- this is being webcast worldwide? This would be what you'd call a universal embarrassment if you vote it down.

[Laughter.]

DR. BEAL: So, for today, actually, there will not be an official vote. This is really a presentation of the concept of the Engagement Awards, which is going to be then, if you give us guidance that we're moving in the right direction, will then be included in the budget, which is something that you'll be voting on at the November Board meeting.

And so, now is the time to give us feedback in terms of general directions, is this

the right strategic framework, but the actual vote is going to occur in November with the approval of the budget.

And so, the Engagement Awards, conceptually, is something that we've wanted to do to really provide a wrap-around to the work that we're doing. This is a quote from Joe who really talks about some of the vision that Gene provided to us in terms of really thinking about the role and the importance of engagement. We've talked a lot as an organization about the importance of doing research differently and really it was Gene, in many ways, who talked about having the vision and the leadership to bring patients, caregivers, and other stakeholders to the table to engage in the research enterprise.

And so, initially we actually talked about this as an Engagement Award, but as we thought about it said that it was absolutely clear that having Gene's name on this as part of the legacy for the vision and the leadership that he provided would make absolute sense.

So, with that as a backdrop, let's talk about exactly what is it that we mean when we talk about the engagement awards.

One of the things that we're actually interested in thinking about today in terms of our questions for the Board -- and you'll understand what it is that we're talking about -- but there are knowledge awards, training and development awards, and dissemination awards.

So, Harlan, remember you were asking questions about different ways to tailor the work that we're doing, we can actually tailor that work through the development of these different types of dissemination awards.

So, as you were saying, what are the opportunities for outreach, what are the opportunities for learning from other communities what their needs are, this is a mechanism by which we can do that. And what we're interested in is hearing from the Board, what are some of your recommendations or ideas for -- really what are some of the types of awards that we can make in

each of these categories?

So, with that said, the Engagement Awards, really as with everything that we do, starts from our strategic plan. So, this should be familiar to you because it starts with our mission, our goals, as well as our strategic imperatives. And as you know, within the strategic imperatives, we have an imperative related to engaging the community and getting back to something that Allen was saying, engaging the community to help create demand for the work that we're doing.

But in addition, we also have a strategic imperative, which aligns with disseminating our work. And so, as we try to think about the different strategies that we work on, we really try to think about them within the context of being an overlapping Venn diagram, that engagement is not separate from dissemination, but in fact that they work together synergistically.

And so, for those of you who are familiar with the strategic plan -- so, as you know, underlying each of our pillars, then, there's a

mini strategic plan, and within engagement we have three strategic priorities. The first is to develop the PCOR community, so to develop the people who are interested in our work, secondly is to engage the community in our research, so the work that we're doing around involving people in our merit review and the requirements that all of our research projects have patient and stakeholder participants, and then third is to disseminate -- I'm sorry, to promote dissemination for implementation, and so everything that we do within engagement really is with a view towards how do we address these three strategic priorities.

We, working with the COEC, have actually developed a theory of change in terms of thinking about how do we meet each of these strategic priorities and basically based upon the theory of change, we say, okay, what is it that we're trying to achieve in order to get to these three strategic priorities? What are the facilitators that can help us move there as well as some of the barriers that we may have to address? And then what are

some of the activities that we as an organization can support to try to get them?

And so when we think about then the work that we're trying to do with engagement, we recognize that there is a major research enterprise that is part of the work of PCORI and the analogy that I've used is each one of those research projects is solid, is straight, is really directed, and is a major brick in what it is that we're trying to build. And as we think about the Engagement Awards, what we're trying to do is really help pull those bricks together so that at the end of the time of PCORI or in three years, five years, seven years, we have a cathedral rather than a pile of rubble.

And so, the way that we think about the Engagement Awards is, what is the wraparound that we can help to provide to really make sure that each and every project which goes through the merit review and we know from a methodologic perspective is sound, we know from a patient engagement perspective is sound, but what is the wraparound

that we can do to make sure that those projects really hang together well to form something which is the execution of our vision?

So, what you see here from the Engagement Awards, as I said, we have three pillars for the engagement strategy -- developing PCOR, engaging the community in research, and promoting dissemination for implementation. And so, as we've thought about, then, the Engagement Awards, we said that we should have awards that really help to drive each of those areas.

So, when we think about the efforts to develop community, what we've established is something that we call Knowledge Awards, so these are the awards that help us understand the field, understand the groups that we're trying to reach out to, understand some of the challenges that we're trying to address, as well as give people an opportunity to understand us.

And so, whether these are activities that around background papers or convenings or efforts to try to really exchange knowledge about the work

of PCORI, we think that that exchange of knowledge and information is how one gets people to know about us as well as generates trust.

The second area is around training and development and that is really the work around engaging the community in research, and so this gets to our efforts to really try to develop a skilled, PCOR-ready community. One of the things that we've heard time and time again from this Board is, how are you getting people out there, how are you getting the folks who are not the usual suspects involved with the work of PCORI, and this is a mechanism by which we will be allowed to do that.

So, as an example we have the data challenge, which was a project that we did, but going forward would be the kind of thing that we can do as part of a training and development award to help bring patients and researchers together to really engage them as partners in research.

And then our third is our efforts to promote dissemination for implementation, and so

this is what we call the Dissemination Awards. And so, again, this can be the kinds of things where we're doing surveys to understand the needs that different groups have, to really understand who are the different groups that we're trying to reach and what are the opportunities that we have for leveraging their capacity.

And so, this is exactly the type of area where when the questions come up from the Board, how are you going to reach out to these different groups, how do we know who they are, this is the mechanism by which we'll be able to answer those questions.

I think what's important to know, though, is that as we think about the Engagement Award program, all of these awards are really fully designed to enhance the impact of PCORI's work and research, and so they really are an effort to try to build upon the research portfolio that we are developing to try to move it forward and carry it so that it has a greater impact.

So, just in summary, as we thought about

these Engagement Awards, we really wanted to have them designed to be wraparound support to enhance the efforts of our major research projects. These are not meant to be research, but really are meant to be the kinds of projects that support knowledge of PCORI's work, also to enhance training and development of audiences to really engage with the PCORI agenda, particularly the non-usual suspects, who I know is a priority for this Board, as well as to think about what are the opportunities to disseminate the results of our research and to promote implementation into practice.

These are really designed to be smaller awards, up to around $250,000 in total, and really to be short-term awards, so no more than two years in length.

In addition, other objectives that we have from this program are to try to engage new groups that have not previously been involved with PCORI and to develop new mechanisms for disseminating our research findings, and really, in general, to promote this concept of research done differently,

because right now we've talked a lot about, we want research done differently, we want to know who these groups are, we want to outreach, we want to train, we want to do all of these things, and yet, within the organization we have not had a mechanism to be able to do that, so this is the place where those ideas can actually be implemented.

So, to date, our process -- and we've actually developed a series of sample projects that we're going to be sharing with you in a moment, but our process to date for selection and contracting has really been very much coordinated through the Finance Department.

We have utilized our procurement processes in order to be able to engage with the development of the contracts with these different organizations and the service agreements, they are contracts because they are really designed to address a need that we have. We go out and solicit them and then we say this is exactly the work that we do.

Some of these are done via sole source capacities, others are done through a competitive

process, but from a compliance perspective, we wanted to make sure that we've done this through our Finance Department.

I think going forward, as this project and this program expands, then we may develop other mechanisms for solicitation, but to date what we've really been doing is working primarily through Finance in terms of this.

As we think about each of these projects, the monitoring of the project, as with any contract that we do, is that for each and every project we have specific milestones that are built in and created for each of the contract that we develop and the awardees have to actually provide us with status reports on a regular basis, both on the programmatic side as well as on the financial side to make sure that they are keeping up.

In addition, we're very much focused on evaluation to make sure that each project is having the impact that it wants to have and we're actually building in metrics for evaluation of this program overall.

So, what we wanted to include today was an example of the types of engagement awards as we think about it. As I said, in 2013, we're really only doing a handful of these to whet your appetite as well as to develop an understanding of what it is that we're trying to accomplish, but if you approve, then, the full program with the November Board vote, then we'll be able to go ahead with a much more robust program.

So, the first project that I wanted to share with you is something which would come in under our Knowledge Awards, and so this is actually a contract that we've already executed and it is with the National Academy for State Health Policy.

As many of you know, payers are an important audience for us, but one of the things that we felt in the organization is that we've not had a real opportunity to understand what are the needs of the state Medicaid directors, and so they are a major payer audience for us. They're very important in terms of the opportunities to really see the impact of our work outside of Washington,

but we really wanted to develop an understanding of what is their need for CER.

So, as Allen alluded to earlier, we often say, okay, we have a push mentality where we want to get the word out, but what we're trying to do with this project is to say, okay, from your perspective as the state health policy person, as a state Medicaid person, how do you use CER? Where does it make a difference? What are some of the things that we can try to do and support to be able to develop a research agenda that really meets your needs?

And so, the goal of this project is really to promote use of our findings by public payers by engaging them now in terms of really understanding what are their needs.

This is a contract that we actually just closed about a month ago and it is slated to end in May, and it is a project -- and we have the details in here -- where basically they're going to conduct a series of surveys and focus groups of different representatives, they're going to go to some of the

national meetings that they have, they're going to look at state legislators, insurance commissioners, Medicaid and CHIP medical directors, but really to do a series of both surveys and focus groups to really understand what is their current knowledge of CER and PCOR, and to get an understanding of their views on the utility of this type of work for their own work, and then to understand what are the potential future needs that we can try to meet.

In addition, they're going to -- NASHP being the "they're" -- are going to then develop a report for us and then to really develop a roadmap that's going to help this audience in their use of CER as well as, then, to host a meeting to really highlight what are some of the project findings.

So, again, this is an example of the type of Knowledge Award where we think, here's a key audience for us, we want to know who they are, and here's the type of activity that we can engage in to understand the needs of a key audience for the type of research that we're generating.

Another type of project, and this is one

that we have not yet finalized but is currently under consideration, is a Training and Development Award. And so, actually, we were approached by the PhRMA Foundation because they actually have developed centers of excellence for PCOR training around the country. And so, what they came to us and said, we have actually a small award from AHRQ to actually hold a conference to really bring together these leading experts on the best practices for PCOR training and they said, do you want to be at the table?

The answer, obviously, is yes, so anyone who is engaged in PCOR training, we want to be involved, and so we're having a conversation with them to see what would be our role, how we can get involved, and how we can get involved and how we can help really set the stage in terms of not only the curriculum that they're developing, but what is the role that PCORI can play in this area.

And so, this is going to be a small award because it is just for a conference, but again, there are a lot of organizations that are out there

that are responding to the work that we're doing and they're developing training and curricula, and so this is an opportunity for us to get involved with some of that training as well.

And then one of the other projects that we're currently discussing as a potential is to look at a survey of the primary care physician community. And so, as an example, you saw the survey results that we did from InCrowd and that was a panel, but what we wanted to do was to say, okay, from the perspective of the primary care community, what is it that you utilize and where do you go for information and how can we then again develop a dissemination agenda that really meets your needs.

And so, again, this is a project which is in the very early stages, but what we've been able to do is get four of the primary care medical societies together, specifically the American Academy of Family Physicians, the American College of Physicians, the American Academy of Pediatrics, and the American Osteopathic Association. They

have all come together and agreed that they will work together on a survey that we would do of their membership.

And so, this represents an opportunity for major collaboration with key primary care organizations and we're having actually just very preliminary conversations right now to determine exactly what would be the content of such a survey.

But we're actually very excited about this because it represents an opportunity to actually collaborate with the primary care societies, for us and them to collaborate, as well as for us to then promote the collaboration with one another. But again, this is an opportunity for us to develop an understanding of their needs in terms of dissemination and where do primary care physicians go for information. So, more to come on this.

And these are just details, as I said, this is a follow up from the InCrowd survey that we did.

So, what I want to then spend a little bit of time talking about is something that you all

have heard a bit about before and this is a project that I know the COEC is very familiar with, but it's the Pipeline to Proposals Project, which I know you have seen that we've issued the RFPs on this.

But this, again, represents a major effort on training and development and is addressing some of the issues that you all have raised as some of the concerns that you've had.

So, one of the things that we've heard time and time again is how do you get the non-usual suspects in the door, how do you get them involved? In addition, when you have, say, a project that has been reviewed but maybe was an interesting project but didn't have a very robust patient engagement plan, what is the opportunity that is available for trying to give those people additional support?

And so, in order to respond to that we've developed what we call the Pipeline to Proposal Project, which is where we have developed essentially three different funding mechanisms for different types of organizations or individuals to

come together to engage and participate in the development process for submitting an award to us.

So, the Tier 1 awards are what we call just the opportunity to bring groups together. So, if you're a group of physicians at an FQHC or if you're mothers of children with a specific condition or if you are patients who are all having a certain condition, this is an opportunity just to put a little bit of seed money together for those people to come together and start to think a little bit about what might be some of the research questions and issues that they may want to address from their perspective. We call those the Tier 1 awards and they're very small awards for $15,000 for up to nine months, but they're really designed to be the kind of seed money that we put out into the community to help encourage others to really come together and think about what might be some of the priorities that they have.

Tier 2 is really thought of, then, the next stage of awards where let's say you have a group of parents who have come together with

children with a particular condition, but now they're saying, okay, so we understand what some of the priorities are, but we actually now need to really link with researchers and understand who are the researchers who are out there who can work with us in this effort.

And so, the Tier 2 awards are really designed to be a bit more robust but to take these people and really marry them together. So, again, these are relatively small awards, they're for $25,000, up to 12 months, and really -- you know, I keep saying that these are the donuts and community center awards, but they're really just the opportunity to fund the bringing together of patient groups as well as then researchers to start to think about developing research teams.

And then the Tier 3 awards are really the bit more robust awards, these are for up to $50,000, and again, up to 12 months in support, but really they're designed to be the bringing together -- the patients, the researchers have come together, and then let's develop the plan, let's

develop the research idea.

And so one of the things that you should see is that we think about each tier as feeding into the next, but any organization, if you have already done that preliminary work yourself, you could come in as a Tier 2, you could come in as a Tier 3.

We also are thinking about Tier 3 as a mechanism where we have identified projects that have gone through the PCORI funding process and have not been funded, it's what we call the "Close But No Cigar Awardees" who maybe have a very good idea but have not necessarily been able to develop the kind of patient and community engagement plan that we'd like to see.

And so, this is something that could be identified by our research team as then we promote them and encourage them to go into Tier 3 to really develop that robust patient engagement plan that we would like to see as part of the proposal that they submit to us.

So, again, these are the details of

exactly what would be in each of those tiers, but as I said, Tier 1 are the smaller awards, just $15,000 for up to nine months, and really, as we think about it, these are available to individuals, consumer/patient organizations, clinicians, and even researchers or a combination of those, but this is really, you know, the donuts and community center funding just to give people a space and a place to be able to come together and meet to think about how they can engage in the PCORI process.

The Tier 2 is really available to emerging research and non-research partnerships, but the big thing is that this is about partnerships and bringing people together. Again, these for up to $25,000 for up to one year. And then the Tier 3 are the larger awards, $50,000 for up to one year, but really they're meant to be available to the advanced research and non-research partnerships to make sure that they have the capacity to develop that robust engagement and research plan that we require in all of our awards.

And so, particularly for the Tier 1s,

which is where we started, this is actually the small, small investments, and one of the things that we decided to do is many of these groups do not even have the tax ID number. I think this is something that we can all relate to if you're that small organization, and so what we actually did is we actually issued an RFQ to ask for an Intermediate Funder, so the IF stands for Intermediate Funders, and what we've said is that we want entities that are out there in the community that are established, nonprofit organizations, that are working in this space. But what they can do is serve as the funder from us, and then they provide not only the financial support for all of these smaller organizations, but they can also provide some of the background and IT support to some of these organizations.

And so, as I said, we issued the RFQ for this a couple of months ago and actually on Monday or Tuesday we're going to finalize the contract for a recipient in Colorado who's going to work to help support our pilot in this area, which is going to

essentially cover potential awardees in the entire western region of the United States.

Immediately following, for those of you who are interested and not in the western part of the United States, is, as I said, we're going to start immediately with the Tier 1 awards and we have the Intermediate Funder and then we will then send out the announcement for the RFP to go out in October but then immediately following we're then also going to then send out a request for additional Intermediate Funders for other parts of the country.

But what we wanted to do was do this in stages so that we can learn from each stage before we then launch into the subsequent stages.

And then as we get to Tier 2 and Tier 3, our plan for Tier 2 is to announce that by the end of this calendar year, and for Tier 3, to announce that early in 2014.

In terms of the other Engagement Awards, as I mentioned, we have a number of examples that are now in development and so these are in various

stages of development and we plan to then, once you all have approved then the concept of the Engagement Awards in general, is to then develop our online application process and portal, which is targeted to be open by the end of 2013 and then we will launch in full force in calendar year -- now calendar year, not fiscal year -- 2014.

So, one of the things that I wanted to propose or show you is that as we're thinking about these Engagement Awards, we're thinking that we would like the budget for this to be a $15 million budget request for approval in November when you get the full budget.

As we've thought about what our needs are for 2014, the vast majority of the work actually is going to be in work in training and development with some work then in knowledge and a minority of the work actually in dissemination. But given that we're now in the early stages of what we're trying to do in terms of building the PCOR community, we think that the lion's share of our investments will be in this area.

I think that the relative contributions for this pie chart are going to change over the course of time and this is something that we would be discussing. Steve is smiling at me, I'm wondering why. And so, as I mentioned, right now we're working on pilots to be developed within fiscal year 2013 within each or the areas, and so I hope that each of the projects that we presented here and the ideas that we have behind these projects are a good demonstration of what it is that we're trying to do.

But in closing, the specific questions that we're interested in is as we've been thinking about what is the role of the Engagement Awards in terms of Knowledge Awards, Training and Development, and Dissemination, now is the opportunity that we have for ideas from the Board on very specific projects. And I think part of this is we -- you know, I have been here now for two years. There's a lot of ideas that come out of this Board, but we don't have the mechanism to now take those ideas forward. And so now, this is the

opportunity that we have available to be able to put those ideas into place.

So, with that I'll close and open it up for questions.

VICE CHAIRMAN LIPSTEIN: Anne, the reason I was smiling was -- and I'm hoping that Gray won't take this lead from Gene -- every time we're way behind schedule, Gene delegates the authority to me to moderate the meeting.

But let's open it up for input. I'm going to start with Debra. I think I'll just -- which is this, counterclockwise?

UNIDENTIFIED SPEAKER: Clockwise.

VICE CHAIRMAN LIPSTEIN: Clockwise. We'll go clockwise. Debra.

MS. BARKSDALE: And this is just a clarifying question related to the Intermediate Funders in Tier 1. Do they actually award the funds, review the applications or proposals, and actually distribute the funding? Is that their role?

DR. BEAL: Right. So, their role,

actually, is we would award the funds to them and then they pay, then, to -- on behalf of those, because they just have the internal accounting that allows us for appropriate oversight.

Some of these other organizations just don't even have the infrastructure and so they'll be paying the bills on their behalf. So, if you need reimbursement for a trip or for food or for something like that, the Intermediate Funder pays it because they have the capacity for us from an accounting perspective.

DR. ZWOLAK: Bob Zwolak, Board. So, I really support this concept, obviously. The question is one of resources. If you have $15 million and grants for $15,000 $25,000 and $50,000, that's something like 600 grants we're going to give out. Do we have the staff power to accomplish that efficiently?

DR. BEAL: So, that is actually then part of the discussion that will come forward in November because there would be staffing implications.

As I've thought about this, I think a program like this would require probably two people to manage it. We would need someone from a programmatic perspective as well as someone from a project management perspective. Although the number -- I think, Romana, do you remember the number of projects we ended up thinking -- it's more like 60 projects a year. Yeah. It's 60 projects per year. Yeah.

DR. ZWOLAK: Six?

DR. BEAL: 6-0.

DR. BARNETT: I actually had the same question that Bob did and I don't quite understand the math that gets you to 60 projects. I think it gets to be a very large number.

I don't want us to get too far down into the weeds around exactly how it would be administered, but obviously you'd have to figure this out. The use of the Intermediate Funders would help in that, but I think not only is the question kind of how you coordinate and pull off the contracting for all of those, it's how do you

make sure that somehow we're pulling the learnings out of each one and then making maximum use of those learnings and then disseminating those learnings? What we don't want to do is just sort of sprinkle money across the countryside, and I've always loved your analogy about a pile of rubble versus a cathedral. We want to make something out of this.

And I think that's just a particular challenge when you're talking about smaller grants of this type. I love the concept. I love the idea. I'm very supportive, but I think that's going to be a significant challenge moving forward.

DR. EPSTEIN: Any award program that has Gene's name attached to it, I'm fine to give $15, maybe 30 million to. Having said that, one of the things is we have to make the decisions come November. I found the examples you gave helpful and if you could think of even more to just edify me so I've got a better sense, I'm mindful of what Harlan Krumholz has been reminding us about, which is we better think carefully about what the end is

at the beginning, and I didn't have as clear or robust a sense as I might.

Don't have to do it now, just next time.

DR. DOUMA: Allen Douma, Board. I like a lot of the examples. I particularly like the State Health Policy one having been a Medicaid director in Oregon. That's something we've talked about forever and ever. It's important in that to do the follow up, which I don't see there yet, is after you've done all of that interaction, what impact did it actually have on Medicaid programs, for example.

Just a note, you've already changed the D&I to D for I in these slides moving forward. Perhaps a little premature.

I also -- I think in the example of the slide -- and I have to go back to it -- is the one that has Tier 1, Tier 2, Tier 3, Tier 4. There's a number of questions embedded in that and I think the way to even raise the questions is take examples and just see what happens along the way.

For example, in one of your timelines that

you showed us, you've got -- we're putting out the RFP October 15th and it closes November 15th. Considering the people we're talking about, how in the world are they going to even know about it much less respond to it in 30 days? So, maybe we ought to be careful about timelines, which reflect actually who these people are.

DR. BEAL: Let me just comment on that because part of the reason why we're actually keen is that we know that this was previously the micro contracts project, and so it is part of this fiscal year, and so if we expand things out then it means that we're making commitments into the next fiscal year, which is fine, but I just wanted to say that part of the push that we had was we wanted to essentially make use of the budget that we were given.

DR. DOUMA: I'm all in favor of making things move more rapidly, but I think it's just unfair, and it's almost inappropriate to say who we really want and then set up a system that we can't get them.

MS. HOLE-MARSHALL: Did the concepts go through the COEC? That's kind of the mechanism by which these came forward? So, again, back to the AHRQ and how we want to spend our money, we're looking at an approximation of $15 million on very important activities, but I can tell you, and I don't know if the COEC was briefed prior to the NASHP award, that there are similar AHRQ activities that have occurred.

And so, was there any discussion about whether that was more appropriate for AHRQ, whether AHRQ was sufficient in terms of the Medicaid learning network, whether their funding was running out so we were going to pick up that funding, what learnings had been completed from that, but it's very duplicative, honestly. And I worry about that.

And so, it's back to -- I understand that there was some roundtable where there is now public information about AHRQ, but I don't see how that connection is occurring with us.

And if it's in a subcommittee, I think

that's great, but I'm not hearing that even at the report out to the Board. So, again, I worry about us spending funds on really great stuff that's replicating other work and where that takes us away from our core mission of funding science.

DR. BEAL: Sure, sure. So, I can say that we looked at what information that we had as we developed that and I can say actually with absolute certainty -- and I think you're making a good point -- that every project we develop, we don't necessarily say, how does this then align with AHRQ, because some of them are not necessarily dissemination relevant and I think you're raising a good point and it's another part of the business check in that we can do.

DR. DOUMA: Just a comment and this I think will come up tomorrow when we're talking about governance, one of the things we need to determine is what is the role and responsibility of each committee, and in many ways what the committee does is we don't really vet in the sense that we vote to ascend something to the Board as a report

of the committee. We're provided background information and give our comments on the way to the Board, and if that's the way we want to continue to do things, that's fine, but we just need to understand that that's what's going on versus the committee taking more of a vetting or an oversight role in what actually gets to the Board.

DR. NORQUIST: Yeah, so -- Gray Norquist. As the Chair of the COEC, I think that's exactly right. I mean, I think that's the decision we're going to have to make is to how much more power, if you will, are we going to give to these committees to get some things done, to streamline so we don't have to have these delays and get through.

I think the bigger issue for us has been this question of what is success and success at an even more global level than just these three, which is, what does success in engagement mean, right, and toward the greater end of ensuring that we have a network of people out there who are ready, willing, and able to do PCOR, right, and so that's what our struggle is is trying to do that, and what

are the metrics to getting there?

So, what is our goal for 2019, 2050, whatever, and what are our intermediate goals as we get there is what we've also struggled with.

So, the idea here is just to put a few of these out, not to blow all the money at one time on a bunch and to see. And I think you're absolutely right, whoever mentioned it, is that we've got to learn from what we do because we may find quickly some of these awards are just not worth it and we should just stop right now with those and move on to something else.

VICE CHAIRMAN LIPSTEIN: Harlan. And then I'm going to draw this session to a close after Harlan speaks.

DR. KRUMHOLZ: Thanks. I do think this is a really important issue. I know we're ending on it before lunch, but the issue of this coordination with AHRQ -- I'm sorry Richard's not in the room -- but it's still not clear to me exactly how well -- Jean's here -- and it just seems like we need to be able to have -- in the engagement piece, it

shouldn't be this -- we're doing engagement and they're doing engagement or even that I've just heard about that from you, Leah, about the redundant activities.

And so, I just am making a pitch to say that these things, I think, need to be brought together in ways at least that maybe the Board can appreciate better. I'm sure that behind the scenes they are, and in making these decisions, the question I have is if there is -- between PCORI funds X amount of engagement activity going on and dissemination given that AHRQ was charged with a lot of that, should 80 percent of that activity be on the AHRQ side? And if we're doing the 20, where's our 20 -- what are we doing that they can't do? In a way, that's what I sort of want to know, because there are things we can do that they can't do. We've talked about survey work, for example, and other things like that, and anyway, go ahead, Jean, but this is where I think this is really important that we're working together.

MS. SLUTSKY: I totally, totally agree

because it doesn't do anyone any good if we're duplicating and not partnering, but the actual program that Leah's talking predates, actually, both PCORI and actually it predates our legislative mandate to do CER in 2003. We've convened the Medicaid Medical Directors in a learning network for, gosh, I can't even -- I can't remember when we started that, and it's not the Medicaid directors, it's the medical directors, because they tend to be less -- they don't turn over quite as quickly as the Medicaid director, which really serves at the pleasure of the governor and when governors change, they change.

So, that's our program. You know, I wouldn't have even thought, to be perfectly honest -- I didn't know about these awards, so I didn't -- wouldn't have even thought to have brought that to your attention. Had I known that you were going to contract with them I would have said, yeah, and here are the very active Medicaid directors.

But, you know, Rick is gone for the day, but I totally agree, he agrees, we should be

partnering here. There are things that AHRQ can't do, there are things that you can do, we have longstanding relationships with different groups that we can share with you. This is -- this has to be an integrated activity.

DR. KRUMHOLZ: To me, Harlan Krumholz again -- I know, Steve, we've got to go. Just this final thing is that I just think we need a unified organizational plan about how together with the funds that exist, the thing that worried me the most is when you just said "I didn't know about this."

MS. SLUTSKY: And I didn't mean to be pejorative.

DR. KRUMHOLZ: No, and it's not critical. There's a lot of things in the air and it's not critical of Anne either. It's just, there's so much going on, this is our chance, I think, to try to figure out some structural ways. There's amazing work going on. I mean, it's breathtaking, it's just a matter of just trying to line it up. That's all.

VICE CHAIRMAN LIPSTEIN: So Anne, I think the gist of the feedback that I'm hearing is that the Board is broadly supportive of the idea of Engagement Awards.

DR. BEAL: Mm-hmm.

VICE CHAIRMAN LIPSTEIN: How we do those Engagement Awards and at what scale and how we coordinate that work with the work of the Agency for Healthcare Research and Quality needs to be addressed, so when you come back to us in November, we can take up those topics, I think, in some greater detail.

What I'd like to do is, for the benefit of the broader audience listening in is to remind everybody why we felt -- why our Board feels that tying Engagement Awards with Gene Washington was an important thing for us to do to honor Gene's service to our organization. Gene was the champion, almost from the get-go, of making sure that the end user of CER was involved in every phase of the research process.

And we're talking about the patient and

we're talking about the caregiver, and the clinician, and the policymaker, and the payers, and the delivery system, and the pharmaceutical companies, and the device manufacturers, to the extent that everyone's engaged in the research process. Gene helped us to understand that it would facilitate dissemination, it would facilitate uptake and implementation and what he encouraged us to do throughout his tenure as our Board Chair was to make sure that our process was as inclusive and as transparent as it possibly could be.

And so, whether or not we have patients and stakeholders helping us with refining the research questions or choosing and validating the comparators or the outcomes, or helping us to identify the study population, or helping us to develop recruitment materials and survey instruments, or whether we're just getting comment on interval findings, the role of our stakeholders is so important.

And so, I hope you all will join me -- I know he left the room because he was a little bit

modest and humble about having his name tied to anything, but the idea that Gene's name will live on with the PCORI organization in conjunction with engagement, is our way of honoring his service to our Board.

So, I hope again when you do see him, because he snuck out, you'll join me in acknowledging the just wonderful contribution to the PCORI Board.

And we will look forward to hearing back from you in November about how the Engagement Awards have taken shape and how they will be presented going forward.

We are going to take a 35-minute break for lunch. I'm sorry to ask everybody to eat quickly. If Gene were here he would tell you to eat slowly, but he's not.

Okay, so we'll see you all in 35 minutes.

[Whereupon, at 12:41 p.m., a luncheon recess was taken.]

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

[1:19 p.m.]

CHAIRMAN WASHINGTON: Welcome back, everyone, to the afternoon session of the Board of Governors Meeting for the Patient-Centered Outcomes Research Institute, PCORI. We are going to now shift into yet another area of focus for PCORI, this one related to research methods, and I'm going to ask our executive director, Dr. Selby, to introduce this topic and presenter.

DR. SELBY: I won't say much, since we have the chair of the Methodology Committee -- still relatively new chair of the Methodology Committee, Robin Newhouse, here to make the presentation. Just to say that we are just delighted that the Methodology Committee under Robin and Dr. Steve Goodman has just -- seems remarkably reinvigorated and focused on a number of key areas, and I know Robin's going to touch on all of them today, so it's -- from the staff's perspective, we're just enjoying the opportunity to work more closely on a number of fronts with the

committee and think the Board will be delighted to hear this report as well.

MS. NEWHOUSE: Thank you, Dr. Selby. I'm Robin Newhouse, chair of the Methodology Committee, and I present this report on behalf of our committee members to represent some of the work that we've accomplished, and I also want to give a little shout-out and a special thanks to all the help that David Hickam has given us and support as well as Katie Rader and Julie McCormack. We couldn't conduct this work without their significant contributions that they've made to keep us moving forward and organized. So thank you.

So in terms of background, the four things that we are going to cover today include the status of the methodology report, the development of new methodology standards that -- we recommend two and have a couple other that I'll present to you and give you a status of those recommendations. Here we are with dissemination implementation again. I know we had a quite vibrant discussion this morning about dissemination implementation, and this time

we'll be talking about the methodology standards.

UNIDENTIFIED SPEAKER: [Off microphone.]

MS. NEWHOUSE: No, I do not. And then the last being the methodological consultation activity. Thank you.

UNIDENTIFIED SPEAKER: Sorry about that.

MS. NEWHOUSE: Oh, that's all right. I was wondering how they were going to change, there --

[Laughter.]

MS. NEWHOUSE: Okay. So these are the four areas that I just mentioned, in terms of what we'll be talking about this afternoon.

So the first item is the methodology report, and just the brief history of the methodology report was that the methodology report was reviewed by the Board in May of last year, 2012. There was an extensive public comment period by which we evaluated each public comment that we received, made changes to the methodology report, and then the draft methodology report, the draft methodology report revisions are going to be presented to the Board in November, is the short answer.

The standards from those methodology report revisions were posted in December after approval by the board, so the standards are already approved. What we're talking about today is the methodology report in whole. So I just want to again thank a couple of our methodology members for a significant amount of work on this methodology report, and that's David Hickam and then Mark Helfand, also, is leading the effort along with Al Berg.

And the difference in this methodology report that you'll see is not only will you see revisions in the text around the methodology standards and the explanations, but what they've done is something quite innovative and impressive. And they've developed a whole group of examples of how those standards are applied. And they come in ways of published research studies, so for example some of the psychometrics or some instruments that are being used to provide some examples of psychometric standards. Or some stories of patients, so that you can see what the patient

engagement standards will look like and mean.

So there is some further work being done and the methodology report is now under review by a subgroup and I think David, I'm going to rely on you to provide the timeline for the methodology report. And then the other thing I would say is if you'd like some examples of the stories that you'll see in the methodology report before you get them, Mark Helfand left me one copy, so I do have it and I'm willing to talk with you about it and share it as a preview if you have some questions about what those stories might look like. David?

DR. HICKAM: Thank you, Robin. So the report is basically at the final stage of consolidating the comments from a set of reviewers that included some members of the PCORI staff, some members of the Board of Governors, and members of the Methodology Committee -- actually, the whole Methodology Committee has seen the report and had a chance to submit comments on it. We plan to finish those revisions by the end of September, which as you all know is like next Monday, and then move

that final text to the PCORI production group to start the process of preparing it for a formal release, and so we would expect that the Board of Governors will have a chance to review that prepublication version sometime in the month of October.

MS. NEWHOUSE: Go ahead, Gray.

DR. NORQUIST: Are we asking questions now, do you want to wait till you finish before --

MS. NEWHOUSE: Yeah, we probably should, for the methodology report, yes.

DR. NORQUIST: This is Gray Norquist. I was just going to say, if you haven't seen those patient examples, they're really very good. We looked at those earlier, I think, Debra, you and I and some others actually looked at these and it's really just an incredible -- brings a whole life to that report that can be kind of dry at times, but I think it was just an incredible job that you guys did.

MS. NEWHOUSE: Thank you. Yes. I think you'll be pleased.

CHAIRMAN WASHINGTON: Okay, other questions, comments, at this point? Gail?

MS. HUNT: Gail Hunt, Board member. I just wanted to suggest that when you're doing the -- making the changes to the report, if you go back over that and there are quite a few places where it just reflects patients and not patients and caregivers, so I'd really appreciate it if you could go back and be sure that you put in the "and caregiver" part there, because as we all know, there are quite a few times when it is the patient and the caregiver together. Thanks.

DR. HICKAM: Thank you.

MS. NEWHOUSE: Thank you, Gail. Good suggestion. Much appreciated.

All right. So the second issue we'd like to bring up is the development of new standards. As you know, the first set of methodology standards were related to areas not that we knew a lot about or not that we knew nothing about but they were areas where we thought we could leverage the greatest improvements in improving the rigor of

patient-centered outcomes research studies. The development of new methodology standards was our next agenda item, and there was one area that we did not fund a contract last year that we thought was important. The first was cluster-randomized trials. So we're working on a PFA for a contract for standards around cluster-randomized trials. The second area where we thought we could make a difference is around complex interventions. So by nature many of the interventions that are helpful to providers and patients are interventions that have multiple components and are naturally complex. And yet they're not standards that we can adopt or apply.

So those are two areas where the Methodology Committee thought that we need to start first in the new set of standards, but there were a couple areas that we need some further discussion about. Those two areas are one that we spent a lot of time talking which I appreciate the discussion this morning and I've already had e-mail communication with David Meltzer about the value of

information; we had an extensive conversation at the Methodology Committee yesterday about the importance of value of information and how it could be used by PCORI, and there is a subsequent meeting in progress now to talk further about value of information. So that's a little different but aligned with the discussion about standards and should there be a standard, but it's also a useful technique for PCORI when we think about decisions about priorities.

The second area that we discussed were standards around systematic review. As you know, the methodology standards endorse the Institute of Medicine systematic review work that was done. Many of our members were affiliated with that work, including Al Berg and Sally Morton. And at the end of the report there are another group of research recommendations. So we are having some discussion about what those recommendations are the standards as they're adopted in the whole report, and the specific steps that a systematic review includes in terms of methods. And so we haven't made a

recommendation yet about how to move forward. We need -- have some more work group discussion, but we are going to engage the staff to review the Institute of Medicine report and understand what we can do to create some better guidance for people around what a systematic review is. So I think that's the best I can say right now. So it doesn't look like it's going to come up as a standard, but it is a discussion for us to understand how we operationalize those standards.

So, any questions about the endorsed standards or the proposed new standards?

CHAIRMAN WASHINGTON: We've talked in the past about value-of-information analysis. I remember early on, much earlier on. It was seen as being of high value as we were going to develop priorities. This is as much maybe for Joe and the staff as it is for you, but have we actually tried to connect as we're thinking about priorities, as we're in fact trying to answer some of the very questions that were posed this morning to Brian, using VOI analyses?

MS. NEWHOUSE: Absolutely, and I think that's what Brian was thinking. He was engaged in the discussion yesterday with the Methodology Committee, so it was very timely, Of course we have talked about value of information in the past; in terms of standards we never moved value of information forward as a standard in that first set, but certainly it's come up in a number of venues about the utility of the technique. So we are going to have some more discussion with some recommendations for how it can be used, absolutely. So the discussion this morning was timely and mirrored the discussion we had in the Methodology Committee yesterday.

DR. SELBY: Yes, just to say, as I said this morning, as we put the review criteria for our advisory panels together, we had a close eye on value-of-information analysis. It was in our judgment impossible to do. You can't do full value-of-information analyses on numerous topics; each one of them is like a major modeling effort. We used something called conceptual value of

information, and I think in the end that even turned out to be pretty complex, but I think it's still fair to say that these advisory panels work from a set of criteria that incorporate many of the concepts of a value-of-information approach. And I think where we land in terms of getting as quantitative as the classic value of information versus more qualitative but still preserving the important ingredients of a VOI is what we need to decide as panels and as staff.

DR. KRUMHOLZ: The Methodology Committee's doing terrific work and as I was reflecting on what you were saying and thinking about this, I know we're probably tired of a discussion about dissemination, but it made me wonder the degree to which we -- the work that you're doing is being recognized nationally as authoritative, and the degree to which we've incorporated people into the work who would make that acknowledgment. So for example, are in schools of public health around the country, are they going to teach the methodology standards, are medical schools going to have

seminars on them?

I mean, how can we promote them? There's so much good work here and you've got such good people here, how do we promote them into the proper thing, because I think that to the average person who might utilize them they just come across as one more -- there's IOM reports, there's a PCORI report, there's this and there's that, and they may not realize the true value that lies in what you're doing. We are trying -- we've always been thinking about how do you promote them for people applying for grants, but I really would like these to be taught nationally.

And if I could only find a dean who might be able to take that as a prototype in his institution and really make the mark as he was leaving an organization. And we could call these the Gene Washington Statutes.

[Laughter.]

CHAIRMAN WASHINGTON: Just pour it on.

DR. KRUMHOLZ: In all seriousness, though, I'm listening and I think what can we do to

establish the authoritative nature of these and to help people understand how convenient it would be to bring this into the teaching environment and to make these the standards in a way that otherwise they might just be put on the shelf and ignored. So have you guys thought about that? And what can we do as PCORI to help engage that academic community or the teachers about this?

MS. NEWHOUSE: That couldn't be a better lead-in to the dissemination recommendations that Bill Silberg has helped us with and Brian Mittman. We have a detailed plan. It's a five-phase plan which does include a high level of engagement and tailoring the message and the usage and trying to understand what the community needs and what we can provide for them. So we are going to cover that. Thank you.

CHAIRMAN WASHINGTON: Allen.

DR. DOUMA: Allen Douma, board. I just want to reinforce what hard work you guys are doing and I think PCORI as a board ought to be really proud of that. With regard to dissemination, I

think we need to work harder on that, and both with regard to the standards as well as the value of information I would hope that sometime soon that we can figure a way of translating that so it makes sense and it's compelling to people who aren't in research. I think the average person in the universe could listen to a message if we crafted it well and promote it well enough so that they understand what this is all about. Because unless we get a wide body of people supporting what you do, which is really sort of the core of what we do, we're not going to be consistently supported.

CHAIRMAN WASHINGTON: Thank you, Allen. Harlan?

DR. WEISMAN: Harlan Weisman. I think this is great, and I agree with what Harlan K. said. In terms of the importance, this is our first body of work from PCORI to disseminate and to have implemented and so I think it's going to be a great test and experience for us to see -- make sure that we're successful at it.

One question: you talked about new standards, and

when the original document was being formulated, this was always called version 1.0, I guess, and I guess we're getting the revisions that will be 1.1 or something, but there was always this discussion of ongoing evolution not only in bringing new standards, which look very important, I have a question about one of them, but also about going back and looking at what you have already written and doing more, and I was curious about that.

One area of particular interest for me that I find a real stumbling block but one of the Methodology Committee review members wrote an article in the New England Journal recently about that, about it, and that is we keep talking about PROs and you have a PRO paragraph, really important area that lots of different organizations working on it, but finding patient-centered PROs in which are valuable information back to patients is something that I think I'd like to see addressed, and I'm not sure that should be number one on the list, but there are a lot of other topics in there, in the original report, that I think are important.

In terms of -- so the question is, working on version 2 at some point and what the thoughts are about that, and second was on value of information I wanted to follow up on Joe's comment because I was on -- I was one of the reviewers on those early series of contracts in which value of information was one of the sets. I think we may have awarded two different institutions to write reports, but what struck me in reviewing the proposals and also the workshops that followed is that although value of information sounds so obvious and such the right thing to do, the methods were, at least for somebody like me, fairly opaque and not really clear how you could broadly apply it. And I was wondering whether this is an area that has advanced or evolved to a point that we really can talk about it in a way that would be meaningful in a more broad way.

MS. NEWHOUSE: And this was the discussion in the Methodology Committee meeting, and then, so what we came to the conclusion was, or the conclusion we drew, was that there was some utility

in looking at the multiple methods and trying to interpret what strategy might be appropriate under the circumstances for use, so in setting priorities, and this is not an area of expertise for -- this is David Meltzer's expertise. But that he felt like there were techniques that could be matched to the need without getting way too quantitative.

So and the other thing I just want to mention is you asked the question about the standards and revisions of the standards. The standards aren't static. We've not come up with a recommendation for how often we should review them or do another landscape. We do need to do that. The intent of those standards was not that they would stand for years without some revision or some review.

DR. WEISMAN: Do you have a plan to -- have a plan, I guess -- I know that the process was grueling to just get this one done, and a tremendous amount of work went into it, and what turned out to be supposedly a part-time job became

all-encompassing for the committee. But throughout it, there was a continuing statement that there needed to be more elaboration of certain areas. So I understand you're not prepared to do it now, but when in the life of the Methodology Committee would you think, looking back at the standards and prioritizing the areas that maybe further expansion might be a good thing?

MS. NEWHOUSE: So you're talking about expansion in the text, or you're talking about expansion of standards?

DR. WEISMAN: Both. I know you're adding to them now, but even the current standards there was a sense that there was a need in certain areas for further elaboration or more time spent on.

MS. NEWHOUSE: And I think these revisions, I would say these revisions, the contribution, the revisions, the discussion that we've reviewed should meet some of those concerns. In terms of next steps for standards, one other point that I wanted to make is our goal was to continually understand which standards are needed

to advance PCORI's work and increase the rigor of studies conducted by PCORI. So we do see that as an ongoing effort and without an end date. So there could be unknown standards. So we do need to prioritize where those efforts need to be spent.

But the other thing we did talk about is soliciting input from the public. We looked at a couple mechanisms that PCORI has used in the past, one of which is just call for suggestions via the Internet. And we also talked about outreach to professional organizations as we move forward in terms of a stakeholder engagement to understand what the community needs from us.

CHAIRMAN WASHINGTON: Okay.

MS. NEWHOUSE: All right. So, next we'll move to dissemination and implementation activities, and so Allen's smiling, so --

[Laughter.]

MS. NEWHOUSE: -- that's good, so I just once again want to thank David Hickam and Bill Silberg and Brian Mittman for their leadership in this area. Many of us helped and contributed, but

they have a very comprehensive plan for dissemination and implementation of these standards.

At this point, the standards have been reviewed, prioritized, we've made some recommendations for next steps for both dissemination and implementation, and at this point the recommendations are around core training activities and workshops for dissemination as well as training materials. And extending from those training materials would be tools that reviewers can use to review the proposals as well as tools for applicants that would be submitting the proposals, but I would say that Bill and Brian have put together a comprehensive plan for engagement of the community in the implementation of the standards. So David, did you want to add anything to the implementation plan?

DR. HICKAM: Yeah, I think the only thing I would add is that the implementation plan is kind of a three-year plan, so there are some immediate activities that we want to get out to the key

audiences, particularly PCORI peer reviewers, and then to move more in the direction of sort of a widespread dissemination effort and implementation effort that Harlan Krumholz had advocated for. So this would sort of grow and extend over time.

CHAIRMAN WASHINGTON: I was looking at Allen to see that -- did that more fully address your question that you -- ?

DR. DOUMA: Not really.

CHAIRMAN WASHINGTON: Maybe it's time for us to move on, Allen.

[Laughter.]

DR. DOUMA: When I hear a term like "communication plan," it's usually much more robust and detailed but in particular has timelines associated with it. And unless we have timelines, it's easy not to do anything at all, one is because there's nothing to measure against and the other is nobody knows when they're supposed to do it. So I would certainly love to see a much more robust communication plan than what I'm seeing right now.

CHAIRMAN WASHINGTON: I just assumed that

as part of the more comprehensive plan we would have clearly delineated the audiences.

MS. NEWHOUSE: Yes, we would --

CHAIRMAN WASHINGTON: Because Allen was referring to everyday consumers; on the other hand Harlan K. was thinking about the academic community and I do see some value in students being introduced to this very early on and residents and not just medical students but students across the health sciences perspective. So.

DR. WEISMAN: Journal editors, too. I mean, the way to ensure standards get in place is if journals make decisions based on certain standards of research.

DR. KRUMHOLZ: So I just want to take this opportunity to again beat this drum that I've been talking about which is really our results-based accountability. I guess that's really what I should have been calling it from the very beginning. And so, in this particular case what I'm asking is not how many people are going to be exposed to the information, not how many

dissemination channels do we have, not how many meetings are being held, but what are we holding ourselves accountable for the results of this. So if we said gee, we really want the standards to be taught in 10 medical schools in the country as a start, within 18 months, you know, we think that X needs to happen, not that we sent this out to journal editors and they wrote us notes and said thank you, but if I would say to you, Harlan, if it's journal editors, then what's the metric? What is it --

DR. WEISMAN: It's adapted. It's adopted.

DR. KRUMHOLZ: But in other words, we want five journals to have said as part of our criteria for evaluation, for our reviewers, we send them links and we expect that they're going to be using these standards. I'm only --

DR. WEISMAN: That they agree to use those standards. And use those standards.

DR. KRUMHOLZ: All right, so they may draw up policies. I mean, I don't mean to -- that's right, and I don't mean to get to the nitty-gritty

of what those metrics are, but I want us more and more to be adopting this idea of what's the end result and then how do we get to the end result. In terms of this, I really want people using it. I want people teaching it. So that's what -- if that's true, then we put on our thing within 18 months we somehow have found two classrooms where people are going to teach classes where this is part of the text. I said to Robin, why not make this an e-book on Amazon that's given out free?

So then you hire a medical editor, they're putting this together, it's a book, it says "PCORI Standards." It's an e-book. And around the country, we would say we want a thousand downloads of the e-book and we want it to be used as the primary text in X number of classes. And I'm just throwing out ideas. But the notion is to say how would the world be different, what would it feel like, and we can then say that now we know where we're going. We know what success looks like in this domain, and now the plan is get there. And some of it can be prototyping. I mean, Harlan,

you're alluding to this -- I just want two classes using this text next year, somewhere in the United States, and then I want to hear how they did it. And you know what? We're PCORI. I'll give somebody money to develop the curriculum. I'll do an X Prize. We'll do it, but give me an X Prize.

Say I'm going to give $20,000 to a teacher in this country in a school of public health who makes a successful proposal about how they're going to develop a curriculum that can not only be used locally but is easily scalable and generalizable to schools around the country and whose primary text is the PCORI methodologic standards as text. And then we will also promote, we're going to put aside another $20,000 for development of tools which can make the classroom more adaptive, more progressive, maybe flip the classroom, so ultimately we'll create the lectures and they can do flip classrooms where they're just discussing the methodology and we say we're going to help change education around methods, because we're going to put in, in the end we'll put in $500,000 in developing tools, teaching

the teachers, and we have curriculum development, but it starts by saying have we got two teachers who want to do it and you do it as an X Prize.

Because you say we've got money we got holding out here in front of this in order to get the -- Because now we know what success looks like. So we say okay, that's where we're going, what would it take to get there. And it's not just waving our hands and saying, "Gee, I really wish somebody would take a look at this thing, because it's really good," but we're like -- we got somewhere we're going.

DR. DOUMA: Let me just reinforce what you're saying is absolutely true, try to wean it down to a paragraph.

[Laughter.]

DR. DOUMA: Every good --

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. KRUMHOLZ: It was one breath, too!

DR. DOUMA: You do it so well. Every good communication plan starts with development of what's really a strategic plan; every good

strategic plan is based on what Harlan is saying, is what's the end point we're trying to reach, then we work backwards from there, which then creates all the milestones with timelines. And I think this is so important that we ought to do a more formalized development, if we haven't already.

MS. NEWHOUSE: Thank you. Well, we have a chart, but not a timeline chart, so we can certainly do that. And I love that idea, and I love the inspiration, but the other thing I wanted to mention is I know that Agency for Healthcare Research and Quality also has some training funds available, so I think -- everything you're saying I can actually see a lot of this work being done by AHRQ in their RFAs for training.

DR. KRUMHOLZ: But again, just like we were saying before, though, I think that there should be one plan that's shared, not -- I hope you got -- I mean you're doing great work, but there should be one plan that's shared.

MS. NEWHOUSE: But they clearly state that the methodology standards need to be used in those

RFAs.

MS. GOERTZ: It's in --

DR. WEISMAN: I couldn't remember it, I had to Google it, but there's that international committee of medical journal editors which set the standards, and you know Arnie probably better than any of us. But what would it take to get this adopted by them? And if there is a problem --

DR. EPSTEIN: Ask Arnie.

DR. WEISMAN: That's why I'm saying that.

[Laughter.]

DR. WEISMAN: I've been wondering all day why Gene sat us together.

[Laughter.]

CHAIRMAN WASHINGTON: I'll tell you after I leave the board. Okay, Robin.

MS. NEWHOUSE: Yes.

CHAIRMAN WASHINGTON: This has been great feedback, I hope.

MS. NEWHOUSE: Yeah, great discussion. Thank you so much.

So the last issue that we'd like to bring

before you is just the idea of a methodology consultation initiative. I think we already had some of that discussion today. It just was a great primer for this discussion as well.

The Methodology Committee is interested in being helpful to the Board in making their decisions and anything we can do to be helpful around these methodology issues, and so the idea was conceived and actually presented at the last board meeting about a methodology consultation initiative by the Methodology Committee, by which we would provide expertise around specific areas on research projects and then so that was discussed, let's see, in May of 2013 at our last board meeting, and then to provide input on areas where you have specific questions or issues.

So I think the other thing that I'd like to tell you is that the Methodology Committee also generated a list of potential members that could provide some assistance with those kinds of activities. And it aligns really well with the discussion we had about the clinical trials

advisory panel this morning, and I think some of the questions that you raised were exactly around this kind of activity and trying to distinguish the difference between the clinical trials advisory panel and this methodology consultative activity. So I see them as aligned. So I appreciate the conversation we had earlier.

Anything else about the methodology review that you want to bring up, David?

DR. HICKAM: Well, just that I think the proposal for subcommittees of the clinical trials advisory panel is basically pretty much the same thing as the methodology consultation plan that was earlier developed by the Methodology Committee, so I think these two efforts have sort of merged together.

CHAIRMAN WASHINGTON: Okay.

MS. NEWHOUSE: Yes, and I think actually we spent a lot of time talking about the clinical trials advisory panel, so what we would like to discuss is really how can we be most helpful to you. And any suggestions, any discussion or ideas

about how we can best help you accomplish PCORI goals is what we'd like to hear.

CHAIRMAN WASHINGTON: At this point we're approaching two o'clock and we do have guests that will be presenting and that have traveled some distance to present starting at three, and between now and then we have a presentation from operations as well as the public comment period. So in response to your question, Robin, I think we just had a lively and informative discussion, I'm going to ask if anyone has additional comments that they pass them to you.

MS. NEWHOUSE: Thank you.

CHAIRMAN WASHINGTON: And I would like to convey my thanks to you and David and other members of the Methodology Committee and staff for absolutely superb work. As you've heard from those who looked at the report, it really is an important and exceptional piece of work and I think it will be highly valuable. What you heard was the sense that we want to make sure that it gets communicated so that people really can use it, and we need to be

proactive about it and push it.

MS. NEWHOUSE: And we share that goal.

CHAIRMAN WASHINGTON: Yes, I knew you did. Thank you very much. Thank you, David.

Next, Joe, unless you want to introduce this, I'll just -- why don't you introduce it, please?

DR. SELBY: Just to say that Regina is here, our COO, and she has several topics that she's going to present on -- these really come directly out of conversations with the FAAC, not to say that necessarily she's bringing endorsements of the FAAC on each, but we'd really appreciate the role of the FAAC as the sounding board for these kinds of really complicated and strategically strategic questions. So I think you'll appreciate the relevance of the questions and we look forward to your input on them. Thanks, Regina.

MS. YAN: Thank you Joe. In this report, I would like to go over several items with you. As Joe mentioned, these are items that have been reviewed and discussed at the FAAC meetings. First

is the midyear financial review. We have quarterly financial review with the finance audit and administrative committee. And we also want to discuss the award to contract process improvement. This has been an item that has a lot of the Board members who have been concerned about the long time it has taken us to execute the research contracts, so I want to talk about what we have done to improve that process.

Thirdly is, as we're preparing for our new fiscal year, 2014, which will actually start October 1st, we are also working on our operating plan as well as our staffing plan development and a lot of this discussion is moving through different committees. I want to briefly go over the process with you and the kind of things that we are taking into consideration as we prepare these plans.

First, this is our midyear financial review. If you look at our budget for 2013, we have a budget of $134,000,000. That is for a full year, a full 12 months. Because of the board's decision earlier this month to change our fiscal

year to start October 1st through September 30th, so for 2013 we're going to be a short year, and we are going to fold the last quarter of this calendar year into a new fiscal year, 2014. So in some ways we may not have very good comparisons between '13 and '14, since one is 9 months, the other one is 12 months, but I think if we have to make the change, it's easier to make it early on in the life of the organization as later the comparison is going to be more important than now.

And our 6-month budget is $53,000,000, and our actual spending is $23,000,000. So obviously we are spending under budget, below budget in quite a few areas. Number one is if you look at the research part, the $85,000,000 we actually put in the budget for research only represented what we thought at that time, the actual research spending from our research contracts. It does not represent the commitment we make, not the funding award, which is a different number we're looking at. And because there was delay in executing this contract, and also that the way most of our contracts were

structured at that time, we were only collecting financial report twice a year, once is in April, the other one is in November, so we only have two points in a year to be able to capture those expenditures. And in April, when we collected the reports, it was kind of pretty low, in a way it's kind of expected. So that's what it is. I will talk a little bit later about what we've done in order to facilitate that, make it better.

So this one shows that we are under spending in most of the budget item; however, if you are looking at our spending to try to gauge the level of our work, actually, most of our work is involved in making funding commitments. So if you look at the accumulative funding commitments we've made so far to over $262,000,000, most of them were made this year. And that's where most of the staff work is devoted to.

I've mentioned why some of the budget items we are spending below budget. Another area is administrative expense. We have put in quite a big budget item for our IT systems, our major IT

systems that we are implementing in order to support our work, and as of June, a lot of those systems were just being contracted for development, so there was a little lag time in that.

So that is the very brief financial review on where we stand in June. I want to talk about what we have done so far to improve our own performance --

CHAIRMAN WASHINGTON: Regina, before you shift gears here, Kerry, any context here for us, anything to add?

[No response.]

CHAIRMAN WASHINGTON: Thank you.

MS. YAN: All right. We have taken several major steps to improve our own performance in contract execution. I start with the one at the bottom, number one is that goal for ourselves, we have set a 90-days goal, and in order to meet those goals, we implemented several things.

Number one, is we met with a group of university administrators to get their feedback about the concerns they had regarding our research

contract. One thing is, I think it was discussed earlier, a lot of people were looking to their own experience with NIH contracts and other contracts, so ours is a little bit different, so people were having some adjustment to it, so we have talked to them, we have taken into consideration some of their suggestions, and we have incorporated those suggestions into our revised contract template to address some of their concerns.

Secondly is, that with the help of Mary, she's only been with us for a couple weeks and we are already seeing significant improvement and help for us in speeding up negotiation, contract negotiations. Oftentimes we have very specific, sometimes minute modification requests from university legal counsel, and now it's much easier when we have in-house counsel who can look at the issue and make a determination and then we can move much faster in getting those contracts and those negotiations resolved.

And if we look at the difference from the first quarter of this calendar year and the second

quarter of this calendar year, all the contracts that we executed during the first quarter -- actually the second quarter of the calendar year were contracts that were approved by the Board 160 days ago. With the third quarter, we're looking at 97 days, so we have cut the time significantly and lowered the number of times, days that it takes, and we anticipate that we will continue to improve that. We hope that one day we will be able to do a 60-day turnaround.

This would involve both work from the staff but also, I think, recipients, once they're a little bit more accustomed to our contract and our terms, we've worked out all the kinks, and I think that will become a lot more smooth as far as the process is concerned. And we also want to be proactive in our webinar with our applicants to try to make sure that they understand what the contract will look like, we post the templates on the website so people can look at it ahead of time. We hope that all these things that we do will speed up the process.

Any questions on this? And this is of course important for us as a very key issue, but as we move further along in increasing the number of awards that we have there will be other areas that we will have to tackle in our portfolio management.

CHAIRMAN WASHINGTON: -- to Regina, 90 days certainly would be an improvement over 160, but why 90? What is, what would be considered best practice here? You mentioned one agency, in this case NIH, but what about AHRQ, what about the foundation world, what about Robert Wood Johnson? Some of the same institutions that you're dealing with, these other organizations deal with them.

MS. YAN: I think a lot of it has to do with us being new with new templates that took us a long time. For a lot of other foundations and agencies where people are very familiar with what's in it, then they have much shorter turnaround time. Maybe Jean can talk about AHRQ's experience in that?

MS. SLUTSKY: Yeah, so, I think part of it is because these are not really grants but they're

not really contracts, and so the contracting offices at the universities probably don't quite know what they're looking at. For a grant award, 90 days is an aspirational goal for some organizations, so I think that that's particularly if you're negotiating any copyright issues or issues regarding prior publication, which are in authorizing legislation for PCORI, so I think you have to negotiate those things with applicants.

DR. BEAL: [Off microphone.]

MS. YAN: And you have a microphone right next to you, too.

So there are two parts to it. One part is whether we can kind of get our process smoothed out and predictable; another part is our recipient's eye as to how fast they can turn it around. Okay?

CHAIRMAN WASHINGTON: Okay.

MS. YAN: Right now we have, all our departments have prepared a 2014 operating plan, a work plan, with major activities that they plan to do in 2014, and we are reviewing that with all the committees and want to make sure they're

comfortable with what we plan to do next year and our priority, and we will also be reviewing the draft budget with them tomorrow. I will be at the two committee meetings to go over the draft budget with the committee, get their feedback, and so we want to make sure that in November, when we bring the 2014 budget to you, they have already been reviewed by the committee and we have incorporated their comments into the budget.

Now as we prepare for 2014 we are also looking at our staffing plan, and one thing we do is try to take a look at the work volume of our staff. We took a very quick look at this last year, look at what we've done, and in 2013, this calendar year, we're expecting to make a commitment of about $427,000,000. In 2014, $500,000,000, so we are trying to make sure that we have sufficient staff capacity to support that volume of work.

Secondly is that we also look at all the associated activities that come with supporting that volume of research funding. If we look at this past year, we have announced 21 funding

opportunities through all our PFAs. We have received over 1,200 applications, we actually, we have opened a special phone line for our applicants, and we have vetted over 1,000 reviewers, and we have to review the application to the reviewer, we have to vet them, we have to train them, we have to assign applications to them, so it's a very elaborate process, and we have responded to 14,000 Help Desk inquiries, and we have done 40 webinars, we have over 5,000 registered participants. So this is all the volume that the staff have to support, and we would only expect that that would increase as our volume increase.

We are also in the process of developing policies and procedures and systems for future years to make sure that we have a transparent and logical process in handling our work.

For science engagement they also have a lot of roundtables and meetings that they have to support. In addition to that, we are implementing four major systems to support all the work that we

have. One is a flux -- a system that will support applications, processing of applications and contract management. We will be rolling out a CRM to support our engagement in communications activities. We are revamping our website to make it easier for our applicants and other stakeholders to find information on the website, and we also have a human resources system that we are implementing right now.

So all the above activity that I just went over with you currently is supported by 80 employees plus some consultants. Currently we have 38 vacancies that we're trying to fill and look at our last year's experience has taken us quite a long time to fill a lot of our positions. We try to do it very carefully, but we do need the people with the right kind of skills to join us to help us with our work.

So as we work on the 2014 staffing plans, some of the things that we are taking into consideration in developing that plan, one is looking at the increased level of funding

announcements and the review and selection process that we have to support and the growing portfolio of awards that we need to manage and the institutional objectives that we have to achieve based on the board-approved strategic plan, which we will discuss tomorrow. Another thing is starting this year we have to give you a report card on our performance, so we also have to track that and produce the report, performance report, to you.

On the operations side we are developing the operational dashboard for FAAC to look at, since every function within operations they have their annual goals and metrics. And then we are also looking at the functions that are currently supported by contractors, particularly those ongoing functions such as scientific review officers. We know as long as we are making funding announcements we need those functions that we should do it, bring that in-house.

So I have some strategic questions for you and hope that I'll get some feedback and guidance

from you.

For the financial review, is there any other information that you would like to have, that you think would be helpful to you? And also for the indicators we just talked about award-to-contract the other indicators that is important to you in measuring our operational performance. Lastly is, as we develop these staffing plans, what are the other considerations that you think we should take into account as we go through this process?

CHAIRMAN WASHINGTON: Okay. Thank you, Regina. Kerry, you want to, please --

DR. BARNETT: Well, I would just say briefly that in light of the governance report and activities that we've discussed and will continue to discuss, the goal here is not to try to pull the Board down into the administrative details of the organization. Quite the opposite.

I think it's very important that we don't devote a lot of time kind of getting into the real nitty-gritty. But we do have an important

responsibility as a board to make sure that the organization is sort of fundamentally sound.

And that's really the intent of kind of a periodic administrative update. It's to focus on high-level, more strategic budget and finance issues. It's to focus on any issues that might be surfaced through an audit, which has not occurred so far, by the way. We haven't had any significant issues arise through our audits. And it's really a matter of the Board having a look out for any significant issues that we think might be weakening the sort of superstructure of the organization.

And at FAAC we had some real concerns at one point around our timelines related to finalizing contracts, and Regina and her team have really stepped up and, as you just saw, they've really been very assertive, I think, in addressing that. Ways to go still, as you just heard from Regina, but tremendous progress made.

So the idea, really, is I think for the Board to kind of hit that sweet spot, that right altitude as to where it wants to play in these

kinds of issues without getting into the minutiae, the administrative minutiae of the organization, because that's really Regina's job, that's Joe's job, and everybody sitting back here.

CHAIRMAN WASHINGTON: Steve had some others -- was this on this?

VICE CHAIRMAN LIPSTEIN: Yes.

CHAIRMAN WASHINGTON: Okay, Rick, and then Allen, and Steve.

DR. KUNTZ: Rick Kuntz, board. I think Kerry was trying to prep for my comments a little bit. I think that we probably should review some of the high-level finances. I think the tools used I couldn't understand, so maybe we could work on that a little bit more. I didn't understand your revenue, your P&L.

And I think our biggest concerns are to make sure that we have a good pace of funding that keeps pace with the work. And so I think a five-year pro forma would be nice to have just to see how you think the funnel's going to look over time and how our funds flow at a very, very high level.

I mean, I agree with everything Kerry said, we don't want to get down to the details, but if you do want to offer something about how we're doing financially, I just have to have tools that I can read. And I just think that I couldn't follow your negatives and positives and revenue -- it wasn't clear to me what you were trying to say on those things.

It's a minor issue, because I have full faith that these things are going pretty well, but if we do, if we are stewards of this amazing amount of money, that we've got to do, then we probably should have a way to make sure that things are keeping pace over time. So I think the five-year pro forma would be nice to have even if it's a large guess, just to be able to see that the flows, that the funds are flowing and keeping pace overall.

And then the other thing is with the staffing, just a very high-level connection between the workload and the capacity tool that you're using would be very nice to have just to see how

you're planning staffing out just to be able to, for us to get a sense that are there things that we can do to provide more resources or other things as well. I think it's a big burden to take on all of this without having some connection to the Board overall, so again I think it sounds like things are going just fine, I would just probably like a little bit lower, so from my altitude, I think I was in space, I'd like to come down to about 60,000 feet and not go much lower than that. Thank you.

MS. YAN: Great, thank you. I just wanted to really quickly say that as far as hiring's concerned, I know that some committees have already offered to help because you know the people who have the kind of skills that we need for our work.

DR. DOUMA: I want to reinforce what Richard was just talking about. I think I couldn't follow it quite as closely as I would like to. Again, I agree with Kerry. There are limits to how many weeds we want to whack. I think we need a little bit more information.

The question for the Board is to what

extent does the Board want to be involved in allocation of our resources when we put X amount of dollars toward one particular project, program, research, et cetera. At this point it seems like we're relying pretty much 100 percent on the wisdom of staff, which may be where we want to be. We approve, but we approve things sort of with the budget attached, and we don't question whether the budget, whether something ought to be $30,000,000 or ought to be $10,000,000. And that's something that we may not want to do.

On the last subject, those 14,000 phone calls? The Help Desk?

MS. YAN: Help Desk.

DR. DOUMA: I hope we, for across the board, are categorizing them all and feeding them back to all the employees and maybe to us with regard -- because a lot of the calls are basically because people don't understand who we are, what we are, and so we can feed that back into a heightened or a more focused communication plan.

CHAIRMAN WASHINGTON: Okay.

MS. YAN: We are categorizing those calls and then we are also using the result to improve our application guidelines.

DR. DOUMA: Excellent.

CHAIRMAN WASHINGTON: But Allen, to your question, again, ask that allocation question. I mean at the high level, we are determining what goes -- if you go back to Brian's slide, we are determining what goes into broad RFPs versus what goes into targeted areas, because we make those decisions at the Board level. So your point was referring to --

DR. DOUMA: Well, for example, engagement, that's a number that we weren't involved in choosing as far as I know, and even the allocation of the total amount of research versus in dissemination versus prevention et cetera versus disparities. That split of allocation of resources, dollars we don't -- as far as I know we don't vote on. So it's -- you're right, the example you gave is absolutely right on, and I think that's probably a place we should be at that

level, and the question is should we be sort of at that level across the organization a little bit more fully.

CHAIRMAN WASHINGTON: Okay. I think that's an important question, so -- Joe, you following it?

DR. SELBY: Yeah.

CHAIRMAN WASHINGTON: Just put that on the list of the big strategic questions. Steve?

VICE CHAIRMAN LIPSTEIN: Yeah, I think that with each successive board meeting and actually with each successive budget we have a clearer picture of the work that needs to be done, the amount of work, and the kinds of people that need to do that work. And we are getting to where we have a more complete administrative staff.

And so, I do believe the role of the Board now becomes -- Allen, in answer to your question; is that it is up to staff to make recommendations to the Board and to ask for critical review of those recommendations, and either we then approve them with no changes or we ask for some changes or

we send back for more work. But we do want that work to be initiated by the people who are working full time for PCORI. And we have that group now.

I am increasingly comfortable that staff leadership, which would be Joe and his chiefs, have a better understanding of what we expect and the work to be done. And so, as we go up to, say 118, 120 full-time staff, that is reflective of our understanding of the workload now -- a really keener understanding of the workload than we've ever had before. It also reflects a couple things. I think staff has heard us loud and clear that we want to devote the majority of our resources to research and to the conduct of research and to the dissemination and implementation of research and not to administrative overhead.

Having said that, we can't do the first two very well if we don't have the right staff and the right number of staff and the right kinds of staff. And so I think the staffing plan is really beginning to take shape in a mature way and in a thoughtful way, and so I just guess, Kerry, I

wanted to weigh in that I think we should be getting more comfortable with that notion and it is certainly directionally correct. We will never know whether we should have 118, 116, 112, but it is directionally consistent with the work and the expectations of this board.

CHAIRMAN WASHINGTON: Steve, while I agree with you completely regarding the staffing plan, I certainly agree with you in terms of the high quality of staff we have and the fact that we've got to accept the assumptions regarding what the increased numbers are, I've said this to Joe, it's a big job, and I think that Regina has laid out the reasons why in a qualitative way.

But I think just in general we ought to have a set of metrics against which we are measuring the size of our staff and the productivity of our staff, and that's why I keep coming back to the question what are sort of some best practices, but what are the industry standards. I mean, for example, you can take one standard that could just be dollars out of the door

and staff per dollars out of the door.

I know we do a different kind of work, but if you took that standard, it may be that we are way overstaffed just by that number, and then there should be an exercise that says this is why we need more staff, because we do things differently. If we just take the percent of our overall budget, not just research out of the door, and what we're paying on administration, we saw some data early on, we sort of know what that is. It's around 10 percent, and I think you brought that. I don't know where we are now, but again, if we are under that, the Board may feel good about it, but the truth is we ought to have the same level of rigor in saying why are we under it. And it may be that we're understaffed.

And so, what I don't see and I'm encouraging that you develop for the Board and for yourself is that set of metrics that say we're comfortable where we are relative to what others are doing that we think are comparable to us, because you're right, given where we are now, this

makes sense to increase -- not that we want you to do more work, but I'm not sure where we are right now relative to where we should be for the amount of work that we're doing.

MS. YAN: We have done quite a bit of benchmarking, industry benchmarking, which will be presented to you together with our 2014 budget.

CHAIRMAN WASHINGTON: Great. Thank you. Okay. Before we move on, I want to thank all of the presenters for just absolutely terrific presentations, very informative. We liked your questions. Dr. Beal, I had to step out for yours, but I understand yours was the best.

[Laughter.]

CHAIRMAN WASHINGTON: Just joking. But no, I want to say thank you to you as well. And I want to, again, convey our gratitude to all of the, all of our partners. These are the members of the advisory boards and the other consultative groups that we work with from day to day for your input and for your continued engagement.

And so, in closing, we are where we are,

and I feel like we're in a great position because of the terrific staff that we have working with the other partners that we have outside of PCORI. And so we're not finished for the day, but we are finished with those presentations, and I wanted to underscore what I felt were outstanding presentations this morning, which led to some outstanding discussion. Okay.

So with that, we're going to prepare for -- are you ready? We're going to prepare for the public comment.

DR. SELBY: That's right.

CHAIRMAN WASHINGTON: Because we're right on time. Beal?

DR. BEAL: It's Sue.

CHAIRMAN WASHINGTON: Sue. Okay, thank you. It's not in my notes, I'm ready. Sue.

MS. SHERIDAN: I'm ready.

CHAIRMAN WASHINGTON: We're ready.

MS. SHERIDAN: The floor is mine. All Right. Good afternoon. This is Sue Sheridan. I'm Director of Patient Engagement and this is the time

that we invite the public to make comments about PCORI. You know, honoring our mission to do research that's guided by patients, caregivers, and the broader healthcare community.

So, thank you Dr. Washington and first we're going to take comments from people who have registered and then we'll invite comments from people here, if they would like to speak up.

After everybody has spoken, we'll see if they're comments by phone. I think we have an Operator on line, Debbie are you with us?

OPERATOR: Yes, ma'am.

MS. SHERIDAN: Thank you. And those who are offering comments, we're going to ask that you limit the comments to three minutes. We want to have some robust discussion after your comments. and we also offer, for those who are listening that prefer not to talk, if you would like to submit your written testimony to us at PCORI at info @pcori.org. And I also want to stress for those of you who have additional materials or if you send in comments that we don't hear today, that we will

follow-up with PCORI's staff and with our Methodology Committee and our Board of Governors and our leadership because your comments are important to us.

So at this time I would like to invite Sara van Geertruyden who is with PIPC. Sara, are you still here? Good.

Sara is with the Partnership for the Improvement of Patient Care. And Sara has been active with PCORI, she's also on the Patient Engagement Advisory Panel that just met.

MS. VAN GEERTRUYDEN: Thank you.

So thank you for this opportunity to comment. My name is Sara van Geertruyden and I'm the Executive Director of the Partnership to Improve Patient care, also known as PIPC. And a member of the Patient Engagement panel, which I attended last Friday and Saturday. And thanks to Sue, she did a very good job of managing that.

I wanted to express first and foremost the appreciation of a recent roundtable PIPC convened with people with disabilities. It was a really

wonderful and engaging conversation. I want to thank Dr. Romana Hasnain-Wynia and Dr. Chad Boult who provided insight into PCORI's processes for funding research to the group and then allowed them an opportunity to provide to PCORI their recommendations for how PCORI's work could better address the needs of people with disabilities.

Just to sort of recap those recommendations, they talked a lot about research priorities and then data infrastructure and dissemination. And so, in terms of the targeted funded announcement process, the roundtable group of people with disabilities had some consensus on three topics that they would like for PCORI to consider to further in terms of its advisory panel considerations.

First, integrated care coordination is a priority; including the provision of community-based long-term services and supports. second, the group emphasized that barriers to access to care is a significant challenge for people with disabilities. And some examples that they gave

were lack of accessible medical and diagnostic equipment; failure to modify policies and procedures in order to accommodate people with disabilities. And disability stereotypes that affect care and treatment decisions; including life sustaining care. and some examples of needed system changes included healthcare provider education as well as procedural and substantive civil rights protections in the context of healthcare decision-making.

And then the third topic was technology-enabled supports including complex rehabilitation technology, such as high-end wheelchairs; devices including hearing aids and augmentative communication systems; respiratory support technologies; health information technology; durable medical equipment and prosthetics and orthotics; lifting systems and other supportive technologies to monitor health status.

PIPC members and our roundtable participants are eagerly awaiting the Pipeline to Proposals as well. I would emphasize to you as I

did to the Patient Engagement Panel this weekend, that the opportunity there is to harness the research priorities of patients and their providers. There was a great discussion on our panel about how to make researchers more accountable for following the lead of patients and providers in the development of research. But I hope the Board will advance in its implementation of the Pipeline Program.

With regard to data and infrastructure development, the roundtable participants conveyed to PCORI the significant challenges surrounding the development of data related to people with disabilities and want to work with PCORI to address those needs.

And on dissemination, the roundtable recommended that PCORI develop protocols for the dissemination of research findings in consultation with organizations and individuals representing people with disabilities to ensure that they meet certain criteria for accessibility while representing policies that are proven to enhance

clinical practices.

PIPC has provided to PCORI some best practices for dissemination that were informed by our roundtable series, as well as PCORI's authorizing statute. We also focused on the need for dissemination to be informed by patients and providers who are the ultimate users.

So in closing, and just to channel Tony Coelho, our Chairman for Amendments, I think the real opportunity at PCORI is bringing together patients, providers, and their caregivers. harnessing the gaps in knowledge that they need at the point of care. Keeping them engaged in the research throughout the process and particularly in terms of dissemination. I can think of no other community that will benefit more from better dissemination practices than people with disabilities. And there are other communities like them that have a lot of expertise that they can be feeding back into PCORI.

So, I know PIPC has given you a lot of guidance in the past about the prioritization

process and we urge you just to keep us in mind and to look on our website. We have a lot of really good materials there that we hope you'll use.

MS. SHERIDAN: Thank you Sara.

We're going to now go to our phone lines. I believe we have Michelle McGhee from MedStar. Michelle, are you there?

OPERATOR: There is no one by the name of Michelle connected by the phone.

MS. SHERIDAN: Okay. We'll go onto Tonya Davis with UNC-Chapel Hill. Tonya, are you there?

OPERATOR: We only have one person connected by phone Ma'am, and it's Terry Young from HHS.

MS. SHERIDAN: Okay, go ahead Terry. Thank you.

OPERATOR: Terry, your line is live if you would like to make a comment.

[No response.]

OPERATOR: Terry? Their line is connected Ma'am, but they're not answering.

MS. SHERIDAN: Okay. Is there anybody

else in the audience that would like to make a comment?

[No response.]

MS. SHERIDAN: I guess this indicates that we're answering all of the public's questions and doing a great job. Are there any comments by the Board? Leah.

MS. HOLE-MARSHALL: Can you ask for one more survey of anybody else online that would like to make a public comment?

MS. SHERIDAN: Debbie, could you check to see if there's anybody else on the line, please?

OPERATOR: If anyone on the line would like to make a comment please state your name and company.

[No response.]

OPERATOR: No, Ma'am. There's no one answering.

MS. SHERIDAN: Okay, thank you Debbie.

For those of you watching the webcast, if any of you would like to submit questions of comments, once again we are collecting these via e-

mail, so I would encourage you to submit them to info@pcori.org or if you know particular staff members or leadership that you would like to share comments with, please don't hesitate to do so.

So with that we will close the public comment, unless the Board or anybody in the room has something to offer.

CHAIRMAN WASHINGTON: Thank you Sue.

So we are seven minutes at this point ahead of schedule. We have seven minutes left. And since I did cut off some discussion this morning, is there a point related to any of the topics that any Board member wants to raise that we would limit discussion about to seven minutes.

[Laughter.]

CHAIRMAN WASHINGTON: Okay. The clock is ticking.

MS. BARKSDALE: Where did she go? I have a quick question. On one of the slides previously, maybe Joe can answer. We had 80 staff plus contractors. How many contractors -- how many contracted people do we currently have?

DR. SELBY: I will turn back to the presenter, Ms. Yan.

MS. BARKSDALE: There she is.

MS. YAN: We have 80 staff. We have about three dozen contractors right now.

MS. BARKSDALE: Three thousand?

MS. YAN: Three dozen, not 3,000.

CHAIRMAN WASHINGTON: I think the important question here, and we just had a conference call last week. It's not just the number, but how much are they costing us and it's millions of dollars. And so, we had a conference call last week; Regina, Joe, Kerry, Steve and I, to talk about a firm timetable for transitioning out consultants in roles where we know they could and should be replaced by staff. And I think you will be reporting that timeline sometime very soon.

DR. SELBY: Right. And essentially we're aiming to cut the number of contractors that we're routinely recycling and re-engaging with to near zero by the end of the year. There's going to be just -- some of it involves hiring highly qualified

people that could take some while longer.

For example, we have 10 scientific review officers who manage our applications -- the merit review processes. And, you know, we're increasing the number of merit reviews we do, and those 10 people will ultimately be recruited as staff, but it will probably take a little bit longer than January 1st to get all of them replaced. But on the contracting side, we're really aiming to move even faster so we will really be staffed by January 1st.

CHAIRMAN WASHINGTON: Excellent, very timely question. Allen

DR. DOUMA: Yeah, your presentation about the need for extra staff was persuasive. I see all the extra work we're doing and I think it's good. My concern though, is if we're adding 20 and getting rid of 36, we're losing FTEs. Is that -- when we need to be adding capacity.

DR. SELBY: I actually -- the figure I showed, and I think it was pretty close to what Regina showed was 38. So, adding 38. But that's

really -- that was through the end of calendar year 2013. When we come back and after our discussions with the committees, the numbers will be larger than that.

DR. DOUMA: So the consultants are on the operations side as well as the science side?

DR. SELBY: Yes. Yes. Especially, contracting.

DR. DOUMA: Thank you.

CHAIRMAN WASHINGTON: Okay. If someone has a last minute comment that they want to make, please do. Otherwise, Mr. Vice Chairman, anything you want to add before we --

VICE CHAIRMAN LIPSTEIN: [Off microphone.]

CHAIRMAN WASHINGTON: Okay, it is time for a break, so we're going to break. We will start promptly at 3:00 p.m.; we have a program that involves outside guests.

[Recess.]

CHAIRMAN WASHINGTON: Welcome back, everyone, to this last session in the afternoon of the Board of Governors Meeting for the Patient-

Centered Outcomes Research Institute. We're very pleased to have some of our awardees with us this afternoon, and I'm going to ask Dr. Selby to introduce this session.

DR. SELBY: Thanks, Gene, and let me add my thanks to the investigators, the patient co-investigators, and the stakeholder representatives who are going to be parts of this celebratory panel. The idea here is that, as we've said this morning, we've now funded a large amount of research. We've required that applicants come together with patients and stakeholder partners.

And from each of three of our programs from addressing disparities, from the assessment and prevention, and diagnosis and treatment options, and from the improving health systems programs, we've selected a project that we thought a project that we thought was exemplary in the way that it prepared its plan and it engaged patients in the preparation of the proposal and described its plan for engagement. And we also think these are exemplary research studies in their respective

areas.

So I want to thank everybody. These are the first three investigators that we -- our eyes and hearts settled on and all three were able to come from as far away as Seattle and Atlanta, and as close as G.W. And they're patient partners, same traveling arrangements, and the stakeholders most appreciative for you being here.

We want to actually model what engaged research looks like, both engagement on the team and then engagement of the team with the larger stakeholder community. As we've said many times today, it's all ultimately about getting the questions right and then getting results they can disseminate.

So Dr. Anne Beal, our chief officer for engagement, is going to moderate this panel. And at this time I'll thank Anne and turn it over to her.

DR. BEAL: Thank you, Joe. So, as you heard, today's presentation really is for you all to hear about some of our projects, but, also, one

of the things that we're hearing loud and clear on the engagement team is that the field wants to know how to do this. And so I know that the Board members last week were invited to our webinar where we had over 300 participants to hear just about these kinds of models. And so every opportunity that we have to share some of our successful applications, we're certainly going to avail ourselves.

So the first project that we're going to talk about today is from our program on addressing disparities and the title of the project is "Nueva Vida: The Intervention on Improving Quality of Life in Latina Breast Cancer Survivors and Their Caregivers." Presenting today will be Dr. Kristi Graves -- say hi, Kristi -- as well as Margaret Darling and Roberto Londono.

So, Kristi, I'll turn it over to you.

MS. GRAVES: We are very excited to be here, so thank you very much for the invitation. And I'm thrilled to present with Margaret Darling and Roberto Londono, my patient and community

partners.

So as we all know, cancer is a significant health burden for all of us, and one in three Latina women will face cancer in their lifetime. And so being able to address the needs of these Latina survivors is very important. There's documented evidence that Latina survivors have lower quality of life compared to non-Latina survivors. And so our project sought out ways to address this disparity.

In conversations and in working with Margaret and Nueva Vida over the past several years, they have come up with an intervention that they wanted to test on a broader scale, that they felt addressed quality of life needs and issues of survivors and their caregivers.

So the aims of our project are to do just that. We want to address the quality of life needs of Latina survivors and their caregivers. And we're doing that by testing this intervention that was developed by a community-based organization. They came to me and said, Kristi, can we test this

intervention on a larger scale and in a research rigorous manner? And I said yes, let's go for it. And so our first aim is to look at impacts six months after the intervention on quality of life outcomes.

We're doing this with the Patient-Reported Outcomes Measurement Information System, a standardized quality of life way to measure health-related quality of life. We'll be able to compare these outcomes to other cancer survivors as well as to the general U.S. population. We hypothesized that there would be specific mediators of the impact of the intervention on quality of life based on our clinical experience and research experience as well as the observations of our community partners and our patient partners, and that's through increased self-efficacy for communication, improved social support, and decreased distress. We're also interested in looking at the impact of our intervention on communication not only between the survivor and her caregiver, but also communication with their healthcare team. And we

are interested in exploring satisfaction with care.

So the potential impacts of our research findings for patients, foremost we hope to improve quality of life as well as the quality of life of their caregivers. And we hope to make a dent in improving adherence to follow-up care for these Latina survivors by improving communication with their healthcare team.

For clinicians, there's some indications that clinicians don't always feel confident in how to provide referrals for support services or psychological needs, so we hope that by creating an empirical evidence base for what types of programs work, particularly for underserved breast cancer survivors, that that will help address some of those confidence needs.

For stakeholders, including the community-based organizations we're working with along with other community-based organizations, we hope to provide some empirical evidence about what works best for providing care for the Latina survivors and their caregivers as well as family members that

they serve.

And then finally, for researchers, we hope to serve as a model for how you partner with community-based organizations and, also, to provide a way of assessing outcomes through state-of-the-art assessments, such as PROMIS.

And now I'll turn it over to Margaret.

MS. DARLING: All right. Thank you, Kristi, and thank you, PCORI, for the opportunity to speak about the project evaluating Nueva Vida's Caring for My Caregivers. Today I'll show the community perspective and three features of our project that enhance community engagement and, in that, strengthen its impact.

The first is the active and initial role of organizations. The second is the flexibility that is built into the project that will facilitate working with distinct populations. And the third is the continued support of community voices.

With that, I'll begin with the organization's active role. The intervention arose from a need to address the trauma experienced by

Latino families following 9/11. The Latino men, women, and children in the Washington area were experiencing symptoms of post-traumatic stress, and many didn't have the resources for counseling to process the trauma. So Nueva Vida's founders created a program that allows families to process the event together and individually at the same time.

Seeing the similar trauma that families go through with a breast cancer diagnosis, Nueva Vida tailored this multidimensional program for Latina survivors and their caregivers by providing bicultural and bilingual services. This design allows each to speak more freely, not holding back for fear of hurting their loved one. And through our relationship with Kristi, the idea arose to evaluate the community-created intervention.

And as we prepare for the next steps of the project, Nueva Vida staff will travel to New York and California as a part of the trainings for interventionist at other sites. This not only allows the community voice to continue to be

influential throughout the process, but also builds capacity and empowerment within our organization.

The second component of this project is the project's flexibility in working with different settings. To combat logistical hurdles we sought from the outset to be flexible. With 4 different organizations serving anywhere from 70 to 300 Latina breast cancer survivors annually, we made eligibility requirements very broad. We also incorporate flexibility in the intervention itself. The multidimensional program was originally 12 sessions, but in considering each organization's resources, we elected an 8-session intervention. This will allow each to build from a set of four core session topics shared across the sites and allow each individual site to tailor the remaining sessions' content to their population's needs.

But more than that we hope this flexibility will also bolster the intervention's transferability. The same responsiveness to organizational context that reduces logistical hurdles in this project will also enhance the

ability for other organizations to implement the intervention according to their own context.

I'd like to end my comments today with my final observation from the community perspective, which is that throughout this project, community voices have been tremendously incorporated and supported. When first discussing the project, Kristi sent Nueva Vida questions upon questions about the program: how did we implement it in the past, what we've used to develop it, and what findings we had. And as you can all see, the significant effort to better understand the community was incorporate throughout the proposal.

Kristi has also supported me and others at Nueva Vida in our efforts to engage with the research community, going well beyond the scope of the project, whether it's connecting us to potential partners or reviewing abstracts. All of this helps to build capacity within our organization and enhance the community perspectives in the research arena.

Thank you.

MR. LONDONO: Buenos tardos.

MS. DARLING: [Interpreting.] Good afternoon.

MR. LONDONO: [Speaking Spanish.]

MS. DARLING: I just want to thank you for Nueva Vida because this project is really important for us as caregivers. It helps us understand better how to give the support and care we need to our loved one.

We learn how to --

MR. LONDONO: [Speaking Spanish.]

MS. DARLING: Can you help?

DR. BEAL: So, with this project we're learning how to take care and how to help people with cancer, how to communicate, and how to help them with their problems.

DR. BEAL: I do not speak Spanish, let's just be clear.

[Laughter.]

DR. BEAL: Oh, Orlando Gonzales.

[Laughter and applause.]

MS. GRAVES: True community engagement.

MR. LONDONO: [Speaking Spanish.]

MR. GONZALES: Yeah, so he's basically relating his ability to be able to cope with the scenario in terms of being able to convey treatment options and convey any of the experience that the family's having.

MR. LONDONO: [Speaking Spanish.]

MR. GONZALES: And he's just saying thanks and he wants to really look at the project proceeding.

MS. GRAVES: And I missed one important slide. So thank you, Mr. Londono, for sharing your experiences and, Margaret, for sharing the community perspective.

And I want to just highlight our other community partners. We have four community-based organizations: Gilda's Club New York City, Latinas Contra Cancer, LatinaSHARE, and Nueva Vida. And these partners significantly inform the work that we do at Georgetown. We have our advisory board, of which Mr. Londono is one of our caregiver representatives. And then we also have support

from our other academic and community partners listed there.

Thank you.

DR. BEAL: Thank you. So we'll open it now to discussion and questions from the board.

CHAIRMAN WASHINGTON: Mr. Lipstein.

VICE CHAIRMAN LIPSTEIN: Wonderful presentation. I wish I could say that in multi-languages.

Can you share with us, there was a slide earlier about some of the outcomes that you--can you give us a little insight? Keep going back. Can you give us a little -- that one -- can you give us a little insight into how you measure decreased distress or how you will measure improved quality of life?

MS. GRAVES: Sure. I'm a clinical psychologist by training. And we'll measure distress -- we have a couple different measures. They're all validated and have been translated into Spanish. We will be using the Brief Symptom Inventory for assessment of distress.

And then in terms of quality of life outcomes, we're using Item Banks from the Patient-Reported Outcomes Measurement Information System, PROMIS. It's a standardized measurement system launched by NIH in 2004. We're very fortunate at Georgetown in my program to have the creator of PROMIS on our team as well as a woman who is a psychometrics expert. She's one of our co-investigators.

CHAIRMAN WASHINGTON: Dr. Graves, I, too, want to convey my thanks and congratulations to the group for this excellent work. However, I must confess, I still don't understand the intervention. Can you just give us the broad outlines, high-level components of the intervention?

MS. GRAVES: Sure. Within my three minutes I was hesitant to get into the intervention, but I'm happy to do so now. And Margaret, please feel free to jump in.

What Nueva Vida was offering is they saw needs of the Latina survivors and their caregivers and families, and these people would come to their

offices. And they, based on this earlier program that they had done after 9/11; the woman who helped create this is a mental health professional and a breast cancer survivor, and she found, based on the needs of the Latino community, that if you separate the survivor and the caregiver into different rooms once they get there, but they talk about the same topic: how to improve communication, how to recognize if you're experiencing distress, how to manage your stress, how to communicate with a healthcare provider. So different topic areas, but the survivor and the caregiver are in different rooms.

That allowed the survivor the flexibility and the comfort in sharing what was really going on with her without worrying about becoming a burden to the caregiver or without causing increased distress to the caregiver. And then the same was reversed. The caregivers didn't always feel comfortable sharing exactly what they were worried about, if they were worried if their survivor was going to, you know, continue to live, how to manage

some of the side effects. They didn't want to burden their survivor with this information or, in some cases, confess things they were unsure about or conflicted about.

And so, by separating them into different spaces physically within the same building and then coming back at the end of the topic session to talk about what they learned over food and to kind of have a joint conversation, Nueva Vide noticed that that really made a difference for the skills that the survivors and the caregivers were able to learn and then take home and practice. It made it a safer space.

So I don't know if Margaret has anything to add.

MS. DARLING: Yeah, that separation allowed the space for caregivers and survivors to more vocally kind of explain what they're feeling among peers, among people that are going through similar feelings. And then by coming together having had that moment away from their caregiver or from their survivor, by sharing a meal, which is

kind of the second component of the intervention, they were able to kind of take what they had reflected on and what they had gained through that first part of the intervention into their relationship and perhaps improve the area of that week's focus.

CHAIRMAN WASHINGTON: And a final question from me. Who's the intermediary in this case? Who's taking the respective groups into the "next room" or the room next door?

MS. GRAVES: So that will vary by community site. Nueva Vide has trained mental health professionals who run these programs, but not all of our community partners do. So, for example, at Share up in New York, they use a peer support model. And so we very carefully crafted our plan for training the interventionists and monitoring intervention fidelity, and we'll do the same with the interventionists in New York. So it's both mental health professionals and peer supporters who go through a very specific training.

CHAIRMAN WASHINGTON: Gail.

MS. HUNT: Gail Hunt, Board member. In addition to measuring using certain instruments, you've mentioned measuring quality of life and satisfaction with care of the survivor, are you separately measuring quality of life and reduction of stress, for example, of the family caregiver?

MS. GRAVES: We are. And based on our sample size, we should be powered to look at interactions between the two. For example, if the caregiver improves, but the survivor does not, what predictors might lend itself to that pattern of coping and adjustment?

CHAIRMAN WASHINGTON: Dr. Krumholz, you weren't in the room, but could you go to the next slide, please, Dr. Graves? This touched up on a point you made earlier about being explicit up front about what success looks like and being able to clearly describe what essentially the results section might look like. I thought that this was a good framework for at least thinking about the categories and, clearly, the targets of the intervention.

Do we have a question while Harlan's looking at that? Yes, please.

DR. NORQUIST: Gray Norquist. I'm actually a mental health professional myself. What interests me, though, is -- and I think this is very relevant and I've had some -- I was just telling Steve here about a personal case I had last week with somebody who has cancer, about a similar issue. But what I wonder about is what you're thinking is in the long run of how you're going to have this implemented, you know, in other places. Because I think it's nice to have -- there are not going to have a lot of places with mental health professionals, even some peer support. And what's your thinking if you find out that this really does make a difference, improves let's say the outcomes of these women? What's your thinking about how you might be able to implement this across? Because in many areas it's not going to be a robust health provider system.

MS. GRAVES: That's one reason why we were excited that there are different models for care

delivery at our partners. And one of our partners is Gilda's Club in New York City. They're part of the Cancer Support Community, formerly known as The Wellness Community, that has national offices across the country and even some international collaborators. And in communication with Lily Safani, the CEO of Gilda's Club New York City, she indicated that they are very willing, you know, pending positive results if it seems to work, to help us disseminate this to other Gilda's Clubs in the country as well as the Cancer Support Community and all of their affiliates. So we're very excited about that possibility. They have newsletters, they have, I believe, conferences, and lots of ways to disseminate the information to all of their affiliate agencies.

CHAIRMAN WASHINGTON: Allen.

DR. DOUMA: In my listening to what you're saying, it's a six-month intervention, is that correct?

MS. GRAVES: We're assessing outcomes six months after the intervention is completed, so it's

eight sessions.

DR. DOUMA: And they're how -- weekly?

MS. GRAVES: They are every other week. In my past research I've done things weekly and in close communication with our partners, they said that's not going to work for Latina survivors and their caregivers. So we compromised on two times a month every other week for eight sessions, so four months.

DR. DOUMA: Okay, I'll make the assumption, and I think is really solid ground, that you're going to show benefits.

MS. GRAVES: I hope so.

DR. DOUMA: I think you will. The question that I have is are you going to be able to measure extinction of the benefits at 12 months, 24 months, et cetera?

MS. GRAVES: I think that's a -- I'm not sure if we have resources to go back and I anticipate that there will be sustained relationships with the survivors and caregivers with all of our community partners. And I hope

that we can go back and do some sort of longer term follow-up.

DR. DOUMA: I hear there's an organization called PCORI that might be interested.

[Laughter.]

MS. GRAVES: I've heard of them.

CHAIRMAN WASHINGTON: Ms. Darling and Mr. Londono, based on your experience with this study, is there any advice you would have for the Board about how best to do this kind of collaborative work with researchers and leaders and caregivers in the community?

MR. LONDONO: [Speaking Spanish.]

MR. GONZALES: He doesn't have any specific recommendations, but he really has found that the courses and the interventions that have been provided to him have been very beneficial. And so he really can't say what it's like, you know, without, so it's just beneficial.

MS. DARLING: And I guess as my perspective, coming from a community-based organization, I think something that's going to be

really patient-engaged, community-engaged, it's always beneficial to start earlier rather than later. And so, getting that input up front in the formation of the project makes a lot of sense to have the limitations of each community in mind as you're thinking about the initial formation. And I think that helps kind of give you some creativity and flexibility in the design of your project that, hopefully, will then be beneficial to you toward the end.

CHAIRMAN WASHINGTON: Rick.

DR. KUNTZ: Rick Kuntz, Board member. First of all, I just want to congratulate you on taking on a project that is really critical and I think this fits exactly with what PCORI's trying to do. And I think you're addressing some really critical issues in an area that we need more evidence on.

Just for the structure part, I just may have missed this, are you doing a randomized trial?

MS. GRAVES: Yes. So we're comparing the Nueva Vida intervention to usual care offered at

these agencies, which could include support groups, individual therapy. So it will be a very robust test of the intervention since some women will be getting existing care or maybe if they choose, you know, no care. So we'll randomize eligible patients and caregivers to either the Nueva Vida or to usual care. And if they choose to look for services, then they certainly will do so.

DR. KUNTZ: And at the end of six months you allow the people who got randomized to the control arm to then rollover to the other one?

MS. GRAVES: Yes.

DR. KUNTZ: Thanks.

CHAIRMAN WASHINGTON: Dr. Selby.

DR. SELBY: I want to add my thanks to all three of you. I had a question. Given that Nueva Vida and patients were involved in planning this study, what were the thoughts about randomization? Sometimes, you know, making a choice to do the study as a randomized trial is the right choice scientifically, but it doesn't always go down well with the community, and I just wondered what your

thoughts were.

MS. DARLING: Well, I guess, speaking from Nueva Vida's perspective and in talking with our survivorship manager, there was an initial concern for us for the patients that would be assigned to the regular care. And so I think with that we had kind of built our numbers to allow for if some needed to drop out or seek additional care, that we had built that in, is my understanding. And you can probably speak more to what we had done to kind of assuage those concerns.

MS. GRAVES: Sure. I think, you know, in designing a project to be scientifically rigorous, but represent what's really happening in the real world, there are comprises on both sides. And so, you know, we looked to broaden things like eligibility, who's going to deliver the intervention, the types of things that everybody wanted to measure as outcomes. But one thing I felt pretty strongly about was, you know, if we want a true test, then we need to randomize. And so in talking with the partners about what that

would mean, allowing the patient and caregiver dyads who didn't get the intervention to come in afterwards, providing all of the information and resources about how to run the intervention, that assuaged some of the concerns about randomization.

CHAIRMAN WASHINGTON: Just on a related question, Ms. Darling, do you have in your organization the equivalent of a review group, a board that makes a decision on whether or not you will have a study conducted in your operation, your clinic?

MS. DARLING: We at Nueva Vida don't have our own IRB. We operate under Georgetown's. But we do have members of our board that kind of serve as advisors as we do our own evaluation of our own programs.

CHAIRMAN WASHINGTON: Okay.

MS. GRAVES: And I'd like to point out that Nueva Vida's very unique in that Margaret holds the position as research and evaluation specialist at Nueva Vida, and that's a very unique position at a community-based organization. And so

they came to the entire project with a lot of research understanding and background.

CHAIRMAN WASHINGTON: Christine.

MS. GOERTZ: Christine Goertz, Board member. I also want to thank you for this project and for spending some time with us today. Just first a technical question, which is, you know, how many people are in the study and do you have each of your sites sort of individually powered to detect differences since it sounds like they're going to be so different? So that would be my first question.

And then my second question is I'd be interested in hearing the story of how you got together, sort of whose idea it was and how you came together to build this project.

MS. GRAVES: I can answer the first power question and then if Margaret wants to talk about the story behind it.

So we're not powered to look individually at each site, but what we are powered to do is incorporate site into our final models, to see if

there is an impact by site. The Latino population served here in Washington, D.C., our two partners in New York City and California, they are different, they come from different places in the world, and so we'll be able to look at some of those differences. And one of our partners is particularly interested in that fact, you know, which specific country of origin or which area of the country might impact outcomes.

MS. GOERTZ: And how many people altogether?

MS. GRAVES: We have 200 dyads, so 200 survivors and 200 caregivers.

MS. GOERTZ: In each group or --

MS. GRAVES: Total.

MS. DARLING: And with regard to the story, Kristi had hinted earlier that this is a Nueva Vida intervention that we had kind of, through our ongoing relationship with her, approached her with the idea of evaluating the model and seeing what impact it has. And so when we came to her we had had established relationships

with these organizations through our Compañeros de Apoyo training. We had brought Latina survivors from some of these organizations to our trainings and so we had been working with them and knew a lot of their leadership. And so last summer as we were -- we got them all together and were discussing the proposal and seeing what would fit within each organization.

CHAIRMAN WASHINGTON: Harlan.

DR. KRUMHOLZ: Again, terrific and not easy to present in front of a board all this, but congratulations on the funding and the project. Can you just give -- the one thing I'm very interested in is the challenge of actually getting authenticate contributions by the people that you're trying to help.

It's easy for us as a board to say, well, this is what our aspiration is. It seems really hard to operationalize because of the sort of lack of -- well, there's a hierarchy, you know, in empowering people to contribute in ways that they can contribute, to feel confident that they can,

and finding the places where they are expert in their own experience so that they can. And I wonder if you have any insights for us about what went well and what was challenging in trying to fulfill our aspiration of trying to really get the people that you're enrolling to contribute to the thoughts, recognizing that you already had an intervention that had been contributed to by many people. But can you just reflect on that a little bit?

MS. GRAVES: Sure. I think, at least in terms of this specific project and how we're structured, the conversations began very early. And I've been working with Nueva Vida for a number of years on smaller projects, some qualitative research, and so that relationship was already established. And many of the Board members of Nueva Vida are Latina breast cancer survivors themselves.

And then in talking with these other organizations on the phone and getting their input, I think that mattered. And we are very proud of

our advisory board. We have our caregiver, we also have a Latina breast cancer survivor, as well as some clinicians.

On August 22nd, we had our first team meeting and we had everybody around the table. And it was so exciting to talk about the project and how we're really going to get things off the ground and hear all of the different ideas, and so, at least from my perspective, kind of laying the groundwork from the beginning that everybody has a unique perspective and that those are all very important.

DR. KRUMHOLZ: Do you have -- maybe you can reflect, but let me also just say there are so many investigators who are feeling challenged to this. You had existing relations. Do you have any advice for them on both sides about how to get investigators to have the courage to do this? And what hints would you have for them?

MS. DARLING: I think continuing to have an open dialogue. I know with Kristi and especially in our initial team meeting where we

were coming together to theoretically discuss, you know, what were the steps that we had proposed and what would be what we were doing, we were still in conversation tailoring that to what the current needs now of those organizations were, and so I think having that openness to a little bit of change. And Kristi did a fantastic job of being really receptive to that, and I think that receptiveness of her as an investigator has helped to continue the relationship and make us as organizations feel more able to come to the table with our perspective.

CHAIRMAN WASHINGTON: Steve, we're going to need to wrap up, so you get the last word.

VICE CHAIRMAN LIPSTEIN: My question was really not of them, but it was actually going to be of Joe or Anne. Just I'm curious, since you have this population defined of 200 breast cancer survivors, if somebody else wanted to study the variability of their surveillance, their post-treatment surveillance, since that's not the research question in play, is it out of bounds to

marry up an investigator with an existing cohort just because it's a related population? Does that never happen in the research community or is that something that has any value at all? Do you understand my question?

DR. SELBY: Yes, and I think it's probably not out of bounds if the research team and the patient population and the community thought that that other question was important. You know, you wouldn't have the randomized design for that. Those interventions wouldn't be randomized, but you could consider them a group of women, a cohort of women.

VICE CHAIRMAN LIPSTEIN: The variability [off microphone].

DR. SELBY: Pardon?

VICE CHAIRMAN LIPSTEIN: The variability in -- you know, when everybody starts better communication and they undercover there's variability in how they're being cared for post-treatment, that could cause stress, that could be one of the distress factors.

DR. NORQUIST: No, it's okay.

CHAIRMAN WASHINGTON: It's okay? Yeah. Believe me, you're going to have another chance. We have two additional exemplars to present. And so we want to thank you all, first, for taking on the project and for coming to present this.

[Applause.]

DR. BEAL: So while we're waiting for the next group, we've seen the benefits of diversity in the workplace, so we're pleased to have Orlando Gonzalez on staff.

Okay. So next up is a project that comes out of our program on assessment of diagnosis and prevention in treatment options. And one of the things that I often say is no good deed goes unpunished, so this is a particular team that we actually heard from last week and they presented at our webinar, which I think was particularly well received.

But this is a project titled, "Cognitive Anti-Epileptic Drug Outcomes in Pediatric Localization-Related Epilepsy." And we're going to

hear from Dr. David Loring. David, say hi.

DR. LORING: Hello.

DR. BEAL: As well as then Brandy Parker and Adam Hartman.

Now, what is different from this presentation as compared to the previous one, the previous one had two of the patient partners from the project, but in this one David and Brandy are from the project itself, while Adam is actually a commentator from the American Academy of Pediatrics. And part of what we were trying to do is to get an assessment from others who are outside of the project about the relevancy of the project being discussed.

So, David.

DR. LORING: Thank you very much. I think I speak for Brandy and essentially thank you very much for the opportunity to speak and resent to you today and this afternoon.

My project is on epilepsy and, in fact, taking a look at an under-recognized or I think an underappreciated aspect of epilepsy. Epilepsy

represents or occurs in approximately 1 percent of the population, and that's, of course, both adults and pediatrics. And whenever an epilepsy syndrome develops, the number one treatment goal is to stop the seizures.

However, there's another host of factors that are probably relevant to sometimes the treatment selection. Sometimes that's the cost of the medications, the ease of dosing, the administration. And, more importantly, from an overall quality of life or ongoing adherence perspective, it's the actual side effect profile.

I'm a neuropsychologist and I'm interested in things that involve both cognitive effects as well as behavioral side effects. And what we know is that all the medications that are used to treat epilepsy, all of them are associated with risk factors associated with slowing of cognition, affecting memory, and so on. And they also are associated with risks of behavioral side effects, including irritability and mood variability as well.

Our project is taking a look at three common medications that are used widespread and agreed upon that are equally effective in treating epilepsy, but they're cognitive and behavioral side effects are unknown. Children are going to be enrolled in this study between ages of 6 and 12 and this is a particularly vulnerable group because any sort of cognitive side effect or behavioral side effect that occurs at this time during critical periods of cognitive maturation and growth will have implications with respect to long-term graduation rates, school, and ultimately employment, and so on.

I'm going to talk a little bit about the stakeholders because that's the issue that frequently comes up in e-mail conversations that I have from various different applicants around the country who are interested in making applications. When we were formulating our research strategy and our research plan, we were able to identify three stakeholders that we wanted to incorporate into our specific project.

Obviously the children who developed their epilepsy as well as their families are our primary stakeholder. We also were able to have interactions and dialogue with the physicians and the healthcare professionals, broadly speaking those that are taking care of the children with epilepsy and their families. And finally, we have a couple different approaches with respect to the epilepsy advocacy groups and patient partnership that we have.

Now, if we explore the literature, we don't have to look very hard to find out that as soon as there's a new onset of epilepsy, the two things that are commonly reported, again, in the surveys and the literature, but certainly with the clinical experience for those of us who take care of children, are, oh, my goodness, it's a devastating effect to see your child have epilepsy. And then when you come to terms with the realization that it's going to require long-term care and intervention, what's the long-term effects epilepsy going to have on my child? How is it

going to affect school? How is it going to affect -- oh, my goodness, this is a long-term situation that I'm going to have to be dealing with and addressing. So what are the long-term effects of the epilepsy?

Following that up, what's the long-term effects of the medicines?

Unfortunately, my child's going to have to take epilepsy medicines for perhaps the remainder of their life if the epilepsy's not outgrown. What's going to be the effects of the medicines? How is that going to effect -- and this is a particularly relevant thing for this sort of research design because we can't control a person's epilepsy. We know there's cognitive and behavioral side effects associated with that. However, the selection of a specific medicine to treat epilepsy is the one thing that's under the -- it's a selection that can be based upon a dialogue of the patient, the family, and the physician. That's the one variable that can be altered.

In terms of the children and families

engagement plan, there's a couple different things. We had information from many of -- like I said, with respect to the literature, but we're also able to have Brandy Parker, who is here today, who's an adult patient who's had a child-related -- having some autism following in utero drug exposure. And that's Brandy and she'll speak on this.

I think we might get into this a little bit later, Brandy has a formal representation on the Executive Committee for this trial. This is a trial that involves 12 different clinical recruiting sites in which we're going to recruit a target of 300 children with new-onset epilepsy. And she has participated throughout a phone call, weekly Executive Committee calls, both during development and, more importantly, after we were fortunate enough to be awarded, as we try to fine-tune and make decisions with respect to what sort of detail and information is probably most important for our manual of operations.

Switching over to the physicians and healthcare professionals, if we take a look at all

the societies that we're able to, we're talking about the need to take a look at the behavioral and cognitive side effects. This included the American Academy of Neurology, the Child Neurology Society.

The American Academy of Pediatrics had a statement that the neuropsychological effects are incompletely described. The AHRQ, school performance should be evaluated in children, and that's school achievement based upon epilepsy treatment.

Taking it a step further, the way that we actively engaged our healthcare partners was through Survey Monkey, a survey that we performed. We were able to get the e-mail list from the Child Neurology Society, and we asked really just a couple different questions: What's your preferred treatment medication for the scenario of the children that we have here? And then also to identify what they consider to be appropriate, first on treatment because there is no evidence base to guide this and the physicians would acknowledge that they're prescribing tendencies

tended to be where they went to school or how they were trained and so on. These just carried over into the practice.

And then, I think, the more important thing, the more important question that we asked, is in the absence of differences in treatment efficacy or treatment effectiveness, in the absence of differences and controlling seizures, that is, would differences in cognitive and behavioral profiles affect your initial treatment preferences? And the response to that survey was 98 percent yes. So that addresses the issue that the awareness of the stakeholders with appropriate data, it would alter and, hopefully, shape practice parameters. We can skip over that quickly because it's described.

I want to move on now to our epilepsy advocacy groups. There's two approaches that we had. I've been in epilepsy-related clinical care and research for a long time and fortunate in that time to have established a partnership with the Epilepsy Foundation where I have done grant

reviews, led organizations of cognitive and behavioral initiatives, and so on. They, of course, were very supportive of this research and they will provide kind of web-based resources for education. And this is continuing to be a work in progress and we're going to do this with Brandy's organization, too. But I think it's definitely true that now as more and more individuals and families become engaged in active web-based dialogue, searches and so on, information that is accurately presented through societies such as that, that are identified high on the Google search list, that will begin to empower them to have productive conservations with the healthcare providers.

I'm also going to be participating in the Epilepsy Foundation Public Policy Institute, and that's something that's held every year here in D.C., that's given to parents and teens, both to talk about the project, the goals of the project, but, again, to engage them in terms of the research and taking responsibility for guiding their own

healthcare needs.

Brandy Parker, I won't say very much because Brandy's sitting here to my left and she will present her interactions with both the study and her organization as well, but Brandy is a founder of more grass-roots type of an approach that deals specifically with women and children with epilepsy. And what we've already done through PCORI's support is to have a little podcast describing both the issues related to cognition and the comorbidities associated with the diagnosis of epilepsy, but also treatment, risks, and concerns, as well as to talk about our project as well.

So I'll turn the microphone over to Brandy now.

MS. PARKER: Hi. Part of my -- obviously I have epilepsy, so I'm very passionate about it. I got involved in this project with Dr. Loring to see the cognitive outcome on children.

My story is that I have epilepsy. My son was diagnosed with autism after being exposed in utero to seizure medication. So I saw he was

exposed for a very short time. And when Dr. Loring approached me about this project, I said what about the kids that are getting this from a really young age? Their brains are still developing. What's happening to them? So my role is to kind of give the patient perspective. I also give a parent's perspective because I have a child with autism, so I know what kind of information do I want to disclose and do I want not to disclose.

So we just had our investigators meeting this past weekend in Atlanta. And, you know, a big thing is getting people in research. How are we going to get these parents to participate? And for me, I think one of my big things is you have to have trust. So when these children are newly diagnosed in the emergency room and they're seeing a physician, we are going to give them a packet, explain a little bit about what the COPE Project is, give them a little bit of information about the Epilepsy Foundation, and as well about my organization. It builds a trust. They're going to go there and then they're going to be more apt to

participate.

We also obviously are going to do the podcasting that we talked about. One of the other big things that I pushed for with this project is that we were going to have a survey for the parents, they were going to ask questions, and I really pushed that we have a survey for the children. I think we need to have better advocates from a very young age. And doing that, you know, they 6 to 12, you're teaching them to take ownership of their epilepsy from very young. The questions may start off, you know, very small. We haven't worked through all the questions yet. But I think that obviously PCORI's all about patients and we definitely need to have our patients involved.

Oh, they have the wrong slide deck, okay. Sorry. It's supposed to be a different slide. That's okay.

One of the things that we talked about this past weekend when I presented was that, you know, every picture has a story. Every picture

tells a story and every patient has a story to tell. And this is really important and we had a picture, that's what it was. So that's really my role through this project is that I keep offering that patient perspective. You know, I was 15 when I was diagnosed with epilepsy, so I keep reiterating all the different viewpoints from a patient and then also a parent, and what kind of information do we want to disclose.

DR. LORING: Thank you.

DR. HARTMAN: Thank you very much for inviting me to participate on the panel today. In addition to being a child neurologist, I also used to be a general pediatrician, so I've actually sat and played multiple roles in this issue. Today I'm speaking as a representative of the American Academy of Pediatrics.

Dr. Loring's study is important because it addresses a very important issue, which is medication-related impairment of cognition in children with epilepsy. Importantly, regardless of the results, we will learn something new, and

that's important. One issue that we'll discuss later that I think needs to be addressed is how this information will actually be implemented down the road, but I really do like the design of this trial.

As you know, epilepsy is characterized by mis-wiring of the brain cells that lead to individual seizures. As Dr. Loring mentioned, it's not a rare disease; it affects 1 percent of the U.S. population currently.

The epidemiology of epilepsy is interesting, but really what we're concerned about is its impact on people's daily lives. And relevant to the COPE study, the current definition of epilepsy includes not only seizures, but also its cognitive, psychological, and social consequences. The COPE study focuses on the comorbidity of cognition, which includes attention, language use, decision-making, memory, learning, and problem-solving. One measure of cognition, namely IQ, when you look at a population of patients is actually in the low average range,

which suggests some subtle level of impairment. But what does this actually mean for an individual person with epilepsy?

The diagnosis of epilepsy really shouldn't change a family's aspirations and hopes for their children. Many successful people from all walks of life have epilepsy, as you know: members of all three branches of our government, physicians, scientists, attorneys, businesspeople, teachers -- the list goes on -- football coaches. People with epilepsy have families and can enjoy full lives, as you see. But statistics indicate that all of these accomplishments, however, may be somewhat more challenging for a person with epilepsy to achieve, but, obviously, we all try our best to optimize the quality of life for all of our patients and their families.

A growing body of research indicates that complete seizure control is not always required for a high quality of life in many patients. Rather it's other factors, like getting through school and social engagement, that really make the difference

except in those who want to drive.

There are many factors that affect cognition in people with epilepsy. First, the mis-wiring in the brain that leads to seizures also can lead to problems with other brain functions, such as cognition. Unfortunately, as Dr. Loring mentioned, we cannot change brain wiring -- at least not yet -- but the other main factor leading to abnormal cognition is the medicines we prescribe, which, as he pointed out, we can control. But medicines are a two-edged sword. They work by altering brain function. That's how they prevent the seizures. But they also, obviously, then in individual medicines can affect cognition, but to different degrees. Not all medications are created equally.

Other medication-related factors that may affect cognition include degree of sedation, dizziness, vision changes, behavioral agitation, anxiety, mood changes, and other physical symptoms. Again, the prescribing physician and family have some ability to control the medicine we use.

Another issue that's beyond the scope of this discussion, of course, is whether there's a difference between brand name and generic medications. And we really, truly don't know the answer to that question yet.

In the clinic, my approach to treating patients, which I assume is pretty similar to what everyone else sitting around the table does, is to discuss potential benefits of a treatment versus potential risks. Although we subscribe to the dictum put forward by the Citizens United for Research in Epilepsy Organization, which is no seizures, no side effects, ultimately every currently used medication is associated with some side effects and the use of medicine has to be worth the potential adverse effects. Many patients and families are willing to accept the risk of a rare complication if a given medicine has a high likelihood of allowing the patient to get through the school day without having seizures that interfere with activities and learning.

Ultimately, families and patients have a

right and responsibility to make informed decisions. And so with our expertise and advice, together we make a decision with all of the facts on the table, and that's where the COPE study becomes so valuable. A difference in cognitive side effects, if any, needs to be included in that conversation with families about which medicine we will use. If two medicines work just as well for a given epilepsy syndrome, then commonsense would dictate that we should prescribe the one with fewer side effects.

The results of this trial, I imagine, will be published. I'm also on an editorial board. I can't imagine it won't be published, but the story doesn't really stop with the publication of results.

Dr. Loring mentioned the Epilepsy Foundation is one constituency that will be targeted specifically, but I would also suggest that another constituency to be targeted is primary care providers who, in many cases, will be more familiar with the patient's educational status; is

more accessible than a neurologist. And a primary care provider also frequently as an additional sounding board for decisions like these. Everyone caring for the patient has a stake in the result of this trial.

Another challenge, and this is really after the trial, so my comment isn't directed at this particular one, but how do we change providers' patient counseling and prescribing behavior? Because that's ultimately what we hope the trial does.

Regardless of the outcomes, this trial should change how I talk with patients and their families. Once the results have been published, I would advocate for fresh thinking in the way the data are put into actual practice. The best example for affecting change in my practice when I was a general pediatrician was an instrument developed by the American Academy of Pediatrics. And although I'm representing them today, other professional societies have similar programs as well. The general term for these instruments is

Practice Performance Assessments, and they basically allow practitioners to periodically compare their performance to peers, in a sense -- going back to pediatrics -- using peer pressure to affect behavior.

There are also other means of doing this: pop-ups on electronic medical records, and so on. I think if we put our minds to it, we really probably could come up with some fresh approaches because all the ones I've just mentioned have some problems.

And so to summarize, COPE is a very important trial with a clinically useful comparative design. The results generated from the study will be informative to us as prescribers, to our patients, and to our family partners. I would advocate for further thought about how the study findings for this study and others are implemented.

Thank you for the opportunity to speak today.

CHAIRMAN WASHINGTON: I'm going to start with -- well, first, thank you all for coming and

for the presentation and, more importantly, for undertaking this work, which will yield important findings with pretty broad implications for practice, and I'm delighted that you put it in context for us.

I'm going to start with Larry Becker.

MR. BECKER: Larry Becker from the Board. So Dr. Hartman, that was really heartening, the conversation that you just had around, you know, what you plan or think you'll be able to do. Assuming that all works out, how do you propose to get other clinicians, other providers, other patients, other caregivers to look at that research and to consider it for adoption?

DR. HARTMAN: So I'm not a part of this trial. So Dr. Loring, I would imagine, would want to have something to say about that.

I think the dissemination of information is obviously the critical first step. It has to go through a peer review. It has to go through the typical vetting process. But I think one question is whether there can be an effort. And again, this

is really, as I understand, a little bit outside the design of the trial.

But I think that the next step would be to approach professional societies. We all have maintenance of certification requirements for licensing on our boards. And so I think that would be -- that component 4 is really where this sort of hits. So I think partnering with -- so I guess I should please give Dr. Loring more money, so that he really can take this to the next step. Because what we really need to see is what's going to happen in that next step.

And I think that partnering with the various boards is probably the next, at least in my mind and maybe I'm being a little parochial about this, but I think partnering with the boards of certification really is a useful next step to the American Board of -- the American Academy of Pediatrics has offered various types of instruments which I think are very useful and I think as we look forward to maintenance of certification, the other societies, other professional societies,

would be just as interested. And as long as it counts for credit for everybody, I think that it would be a very useful type of an exercise.

CHAIRMAN WASHINGTON: Dr. Douma.

DR. DOUMA: Allen Douma, Board. A lot of the emphasis that we all on the board, and I in particular, is looking at what the patient wants, what outcomes they want, a risk-benefit analysis comparing one to the other. In looking at your protocol, how will the dosage be titrated? And will that be uniform across the study? So that somebody who's -- I'm a physician. I'm saying my goal is to prevent everything seizure ever versus my goal could be I want to prevent seizures to once a month or once a week because I know that if I don't, then there's going to be more side effects.

Do you have some kind of control over that or do you have the power to study it?

DR. LORING: That's a very good question. What this study is designed to do is primarily reflected clinical practice, but we, nevertheless, have to have some sort of limitation to ensure the

scientific rigor. So we have three medications, ultimately based upon survey and discussions and so on. And the children will be randomized to one of the three. We have the titrations schedules prescribed, so everybody has agreed to a titration rate that is within accepted ranges for this type of nuance treatment. You want to treat patients with the lowest effective dose, so we have shot for that range.

Then we have loud and built into the study design additional dose increments as needed, based upon clinical judgment, not to exceed a total number for study design purposes. And after they continued -- or if they should continue to have seizures after they have reached the top dose that we have in our study protocol, they'll be considered treatment failures, but they'll still be encouraged to participate in the study with respect to our cognitive and behavioral end points that, I don't think I've mentioned yet, is at a six-month outcome after treatment initiation.

CHAIRMAN WASHINGTON: Okay. I have a

question for Ms. Parker. You mentioned that you were on besides an Advisory Board, the Executive Committee --

DR. LORING: Executive committee.

CHAIRMAN WASHINGTON: -- you went down to Atlanta to the meeting.

MS. PARKER: Yes.

CHAIRMAN WASHINGTON: One, are there other patient advocates on the Executive Committee? And two -- so the answer's no?

MS. PARKER: No, that's right.

CHAIRMAN WASHINGTON: It's you.

MS. PARKER: Just me.

DR. LORING: Let me just follow up on that. There are two members of the Executive Committee who have actually children with epilepsy, so they have kind of shared roles a little bit that way.

CHAIRMAN WASHINGTON: Okay. How would you define your role in? And what in that experience has met your expectation versus maybe left you feeling like, well, we could do something better?

MS. PARKER: They asked that on the webinar the other night. I'm fortunate; I have a great group of doctors that I work with. They value my opinion just as much as the other doctors in the room, and I'm not a doctor, so the answer's is we all work together. I think that they key is finding a patient partner that is very passionate about what your particular research project is in. And obviously, I have a personal connection.

So I think it's a little intimidating, probably for the patient partners going in there with all the doctors. But I ask questions and I say, Dr. Loring, I have no clue what you just said. Could you explain that to me? And they do not make me feel stupid, they explain it, and that makes me, I think, a better patient and a better advocate as we go through the process.

DR. LORING: I would like to follow up just a second. One of the things that I frequently get asked is how do you engage the patient in terms of the development process and so on? And I think the one thing that I think Brandy represents well

is you need to engage early and you need to engage frequently. And based upon our weekly phone calls, I think that that has allowed her to feel more comfortable in a setting that's not her baseline de novo way of interacting.

CHAIRMAN WASHINGTON: Dr. Krumholz.

DR. KRUMHOLZ: I want to thank all three of you. Brandy, I have a question for you. I'm Harlan Krumholz. I'm one of the Board members.

So this is really important. This is just what we're trying to do. By the way, really important topic and it's thrilling to see a patient and an investigator with this kind of connection and relationship and working together on the project. And it's just what we're trying to foster through this effort, so, I mean, you can only imagine what it feels like on our side to see the two of you present and talk about this, and then to be connected with AAP and sort of thinking about dissemination in the broader range, it's really perfect.

As you think about this project and your

involvement in it, can you reflect on something you think would be different if you had not been involved? How do you think -- is there something where you said, gee, they were going to turn left and I got them to turn a little bit further right than they might have? Otherwise, it's not a criticism, you know, because we investigators, we miss things unless the patients help us see them. And can you give us some examples of where that might have occurred?

MS. PARKER: Okay. Well, one example would be the survey for the children. When they're looking at this, they're looking at -- they're interacting a lot with the parents. I mean, obviously, they're interacting with the children. But my big push was that the children have a survey, they have a voice because they are the patient. And so that was probably around my biggest things. I mean, they weren't against it, I just don't think they had thought, like, oh. Because some of the investigators were like, well, they're kind of young. And I'm like, well, you can

put that in a six-year-old level. You're teaching these children to be advocates for themselves from a very young age. So nobody objected. It was just a perspective they probably hadn't thought of.

DR. KRUMHOLZ: And what were they -- I know you were talking about making them advocates, but what are they asking them? Are they actually asking how they feel? I mean, what is it that they're surveying? What are you doing with the patient subjects?

DR. LORING: With the patient subjects, when they're old enough, we're doing standardized measures, like they use self-report. But we're also administering the NeuroQual quality of life instrument for them. And I think they kind of tie the two perspectives together by their actively participating in the research project. They're coming to terms with their epilepsy, their treatment. And it's a secondary association, but it's clearly implicit that they are participating in this because they have a condition that requires medical intervention. And had they not had that

seizure treatment, they would not be in that role.

DR. KRUMHOLZ: This is my final follow-up. So, I mean, these are great just to hear.

So you've got AAP representation sitting by you. How do you infect the rest of the pediatric research community with the spirit of what you're coming with today? And how does your national meeting have platforms where you can talk about what you're doing and get people thinking this way. Is there something we can learn from that?

DR. LORING: I can't answer for the societies. I can do and I plan to do everything I can in my role. But I want to just follow up with one of the things, I think, that you were suggesting with respect to her specific interaction and her specific contributions.

Her contributions are ongoing. For example, based upon our investigator meeting yesterday and the discussions there, we have now plans for Brandy to visit underperforming enrolling sites to kind of engage them with the enthusiasm

that she is sharing with us today. And that, we hope, will partner in a unique way with those sorts of sites.

CHAIRMAN WASHINGTON: They tell me that we're really pressed for time, but, as you can see, we're engaged in this discussion. We want to get a little bit more, so I am going to recognize [off microphone].

[Laughter.

[Off microphone discussion.]

DR. ZWOLAK: I'm Bob Zwolak on the Board. I'd like to ask a question of Dr. Loring and Brandy as well.

We talk a lot about dissemination at PCORI. And we've heard what the physicians are going to do. But if you find new outcomes, new side effects, new combinations of drugs that are good or bad for these children, how do you think this information would be best disseminated not to the doctors, but to the patients and caregivers?

And does it make a difference in how the dissemination occurs if it's a generic drug or not?

MS. PARKER: Well, from a patient perspective, I think it's very important to tell right away. I've lived that and now my son has autism, so I think it's extremely important.

I think that, you know, for me, I'm one of those people who need to just tell everybody: patients, doctors, I mean, news, you know. As far as how we would go about that, I think obviously Epilepsy Foundation is way bigger than I am, so the Epilepsy Foundation is a great source to be able to do that. All the epilepsy advocacy groups, I know that as we get information, we're going to continue to do that. Our organization focuses on personal stories to change the tide for epilepsy. So, again, people come to our site, you know, we will have different -- you know, we have a web thing -- I'm sorry, we will have some webinars. We also will -- we do our podcasting. So if there's new information, we will update as well.

I think as far as engaging the patients, I think it's just education all the way around. Patients are searching. This is one of the things

Dr. Loring and we talked about at the meeting yesterday in Atlanta as far as giving a packet to parents. You know, when their child gets diagnosed with epilepsy, the first thing they're going to is the Internet. You release them from the hospital, that's where they're going. You know, they put their kid to bed and they are just panicked, you know. So I think, obviously, the more things we can do out there on the Internet, that's where people go, number one.

[Off microphone discussion.]

DR. EPSTEIN: This will be easy. One of the themes we had before you got here was how important clinical trials might be for learning this kind of important information. Can I ask how you're budgeted for this?

I'm serious. One of the issues that we have been talking about is raising the amount of PCORI awards and I wonder if we could even say -- how many patients you had, how you figured out the right number and were you influenced by the limits that we have for PCORI awards? Would it have been

helpful to have a higher limit?

[Laughter.]

DR. EPSTEIN: If so -- if so -- we have a --

[Laughter.]

DR. LORING: Yes.

DR. WEISMAN: Shocking.

DR. LORING: It's hard to find words -- but in all seriousness, as you suspected it is very difficult to put a clinical trial together with the current limitations. And fortunately we have enrolled sites that have participated in clinical research and it reflects the desire for these treating clinicians to find out this information that they consider to be critically important. That they are essentially are doing it at a loss with cost-sharing to participate.

So, we were able to fully remunerate them at the effort they are putting it. But it's simply reflects the terrific site investigators that are participating in the trial.

CHAIRMAN WASHINGTON: Terrific discussion.

[Off microphone.]

Are we ready for the next presenters?

DR. BEAL: So our first project that we heard from was East Coast and then this last group took us down South to Atlanta, and now we're going to jet out to the West Coast to hear from a group from the Group Health Research Institute in Seattle.

This particular project actually comes out of our program on improving healthcare systems and is a project titled "Creating a Clinic-Community Liaison Role in Primary Care: Engaging Patients and Community in Health Care Innovation."

So speaking today will be Dr. Clarissa Hsu. Clarissa, just say hi. And then the patient partner is Janice Tufte and then we will also then be hearing from Marci Nielsen, who is actually from the PCPCC; which is the Patient-Centered Primary Care Collaborative.

DR. HSU: Well, Janice and I would really like to thank you for inviting us here today. We really feel excited and honored to be part of the

first round of projects funded. And as already has been said, the project was originally entitled "Creating a Clinic-Community Liaison: Engaging Patients and Community in Health Care Innovation." Let me see if I know the right button here. Sorry.

But as we've gotten started and with planning and with focusing our project, we revised our name a little bit and now we're calling it The LINCC Project. And LINCC stands for Learning to Integrate Neighborhoods and Clinical Care. So I'm going to refer to our project now as LINCC from here on out.

And a core of the LINCC project is developing a role or function within primary care teams that is focused on connecting patients to community resources. To really help them improve and/or maintain their health.

So there are a wide array of stakeholders that we're engaging in this project. Now the first with any research project we have our research team, which is at the Group Health Research Institute. However, in addition to the researchers

we are actively engaging the Group Health leadership. They have taken on implementing this project -- when we design it. We're engaging three group health pilot clinics so the staff at those clinics -- we're engaging patients in numerous ways, which I'll talk about in a little bit. And then, we're engaging the local communities around the three pilot sites.

So, since Group Health is such an integral part of this project, we felt like we needed to provide a few key facts about Group Health. Group Health was formed in the 1940s in Seattle, Washington. And the intention was making healthcare accessible to working class people. In what has evolved as a consumer governance or patients governed healthcare system that integrates healthcare delivery and healthcare insurance in one organization.

Group Health has 25 ambulatory care clinics across the State of Washington, and all of them offer primary care services. Group Health has achieved a Medicare 5-star rating. It's an NCQA

Level 3 patient-centered medical home and it's also been held up as a model by a number of academics and policymakers.

So, Group Health has long been committed to be a learning healthcare system even before that term was popular. And in doing so, they created in the 1980s the Group Health Research Institute, which is committed to doing practical research that helps people stay healthy and improves the quality of care.

One thing that's important to know about our project is it is integral to Group Health's own thinking about how they're going to improve care. And it's part of what Group Health is calling their Medical Home 2.0. So they had five years of very successful implementation of a patient-centered medical home initiative and now they're actually re-thinking and improving upon that. And so, they have a number of key things and this slide kind of highlights the key things what they're doing. And circled there is the LINCC Project, which is part of the outreach piece of the work that they're

doing.

So this is really seen as integral to what Group Health is doing to improve care over the next couple of years.

The project has several components, and the first one is this collaborative design process. And we're developing a way -- this is critical to the projects, developing a way for patients and clinical staff to collaboratively design care together. And then, and so I will be talking about that a little bit more -- and then what they design will be implemented by the healthcare system and then we'll evaluate that.

And this will all be done in collaboration between the project team -- the LINCC project team and the delivery system.

So, we always get a little attentive when we start talking about what this will be, because we want to leave a lot of space for the patients and the clinical staff to actually design what this is. But at the core of the LINCC project is finding a way, either role or function, to help

patients access community resources. It will help them make better choices about their healthcare and maintain and improve their health.

So, really maximizing those uses of community resources and I actually have been out in primary care clinics and some other projects, and really see this as a critical avenue that's going to be important in primary care across the country.

And there's growing recognition of this. And one thing that's unique about our project is that it's not just for the high utilizer -- high needs patients, this is really for the whole other group of patients. Now, we'll have to do some identification of patients, so but -- we're leaving that for the staff and the patients for how you identify patients who will get access to this new role or function.

So there are a numbers of -- that was kind of a brief overview of the project itself. There are a number of ways of engaging stakeholders and so, the rest of the presentation I'm going to focus on those.

So the first and one of the most critical pieces of our project that we've already started within terms of patient engagement is thinking about is the incorporation of patient co-investigators -- we've labeled them. And we have two patients who have actually asked to be members of our science team, our research team. And one of them has joined me today. So I'm actually going to let her talk about her role. This is Janice Tufte.

MS. TUFTE: Thank you for having us.

This has been a very interesting experience and very different from our previous patient advisory work at Group Health. We have been included and interact as research members of the science team. Together we discovered that there was a learning curve to increase our ability to function well as members of the team, including human subjects training; gaining some basic research design skills. All while learning and understanding the different roles and expected contributions of different members of the team.

My colleague and I each bring a different,

unique set of skills. Michelle has organized community advisory boards for a public utility and brings facilitation experience. Both Michelle and I have extensive community engagement experience. In my case, I run six community projects. I am active in local government and planning in areas of poverty. In one project, Emergency Muslim Resource Guides, offers community resource contact information of medical/dental clinics, ethnic-specific social services and more in three counties. Thank you.

DR. HSU: And one final thing I want to mention is that we're talking steps to document our lessons learned and where we've interviewed both our patient cohorts and all of our team, and over time we will hope to do some follow up interview because we really want to document what it's like in this experience of incorporating a patient and we got some start-up funds from our institute. We have something called a development fund, to do those initial interviews and we will be looking for funding for the additional interviews elsewhere.

So, as I mentioned, this collaborative care design process is a really integral way we're involving patients. And one of the things we're doing, is what we're doing is we're adapting lean design tools -- which lean comes out of the Toyota system of manufacturing. And the whole idea is that you get the frontline staff -- the people who are doing the work, to design care.

Well, within healthcare we're not just driving widgets into something. We are actually interacting with another human being, so the thinking was that we actually needed to have both the frontline staff and patients design the care together. So that's what we're doing.

And some of the things that we need to tackle are how are you going to recruit people to be on these design teams? And we wanted to get beyond the kind of usual suspects, who -- you know, they are very articulate like Janice. Very articulate, very skilled but may not represent, you know, your kind of average patients or the range of patient experience. So, we're actually going to

use techniques from research recruitment to really get a sample frame of patients and make sure we sample for range of gender, age, and certain characteristics like ethnicity or whether they're on Medicaid and to make sure we get a real range of patients into this design process. And the hope is to get 10 patients in the room with 10 clinical staff to do this design work.

So once we have the patients recruited, we also want to make sure that they're trained and we're going to give them training in how healthcare works. So, that they go into the design process knowing that the staff are thinking about things other than just patients. They may be thinking about union contracts, they may be thinking about billing. They may be thinking about regulations -- governmental regulations. So that the patients come in understanding some basics about healthcare and design.

And then finally, we're going to evaluate that whole process and see how it works because we truly see this as a pilot project.

So, another thing we're doing is that we're recruiting patient advisory panels in each of the communities that surround each of the three pilots -- clinics. And these are really focused on community groups and infinity groups that will maybe be affected by this role. But the advisory -- they will advise us on a number of things, not just the advisory to this liaison role. They'll advise more broadly about the project in general.

So, and then we have a patient's survey that will look at patient experience and outcomes. And we will do a pre-/post-surveys with patients at the three pilot clinics and then several control clinics. And we spent a lot of time developing this survey, because there is very little that's been developed at this point regarding how you ask patients about their community-clinic linkages. So we had to do a lot of initial survey development. But we will also be looking at more standard things like communication with a primary care team, the use and follow up of community services, patient activation and some health

behaviors and standard overall health outcomes.

Both, in terms of the collaborative care design and the intervention, we'll be doing a lot of documentation to know exactly what was implemented. How things rolled out, because often times you have plans and then there's really what happens, right?

So we'll be documenting that through observation, through interviews with participants, and then we'll do focus groups with patients who have actually experienced the intervention that's implemented.

So we wanted to end by talking about the benefit of the project to patients, because in the end that is why we're all here. And the goal of the LINCC Project is to ensure that patients have access to the information that will help them make better choices about their health and healthcare. In particular, we want to make sure that they have better information about the resources in their communities that can provide support for things that are going on in their lives that may affect

their health or their ability to make healthy behavior changes.

We believe this work will increase patient satisfaction and the patient-centeredness of healthcare by honoring the whole person. And of course, ultimately our goal is to improve the health of patients in the community as a whole. So we very much appreciate being given this chance to briefly share key aspects of our project with you today. And we're still at very early stages of the project, so we're hoping we have a chance to come back and share our successes and lessons learned at a future date.

So thank you very much.

CHAIRMAN WASHINGTON: Dr. Nielsen.

DR. NIELSEN: Good afternoon, in the interest of time I will be very brief.

Thank you for including us here this afternoon. I am Marci Nielsen. I am the CEO at the Patient-Centered Primary Care Collaborative, which is a terrible acronym, but I love that Anne got it right. The PCPCC.

A little bit about what we do. We're a thousand member organization that is basically comprised of physicians, nurses, social workers, other kinds of healthcare providers. Together with employers and health plans and consumer organizations and community organizations. What's unique about the PCPCC is our broad stakeholder-ness. So that's what's unique.

What we share in common with you, is out title of Patient-Centered Primary Care Collaborative, which as I listen to Dr. Hsu talk and listen to Janice, I think and appreciate that Group Health, which has long had tremendous success around building patient-centered medical homes, is focused on patients but most of the time none of us are patients. Knock on wood, thank goodness.

We are persons who are occasionally patients for the six hours we spend on average in a clinical setting in any given year. Five thousand hours being awake in a non-clinical setting. And so, what does that mean to all of us and to the research that's being done? And I think the

research that is being done in Washington is particularly important because we're learning more and more, thanks to PCORI, thanks to researchers like Clarissa, who are focused on getting patient engagement and real outcomes to inform health plans and employers and to have all of us pay for it.

But how do we incorporate patients and persons in research settings? And that's very novel. I so appreciate the role that Janice plays and how much training and effort it will take for folks who are not PhD trained as researchers. and then, how do we translate that -- not only into information that's useful for disease advocacy organizations, but into organizations like mine. In some ways we are like the Tower of Babel.

My job is to translate for employers who do not speak the same language as physicians, who do not speak the same language as patients and community members who also don't speak the same language. So, thank you to PCORI for investing in this kind of research. Thank you to Janice and Clarissa for doing it. And my job will be to take

this complicated information and try to translate it for various audiences and look forward to the early research becoming later research that demonstrates how we improve health.

CHAIRMAN WASHINGTON: Great presentations. You've set the stage. Any comments and questions from the Board? So we're going to start with Rick and then we'll go to Leah, and then Allen.

DR. KUNTZ: Rick Kuntz. First of all, this is a fantastic study. I think you're taking on some really common, intuitive ideas and being creative and I applause you for this effort.

The last comment you made about the translation is really going to be critical though. This is -- you've got quantitative and qualitative data that you're going to be looking at and processing. Do you view this as a pilot phase essentially that's going to help you construct a more evidentiary based system to be able to show the great stuff you've done, to use as a model to move onto the next level. And I kind of just -- maybe a little bit about how you're structuring it.

DR. HSU: Yeah, we definitely see this much more as a pilot than maybe some of the other -- like a randomized control trial, you know, in terms of the collaborative care design. Very much pilot and we're open to it being successful or not, and taking the lessons learned and disseminating those as well.

We hopefully will be successful and we would hope then to put together a toolkit that others can use. And that's actually part of our dissemination plan, but you know, we need to look at how things unravel -- or not unravel -- rollout.

[Laughter.]

DR. HSU: Hopefully they won't unravel.

DR. KUNTZ: So just as follow up, are you planning to use your rich dataset in Group Health as a base to see how they will compare against like patients, just trying to understand how -- what's the first effort to demonstrate the value.

DR. HSU: Yeah, the patient survey is key to that. So we do have control clinics that will be engaged in that as well. So we're looking at

patients pre-/post- in both the intervention sites and control sites.

One thing, you know, that's really tricky is because we're having the patients and staff design this in the process, is figuring out if there are specific populations that we should over sample. So that's been a little bit tricky. But we also have administrative data that we're asking patients to allow us to use, as well, that will look at some of these utilization data and things that affect patients, you know, in terms of their healthcare use and experience, as well.

So, yes, we do have administrative datasets that we plan to look at. But I think the ley thing is the patient survey and looking at that.

CHAIRMAN WASHINGTON: Okay, Leah.

MS. HOLE-MARSHALL: Thanks for coming both of you. I appreciate it. This is so very exciting.

My question, I think, is that of the three that we've heard about, I think the most structure

I've heard around the patient or stakeholder engagement, you provided some structure around that, some training for instance. A stipend. And I'm just wondering how, you know, PCORI might learn from those different models, since it wasn't probably part of our initial plan to gather that type of feedback out of the research. So, as our engagement teams move forward with their seed money work, perhaps we already have a set of studies or investigators that would be willing to participate along with partners of what they've found about what works and what doesn't to ensure that you can participate fully and you can learn what's appropriate.

DR. HSU: So we are very enthusiastic about sharing any lessons learned. And like I said, we realized when we started working with Janice and Michelle, we actually hadn't quite anticipated the level of training that they would need and we realized, "Wow. This is really a big deal."

And so, that's why we sought out the extra

money to do these in-depth interviews at the very beginning of our process. And so, we have those to document the baseline and we're very interested in looking at how that evolves over time in terms of how people are thinking about this role of having a patient on the science team and what kinds of tools are needed. We definitely, already started compiling a list of kind of lessons learned of what people need to actively participate.

And then, we have Janice and Michelle fill out a kind of quarterly survey and then that we discuss as a team to say, "How are you feeling about your participation? Do you feel respected? What can we do?" And maybe Janice, do you want to talk a little bit about that?

MS. TUFTE: Yeah, I would like to share a little bit about. I believe both the other patient co-investigator and myself were a little bit nervous and with trepidation, what this was. But both of us really believe in patient activation and seeing the ECA and just healthcare, to see it change, to see progressive change. So we both

fully believe in that and we're both in governance at Group Health in different levels.

But neither one of us anticipated the human research subjects training. I was told, it will just be four hours, you know, for each one. It took both of us 10 hours for each module. We had two different modules. We also took the Clinical care, which I'm not really sure why, but we did. And so, we know a lot about that as well now.

But actually, it was a good idea because we did learn a lot about how the whole process works. And that was one of the biggest hurdles to overcome. I just wanted to mention it was before my Ramadan. So I really wanted to push through before Ramadan. I did not want to have this stressed out during then. So I pushed through in about a week and just really went through it, and the other patient co-investigator took a little bit longer.

As far as the rest, what we did for the first couple of months. We meet weekly by the way

with the science team and/or the delivery team once a month. We were meeting a half an hour before each meeting with one of the key administrative -- Kelly, one of the key administrative assistants to talk over any issues with the agenda beforehand so we wouldn't -- we found out that we were taking up time in the meeting to ask for a clarification. And so, that really helped immensely. Now we feel comfortable enough and we know where to find acronyms, we know where to research. We also have articles coming to us. So we're able to read that ahead of time. So we just meet once a month.

Another very key component I felt was very interesting is, well -- Michelle had some caregiving experience and I've had a little bit, I came from a medical family. So both of us have some, you know, experience and resources in research on our own, but not in an academic way. But, what we found -- oh my gosh, I totally lost my train of thought.

I just lost it. I don't remember what I was going to say.

Anyway, I'll just drop it there, but we both are very happy to be a part of it and we have found that there is some roads -- but we're also all learning together at the same time and we're very excited to be one this and hoping for a positive outcome.

MS. HOLE-MARSHALL: Thank you. I'm really appreciative of the input and I think what it teaches me in terms of watching the different groups, is there's probably a gradation of stakeholder, patient, caregiver support and input and collaboration that could occur. All being very valuable and us learning better about where those different levels of input and engagement are would be helpful.

MS. TUFTE: I just want to add one other thing. I fully believe as an individual and coming from a patient level that having people at different levels on the research team, that's what I was going to say that biostaticians and medical anthropologists and primary care physicians, all of us working together at the very beginning was a

little bit overwhelming, but once we calmed down and understood what was going on and felt more comfortable asking questions, everything became easier. But I do feel that we are -- you know, we are presenting a different voice and it is important in the whole process Thank you.

CHAIRMAN WASHINGTON: Dr. Douma.

DR. DOUMA: I want to thank you very much. This to me is an example of what PCORI can do differently. We have the opportunity to look at alternative ways to helping people. And your people-patient ration, a 1000:1 almost, I think is something that we all ought to pay attention to, all the time.

I hope and presume you're in communication with Oregon folks, RCCOs. That's increasingly becoming the understanding of what you're doing is to what they're trying to accomplish. And I guess the only -- maybe you can think along the way. This is -- as part of your process is, is it important to have the linkers or navigators or whatever you want to call these people inside the

healthcare delivery system versus outside as part of a refurbished, revamped and reinvigorated public health system.

DR. HSU: Again, Marci is not actually on the project. She's our stakeholder commentator. But, I think that's a really great question and we have something interesting going on in one of our pilot sites. They are part of the -- they have a community transformation grant from CDC and they actually have a lot going on, more generalized around community health workers doing some of this type of work.

So we're going to have a kind of natural observation experiment about internal-external, but we felt in terms of the healthcare systems, that it was really important for it to be internal to the team and like I said, I've been doing a lot of work where I'm going on site visits in primary care clinics, and I've seen that the primary care teams are really feel like there is a need and patients, to make these connections and I really see this as a trend in the next 5 to 10 years. That I think

there will be somebody like this in every primary care clinic in the future.

So, I'm happy to be on the cutting edge of trying to figure that out.

MS. TUFTE: I would just like to add to that. For instance, what might happen in a rural or community center where there isn't a lot of resources, if somebody comes in with diabetes or obesity, whatever the range of issues are. And however, the community liaison role appears, however it will manifest, could introduce them in opportunities to how to care -- self-efficacy, how to bring about their own care, by going to perhaps the YWCA, being a part of a you know, a senior gym, taking yoga.

As well as if you take advantage of the food banks, they have free training in Washington State or cooking classes. They will come and teach you how to cook. How to live with very little money and eat nutritiously. So we also have quite a few neighborhood food gardens. And so, how we could incorporate those together where there isn't

in, like Seattle, where we have a huge amount of resources.

I want to add one other thing. In Tacoma, Pierce County, is one of our areas. There is a high turnover of services and service providers. And so, that could be a possible barrier, because you might hookup a stakeholder with one of those providers that provides care and the grant is lost. So, later down the road that's not available. So this would have to be continually up-kept. So, that's something to think of.

CHAIRMAN WASHINGTON: Dr. Nielsen.

DR. NIELSEN: And I would just underscore the point that you were making about having patients internal to the health system improving it and their role, particularly for folks with acute healthcare needs. But the importance of going outside of the clinical setting and out into the community and the role the community health workers can play. Often for folks who are not yet in need of acute healthcare services, but we can prevent illness when we're out in the community. And so,

we need to think about both. Learn from both and incorporate those research findings back into how we're delivering healthcare services, public health importantly.

CHAIRMAN WASHINGTON: Another terrific session. Anne, do you want to add anything before we -- Dr. Beal?

DR. BEAL: Just a word of thanks. Thank you.

CHAIRMAN WASHINGTON: Well, thank you very much. All three of you.

[Applause.]

CHAIRMAN WASHINGTON: I have one suggestion as I'm departing. But that is picking up on, I think, Harlan used the phrase results-based accountability and there was a series of questions about: What is the result? How will the world be different? What does success look like? What is the endpoint we intend to reach?

All three of these were exemplars. The projects we funded. It would be great if we sort of followed them, somehow. No, but I mean followed

them meaning, come back and yeah -- in three months, because what I heard and what I liked about this idea of resources based is, we don't have to wait until the end, because there are already proposals that we've funded. So, we should have some sense of what it looks like. And then, we'll get reports from this group so they really do become exemplars of progress that we're making in the organization. I think it would be an important exercise.

And I know we're running late, but Dr. Norquist has stated if you any further comments on this, to e-mail them to me.

[Laughter.]

CHAIRMAN WASHINGTON: He says e-mail them to me, Gene Washington since this is my last session. We're now at that moment -- Steve, and I sort of feel like -- I feel kind of handicapped, because my copilot is --

UNIDENTIFIED SPEAKER: He's right --

CHAIRMAN WASHINGTON: I don't know if you all have noticed, I've been looking around the room

and saying, well, you know, where --

VICE CHAIRMAN LIPSTEIN: I'm your wingman, right here.

CHAIRMAN WASHINGTON: Where is Steve here? You know, it's real simple for me. This has been both an honor and a pleasure to serve in this role for the last three years. And I sincerely mean it when I say that this will serve as one of the highpoints of my -- not just my professional career, but really my life, having had the opportunity to work with just an extraordinary group of individuals who now represent this really, truly remarkable community of leaders that's helping to fulfill the potential of PCORI.

I am supremely confident that you will under new leadership, and I will certainly be wishing you the best. In my bicycle-like analogies, and I use them all of the time from false peaks. For those who follow, and there's the rider that's out front. It's definitely a team sport. You may hear about the top riders, but when the rider out fronts drives the team so far, he or

she drops off the back or just off the road.

I'm just sort of dropping to the back and it's now Gray's turn to come up to the front along with Steve, whose been at the front. Knowing that you've got just this fantastic team and that also includes our phenomenal staff.

And so, I'm going to mark this moment of sort of peering off the front and having you come to the front with this official pounding of the gavel. Someone should officially mark the time. And anybody that --

VICE CHAIRMAN LIPSTEIN: [Off microphone.]

CHAIRMAN WASHINGTON: You can take my blood pressure, it's going to go down with each pound of this.

DR. NORQUIST: And mine's going up.

CHAIRMAN WASHINGTON: Okay. By the authority vested in me, by -- who does my authority come from in this forum?

DR. DOUMA: GAO.

CHAIRMAN WASHINGTON: That's right. GAO.

I officially pass off the Chair role, I

was about to say Chairmanship, but Chair role as the Chair of the Board of Governors to Dr. Gray Norquist.

And so it shall be.

[Pounds gavel.]

[Applause.]

[Shake hands.]

DR. WASHINGTON: Thanks everyone and we are adjourned.

DR. DOUMA: Wait. You can't --

CHAIRMAN NORQUIST: Yes, it's adjourned.

MS. HUNT: Adjourn us Gray.

CHAIRMAN NORQUIST: It's adjourned

[Whereupon, at 4:50 p.m., the PCORI Board of Governors meeting was concluded.]