PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
September 19, 2011

Cedarbrook Lodge
18525 36th Avenue South,
Sea Tac, WA 98188

[Transcribed from PCORI Webcast.]

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

APPEARANCES:

BOARD OF GOVERNORS

Debra Barksdale, PhD, RN
Kerry Barnett, JD
Lawrence Becker
Francis Collins, MD, PhD
Leah Hole-Curry, JD
Allen Douma, MD
Arnold Epstein, MD
Christine Goertz, DC, PhD
Gail Hunt
Robert Jesse, MD, PhD
Harlan Krumholz, MD
Richard E. Kuntz, MD, MSc
Sharon Levine, MD
Steven Lipstein, MHA [Vice Chair]
Grayson Norquist, MD, MSPH
Ellen Sigal, PhD
Eugene Washington, MD, MSc [Chair]
Harlan Weisman, MD
Robert Zwolak, MD, PhD

AGENDA

AGENDA [Continued]

P R O C E E D I N G S

[1:03 PM PST]

CHAIRMAN WASHINGTON: Welcome everyone, to the Board of Governors meeting for the Patient-centered Outcomes Research Institute. This is our sixth Board of Governors meeting, and it really marks our one-year anniversary, which officially will be this coming Friday, September the 23rd.

For those of you -- and I see a few familiar faces in the room who have been at each and every one of the meetings, I thank you, again, for your continued engagement, likewise to those of you on the phone, who have been participating in each meeting. Thank you. Those of you who are new to the table and newly involved, I want to welcome you and thank you as well for taking the time to join us today.

As usual, we are going to hear reports from our standing committees, but in addition, at this meeting we are also going to hear reports from a couple of working groups that will set the stage for discussion on a couple of key issues that we

need to advance at this time.

At our last meeting, in July, I had the great pleasure of introducing our neophyte Executive Director. I think he would at this point, whether he considers himself a veteran Executive Director, might be a question, but I think he would say he certainly has gained a great deal of experience in the two months. And he might even say he's a somewhat bruised Executive Director after dealing with Vice Chairman Steve Lipstein.

[Laughter.]

CHAIRMAN WASHINGTON: So with that I'm going to turn the program over to Dr. Selby.

DR. SELBY: Thanks, Gene. Hello everyone. I'll say it's very nice to be here in the beautiful Northwest and I was going to say I'm not bruised, but I might be a little wrinkled after two months. It's been a lot of fun. We've accomplished a lot. We have just a raft of decision-making activities on board, and you'll see some of them today if you stay tuned for our board meetings over the next six to eight months. I think you will see PCORI really

coming into shape and declaring its identity even more profoundly than it has done to this point, because there's a lot of decisions that we have to make about things, like funding.

So, I want to just spend a few minutes highlighting our activities in these first two months that we've actually had some PCORI staff in Washington. And we pulled together to work with the Board and the Methodology Committee to discuss how this staff is anticipated to grow over the next few months and just present to you some of the critical milestones in the timeline over the next nine months of PCORI's life.

Among the activities that staff, Board, and the Methodology Committee together have worked on, and I really would like to extend a sincere thanks to the staff, the interim staff who were there before me, the staff who have come on since I arrived, and to the Board and to the Methodology Committee. Everybody has been pulling remarkably hard. It's an exciting place to be. It's been a lot of fun. But there has been, no doubt about it,

a lot of hard work on everybody's part.

We can say now that compared to two months ago we have a set of HR policies that put us in a position to hire people. You will see job descriptions on the newly-designed PCORI website. We've been refining our purchasing and RFP policies, that's pretty essential because we've issued our first RFPs. Conflict of interest policies at a variety of levels are being developed. This includes conflict of interest with respect to being a Board member or a Methodology Committee member. Conflict of interest when it comes to reviewing grants and conflict of interest and conflict of interest when it comes to the possibility of applying for a PCORI grant.

As I said, and you'll be seeing it later on this afternoon, I think or possibly tomorrow morning, we have a newly-designed PCORI website. And, as I implied, there's a lot of new material on it, including funding announcements and job descriptions -- job searches. Just a couple of these or more, the outreach is just something that

I've been doing a lot of in Washington, and developing IT infrastructure is something we're doing mostly for staff, Board, and Methodology Committee just so that we can communicate more effectively.

We'll talk today a bit about growing our staff and talk right this minute about long-term space.

So, we've been located temporarily in space in the business district of downtown D.C., but we've landed a very nice home, long-term, for PCORI. And this is a building at the corner of 19th Street and L Street in Washington D.C. It's not an extravagant building, but it's a very functional building, it's a green building. It's got exactly the amount of space we think we're going to need over the next several years. And we're up on the ninth floor, where the arrow points to and that's where we'll be. We're very close to the Red Line, as well as the Blue and Orange lines. So no matter whether you fly in to Dulles or National, we're easy to get to. No matter whether

you live in Maryland or Virginia, we're easy to get to.

The July Board meeting, for those who were there, raised a number of urgent issues. And being my first Board meeting where I was really the in situ Executive Director, I paid attention. The first issue was that with the arrival of me and the prospect of more PCORI staff, we really needed to clarify decision-making and how decision-making was going to go forward. Up to that point it had been a Board activity, because that's who was there.

But also, there was a clear sense that we needed to take some time to have more substantive discussions than we could really have in a day and a half of Board meetings. Not only among ourselves, but also discussions between the Methodology Committee, which was separately appointed by the GAO and separately specified in the legislation, but very clearly a partner with the Board.

We did that yesterday. We arrived here yesterday and had a very fruitful discussion with

the Board in the afternoon and with the Methodology Committee in the evening on just on how we will partner more effectively going forward.

The second urgent area was the area of patient engagement. And the Board really expressed itself strongly in July that we have to make clear that PCORI aims to engage patients if we're going to be conducting patient-centered research in ways that we haven't seen before. And that one of our first hires should be a patient engagement officer, or Chief Patient Officer I think was the language used last time. And I'll get a little bit more to how we've addressed that in just a minute.

The next was the urgency of getting on with developing the National Priorities and you're going to hear about the National Priorities tomorrow morning here. But before PCORI can really fund its major or primary research, it by statute has to elaborate National Priorities and a Research Agenda. And that process we recognized in July has to get started and has to move rather briskly so that by early in 2012 we can begin producing RFAs,

RFPs and get funding onto the street and get PCORI's primary research underway.

We also heard about the PCORI Pilot Projects. A round of research funding that the Board had decided it did want to put on the street in 2011. This was an RFA that was been developed largely by Board members. Since July, staff has joined them in that effort. And so, that was another urgent issue.

And the last urgent issue was that the Methodology Committee really needed support to get started issuing the RFPs and planning its Methodology Report.

So, we took patient engagement. The Board formed a Patient Engagement Working Group of seven members. They very quickly developed a job description for the Director of Patient Engagement. We said that in addition to a Director of Patient Engagement, we want a Director of Stakeholder Engagement to engage providers, caregivers, employers, health plans, health systems, health services, researchers, and other researchers,

government, and industry. So, we created a job description parallel to the Patient Engagement Director called the Director of Stakeholder Engagement, and a third position called the Director of Communications.

And together, these three positions are all posted on our website now. Together they form an arm of PCORI that we might call the external engagement arm. But I think it sends a message that we indeed do aim to be engaged with patients and all of our stakeholders from the beginning in every aspect of research, and you know, with a deployment of resources that hasn't been seen previously.

The next urgent issue was the National Priorities and the Research Agenda. We have a working group that's leading the National Priorities discussion, and it's the co-chairs are Carolyn Clancy and Arnie Epstein from the Board. Staff has put a lot of energy into working with them and supporting this effort.

We've conducted an environmental scan and

you're going to hear more about this tomorrow on previous priority setting efforts and frameworks, criteria that were used. We've recognized the close link between the National Priorities and the Research Agenda. The Research Agenda Working Group is led by Board members Harlan Krumholz and Leah Hole-Curry. And we want to link the Priorities and the Research Agenda-setting process. Again, you will hear more about that tomorrow morning. But we really take it very seriously that that's got to be completed in fairly short order so we can get on with funding.

This just illustrates that on the top, the National Priorities, we have developed candidate priorities. Over the next three months we will be reaching out to stakeholders, all stakeholders, intensely, by a variety of mechanisms. Probably following that we will put a revised set of priorities before the public for comment and we will have finalized priorities, at the latest, by March and we actually hope we can do it sooner.

In parallel with the research priorities

is the elaboration of the Research Agenda. A more specific description of what we're going to be interested in funding. But, it involves the same steps of collecting stakeholder input. We think we can do a lot of that concurrently, public comment and a finalized Research Agenda. So, this is probably conservative and there's sentiment on the Board that we can and should move even quicker. So I think, you know, those are outside dates for when we'll have the agenda and the priorities finalized and can begin issuing RFAs, RFPs.

The Pilot Projects work has been led by Christine Goertz and Gail Hunt of the Board, and again, supported by substantial staff input. We posted the initial areas of interest that were going to be part of these Pilot Projects and you will hear more about that tomorrow. But, I want to say that we got on the order of 155 statements of input on our website. We reviewed them carefully, synthesized them, and revised and added to the areas of interest as a result of that input, developed the application form and instructions.

We're now working very closely with NIH staff because NIH, we're very happy to say, will conduct the reviews. We will, PCORI, will conduct the initial administrative reviews but NIH will use its very finely-oiled review process to do the study sections and score these applications from a technical merit perspective.

I want to say that we will have patient and other stakeholder reviewers added to the standard NIH Review Committee. So, and again, you will hear more about that tomorrow from Dr. Goertz.

And supporting the Methodology Committee, the Methodology Committee's report will come later this afternoon. But we facilitated the hiring of interim researchers to work with Methodology Committee members in getting the report sections drafted and two of the working groups have now posted RFPs. So this is work they need done that will inform the Methodology Report. Methodology Report comes out in May, but you can go to the website and find two RFPs on patient-centeredness, one RFP on research prioritization. And we are

working closely with the Methodology Committee now to articulate the review process when we receive these applications. The due date for these is the end of September.

PCORI has already closed one application. And this was for a piece of qualitative work to help us with the over 600 statements we received on our website in response to the working definition of Patient-Centered Outcomes Research that we posted. This RFP called for qualitative synthesis of these responses for pulling out the key points and messages for specifying a set of questions. The synthesized information will go back to the Methodology Committee and if you look at the timeline at the bottom of the page, between September 30 and November 15, the Methodology Committee will revise the definition. And then, the successful applicant for this work will spend from November 15 until the end of the year doing more qualitative research, getting input on the revised definition.

We think that by the end of the year we

will have our working, vetted definition of Patient-Centered Outcomes Research. We believe it will be an important publication, and of high interest to people who want to know what PCORI really means when they say Patient-Centered Outcomes Research.

PCORI staff is going to grow rapidly, beginning with the hiring of additional administrative assistants in mid-October. We've conducted a search for a Chief Operating Officer and we expect -- hope to -- you know, we've just about finalized that search and we're hoping that we will be able to actually have our COO in place by about the first of November. Shortly thereafter we'll be adding a Director of Staff, and he or she will begin hiring more Program Staff to support the various committees of the Board and the Methodology Committee. A Director of Finance should start before the end of the year.

We've posted for PCORI scientists. We are hoping that our first scientists will be on-board by early in December. About the same time, those

three engagement directors will appear and before the Pilot Projects are funded we will have Finance and Grants Administration Staff in place, so that we'll be able to handle the Letters of Intent from the Pilot Projects, which are due November 1st. The actual arrival of the applications in our shop on December 1st. The beginning of negotiations with successful applicants after the funding decisions are made at PCORI's March Board meeting. And then, the actual issuance of the funding in May.

I want to just say a word about -- and this is a draft of a beginning of an organizational chart. It says some things about our aspirations. We had a healthy discussion this morning and it may well not be our final organizational chart. But it shows you that we see a large set of scientific activities and we see a large set of engagement activities. And we see those linked. So if we have a research scientist or scientists who are particularly interested in patient engagement, they'll be working closely with the Director of

Patient Engagement to make sure that we actually study what we're doing in a way of patient engagement.

Similarly, if we have a research scientist who is interested, and we will, who is interested in stakeholder engagement; that's clinicians, health systems, health insurers, employers, et cetera. They'll be matched with a Director of Stakeholder Engagement. And again, we will study what we do and what works in a way of engaging stakeholders in the research endeavor and similarly with communications and dissemination.

So, that's the thinking to this date and the staffing that we see coming within the next six months.

So finally, just to give you a sense of some milestones and activities that we'll be engaged in over the next six months, between now and November, in particular, we will be working hard to get by a variety of means stakeholder input on the National Priorities and the Research Agenda. It needs to be thorough, it needs to be balanced.

Then that needs to be incorporated into the priorities.

November-December we will finalize the first draft of priorities, and right now the plan is that it goes to public comment at that point. Working on how these priorities are expressed in ways that reflect the patient perspective. And also, determining what are in among priorities. And are there priorities that are by the Board's decision left out? PCORI is going to, we believe, need to focus some. So that will be a topic of, I think, iterative discussions over the next two to three months.

January and February, February will see us finalizing the draft Research Agenda. And that gets even more specific about what's going to be in and what's out in terms of the research we'll fund. And it will lead us directly to our first RFAs that will be, you know, on the street not long after the Research Agenda is out. But just for example, to what extent will PCORI fund data infrastructure? There's a great argument that's an important part

of a patient-centered CER agenda.

To what extent will translation and implementation research be funded by PCORI? In fact, there's arguments that it may be more valuable to the public's health to work on translation and implementation of research when evidence is available, than on generating new evidence.

To what extent will we focus on systems research in contrast to more classic head-to-head comparisons of therapies? Might we and to what extent would we get involved in examining pharmacogenetics? To what extent will we put our funds toward funding large and perhaps costly clinical trials versus typically somewhat less-expensive observational studies? Those are just the kinds of questions -- and I don't mean to suggest that any of them have been yet addressed in-depth, and certainly not answered. But those are the kinds of issues that will be on the table as we start to shape the agenda and drive toward our first round of RFAs early in, or by --

certainly by mid-2012.

So, Gene? That's an update. And I'd be happy to take a few questions if there's time.

CHAIRMAN WASHINGTON: Yes, there is time. Why don't you -- okay. Questions, comments from Board members?

Leah. And Leah, for those on the phone, would you please give your name?

MS. HOLE-CURRY: Leah Hole-Curry, Board of Governors. Thanks, Joe, that was great. There's been a lot of work done since you've come on board. So I think I can speak for all of us in saying how appreciative we are that you're here.

I did have a question about the timeline. And as you mentioned, there's some discussion about speeding that up, but also wanting to understand what that would mean. So, as we find more information about that can we update kind of those charts related to that, as we make decisions about that?

DR. SELBY: Yes, certainly. The question about the timing focuses, to some extent, on what's

meant in the statute by public comment. So as some people read the statute, we would spend a fair amount of time developing the National Priorities, taking them to stakeholders, getting their input, and coming up with a kind of completed draft. Maybe you could say our best shot and putting that out for public comment.

Another interpretation might be that that process of engaging stakeholders is an iterative process which is itself public comment. And, you know, I frankly think that that's something the Board has not entirely worked through yet. But it likely does have some implications for the exact timing of the completion of the National Priorities and the Research Agenda.

CHAIRMAN WASHINGTON: I thought I saw another hand. Okay. And Joe, I would just reiterate what Leah Hole-Curry just said regarding the amount and quality of work that has been done under your leadership. And certainly, I have felt a great deal of relief since you arrived, just in terms --

DR. SELBY: That's the idea.

CHAIRMAN WASHINGTON: -- of operations of the Institute. So, we're glad you're on board.

I did forget to have the minutes approved. This seems to be a recurring theme.

[Laughter.]

CHAIRMAN WASHINGTON: So, can I have a motion please regarding approval of the minutes from the last meeting?

UNIDENTIFIED BOARD MEMBER: So moved.

CHAIRMAN WASHINGTON: Okay.

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: Are there comments?

DR. BARKSDALE: Again, I was omitted. Debra Barksdale. I was omitted from the minutes. I was here, really.

CHAIRMAN WASHINGTON: Okay. Is there evidence that you were here?

UNIDENTIFIED BOARD MEMBER: I saw her.

[Laughter.]

CHAIRMAN WASHINGTON: Okay, okay, okay. So we will add Debra's name.

MS. SLUTSKY: Gene? This is Jean Slutsky. Could you make sure that Carolyn Clancy was noted that she was also at the July meeting?

CHAIRMAN WASHINGTON: Okay. So corrected. So, I have a motion and second with modification to include the addition of the two Board members who were present but not listed.

All in favor?

[Chorus of aye.]

CHAIRMAN WASHINGTON: Okay. All opposed?

[No response.]

CHAIRMAN WASHINGTON: So the motion is carried. Okay.

Sorry. Steve, you played an integral role in helping us to forge ahead in this important area of patient engagement. So do you want to introduce this next topic, please?

VICE CHAIRMAN LIPSTEIN: Thank you. My name is Steve Lipstein. And let me just add my welcome to that that Gene expressed to those of you who have come to observe the meeting for the next day and a half. It's great to be here in Seattle.

And Leah, just another word of thank you for being our host. This is just -- it's been a remarkable visit and Seattle is so beautiful. And the sun is out today, and for those of you who are watching on webcast. So, it's great to be over here in this part of the country so that we can extend the work of PCORI to even more people and more stakeholders.

And toward that end, Mr. Chairman, we convened a working group of the Board with Gail Hunt and Larry Becker and Sharon Levine and Harlan Weisman and Allen Douma and Freda Lewis-Hall, who is not here today, and Ellen Sigal. I don't know if Ellen is up there in the sky listening in or not. Ellen, are you up there?

[No response.]

VICE CHAIRMAN LIPSTEIN: Anyway, it was a great working group and as Joe mentioned, the group developed really two products that Gail Hunt and Larry Becker are going to speak to on behalf of the working group.

The first product, which has already been kind of adopted and put on the website, is the

position description for the Director of Patient Engagement. The second product are a series of kind of guiding principles that we would like for the Board to consider with regard to the creation of advisory panels. And so, Gail and Larry are going to explain that on behalf of the working group, and then we'll open it for discussion.

CHAIRMAN WASHINGTON: Thanks, Steve. Gail, are you going first?

DR. HUNT: Yes, I'm going first. And then Larry, we're going to kind of tag team, okay?

MR. BECKER: Tag team --

DR. HUNT: Okay, I'm hitting the -- nothing's happening.

UNIDENTIFIED SPEAKER: You need lessons from Arnie.

[Off microphone discussion about slides.]

DR. HUNT: Oh, so the COEC was supposed to have been first?

UNIDENTIFIED SPEAKER: No.

DR. HUNT: Oh, okay.

UNIDENTIFIED SPEAKER: I don't think there

are slides, Gail.

DR. HUNT: Well, yes. They're -- okay, all right. Maybe there aren't slides, sorry, sorry.

All right, so how do we go blank? There we go.

So, basically our working group had decided that the PCORI advisory panels would be characterized across four dimensions. Subject matter, that's the questions and topics of discussion that they would have their charter duration, longer versus shorter duration. Membership, individual stakeholder segments versus multi-disciplinary, and their experience base. That is patients both active, former, and chronic; family caregivers, clinicians, professionals, researchers, applicants, and policymakers.

So with regard to subject matter I'm just going to talk to the first couple and then Larry's going to take over. Each advisory panel for PCORI would have a specific charter that would clearly define the questions to be asked of the advisory

panel, the problems to be addressed or the topics for discussion. So, what content is in scope, what content is out of scope for them? Each such charter would delineate the panel's intended duration, membership descriptors, and the requisite experience that we wanted.

And the concept of the advisory panel is, they would provide advice and make recommendations to PCORI and help inform the decisions of the Board of Governors, the Methodology Committee, and the Institute staff. Some meetings of advisory panels would be conducted in sessions open to the public, but open sessions would not be required of all the panels.

So with regard to the advisory panel members advisory panel members can, we thought, really learn and grow together accumulating and retaining PCORI experiences and knowledge. They can advise in shaping priorities, developing the Research Agenda, refining research questions, and informing study design.

They can help to guide and improve patient

engagement efforts, evidence dissemination approaches, and facilitate uptake and adoption of the evidence by all stakeholders. They'll commit time and energy to the issues that they really care about, because they'll be selected on that basis. Advisory panel members should know why we've chosen them, what we will provide them, and what we will expect of them.

Charter duration. They will be convened on a schedule that's consistent with their assigned work as specified in their charters. Some of them will have charters of longer duration and may consider a variety of topics during their tenure. Some will have shorter duration, maybe only one or two meetings, and may be asked to consider a specific single topic. But all panels should be chartered for an initial, specified period of time subject to Board review, and then reauthorization at the end of the initial period.

Advisory panels of shorter duration, may serve as subject-specific focus groups. So if we want a focus group that's going to be around a

particular topic we could convene an advisory panel just to be of short duration, maybe even one or two meetings, to serve in that capacity.

An advisory panel charter shall be for no more than two years long, at which time they can then be re-chartered for subsequent periods of up to two years with the idea that the panels would be reviewed on an annual basis.

Larry?

MR. BECKER: So, I'm Larry Becker.

So as we put this together we had a lot of questions. We don't -- as this begins to -- as we put panels together we're not entirely sure what questions are going to be. We don't know exactly how this is all going to unfold. And so, we tried to cover as many bases as we could. So, the membership on these may be made up of people with similar experience. So it may be all patients.

On the other hand, it could represent a mix of people. So depending on the kind of question and on the kind of focus that we want to have on the panel, and we tried to leave this about

as fluid as we could, not knowing whether and what kind of questions we would ask for each of these panels and what help needed to be done with each question.

In terms of who gets on the Board, we would look for nominations from a wide variety of sources. So, advocacy groups, professional associations might be one set. We would have open solicitations where people could apply through the website in giving us their background.

There could be recommendations from methodologists, from committees, existing panels. But we would take input from all quarters to try to set up these panels and get them populated.

We would make sure that there was a diversity, not only in the kinds of folks that are on these panels but as it relates to age, their, you know, gender, ethnicity, race, economic status, geography, language could be another example of where we want diversity.

In terms of size we had a discussion about, you know, what's the optimal size? And the

group came to an agreement that perhaps the optimal size is somewhere in the 9 to 11 member range. Large enough to be representative, but small enough to get the work done and to make sure that the cycle time of these things are well-done.

So, in terms of the types of experiences, you know, some of the examples that we put forth -- and by no means is this inclusive of everybody that we would consider, but clearly active or former or chronic patients, consumers, researchers, policymakers, caregivers, clinicians, other professionals, advocates. All walks of life, all kinds of people. Again, depending on the kind of questions that each of these panels is trying to answer.

So, as we put these together, we thought about how would these get staffed? How would we sort of approve, put in place, the actual panelists to be here?

And so, in step one, the staff would begin to solicit, pull these things together, and make a recommendation, ultimately, to the Board for the

membership of these panels. And the Board could simply just approve it as it stands or, based on some knowledge, you know question to make sure the process was followed. We had the right kinds of membership, that it was diverse enough, that it represented the questions being answered.

And we think that there could be a number of advisory panels at any given time. We'd look to the staff; we'd look to the people at the Institute to get us a sense of what's the process capability here? How many of these things could we possibly run at the same time to answer the questions so that we can be effective.

And so, that leads me to my last point. And that is, that we felt that we needed to make sure that we had good cycle time. And in doing that, we felt that we should consider putting some expertise to this in terms of facilitation, in terms of forming these groups, creating them with a repeatable process every time. So that you know, as you bring together 10 people for the first time, many of whom won't know each other, they can get up

and running in an expeditious fashion. And that every time you start to do this, everybody will know what the process is. We'll learn over time as we do panel after panel what they need to get up and running. The statute talks about us making sure that we support these people, that we get them the kind of information that they need.

So, we'll learn over time but we've got to have a good assimilation process so that our cycle times are as quick as we can so we get meaningful feedback in an expeditious manner.

So I'm going to stop there and ask for questions. And Gail, did I leave anything out?

DR. HUNT: The only thing that I'd mention is that we did talk about having this small group of two or three facilitators who would be the same people orienting the panels over time, because they the facilitators would really get to know PCORI, understand our process. It would relieve a little bit of the staff. The staff wouldn't be obliged to do the reorientation or the orientation of the advisory panels as they each came on. And so there

would be a process. And those two or three people would be responsible for that each time.

VICE CHAIRMAN LIPSTEIN: Joe, before we open this to questions, Joe and Gene. Just to remind the Board, as well as, those watching on the webcast and those here observing, here in Seattle. The statute that established PCORI encourages us to make use of advisory panels to basically extend the input that we have to establishing National Priorities and a Research Agenda. And so, the purpose of these guidelines was not to be hard and fast rules, necessarily. But as we bring on the Director of Patient Engagement, the Director of Stakeholder Engagement, Director of Communications, as well as, the scientists who will be helping with gathering all that input, that we be able to hit the ground running with advisory panels. And that staff have kind of Board input into how the process should work.

And so, we expect the process to be iterative. And as a learning organization, we will learn as these advisory panels are created. But I

think the Board has now at least the benefit of the best thinking of these seven individuals, and again I would just kind of commend them again for the amount of time, energy, and thoughtfulness they put into the process.

CHAIRMAN WASHINGTON: Steve, I'm going to ask if you would direct the discussion among Board members.

VICE CHAIRMAN LIPSTEIN: I'd be happy to. Debra?

DR. BARKSDALE: Debra Barksdale, Board of Governors. I have a question under membership. And when I initially read this I was, I guess, a little bit confused about where it says that individuals with similar experience and expertise. I think now I understand what you meant. But on initial reading of this, it seemed that you would want people with diverse experiences around an issue.

I think you're using the word "experience" to mean type from what you just said, patients or providers. Is that correct? Can you clarify that

for me?

MR. BECKER: Yes. So, I'm not entirely sure what the panel should be made up of, because we don't have the questions that we're answering yet. And so, we envisioned different kinds of panels. So, broad diversity in terms of the skills and experience in one case. But then maybe we want to focus on something very specific. And so, you might just have a panel of patients, as an example or you might just have a panel of nurses as another example.

On the other hand, every one of those panels ought to be diverse in their experiences so if it's nurses, from different places, different kinds of experience in the nursing profession.

So, not that we know exactly what they're going to be, but we tried to leave the guidelines open enough so that we could be flexible based on the question.

VICE CHAIRMAN LIPSTEIN: Debra, so one of the other examples that came up during our working group deliberation was if PCORI wanted to fund

research in a specific type of medical condition. I'll pick diabetes, or you and I talked about chronic pain yesterday. We might want people who have had that similar experience of having that medical condition, or of experiencing that kind of pain. So that if we were developing research questions or study design, we could be certain to include the perspective of people who have actually lived with that specific experience or that specific condition.

But you are absolutely correct; there may be other examples where our research will be cross-cutting. And we will want a diversity of experiences and a mixture of perspectives in the room at the same time.

DR. WEISMAN: I think, you know, some of this is designed, Debra, to allow a formal chartering process so that it's really clear what the questions are and whom should be on the committee. So they may be very uniform in experience under one realm, but very diverse in another depending on the question.

But the idea here is, and this guideline is to have whatever group is asking for this advisory panel be very thoughtful in specifying what's important in terms of the various characteristics of the members.

VICE CHAIRMAN LIPSTEIN: That was Harlan Weisman. Do we have to announce who we are again? Because it's webcast, they know who we are.

DR. WEISMAN: Thank you, Steve.

VICE CHAIRMAN LIPSTEIN: Okay. Sharon.

DR. NORMAND: Hi, I'm Sharon-Lise Normand from the Methodology Committee.

So I actually had two questions. Might be a little mundane, but the first question relates to have you thought of criteria that you're going to use for reappointment? You talk about reappointment, and I'm not sure what that means. Maybe they're fatigued or they're not -- I mean, did you have some discussion about what criteria were needed for that? And then, maybe I'll say my second question.

And I don't know, I have no idea if this

is applicable or not for these panels. But often you think of advisory panels, you think of conflict of interests. And is this at all applicable to the panels?

And I can imagine in some situations where it may be, and maybe somewhere that's silly to even think about. But I just wondered if the committee thought about those two things.

VICE CHAIRMAN LIPSTEIN: Sharon-Lise, I think I'll let other members of the panel bring up -- the second issue I know we didn't discuss.

DR. WEISMAN: This is Steve Lipstein.

VICE CHAIRMAN LIPSTEIN: Oh, this is Steve Lipstein. That's right. Thank you, Harlan. Harlan and I will watch out for each other in this.

I know we didn't discuss the conflict of interest issue. So I think that that's a very good point that we'll have to double back and pick up on.

The first issue was, and I guess Sharon Levine can speak to this. Sharon kind of encouraged us to make sure that the panels were

reviewed annually. So, that we could see if they were on charter, if they were producing the kinds of work that they were intended to produce, and then, at least after two years to get a sense of whether they should be re-chartered or whether or not the same issues should be repopulated with other individuals who could then add even additional perspectives.

But all we got to, I think -- Sharon, keep me honest or Larry, is that we got to the fact that they should be subject to annual review and re-chartering every two years. But that's about -- I don't know that we discussed criteria. Larry?

MR. BECKER: This is Larry Becker. So, the other thing is, I wouldn't want to leave the impression, either, that every panel is two years long. So, some panels might be a question. And in three months, they can provide the input to the question.

So it's going to be sum and some, relative to the question being asked.

DR. WEISMAN: This is Harlan Weisman

again. The chartering template that we developed, actually says it's a maximum of two years. And I think the same would be true with the one-year review. So, we're just again, asking whoever is asking for the panel, whatever group, that they're very thoughtful in thinking about it and thinking about what they think the duration should be, what a reasonable duration should be, and putting that limit so that we're very clear not only to ourselves when we charter the group but also to the members that there is aligned expectations on what the deliverables are and for the length of service that we're asking for.

I think, you know, there's a lot of discussion that we thought a lot of the work should be done in less than, you know, in two years or less. But, you know, it's conceivable that it might be longer. And Sharon-Lise, it's a great question. I almost wonder whether we'll have to learn as we go about what are the criteria, assuming that most of them will finish their jobs right away or within the original charter.

VICE CHAIRMAN LIPSTEIN: Sharon and then Ethan.

DR. BASCH: Hey, Steve.

DR. LEVINE: I think it's a great question, and I think at least in my own mind, we spent a lot of time talking about what the -- that we had an obligation to the panel members to be very clear up front about what the expectations were. And as Larry said, to provide the support and resources necessary for them to carry out what they were committing to.

I think we all are somewhat concerned about not frustrating people, particularly as we're learning more about this process. And I think one of the obligations we have as we charter these panels, though we didn't specifically speak to it, is to say what we anticipate the timeframe to be, under what circumstances we believe it would need to be extended, and what the criteria would be. We just haven't fleshed it out. But it's a good point and I think it does deserve some consideration.

And it may be different for different

panels. But we could probably come up with some general criteria.

VICE CHAIRMAN LIPSTEIN: Ethan?

DR. BASCH: Sure. Hi, Ethan Basch from the Methodology Committee. I just wanted to mention that later today in this meeting we'll be presenting the ongoing work of the Methodology Committee's Patient-Centeredness Work Group, which has as its focus developing methods and standards for integrating the patient perspective into the selection of research questions and the design of CER and PCOR research. And it would seem reasonable to coordinate this effort, since some of these methods will involve how to engage various stakeholders in different contexts, including stakeholder panels.

VICE CHAIRMAN LIPSTEIN: So I think, Ethan, towards that end one of the things that we envision now was that this particular work group would disband, but the product of our effort would be now shepherded by staff to incorporate what the Methodology Committee has been working on, as well

as these suggestions that Sharon-Lise just came up with, and the additional input gathered here today.

Bob, then Leah.

DR. ZWOLAK: Bob Zwolak. Larry, do you envision standing panels? I realize a panel has to be renewed annually and the duration of the charter would be two years, but do you see panels that would be so critical that they would be renewed in perpetuity?

MR. BECKER: So, this is my opinion. In perpetuity, personally, I don't think so. I think that when you name a panel of 11 to 12, 10, whatever number of people you have, you by definition begin to focus them based on their set of experiences. And I think that in order to make sure that all views are considered, I don't think anybody would get a lifetime membership on one of these panels. I think that you need to change; you need to be able to incorporate different views over time.

VICE CHAIRMAN LIPSTEIN: Bob, this one got a lot of conversation at the working group. It was

deliberated, and we started off with a construct of standing versus ad hoc. And then we moved to a more flexible construct which was longer duration versus shorter duration.

But there was a suggestion made that we talked about, which was should there be, for example, a patient advisory panel that would last for the duration of PCORI the same way we have a Methodology Committee that lasts for the duration of PCORI? And I think what we concluded was, that wouldn't involve enough people. In other words, there aren't 9 to 11 people out there that could speak on behalf of all the patients in the country. And that it might be better if we convened multiple advisory panels made up of patients and we're more inclusive so that we could actually hear more voices.

But we struggled with a concept of finding 9 to 11 people that would represent patients across the United States of America, representing all the different kinds of sub-populations and medical conditions that we've been encouraged to consider

as part of our work. But we did talk about it a lot as a working group. And so, it was a very important part of what we've considered.

Leah?

MS. HOLE-CURRY: Leah Hole-Curry, Board of Governors.

So, this is great work. It's really helpful. We've been talking in the Program Development Committee around -- and we're going to hear later tomorrow on National Priorities and the Research Agenda. And the statute talks about this being a place where PCORI may invoke these advisory panels.

So, two questions. One is, I didn't see triggers in here for this. And I know we've received some public comment already, and in our statute it says we shall if we have any rare disease research have an advisory committee. So, should we put something in here in this framework? Or is that really an implementation issue for staff?

And then just using this framework, maybe

some of the first test cases might be an advisory group around National Priorities and the Research Agenda. So, is that back to this work group? And I think I heard the answer is that this is going to move to staff, then?

VICE CHAIRMAN LIPSTEIN: Yes. So, hopefully once we recruit the directors -- the three directors, Patient Engagement, Stakeholder Engagement, and Communications. As Leah, for example, if we wanted to trigger the creation of an advisory panel, so one of the things we did discuss as a working group is, who gets to come up with an idea to create one of these? And we pretty much concluded everybody has the opportunity to suggest that we create one of these. But once we do, then staff would develop a charter that would be subject to Board approval.

So, Board could initiate this. Methodology Committee -- what we may get suggestions from the broader stakeholder community to do this and so we didn't want to limit that.

But you're right. There may be

consideration given to when either a patient group or a particular problem should trigger a panel.

MS. HOLE-CURRY: Okay, thanks.

VICE CHAIRMAN LIPSTEIN: Any other comments, suggestions? There's this guy raising his hand and holding up three, four -- like he has four ideas. But I think he's just timing the webcast.

Mr. Chairman, I think that again, this is just a -- I think the working group felt as though the creation advisory panel holds great promise as a source of input. And both into framing the questions, the design of the research, and then importantly, and again, Sharon often reminds us that. And then, when we get into the whole sphere of how we communicate, disseminate, implement, and uptake, advisory panels can play a very, very important role.

So, we're hoping that our guidelines will be helpful and that we'll soon be creating our first panels.

CHAIRMAN WASHINGTON: Thank you, Steve.

This is a topic that we will be discussing in an ongoing manner. And while we're not posting these proposed guidelines for official public comment, we would encourage anyone that's listening or anyone that's present here to send us comments on the website. In fact, I would underscore that we welcome comments on any of the topics that we are discussing today and we do take them seriously. And you can just send them to PCORI.org.

Okay. So, the next topic for discussion is a report from the Dissemination Work Group, which is being co-chaired by Dr. Sharon Levine and Dr. Carolyn Clancy.

Carolyn, are you on the line?

[No response.]

CHAIRMAN WASHINGTON: Okay. So Dr. Levine.

DR. LEVINE: Thanks, Gene. Thanks so much. And as Gene said, Carolyn and I, actually we convened the first meeting of this Dissemination Work Group last Tuesday. So this was our first time to get together

And as Gene said, it is a joint working group not just co-chaired by Carolyn and myself, but a joint working group between AHRQ and PCORI on dissemination. The members of the group include Joe Selby, Gray Norquist, Freda Lewis-Hall, Gail Hunt, the tag team of Brian Mittman and Robin Newhouse representing the Methodology Committee, Jean Slutsky and Howard Holland from AHRQ, and Gail Shearer and Richard Schultz are also participating in the meeting.

And as we do with many of the things that we do when we start something new, we go back and look at the statute and what does the statute say? And clearly, the rationale for a joint working group is that very clearly within the statute, the responsibility for dissemination, which is not defined. So like Patient-Centered Outcomes Research, it is not defined, which we see as a blessing actually, and a gift. And making available the results of research -- are clearly established. And I'm going to just review for the Board what the statute actually says.

Dissemination in the statute, and I want to thank Richard Schmitz for doing a word search for me, is referenced in relationship to AHRQ and in specific, the Office of Knowledge Transfer and Communication. PCORI's responsibility is, at a minimum, that we make information available to the public through our website based on the information in the research that is conducted by the Institute.

So, at least in the drafters of the statute there was some distinction between dissemination and making available. And Carolyn from the very beginning, has said that one of the opportunities we have as PCORI in this arena of dissemination is there are things that a government agency cannot do that PCORI, as a non-profit independent 501(c)3 actually has the availability or the opportunity to do. Things like conducting surveys.

And so our group, I think, is interpreting what the statute says as the minimum of what we can do. But there is nothing within the statute that limits our engagement in this work to "making

available through our website."

And so we began our first call together, and Carolyn did a lovely job of sort of giving a broad overview both of sort of where AHRQ and, in particular, the Effective Healthcare Program and the Office of Communications and Knowledge Transfer have been. And we will be scheduling and conducting a more in-depth briefing of the working group on all of the work done, both under ERA, under the ERA funding as well as through the Effective Healthcare Program on dissemination. And quite honestly, what they've learned about what works and what doesn't work. And I know that AHRQ has some pretty interesting projects going on right now trying to actually address not just dissemination, but figuring out how to actually increase and measure the uptake of research findings in the broader communities, both patient communities as well as provider community.

So as we begin our work, our first meeting, someone summarized and I can't remember who in the work group summarized what this is all

about. Which is, fund research to learn what works for whom and under what circumstances. And then, figure out how to get the information out to people who can use it and get the information out in a manner that is accessible and highly useful to people who can use it in order to make the best possible decisions about their health.

And so, our focus is really on how do we ensure that the information, the evidence, and the research findings are translatable to the point of decision-making in the clinical environment. Whether that's in self-care for someone engaging with themselves in self-care, a physician and patient making decisions together, or a patient confronted and physician confronted in the hospital with choices around interventions in a significant condition -- serious condition.

Our work plan which is really what we were here to, want to bring to you today, as I said, AHRQ is going -- AHRQ -- Howard Holland and Gene, I think, are going to -- and Carolyn are going to do a briefing for the PCORI members of the working

group. One of our interests and challenges is to bring the working group members up to a level playing field in terms of understanding what has been done and what is out there. And looking at, again, the implications of the legislation on how we could begin to approach potentially developing and enhancements to what -- to the kinds of things that are going on. And looking at unique and novel ways to not only disseminate and facilitate uptake, but also to measure the impact. And I think this is one of the big gaps is, how do we know we're making a difference? And what are the metrics we might possibly use to measure the impact of novel methods of dissemination?

An additional briefing, our second large work group meeting or second work group meeting is going to be to review the results of research done by RAND for the Secretary of Health and Human Services using five case studies of major clinical trial findings. I don't remember all five but KATIE [phonetic] and, I think, COURAGE were two of the five.

So what happened when the research findings were released to the professional community and through *USA Today* and *Wall Street Journal* and many of the local newspapers? What happened? And it's qualitative research, not quantitative research. It's just case studies interviewing multiple stakeholders about not only what happened but actually, what didn't happen in response and why. And I think, and Carolyn reminded us that what has now become sort of medical wisdom that it takes 17 years to translate a research finding into a change in clinical practice just is too long. And what is it that we can contribute in that arena?

I think we're also mindful of the fact, and Gray reminded us, that we don't want to revisit work that's already been done. We really do need to look for unique opportunities where PCORI in concert and partnership with AHRQ can add value and bring to the work things that have not already been done. So, we aren't interested in reworking or redoing the work that is already done. And then

ultimately, once the work group feels it has been steeped sufficiently in understanding what the current research or at least the current wisdom is around dissemination -- is, we're going to need to figure out and define the scope of work that we're going to get engaged in.

And I'll -- just as an example, one of the questions that was raised in our conversation was, where on the spectrum of dissemination does PCORI want to play? Is it just about getting information out in more effective ways through different channels and getting it out to, for example, trusted intermediaries I think was the term used; professional societies, consumer organizations. And that that handoff would be what PCORI would do versus understanding that real impact comes from behavior change. And that it's only when we understand how to translate the research findings into meaningful behavior or behavior change at the point of use of the information that we will actually achieve the return on investment on the research that PCORI is

going to do.

And so, how far down the pathway of getting involved in doing research around behavior change and engaging PCORI as an Institute and going beyond the handoff to others but actually directly getting involved in trying to facilitate uptake and utilization of information by both patients and consumers. The patients, consumers, and providers.

So at some point down the road, not too far down the road, we will have a more in-depth discussion around so where in this spectrum and what is the work PCORI can do. We have a little time, because we don't have any research findings at the moment to disseminate, on the one hand. On the other hand, the question has been raised are we limited to dissemination of the research findings that come from the research we are going to fund some time in 2012. Are there other things that we ought to think about or include in this process of dissemination and uptake?

And again, that's something I think that the group will struggle with and hopefully be

prepared to come back to the Board with recommendations. At least in terms of how to think about this and where we want to go with that.

Did you have a question?

MR. KRUMHOLZ: Harlan Krumholz. I was just wondering to the extent to which you're thinking about tools and incentives to facilitate the dissemination. Because part of this will be about both providing the vehicles and means to do it, but also creating the milieu that is drawing out, you know, where we create the demand for the information, not just -- I think when we just push out we're competing with a lot of other information. But if you can create the right circumstances where actually people are pulling information, not having it pushed at them, and sort of figuring out how we do that well might even be the subject of some of the work that we might fund in order to -- as I've said before, I don't think we adequately employ the social scientists in medical research. We don't bring in cognitive psychology and sociology and anthropology

concerning cultural issues.

And really, you know, we advance our basic biological sciences much faster than we are doing our social science knowledge within medicine. I mean, social science work all the time in a lot of different areas, but we're not integrating it into the medical research area to the extent that it really potentates the kind of thing you're talking about.

And, of course, when we talk about dissemination we're also talking about implementation. That is not merely spreading that knowledge, but having it be embedded and useful to people. That is, how do we create it so that it's going to be useful?

DR. LEVINE: I can give you my personal opinion about that. We haven't had -- it's exactly the conversation we need to have. And I would put incentives in quotes among tools. I mean, I do think we need to look at what are the potential tools to facilitate uptake and utilization of the information. And how involved do we want to get?

Personally, it's a passion of mine. So if I could commit PCORI, I'd say the whole way. I mean, we ought to own this. What did Gene say yesterday? Seize the mandate. Create a mandate and seize it.

But I think that's a conversation the Board really needs to get involved in.

CHAIRMAN WASHINGTON: Okay.

DR. WEISMAN: Harlan Weisman. You know, one of the early conversations we had before when we were talking about what kind of grants we wanted to fund was that -- was not just to fund research that talks about engagement, but to fund research in which engagement and the handoff isn't just part of it, but the change in behavior, if that's necessary, is part of it that we ask our researchers who are applying to us to take that on seriously as part of their research proposal.

And, you know, I was given the framework of different ways of communicating four levels. One is telling people something, one is selling an idea to them, another one is engaging them, and the

other one is getting true commitment. And, you know, I can tell somebody as a cardiologist, you know, you should use a treadmill because it will help you exercise. Exercise is good for you. And, they'll forget.

Telling is good when you see somebody stepping off the curb and there's a bus coming and you say, jump out of the way, there's a bus coming. That's -- telling is usually effective there but it isn't in other settings.

Selling works like if you want them to buy the treadmill, the salesman is very good at getting them to buy the treadmill, but they're still not going to use it. So engaging would be having the conversation with them about the benefits and what's important to them. And showing them how that might be an important part of their life if they were to do it. But commitment is really, you know, getting them to say this is something really important to me. And that's a very different level of talking or communicating.

And I would -- I agree with you, Sharon.

I think we should be in that engaging commitment territory as opposed to just telling, because telling doesn't work. Everybody knows exercise is good for you and smoking is bad for you, but there are a lot of smokers out there and there are a lot of people who don't exercise. So, telling isn't usually sufficient.

DR. LEVINE: One other thing I do want to mention is that Brian Mittman is an active member of the group. And Brian is committed to essentially trying to help us figure out in sort of a, I'm going to use the term landscape review, but it's not really -- it doesn't fully explore it. Sort of what the gaps are and how we can mind the gaps, if you will, both in terms of research -- methodologic research, as well as, traditional research in terms of trying to answer the question about what is effective and what is most successful.

CHAIRMAN WASHINGTON: Allen, please.

DR. DOUMA: Allen Douma, sorry. I want to really confirm what both Harlans are saying and

what you're saying about your passion.

I think this is a critical issue. It is the core, really, of what is preventing most of comparative effectiveness research being effective because it's not being utilized. And I think particularly Harlan 1, that the use of the -- Harlan Krumholz, the use of the word "demand" --

UNIDENTIFIED SPEAKER: What is 1? Is it actually Obi-Wan?

[Laughter.]

DR. DOUMA: Obi-Wan Kenobi.

DR. WEISMAN: Harlan 2 tries harder.

[Laughter.]

DR. DOUMA: And he does a good job. The whole concept of demand is core and critical to what we are talking about. I think it's also important to understand that there are three different types of demand. There's demand from the patient, there's demand from the provider, and there is demand from the team -- the patient-provider team. And it's to the extent that we can really get that team to demand what we're talking

about will be most successful.

CHAIRMAN WASHINGTON: Gray and then Leah.

DR. NORQUIST: Yeah, Gray Norquist. As someone else on the work group with the same passion, because I think that Sharon and I have both felt that way.

I think our key issue right now is really to interface. And I'm looking at Jean because she's representing AHRQ, is to figure out exactly what AHRQ is going to do. What others -- and figure out what our unique role may be in this. It may be the patient-centeredness, which is not something that really I think has been there. That may be something that we can do or maybe some particular areas.

And so, that's the key issue we have to address first, and then put our passion to work in the areas that make the most sense.

CHAIRMAN WASHINGTON: Excellent point. Leah?

MS. HOLE-CURRY: I withdraw, that's what I was going to ask. I think we do need a report from

AHRQ about the funding mechanisms and their plans to spend, even if we don't have dissemination -- PCORI-specific dissemination activities right now.

DR. NORQUIST: And I think the good thing is that they're willing to work with us. And I think that's a very good thing about this. Is a true collaborative process, and I think to Carolyn and Jean's credit is that their interest here is just not having money and doing their own thing, but that they really want to work with us. And so, I think that's another key aspect of this.

CHAIRMAN WASHINGTON: But what I also hear you saying is that, Gene Washington, is that we should be quite discriminating as we make decisions about our investment and what we're going to pursue in this area. And I think it's a key point. Jean, please.

MS. SLUTSKY: Yeah, Jean Slutsky. I actually have to say, I've never been to a meeting where there have been so many duplicate names. So, but -- Jean is easier than Harlan, no offense or anything. Thank God my mother didn't name me

Harlan.

[Laughter.]

MS. SLUTSKY: So -- no offense taken. As a woman, right.

I just wanted to tag on to what Gray said. You know, one of the things that we know about research and dissemination, translation, and implementation is that it's a multi-factorial process. And that you need to use a lot of different mechanisms, methods, and approaches to reach audiences. It's really hard.

So, that's what's really exciting about both of these organizations being charged to look at dissemination and implementation and translation, because that provides the opportunity to explore all the different avenues and venues to actually look at this from a holistic point of view.

DR. LEVINE: Can I just make one final --

CHAIRMAN WASHINGTON: Yes. You're going to have to wrap it up, because we've got to move to the public session.

DR. LEVINE: Yes, sir. One final comment, which is that this work group is made up of a representative group from the PCORI Board. And that also to point out, that in the statute the Office of the Controller General at a minimum of every five years is directed to evaluate the success of our dissemination efforts on changing the health status of Americans. And so, there really is an endpoint here where the Office of the Controller General is supposed to look at our work and say, this work, this dissemination work, actually made an impact and changed the way people get healthcare services or health services, and the way they approach making health decisions. So, that's in the statute, which is great.

CHAIRMAN WASHINGTON: That's great. It's a high bar but we always should expect great things from this group.

DR. LEVINE: Thanks.

CHAIRMAN WASHINGTON: Thank you, Sharon. Okay. We now will move into the public comment period, which is scheduled for the next half an

hour. And we have three individuals that have signed up. And after we hear from these individuals, then we will go to the phone line to see if anyone would like to comment.

I would, again, encourage our participants to limit your comments to three minutes. And I'm going to turn it over to Richard Smith.

MR. SMITH: All right, we'll use this podium for the public comments. And I'll call the individual's name and their affiliation, and just repeat your name and affiliation when giving your remarks.

The first commenter is Eric Nilsson of Insilicos.

MR. NILSSON: Hi. Thanks for the opportunity to talk to you today regarding this very important subject of comparative effectiveness. Can you hear me? Yeah?

My name is Eric Nilsson, and I am President of Insilicos, a Seattle company developing diagnostics for cardiovascular disease. Our goal is to fundamentally improve the way

atherosclerotic disease is diagnosed and treated. I'm also here today on behalf of the Washington Biotechnology and Biomedical Association, whose motto is -- it's new, so I have to read it, “Innovation realization from breakthrough discoveries to better health solutions.”

And, my message here is pretty simple. Thank you for what you do. It's important. And place the needs of patients first and continue to maintain a high level of transparency and openness.

It's ironic as I was preparing my written comments, which you have, but I was also dealing myself with someone very close to me who was dealing with a difficult medical, and probably, intractable medical condition. And, I guess you have access to a lot of very compelling patient testimony, so I have nothing very remarkable to report there. I, in fact, have something very unremarkable, which is, we will all ultimately be patients. And when we are, we will make different choices because we're different people.

So, one of the things that CER can do is

make the choices that we and those close to us will face simpler. But CER can't replace those choices. That we will, ultimately, as patients need to make those different choices.

And that's the message that the people who have dedicated their lives to biomedical research that I indirectly represent through WBBA and the people that I work with, would like you to hear today.

Thank you.

CHAIRMAN WASHINGTON: Thank you, Mr. Nilsson.

MR. SMITH: Our second commenter is Barak Gaster of the Consortium of Academic Health Centers for Integrative Medicine, and an Associate Professor of Medicine at the University of Washington School of Medicine.

MR. GASTER: Good afternoon. My name is Barak Gaster and I am an Associate Professor of Medicine at the University of Washington and I'm here representing the Consortium of Academic Health Centers for Integrative Medicine, which includes 50

premier academic centers in large medical systems around the country, including UCSF, Duke, and Yale. Which are dedicated to the study of integrative/complimentary medicine.

This consortium and the field of integrative medicine in general is, by definition, interdisciplinary; including physicians, nurses, and healthcare professionals of all kinds, including public health professionals. All health professions are important to patient-oriented research.

I'd like to thank you for the opportunity to speak and say how supportive I am of the work that you're doing. In the two decades that I've been practicing medicine, teaching students, and doing research it is, indeed, a struggle to have such a giant gap in terms of what we need to know in order to make good comparative decisions for our patients.

My academic career has been dedicated to understanding the evidence behind integrative/complimentary medicine. I've

approached this topic as an open-minded skeptic working hard to bring disparate results together that doctors, patients, and students can use to know what works and what doesn't.

When I first began working in the field of integrative/complimentary medicine 15 years ago I often wondered whether it would just be a fad which would fade. The data, however, now speaks strongly that this is not the case. That integrative/complimentary medicine is becoming more mainstream and more utilized side-by-side with conventional medicine.

Given the continued heavy utilization by the U.S. public, I strongly encourage PCORI to include in its strategic planning the study of integrative/complimentary therapies, given that these therapies are generally safe and are perceived by many patients to be very effective.

From a patient-centered point of view, the study of integrative/complimentary medicine is crucial so that we can understand especially from a systems point of view what works and what doesn't.

There are many leaders in academia, including many at the Consortium of Academic Health Centers for Integrative Medicine who have the scientific expertise to help make integrative/complimentary medicine more evidence-based, and I encourage you to help us to achieve that goal.

Thank you very much. I am happy to answer any questions.

CHAIRMAN WASHINGTON: Okay. Thank you, Mr. Gaster.

MR. SMITH: Our third commenter is Robert Cihak [phonetic].

DR. CIHAK: Thank you, Richard. That's one of the many acceptable pronunciations of my name. I say it Cihak. I didn't even know how to spell it right until I went over there to my home country. I didn't have any accents at all.

Thank you for all of you to come to Seattle to hear these comments. And pardon me while I start my personal stopwatch and reminder here.

I graduated from Harvard Medical School a

long time ago and have been a physician for more than 40 years. I am now retired from active practice, representing myself. And you have my comments that are already submitted.

So now I have a perspective as a patient and a physician. And as Mr. Nilsson remarked, we are faced with lots of choices. I've learned as a physician that everybody is unique. In my own life, my own medical needs and desires change from year to year, and sometimes even from minute to minute. If all of a sudden I develop a pain, I've got a very different outlook on things than I did just the minute before, literally.

Now, cost-effectiveness research might be of some value in studying different medical care treatments, but I'm concerned that used inappropriately, such as in government-controlled medical systems, comparative research could also result in cost containment restrictions limiting optimal care and access to it, undermining doctor-patient relationships, and discouraging continued medical progress.

Government bureaucrats getting between patients and their doctors is an increasing problem. We've seen a lot of that already. For example, Medicare, FDA. A lot of those efforts have been getting in the way and not helping out.

One example might be efforts to reward doctors for doing the right thing. A friend of mine just pointed out just about 10 days ago in the *Buffalo News* in New York State there was a comment about a woman complaining about a hospital bill charge for a pregnancy test. She was 76 years old. And my suspicion is that instead of using common sense, the doctor might have been trying to get a good grade in a best practices scoring system based on some of these quasi-governmental systems.

In a slightly less silly but potentially more dangerous process, we're seeing battles of experts on the use of Avastin, for example, an anti-cancer drug that's a miracle drug for many breast cancer patients or a drug that's just too risky for these same patients, depending on which experts are talking.

A similar problem -- we're seeing very similar problems and have seen similar problems with the FDA. That it's supposed to identify when drugs are safe, and more recently when they're effective. All of a sudden, one minute a drug may be unsafe and ineffective and the next minute when the prognostication comes down it's safe. At the same time, the FDA retards use of medical drugs. For example, beta blockers were in use in Europe for six years before they were allowed in this country. The FDA said, well this drug will save 10,000 American lives a year. Well, if you track back over 6 years, that's 60,000 lives wasted, in essence.

So, the effort -- any effort to try to treat everybody the same way is doomed to failure. And I would recommend that available resources be used to promote ongoing scientific and clinical research, rather than going off in whole new directions once again.

I'd be pleased to try and answer any questions you might have.

CHAIRMAN WASHINGTON: No questions, but thank you, Dr. Cihak.

MR. SMITH: That's all of the commenters that we had signed up on site. We do have a number of individuals who are participating via teleconference. So, I wanted to take the time to check with our operator, Carla, to see if anyone online wants to provide comment.

OPERATOR: We do have several questions. Your first one comes -- if you would like to ask a question at this time please press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key.

We'll now pause for the Q and A roster.

[Pause.]

CHAIRMAN WASHINGTON: Okay, I think, Richard, we're going to take that silence to mean that no one on the teleconference has a question.

OPERATOR: There are no questions in queue.

CHAIRMAN WASHINGTON: Okay. I would like

to provide anyone in attendance who has not signed up but would be interested in an impromptu moment to provide a comment to signal to Richard that you would like to speak.

Okay. No comments regarding anything you've heard this morning, no comments on the guidelines?

UNIDENTIFIED SPEAKER: There's one.

[Off microphone discussion.]

[Laughter.]

CHAIRMAN WASHINGTON: Oh, that's a real challenge there. He's thrown down the gauntlet there.

DR. EVANS: Good afternoon. I'm Heather Evans, I'm an Assistant Professor of surgery at the University of Washington, but I am also one of the K-12 comparative effectiveness research scholars, one of four at UW.

And I just wanted to take this moment to thank PCORI for doing the work that you do, and providing us with hopefully a mechanism that will allow us to continue the research that we're

learning how to do right now.

Thank you very much.

CHAIRMAN WASHINGTON: Well thank you, Dr. Evans, for that comment, but also for joining us today. Okay.

So, we have 15 minutes left in the public comment period. And we have committed ourselves to operating in a way that we would still leave that open, which means after I recognize Allen -- unless Allen, you've got a suggestion for the next 15 minutes.

DR. DOUMA: Allen Douma. Well, I just wanted to make a comment to follow up your suggestion that any time anyone wants to send us comments, questions, concerns go to the website.

A little clarification on that. You go to the website, which is PCORI.org. When you get there, we actually say there are no current input opportunities. That's not true. There's always an input opportunity. And what we give there is info at PCORI.org as a contact point for being on our mailing list.

At this point I suggest -- with your approval -- that info@PCORI.org -- be the contact point for anything.

CHAIRMAN WASHINGTON: Okay. I'll ask Richard to comment on that, because he knows just on an operational level, or Joe, which works best?

MR. SMITH: That address is advertised as a general contact point. So any questions, comments of any nature can be sent to that address.

CHAIRMAN WASHINGTON: Which address?

MR. SMITH: Info@PCORI.org.

CHAIRMAN WASHINGTON: Okay.

MR. SMITH: And also --

CHAIRMAN WASHINGTON: This is a very diplomatic way of saying I gave the wrong e-mail -- I mean, I gave the wrong contact information. Okay.

[Laughter.]

MR. SMITH: And --

CHAIRMAN WASHINGTON: You didn't have to go through all that trouble, you could just correct me.

MR. SMITH: And on the "Provide Input" page, at the bottom there's a form where you can e-mail the organization directly through the website. And that's automatically delivered to info@PCORI.org.

CHAIRMAN WASHINGTON: Thank you, Allen. Any other comments related to -- please. I see a hand.

MS. BUIST: Hi, thank you. My name is Diana Buist and I'm a Senior Investigator at Group Health Research Institute here in Seattle. And I'm delighted that you've actually come to our corner of the country, the other Washington, as we like to be known.

This week actually we're having a comparative effectiveness research training program at the University of Washington. And many of the people are still at the University telecasting this so that they can see how PCORI works, and a few of us came down here.

But one of the things that we talked about this morning that I just wanted to sort of comment

on that I hope is still at the forefront of your mind, as you think about how you're going to be making funding opportunities available to people, stakeholder engagement and stakeholder-driven research is historically not something that can be done through traditional grant mechanisms. The mechanisms are too long to review. We're unable to get rapid responses to stakeholder input questions that can be translated quickly.

And so, I just wanted to bring that back to you as something that we just had a panel discussion on at the University of Washington this morning. That we are still looking very hard at how to integrate innovative methodology so that we can get rapid responses to stakeholder-guided research that will fill evidence gaps. And we just simply need your help in that manner, as you think about how you're going to put out grant opportunities, how you're going to review them, and how you're going to be efficient in that process.

DR. SELBY: Thanks, Diana. Just take the opportunity to mention again our PCORI Pilot

Projects, which will be appearing at the end of this month, the RFP at the end of this month. So, it's almost exclusively methodologically-oriented research and one or two or three of the areas of interest have to do with patient and stakeholder engagement. So, we completely agree with your point and are putting our beliefs into practice.

CHAIRMAN WASHINGTON: Okay. If you've already had a roundtable this morning, then you're prepared to not only submit us some thoughts as we move ahead, but sounds like you're already prepared to respond to this RFA. Well done.

Other comments? Okay.

Well, I'm looking at you, Sharon. Only because I'm not sure whether we want to use the next 10 minutes as sort of an open mic or we want to just get started a few minutes early, recognizing that if someone has another comment that at least we're present.

I'm hearing nods for let's move on to the next presentation. Is that? Unless there's another suggestion.

Leah?

MS. HOLE-CURRY: We could just call at the end of Sharon's presentation, leave five minutes or so to call again --

CHAIRMAN WASHINGTON: Sounds great.

MS. HOLE-CURRY: -- for public comment. Make sure there aren't any.

CHAIRMAN WASHINGTON: Okay, great idea. Thank you.

DR. LEVINE: Great. And so, this is our report of the Communications Outreach and Engagement Committee. And I think one of the things you'll see in each of the committee reports as we go through the days is the degree to which there is overlap and, hopefully, representative of coordination among the different efforts. And clearly, the issues of communication, outreach, and engagement are on the minds of every one of the major work efforts that are going on in PCORI.

CHAIRMAN WASHINGTON: Just remind our audience both here and on the phone that we are shifting into a period, as I said earlier -- the

earlier reports were from working groups, these ad hoc groups which take on a specific topic. Now we're moving into reports from standing committees of the Institute.

Okay. And this one, Communication, Outreach, and Engagement, is currently chaired by Dr. Sharon Levine.

Thank you Sharon.

DR. LEVINE: Great. Thank you.

And just as a reminder to the Board and to our guests, the members of the committee. Myself, Debra Barksdale, Bob Jesse, Gray Norquist, Ellen Sigal, and Harlan Weisman. And for those in the room, those are our high school graduation pictures.

[Laughter.]

CHAIRMAN WASHINGTON: Like Harlan.

DR. WEISMAN: I try harder.

[Laughter.]

DR. LEVINE: And again, since we have -- I'm also going to remind the group about the charter. And we created these charters really as

we began our work. And I think we may at some point want to actually think about revisiting them as we get clearer and the work we're doing becomes more refined.

But as we established it, the charter of our committee was to advise and assist the Board of Governors of PCORI and provide recommendations to the Board regarding the Institute's communication and branding work. And, the branding work, I think, I hope these Power Point templates convince everyone, is quite compelling.

Strategies to engage all stakeholders in the work of PCORI. And Joe's report, I think, reflects that in terms of the hiring and the future staffing of the committee.

And methodologically sound approaches to disseminating and implementing the research results and ensuring their utility to patients and clinicians. And we clearly wrote this before there was a thought about a Dissemination Working Group or exactly how -- we knew that the work of dissemination was to be owned by the Board, but we

weren't quite sure about how that was going to be deployed.

And so, to some extent, this reflects our intention to work with the Methodology Committee, which we have done. And to at least begin to lay groundwork around thinking about dissemination and the critical role it will play. And I'm going to skip the little agenda for this report. And some of this Joe covered, actually, in his report.

Our first real thrust into opportunities for public input beside the stakeholder engagement opportunities at our Board meetings and the open mic or the public comment periods during the Board meeting was when we put out the working definition of Patient-Centered Outcomes Research. And this was work of the Methodology Committee. They had a sub-group that felt that it was critically important to put a definition around Patient-Centered Outcomes Research for a number of reasons, and asked our committee to assist them in figuring out how to put that work out there and get feedback on it for an iterative process of refining the

definition.

And as Joe said, the open period was July 20th to September 2nd. While this was not something that was mandated in the statute, we felt that particularly now in our early stages that it was critical for us to actually open up as many opportunities as possible in our early work to get public input. And the period of time this was open was within the 45 to 60 days.

We have gotten over 600 responses, and all the responses to the 5 questions that were sent out about the definition will be posted on PCORI.org. There's some technical issues that need to be resolved in the next day or so. But they've been organized and anonymized, if that's a word, so that they can be posted in their entirety.

And we have issued an RFP for proposals. And as Joe said, that contract has actually been awarded now to analyze and summarize the input. And for recommendations on methodologies, and will be used to get recommendations on methodologies to take this into Phase 2, which is taking the

definition out to patient groups. And as might have been accepted for the majority of the responses around the definition were from the research community, from academic medical centers, from physicians. And the feeling was that largely because the technical nature of the questions, that that was not truly in a patient-centered manner. This has to be translated into something that is comprehensible and meaningful to patients. And that was not going to be achieved, necessarily, through this survey process. And so, the second phase of this work will be focus group with patients.

And this is just a timeline for the analysis and summary of input on the working definition. I hope those of you in the room can read the dates. This will -- the intention is this will come back to the Board for acceptance of the definition and consideration of the revised definition after the opportunities for input at our January meeting in 2012.

And -- oops. Lost the presentation.

That's not the end of the presentation.

UNIDENTIFIED SPEAKER: It is now.

[Laughter.]

DR. LEVINE: It is now, yes. So, I will proceed without the slides.

CHAIRMAN WASHINGTON: Just ad lib here.

DR. LEVINE: Okay. So, we've had some questions and I think some comments from those who observe us and who have attended the meetings. You're taking an awfully long time to define Patient-Centered Outcomes Research. And I think the Methodology Committee has felt very strongly and I think the Board has supported this that this definition is going to be fundamental to our consideration of the kind of research that actually qualifies as Patient-Centered Outcomes Research.

And that we have an obligation to be crystal clear in what we mean, and to actually have a definition that we can attach to research proposals, so that the investigators understand what PCORI's, what the Institute's definition and the Methodology Committee's definition of Patient-

Centered Outcomes Research is so that there's no mystery as to why some proposals are funded and some are not.

And it was really, I think, I don't think there's anyone -- perhaps we can get more efficient in this process of iterative feedback, but I don't think anyone felt that this was something that we could do a quick and dirty piece of work on.

The definition will continue to be revised over the next several months to ensure that it emphasizes the patient-centered focus of PCORI's mission is consistent with the intent of the statute that established PCORI, and is broad enough and clear enough to support the range of research that PCORI will fund.

The second opportunity for public input was, again, Joe mentioned this -- was the topics for PCORI Pilot Projects. We did get more than 150 responses. I guess it was -- all right, and it came back. 155 projects. And again, the period of comment was August 1st to 30th.

The demographics of the respondents, I

think, given the technical nature of the Pilot Projects these are really methodologic -- intended to be methodologic projects. So, the fact that there isn't a large representation or a majority representation of patients -- I think it was 17.45 percent of the 150 responses. I'm sure that rounds up to a whole person. In response to the working group's -- sorry, in response to the questions around the Pilot Projects, is really reflective of the nature of the first Pilot Projects. And clearly if we're doing our work well, will not be typical of the demographics of subsequent public input processes.

Okay. We've -- to date PCORI has issued four requests for proposals, including the working definition of Patient-Centered Outcomes Research. Three that have come from the Methodology Committee and Joe mentioned these. The review and synthesis of evidence for eliciting the patient's perspective in Patient-Centered Outcomes Research, which is a literature review. Expert stakeholder interviews to identify evidence for eliciting the patient's

perspective in Patient-Centered Outcomes Research, again, an interview process. And then, methods for setting priorities in research, which are intended to be white papers. And I know the Methodology Committee will include more details about this in their report.

For the question of so how have we distributed information about this, for each of these RFPs, PCORI performed outreach to our e-mail list of subscribers, which is more than 620 at the current time, supplemental lists of clinical and translational research centers, academic research institutions, and provider and advocacy organizations.

And I would say that for each of these RFPs, the Board and Methodology Committee members have then forwarded them on also to their own networks and their institutions and those whom they know are -- might be interested in this or suspect.

And I do want to reinforce because we get questions about this all the time. Because we are not part of government and are an independent non-

profit non-governmental organization, we cannot advertise these funding opportunities in the Federal Register. So we get questions all the time about, well, that's where I go for information. Why isn't it there? And we've gotten counsel that we cannot take advantage of that.

And I hope some of you have had a chance to look at the PCORI website. It was up and active last week. And it looks better, it's more user friendly, hopefully. It includes visual changes based on the logo and color palette that we approved at the July Board meeting. It will support the expansion of PCORI content and opportunity for interactions as the work progresses.

There is an easier mechanism now for joining the PCORI mailing list and providing input that Richard referenced and the Executive Director's Corner, I think, currently has the first, from the Executive Director's report, that's now up on the website. It wasn't when we got the e-mail last week about it, but it's currently now

on the website. So, anybody who is linked to the web right now can look it up and hear what Joe has to say.

And the Pilot Project funding, again, the announcement will be on PCORI.org on September 28th. And the period -- it will be open from September 28th to November 1st. Again, we'll go through the direct e-mail to stakeholders, potential applicants. There will be proactive media relations, which is essentially issuing a press release -- for us is essentially issuing a press release and making contact with media that have covered us in any way, shape, or form asking if they're interested in promoting this, Board and Methodology Committee members and other grassroots efforts.

And we have a number of -- a large number, actually, of presentations, Speaker's Bureau presentations, scheduled between now and November 1st. And the content around the announcements will be integrated into all of those Speaker's Bureau presentations. And there will be a Q and A

teleconference for applicants. But that goes beyond the -- getting the word out.

And I'm just going to go to Speaker's Bureau just so folks can see, I don't know if you can read that. It's kind of small. But we have I think eight or nine upcoming opportunities where Joe or Board members will be speaking at large industry events representing patient meetings, consumer meetings, as well as professional meetings. And the content about the announcement will be promulgated at that point, in those presentations. So it's really an opportunity to get the word out to those who might -- who might actually consider applying for one of the Pilot Projects.

One of the things that, and this, again, is just kind of a summary and a bit of a look forward. We've made a commitment that we will engage -- we will make a concerted effort to engage with stakeholders around Board meetings. And what we've tried -- what we've done since our first two meetings where we had general stakeholder forums is

tried to tailor the approach either to the unique nature of the environment in which we're in, or trying to bring in different groups and different experiences brining in different groups of stakeholders in each venue. These are opportunities. We have a large group of Board members, and the opportunity to use the time we have to hear different stories and hear different perspectives about our work.

In March and May, in St. Louis and New York we had general -- invited people to come, had a series of questions, and got fairly general feedback. In July, we left our meeting venue and went out into the community, if you will. We had two small group meetings with patients and caregivers, and eight small group meetings which convened 43 different stakeholder organizations to provide input and feedback to PCORI. We were in Washington. Many of the organizations that many of you represent have offices in Washington. And we felt we really wanted to honor the location and to try and concentrate as much as we could the

opportunity for input.

I'll speak about tonight -- our Stakeholder Engagement Forum tonight. And in November when the Board is going to New Orleans, Gray Norquist has taken the lead on identifying clinical sites where the Board -- where groups of Board members will go out to two different clinical sites in the community and folks can ask Gray what the details are, where we stand on that. Again, to get a bit of a different perspective on what the issues are and how the work that PCORI does might actually potentially help those different community members.

And this evening, and again, thanks to Leah for organizing this, we have invited groups from the Pacific Northwest to make brief presentations to the Board about their work or their perspective and how it can inform PCORI's work. And we have three very different groups coming. Native American and Alaska Native healthcare folks, complimentary and alternative medicine researchers and providers, and Seattle is

home to a large organized provider community and to several large, robust research enterprises that have a long and storied history with comparative effectiveness research. And we will hear from them this evening. Everyone here is welcome to join us from 7:00 to 9:00.

And the final, this is my final slide. Again, as Joe mentioned, we have posted and they're currently posted on the website, position descriptions for three roles that we are recruiting. These are senior-level roles, director roles, that are essentially external -- collectively will represent an external engagement SWAT team. A team of experts who will share the work of communicating with the communities with which we -- who have an interest in our work and with whom we desperately want to interact with; Director of Communications, a Director of Patient Engagement, and a Director of Stakeholder Engagement. And the term really represents the provider community; physicians, nurses, industry, policymakers and they will work together to ensure

seamless and hopefully very effective mechanisms of being sure that we're hearing what we need to hear and getting the input we need.

And they, together with Joe, will develop and implement and bring to the Board a strategic communication plan.

And I think that's it. I'm happy to answer any questions.

CHAIRMAN WASHINGTON: Thanks, Sharon. Both for your work and for that summary of all the activities underway.

Opening it up for questions, comment. First we have Harlan W. and then Debra.

DR. WEISMAN: Sharon, first of all, thanks for beautifully summarizing the work of that committee.

You mentioned -- and I'm really glad that you did, that there's been buzz, I guess, about why are we taking so long with the definition of what PCOR is and you explained its importance.

The one thing I wanted to supplement to what you said, is that while we are getting that

input, it's not really holding us up. In that, you know, we did adopt it as a working definition that we would refine through the processes you said. But the work has gone on and I don't think anything is being held up, as you indicated, with all the RFPs that are going out already.

CHAIRMAN WASHINGTON: Good point.

Other comments? Debra, please.

DR. BARKSDALE: Mine is easy. It's a technology issue.

PCORI owns the domain names of .net and .com, and they both have the old website. So I just wanted to make sure that you knew that.

DR. LEVINE: Oh, thank you.

CHAIRMAN WASHINGTON: Okay, Gray?

DR. NORQUIST: So, one of the other things that I often talk about is my concern about reaching the populations who are marginalized and underrepresented and I think we have some way to go on that. And we are, I think, really trying our best to do that.

One of the ways in which we can do that is

partner with others, which Sharon and I have talked about. And when I -- Sherine and I were at the IOM collaborative meeting that was mentioned up there in July, and met, there was also a discussion about health disparities. And I think we have an opportunity to partner with HHS, particularly the Office of Minority Health and I've talked to Dr. Rashid there. And so, I think there's a collaborative effort we can do with other partners like that, because we don't have all the funds. We're not the only ones that are thinking about this. But I think there are other opportunities we have outside of our standard partners of AHRQ and NIH that we could also take advantage of.

And I'm just saying this publicly because I'd like for others who are out there who have ideas, you know, about what we could do to reach some of these populations -- could be very helpful.

So, part of the plan in New Orleans is to go to the community, because often we've asked the community to come to us. And I think we have to take advantage of our being there but go out to the

communities also.

CHAIRMAN WASHINGTON: Thank you. Well, Sharon, as you mentioned in your introductory comments there is considerable overlap in what's going on in the COE with activities in the working groups as well as with the methodology. And we all see that as a good thing. And so, that's one of the reasons why I think there's so few comments or suggestions at this point.

Which means that through an iterative process, we have clarity and we're in agreement about what we need to do next. So, thank you.

I have Harlan K?

DR. KRUMHOLZ: I just want to make one other point. I mean, I think it's extraordinary the investment that's been made and the speed with which it's been done, because this is one of the more difficult and challenging areas for us.

One of the issues that's going to be very important for us is how to manage expectations. Because as we invite the world into our process and try to make sure that we bring in the input, one we

have to make sure we're getting people whose voice is normally not heard, and then we have to figure out how we're going to respond, how do we make people feel that it wasn't a futile effort just to throw the comments forward. But that there was some meaning that was attached to, and then some action that was taken. Not necessarily as a result of each individual one, but that we have ways of incorporating it, sincerely and genuinely, authentically incorporating what we're hearing.

And I think the work that we're doing with the comments, and the groups should know that in hiring someone to help us bring the themes out of all these comments, I thought that was a tremendous -- before, because one thing for us just to flip through comments that are given to us, but to adopt a methodology to try to -- using qualitative research methods to try to bring out the themes, as well as, some of the specifics and identify some of those key things, I think, is again a very advanced way of thinking about how can we make everyone's comments meaningful as opposed to just going

through the motions of trying to get people to bring this in. But then people are wondering, well what's going to happen to it? Does this really matter?

And if we can make this tangible to people, I think that it will help us in the long run.

DR. LEVINE: And I should have mentioned that in addition to just posting the comments and scrubbing them and then posting them, there will be an executive summary and analysis that's posted on the website which will reflect how the -- which changes in the definition resulted from the public input process. So that's clearly the intention.

DR. WEISMAN: We actually started there and said, well because people might not recognize their own comments in whatever we summarized, we thought it was also if we could de-identify the comments to put everything on there. So it's fully transparent. People can see all the comments, their own as well as our summarization and how we synthesize the information.

DR. LEVINE: And we will be much clearer upfront in future public input processes about posting comments and making comments that are sent in available on the website. We had some concerns this time because we just quite honestly didn't do it. So that's why we took great pains to ensure that we weren't violating anyone's confidentiality.

DR. KRUMHOLZ: And the truth is, it could be a great source of information for people who want to do research to look at the kind of comments. And for us to be able to index and tag some of this so that somebody wants to go online, I mean, if we really get people knowing and be confident that the information they give us is going to be used and available and beyond us, it may encourage people, and I think Gray's point is so important. That we have to find ways to get to populations that haven't normally been able to have a voice.

But then, if I'm interested in doing research, I might wonder what are people saying? You know, and if I can -- if it's indexed and

tagged, I can go in there and say, well what are people saying about X? And I'm going to get some authentic information that I actually might even incorporate into my grant applications as some preliminary study data about where the need is. And I don't mean just to PCORI, but I mean anywhere, because it's helping me say there is a need out there. It's being expressed and this is how, you know, I can use some of that information.

So for us, I think creating this as a resource if we can really get, you know, 20,000 people to make comments -- and we'd be able to build the capacity where we can organize that, post it, use it, search it, it becomes in its own right away that we give voice to people who ordinarily don't have a way to speak to researchers. Don't have a way to bring forth those priorities.

The more that we can bring the voice to people who are the farthest from having a voice right now, the more successful we're going to be. And I think that could -- I could envision a system that we do where it's a dividend. Because we're

doing it to help us with our work, but it might help a lot of other people with their work also.

DR. WEISMAN: You know, just to clarify -- I mean, not clarify but to expand on what's being done. The group that will be doing this for us will do exactly what you said. They're going to database it and then they're going to search and they're going to use algorithms to create the synthesis. Just as you said.

What you're going on to say is, can we make that available? And I don't know. That's something we should certainly examine.

DR. KRUMHOLZ: And if they use standard -- I mean, there are ways to do that. And if you had an organization with some money, they might be able to invest in something like that.

CHAIRMAN WASHINGTON: Okay. Allen, please.

DR. DOUMA: I want to take us back just a few minutes ago and just reaffirm the whole issue we need to change the demand curve. And I left out when I made that comment about the demand curve.

Because people who aren't patients actually make the vast majority of healthcare decisions on an ongoing basis, and we need to be able to reach them.

And one of the things that's really critical, which Joe has already put in the job description for our new Director of Communications is creating a communication strategy. And I'm presuming hopefully that's a full-blown strategy which has goals, objectives, metrics, timelines.

But particularly, I hope that we have core to that communications strategy is the strategy with regard to how to change behavior and create demand. And then we can meet the passion that is in a lot of people on this table.

CHAIRMAN WASHINGTON: Excellent point. At this point I'm going to re-open -- Sharon, to you and all the members of your committee. I'm going to just re-open the floor for any comments from the public participants who are here today.

Okay. While we're waiting, what I'm going to propose is that we will take, oh, somewhere

between -- looks like it's about 17 minutes then we'd start at 3:20. Does that sound right to you?

UNIDENTIFIED SPEAKER: Sure.

CHAIRMAN WASHINGTON: So, I'm just going to ask one more time. No public comments. Then, we are going to take a break and reconvene promptly at 3:20 to hear report from the Methodology Committee. Thank you.

[Recess.]

DR. GABRIEL: [Webcast resumes in mid-sentence.] Thank you very much, Gene. And thank you in particular for making room for our whole team up here. Our presentation today is really going to be a team effort.

I'll start out with just a few introductory remarks and then we'll have each of our work group leaders that are seated right next to me here will go forward with an overview and update of their work group. And we're really looking very much for input and hoping to generate some discussion at the Board regarding our plans and our next steps. And then, Sharon-Lise and I

will close up at the end.

So, I saw my slides three times this afternoon already, but there they are.

[Laughter.]

DR. GABRIEL: Pardon me?

[Off microphone discussion.]

DR. GABRIEL: Okay. So as I said, I'm just going to make some brief introductory remarks to remind you of our charge. Obviously, making recommendations regarding methods for Patient-Centered Outcomes Research, establishing priorities to address research -- to address gaps in research methods and their application, and we talked a little bit about the Pilot Grants Program and what grants programs might follow. And we hope that there's some funding -- Methodological Grants Programs that follow in the future to fill some of the gaps that we are -- that we will identify through our Methodology Report. And also, to provide guidance about the appropriate use of methods for Patient-Centered Outcomes Research.

Just a reminder to the Board regarding how

we're structured. We have three work groups and a Report Assimilation Group. The Patient-Centeredness Work Group, chaired by Dr. Ethan Basch, to my right here, whose goal is to develop methods to incorporate the patient perspective into all phases of Patient-Centered Outcomes Research. And soon as I'm finished with my introductory remarks, Ethan will take over and talk about their work group's activities.

The Research Prioritization Work Group chaired by Dr. David Meltzer, to his right. The goal of which is to inform prioritization of new research studies. And then, the Research Methods Group, chaired by Steve Goodman, to the right of Joe over there, developing methods to use data design and statistical analyses for the conduct of Patient-Centered Outcomes Research.

The Report Assimilation Group, which will follow, Mark Helfand chairs that group. And after the brief presentations of the first three, Mark has some comments that he will share with us regarding the assimilation task of that group. And

as you recall, that group's task is to really -- in real time, bring together the work of each of the other three groups and begin forming the Methodology Report as we're moving forward.

So this is a very busy slide, and I don't mean for you to look at it in detail, but it's our activity timeline. And you can see the kind of vertical blue things are work that we've already completed or at least is well underway. Of course, our charter, our work plan. We've hired interim researchers, two of whom are with us today, Howard and Crystal. So, thank you for being here. And we've begun the work of the PCOR definition, along with Sharon Levine and Joe and the staff.

There are solicitations and literature reviews and white papers being commissioned by the various work groups, and you'll hear more about that. But each of those activities has a timeline and a task list associated with it. There are some workshops, as you see there, that are being planned by each of the work groups. And you can see their final due dates all coming together to create a

final report in May 2012 as dictated by the statute.

So, and these are just some discussion points that will come out in each of the groups. But really, things for the Board to kind of begin to think about because these are the issues that we really need your input on and we need your guidance.

And so, with respect to the first one. The importance of methods that will be generated by the patient-centered work groups for incorporating with the patient engagement activities of the Board and we had that discussion last night and a little bit today. And that's top of mind for us, is if we could have more discussion, more input from the Board as to how best bring those two activities together.

Likewise, the methods generated by the research prioritization work group vis-à-vis the prioritization framework set by the board. How do those two things best fit in and how can we be as complimentary as we can to one another's

activities?

You'll hear from Steve about the generation of tools and standards for the Methods Report and understanding that this is a long process. The statute specifies that there's a report due in May but there's an expectation that this is a living, growing activity that will be updated and improved with new research on an annual basis. And so we'll talk a bit more about that.

We're extremely grateful for those of you who participated in the two Board-Methodology Committee calls led by Mark Helfand and the Assimilation Group. And your input and your ideas really did change our direction in many spots already along the way. And we hope that you agree with us that that's the first step, not a final step. And we'd like your thoughts on how best to continue that interaction and how best we can continue to receive input regarding the -- especially regarding the Methods Report, but any of our activities going forward.

So these are things just to kind of keep

in mind. They will come up again as high points of the discussion. And I think we have a very small number of slides, and hopefully that will stimulate discussion.

So, I will pass this to Ethan who will take us through the Patient-Centeredness Work Group activities for starters.

DR. BASCH: Great, thanks so much, Sherine. Hi, I'm Ethan Basch from the Methodology Committee. I chair the Patient-Centeredness Work Group and will be presenting our really very collaborative work of the other members of this group, including Mary Tinnetti, Naomi Aronson, Brian Mittman, and then our representative from the Report Assimilation Group, David Flum. And we've actually had broad input from the Methodology Committee for the work that I'll be talking about.

Just to give the Board a sense of what the scope of the Patient-Centeredness Work Group is. We have the charge to identify methodological standards for incorporating the patient perspective into various aspects of PCOR. And we've divided

this into three key areas. The first is the development and prioritization of research questions. So that's not prioritization of research topics, it's really the more granular questions once a topic has already been established. So, we're not involved in identifying or prioritizing broad research topics. It's more once those topics are identified and we start to think about research, what are the research questions of interest that are patient-centered?

The second, is to bring the patient voice into the design of specific study components? Most notably the selection of interventions, the selection of comparators, and outcomes, and this includes, of course, patient-reported outcomes, although we acknowledge that patient-reported outcomes are not the only patient-centered outcomes that are used in clinical research.

And the third area is within the process of clinical decision-making and then, care delivery. And it was suggested to me that in order to, you know, help everyone to get their arms

around this, maybe to give a specific example operationally of how we think about this and contextualize it.

So, I'm an oncologist. And an important area in oncology is the control of nausea and vomiting around cancer treatments. And a number of clinical practice guidelines have been produced and disseminated within oncology to guide decision-makers around these therapies.

And these guidelines for the most part are based upon systematic reviews of existing literature. And when looking in a little bit of detail at the literature, it becomes clear that most of the endpoints that are used are vomiting, not nausea. Nausea is rarely included. And in addition, the measures that have been used in these studies were not developed with patient input. And there was really little or no qualitative research in patients who experience, right? Nausea or vomiting, in order to decide how to measure, what to measure, what score changes are clinically meaningful, and so on. Yet there is a fairly

robust body of existing literature around the control of emesis during cancer treatment.

And so, when we think about this in terms of this continuum, what we're really talking about is from start to finish when developing research questions and developing studies and then ultimately analyzing and disseminating those results, how do we assure that the patient perspective is integrated into every aspect of these processes from a methodological standpoint? And so, that's what we're engaged in.

So, to give you an update on the activities of our work group. Two RFPs, which Sharon alluded to earlier, were released and are out. We've received LOIs for these, and I'll show you our timeline in a moment for expecting the responses.

Theses two RFPs are complementary to each other. The first regards the review and synthesis of evidence for eliciting the patient perspective in PCOR. And the second is the conduct of expert stakeholder interviews to identify evidence for

eliciting the patient perspective in PCOR. And the basic idea of these RFPs is for us to have a sense of the landscape of what practical methods have been used in order to engage patients and their surrogates in the selection of research questions and in the design of clinical research.

And I should note that we particularly highlight methods for reaching difficult to reach patient populations, and also stress that we're interested in looking at the landscape not just in healthcare but beyond healthcare. We're very interested in what other industries have used in order to engage patients, consumers, other stakeholders, which are complementary to these activities.

This is our timeline. So, the proposals for the RFPs are due on October 6th. We have a very quick turnaround. We'll be selecting the vendor on October 13th. So we only have about a week to turn this around.

This reflects the very tight timeline that the Methodology Committee has in general for

preparing our Methodology Report in May. So we have a compressed timeline but we feel a realistic one for achieving our goals. And the final report by the vendor who is selected will be due on March 1st.

There are several other activities that we're talking about. The possibility of an open RFI to elicit broad perspectives on these issues. We are discussing a workshop for presentations and discussion to help consolidate our thinking in these areas. And finally, we, of course, will be developing the relevant sections around patient-centeredness for the Methodology Report.

We had one question for the Board. This was touched on last night to some extent, and has been alluded to today. Which is, how does the work of this work group complement ongoing or planned activities of the Board? Or I guess actually of Joe's staff. And how can we effectively collaborate as we formulate these methods?

DR. GABRIEL: So, if it's all right -- is it all right, Dr. Washington, if we pause after

each of the work group presentations for questions or discussion?

CHAIRMAN WASHINGTON: Absolutely. You're in charge.

DR. GABRIEL: I'm in charge? Okay.

CHAIRMAN WASHINGTON: I'm going to ask you to direct any questions or comments.

DR. GABRIEL: Okay, questions.

CHAIRMAN WASHINGTON: Be careful what you wish for.

DR. GABRIEL: I didn't wish for this, just to be clear.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: But Ethan, I would, I mean, I think there's obvious complementary work going on, because if we think about what Sharon just presented and in the upcoming reports about whether we're thinking about figuring out how to involve patients and stakeholders in a variety of either setting National Priorities, developing research questions, the Research Agenda -- the learnings of these two

particular RFPs, RFAs, whatever we call them -- I think will be germane to almost every aspect of what we do.

So, I think the overlap is very on-target.

DR. DOUMA: Allen Douma.

DR. GABRIEL: Allen then Sharon.

DR. DOUMA: Okay. I apologize if you said it and I missed it. With regard to the timeline of the patient-centered RFPs, where are they now and when will they be something that we would be able to take a look at? And, et cetera, et cetera.

DR. BASCH: Yeah, absolutely. So the RFPs were issued, the solicitations went out and our deadline for receiving Letters of Intent has passed, we've received our Letters of Intent.

For those who choose to put in an application, those are due on October 6th and we'll be making the award on October 13th. And then, we'll have ongoing dialogue with the awardees, obviously, with the final reports being due on March 1st.

So, I would anticipate that the Board

would have access to the reports immediately in March of 2012.

DR. GABRIEL: Sharon and then Christine.

DR. LEVINE: Sort of an invitation, Sherine, to you and Ethan -- I'm sorry?

UNIDENTIFIED SPEAKER: Speak into the mic.

DR. LEVINE: Okay. An invitation to think about if there is a point in time where it would be useful to ask one of the Board members to join your work group for the purpose of coordination, integration, communication if you've -- if there's a point at which you think that perspective would be helpful, I'm sure you'll get volunteers.

DR. BASCH: Absolutely. We actually talked about that in our closed session this morning. We would really welcome that. So maybe we could talk about that. Thank you. Go ahead.

DR. GABRIEL: So, how about right now in terms of including it.

So, really -- I mean, we did talk about it this morning. And if there -- we would love to invite Board members who might be interested if

it's all right with the chairman to just send us an e-mail and we'll sort that out.

CHAIRMAN WASHINGTON: Sure, I think we need to do [off microphone].

Gene Washington. But I would just say, we need to be more proactive and organized. So, Joe and I will follow up after the meeting to identify Board members' interest, because it may not be just this one working group.

DR. GABRIEL: I hope it's all of them, in fact.

CHAIRMAN WASHINGTON: Okay. Great suggestion.

DR. GABRIEL: Gail Hunt, I think Gail was next, then Christine, then Gray.

DR. HUNT: Yeah.

CHAIRMAN WASHINGTON: Sorry, Gail.

DR. HUNT: Gail Hunt -- that's all right, I'll just stand up.

I'm really interested in the timeline that you were talking about February getting your final reports in. Maybe earlier we could have an

opportunity as the Board to take a look at some of the -- what's coming out of it. But I'm thinking of it tying in with the RFA that we are going to be -- PFA, that we are going to be getting out where they're going to have to -- at the end of September and then they have to have their Letters of Intent in and then they have to actually have the proposals in.

And if there's some way we're going to be expecting that the people who are going to be preparing those proposals will in some way be thinking ahead about the issues of engaging patients in the outcomes of the PFAs, even though it's, you know, it's like a year out or maybe in some cases two. But it would be great if there would be some way they would have the access to some of that information. Not in preparing their proposals, but early on, so that when they're thinking about how they want to be doing dissemination they can be taking advantage of what you guys have gotten back from your projects.

DR. GABRIEL: Christine?

DR. GOERTZ: Yes, thank you. I see a real advantage for us to coordinate closely as we put the Pilot Project PFA on the street. And in learning lessons from you, because you're having some experiences with peer review and some other aspects just a little bit before us. We may be able to incorporate some of those lessons that you are going to learn through your review process and just your grant receipt process. I think that would be really helpful.

And also, I think we should find a way to keep your RFPs posted or available so that potential grantees for the Pilot Projects will know what kinds of work we've already solicited so we don't have people that are trying to do duplicate work that whatever they might propose would be complementary rather than duplicative as we're moving forward.

DR. GABRIEL: Excuse me. I know the Board knows this, but just for those of you who are here. These of course are grants -- contracts versus grants. So, these solicitations are very specific

in terms of what we want back. And the kind of information and the content we want back is specifically the content that will help us create our Methodology Report.

So unlike the grants, which are of course much more open-ended, there's just a difference. Really more for those in the public, than the Board, because the Board knows this, but I completely take your point that they need to be complementary and they should leverage one another.

Joe?

Oh, I think -- yeah.

DR. SELBY: Joe Selby. This actually builds on Christine's comment. And I'm thinking specifically of the ways that we make the review of the Pilot Project applications, make it distinctively PCORI.

And one of the ways is by having an additional criterion -- review criterion that's called patient engagement. A second way that's linked to that is by making a presentation to study sections before they start on their work that

conveys PCORI's intentions, what we're looking for. And I'm thinking that there, the work you've commissioned might be some of the richest and most thorough information that we could provide to a study section before they start on exactly what we mean by patient engagement and what is known about the methods.

DR. GABRIEL: Gray?

DR. NORQUIST: Yeah, so I think what you're -- Gray Norquist. We really do need the interface. And I don't know who's going to volunteer, but definitely this -- our committee should be very strongly working with them because we would like to see, actually, the responses that you get, proposals, because we were thinking of doing a landscape, ourself. And we said, wait a minute. Let's stop and see what these are going to do.

But I think because it's a contract we have the opportunity to work with the vendor during the whole process, which is a little different than the grants. So, I think we should build in

something where we're actively working with them as they go, because that could inform us whether we need to go with something a little bit different but could help you.

So, I don't know who you're going to assign or what, but I think we need to have more than maybe one or something. But maybe we need to have at least one of you -- well, we do have Brian on our committee. But I'm thinking about this particular Methodology sub-committee. We need some interface with our committee for a while. Right, Sharon?

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. NORQUIST: Yeah. Well, I'm talking about our committee on engagement. But also, you're talking about the Dissemination Work Group now?

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. NORQUIST: Oh, that's right. You're right, I'm sorry. But so, we need -- you're right, I'm getting them confused. But you're right, yes.

DR. GABRIEL: Okay. Any other questions,

comments? Debra and Leah.

DR. BARKSDALE: I just had a more general observation in the terminology that we've been using is not a reflection on this work group. The Board has been doing this too.

RFAs, PFAs, RFIs, RFPs.

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. BARKSDALE: Yes, yes. And since we are appealing to a broader stakeholder audience and not just academicians, we need to be very mindful of that.

MS. HOLE-CURRY: Leah Hole-Curry, Board of Governors.

I think, I guess, I would frame the question a little bit differently for each of the work groups. What you started with, Sherine, the Methodology Committee in addition to many other support roles that I hope you can play with PCORI has a very targeted statutory responsibility. And I know that you all feel that impending deadline.

So, I guess my question -- I mean, maybe would be two-fold about how does the Board support

your activity? And also, maybe what the touch points are.

But yes, there's a lot of overlap with our general work streams and what we're trying to accomplish on the Board. And ultimately, that we have everything coming together to make PCORI products overall fit. But you guys have a very specific job and you did a very nice outline at the beginning of how to get there. So I would just -- I would tweak the participation, at least for the first report, in terms of how can the Board be informed, help each other with communication flow. But it's really to ensure that your report gets completed and that we think the right things are being addressed in the report, rather than just kind of overlapping topics.

So, I just think that we need to be careful about how we phrase the question in terms of the interaction at this point to make sure that that report stays paramount and that these activities are feeding the report and we're asking the Board the right questions about, you know,

information to the report. Just to help us keep focused on that initially.

DR. GABRIEL: Right. And that's exactly where we are. And I think the suggestion of having Board members actually participate with the work groups, each of whom has, you know, one or two or three, maybe, chapters of the report is going to really help us get there in a much more specific way.

Rick?

DR. KUNTZ: First of all, I think this is great work and I just wanted to make one comment about potential ways that we can collaborate in the design for study part.

It's interesting how you're going to look at the methodology to potentially incorporate patient perspective. And you talk about the selection interventions, the comparators, the outcomes specifically. And I'm trying to envision as we put together our Research Agenda, will we be putting guardrails and boundaries on the types of solicitations we get from investigators by making

them fit into a methodology or design or would it be something you would add after they get the solicitation.

DR. BASCH: It's a great question, and thanks very much for that. And I think that Steve will probably touch on this as well.

We see the products of this work group fitting in perfectly to the Translation Table, which in turn is intended to be used as a guide for selecting designs of research to answer particular questions.

And so, this is seen as a filter or a lens. And Mark will touch upon this in his presentation, for a way that we think about how PCOR is designed or envisioned.

So I wouldn't maybe go so far as to say it's an expectation that research should be carried out in this way, but this is really putting out there that when one is conducting PCOR that these are approaches that are reasonable in order to assure that we are truly being patient-centered. Right? So it's not a stand-alone project.

DR. NORMAND: And I'm just -- Sharon-Lise Normand, Methodology Committee. I would just add to that. And I think it's aligned with Dr. Selby's suggestion when these are being reviewed -- when the new -- I don't want to use an acronym now, but the Program PCORI Funding Announcement comes out and there are applications that are submitted. Again, I think part of the review process should take the points that the Methodology Committee is making in terms of, is this a patient-centered outcome? Have the investigators thought about -- how did they design their comparators? How did they design their treatments? How did they design their outcomes?

So, I think in some ways it's not -- it shouldn't be prescriptive, but in terms of assessing the matching of the grant to our -- this organization, it should be used in that framework.

DR. BASCH: Yeah, absolutely. I think the thought is that both within solicitations there could be a definition of what we're thinking about here, or descriptions. But also, in the review

processes, as Sharon-Lise described. That's right.

DR. GABRIEL: Allen.

DR. DUOMA: I'd just like to urge us not to be too literal when we talk about patient-centered, that we actually look at people-centered. And the whole issue of self-care and primary prevention and most of secondary prevention, there obviously is -- more decisions are being made in those genre than everything else combined. And so, we need to make sure -- I think it's hard to tell from your request for proposal that we're actually -- want to be engaged in those activities.

DR. BASCH: That's a great point, and one we've spoken about at length. There are different ways to think about this. For example, to what extent is one interested in the perspectives of populations at risk versus people with disease, right? Just folks. We have spoken about that.

We've retained the terminology, since that's the name of the Institute. But your point is very well taken, absolutely.

DR. GABRIEL: I think Arnie, you had a

comment?

DR. EPSTEIN: Ethan, that was really a very lucid, thank you.

So I'm really intrigued by the notion of what you're trying to do. I think it's potentially really important to raise the bar for methods and get some standardization. And I'm trying to think of how we get it into our process.

I can imagine easily getting into the literature and becoming the standard. And the kind of writing you're doing is going to help with that.

When I think about our process it's a little more challenging. Here are some avenues, but I'm wondering what you're thinking. One is to get it into our Funding Announcement and saying, by the way those of you who are going to pursue survey-type research we expect focus groups, cognitive testing, pre-testing, and on.

But I wonder how we get it in the review process? Because we're talking about having 600 reviewers? And so, how do we get them to read the homework of your -- and then apply it? Or is there

another method you're thinking of doing it? Because it seems really meritorious.

DR. GABRIEL: I'm sure Ethan will comment, but I was just going to suggest that, in fact, everything that all of the work groups are talking about -- that question would be relevant to all of our activities and probably important for all of our activities.

And we've just started to think about this today and others might want to comment. But creating, as Ethan said, a PCOR filter or PCOR lens, so it's not a matter of here, read the, you know, 300 papers that have been produced by this group of individuals who we've funded. But how do we distill that into something that we can easily understand and what goes through the PCOR filter or the PCOR lens, however we pull it together, we can feel comfortable truly aligns with the mission of PCORI and truly aligns with our definition.

And so, that's, you know, the discussion that we've just started to have. And I don't know if others want to add.

DR. BASCH: You know, I -- it's a great comment and you know, I think we have a big educational burden upon us and we really have to think upon -- not a burden, but it's a mission. You know, likely this needs to be a review criterion. And it needs to have -- it needs to be very discrete with clear materials.

DR. EPSTEIN: What you're talking about could really raise the whole standard.

DR. NORMAND: And I think what we had discussed with Christine, some of the ideas that came around related to, you know, the Scientific Review Officer who is in charge of shepherding grant applications through. That's part of their charge to make sure the reviewers -- we have a template that says here are the criteria that judge a particular application. We have a bulleted list of criteria, the Scientific Review Officer is charged with making sure that that review was conducted to that extent -- you know, to the extent possible.

But there are some practical steps we can

take. They may not be all of them, but certainly there's some practical steps.

DR. GABRIEL: Pardon me. Yeah, I was just -- if I have the Chair's permission I was just going to remind the Board that we really do have three other presenters. Not that you've done this before, but Dr. Weisman?

DR. WEISMAN: Just real quickly, because the thought did occur to me. You did talk about workshops in your presentation. And the entire Board has talked about some kind of meetings and others around PCOR that this may be an opportunity for us to offer, you know, training of two different kinds. One of them is for people who are already skilled in the art of doing research who have to learn about PCOR. And the other is, that we want to attract individuals who have never perhaps done any kind of outcomes research or comparative effectiveness research but are interested in the kinds of issues of patient-centeredness that we are, which would be another kind of training obligation that we would have.

Maybe because they would be starting with a blank slate they would be more receptive to the training.

DR. GABRIEL: Okay, thank you. I think we'll go on. Actually, I'll make a really quick comment before we do the discussion, especially Arnie's comments really reminded me of the discussion we had at our table yesterday afternoon with the Board where Dr. Washington and others were talking about the importance of changing the culture and changing the conversation. And in addition to, hopefully, if we create a standard that can be used for all of our research and others will adopt it that could have the impact of changing the culture and changing the conversation around PCOR.

So, Dr. Meltzer?

DR. MELTZER: I'm glad to talk about the activities to-date of the Research Prioritization Work Group, which in addition to myself includes Jean Slutsky, John Ioannidis, Al Berg who is our representative from the Report Assimilation Group Committee, and Clyde Yancy.

The mission of our group is to provide guidance concerning the use of methods to inform the establishment of research prioritization approaches that best fulfill PCORI's mission. What does that mean? It doesn't mean that we're going to set research priorities. It means that we're going to try to provide advice that is useful in terms of developing a process that can help PCORI make better decisions. And, in particular, to look at the role of methods in doing that.

And our targets are really both to help the Board as it develops these processes and to help the broader community that will participate in PCORI activities as they participate in this process. So that they're able to put in better applications that better address these objectives.

Our scope of work is really focused most immediately on producing a section for the report that will be due in May that will address the role of methods in informing the establishment of research priorities.

There's really the core part of this is

that we'll be commissioning some white papers on various methods that we think may be useful to PCORI as it tries to establish a process for research prioritization. These include the generation of topics, the role of gap analysis and systematic reviews, value of information analysis and peer review. And I want to take a moment to talk about each of these. Because I know it may not be clear to many people what each of these means and how it may be useful.

So, topic generation really is about generating a sufficiently large list of topics that might be considered for research to make sure that as we prioritize we're prioritizing among the right set. It's well-known in decision-making that one of the classic failures of decision-making is not considering the right set of options when you begin. So you have to start with a large set of options, and there are a variety of ways to do that.

One way, of course, is to involve the people who will actually be making the decisions.

And so, we'll be working very closely with the patient-centeredness group to look at the role of patients and other stakeholders in the generation of topics.

Another approach, a method, as it were, is to do environmental scans that look at the whole literature that's published in the area and try to generate topics that might be of use. One particular way of generating topics that is often used in health is systematic reviews. And within systematic reviews, gap analysis is a method that's often used to identify particular questions that seem most promising for study. And there's been a rich set of work done in this field, and a lot of it has been recently reviewed by AHRQ and so we'll be standing on the shoulders of that work as we review these topics.

Once a sort of adequate set of topics has been generated and some work has been done to try and focus them and ask what particular questions might be asked, then you really face this question of prioritization and you can think about

prioritization as having sort of a quantitative element to it on the one hand, and a qualitative element on the other.

And value of information analysis is a particular approach that's generated increasing interest really around the world to try and quantify the prospective value of research studies in terms of their, for example, population health impact, although they could be done in other ways. And one of the interesting things we'll be doing is trying and extend these methods. For example, to reflect in particular, the variations among individuals. And this will be another place where the involvement of the patient and the patient perspective is critical.

But, these value of information methods have their limitations. There are certainly elements they can't well reflect, and human judgment is critical, and this is where peer review process is really going to be critical. And by peer review, I don’t mean peer review of academic papers or publications as people often think about

it. We really mean peer review of scientific proposals.

And at first blush you might not think of this as a method, but it really is a method. It's a tool that we use, and there are certain things that we know and often things we don't know about what makes peer review more or less effective. I think the question that was just asked about how methodological standards will be incorporated into the peer review process is a beautiful example of the things that I think PCORI will want to study to make sure that the reviews that are produced are ones that really best help us realize our mission.

Now these four white papers together will each examine these topics, each of which we think is important. But it's really critical to understand how they fit together. And so, we'll be holding a conference in January of next year to try to synthesize these papers where the individuals who have prepared them will discuss them and try to understand what are the strengths and weaknesses of each approach, and then how they all really fit

together.

So our progress to-date. What we've done so far is to identify these methodological areas of interest and research prioritization. We've identified the first interim researcher to begin to assist our work group, and we've released an RFA for these white papers that was released on September 9th.

Our next steps are to wait for these proposals to come in on September 30th. And then, we'll have about a two-week period to review them and select among them. And then, on October 14th we'll announce the awardees for these papers.

We recognize that the proposals that we get may not fill in all the areas we need, so we'll be using interim researchers to fill in some of the areas that aren't adequately addressed though the RFAs.

And then, one of the really most important things we'll be doing over the coming months is trying to work very closely with the Board, we hope, to explore the role of these research

prioritization methods vis-à-vis the broader PCORI prioritization process. In other words, how are these methods actually going to be useful given the process that the Board develops as it does so? And we hope that that will be a very good opportunity for us to work closely with the Board.

And so, this really leads to our question for the Board, which is how can we best work with you to understand your evolving plans for research prioritization so that the methods we are studying can be of most use to you as you develop that process?

So, thank you.

DR. GABRIEL: Rick?

DR. KUNTZ: David, that was great.

DR. GABRIEL: Thank you, David.

DR. KUNTZ: In your prioritization process, it seems like your initial first effort is to focus on the gaps and also on information value.

How do you incorporate the needs analysis? For example, IOM would say, you know, what's the largest burden on morbidity and mortality? Do you

have a methodology for looking at these?

DR. MELTZER: Yeah, so actually you think of value of information analysis as sort of a suite of tools. And needs analysis, in some sense, is one subset of that suite of tools. Very much like analyzing burden of illness. But fundamentally, they are quantitative approaches that look at one element of what would be a calculation of sort of the expected benefit of a research study.

One of the huge challenges in value of information analysis is that you very frequently are lacking data that you would like to have available. And so often it ends up collapsing to a more simple measure, like burden of illness or needs. And in those cases, I think it's often still valuable under some circumstances. But having the value of information lens on it helps you understand also the limitation.

For example, something may be a very large problem but there may be very little we can do about it. And that's probably not a great area for research, although sometimes you try anyway.

DR. GABRIEL: Bob and then Allen.

DR. ZWOLAK: David, that was a very nice presentation. The question I had is how do you see the work product of this research prioritization work group fitting into the timeline of our other responsibility of developing the research priorities?

DR. MELTZER: Yeah, we've thought a lot about that and at moments tried to accelerate things even more rapidly to do that, although we of course have to respect appropriate processes in doing that.

But honestly, I think the most important answer to that question is that the research priorities will change over time and the process will develop. And the way I view the current objectives, it's to set the first set of research priorities. And those I am sure will evolve as PCORI learns more about Patient-Centered Outcomes Research in general as its Research Agenda improves.

And so, our hope is that this can be a

continuing process over time. One that -- that theme of sort of continuing improvement over time I think is an incredibly important one. And it's one, for example, that I hope we'll really learn to apply to our peer review process.

One of the striking things even in the early work that we've done is how little strong evidence there is about what makes for a strong peer review process. And the amazing thing about this is that this is something in our control. We have the ability to generate this evidence. And I hope that PCORI will be a major contributor in improving the science of the peer review process.

DR. GABRIEL: Allen?

DR. DUOMA: Question and suggestion. The question is, in doing VOI, value of information analysis, is there anybody who has been able to quantify the value of relieving the fear that somebody has from -- with a severe headache because they think they have a brain tumor? That's an example of the direction.

And I'll hold off the second.

DR. MELTZER: Yeah, I can't answer that specific question.

[Laughter.]

DR. MELTZER: But nevertheless --

DR. DUOMA: In that bucket.

DR. MELTZER: But in that bucket of sort of specialized questions that seem amorphous and hard to answer, I think there are methods out there where you ask people about their willing -- their eagerness to solve that problem as opposed to some other problem or their willingness to pay to do that. Their quality of life in a state of anxiety.

These are not perfect methods. But they are out there and we can think about them and learn about them and learn about their strengths and weaknesses, where they give similar answers, where they give different answers. We can scale the prevalence of that compared to the prevalence of other things.

I do not think there are perfect measures of any of these things, but our goal has to be to try to make them better over time as we really

understand also what their limitations are.

DR. DUOMA: Great. No, I think it's fantastic that you're going down there. I personally feel that a great deal of the unnecessary utilization of medical care, we think it's unnecessary, is trying to relieve fear and anxiety, which we don't measure.

With regard to how you can work better with us or more with us, whenever you have information like the white papers, whatever you can share I think, you know, please share. Particularly once you've selected at some point, then you probably can share that information more than the others.

And I would suggest we look at how we can just put that up online so everybody can see it as well at the same time.

DR. MELTZER: That would be great.

DR. GABRIEL: Thank you. Harlan and then Harlan and then Steve.

DR. KRUMHOLZ: Thanks, David. That's really -- it's really great. You know, it does

seem like it's constituency-based in how you talked.

I was thinking about it just in the context of what we're doing if you were a Review Committee and you instructed the Review Committee, as you look at these grants. Pretend that they're completed, pretend they've got the finished product. Pretend, though, that they own it and you'd have to buy from them in order to free it for the world. How much would you pay for it, you know?

DR. MELTZER: Yes.

DR. KRUMHOLZ: Because it sort of puts in perspective for you, though, how valuable is that information that represents the product of that grant. And if they owned it and they wanted to sell it and we were in that business of trying to free it for the country, you know, that would put certain perspective on the way you thought about the review process. And putting an onus on us to say we really want useful knowledge. Because if actually we'd say, gee, if I had that, I don't want

to pay a dollar for it but we're going to pay $5 million to do the study, there's a little discordance in that piece.

My question for you about this is that it seems like it would work better when you're getting very granular around specific areas, but if our decision would be to pursue more thematic and paradynamic approaches towards our priorities and be more investigator-initiated with regard to what we're going to respond to. That is, we say, we're interested in patient-centeredness, we articulate our values, we put out our priorities. But we recognize our constraints.

We're asking people to really put together teams of people from the community, practitioners and researchers, in order to address problems that they're going to -- they think are important. And that's difficult in and of itself. So we want people to figure out what their sweet spots are. And we're going to judge the grants based on what they're going to produce, but we're not -- we in the end are not sure we're going to be smart enough

to know who can create that opportunity. That it's not just the priority but it's the opportunity. How does that fit into this process?

DR. MELTZER: Yeah, I think this question of how good we are at identifying the most important questions is a wonderful question. And I'm glad to hear skepticism as to whether we're able to do that well.

And I think this emphasizes the importance of studying areas like topic generation. And if one, in fact, recognizes that we're not always so great at generating topics that push us towards more investigator-initiated awards.

The second thing that I would say is that tools such as value of information analysis may be very useful to investigators as they write their applications. And one of the questions our group will look at is the extent to which those methods, such as value of information, can be practically applied by grantees in describing the significance of what they're doing. I mean, it's really quite interesting. Sort of no self-respecting

investigator would put in a clinical trial without a power calculation. But in the significant section of our grants we sort of say, oh boy, this is a big problem. And that seems to be enough for everyone.

Hopefully, we can learn to do a little better about that. Now, one has to be careful because you can't do $150,000 value of information analysis to prioritize a $25,000 research project. So, we've been thinking a lot about that and I and others have done some work with AHRQ looking at less-expensive ways to use value of information principles as a way to inform priorities. And so, those may be some examples.

This is sort of a suite of tools, and we want to help people think about the best way to do these things.

DR. KRUMHOLZ: And I think just a quick follow up. I mean, just the framing and the conceptualization, even if people don't go through the entire process of doing the entire study. I'd love to see that in agreeance where people are at

least making the case in that construct. That's really great.

DR. MELTZER: Absolutely. There are beautiful examples even recently of large, expensive clinical trials that were funded despite the fact that there were very likely substitutes for the treatment being studied that were very close. And, in fact, were quite likely to be available even before the study was done. And those are investments that you should be careful with making.

DR. GABRIEL: Harlan W.

DR. WEISMAN: Yeah, I think the current conversation covered the comment I was going to make, which was that maybe more than our prioritization, our immediate prioritization, because we do want to accelerate that to some extent beyond your timeframe. It is the actual grant prioritization, granting process where this may be of terrific value. Plus as you indicated, the ongoing look at priorities.

The question I had about this is one of

the things that comes up in peer review a lot, but just in life in general, are the pre-suppositions or pre-conceptions that we all carry around with us about how the world works. That often means that new ideas or new ways of doing things don't get done immediately. And there's lots of, you know, at least anecdotes of somebody who had a thought about something really important and couldn't get funded, you know, for many years because the usual study sections just didn't get why this was so important.

And so, what I was wondering is, in any of what you're doing is there anything that unearths or flags the idea that lets us know whether, you know, how much bias is coming in -- in terms of our -- not the conscious bias, but the -- maybe the unconscious preconceived notions.

DR. MELTZER: Yeah. We haven't gotten deep enough into our analysis of what we know about the peer review process to answer that ideally. But what I will say is that clearly there have been changes in some institutions, grant review

processes such as NIH, to try to put more emphasis on innovation, for example, as a value.

I'll also say -- and this is very much a sort of personal belief as opposed to any reflection of any belief on the committee. That certain elements of process in grant review such as triage processes tend to make it more difficult for innovative ideas to come through, because people may not see the value in innovation. It just seems confusing or doesn't make sense to them.

And so, I hope that one of the areas we'll look at very carefully is the triage processes. I think many people in the room may know NIH now has a process where the bottom half of applications aren't discussed. And my sense is that the failure to discuss applications may lead to less appreciation of innovation. And I'm not sure that's in the long-term interest, particularly of a field such as Patient-Centered Outcomes Research. Where really in many ways we're all about innovation.

DR. GABRIEL: I think it was Joe and then

Steve.

DR. SELBY: Just struck me that yesterday we were talking about the way in which PCORI was blessed to have a stellar Board and a stellar Methodology Committee. And that most organizations don't have particularly a Methodology Committee on day one. And so, these presentations have already kind of been driven home, the common ground and in the utility. The need we have for your input.

I wanted to just put two other areas on the table. I mean, the first is the National Priorities. I know that in some ways some of your methods speak more to selecting the right research question given the priority, but particularly in the area of topic generation it, I think we'd like a chance to run our strategy by you before we go out and engage with large stakeholder groups. And I know your committee is especially strapped. So, I think I propose that we come to your committee.

And since you haven't gotten to hear our presentation yet, run it by you. Unless you're here tomorrow morning we'll be doing it again

tomorrow morning. But -- and get your input with respect to topic generation.

The second is, we've said that you know, the review process we're going to go through with NIH for the Pilot Projects is itself a pilot. We want to test how it goes. And so, I think it would be extraordinarily, I think I said this a while ago, but now I'll redouble my comments that we said we want to evaluate that. And I think it would be just a really extraordinary opportunity to evaluate whether the theme of patient-centeredness came through in the process, given that there were patients there. Given that we had particular criteria and instructions beforehand.

So, thank you.

MS. SLUTSKY: Can I just respond to that? I mean, in addition to -- I'm on the sub-group too. And in addition to, you know, interacting with the sub-group there are some ARRA-funded projects that could potentially help you. One is, I can tell the jet lag is jumping in, is a process of developing a methodology for horizon scanning. And that was

funded by AHRQ under ARRA, and we're about halfway through that process. And white papers are going to start coming out for public comment in the very near future. So, not only will that inform this sub-committee, but I think it will be enormously useful for PCORI.

We also have a series of papers on research gap analysis that are coming up in draft form that will predate a more thorough review of gap analysis that will be useful to PCORI.

DR. GABRIEL: Steve?

VICE CHAIRMAN LIPSTEIN: David, can you go back one slide? Arnie can help. No, one more. One more. There it is. Value of information analysis before peer review.

Harlan triggered this question in that he brought up the subject of investigator-initiated research. And if PCORI, you know, if all investigator-initiated research today was patient-centered, you would wonder why we would have a Patient-Centered Outcomes Research Institute because there wouldn't be any question as to

whether it was patient-centered or not.

So, as you do value of information analysis, and you talk about segmenting the population into different groups which may have different priorities, okay? So, different groups of people may have different priorities. And we want to be sure that whatever we fund is of the greatest benefit to the most people.

And an investigator can always find a group of patients or a cohort of patients for whom their research is a priority. So how will that part of this help us to do that hard work and to assure the public that we have picked the right priorities? In other words, is there something inherent in that third blue box that gets us there?

DR. MELTZER: I think there are some tools that help us. The way that I've personally found the most useful in thinking about this is that there's a set of individuals who each have different preferences. And because of their preferences they get different value from different pieces of information or different decisions that

could be made.

And when you provide information or you make a decision, you are helping different sub-groups differentially. And so, there's this idea of sort of the expected value of individualized care. What's the value to the population when you make care more individualized? And this is work that Anirban Basu, who was the lead author on, Anirban Basu was one of my students in Chicago. He's now here at the University of Washington. And he and I and now others have done work trying to quantify what the value is to making those individualized decisions.

And when you do that, you get the value to the person or to the group. You can then think about how large that group is and how much value you've produced for that.

Now, that may or may not be enough to make a decision because, of course, if the group is very small but the benefit is very big you may feel differently than an outcome where you have a very large number of people who benefit but each benefit

a little. So, distributional concerns can matter. And a lot of that can be fed into decision-making.

So, I think what we want to begin to do is to try to characterize the distribution of benefits to sub-groups as best we can, and understand what they are. And those sub-groups can be very complicated. They're not just people who differ in preferences or health attributes. They could be people who differ in choices and the decisions they make and the economic resources they have available. And how informed they are. And each one of those things can shape this. And that's where this gets to be really challenging research.

But I think these are somewhat answerable questions.

VICE CHAIRMAN LIPSTEIN: So, given how challenging it is that you just mentioned, it sounds like it would be unreasonable for PCORI to require that every proposal that we receive go through that distribution of analysis. In other words, what's the value of the benefit to how many people? Is it big benefit to few or little benefit

to many?

We couldn't require -- could we require that of every proposal?

DR. MELTZER: No, I don't think it's reasonable. But I think what one can move towards is an understanding of those issues.

For example, you could say -- to give an example. We've done work on intensive therapy for diabetes. We would argue -- I would argue that based on our research, intensive therapy for diabetes particularly among older people often causes as many harms as it causes benefits.

But we also find that there's a sub-group in whom it's clearly beneficial, okay? Identifying that group, focusing on that group and what this research could mean to them would be an example of something that would move towards this and not be an impractical way of thinking about it.

So, you know, we are never going to make perfect prioritization decisions but we can move towards better. And that, I think, is the goal.

CHAIRMAN WASHINGTON: Can I just say on

this question, Steve, I would see us applying this at the Board level, sort of over continuum of the research that we are funding, rather than having to set a requirement.

You know, when I saw that, you know, to me that's where the impact is and the real value added of such an analysis.

VICE CHAIRMAN LIPSTEIN: Yeah. Gene, what I still don't have an appreciation for is how hard it is to do that. So, if we do that at the Board level, is that a hard thing to do?

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. MELTZER: Yeah, to make the -- that there are older people who have very long life expectancies and should be thinking about things 10, 15, 20 years down the road.

VICE CHAIRMAN LIPSTEIN: Right. So I guess what I'm hearing is that that's a construct we will be able to employ even though it's very hard to do.

DR. MELTZER: To some degree we should be able --

VICE CHAIRMAN LIPSTEIN: Which you said was very hard to do.

DR. MELTZER: -- to add some of that into the process. And hopefully over time we'll get better at it.

DR. GABRIEL: Imperfect but helpful. So, we'll go to Harlan and then Mark and then we need to go on to Steve's work group.

DR. WEISMAN: I really liked the way David Meltzer answered your question. But just to reinforce parts of it, because you said, how do we ensure that we do the greatest good for the greatest number. And that's, you know, Dave Hume, another David. That was his philosophy that was, you know, really troubling because what happens in society -- and that was his rule of society, is that the most disadvantaged people who may be small in numbers suffer the most at the hands of optimizing the greatest good for the greatest number.

So, clearly wanting to do that. You know, and there were counter-philosophies saying that

what society should do or PCORI could do would be to help the most disadvantaged, because they need the help the most.

And the reality is, it comes down to judgment. And I would therefore say what Gene said, which is that we should take these factors into account in deliberation. But when it comes down to it there aren't any easy rules here. It requires discussion and debate and going back and forth to discuss these various kinds of factors that are important. And it's never as easy as some arbitrary greatest good for greatest number, or help the ones that are least able to take care of themselves, or categorical imperative.

DR. HELFAND: Mark Helfand, Methodology Committee. So a lot of these comments, Steve's and Harlan's earlier comment, they fit together in this, you know, we're already talking about trying to get them into the process for peer review and so on. But there are a couple of points I just wanted to bring out because -- so we don't lose them.

So one of them is, you know, ultimately

how do we tell if it's the real thing? And it's really an important question that people care about that's affecting their decisions and it would help them make better ones and so on? And I think, you know, even if they can't do a big analysis, we have agreed that's not what they have to do.

People who write proposals typically sort of say stuff like that. They say, oh, this is a very important question that affects a zillion people and everybody cares about it. How do we go from there to saying whether that's genuine or not? And I'd connect that a little bit to, I don't know if I'm doing this fairly, Harlan, but to Harlan Krumholz's earlier comment about questions coming, if I could paraphrase a lot, you know, questions come from real lives and real practice. And if you can harness that ability to get a feedback loop between what's actually happening and people who cared about it into what PCORI's Research Agenda is, that helps you with, I don't know what the word -- the right word is, but with the provenance of where these questions came from and can help you a

little bit.

And so, there is an element of that that I think we can try to join with these other approaches that we're talking about.

DR. MELTZER: Gene, could I just add one last comment? One of the wonderful things I've learned from Steve Pauker over the years, for those of you who don't know him, is really one of the pioneers of clinical decision analysis, is the idea that decision models when they're constructed are invaluable not so much for the results they give, but the process they lead you through as you get there.

And I think that's very much the hope with a lot of these research prioritization methods. That they'll get us thinking about the right things, and then with a robust peer review process those issues will be brought forward and discussed and we'll get a sort of comment about the distribution of benefits. I mean, how often do you hear that in an NIH study section or any study section? Not too often. So, I think this is one

of the hidden benefits of methods, even when they have imperfections.

DR. GABRIEL: Thank you, David. Dr. Goodman.

DR. GOODMAN: Next slide.

UNIDENTIFIED SPEAKER: You have to do it yourself.

DR. GOODMAN: Oh, I see. I have to do all this work myself. Okay, there we go. Don't we have a committee for this clicking?

[Laughter.]

DR. GOODMAN: Okay. So, our working group does everything else. So, we are the Methods Work Group of the Methodology Committee. And, oh, sorry. Yeah, here we go. See, it didn't work. There we go.

And this is made up of myself, Mike Lauer, Robin Newhouse who is my co-chair, Mark is the liaison to the Assimilation Group, Sebastian Schneeweiss, and Sharon-Lise is -- comes to our group whenever she can as the designated biostatistician. And we also have a new

researcher, Crystal Smith-Spangler who is right here behind me, who is also responsible for some wonderful work in preparation for this meeting.

So what is our scope of work? You've heard some of this already. We're directly responding to the legislation in terms of two of the deliverables specifically that we have to produce by May. Which is, one, developing a translation tool. We like to think of it as an instrument or tool rather than a table because a table implies a particular format that helps guide researchers and reviewers from the research questions that are posed. And so, in this sense we're taking a hand-off from Ethan's group. We're a little bit silent on how that question should be posed, in the sense that we don't explore the patient-centeredness of it. But that's a critical issue here, is whether the question is the kind of question that PCORI should be investigating.

And we go from there outlining a set of criteria that will specify those designs that best address the question. And perhaps most importantly

for the Board and for reviewers, that are really non-responsive to that question. And that might be our most important contribution to the committee.

The second mission and track of work is, again, outlined by the legislation, which is to review and issue statements on methods standards. Now, we don't love the word "standards" because there are very few methodologies that aren't in flux and aren't improving. And standards also can be a straightjacket and prevent innovation.

So, we see these as guidelines for, in a sense, best practices in implementing the various methodologies that might be employed in the design and analysis of studies. And these are both abstracted from formal methodologic standard statements that have been issued in just a few areas by expert bodies like the IOM or the FDA or other entities. But the vast majority of methods don't have official bodies that issue standard statements.

So, a lot of this work will be work synthesizing methodological papers and guidances,

again, about best practices. There are plenty of technologies about which there are books but they're not what we would call expert bodies that issued standards. But they're certainly standards of a sort in terms of outlining current best practices.

And the flipside of this is identifying areas for further methodologic research. So in looking at where the state of the methods are today, we also will identify where they need to go, particularly in the area of Patient-Centered Outcomes Research, which hasn't been a huge focus of many of the methods that we'll be talking about.

The third stream is to look at the whole question of the use of electronic data records and systems as a platform for patient, you know, for PCOR. And this we think is a real opportunity, as we put here, for PCORI to take a leadership role, because there's a huge amount of activity going on in this country in the electronification of health data. Very, comparatively little attention has been given to how that information can actually be

used to answer important research questions.

And these systems are being designed and implemented as we speak, and in many ways and in many places maybe getting in the way as much of good health research as facilitating it. And there have been a lot of activities to help bridge that gap, and we can be a central federal leader in making sure that these activities are brought to the attention of -- at a high level sustained, perhaps, with funding and used to establish standards for future directions of development of these networks, many of which don't talk to each other or don't capture the information we need.

So what progress have we made to date in these three areas? We -- and we'll talk about this in a second. We've established initial specifications of the dimensions to be used for the transaction instrument. And I'll talk about those momentarily.

We've developed a prototype for standards documents that combines expert statements and published examples from the literature as well as

our own input. And finally, in the electronic data arena, where we feel that we need a lot of education ourselves, because one of the problems in that area is that the people who are developing the systems and the methodologists are very separate communities, for the most part. And in fact, there's very few people on our committee with any expertise in this area.

Now Jean, her shop has been funding one of the most ambitious series of meetings and papers and they call it the Electronic Data Methods Forum, or EDM. And that's really just in its first year. And many of the products of that research program are actually just coming out right now. They had their first meeting in February, but they had commissioned a series of white papers that are directly on point that are actually due, I think literally, this week or something like that. So, we're going to benefit a lot from them.

Our Deloitte folks who have actually had some expertise in this area, have been interviewing a wide array of opinion leaders in this area to

both set out what they and we think are the key issues that PCORI should think about, and to set the stage for the planning of a workshop in January where these -- where those issues are discussed.

So this is -- we don't have a specific agenda in this area. What we're doing is, we're acting in an exploratory and advisory role to help you figure out what that agenda might be, both for future research priorities as well as for methodologic development.

Sharon, did you have a question?

DR. LEVINE: I just wondered if you're including in the work the developers of these EHR software systems?

DR. GOODMAN: So, yeah, absolutely. Yeah. They are key, if we don't get them in port, nothing will ever change. That is definitely a very important constituency, a key constituency.

So we're not showing you the full agenda for the electronic data methods work. I'm just showing you here what we're talking about when we say dimensions and format.

So here are examples of the dimensions to be used or proposed to be used in the translation instrument. And we start, of course, with a patient-centered question that defines the condition, the population, the treatment, the comparators, and perhaps most importantly the outcomes and the setting in which the research is to be done.

And then, the choice of design or the choice of acceptable designs involves weighing a lot of factors. And these factors are those intrinsic to the research design itself, which can include what we call internal validity, or is, how far are we away from the answer on average, just by nature of the design of the research.

External validity that is the population we're studying close to the population in which we actually want to know the results. Precision, are we far from the result simply because the study is too small? And you can be far away by chance. A key issue is, of course, heterogeneity. A technical term for, are there sub-populations?

Maybe not down to individuals, but as close as we can come, that have a different profile of risks or benefits such that we should either be studying them, avoiding them, or making -- tailor treatments on the basis of that profile. And, of course, there's the ethical aspects of the research itself.

Extrinsic factors, which again, also often be more important than the inherent properties of the design, are how quickly does the decision have to be made? Which can be a function of both policy issues or is the technology changing every six weeks? And we can't wait three years to have an answer about technology that's going to be obsolete.

The logistical burden. We may not be able to literally have the money to study in a randomized controlled fashion 10,000 subjects. So, the complexity and the cost.

Now one point there that has come up in our conversations is that's something that research funding agencies can affect, because the logistical burden of setting up many of these studies is often

huge simply because data networks or collaborative systems haven't been set up. Or the ones that were set up in prior research enterprises have been destroyed because the funding didn't continue.

So this issue of the logistical burden, which often is a deal-breaker when we're talking about the optimal studies, is something that might be on PCORI's agenda for the future. Which is, how to make the best studies easier to start? And so, we don't build and destroy, build and destroy the networks that are so hard to get together to make research easier.

And finally, there are the constraints that we all know about. Is the data in the data systems? And this interfaces with the Electronic Data Initiative. Is it there, was it measured? Was the outcome measured? Were the other patient characteristics measured?

Again, that's often where the research decision is set. You might want to do a -- you might have a great platform for retrospective study, but the data is not in the data system. And

other things like is randomization possible?

So those are the kinds of dimensions we're thinking about. These may be tweaked, they may be added. But it's all these things that enter into a typical consultation. And hopefully, we'll be able to combine these in a creative, user friendly way so we can define which approaches are most within the acceptable range and which ones are really not things that should be considered as responsive to the questions posed.

Yeah, Steve.

VICE CHAIRMAN LIPSTEIN: Can I ask a question? Going back up to the top where the question -- where you show the question -- you say condition, population, treatment and comparator. The issue of comparability of populations. So, many times the medical community will come back and say it's not just comparing the treatment to a comparator, but my patients are different.

DR. GOODMAN: Yeah.

VICE CHAIRMAN LIPSTEIN: So, how do you deal with the questions of population

comparability?

DR. GOODMAN: Well, that's in this external validity or generalizability or transportability. That's the second bullet there.

VICE CHAIRMAN LIPSTEIN: That's where that comes in?

DR. GOODMAN: Yeah, that's where that conceptually comes in. The question is, how do you actually deal with that? And then, you have to look very, very carefully at what are the dimensions on which they're saying the populations are different? Are they saying they're different because, you know, they are a different height and a different hair color? Are they different in some way that there's actually a plausible either biologic explanation or evidential basis for saying that population is different?

It’s not enough just to say my patients look different. There has to be an evidentiary base for saying they are different, or a reason to explore that in the studies. I mean, that may be the purpose of the study is to explore the

difference between those populations. That can be an aim of the study.

We may already know that X treatment works on average for a given population. But there may be evolving information that suggests that a particular genotype or a particular sub-group or a racial group is in fact not responsive or is subject to more harms. That's the reason for a study.

VICE CHAIRMAN LIPSTEIN: So, but it isn't just biological differences. It can also be environmental differences.

DR. GOODMAN: It could be.

VICE CHAIRMAN LIPSTEIN: In light of circumstances.

DR. GOODMAN: It could be if they plausibly affect the effect of treatment, yes.

DR. GABRIEL: Do you want to take questions now? Or do you want to go to your last slide and then take them?

DR. GOODMAN: Well, I'll take questions on the Translation Table part.

DR. GABRIEL: Okay.

DR. GOODMAN: And then -- yeah.

DR. DUOMA: If we're truly patient-centered, it's not just the effective treatment, it's the desire for outcomes that can vary from patient population to patient population as well. The treatment can be the same, it's just I don't want the result that that treatment gives and that gene does.

DR. GOODMAN: Right. Well, what that person needs still is the evidence in which those outcomes are measured. And one person may put weight on one outcome, quality of life, and the other patient may put emphasis on survival. And, you know, you can look at the same study and see that people who survived longer were more miserable. And you can make your choice.

But you have to have the evidence there in the first place.

DR. EPSTEIN: Steve, what are the parts that you focus on that are most patient-centered?

DR. GOODMAN: I would say the question

itself. I mean, that's really where the patient-centeredness, the choice of outcomes, the choice of the condition, the choice of the comparators, the setting. That's where I think the patient-centeredness most comes in.

I would say what follows is, you know, is certainly ethical dimensions. The heterogeneity is a big place in the sense that you get as close as possible to sub-groups that might have differential response or meaningfully differential response. Other folks can maybe see other dimensions for it.

But I think the question itself is 90 percent of the game. And then, the kinds of things that you measure about people, which goes into some of the outcomes, that allows you to separate them into sub-groups that allow for meaningful comparisons when they, in fact, exist -- or differences, would be the other place. Or perhaps you or others could add to that.

DR. GABRIEL: Rick, and then Harlan W.

DR. KUNTZ: Well, first of all, it's really great you're taking on this amazing task.

And I know that the Translation Table has been somewhat ambiguous in trying to put your handle around it and to many it's kind of a Rosetta Stone of the Nth degree. Do you envision this as actually a stress test device that you would apply to original research that's proposed? Or is this actually a device that provides a range of methodologies for a question that's asked?

DR. GOODMAN: It -- well, measuring my stress?

So, I see it playing both roles. And actually we very actively discussed it this morning. Is this -- can this be used to define -- what's more important? Defining the best design, defining the unacceptable designs, ranking the designs? I mean, in a sense there's no ranking, it's difficult to rank designs in the same reasons that it's difficult to choose best treatments for everybody.

What's most important to you will determine what of several design choices you might choose. But what's more important for the PCORI is

those designs that really, and this feeds into what David was talking about, are very unlikely to yield meaningful information that's claimed in here. You know, there are many, many studies of diagnostic tests that don't even come close to anything resembling patient outcomes. Or, of registry studies, registries are often put out there as an easy answer to many questions. But in fact, the range of questions they can answer is very, very limited.

I would also include issues, you know, regarding the data availability. If the information is simply not there, a claim, you know, no matter how big your sample size is when you're looking at all the claims in Tennessee in a 10-year period, if the outcomes are not measured properly or the relevant patient characteristics are not there, it's a useless study. It doesn't matter if it's 10,000 or 10,000,000.

So, helping define what are the -- in a sense, the best studies, to answer your question. Now you may not need the best, by the way. You

know, given what -- how much you need in any given situation you may just need enough. And what may be much more important than the best is getting enough to make decisions in the next six months. That's plausible at acceptable costs.

So, I would say it could play both roles, and this could be advisory both to reviewers, to researchers, and, you know, it will be a work in progress. Because obviously this is -- this sort of captures all of science. And we'll do as much as we can by May and then we'll do more after that.

DR. GABRIEL: So, Harlan W. and then Bob and then we need to go on to Mark.

DR. WEISMAN: So the question was whether you want to go to the last slide or because I can defer my question to the end.

DR. GABRIEL: So, the last slide is simply a timeline or a next steps. And really, I think, you know, each of these groups kind of identified a question for the Board. But you're already answering, you're hitting on the question that we were going to present.

DR. GOODMAN: Yeah. What I should do, is just the lower part of this slide, I'll just read through it. So, what should you expect to see for these methods or standards documents? That's actually a very different product here.

So we're developing a prototype for a document that first of all talks about the method. It talks about the key sources that we extracted or are going to develop recommendations from. What those recommendations are, our own commentary on it, particularly looking at it through a patient-centered lens, published examples of best practices, and other tools for researchers.

So, we see this definitely as a communication tool to the research community saying not go read that book but, you know, here are the published standards that you should adhere to or try to aspire to if you're going to submit a study to PCORI.

One other area where we discussed this morning is on -- is the area of where we could take leadership of reproducible research. That is,

there's lots and lots of discussion about the extent to which scientific results are reliable, and there's already a pretty mature conversation in the research community about making the methods as accessible as possible so we can issue the current state of the art in how scientists who submit to PCORI can make their methods as transparent as possible so they can be subject to meaningful either analysis or scrutiny. So that would be an example of one of many methods.

Again, we're not going to address the entire landscape by May, but we'll choose what we think are some of the big ticket items that cut across many, many methodologies. And then, we'll move on from there.

DR. GABRIEL: Harlan?

DR. WEISMAN: I just think, Steve, that this, and the work that you're doing, is incredibly important and I'm just going to concentrate on the health informatics piece of it. And you've already alluded to the fact there's a lot of stuff going on and the EMR and EHR-type work.

There are a number of efforts under way today. One of them is OMOP, which is the Observation Medical Outcomes Partnership, which NIH is doing and they're doing their thing.

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. GOODMAN: Yes, at NIH. Yeah.

DR. WEISMAN: And FDA's Med EPINet, which is the medical device version of it, is just getting underway.

There's the whole meaningful use issue that CMS has underway with, nobody quite knows how to use this stuff, but you by 2014, I think it is, we have to show that they're meaningfully being used in practice. And I think this work is going to be incredibly important, because right now it's a world of chaos.

And I also think it's going to be important not just for PCORI but just in general as a place where PCORI can work in terms of helping issue standards or at least guidelines or some trusted source for how to do this work in all sorts of ways. One of which is, you know, the business

that I'm involved with and Rick is involved in and that's in medical innovation, because one of the questions -- by definition, something new has less known about it than things that are established. And that will always be true.

So, what is it that we need to know before something that's really, has the potential to be meaningful, and has standard efficacy and safety information available? What are the competence intervals around -- have to be, before you let it out in the real world? But then, how do you go on and learn about it and continue to learn as you go about its profile? And where it works and where it doesn't work, and what are the situations that are most important? And today, there are all types of efforts underway to try to understand that. But none of them are successful and there's a lot of frustration around this whole issue of introduction of new treatments or new diagnostics when existing ones are around. But how you study it in the real world, which is always the remaining question. No matter how many patients you studied before a new

therapy gets out there, you still are left with what happens in the real world? And I think these approaches are to be incredibly important.

And it sounds like you're already tapping into all these other ongoing efforts.

DR. GOODMAN: We're trying to capture them all and figure out what role.

DR. WEISMAN: And who from Deloitte is?

DR. GOODMAN: Reneisha Watson [phonetic] and Howard -- what's his last name?

OVERLAPPING SPEAKERS: [Off microphone.]

DR. GOODMAN: What? Oh, sorry, yes.

DR. GABRIEL: Would it be okay if we went to Bob and you could try and manage both questions, respond to both together? I'm just a little worried about time.

DR. GOODMAN: Yeah, yeah, yeah.

DR. WEISMAN: Go ahead.

DR. ZWOLAK: Bob Zwolak. My question is actually somewhat like Harlan's but vastly more simple.

DR. GOODMAN: Those are the most dangerous

ones.

DR. ZWOLAK: And it does involve, in fact, Informatics and the EMR. We seem -- the country seems to be coalescing around maybe half a dozen major EMRs. And my impression is that if we can harness the data collecting capability of those EMRs we could develop very rapidly the kind of data that I think Harlan and I both think is needed and especially potentially with ICD-10 on the way for more granularity.

But there seem to be proprietary and fiscal blockers out there, potentially to the use of these EMRs. Have you looked into that or do you plan to look into that?

DR. GOODMAN: Well, that's one of the four or five topics that was proposed as a major and potential focus for the workshop. So that's certainly on the table. And to the extent it affects functionality, it has to be on the table because -- so, yes.

DR. GABRIEL: Okay. Well, thank you, this was a terrific discussion across all three work

groups. And just to thank again the three work group leads and all of the members for their very hard work. I think you've seen the progression and the maturity and the evolution of our work.

I had mentioned, I think I mentioned more than once that -- I think we'll hold off. I think I mentioned more than once that the Assimilation Group really pulls information together real-time and tries to knit it together into a story, into the report. And Mark has been doing that even as we've been chatting here. And is preparing, has prepared his remarks just to kind of be shared with the group verbally and to get your reactions.

So, Mark?

DR. HELFAND: Yeah. Since I don't have slides I can't show the pictures. But you've already seen them because we're each a liaison to a different group that's already been shown. And so, Al Berg and Dave Flum and I are the members of the Reporting -- oh, we've got it. Actually you got a slide for that. Okay, never mind. All right. That's my whole slideshow. Okay.

So we're going to return back to the overview level about what this Methodology Report or the May 2012 Methodology Report is going to do, and rather than the detailed level we've just gone through. And recall that our group, as Sherine has said both at this meeting and the previous meeting, is to resolve overlap issues between the other work groups and knit the pieces together, identifying and making sure we cover the ground we want to cover in the May 2012 report and later.

And part of that, as you know, part of that effort of making sure we cover what we need to cover and the first, in the May 2012 report is to get and use input from Board members regarding the report, as we've done over the last few weeks.

And I have to say if you -- you know, from the discussion today we've -- I'd say I don't think we can take any credit for it in our work group but there's been a lot of resolving overlap issues and seeing how these things fit together that has just happened with the three work groups. I don't, you know, what credit we deserve but it makes our job a

little easier.

Okay, so I don't think we deserve any credit. I don't think we deserve any credit.

UNIDENTIFIED SPEAKER: [off microphone.]

[Laughter.]

DR. HELFAND: Let's lead up to the May 2012 report and what the, you know, what the scope of that is. So as has been said before, Methodology Committee's sort of, you know, real obligation here is to produce a report that will include a Translation Table which you just heard explained, some recommended standards, and recommended actions deemed necessary to comply with the standards.

So, let's pull back as Dr. Selby said earlier this morning. PCORI needs to do research. And a patient-centered question is the starting point for that research.

And Ethan as well as public commenters and Board members have said, Ethan and his example of nausea related to chemotherapy. That sometimes as a patient or family member or a practitioner, we

learn that the patient-centered outcomes are unknown. Or, the only information about them is incomplete or even biased sometimes. And in this situation, disseminating the information we already have isn't enough. But neither is doing -- just doing more research. And to be useful, that research needs to be on target for you, and it needs to be carried out in a credible, trustworthy, timely way.

And this is what we mean by putting the research questions through the PCORI lens. Getting the questions right and judging their importance on the basis of their value to patients is part of the mission of PCORI, and also part of the methods for Patient-Centered Outcomes Research.

So the Methodology Committee's main job is to ensure that PCORI and, we hope, other research organizations, answer patient-centered questions in the best ways possible. And as you've seen, especially with Ethan's group, we're looking at ways to get the questions right from a patient-centered viewpoint and from Steve's group at ways

to answer the questions choosing among reasonable options for getting the research data, for designing the studies, and for analyzing and reporting the results.

Now an important aspect of this is that the more new and different and patient-centered the questions are, the greater the need to take care that the way we answer them, the methods we use, are fair, practical, and reproducible. Often we'll find there are solid and good innovative ways to do that. And other times, we'll find there aren't.

So the other big part of our job is to identify these situations and recommend steps to improve our infrastructure and techniques, which is a long-term and ongoing program.

So if you look at the Methodology Report for May 2012, it will lay out the rationale for a Methods Report. And what we hope is that it will bring us from looking at questions and prioritizing questions through the patient-centered lens of PCORI to standards for how to conduct research to answer them.

As a first installment, it's intended to enable PCORI to take the first steps to establish and carry out the Research Agenda as PCORI is required to do. And today, which I was very pleased to hear all the discussion about ways to do that once that is sort of set. That the standards are a step for PCORI to write its funding announcements, evaluate proposals, reevaluate research that's underway, and perhaps affect how we look at the reports of that research.

A lot of the discussion today has been about, well how do we do that? What's the concrete way? Does this go into criteria that researchers who are submitting proposals have to address? And all these things are something that I have to say, while I'm very happy to hear that that was such a big part of the discussion today because it means that between now and May, perhaps in this report that's aimed at this goal, getting started, we would get sort of a richer follow up for the how to do these things. How to implement -- [microphone turns off] -- rather than having to do that

sequentially, have the report come down in May and then start thinking about that.

So, I was very pleased with the way things knitted together today. And I'll stop there.

DR. GABRIEL: Okay. And I actually have three more slides, but we'd be happy to -- if there are questions now or we could finish. But really, the issue related to the Report Assimilation Group is how can we continue the conversation that we started with the Board that Mark started and led with the Board with those two conference calls, which have been you know, once again very helpful and very eye-opening in many ways. And we don't want to stop there; we want that to be a first step.

Okay, I'll finish up. Okay, wrap up. You'll be happy to hear.

So, just to give you a sense of how much interest there has been in the solicitations for these contracts that we're looking to fund. We've had a total of 62 letters of intent received. That's kind of good news and bad news, since we

have to review the resulting proposals that come in. Maybe not all 62 will end up submitting proposals, but that's very encouraging.

What you see there in the list of questions is that we've also received quite a number of questions and comments about the solicitations that will actually help us the next time we go out and solicit this kind of work. So again, the kind of continuous improvement notion that seems to be part of everything we do.

The other comment that I would make here is when we look at the list and we're kind of keeping it confidential for the moment. But when we look at the list of individuals and groups who submitted letters of intent, it's really not the usual suspects, which is reassuring. We're getting a much broader community of respondents, if you will, from different organizations. It's not what you would expect, I don't think, in response to an NIH solicitation. So we see that actually as a positive, credible, but not the usual suspects types of respondents. But, more to come on those.

The other thing I need to do, and actually, Sharon-Lise is going to comment on this, is the first response for proposals are due for these, again, contracts not grants. But the first of these is due to arrive September 30th. That's the deadline. Obviously prior to that time we need to have in place a review process and a set of principles that guides that process that we can look to. And I'll just ask Sharon-Lise to go through the slide, and then we're done, almost.

DR. NORMAND: So, thank you very much. So as Sherine indicated, we wanted to make sure as the Methodology Committee that we had our process down before we actually saw anything in terms of receiving the actual proposals, which are contracts.

And so, we have envisioned a four-step process. The first is an administrative review. And by that, we are hoping that the PCORI staff would look to make sure that it was sort of the right response that the page requirements, all that kind of stuff made sense, but importantly, also

identified conflicts of interest for the members of the Methodology Committee. And so, to make sure that that happens, so that's the first step.

And once the conflict of interests are identified, then it would go to a content review. And by content review, that would mean it would be directed towards the working group that actually put together that solicitation. That working group would be supplemented with other Methodology Committee members, to the extent possible because we need more heads than that are involved in each working group. And that working group would sort of ensure that the content is aligned with the spirit of the particular solicitation that was submitted.

And then, it would actually go to the full Methodology Committee for a full review. And so, again, absent those people who have a conflict of interest -- and so, these particular contract responses would be reviewed by the full committee, again, to sort of assess as a group whether or not they're meeting the needs as the Methodology

Committee sees it.

We anticipate this being very timely in terms of our entire review process. That is, the PCORI staff, make sure that they're aligned with the usual rules. We identify the conflicts of interests. The content review is undertaken by the working group, supplemented with some Methodology Committee members. Then it goes for a full Methodology Committee review.

And then, we will make some recommendations that then will go to Dr. Selby. And really, it's Dr. Selby's call in terms of who the particular contracts get awarded to.

And again, we're really adamant that we need to have this all written out and sketched out before we see anything. Right now we only know the Letter of Intent. We actually are blinded to sort of, you know, we don't see any of these things. We will not see any particular proposal without sort of going through this process.

And so, that's a brief process that we've been thinking about, have discussed, and one that

we think is a reasonable one to make sure that we're on our timeline.

DR. GABRIEL: And again, we're hoping to do all of this probably in two weeks. Applicants are notified two weeks after submission.

This is my last slide, and it's really just a reminder of the timelines. And you've now heard detail about all of those green boxes. And so just to give you a sense, again, of where we're headed and what we're doing.

And so, I'll stop there. And if there are questions, particularly regarding Mark's comments or really anything, we'd be glad to entertain them at this point.

[Applause.]

VICE CHAIRMAN LIPSTEIN: Yeah, Gene, I was --

CHAIRMAN WASHINGTON: Sherine's still in charge.

VICE CHAIRMAN LIPSTEIN: Sherine, I was just going to say, Sharon and I were commenting. If you all are as smart as you sound, we are truly

blessed.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: I mean, this is just an incredible amount of work. And it just highlights the potential that we have if we're able to employ all this work in setting priorities and establishing a Research Agenda. So, thank you.

DR. GABRIEL: Thank you.

CHAIRMAN WASHINGTON: Steve is already making my summary comments. But I will just add on to that. It's not just an incredible amount of work. I mean, it's beautiful. And it represents just terrific progress. And it also shows what happens when you really focus because you've got a real deadline looming on the horizon.

And, you know, actually I'm looking at Sharon as I'm hearing this because I'm already thinking, wow. We should, today, be planning the dissemination effort around all of this. And it's not just a report, it's the findings, it's the recommendations. There's, to me, this would represent a significant contribution not just to

the PCORI -- I keep reminding us, this report is for the nation as it relates to methods. So, thank you.

And, you know, I wanted to stand up and applaud, but I said, oh, we don't applaud at PCORI Board meetings, but you've already done that. Because I felt like I was watching a performance of the L.A. Philharmonic. So, Sherine, your new name is Dudamel because you've been orchestrating. And I've got to come up with a name for Sharon-Lise, but I'm working on that and I'll have one by tonight.

DR. NORMAND: You know, what I wanted to say, and I know Sherine is dying to ask Gail, but we've got all of our Methodology Committee members behind us. And I don't want anybody to think it's just us sitting up here.

[Applause.]

DR. GABRIEL: So Gail, do you have a question?

DR. HUNT: Yeah. Sharon-Lise, could you just really briefly, what's the distinction between

the content review and the programmatic review that is the committee? And then the whole, I mean, is the sub-group and then the whole committee.

And also, isn't this January 2012 workshop or summit that you guys are going to hold on methods, isn't that really a way of sort of showcasing the outcome of what you all are doing on a national level?

DR. NORMAND: Well, I think there's several, so let me answer the first question first.

So, the difference between the content review and the full Methodology Committee review. The first is really to -- for the working group to really, for them, because they've been working about it, thinking about it, breathing it, and saying you know, these really make sense. And they're actually going to come up with some preliminary scoring system. Think of it that way. And they're going to come back and say we had 20 solicitations, 20 responses on this. We think that these five make it. And so, that's their job, is to really -- because they wrote the solicitation.

They really need to review that.

The programmatic review is really for all of the proposals that come in. That we can actually select them as a full group to say, well is it really -- are these meeting all our needs. And maybe there was something that came in that perhaps the working group felt, it's not really responsive to this. But it may be that when the full Methodology Committee sees it, we're going to say you know what? That's actually going to fill a hole.

I think that's what we're thinking, but I would like to ask Sherine, is that?

DR. GABRIEL: For those of you who are familiar with NIH, it's kind of study section counsel-like. And we might make different choices looking at the whole collection of proposals across all of the work groups, given the broad program, the Methodology Report that we're trying to address.

So that's the best I could do. And in terms of workshop, I think you're exactly right.

That would be the goal of the workshop. I mean, the workshop. And you've heard two or three different workshops being proposed. We haven't exactly decided is this going to be one big one or, you know, maybe, you know, holding three separate workshops may not be as efficient. And so, we haven't worked through those details yet.

DR. NORMAND: But they are focused on -- they are really targeted workshops on specific topics. For example, Dr. Meltzer's talking about sort of convening all of the researchers that are responding to research prioritization methods. And so in some sense, you know, they're very targeted on the one hand. On the other hand it would benefit everybody. So we're trying to balance time and topics.

DR. GABRIEL: Right. They have to serve our needs in terms of answering the questions and bringing the expertise that we need to bring to bear on for writing the report, the goals of the report. Christine?

DR. GOERTZ: Christine Goertz. Sherine,

how many applications are you planning to fund in each of these categories? Because I guess I've been assuming all along that it would be just one. But now listening to this conversation I'm just wondering if it might not be several. And if there are some idea of how many applications you would be thinking about funding.

DR. GABRIEL: So I think that, I'll look at my colleagues here, but I think the short answer is that we don't know yet. Because it really depends on what we get and the extent to which they kind of fulfill our needs.

We also have -- because we are just very narrowly focused on certain objectives, you know, again for the report. So we may end up not funding any. So it's very different. You know, if it just doesn't hit the mark and actually relying on our interim researchers or relying on staff to really fill in the holes that we need. So we hope that they'll be responsive enough that we'll be able to fund a small number and they'll give us the information we need.

Anything -- anybody want to add to that?

CHAIRMAN WASHINGTON: Could I just ask any of the statisticians, I got in trouble last night about high-end statisticians --

OVERLAPPING SPEAKER: [Off microphone.]

[Laughter.]

CHAIRMAN WASHINGTON: No, no. I already know what the answer is. At least, I hope I know what the answer is.

What's the chances that we won't fund any project?

DR. GABRIEL: It's non-zero. There's always a chance. So, it's non-zero.

CHAIRMAN WASHINGTON: Okay. But the point is, those who are listening, we intend to fund a project. So, we don't, in anyway want to convey to anybody that PCORI on a first run is going to have a zero funding rate.

DR. GABRIEL: I stand corrected. I think it's very unlikely, but it isn't zero.

[Off microphone discussion.]

UNIDENTIFIED SPEAKER: Just say zero.

[Laughter.]

[Off microphone discussion.]

CHAIRMAN WASHINGTON: Thank you very much for coming here.

[Applause.]

CHAIRMAN WASHINGTON: Okay. And on that note, I'll just remind everyone that we do have the stakeholder engagement dinner, not dinner, rather event this afternoon starting at 7:00. And it is here, right?

UNIDENTIFIED SPEAKER: Yes.

CHAIRMAN WASHINGTON: Yeah. So anyone that's in attendance, everyone, in fact, is invited and encouraged to stay. And otherwise I'll see my colleagues first thing in the morning. Joe, did you have a comment or remark? Otherwise we are -- what's the word I'm looking for?

UNIDENTIFIED SPEAKER: Adjourned.

CHAIRMAN WASHINGTON: We are adjourned for today. Thank you.

[Whereupon, the PCORI Board of Governors meeting was concluded.