PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
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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
Carolyn Clancy, MD
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
Freda Lewis-Hall, 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

P R O C E E D I N G S

[1:00 PM]

CHAIRMAN WASHINGTON: Good afternoon.

Welcome to everyone to this Board meeting of the Board of Governors of the Patient-Centered Outcomes Research Institute. I'd like to thank all of you who are joining us here in New York City, as well as all of you who are taking the time to join us around the country via this live Webcast.

If you've not seen it, we have on our website an outline of the agenda that we will follow this afternoon and tomorrow morning. And on that outline of the agenda, you will be able to see what the goals are that we plan to achieve over the next day and a half.

Besides the official business of this afternoon, I also will have the great pleasure in a minute or so of introducing our new Executive Director for PCORI. I would just -- for those of you who have not been following this process for the last seven months, actually, we launched this search back in November, really, with first the

announcement of a request for proposals for search firms. And after a national competition, chose a search firm, which is Korn/Ferry to then lead a search to identify the best candidate for PCORI.

And after a process that involved scrutinizing applications, over 130 candidates, and eventually narrowing it down to a short list with intensive interviews, it's with my great pleasure that the Board has unanimously approved the selection of Dr. Joe Selby as our first Executive Director of the Patient-Centered Outcomes Research Institute.

And so with that introduction, I would like to ask Dr. Selby to stand up so that people can recognize you and welcome you.

[Applause.]

CHAIRMAN WASHINGTON: So, Dr. Selby. So that they could put a voice now with the face and the name, you could just say hello.

[Laughter.]

DR. SELBY: Hello. Hello, Gene. Hello, everyone. For those of you on the Webinar, you

might not be able to see me. But if you are here, I'd be the one that looks like a deer in the headlights right now.

I've been on the job all of two hours, but I've already sat through a four-hour Governing Board meeting. I think this is a once in a lifetime opportunity for myself, and really in many ways a once in a lifetime opportunity for our country to get this right, to get an organization in a place that can assist in generating and disseminating, sharing research that really does improve patient decision-making and outcomes.

So, I'm excited -- very excited to be here. And I will be making some more extensive comments tomorrow near the end of the day tomorrow. So, thanks, Gene.

CHAIRMAN WASHINGTON: Thank you, Joe. And, again, on behalf of the entire Board, welcome.

And as Dr. Selby indicated, tomorrow during the public comment period he will be providing some more extensive introductory remarks.

And so, now to the business. I'm looking

for approval of the minutes.

UNIDENTIFIED SPEAKERS: So moved.

CHAIRMAN WASHINGTON: Okay. Second?

UNIDENTIFIED SPEAKER: Second.

CHAIRMAN WASHINGTON: Okay. Comments?

[No response.]

CHAIRMAN WASHINGTON: All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: Okay. All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay. Minutes are approved to stand.

In this next section of the afternoon program, we are going to have a fairly high-level discussion of the process in which we are currently engaged to finalize our mission statement, as well as our logo for PCORI. We are not expecting a decision today, but we are expecting an update from the group that has been working with us over the last couple of months who will provide us with an overview of the information and insights that's

been gained to-date. And that is, our colleagues at Golin Harris.

And so, representing Golin Harris today is one of the senior partners, Mr. Joseph Clayton, who is going to provide us with an update. And then we'll open it up for questions, comments from the board.

MR. CLAYTON: Is my mic working? Yes, I guess it is. Okay.

As I said, thanks to Gene. We're pleased to be working with the PCORI Board and the Methodology Committee on some important work, which kind of falls under the heading of advancing the PCORI brand. I'm going to spend about 12 or 15 minutes walking the Board through the process, and where we are -- some of the things that we're looking at, some of the key important rules of the road when you're developing a brand and a mission statement.

And before I start, I think I just want to echo Joe Selby's comment. I mean, what we want to do is we want to get it right. We really want to

make sure that the brand, the mission statement captures what PCORI's unique mission is all about. And it is a unique mission. The diverse board gives us the opportunity to pull together an amazing set of perspectives to further that brand.

Just very quickly, we've been working since March with gathering a series of inputs and doing some internal and external research, which has led to brand development and planning. And with this meeting, we're much closer to finding ourselves at the juncture where we can get a brand approved in May, a mission statement. We'd also like to do some more testing, particularly to identify how best to reach out to certain communities in the United States to gain input and a better understanding of how PCORI can deliver benefits and to gather input from various communities.

Where we are today is really we are focusing on a mission statement for the organization that will articulate PCORI's unique value proposition as a research organization, as an

organization that is designed to capture patient input in new, creative ways. We are working on a set of descriptive message for PCORI's activities, as well as a series of logo options. And it is our hope and expectation that during the month of May, we'll have a consensus around this and be in a position to move forward.

Very quickly, I just want to talk a little bit about our branding objectives and remind the Board when we talk about a mission statement, what we're talking about is a very brief statement that activates, directs, leads by example, and serves as a force from within for the Board. This is a guide that captures what PCORI is all about. And truly defines and creates a consensus around where we want to go. It's -- a mission statement is something that PCORI Boards of the future can look at and understand the purpose and the direction and the aspiration for the organization.

When we talk about key messages, we're talking about really messages that more specifically articulate PCORI's work, its value,

and these messages need to embrace the mission. They also need to broadly accommodate all of our communications. So, when we are engaging patients and other stakeholders, it's important that we're communicating consistently and in a way that ensures that our key audiences understand what PCORI's purpose is and understand what we're all about. Messages can be present-tense, aspirational, inspirational. The messages need to stand alone, but together they also need to tell a story. And that's really what we're in the process of doing is, we're trying to identify the story that we want to tell about PCORI.

Obviously, there's also the logo and the entire set of visual identity. The standards that we want to use and that we want to put in place. This will come with a logo. Together, we would put this under the umbrella of the brand and I'll talk a little more about that.

In terms of the objectives kind of stepping back, what -- the way we see the challenge is really to differentiate PCORI and patient-

centered outcomes research provide a very specific point of view. Why are we here? What is our value-add? We want to give audiences reasons to believe in PCORI, and we want to speak to PCORI's benefits and value proposition.

So, we see this as a cyclical. We see this as a set of objectives that build over time. And we see it as fundamentally important to get it right, so that as we begin to layout our agenda, we're doing so in a comprehensive way that all of our stakeholders can understand. We want to anticipate what their questions are, and we want to answer them.

As I said earlier, we've also been undergoing -- we've undertaken a variety of research. Board interviews -- we've also been talking to patients, caregivers, immediate caregivers, and also a variety of participants in the healthcare delivery system: providers, clinicians, nurses, nurse practitioners, to get a sense of how they get their health information, how they perceive PCORI as an organization, what sort

of inputs do they have into our mission.

And I'm just going to share a few very sort of topline observations from the Board interviews. And I apologize in advance, I tried to get this on one slide and probably crunched it a little bit too much. But basically, I want to talk about three things a kind of what we've learned. I want to talk about PCORI's purpose, I want to talk about the ultimate impact of PCORI, and then finally a little bit about PCORI's key audiences as we perceive them. And this was an attempt to get away from the researcher-to-researcher conversation and try to move this more into the realm of communicating more broadly with lay audiences, with patient communities, caregiver communities.

Some things that we've found were a lot of consensus. And this needs to drive up to the brand and inform the brand. PCORI's purpose is really to provide trusted health information to people. The information equation that is part of PCORI's value proposition was very strong in the minds of all the Board members, and really, secondly, to sort of

focus on driving better outcomes in health.

The third bullet I have there is that this is obviously accomplished through research. But in our interviews with Board members, we found a great deal of focus on, you know, what are the results of the research? Where are we trying to go with our research? What sort of outcomes are we trying to generate? So, a lot of attention to the sort of relationship between PCORI's research work and the extent to which it can turn into valuable information that will inform decisions. Not just by patients, but also by caregivers and by providers.

We talked also with the Board about impact. And we think it's important that the brand speaks to impact. What we're striving for here, the mission of PCORI is more informed decisions made by patients, and those who care for them.

Secondly, a mutually better-informed conversation in the examination room. We spent a lot of time talking to Board members about the two parties that are ultimately part of this care

decision equation; providers and their patients. This is a conversation that we want to try to inform through PCORI's research.

We talked a lot about the variety of outcomes that might extend from PCORI's work over time, not just better outcomes in terms of individual health, but also, community health outcomes and more positive, beneficial system improvements that affect the delivery of care. There's a sense that PCORI can be a real driver on some of these key issues. And there's a great deal of enthusiasm for making sure that the brand reflects this.

We spent a lot of time with the Board talking about key audiences. Patient-Centered Outcomes Research Institute. Patient is the first word in our name. And patents and their immediate caregivers have been identified as, obviously, a very core constituency for PCORI. When we see a patient and their information needs, we want to think about PCORI's brand as one that's going to be able to inform patient views and patient

understandings of what their choices are in healthcare. So we spent a lot of time talking to Board members about where does this PCORI brand need to face? It's not Proctor and Gamble, but it is a brand and an organization that needs to be perceived by patients and their families as a resource in an information environment where there is a lot of misinformation and a lot of confusion about what works and what doesn't work for certain communities and certain individuals.

We obviously can be a significant resource to providers. And when I say providers, I'm using a blanket term to describe a number of individuals who are part of healthcare delivery teams. In many ways, the patients and the providers are the end-users of PCORI's work, and we want to make sure that we're getting that information into their hands.

Obviously, health researchers is a fundamental audience for PCORI. It's a research institution. We need to make sure that our communications and our brand is accessible to the

research community, that we're providing the information that they need, and the ability to understand how to work with PCORI, what PCORI's priorities are, how they can engage with PCORI.

And then clearly, you don't have to look any farther than PCORI's Board to understand that PCORI needs to be responsive to a wide range of stakeholders in healthcare. And in our view, PCORI's success will be if it's able to articulate it's mission in a way that's understandable to all of the communities that PCORI serves, and to make sure that we do so in an understandable, coordinated way. But always, holding up front these key beneficiaries; patients and the people who care for them and understanding that we're trying to fulfill the information needs of those individuals.

I'm going to close with just a very sort of simple visual representation of where I think we are right now in terms of understanding what the PCORI brand architecture might look like. We're really focusing, as I said earlier, on a mission

statement. But we're also looking at three basic categories where PCORI's value proposition, if you will, exists.

Number one is, the research. That's who we are, we're a research institution. We have a mission of developing a research agenda that is uniquely responsive to patient-expressed needs and patient inputs. Patients are not the only source for PCORI to identify those inputs and those patient circumstances. But we -- this research needs to be described in a way that's understandable to individuals who want to learn more about patient-centered outcomes research and how to distinguish it from other research.

Secondly, is really what comes from that research. The information that is generated and made available as a result of that research. This second area really, as I said earlier, speaks to a lot of Board member perceptions of what PCORI's value proposition is -- is, getting information into the hands of individuals that can use it. Whether they're patients and families and

caregivers, or providers and really making sure that we're delivering that information in a way that informs a different sort of decision-making. A decision-making that benefits from information that would not otherwise be there.

And then finally, a third area sort of, what do you get when you combine this research with the information and the decisions that can result from that research is really the outcomes. And that's kind of what, when we think about the brand and if we want to identify three core pillars, if you will -- three undergirding concepts for this brand. It is research, information, and outcomes.

And our hope is that we'll secure Board approval at the appropriate time that will allow us to proceed and build out the PCORI communications planning effort in a way that's consistent with this architecture. Focusing heavily on the research -- that's how we get to the information. And then, talking about what that information can mean to our key beneficiaries. And those beneficiaries can range from the individuals that

are involved in the care decision, patient and provider. But, there are a lot of other stakeholders that can learn from PCORI's work and can benefit from PCORI's work. So, we seek to capture the messaging and PCORI's communications planning in these three buckets.

So, with that, Mr. Chairman, I'll be happy to answer any questions of the Board. Thank you.

CHAIRMAN WASHINGTON: Thank you, Joe. Before I open it up to questions, Steve? Steve Lipstein, who is Vice Chair of the Board of Governors, has been leading a group that is called the Mission Statement Group. And you want to provide an update, probably?

VICE CHAIRMAN LIPSTEIN: Sure. Our group has been working with Golin Harris, and with representatives of each of our committees. So there are two from the Methodology Committee, and two from the Finance and Administration Committee, two from the Program Development Committee, and two from the Public Affairs and Communications Committee.

And what we've been doing is, taking the information, the research that Golin Harris has been -- provided, and beginning to work on the vocabulary around the mission statement. And so, we've worked through several iterations. We're still doing our work, have a little bit more work to do before we come to the Board with a formal recommendation.

We conducted two Webinars to get Board input. We've taken advantage of all the research and the focus groups that have been supplied. And so, hopefully we will be able to come forward to the Board with successive iterations of this work in the coming weeks. And then, be able to share with the public the outcome of that effort at our next meeting.

CHAIRMAN WASHINGTON: Our goal is to approve a mission statement at the next public board meeting, which will be in July. And so, with that as a high-level overview of where we are today on this question of mission statement and logo, I'm going to open it up for questions and other

comments from Board members.

[No response.]

CHAIRMAN WASHINGTON: So, I take it that we are all in agreement with everything that Joe just presented, correct? So it won't be difficult in any way for us to finalize a mission statement and present it in July, correct?

I want to remind you all that this is a live Webcast, so.

[Laughter.]

CHAIRMAN WASHINGTON: It's being recorded.

UNIDENTIFIED SPEAKER: Are you looking for somebody?

VICE CHAIRMAN LIPSTEIN: And gee, we are alive. I think what -- I think where we are is -- and the silence reflects that we're a work in progress. And that we have lots of information to digest. We wanted to make sure that we had the full advantage of both public input and stakeholder group input, so that PCORI's work, which -- one of our guiding tenants is to be as transparent and as participative as possible.

So before we really would take the ingredients and bake them into a finished product, we wanted to make sure we had the advantage of very extensive input from both the focus groups that we've conducted, the research that we've done, the input that we've received from stakeholders. And now, we've also received input from every member of the Board and every member of the Methodology Committee. And so, the cooks will go back into the kitchen and we'll begin to iterate a version of the mission statement that we can all get behind, and that we can bring forward.

CHAIRMAN WASHINGTON: I would also invite the public, those in attendance as well as those that are listening via the Webcast, to send comments based on what you've heard in this presentation to our website, so that we can incorporate your suggestions and insights into our process.

So, with that, I will bring this to a close and say, thanks again to Joe and Richard Schmitz and our other colleagues at Golin Harris.

MR. CLAYTON: Thank you.

[Applause.]

CHAIRMAN WASHINGTON: Thank you. So, Rick? This means that you are going to be up just a few minutes earlier than planned. But you've always welcomed a few extra minutes to present in previous meetings.

And I will say to those who have not followed these meetings in the past that our general framework is to focus our activities around the four major groups or committees of PCORI where the bulk of the day-to-day work is taking place. And so, the first of those groups to present during this particular meeting is our Program Development Committee.

Later today, we will hear from the Methodology Committee group, and then tomorrow we'll hear from the remaining two, which is the Public Affairs and Communication, and then the Finance and Administration.

And so, Rick? With that introduction, the floor is yours.

MR. KUNTZ: Thank you, Gene. So, I'd like to go over the next few minutes a summary of the progress that we've made in the Program Development Committee, and then open it up for discussion.

What I want to cover is an update on the landscape review we had talked about earlier, and the Tier 1 grants. The last meeting, you gave us permission to go ahead and start exploring these two areas as activities under the PDC, or the Program Development Committee, moving forward.

I want to just touch on the fact that we still recognize that the national priorities and the research agenda is still in our purview. And that will require us to accomplish the first two tasks before we move into the establishment of national priorities and research agenda that we can bring to the Board with all of its requisite public comment periods.

We do want to talk a little bit and I'll spend some time on this. We're architecturing right now a project strategy for PDC. This would be something that we could bring to the PCORI Board

if they feel that they would like to adopt any of the strategies we're using in PDC for PCORI, and this will be the first conversation about the evolving strategy component.

You want to end the conversation or this presentation with a brief overview of the PCORI research tools, what the special emphasis of the notion of a PCORI network. We had loosely talked about this in the past, and we are just scratching the surface of understanding whether or not this is a good concept for us to pursue further. And we'd like to get a little bit of discussion, just to understand whether or not this resonates with other members of the Board.

The only ask that we're going to have at this presentation is a green light to potentially go ahead with a concept of a network to explore further in the Program Development Committee, and to come back with that exploration and analysis at the next meeting in July.

Getting back to the landscape review, what we initially had laid out was an understanding of

what's out there with comparative effectiveness research. We talked about utilizing either a private or public agency to help us understand the current inventory of CER. Then, discovered that the Lewin Group in Washington, in collaboration with the Assistant Secretary for Planning and Evaluation, ASPE, who had commissioned them to do an analysis of CER review, was doing work that we though was very similar to what we were charged to do.

We evaluated Lewin's efforts in a face-to-face meeting in Washington approximately a month ago, where they were kind enough to bring their group and present to us over the course of a couple hours work-to-date that the Lewin Group had provided in their search engines in trying to understand how to analyze CER research projects.

What became apparent to many members of the PDC during the presentation was the extent of effort that the Lewin Group had done, the broad range of databases they used to cull the various sources of comparative effectiveness research.

And, the monumental effort and expense was to actually perform this, which quickly led us to feel that we should partner with these guys rather than try to do this on our own.

They were kind enough to extend a partnership arm out to us, and to -- at least at this point -- under the collaboration with ASPE, to agree to work with us to provide for us information through its public format that they will provide on CER, as well as also allowing us to propose additional softer routines for any unique PCORI strategies and searches that we might want to do in the future.

I'd like to hear comments from the other PDC members at the end of this talk about their impressions of the Lewin Group approach. But I think it's safe to say that we were all very impressed with the presentation. Their depth of detail and broad inclusion of all sources of CER research and the progress they've made with very sophisticated search engines in order to potentially understand what has been studied in a

variety of different dimensions of comparative effectiveness research.

Those dimensions include not only diagnostic conditions and diseases and therapeutic approaches, but they also included a variety of different infrastructures, both with respect to how research is done and also a variety of different sub-groups of patients who might have significant effects on the impact of therapeutic outcomes and also diagnostic efforts on these patients and their outcomes overall.

So again, we were very impressed by this approach. We plan to utilize the publicly available search engine that will be provided by Lewin Group and have also graciously agreed to take their offer of potentially looking at specific and specialized softer routines that we might want to engage with in the future that would serve the needs of PCORI.

DR. SIGAL: Just a brief question. And maybe one of the same. Is the -- what Lewin Group is doing -- and maybe, Jean, you can answer. Is

what AHRQ is doing? Because I know they're commissioning a landscape. So, I'm just a bit confused.

MS. SLUTSKY: The Lewin inventory was one of the projects that was funded under the ARRA investment and what we're hoping is it can form the basis for the requirement in the ACA under the PCORI legislation. So, my staff and I have been working very, very closely with them on the requirements for this inventory. So it's a reusable and scaleable project.

DR. SIGAL: Okay, so there's no separate entity.

DR. KUNTZ: All right. The next landscape review that we had talked about was understanding different models of stakeholder engagement. As you know, the basis of PCORI is the engagement of a variety of different stakeholders in trying to solve many unmet needs in healthcare. And we felt it would be appropriate to understand what's out there, with respect to traditional and non-traditional methods of engaging stakeholders at all

levels of the research process and agenda, which we're charged with.

We had initially talked about potentially contracting this out to an agency or organization to perform, but as you'll see in a few of our themes, we thought it was important to understand or to take advantage of any efforts that were done by agencies such as the NIH and also HRQ, and realize that, in fact, an extensive amount of knowledge and effort has been expended by the NIH and HRQ in looking at different models of stakeholder engagement.

We recently received from members of the NIH an extensive output -- several binders thick of work that they have done in looking at these different models of stakeholder engagement, which we are currently poring through to try to abstract and to work with. We also intend to work directly with the Methodology Committee and understand how we can partner with these -- with our two committees together and try to develop not only an understanding of the stakeholder engagement that's

out there from NIH and also HRQ and the work that they've done, but to try to interpret how we can incorporate some of these findings as we start to develop our research agenda going forward.

To be more particular, they would include stakeholder engagement in setting priorities, and understanding what to fund from research perspective and even evolved in some of the peer review processes in prioritizing and scoring grants going forward.

And our process at this point is to continue to pore through the work product from both agencies so far, to try to summarize that, to get back to PCORI with respect to results, and to go forward and incorporate this into our evolving research agenda. And we're mainly working with our capacity to be able to digest the detailed analysis so far that's been done. We've brought on a project manager in the last week, and she will be busy going through this as well. But we intend to have a very good summary of the stakeholder engagement by the next meeting.

In addition, we still want to keep open the idea that we can contract this out with other organizations or agencies if we see that there are some gaps that need to be filled in our approach towards engaging stakeholders at all levels of the research agenda. We also talked about the analysis of looking at capacity and dissemination. And again, in trying to understand what has been done and what can be done. We have, again, a couple sources of support here.

And this is a recurring theme, but there has been a lot of work by the NIH and HRQ, specifically understanding what exists out there in terms of talent, human capacity, and research infrastructures for us to look at how we can affect our PCORI special research agenda going forward. And we want to, again, tap into the work that's been done so far in human capital, in training programs, and investments with a variety of different programs that have been established by the NIH and HRQ to understand how we're best suited going forward over time to affect our research

agenda.

We also will work, again, very closely with the Methodology Committee as they come up to speed. They've been in existence for a couple months now -- to understand their views towards the capacity and dissemination, and the needs going forward.

So at this point, our goal is to, again, tap into the resources available already through HRQ and NIH, as well as the VA, who have done a fair amount of analysis of capacity and dissemination throughout the country. And with our new staff, summarize the reports and get back to the Board.

We are going to hold off on outside contractors in this arena as well, because I think we have to look at the efficiencies of what's been done already first. And what we discovered is that there's been a lot of work done by this by the two agencies.

We talked also about doing a methodological scan. The centerpiece of PCORI, or

one of the centerpieces will be methodology. We will obviously try to understand what novel methods we can do to look at outcomes research, specifically patient-center outcomes research. This is essentially the charge of Methodology Committee. So, we put this here as a placeholder to emphasize the fact that the Methodology scan or the review on the landscape will be performed by the Methodology Committee, who is in the process now of determining that process.

We also talked about understanding from a very high level, a brief overview of existing CER organizations and networks. And again, we didn't want to spend a lot of time drilling down and expending dollars and trying to get a very, very detailed analysis. But we felt it would be good for us to have a relatively high level overview of who is doing what, what their missions and goals are, and how we can fit in and refine our added value as PCORI. And that would involve an understanding of what -- at least the large organizations who aim to do comparative effectiveness research as well as

understand at least some inventory of the clinical networks out there that we might be able to partner with going forward. Again, focusing on not trying to be duplicative and trying to leverage as much of the resources that we can in collaboration going forward.

Our first efforts will be to, again, work with our partners in NIH and HRQ to understand what exists out there with respect to these clinical networks. And CER, as well as scanned some of the other public and private enterprises, who might have readily available lists for us at a low cost so that we can get a good, quick look at the organizations.

So again, this is a brief scan. But it's something I think we have to basically have as a landscape available to all of us so that we know from a high level what's out there, and that process is in place.

CHAIRMAN WASHINGTON: Before you turn the page to the next chapter of this presentation, I wanted to open it up to questions or comments from

Board members, particularly from the Program Development Committee on this pretty extensive plan for landscape analysis. Gail?

MS. HUNT: Yeah. I know that the Office of Disabilities has a CER review that they have funded separately by Mathmatica. And I'm just wondering how -- I think it's using somewhat different criteria than the Lewin Group. So, I'm wondering how that's going to be figured into the CER. We need to take a look at that.

DR. KUNTZ: Thanks, Gail.

CHAIRMAN WASHINGTON: Francis?

DR. COLLINS: So, I think we were all very impressed with how far the Lewin Group has come in terms of putting together an algorithm for doing searching for CER studies and assembling that into a searchable form. But I think when one tries to asses whether the algorithm is perfect, no surprise here, it clearly misses some things and it picks up things which, when you look at them closely, probably don't belong. So there's some tuning that needs to go on, and that is part of, I think, the

opportunity now of working with them to help them produce a better product that will be more useful to us.

The other thing we talked about is, whether this could be used not only to say what's there, but what's not there that perhaps out to be. So if one had a dependable inventory of CER studies and if you could layer on top of that, and this might be something that PCORI could do, some assessment of both the quantity and the quality of research in particular areas. Certainly quantity, I guess you can count up numbers of projects and dollars, roughly -- that are spent, but you can also look at quality in terms of exactly what are the publications and what kind of citations are being made to those publications as a rough indicator of how much of an impact they have had.

And you could imagine doing a cross-walk with that kind of inventory, indexed in that way, with where we think the greatest needs are for public health in terms of qualities, dailies, prevalence, incidence figures, and so on. And that

might actually down the road be kind of a useful way for us to begin to identify what maybe hasn't been so transparent before. Which are the areas that do affect lots of people for which there has been relatively less attention as far as CER. We would, I think, love to have that part of the landscape as well.

It was pretty clear from the presentation from the Lewin Group that that sort of next layer up was not part of their specific charge, but it could well be a good partnership with PCORI.

CHAIRMAN WASHINGTON: Arnie?

DR. EPSTEIN: I want to -- I think, agree with both Rick and Francis. And I want to add on what Francis said.

The original idea we had for a scan was that we would find all of the literature that was there that covered a certain area, and we'd find some gaps. And I think that most of us had the idea being that that would be job done. And it turns out that's really just the very beginning of the job. And what you really need is some

information about what's there, what its quality is, what its quantity is, and especially how directive it is for clinical decision-making. The kinds of decisions need to make, and docs.

And I think what came to me -- and I invite other members of the committee to say this -- is, what Lewin's putting together, as valuable as it is, is like going through and doing the most thorough, ongoing literature review and just getting the articles. For every place where we what to investigate an area as whether it's worthy of our attention, we're going to have to do a detailed study about the characteristics of what's known and how that interlaces with the important clinical decisions.

CHAIRMAN WASHINGTON: Sharon-Lise.

DR. NORMAND: I think another important aspect of what Lewin presented that we should highlight is not only what's been done, but they're also looking at what's been funded and what's in the pipeline. And I think that's a very critical piece that they're adding, so that we actually know

what's going on and we're not behind the eight ball on that. So.

CHAIRMAN WASHINGTON: Bob Jesse. From the VA's perspective, much work underway in this arena?

DR. JESSE: We actually have considerable work, both already in press and underway. We have quite an extensive health services research program that spans, you know, across a variety of things. In particular, areas focusing that are probably not so much in the mainstream of out of VA research on TBI and PTSD and things along those lines as well. So, you know, we have quite a strong program.

CHAIRMAN WASHINGTON: Harlan.

DR. KRUMHOLZ: Well, I just wanted to introduce this idea that we could spend actually the entire amount of money doing this kind of scan. I mean, there's such an enormous breadth of work being done. And if you start saying you're going to go into the depth and breadth and describe it in every which way -- and by the way, it changes every minute, because there's new things being funded and we're learning new things.

The Lewin Group is doing a nice job. I suggest we think about this in a way that it provides some boundaries on the kind of work that's being done, and is then we begin to develop our priorities and begin to focus in areas where we think we might provide greater investment, we'll want to go deeper to ensure we're not duplicative of other efforts in those areas. But rather than be pre-emptive and say we need to know the entire universe and put our arms around it -- that would be an enormous job by itself.

And I think it may be enough to bridge on top of what Lewin does, maybe add a little bit of extra nuance and detail. But to hold back from saying we're going to be, you know -- provide the entire compendium to the world on this because as I was watching the Lewin Group, the challenge of this endeavor became very clear to me and the real world dynamic nature of it became very clear to me. And I think what we -- for our purposes, it's going to be useful to know what's going on in the world.

And then, it's going to be useful to be

prepared as we say, we want to do work in this condition. To know deeply, you know, what exactly is being done here so we're not in any way overlapping. Because we want to make sure that ours is complimentary to work for which investment exists, rather than duplicative.

And that's -- I just suggest as we frame it and think about it, that that might be a helpful way to do so.

CHAIRMAN WASHINGTON: Ellen? And -- Ellen Sigal and then Harlan Weisman.

DR. SIGAL: So, Harlan, I completely agree with you. Because when we start to establish our priorities, it's -- this is a little bit like boiling the ocean. We really want to go drill deep in areas where we can add real value. And that's going to be really what our value is -- PCORI is going to be. So, I think that's completely right.

CHAIRMAN WASHINGTON: Okay. Harlan Weisman.

DR. WEISMAN: Yeah. I was asked for some clarifications and maybe Harlan Krumholz and Arnie's comments covered it. But, I wasn't sure is, this

is a one and you're done thing or is this a living compendium that continues? That's number one.

Number two, what does the output look like? Does it sit on a webpage that has the PCORI moniker over it? And if it does, is that some kind of tacit? And this goes to Harlan Krumholz's point. Is that some kind of tacit approval of whatever we're listing in there, whether it's the world or it's a subset of the universe? And because, you know, one of the things we say we're about is, to be a trusted source of information that enables decision-making. And if we have this compendium out there that we're part of, what are we saying to our ultimate customer -- our ultimate target, if you will, who are the patents and the clinicians who are helping provide care? How do they use this and how do they know how to judge it?

DR. KUNTZ: Well, I'll answer those questions and ask my colleagues to weigh in as well.

The landscape reviews were not intended initially to be product by PCORI. They were a

source of information for us to shape our national priorities and also research agenda. So it's a really good question, Harlan. From that perspective, this will be a publicly available search engine. It has a variety of different inputs, and Dr. Normand mentioned. It has "clinicaltrials.gov," for example, so you can see what's actually being developed in addition and they've really solved the software of connecting all these different databases together.

We might have some proprietary access through software routines that we could write ourselves, but at this stage, at least I haven't envisioned this to be a product that PCORI would provide more than just a way for us to inform how do we shape our research agenda.

CHAIRMAN WASHINGTON: Arnie Epstein.

DR. EPSTEIN: Yeah, let me just emphasize a few features in terms of your questions. First, it's not envisioned to be one and done. I think they think this would be ongoing. In terms of what does the output look like, as near as I could tell

it looks like a series of protocols or a series of studies that have been done and in some cases, you'll have abstracts. But by no means will these data be information. That is to say, if you were to be interested in whether it was in PCORI's interest to investigate were there differences by socioeconomic status relate to invasive heart disease diagnostic testing.

This could give you potentially the last 130 articles that were there, and the abstracts. But understanding whether we now have the answers -- all the answers we'd like and what they are, we won't find that there. Let me cede to Harlan to final --

DR. KRUMHOLZ: No, I agree. I think for us, we weren't -- and I would suggest to the Board that we don't think of this as our product, that what we've found is that there are people who've already getting funding, being supported. We should be complimentary and supportive of those efforts. We can cross-talk with them, and -- but that we don't want to put this on our website as something that

is a PCORI product or that we're endorsing. But rather, we want to use it. We are end-users of this in order to help set our priorities with stakeholder input, as we'd bring in a broad range of contributors to help us determine where we should invest our resources.

And then, when we're ready and we have some areas, as Ellen suggested, then we are going to need to go deeper with sort of our own efforts to make sure that we're not duplicative. And with the Methodology Committee, I think we're at our side, working to understand what methods are being employed, what are the best approaches that are going to need to be taken so that we can make wise choices.

But I don't think that there's a sense that we're the resource. In fact, we're the end-user, I think, of some of this in order to help us move forward.

CHAIRMAN WASHINGTON: Okay, Rick? Please continue.

DR. KUNTZ: Yes. Thanks, Gene. So, this

slide is just going to summarize a little bit of the engagement with the HRQ and NIH, because you heard that term used a lot in the previous scans. I just want to emphasize the fact that the first order of business in looking at how to satisfy the goals of our landscape reviews was to leverage as much as possible existing data out there.

The statutes talk a lot about the collaboration between PCORI and HRQ and NIH at various different levels, including involvement of the leaders on this committee, as well as -- and asked for us to look to the NIH and HRQ when possible for help. And we feel that there's a lot of data that can be levered inexpensively and also take advantage of some of the work done so far. So, I just wanted to outline here that we are going to try to follow those guidelines. And specifically, look at their involvement in understanding further how we can embellish stakeholder engagement capacity analysis, dissemination, and also review of the organizations and networks that are out there.

We're not going to only stop at the NIH and HRQ. We talked a lot about the fact that we're scratching the surface of the VA, another fantastic resource available. The Lewin Group -- and then I think after we've looked at those leverageable assets, then we can look at contracting outside for those that are required to fill out the rest of our landscape review.

Moving quickly to our Tier 1 grants. For lack of better words --

CHAIRMAN WASHINGTON: Rick, can you hold off for one minute?

DR. KUNTZ: Yes.

CHAIRMAN WASHINGTON: Freda had a question.

DR. LEWIS-HALL: Yes. So, I just had a question about what kind of private entities would be engaged to deliver some additional information about landscaping. There are a lot of organizations. Gail mentioned one in particular, but there are many more that have aggregated, accumulated, and otherwise pulled together capacity

modeling, studies themselves, and data, and have their own list of networks. How do you plan to engage those in addition to AHRQ, the NIH and the VA?

DR. KUNTZ: Yeah, thanks for that excellent question. So, we have a list of what we would consider to be the preferred providers in those areas, and many are in the private and public sector. With those provisions, we understand they have outstanding capability to answer those questions.

Our process was to go through initially to see what's existing, especially within NIH and HRQ. And I think, also the VA. And then if there are reasons for us to get complimentary viewpoints, we'll quickly go to those levels as well. I think that, very quickly, we'll probably engage a few contractors once we start to meet together with our project manager to work this out. All right. With the Tier 1 grants, for lack of better words we called the process of potentially developing planning grants for us to better be informed about

how we can shape our national priorities and research agenda. And we called this the Tier 1 grants.

And it's important to point out that we are very committed to following the statute with respect to developing a national priority about how PCORI operates with the required and our interests in public comment, as outlined in the statutes, as well as development, subsequently, of our research agenda. We feel, however, that there's ways to engage investigators and the public in our planning side, which we're calling the Tier 1 grants. And we would look at this as a call for ideas.

Specifically, defined to help us understand what framework we should develop as we put together our national priorities and research agenda: infrastructural issues, methodology issues, for example.

The focus would be to think along the lines of innovation. To potentially put together some moderate-sized innovation grants that would quickly define barriers to very specific issues

that we would have required for us to build what we would consider to be our kind of core research agenda going forward. And they would be to articulate the very special topics on improvements in efficiency of clinical research, explored novel clinical research infrastructures, selective statistical and clinical trial methodology, working hand-in-hand with the Methodology Committee on this, as well as novel approaches to patient engagement.

These are not grants focused on what I haven't heard is what it is not. This is not a grant that's going to be looking at an evaluation of potential therapeutic, diagnostic, or preventive interventions. This is more likely or will be the topics of our core research agenda, where we go through the proper processes of public venting, establishing our national priorities, and also our research agenda.

This is not an evaluation of evidence gaps that will also be likely more in the research agenda and it's not an evaluation of unmet patient needs.

These are grants focused on structure and our ability to basically build a program going forward that we think would be very valuable as we look -- and I'll show you on the slide next, as we build our national priorities that we have multiple different inputs to inform this Board into how we should structure our national priorities and research agendas.

And we feel that a set of innovative grants under this title of Tier 1 grants specifically looking at infrastructural methodological issues would be very, very helpful.

We want to -- now that we have a project manager on board for a week, we're going to engage first all members of the Program Development Committee to try to tease out what are these infrastructural, methodological topics that we want to bring forward. As well as, any member of the PCORI committee who would like to engage in this process.

We'd like to finalize these topics and bring them back to the next Board meeting in two

months to get approval to go to the next level of initiating the Tier 1 grants.

Let me just show the next slide, and then we'll stop for conversation.

CHAIRMAN WASHINGTON: Before you go on, we have a couple of questions. So we're going to start first with Harlan Krumholz, and then Sharon Levine, and then Ellen Sigal.

DR. KRUMHOLZ: I just wanted to reinforce that, second what Rick said. And also, just give you a sense of how potentially exciting this could be. Because when we're presenting this, you know, sometimes that can be a little lost. So, the -- not that Rick's not doing a great job.

But I just want you to pause on this. So, the opportunity that we have is, to identify some of the key leverage points in doing research faster, better, less expensively. How we can accelerate the research infrastructure and where those chief bottlenecks that are slowing us down.

Analogous -- if you think about the Gates Grants where he said, well, how do we do a vaccine

that you don't have to refrigerate? When we think about how we collect data, how we enroll patients, how we standardize approaches, how we use technologies. Well, we have the opportunity with these Tier 1 grants to put out some problem-solving grants where we basically are saying to people, come up with a solution. And we want to see what you do with it. You know, in a way like they do that with an incentives approach.

You know, with the Methodology Committee we need your help. But to say, where are those bottlenecks? Where would we want somebody to be thinking entirely out of the box for a way that's completely different about doing this that's going to very highly effective? And we're excited as we develop the program. And part of this will be about envisioning what the program is eventually going to look like. How are we going to have components of it that are going to be something people haven't seen before? And that are going to be entirely new, that then will be collateral benefits in the same way when NASA going to the

moon developed a lot of products that people ended up being able to use.

If we can get these problem-solving grants to address some of these key bottlenecks around a whole range from the spectrum of research, then we hope other people will be able to use those solutions, too. And it will serve as a catalyst for not just thinking we have to research like we've always done research, but that there will be new ways of doing research that is very patient-centered and consistent with our mission and -- our evolving mission, and our goals and aims.

CHAIRMAN WASHINGTON: And so, I would underscore that one of those bottlenecks is listed there in the statement. Novel approaches to patient engagement. So, we're not just talking about research tools and design innovations, we're talking about how best do we engage the patients at all stages in the whole research project, including from the beginning or prioritization.

DR. KRUMHOLZ: Exactly.

CHAIRMAN WASHINGTON: Sharon Levine.

DR. LEVINE: Thanks Gene. Thanks for making my comment. But --

[Laughter.]

CHAIRMAN WASHINGTON: Anytime.

DR. LEVINE: Well, in part -- and in addition, I think one of the challenges is making the idea of participating in research a much more compelling, less frightening, much more compelling for patients in general. And just a reminder, Rick, that stakeholder engagement and patient engagement is jointly owned by Program Development, our committee, and the Board as a whole. So, I think we have a great interest in being involved in

CHAIRMAN WASHINGTON: And the Methodology Committee.

DR. LEVINE: And the Methodology Committee, yes.

DR. SIGAL: So, this is really important. But I want to kind of echo what others have said and build on it. I think it's important that this look different, this feels different. That we reach out to sources that we traditionally don't.

And we also encourage collaboration. I mean, this is really important because a lot of the grants, it would be great if we can ask sectors to work together and put these grants in together. Or certainly, academics not just the same old people that always do it.

So, I guess the question I have is, have we though much about the size of these grants and the, you know, the amount of money or how we're going to do that so it really, truly is different?

DR. KUNTZ: We've only scratched the surface on that. And to tell you the truth, we haven't formally talked among the group about grants, although we've talked a little bit on the side. Typically, incentive grants which is a nice model, are in the $50,000 to $150,000 range. And I think that we're looking for quick solutions here. And by the way, even those modest amounts of dollars from a research perspective, a research grant perspective, have generated fantastic results when there's competition and innovation involved.

So, I think that -- I would just say that

maybe that's a starting point for us, is something in that range. And we'll obviously get more detailed when we have more discussion on this.

CHAIRMAN WASHINGTON: Continue.

DR. SIGAL: I just want to add as we continue to develop this, it would be great to kind of reach out to others and really think about this and to have some perhaps novel approaches. And again, I want to emphasize the collaborative approach and the idea of non-traditional people that we can reach out to on this.

CHAIRMAN WASHINGTON: Just on Ellen's point, I would, again, underscore to everyone participating, those in the audience here as well as in -- away on the Webcast, that we welcome your input on a topic like this in terms of outreach to what Ellen is describing as not the usual suspects. And so, if you have some thoughts, please do register them on our PCORI Website.

I have Bob Zwolak next, and then Christine Goertz.

DR. ZWOLAK: Well, Rick, thank you. The

enormity of this challenge and the enormous potential that it holds just sort of starting to strike and your presentation obviously sums that up.

I wanted to ask a question about the non-traditional stakeholders that we're going to seek. And it may be the source of a Tier 1 grant or the type of Tier 1 grant that may be functional is, how are we going to -- once we've decided we found the landscape, it's going to be a living landscape. We're going to look for gaps in the landscape and then we're going to seek stakeholder input and we're going to seek special stakeholders, those people who have not spoken up and particular, often times are patients and patient groups.

Have you though about a metric of how we're going to quantify the relative input and how we're going to be able to compare input among the non-traditional stakeholders and sort of attempting to quantify a non-quantitative basket filled with input from them?

DR. KUNTZ: Quantify the non-quantitative

basket? No, that's an excellent point, Bob. I think that, again, we've just had preliminary discussions on this. We've discussed that the stakeholders that are not traditionally involved but that would have a great interest in PCORI obviously include the patient, the patient's voice, which we've talked about.

I think the others are those individuals who actually spend most of their time taking care of patients. Who traditionally don't have the time to do formal grant writing and participate in the kind of grant process. How can we facilitate an ability to do research at the highest level with those individuals who have a wealth of knowledge and questions to ask that have not traditionally been involved in the research process. Rural clinics, for example. We would like to look at the Tier 1 grants as -- to be able to say, what would be required for us to do high-ascertainment longitudinal follow up in patients in rural clinics? And what kind of suggestions do you have to be able to solve this specific problem, for

example, is one infrastructural question that we could ask.

So, our viewpoint about stakeholders who haven't been traditionally involved are not too far afield. They're really about getting more of the patient's voice, and also those individuals who care for patients and are not traditionally involved in some of the more traditional research processes. But again, I think that for probably a variety of different views and other embers of the PDC as well.

CHAIRMAN WASHINGTON: I just want -- Bob, what I heard you asking or suggesting that one inquiry might be specifically geared -- one of these Tier 1 grants is geared toward identifying the nontraditional stakeholders.

Thanks, excellent suggestion. Okay. Christine.

DR. GOERTZ: Yeah. I -- and in response to Bob's question that's a theme that is a theme that is run through every single program development committee meeting that we've had. And

one of the ways that you can shape that is, when we put out the announcement for Tier 1 grants, we can specify in that announcement that we require teams that then include, you know, perhaps non-traditional partners. And also, that were entrusted in research that's initiated by people that may not be the -- may not be your basic academic scientists, but are patient groups or others who may have the type of questions that are really directly relevant to what we're answering.

And also, looking at when we're talking about stake, looking at a scan of the environment. One of the things that we're talking about is non-traditional reviews. So, making sure that when we do go through the scientific review process, that this type of information is weighted appropriately. And that we have -- first of all, that the teams are developed, and not just in name only. It's really easy to stick a patient onto a grant as a consultant.

That's a really different thing than having a meaningful partnership and a good reviewer

can pick that up but also, having reviewers as part of the team in some way, patient reviewers. And again, that's easy said. It can be difficult to execute, but thinking of innovative ways to do that.

DR. KUNTZ: Sure.

CHAIRMAN WASHINGTON: Proceed.

DR. KUNTZ: To just finalize a comment for Sharon's comment. We all what to collaborate as much as possible. We're all about collaboration, actually, at the PDC. That's what the C stands for. Program Development Collaboration. And, I think what we want to do is kind of lay the groundwork for this stuff. But obviously, any way we can engage everybody in these topics would be fantastic.

Just to put this in perspective, I just want to emphasize the fact that our real focus, I think, both as our committee and also as a board, is really on a national priorities and research agenda. That's the process that's been very well outlined in the statutes. It is what our focus is

to develop, ultimately. What PCORI is about, as we start to shape our definitions, and also, what is the core research agenda that'll take us into the out-years for the next 10 years.

This is a process which will take a lot of thought, a lot of work, a lot of iterations back and forth. So, when we talked about the Tier 1 grant applications, it becomes one of the legs of the stool, of the many legs, that will help inform us about this national priority. So, I just wanted to make sure that everyone is clear that our idea about these incentive grants or whatever are not circumventing the process. We though -- which was outlined in putting grants out.

This is purely a very special way for us to be informed and to add viewpoints about how to shape our national priorities and research agenda. Just as our interaction with Methodology Committee, the Board as a whole and a variety of different inputs, such as the landscape reviews. And of course, stakeholder input from all different vehicles to drive this.

We have started the initiation of developing a strategy for our Program Development Committee, which might be considered the kernel of a strategy for PCORI. But at this point, we're -- it's a PDC strategy and I'd like to just go through our initial ideas about strategic alignment among our committee.

We're all familiar with the legislation which brought about PCORI through the ACA. And I'm not going to read this, but we understand the importance of trying to improve the ability to make decisions, both at the patient and caregiver level. And it's a great goal for PCORI going forward. If we drill down a little bit further and try to call out what are the key legislative defined areas, we could start to understand how these principles can help us shape a strategy.

So, the legislative defined research is systematic reviews, prospective trials, observational studies, retrospective analyses, and oversight and recommendations from the Methodology Committee. Research to consider potential

differences in effectiveness due to variations of subpopulations and treatment modalities, research that supports stakeholder engagement ensures transparency, as we talked about. And also, research with dissemination of the results of PCORI research, principally, by the Agency for Healthcare Research and Quality, AHRQ and by an increased research capacity.

The implementation of the focus research is to satisfy the goals of informing better choices among alternative strategies to support a strong, patient-centered orientation, and to direct attention to individual and system differences that may influence strategies and outcomes. So, from that, our vision is to produce meaningful knowledge to patients which will inform their decisions, not to dictate them.

This is important, and I think it's a theme that we want to iterate overall as we start to develop a strategy -- is that, we don't aim at this point to determine treatment A versus treatment B is superior. But what are the elements

about a comparison between treatment A and treatment B that fit into the preferences and decisions that are different for each patient, so they can make the best decision for themselves. This is a slightly different way of doing research, although many research agencies try to do this. But we are specifically focused in trying to develop the dimensions of decision-making for patients when we contrast alternative therapies going forward. Yes.

VICE CHAIRMAN LIPSTEIN: Rick, the -- I wanted to highlight the last bullet where you said direct attention to individual differences.

In the medical community, they fall into two buckets. One bucket are what I call case-mix differences, where we try and differentiate among patients based upon their diagnoses, or based on their complicating or coexisting conditions. The second bucket are what I call their life circumstances. And that's where too often the research community just boils all of those life circumstances, differences down to socioeconomic

status. And so, socioeconomic status gets overburdened in all this.

And clearly, income and education levels have an impact but so do the complicating life circumstances of obesity, smoking, disability -- and that could be physical disability, emotional disability, behavioral disability -- substance abuse, whether that be alcohol or drugs. And so, there are lots of coexisting life circumstances that don't show up in any of our databases. They're not collected in the MEDPAR database, they're not collected in most clinical databases. They're not in claims databases.

And so, one of the things that I hope we can get out of that third bullet is the inadequacy of current databases of information when it comes to pointing to the individual life circumstance differences of individual patients, because we talked about this earlier in our meeting. When you get into the exam room, between clinician and patient or between caregiver and patient, those life circumstances are all important in determining

outcomes. And so, we have to get the research community to give almost equal weight to the life circumstances as they do to the clinical circumstances.

DR. KUNTZ: I think those are excellent points, Steve. And I think it's a great segue to the development of our strategy.

I think that we're aligned with 100 percent with what you just said. The strategy that we're outlining here I think was spearheaded by Harlan Krumholz, reviewed very intensely by the PDC. And from these statue principles, we tried to align a handful of metrics to define our strategy.

First, we think the research should be patient-oriented and a view that the patients are partners in rather than subjects of the research. This is an important emphasis that we want to make, is that we're in this together. And we want to view patients as partners in the research process.

We think that PCORI's research could have game changing impact. We think this should be substantive research. Transform the way knowledge

is generated, translated, interpreted, disseminated, and adopted. It's an important strategy.

The results should be meaningful with consequential output. That is that the tangible knowledge readily appreciated by patients either directly or indirectly can make a difference in their choices and their lives. The research should have a national scope, the most diversity and participating insights in individuals. Geographic diversity, as well as socioeconomic, as we just pointed out. The research in our program strategically should be focused on capacity building. If we talk about novel ways of doing research, one has to understand what's the assessment of capacity and is capacity sustainable going forward?

So, with capacity building, we want to have the expansion of the patient-centered outcomes, research acceleration, and to produce timely and relevant consequential research over time and in a variety of diverse settings.

This is critical going forward because as we start to understand that there might be novel ways of doing research or special ways of doing outcomes research, it had the capacity both infrastructurally and human capital to do this research. This is an important strategy.

Yes?

DR. NORMAND: Rick, I want to go to point number three in terms of talking about tangible knowledge readily appreciated by patients. And so one of the things I wanted to ask -- and I'm pretty sure you meant this as well. But when you think about patients, I thicken we're also talking about information that could be used by physicians and by, perhaps, hospitals or health plans. It's not just for patients decision-making, it's for other decision makers. Is that a fair statement?

DR. KUNTZ: I think our first focus was to make sure that we had data that was timely in the process of research, to be able to be used and ongoing. As far as broadening beyond the patients, I think, say, qualified "yes". Although I think

maybe others can comment on this.

DR. KRUMHOLZ: Well, I think -- so the language here is, I think -- you know, purposeful. Tangible knowledge. I think, you know, thinking about this, it actually -- you know, touched and understood. The indirect word here, indirectly, means if you were to go to patients and say to them, this is how this knowledge is being used, they would appreciate it.

I mean, the notion here isn't that it's just used by patients, but notice the word "appreciated" by patients. That is, that they would recognize the tangible importance of what we are producing in a way that it either is going to directly affect their and inform their decisions, or where that they could sit back and say, “Gee, I understand it actually helped the healthcare system to improve or to become more efficient or timely or responsive to my needs.”

But, one of our central challenges -- at least, the idea here as the metric is that if we produce something that if you sit back with a bunch

of patients and explain it to them and they just say, “I don't see how that matters.” Then we've got a problem. But if we go back and say to them, “You know, we helped Steve Lipstein to actually configure his healthcare system such that it's more responsive and better able to deliver care.” Someone could say, “I appreciate that. I understand what that means.”

Now, that's an indirect thing for the patient, but they appreciate it indirectly. And that's what that is meant to capture, that spectrum of what might apply to them individually as well as what might go across indirection. If you have got a bunch of people sitting around dinner and said, what do you think about what we just did?

CHAIRMAN WASHINGTON: Arnie Epstein.

DR. EPSTEIN: So, that explication is really helpful and it makes me think it belongs up there. But Sharon's comment still makes me believe that we have a problem, because everybody's going to trip where she just tripped. I certainly was in line tripping with her.

So, we need to add another bullet that really clarifies that a lot of the things that are really important for patients in a very immediate way that would help them get better care are things which will be decided largely by policymakers, physicians with patient ascension.

DR. KRUMHOLZ: Well, one thing you have to realize is that Rick's showing slides. So these are excerpted from the document that was produced and which has further elaboration in each of these points. But, can be improved and refined.

I mean, it's for the board input at this point. But you should just know, each one of these words has been carefully selected to try to convey that if we're not conveying it clear enough, it needs further elaboration or annotation then we ought to put it in the document to make sure it does that. But for the purpose of the slides, it's meant to be telegraphing the point pulling out some of the key words that are critical.

But clearly, this is going to be a document that guides us. Right now, what Rick is

suggesting is that this is guiding the Program Development Committee's efforts. But we think this is going to be relevant to guiding the overall board, and we should be careful in how the words are selected and what they mean, and communicating them well. And it also goes back to the Golin Harris presentation, about as we look for our brand and the key messages that we want to promote, they should emerge out of the things that we aspire to do. And these metrics really should say to the world, this is how we're going to judge ourselves about whether or not we were successful.

DR. KUNTZ: All right.

CHAIRMAN WASHINGTON: Continue.

DR. KUNTZ: So again, these are the first volley of some of our strategic metrics. And again, mainly we're putting them up here to engage a discussion and to drive a strategy.

Transparency is an important strategy as well as a metric and can be measured by widespread availability of information which is easily accessible and understandable. So, I think it's a

laudable goal.

Stakeholder partnership. Structured to facilitate an involvement and contribution of all stakeholders, constantly looking at whether stakeholders are involved in these processes.

Distinctive design, and a focus on implementation. We talked a lot about the fact that we have to have something that focuses on patient-centeredness, as well as develops and customizes methodologies to be special, to be unique, and distinguishable from other research programs, which is critical.

We do know that there's an unmet need of more information and knowledge available to the patient and caregivers to make the right choice from a variety of alternatives and to understand what they could do to make sure they make the right decisions and we have to have equally interesting and distinctive designs to parallel that. And I think the most important thing of the strategies, again, is the notion of an enduring legacy. Right now, PCORI is somewhat of a 10-year process, which

will sunset -- at least as the statute reads now and we'd like to be able to leave this project with some type of enduring legacy.

And I'll just read it. Establish a legacy through culture promoted that is a new way of doing research and a view towards that. The knowledge generated, standards of articulated innovations developed, and the infrastructure created and the healthcare system improvements. And a variety of different ways of both influence and also the way we change research in general is a laudable goal, but clearly something that we can both set as a strategy and try to measure through metrics.

CHAIRMAN WASHINGTON: We have questions. Why don't we go to Harlan, Rick, before we continue.

DR. WEISMAN: Harlan W., I had a question from earlier that I was going to reserve, but it also comes through on number 8. And it was part of the -- even in your Tier 1 and our -- I think it was our January meeting in California. We had a lot of discussion. It was when you guys were first

thinking about what you were going to do, and we were talking about peer review and the infrastructure and what -- how you were actually going to get things rolling on research.

And that's dropped by the wayside as you're thinking more about, substantively, what are the grants going to be? When you -- where are you now on thinking about what the process is going to look like? Have you given a lot more thought to it? Because, you know, I was thinking, for example, Christine said about incorporating different ways of doing peer reviews --

[Off microphone.]

DR. WEISMAN: -- and probably aren't conducive to number 8 there, or to the kinds of ideas that Christine was talking about, incorporating the kinds of people that Ellen was talking about.

DR. KUNTZ: Well, I think that's a very important question. It's also a broad question which we could spend a lot of time answering. I'll give you a couple high-level responses to that.

And also, I'll ask my colleagues to engage as well.

I think when we have a broad stakeholder involvement that is a distinctive design, in and of itself. And we all know that the basic elements of a granting process, for example, or how to do research involves a decision about what to study, how to set priorities, how to engage the public for either ideas or grant applications; how to, then, review that in a process and also, then to award the grant. You know, follow the results, and then disseminate the results.

Almost all of those steps could be redesigned in a way that would engage more stakeholders than the classic traditional method of engaging only experts. At the same time, I don't think we'll lose the expert requirements for each of those processes by that engagement, if we just carefully put this together.

In order to get that research agenda moving, it really is an element of iterating with what the national priorities are, to get the public comment, and to try to understand more of our

landscape reviews. And also, to get some of the results and applications back on the Tier 1 grants.

So, I still think we're on track with those ideas that you've talked about. It's just a matter of trying to get as much information as possible to be able to come up with ultimately some durable research agenda that I think and I hope will be distinctive in its design here. That will have a focus more on the patients, and will be something that I think will be associated with PCORI in its process. But at the same time, have the highest level of methodology and validity.

So, I don't know if I answered your question or not.

DR. KRUMHOLZ: Well, let me just clarify one thing first, which is that this is about saying, what should we aspire to? What should be the metrics? Are these the values that -- are these core values in the program that we wanted to get? The next step would be saying what satisfied these metrics?

I mean, I just don't want us to get -- we

can get into the details, but I think the first level is, is this inclusive enough? Are we missing anything big? Are there central concepts, as Sharon-Lise introduced, you know, that we might be missing or that we need to emphasize just so that we're going in sequence. Because I think this is at first saying, these seem like values we should aspire to. Then the challenge will be, okay. Well, how are you going to do it? What's distinctive?

DR. WEISMAN: So, let me be really concrete here. If you're coming back to us in July, for example, with a proposal which is doesn't include how you're going to execute on it, I think it's important about what kind of infrastructure or tools you're going to use to support it. So, I have personally as a Board member some concerns if we were to use maybe more traditional model of granting, reviewing. Even if we gave an organization our set of rules, I think it doesn't, you know, I have some concerns about that.

So I would like -- the reason I brought it

that at some point, I think that needs to be discussed with the Board as much as everything else.

DR. KRUMHOLZ: That's great. I mean, the reason to have number 8 up there is so that every member of the Board can ask themselves the question, is this distinctive in its design, focus, and implementation? Is there something special here or is it the same old, same old? And precisely for the reason you're saying -- and for us to have it there, it's going to say -- was, we go through our checklist. We say, well what -- did we satisfy number 8?

And your point is going to be, if we're doing it the way we've always done it, that answer is going to be no. And then we'll have to go -- yeah, start over.

DR. KUNTZ: Another point Harlan. I must make sure I'm clear about this. This is a goal for our research agenda national priorities. This will probably take a year or so for us to settle. What we're coming back in a month is just -- or in a

couple months -- is just some of the topics we do in the Tier 1 grants. That is not going to involve our finalized approach towards doing research. As a matter of fact, we'll likely have -- we'll talk about what that process is. But, we're envisioning a very, very slim and lean process for getting the Tier 1 grants out, mainly for expedition, to try to get it moving.

So, yes. We won't have these issues or how we're going to measure this done in the next meeting. What we're going to ask for, hopefully if we can get agreement, is a set of quick Tier 1 grants that we can get out which will not embody these more enduring strategicals.

CHAIRMAN WASHINGTON: First, Steve Lipstein and then Sharon Levine.

VICE CHAIRMAN LIPSTEIN: Rick, are you a lot -- can you go back to number 3? Do you have the power to do that? Right.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: So, you know, we talked about tangible knowledgeable, readily

appreciated by patients either directly or indirectly and then, we had a conversation briefly about being inclusive. And one of the things I want us to keep in mind or I worry about a little bit is, PCORI wasn't created to be inclusive of all kinds of research. So, we don't get to take the statute and kind of rewrite it to be a research institute that addresses the needs of other constituencies.

Our primary constituency, as described in our name, is to address the needs of patients. There are other research institutes in the healthcare world: the National Institutes of Health, the Agency for Healthcare Research and Quality that have their own constituent groups and their own foci.

But I guess I was wanting to get a better sense of under number 3 is, this was the research institute that was created to help patients, as identified in number 3. And the more inclusive we get, do we get -- do we become more diffuse? And so I guess I wanted to get a little bit more

discussion around number 3 is, do we diffuse our mission? Or do we go beyond the statute if we don't direct all of our research to be very patient-centric?

And so, I understood the example you gave about indirect patient care. And I understood the example that Arnie gave about improvements in the healthcare delivery system. But, how do we keep our focus?

CHAIRMAN WASHINGTON: Sharon was up. If it's on a different topic, we'll continue on this one and come to you.

DR. LEVINE: It's on a different topic -- it's not on Steve's question.

CHAIRMAN WASHINGTON: So, Arnie Epstein and then Francis Collins.

DR. EPSTEIN: I always think it's a little bit of how you place the emphasis on patient-centered outcome research. If it's patient-centered outcome research, the emphasis is really on patient. If it's on patient-centered outcomes, then it becomes really germane to study health

plans and all the other interventions we have that impact favorably on patient-centered outcomes.

CHAIRMAN WASHINGTON: Francis Collins, please.

DR. COLLINS: So, we as a board have been having this discussion from day one, in terms of the uniqueness of PCORI's mission compared to other activities that are out there in the past, and in the present, and in the future. And I think the challenge that we probably are going to have a hard time really meeting is to define some bright line between what PCORI will do versus what other agencies will do. In fact, I suspect we can't define such a bright line, and maybe we shouldn't try to achieve that because it would be a bit arbitrary.

I have to say, certainly PCORI was created to benefit patients. But so is the NIH, so is AHRQ. That's our mission, too. So, to try to define what PCORI is going to be different because we care about patients is sort of a losing argument, at least from some of us around the

table.

So, what is different has to be different in a way that reflects the inputs, the way in which we achieve the decisions about setting research priorities that is focused very intentionally and specifically on patient input. But of course, NIH and AHRQ do that at some level as well as our inventory is already demonstrating.

VICE CHAIRMAN LIPSTEIN: Francis, do you have some sense of what's -- at least on our side of the not-so-bright line?

DR. COLLINS: I think that's still not completely come in to focus, to be honest. I think in some ways, what PCORI is trying to do maybe needs to be defined a bit more by a full sense of the spectrum of what is already out there from other sources of support. And if we set ourselves up to say, well, we're only going to do the kind of research that would not be done under any circumstances by some other source of support, that will be a null set, I'm afraid. So, it's more the way in which the theme focuses on patient

orientation, where the approach to every problem incorporates that from the get-go, not as an afterthought, that is going to define PCORI.

But I would be willing to bet that when we have our full research portfolio and you go down the list, there will be projects there that will look somewhat similar, maybe quite similar to the sorts of things that would have been done by NIH.

All the more reason why it's good that we're doing this all together, to be sure we don't end up with duplication.

CHAIRMAN WASHINGTON: We have multiple hands. I'm going to go to Ethan Basch next, who is a member of our Methodology Committee, and then to Leah Hole-Curry.

DR. BASCH: Thanks. Just a quick comment. It does seem that a unique attribute of what we can do is to include direct patient input throughout the entire process. So, understanding what research questions are meaningful to patients based, perhaps, on qualitative research and similarly employing outcomes that are meaningful to

patients. Again, based on direct patient input from target populations.

CHAIRMAN WASHINGTON: Leah.

MS. HOLE-CURRY: Steve, I have a clarifying question before I have a comment back. Are you concerned about dilution of our purpose? And in the metrics that we're trying to lay out for gauging whether our portfolio eventually and our activities are aligned. We have 1 and we have number 3 that both touch upon the question you asked.

So, I think what I heard you say is, I'm concerned that we might get away from specifically the patient orientation by including the indirect measures in there. Was?

VICE CHAIRMAN LIPSTEIN: No, no, no.

MS. HOLE-CURRY: Okay.

VICE CHAIRMAN LIPSTEIN: I actually -- I understood 1 and 3, and I was on board. And then when we had the discussion of 1 and 3, and we talked about whether or not it was sufficiently inclusive of other kinds of research, that I think

Arnie made the point. That's when I started to get -- I wanted to understand. And I think Francis kind of got me a far way down the path by saying, it isn't going to be a bright line. And, that the kind of research that we do may be informed by patient input differently than patients inform the research agenda at NIH or at AHRQ and I think Ethan made that point.

So, involving patients and family caregivers -- people who are helping to make these choices, informing them in the design of research questions could very well be our unique space. That doesn't mean some of the research won't touch all aspects of the healthcare delivery system.

CHAIRMAN WASHINGTON: Okay. We're on the same topic, Sharon you said yours was a little deviation on this. Okay.

Harlan Krumholz.

DR. KRUMHOLZ: I just want to say, I think what's unique about us is this Board and the fact that the stakeholders are coming together and we hold ourselves accountable for the perspectives

different people are bringing to this. And I think Francis is absolutely right, there's going to be overlap. But I hazard to say that I don't know how many NIH studies begin and include end users from the very outset of the development of the study, and at every phase of that study.

And if we're successful, we will help change the culture of this kind of very basic, pragmatic, practical clinical research that's intended to influence and inform decisions and influence practice. And, you know, we're an incubator of new ideas. We're able to be a catalyst in a way that a large organization like NIH and even AHRQ will have trouble doing because of the way that they sit in the government. We specifically sit outside of the government with these stakeholders, and the way in which we're going to bring in input is going to help define the way in which we conduct the research.

So I think it's going to be less -- and I know you didn't mean this, Steve. You know, these organizations are very patient-centered, too. So

it's not really just the patient-centeredness, but we are taking a very different path. And I think we'll have a different product, and we're going to learn different things. And then we'll share them, because together we want to mutually inform our efforts rather than feel like we're off on the side. And if we discover new ways of doing things, we want that to be disseminated to the research community as well as to patients.

So, I mean, just in terms of the clarity of it, I don't think there's any question to my mind that we are trying to embark on a novel approach and we're going to try to do it in a way that ultimately drives great value to the healthcare system and to individual patients. And the richness of the diversity of this board is going to be, I think, a principle strength and of the Methodology Committee, as they come and bring different perspectives and expertise.

So, it's -- to me, I think that's the piece of this that's special.

CHAIRMAN WASHINGTON: I'd also like to

clarify for all listening that the influence that we seek -- it's not just influence on government agencies. It's influence on all institutions interested in health in the private sector or public sector, or not-for-profit sector, across the country. And so, while we are using these as examples, I had a conversation earlier with Naomi Aronson, who heads the Technology Assessment Group for Blue Cross Blue Shield, who is engaged in similar kinds of -- I know Kaiser has such an entity.

I know there are many other institutions and organizations that are engaged in this type of activity. So, I want everyone to understand. We're using these as examples, but our intent in terms of impact is to influence how this kind of research is done nationally and subsequently, internationally.

So, Sharon. You've been waiting patiently for a while.

DR. LEVINE: And just to tag off what Harlan just said. We are going to achieve those

things, but not -- we don't need to exclude other interested parties and critical stakeholders in the process of doing that to set ourselves as unique. I think that's a critical issue.

And Rick, can you go to the next slide, the one that -- I wanted to -- number 7. I mean, I think whether we're talking about stakeholder partnership or stakeholder engagement, I think we also need to include in that stakeholder segmentation. We need to -- because I think we need to understand for different stakeholder segments, how they want to receive information, how they want to provide information. And how, how the work of PCORI can be of utility to them in the service of a common goal, which is to improve the quality of decision-making that patients are able to engage in with full information and a full sense of authority around the care that they need for themselves. And I think understanding those different segments -- and directly engaging around the issue of how do you want to be involved? How do you want to get information? And, how do you

want to provide information?

CHAIRMAN WASHINGTON: Ellen Sigal and then Harlan Weisman.

DR. SIGAL: I just want to say the same thing that I think everybody is saying, but in different ways. We can't go forward unless we are collaborative and we are unique in our structure. We have a daunting task, and we have to build on what's going on at the NIH and AHRQ and other agencies, and in the private sector, and all over. And we have to bring that together and add value, because we are very lucky to have unique voices at this table. We are independent. But if we don't build on what's being done and collaborate, then we can't accomplish our goals for patients.

So, I think we're all saying that, but perhaps in different ways. And I think it's important to get back to that basic value.

CHAIRMAN WASHINGTON: Okay. Harlan.

DR. WEISMAN: Yeah, I -- first of all, I'm glad that you said what you did about collaboration. I think that is an important add-on

to, you know, how we operate. Not that others don't, but it's an important guiding principle.

You know, in the discussion of what makes us different or at least what is a guiding principle for us, that may not be the focus all the time for other types of comparative effectiveness research because a lot of discussion about what makes us unique is the input of patients and caregivers. That they help guide us, what we decide are our priorities and what research projects we take on.

But also, importantly -- and it was on the slide, is the output. I mean, this is output that I think really is unique as we're intending it, which is that it provides information that's meaningful, that's understandable, that provides knowledge to the patient, and a word that Harlan used that was on the previous slide, was "appreciated" by the patient.

And it's not that other work in comparative effectiveness and outcomes research couldn't have those qualities, but those are

derivative. We're saying that's primary. We're saying, that's what we're about, is to get the patient involved on the inputs, but also on the output. That's our primary target. And I think that really does -- you know, whether or not it's part of a patient's decision, certainly we want it to be meaningful, understandable, contribute to their knowledge and have them appreciate it.

CHAIRMAN WASHINGTON: Okay. Rick? You're back on.

DR. KUNTZ: Great, thanks. Pat had asked me if we were going to have enough time to stretch this out a little bit and I said, don't worry.

[Laughter.]

DR. KUNTZ: I just want to make one comment, because I think a lot was centered on the fact that these individual alignment metrics which are culled out from the statutes and trying for us to get some alignment, they're not individual aspects that stand on their own. They're all together.

For example, if we're going to have game-

changing impact, we're going to transfer knowledge; we need to have meaningful consequential output. So, it's not that nobody else has meaningful or consequential output. When you put them all together, these had to be elements to make our strategy going forward. So, just something to point out.

So, this is now where we get a little bit more creative and when we try to say, okay. We have culled out from the statutes what was the intent of PCORI, and the elements that we thought we'd kind of abstracted, which you just saw, how do we now start to shape ourselves to be unique? How do we start to shape ourselves to have the added value? How do we separate ourselves from potentially other organizations?

And this, again, I think this started as a brainchild from Harlan. And I think it's something we all worked on very intently, is to say from the patient's perspective and from a healthcare perspective, what is it that we can start to align ourselves as we start to develop a strategy?

So thinking about that, when we develop a research program and award grants and start to understand how we can advance the research and clinical, we constantly have to have some ideas in our mind, what are the perennial questions that have to be answered from a patient perspective? Patients want to know in all situations, what will happen to me? What can I expect? What's the trajectory of their disease?

We would identify that as something that is often not known by patients with respect to coming into the healthcare system, you know. What is the natural history of the disease? What can they expect can happen to them after they've been diagnosed with a new disease? Are there ways that our research program can help inform patients about what's going to happen to them?

The next thing patients want to know is, what are my options? And what are the differences among them? Do they actually feel like they've been fully informed with all their options? I think a lot of situations, we can all agree, that

many of us who have been patients or have cared for family members or, as caregivers, can identify situations maybe -- often situations where all those options are not available to patients. That they fully didn't understand all of the possibilities and alternatives that they could have after they've understood what's going to happen to them.

And finally, patients really want to know what can they do to improve their chances of achieving the outcome that they prefer? And this goes beyond just choice of treatment A versus treatment B. This deals with a lot of health and lifestyle changes, other ways that they interact with society, the healthcare system, and so on.

All of these are critical questions that it's probably safe to say the classic, traditional research is not focused specifically on with respect to identifying and comparing therapies going forward. And this, and if we start to scratch the surface and drive some of these important personal questions that patients want to

know, can this inform us about how we could set up a research agenda to help set these.

And finally, the remaining question is not only from a patient perspective, but how can the healthcare system improve my chances of achieving the outcome that I prefer? And that brings in the notion about what we can do to study a variety of different alternatives that affect the delivery of healthcare from a systematic perspective.

So, I'll stop here, but this is our first approach. Again, I think I want to give credit to Harlan to initiate this process, but we spent a lot of time on this to talk about -- from a patient perspective, can we put together a state-of-the-art legitimate and valid research process that focuses on these dimensions?

CHAIRMAN WASHINGTON: Okay. Ellen Sigal.

DR. SIGAL: Rick, I want to give you and your committee a huge shout out and say, bravo. You really hit it, and it is really what is most meaningful and if we can begin to answer these questions that are meaningful for patients and

their families and caregivers, then we will have been -- all of this hard work would be worth it. But a very, very, very excellent job. I think you nailed it.

DR. KUNTZ: I'll take credit for it, although it wasn't mine.

[Laughter.]

CHAIRMAN WASHINGTON: You've taken enough heat that you can deserve this credit.

DR. KUNTZ: Thanks.

[Off microphone discussion.]

DR. KUNTZ: -- the salesman made -- yeah. Last slide --

CHAIRMAN WASHINGTON: Let's just do a time check, Rick. We really do. We have eight minutes to wrap up this entire section. We're going to stop at 3, because we have a welcomed challenge of accommodating all of the participants who have signed up for public comment period.

DR. KUNTZ: Well, we had one small parenthetical topic which we were going to raise, which was the idea of a PCORI network, which I

think we could probably handle in eight minuets.

Well, good. Now that we know that we have -- we're constrained by eight minutes, I feel a lot more comfortable about this next topic.

[Laughter.]

DR. KUNTZ: Getting through it.

What we'd like to do is, introduce the concept of one of the many research tools that we can utilize PCORI. The statutes tell us that PCORI will utilize a variety of different tools, and they're all the usual suspects: to use existing data and to perform state-of-the-art systematic reviews, to perform retrospective epidemiological research, and including data mining. To -- and these aren't totally inclusive, by the way, but they're called out. To do prospective research, such as randomized control clinical trial or observational studies with a variety of methodologies to control confounding.

These are obviously traditional methods which can be modified and customized for the goals that we looked at earlier. But, one

infrastructural possibility that we would like to at least get started -- and when I talk about getting started, start the conversation among our group. There -- we still don't have consensus among the PDC yet about the ideas of a network, but I think that we've talked a little bit about this before and what we'd like to ask the group for is the green light for us to go ahead and start the initiation of exploring the notion of one of the legacies that PCORI can establish is, to have a network.

And again, without getting into too much of the details, the idea is to potentially try to develop an economy of scale, a set of existing and broad-based clinical sites at a variety of different levels of healthcare, where standardization, process, expedition can be the main strategic factors that utilize scale opportunities, it's a scaleable research process, so that we can get more research done, using the state-of-the-art statistical methodologies, answer more questions by leveraging an existing novel

network to go forward.

And again, the ask is to at a very high level get the permission for us to at least from a committee perspective -- to explore this further. To use a few resources to try to drive this, to come back with a report in our next meeting in two months, and then to see if anybody's interested in taking it to the next level.

CHAIRMAN WASHINGTON: Sharon Levine.

DR. LEVINE: Rick, are you envisioning potentially a network of networks?

DR. KUNTZ: Thanks for pointing that out. Yes. Clearly, if we're going to talk about putting a network together, we had to do, as we said earlier, a landscape review of what exists out there in existing networks. So that we can, first of all, can we connect existing networks already. It might be an IT solution, but, yes. A network of networks could be one solution.

But I still think that buried in there is the notion of developing a novel network in addition.

CHAIRMAN WASHINGTON: Francis Collins, and then Harlan Weisman.

DR.COLLINS: I just want to say that this will obviously be a place where collaboration with the Methodology Committee would be of great value, given the questions that need to be posed right away about exactly what kinds of individuals are we hoping to enroll in such a network. Is this going to be population-based? I don't think so. Is it going to be more sort of focused on specific disorders where you're trying to assemble cases and controls?

Is this going to be a virtual network? Is it going to have a bio-repository? How critical would that be? Can you take advantage of some of the newer information, social networks like Patients Like Me that sort of follow that kind of strategy to enable you to do something that's actually quite far-reaching, but actually not too difficult or expensive. At least, not at the beginning.

All those really interesting questions,

and I would think our colleagues in the Methodology Committee would be really helpful in thinking those through.

CHAIRMAN WASHINGTON: Harlan?

DR. WEISMAN: Yeah, I had a question that was partially, I guess, addressed by your questions, Francis. And triggered by Sharon's question.

Because you could imagine -- first of all, I love the idea and I think you should go ahead, but we'll take a vote, I guess, in a minute. But you could imagine that a network looking at cancer versus looking at psychiatry versus looking at diabetes versus looking at orthopedics would have maybe different features, different kinds of investigators, different kinds of centers, and so forth.

On the other hand, it does make sense that you could have a common framework of what are core data sets and definitions and classification systems that you would use. And Francis brought up, you know, markers and genomics. And, you know,

other things that would be included that would be a -- to use your idea, Sharon, a network of networks that would bridge these all together. But it would seem not practical to have a single network that could study all the different things we might want to study to tell us.

CHAIRMAN WASHINGTON: So, let me ask the Board members, particularly those of you who are not on the PDC and those of you who are not involved with the Methodology Committee. If you are comfortable that you have sufficient information at this point to vote thumbs up or thumbs down.

Anyone want to express a concern? I mean, I've heard about this because I've been involved in some earlier discussions.

MR. BARNETT: I would just echo Harlan's comment. I certainly love the idea. Still not quite clear exactly what this network is. But I think the green light that I think you're asking for is to move forward on answering those questions. So, I would enthusiastically vote yes

on that, and look forward to a future discussion where we can get a better sense of what does this really mean and what's the structure behind it?

CHAIRMAN WASHINGTON: So, the proposal is that we would approve in concept that the Program Develop Committee explore what are the options, in fact, for establishing a potential PCORI network. Okay.

All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay, Rick. You're ending on a high note. Okay. Thanks, everyone.

Before we take the break, we will start at precisely 3:15, because we will likely go over the designated time to accommodate all of our public participants. And we look forward to a very vibrant discussion.

I would ask the participants to hold your comments -- I'm going to say, to two to three minutes. Certainly three is maximum. I would also

ask if there are any of you who will be here tomorrow during the public comment period and would like to present tomorrow rather than today to please let Richard Schmitz -- Richard, raise your hand, please -- know, so that we could accommodate you tomorrow. But everyone that signed up will be heard today. And again, I asked you to please look at what you planned to convey and limit it to two to three minutes.

Thank you again.

[Recess.]

CHAIRMAN WASHINGTON: Mr. Richard Schmitz from Golin Harris is going to call up our commenters. And again, I would ask that you please limit your comments to three minutes or less.

Richard, who is presenting first?

MR. SCHMITZ: We'll do this hand-held.

We have, I believe, one person on the phone who has signed up to provide comment. And I think just for expediency we'll handle that comment first. Maggie, our operator. Could you please announce the individual who is on the phone for

comment?

OPERATOR: If you would like to make a comment, please press star and then one on your telephone keypad. That's star and then the number one to make a comment.

Okay. We have a comment from Lorraine Johnson from CALDA. Your line is live.

MS. JOHNSON: Should I talk?

[Feedback on line.]

MS. JOHNSON: My name is Lorraine Johnson, I'm from the California Lyme Disease Association. I wanted to make a couple of comments.

I think that this organization is a very important organization. It could make some needed changes in the healthcare system, and I would encourage the organization to actually make some dynamic change. I think that what is needed is something that is patient-oriented. Someone earlier said that patients were not considered to be a primary stakeholder. And yet, they are the people most affected by healthcare.

I think it's very important to get

research and other interests aligned with actually making sure that patients are receiving quality healthcare. So, I would encourage the organization to use this as an opportunity to be a game-changer and not a duplication of efforts of other organizations, like the NIH or AHRQ.

I would empower the silent groups, which are the patients, and I would do that by asking them to define patient values and using that as a starting place. And I know from my personal experience that the values that patients have expressed to me are choice among viable treatment options, information regarding options, access to care, [inaudible], research that improves quality of life, and cures. And many of the people who are involved with the healthcare system have interests that are aligned with these, but many do not. So stakeholders' viewpoints vary significantly.

So, I think it's important for this organization to start at the center by placing the patient there and then determine what is goal and what is [inaudible] accomplish appropriate patient

care.

I would also encourage you to think about system modifications that you can make. Somebody was mentioning the use of networks. I would encourage you to think about using the Internet as a means of accessing large patient populations through patient advocacy organizations. And I would also encourage you to think about making the types of systemic changes that would matter to patients, including shared medical decision-making, decision-making aids, and those sorts of things that really help patients make the decisions that will determine the course of their lives.

Thank you for your time.

CHAIRMAN WASHINGTON: Thank you very much for your comments, and for your suggestions.

MR. SCHMITZ: Maggie, are there any other speakers for comment online?

OPERATOR: We have no further comments at this time.

MR. SCHMITZ: All right. Thank you, Maggie.

We'll now turn to the individuals who signed up here onsite to provide comment. I will introduce each individual by name. If you would, please repeat your name in case I mispronounce it, and provide any affiliation you have. And the Chair, Dr. Washington, has asked that individuals keep their comments to approximately three minutes.

In addition to providing comments orally here today, you can also provide written comments to the Board by e-mail simply by sending it to info@PCORI.org. The first commenter is David Shahian.

DR. SHAHIAN: Thank you. My name is David Sheehan. On behalf of the Society of Thoracic Surgeons, I appreciate the opportunity to comment on the role of clinical registries and comparative effectiveness research to facilitate shared decision-making.

My comments will focus specifically on the applications to cardiovascular disease, the first priority area in the National Quality Strategy. But we believe that the lessons learned from the

use of registries in this area could easily provide a valuable paradigm for use in other healthcare sectors.

We believe that comparative effectiveness research based on observational data from clinical registries would offer many advantages. Registries such as the STS Adult Cardiac Database provide a readily available portfolio of audited clinical data collected by trained abstractors using definitions developed by clinicians. Our database was established 21 years ago and has records now in over 4.5 million patients. About 95 percent of the cardiac programs in the U.S. participate. And we found that our demographic studies that these data are broadly representative across all ages, racial and ethnic groups, and pairs.

Our colleagues in the ACC, the American College of Cardiology and the American Heart Association have similar databases for inpatient and outpatient care that encompass millions of patients. The STS database alone, or any of the others I've mentioned, would serve as highly

credible sources for comparative effectiveness research to benefit patients.

By further linking clinical registries to administrative data sources, such as MEDPAR, or payer databases, we can harness the unique longitudinal information that those databases contain about re-interventions, readmissions, and resource use.

Finally, by cross-sectional linking of these various clinical registries, we could encompass most of the cardiovascular disease spectrum. This would move us beyond a focus on specific conditions and procedures to provide broad coverage of a whole spectrum of cardiovascular disease.

This vision for comparative effectiveness research already has an exemplar in the NHLBI-funded ASSERT study being conducted by the ACC and STS to examine the comparative long-term effectiveness of CABG or PCI revascularization strategies in real-world populations. This would include specific sub-groups of patients, such as

those with low ejection fraction or renal failure or chronic lung disease.

The total number of patients available for analysis here is on an order of magnitude greater than all previous randomized control studies combined. Comparative analyses have been performed using propensity score approaches and inverse probability weighting. We anticipate that the results of these studies will inform patients and their providers about the potential long-term results of treatment options in various patient sub-groups.

We view the ASSERT study as an attractive paradigm for a comparative effectiveness research enterprise, based on linked clinical and administrative data. We used MEDPAR in this case, linked with both the ACC and the STS data.

This research enterprise could quickly and cost-effectively answer a broad range of questions that will arise in the coming years of healthcare reform, using comprehensive clinically-robust, broadly-generalizeable data on hundreds of

thousands of patients. At least in the cardiovascular world, the necessary data are available now.

Thank you very much.

MR. SCHMITZ: Our second commenter is Sharon Smith. And feel free to go to whichever mic that you're closest to, and we'll have the second mic turned on.

MS. SMITH: Hi. Sharon Smith, the National Trauma Institute. I'm the executive director, and I'm here to represent the national trauma surgeon and emergency surgery community.

We are a non-profit, we're based in San Antonio, Texas, and we came to be because we feel like there is a historic lack of funding and infrastructure for the national trauma community.

The trauma surgery community is very interested in any opportunity to work with PCORI. Our entire purpose is to fund and coordinate clinical trauma research, not basic and not animal science research. We believe trauma is an unrecognized epidemic. That's backed up by

information from AHRQ and CDC and NIH. It's the number one cause of death for age one to 44, more than all other causes combined. And it's the second most expensive healthcare problem, according to AHRQ data.

This is largely a civilian catastrophe, even though we hear so much about the military. There have been 250 times more deaths and 6,000 times more injuries than we've experienced in the two wars.

The gap in funding and the need has been studied and documented for decades. Most recently, in 2009, there was an NIH roundtable on an emergency trauma research. And that report issue stated -- issue states that effective trauma research could be profound, and the potential to improve outcomes and conserve resources is immense.

The national trauma community research community, in its frustration, actually began the National Trauma Institute. Because they had very little time to make decisions, most of what they do is, they would say to themselves is often very

anecdotal. It's not evidence-based, so there are significant gaps in research.

We are still finding our own routes to funding, but we have issued two RFPs and 16 studies involving 28 trauma research centers around the country. We are always focusing on existing research, the best investigators, unusual investigators. Sometimes it's an engineer or a former Army medic that works out of his garage. So, all the things that you talked about today are resounding and echoes of all the things that we've been through. We're a very thin slice of the pie of everything that you're having to consider, but we've often been down -- as you've outlined what you're doing now, its sounds just like what we've been through.

And with PCORI, we hope we can engage to provide you with information on this important research gap and what's possible in terms of clinical evidence. And, I guess in conclusion, we'd like to say that even a 5 percent reduction in the trauma problem would save $35 billion, prevent

1.5 million injuries and save 9,000 lives every year. So, we ask PCORI to make trauma a national research priority for advancements in clinical care. Thanks.

MR. SCHMITZ: Our next commenter is Seth Ginsberg.

MR. GINSBERG: It's on. It is on. Hi. Good afternoon.

My name is Seth Ginsberg, and I am the co-founder of the Global Healthy Living Foundation, a 501(c)3 patient advocacy group which includes the arthritis community, creakyjoints.org.; the psoriasis community, redpatch.org; and the osteoporosis community, creakybones.org.

Our membership is more than 50,000 patients and caregivers from all 50 states. Many of whom rely on innovative biologics to treat their chronic conditions. I'd like to thank the PCORI Board of Governors for allowing patients like me to join this national discussion on comparative effectiveness research, and its future here in the United States of America.

At the Global Healthy Living Foundation, we work to improve the lives of people with chronic illnesses through educating the community on the importance of diagnosis and early, innovative medical intervention. So, patient-focused CER is clearly something we can support.

Like all of you here today, I see great potential in comparative effectiveness research. Good, new health data could allow patients with chronic illness to benefit from better diagnosis and earlier medical interventions, which in many cases will come with long-term benefits.

The issue of patient-centered comparative effectiveness research is also a personal one. I myself am a patient and have been since the age of 13, who suffers from spondyloarthropathy, a form of arthritis treated with biologic drugs. Undoubtedly, one of the most important medical breakthroughs of our time biologics have allowed patients like me and many members of Creaky Joints, Creaky Bones, and Red Patch to live normal, more productive lives. So, the importance of sound

medical research is not lost on me or many of our members.

A concern about this type of research, for many patients, is the potential for CER to be misused in ways that hinder delivering optimal individualized care in order to achieve a cost containment objective. It may appear to many of you that this concern doesn't relate to PCORI work, since PCORI is focused on the development and dissemination of research, not on its use.

I would argue that this, in fact, relates very closely to PCORI's work. The more successful PCORI is in advancing a research program that is patient-centered, not just in word but in deed, the more it will protect against future misuse.

Let me give a couple examples. First, setting research priorities. How you do this is critically important. Selecting what topics to research and how to conduct that research has traditionally been done through a payer-defined health technology assessment model that asks questions that will help payers control costs.

PCORI needs to set up priority setting processes that find out what questions matter most to patients and their physicians. And then, support research to respond to it.

Second, I encourage PCORI to look toward a research agenda that goes beyond treatment A versus treatment B, or test A versus test B. A lot of times, we hear the purpose of CER described as finding out which treatment is best and only paying for that. This is a simplistic, cost-centric view of CER. Doing this type of research could serve this type of misuse.

It also will miss some of the broader areas, where we have real potential to get better value while improving care quality in areas such as reducing unnecessary regional variations in care, and identifying optimal approaches to care management and delivery. Research in these types of areas will help fill a big knowledge gap, and will reflect an agenda that is patient-centric, not cost-centric.

In closing, I would like to urge PCORI to

stay patient-centered. And, to communicate its mission and the purpose of comparative effectiveness research as remaining patient-centered. Sound evidence appropriately communicated and applied by patients and physicians in ways that reflect their individual circumstances and preferences can and should have an impact on cost by supporting high-value quality care.

The Global Healthy Living Foundation appreciates PCORI's time and efforts, and we look forward to continuing to work with you and the institute as it works toward achieving patient-centered comparative effectiveness research.

Thank you again for coming to New York. It meant my travel was very limited.

MR. SCHMITZ: I'm actually going to announce the next two commenters just to expedite the transition. We'll have Peter Pitts followed by Alexander Lloyd.

MR. PITTS: Good afternoon, hello. My name is Peter Pitts. I'm the president of the Center for Medicine and the Public Interest. I'm

also a former FDA associate commissioner. Despite those credentials, I will be brief.

[Laughter.]

MR. PITTS: Firstly, we just -- you discussed early in the session the issue of outcomes. I think it's also important to discuss and to capture outcomes data. There are lots of databases out there. We need to go beyond CMS pilot projects. In the UK, for example, they have done a pretty good job in collecting the data. Not so terrific a job in figuring out how to use it. I think one of the things that this board can do is really be a leader -- a global leader -- in understanding how outcomes data can be used. Outcomes data result in better patient outcomes for everybody.

Second is molecular diagnostics, both for patients and for physicians and payers. Molecular diagnostics is the new frontier. It can be very frightening. It can be inaccurate. But it's here, and it's here to stay. And the more that I believe PCORI can do to educate all the various

constituencies as to the importance of molecular diagnostics, the better and as early in the disease process as possible.

Third, some discussion of adaptive clinical trials. More needs to be done. You know, I would urge PCORI to -- not that we need any more government programs -- but to be a driving force behind adaptiveclinicaltrials.gov, where people can really go to the place where these exist. Any assistance you can give in working to create better or more uniform designs of adaptive clinical trials, so much the better.

Relative to cost control is a theme that keeps coming up. I think that's important to note that cost controls really are a slippery slope to price controls. And price controls ultimately do equal choice controls. These are tough conversations, and I think that PCORI would be wise to steer clear of them, but to be aware of it. Relative to a database that collects CER studies, a couple of issues. Firstly, when it comes to things like KD or all that, it's a garbage in, garbage out

proposition.

So, caution is required there and certainly, relative to the rhetoric. CER certainly by the statute by which this committee sits is clinical effectiveness, not comparative effectiveness. And clinical effectiveness, again, leads to better patient outcomes. Rhetoric counts. So, let's call it as to what it's supposed to be.

And lastly -- second to lastly, quickly -- beware of so-called academic detailing. No one is quite sure what it means or where people's agendas lie.

And lastly, patient-centered, again, let me repeat what Seth said. Must mean that care comes first and cost comes second. Otherwise, the PC in your acronym simply means "politically correct".

Thank you very much.

MR. NICHOLS: Excuse me just a second. I'm Pat Nichols, I'm a consultant to the Board. These are wonderful, rich thoughts. We do have some time constraints. We are having riches of

participants today. So, if our public commenters could remember the request to stay between two and three minutes, we'd be grateful.

Thank you very much.

MR. LLOYD: I will try and follow that. My name is Alex Lloyd, I'm here representing Healthcare Chaplaincy, and we are a non-profit organization that trains and deploys chaplains to hospitals in the greater New York City area. And I wanted to speak to a point that was made about non-traditional stakeholders earlier.

I think it's really important to think not only about patients but also about other hospital professionals who can help and aid in research in these settings. In particular, I'm speaking about chaplains who are spiritual professionals who often sit at the bedside with patients long after the doctors, nurses, and everybody else has left to listen to how they make meaning of their experiences. And to understand how their -- both their spiritual beliefs and their cultural and emotional needs, how those factor in to the way

that they think about their care.

It's important to not forget that as Dr. Lipstein pointed out, that patients do have a plethora of different factors that come into play when they think about their care. And then speaking about the questions that you put up in your presentation earlier, that patients don't necessarily think the same way as doctors about those questions that they often do frame those -- they way they think about those questions in terms of their spiritual beliefs as well as their cultural beliefs and their own values and needs.

So, I just wanted to bring up that point. And also, to point out that one way to improve the quality of patient experiences also, to think about innovative models for providing healthcare. Healthcare Chaplaincy is currently involved in planning and building a facility using an innovative model that New York State has come up with called the Enhanced Assisted Living Resonance Model, that is essentially a model that provides a continuity of care as opposed to bouncing patients

back and forth from one form of care to another, from one facility to another.

So, again, both to provide or to consider spirituality and other factors in the treatment of patients to consider non-traditional stakeholders, like chaplains, in partnering with research. And, to consider different models of healthcare and improving the quality of patient experience.

Thank you.

MR. SCHMITZ: Our next commenter is Dolph Chianchiano followed by Dolores Rogers.

MR. CHIANCHIANO: Thank you. I'm Dolph Chianchiano representing the National Kidney Foundation and its 50,000 patient and professional members.

I want to thank you for the thoughtful discussion this afternoon. We have been concerned that there are few randomized control trials concerning chronic kidney disease, and also that there are few randomized control trials that have patients with chronic kidney disease as participants. Therefore, we appreciated the

discussion of alternative research tools. We might also suggest that you consider the use of epidemiological registries, like the United States Renal Data System, which as a 20-year record in this regard.

My other comment relates to a recommendation from the Institute of Medicine, which as you know recommended 100 top priority areas for clinical effectiveness research. The only topic that concerned kidney disease called for a study of the various options available for renal replacement therapy once kidney failure ensues. However, we suggest that clinical effectiveness research, while it would -- such research would improve the quality of life and quality of care for 100,000 Americans who each year succumb to kidney failure, on the other hand clinical effectiveness research that is focused on different strategies to prevent or delay kidney failure and/or the progressions of disease associated with chronic kidney disease, such as cardiovascular complications, would improve the prospects for

millions of Americans with earlier stages of chronic kidney disease.

In closing, I'm pleased to offer the assistance of the National Kidney Foundation as the research agenda of PCORI is elaborated. Thank you.

MS. ROGERS: My name is Dolores Rogers, I was a health planner in the days of the health systems agency, and learned that whatever was considered that the population needed, nobody ever thought about everybody being insured. So you can offer services but if people can't have access, that was a matter of indifference.

If I have a certain plan and my doctor is on that plan and then I change my job and then I have to change my doctor, what does that do to trust? What does that do to information? When the money runs our lives, it really has a very negative effect on how patients can manage their own lives.

Arnold Relman has a letter today in The Times recommending group practice, patients and single-payer. There's no vested interest in that.

MR. SCHMITZ: Our next commenter is Laura

Newman.

MS. NEWMAN: Okay. Actually, I don't really have prepared comments. My name is Laura Newman, and I have worked with some of you folks as a journalist. I worked on the Learning Healthcare System Project for the Institute of Medicine as a writer, and I used to write “Medical Outcomes and Guidelines Alert.”

I've recently made a move of my own to writing a blog called Patient POV. I represent no one. I consider myself an eyewitness. I consider myself somebody who wants to hear the stories that are not getting through. I'm not affiliated with a drug company, or a patient advocacy group. And, if I do interviews with such people, just like is done in medical meetings, I what to know if, you know, a pain group is getting money from Medtronic. If a -- you know, a cancer group is getting money from Genentech, et cetera.

The reason I'm here is -- and the reason I've sort of made this transition is because I kind of feel like you're over there and the rest of the

world is over here. And I just don't -- I mean, I think this is great that this is happening. That there is a, you know, real strong emphasis and budget for Patient-Centered Outcomes Research Institute. But I think -- I wish you guys would work on some literacy stuff, so that, I mean, people can't come into a room like this and think there are -- you've been immersed in comparative effectiveness research. I don't know how many people here have been.

I mean, I could define it, if I'm talking to doctors. I could talk about research that any of you have been engaged in. I'd like to see patients engaged from the beginning. I mean, many years ago Martha Gould wrote an article, I think in Health Affairs, where she talked about patients in the UK who would show up to evaluate new technology. And it was fascinating to me that you could bring people in to explain some complicated medical device, but I kind of feel like you have to break down some of the assumptions and, you know -- I wish meetings like this would have, you know,

handouts for people.

And if you put on the Website some basic translation sort of information, otherwise I don't see it happening. I mean, I just see it being sort of same old stuff that, you know, AHRQ was doing a long time ago with the patient outcomes reports where, you know, we decide there's too much of this kind of surgery, how can we get it down? And to me, that's not necessarily what matters to patients.

Let me see whether there's, you know, anything else. I'd also -- I mean, I also wish you could sort of figure out ways to do some kind of survey research of broad groups of patients. Not necessarily through health advocacy organizations, because they have their own agenda, I think, and don't necessarily, I mean, I've just talked to patients recently about, for example, orthopedics where they said that they had absolutely no aftercare. And I called the American College of Orthopedics and they said, well, you know, it's so multi-disciplinary, we don't know what to do. But

these were sort of not great patient stories. And, you know, that kind of group is not very well-organized.

So, you know, I mean -- there ought to be a mechanism where ideas can come from patients who have had experiences, that aren't out to flame you or flame a hospital or an organization. They're not looking for a settlement. But, they just have, you know, some simple, you know, ways -- I mean, if you really -- there are some things that could be done that would not be, you know, skin off the budget or, you know, stakeholders going wild against each other. That's -- yeah.

MR. SCHMITZ: That's all of the yeses we had for comments. There were a couple people who had marked "maybe". Would any of the maybes like to make a brief comment?

DR. CARUSO: I'm Tom Caruso, I'm a member of the Biomedical Informatics Think Tank, which is a division of a for-profit organization called Projectivity, Inc.

I just wanted to say that I'm very

optimistic about where this organization is going. I like to see that this -- that PCORI is thinking about passion-oriented. It's also thinking about being an innovative organization with some new ideas about how to do these kinds of things.

I think that from my perspective as a biomedical informatics person -- and by the way, the organization that I represent is made up of about 21 people who are leaders in biomedical informatics throughout the country. I've spent a lot of time now in ONC meetings learning about what's going on with health information technology. The entire environment with regard to clinical or comparative effectiveness research, however you want to call it, is going to dramatically change in the next few years, because information is going to be different out there.

However, on the HIT side, there is not thinking about -- the thinking about comparative effectiveness research is not very clear. And on this side, I don't see a whole lot of thinking about what's going to -- what needs to be in the

HIT side, so that -- to make comparative effectiveness research more effective. And that's primarily what I wanted to say. Thank you very much.

CHAIRMAN WASHINGTON: Well, that concludes the comments. I'd like to first thank all of our commenters for taking the time to provide us with the thoughtful suggestions and points of view that you just shared with us. And we'd like for you to know that we greatly value your input, and we'll be incorporating your insights and suggestions into our deliberations, and into our decision-making.

And so, for those of you who may have additional comments today or after tomorrow, please do go to our Website, PCORI.org, and share them with us.

So, thank you again. And there is another public comment period tomorrow morning for those of you who sleep on this tonight and wake up tomorrow morning with new information you'd like to share with us.

Next on the program, we're going to turn

to the Methodology Committee report. And we have the chair, Dr. Sherine Gabriel and the vice Chair, Dr. Sharon-Lise Normand here at the table to present the committee's report.

Sherine?

DR. GABRIEL: Okay. Well, thank you very much. On behalf of all of my colleagues on the Methodology Committee, I'm happy to provide this update to the Board. And if I can make a brief sidestep, I have to also add on all of -- on behalf of all of us our congratulations to Joe Selby. And just say once again how excited we are to see him join us.

CHAIRMAN WASHINGTON: Joe, we're glad you're still here.

[Laughter.]

DR. GABRIEL: So, just as we start many of our meetings -- virtually all of our meetings -- and I won't read all of this. But just as a reminder of the statute -- at least of the components of the statutes that pertain to the work of the Methodology Committee. What I'll highlight

in this first piece is our wonderful deadline, not later than 18 months with a clock that started ticking before we were even appointed. But I think the speed with which the committee has been working is evidence that we'll make it.

The other thing I'll point out is the key purpose here or function as stated, that the committee shall work to develop and improve the science and methods of comparative effectiveness research, patient-centered outcomes research. And you'll see that in the subsequent slides. And that we'll do so through these two key deliverables, if you will; the methodological standards for research or a port describing those standards and a translation table.

And again, I won't go through all of this, but to give you a sense that the statute has some specificity regarding what that methodologic standards for research reports should contain. And you can see some of the blue-highlighted words are really those that we keyed on for our own strategy. And the translation table, which is a tool -- a

guidance tool that can serve as a reference to determine optimal research methods that might address specific questions.

So, again, just a reminder of our statute and to reassure the Board that as we move forward with our work, we always have this top-of-mind to ensure that what we do is aligned with the intent and the letter of the law.

Okay. So, with respect to our agenda today, a few things to cover. We've sort of divided our work in the Methodology Committee in a few categories. The first is what we refer to as our foundational tasks, is those things that we needed to kind of put in place to enable our core work. And with respect to those tasks, we're going to be asking -- requesting the board for approval of our charter, which I know you've all looked at. And we've also assembled a -- what we call a working definition for patient-centered outcomes research to help frame the scope of our work within the Methodology Committee. And I'll talk a little more about that -- and we've had input -- heavy

input from the PDC. And in fact, you'll see evidence of that if you compare our slides to the ones you've just looked at.

And here, we consider this really not a final product of any sort, but really a beginning step rather than a final step. So we'll be seeking approval of the next steps to refine that from the board. We'll also talk a little bit about our work plan. But what I hope to spend most of my time doing is really focus on what we consider our core tasks, our strategy and thinking to date on how we're going to accomplish those tasks specifically leading to the methodologic standards report and the translation table.

Also, touch on three and four. As the statute indicates, we are to continually evaluate and update our work, which we will do. And number four, we added prove methodological expertise. We see ourselves and hope you see us that way too, as really a resource for the Board and for the institute. And so, if there are things that aren't specifically spelled out in our charge in the

statute where you feel we can bring value to the institute, we're ready, willing, and able to do so.

So, this isn't a very pretty graphic, but it's just a very high-level illustration of what I call the methodology work cycle. And it's just three steps, and we have these little kind of stick people in the middle to remind ourselves again, a constant reminder that everything we do is patient-centered from the inputs to the outputs, as stealing Harlan Weisman's language.

The inputs to the questions that need to be studied, and then the outputs are the work that we create with the methods that we devise, are to address those questions that are most important to patients. So again, that's just a reminder.

But just to start with, kind of the light blue area here. First step -- I don't really have great -- oh, here it is. First step is the, again, a landscape review. But in this case, it's focused on methodological standards. What do we know about methodological standards?

And to use that review to produce, if you

will, best practices around methodological standards in a translation table -- I'll say more about that in the upcoming slides. That review will also help us understand what -- where the critical gaps are in knowledge and/or implementation related to methodology. And those gaps will help us to propose research that will advance methods and provide innovation to address the gaps. And again, all of it is undergirded with the foundational tasks that I'm going to go over.

So, just to go back to these foundational tasks. The first one that I'd like to discuss is the charter of our committee. Much of the work that we do in our 15 member committee, we try and do in sub-groups. The working group that developed the charter through very thoughtful iterative process is named here, and Dr. Robin Newhouse, who is a couple of rows behind me here, led this team.

This just gives you a sense of the tactics and timelines that were implemented. It was, as I said, iterative. We got input from the committee chairs. We received input from the Board at

several intervals, and we're at a position now to look for your review and -- final review and approval.

I don't have the whole charter here, but just to remind you. These are the main categories of the charter, and it really does align with the format of the charters of the other committees. There are some differences that sort of speak to the differences spelled out in the statute.

But I will perhaps stop here and ask if there is any -- if there are further questions related to the charter. And seek approval of the committee -- of the Board, I should say.

CHAIRMAN WASHINGTON: I'll just refresh the memory of Board members that you would have received both the charter as well as a cover letter delineating any differences or highlighting points for discussion. So. Leah Hole-Curry.

MS. HOLE-CURRY: Thank you very much. And to the Methodology Committee, it's clear that a lot of work has gone into this. Being part of other sub-committees, I can appreciate how much time it

takes. So, my question is, there was a section on identifying the major gaps in research methods, outcome measures, risk adjustments, modeling, and statistical techniques, and some other items. And then there were some sub-bullets on recommending methodological standards and then recommending data standards.

But, my question is on measurement standards. And this -- being a non-researcher, perhaps this is maybe for further discussion or maybe this bleeds into Board responsibility as well. But, will there be an opportunity to hear from the Methodology Committee about validated instruments, perhaps? Or, I mean, one of the things that I think is a problem in research is that the same topic might be researched, but different instruments are used.

And then trying to gain knowledge from, again, not to set a prescription, but to give us information, perhaps, about standardized measures so that as we seek to not only fund our own research but leverage other research, we can start

to have more consolidated measures. Or, measures that we deem -- you know, provide us high value.

DR. GABRIEL: So, the short answer is, yes. But I see my vice chair wanting to jump in there. So I'll ask Sharon-Lise to add, if I may.

MS. HOLE-CURRY: Okay, thank you.

DR. NORMAND: So we've definitely have thought about that and actually talked about, especially if we're talking about patient-centered outcomes. You really want to get the information, you know, off and from the patients. And there are certain issues that relate to, for example, the type of intervention that's applied. So I'll make an example, a device. And so often, if you -- a patient gets a device, they know and it's unblinded. And how do you get a good measurement when a patient hasn't been blinded to the intervention that they received?

And so, there are metrics out there. We actually had a discussion today about various entities that have been thinking a lot about getting these types of measures and about the key

characteristics that those measures should have.

So, I mean, I'm just elaborating. The short answer is, yes. But we've actually talked about it again today.

DR. COLLINS: Francis Collins. So, the charter, I think, is a very fine document. It really does lay out a pretty ambitious agenda. And on many bullets, there have been appeared in terms of specific areas the Methodology Committee is going to tackle.

I wanted to follow up, though, on something that I didn't see emphasized as much as perhaps could have been. And it was something raised by Steve earlier in the meeting. And it also is something that I think will become increasingly important. And that is, the perceived tension between comparative effectiveness research and personalized medicine.

And I would hope the Methodology Committee, in the process of going through all of your many tasks of defining methodological approaches, would take that on fairly explicitly

about how you maintain and retain individualized information about environmental exposures, about genetics, about all of the other factors that play into both whether or not a response to a particular disorder is going to happen or not. And also, about patient preferences.

So, it's probably -- you're going to say that it's in here and everything that you're doing. But I just wondered if it would benefit from an explicit bullet emphasis along with the others you have here.

DR. GABRIEL: So, many of the bullets -- virtually all of the bullets, really, are either lifted from or verbatim or reflect the statute. So we tried to stay close to that. But, where I identified our goals, the fourth one was tell us where else you think, you the Board, thinks we can add value to the PCORI process and we'll go there. And I think that's a perfect area that we'll certainly add to the list. I think it very much aligns with a lot of the discussions that we've had.

And, I don't know if Robin, I can't see you, but if you want to chime in at any point related to the charter, please do.

DR. NEWHOUSE: No. We decided to make these responsibilities global, as opposed to be very technical about each aspect of comparative effectiveness. So, we did discuss for a compendium of what we would include but, tended to go back to that global responsibility. So, we will incorporate that in our discussion.

DR. NORMAND: If I could just add, when -- part of our discussions today. Actually when we're thinking about an organizational structure, one of the first things we did talk about was sort of the social and environmental background that a patient presents. And that was in our umbrella. So, just so you know, we are thinking about that.

DR. GABRIEL: And you'll see more of that as you see our strategy going forward.

CHAIRMAN WASHINGTON: The question on the table for the Board is approval of the charter for the Methodology Committee. Can I have a motion?

UNIDENTIFIED SPEAKER: So moved.

CHAIRMAN WASHINGTON: So moved, and --

UNIDENTIFIED SPEAKER: Second.

CHAIRMAN WASHINGTON: Second. All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay, so the motion carries. And so, it's approved.

DR. GABRIEL: Okay, thank you. The next item that we worked on was, as I referred to, the working definition of patient-centered outcomes research. And again, this was the work of a group, all of us really, but led by a group under the direction of Dr. David Flum, who said he would be on the phone. I'm not sure if he is or not. But also, Mary Tinetti, Mark Helfand who is here, Jean and Sebastian, who is also here.

And as I mentioned in my, I think, in my introductory comments, the goal here was to provide a definition that could frame and guide the scope

of our work within the Methodology Committee, with the hope that it could be useful elsewhere. We've had input from the PDC, particularly Harlan K., but as I said, we really see this as a beginning step, not a final step. And we'll be looking for more input.

Let's see here. So, here it is. It's a two-part definition. The first part -- let me see if this will work. Oh, yes. Isn't that cool?

The first part, the top part, is really -- really describes what patient-centered outcomes research is intended for. It's purpose, if you will, a very high-level description. PCOR helps patients -- helps people, and that's a particularly chosen word, make informed healthcare decisions and allows our voice to be heard in assessing the value of healthcare options. It answers questions like, and these questions ought to be very familiar from the last hour's discussion, questions like, given my personal characteristics, conditions, and preferences, what shall I expect will happen to me? What are my options? What are the benefits and harms of those options? And, what can I do to

improve those outcomes that are most important to me?

So again, it's a high-level description. It speaks to what PCOR is intended for and puts the patient's voice central in that.

And then below that are some characteristics of PCOR. And these characteristics are meant to be really how to operationalize the definition for perhaps more technical users. And I won't read all of this, and you can look at it, but assessing the benefits and harms. It's inclusive of an individual's preferences.

So here's the point that Dr. Collins raised a bit earlier and incorporates a wide variety of settings and diversity participants. And also, focuses on optimizing outcomes while addressing burden and other perspectives. So, again, a high-level definition and then a bit more specificity to operationalize that definition.

What we're seeking from the Board, as I mentioned, is approval of these next steps. So, approval to allow the Methodology Committee to

adopt this as a working definition to guide our work going forward and to invite additional -- I mentioned we've had some input, but there's more input that can be sought from other members of the board and other committees. So, invite detailed input from the board, as well as from other stakeholders and the public. And develop a systematic process of synthesizing that input and revising the definition and then bringing it back.

So, this is what we're seeking approval for today.

CHAIRMAN WASHINGTON: Okay. Harlan Weisman.

DR. WEISMAN: Sherine, I like the definition. I made a comment probably on a variant of it to Harlan K.—

[Off microphone.]

DR. WEISMAN: -- a few -- I'm being censored with this.

[Laughter.]

DR. WEISMAN: To Harlan K. a while ago. You know, the definition, I think, covers healthy

people who want to know how to stay healthy, but it's a little bit of a stretch for me. I mean, you can read it into it if you go back to it, maybe. It sort of says, you know, because the questions are really more directed or seem to resonate more for a patient who has a disease who is looking for treatment, rather than for somebody who is looking to prevent or -- either to maintain their health or to prevent disease.

I think you can get to it. I mean, it's not precluding that. And the same -- I could have made the same [microphone feedback] -- I'm sorry, I could have made the same comment earlier when the Program Development Committee also spoke. I think it's just something to talk about, because when you talk to people, you know, they're really interested in, you know, how do I maintain my health? Do vitamins work? I know exercise is good, but what kind of exercise? And we were talking about personalized medicine.

I think we know now that probably different forms of exercise and different diets

work for different people. But boy, you know, you read something one day and then the next day you read that, nope, that doesn't work. You know, antioxidants are really good for you. Nope, antioxidants kill you. You know? So, there's a lot of confusion there. And that, to me, sounds like it would be a good subject, perhaps. We'll see what people want for the kind of patient-centered outcomes research we're considering.

And I have trouble stretching into it a little bit, but I don't think it precludes it. It's just not as overtly there.

DR. GABRIEL: And this is the reason we're bringing it here today.

DR. KRUMHOLZ: I do want to say that I commend the group.

CHAIRMAN WASHINGTON: Please. Harlan. Was there someone in Methodology?

DR. GABRIEL: No.

UNIDENTIFIED SPEAKER: No.

CHAIRMAN WASHINGTON: Okay. Harlan, would you state your name, full name, please?

DR. KRUMHOLZ: Harlan Krumholz.

I wanted to commend the committee who was really wonderful to work with, and who was very interested in aligning with what was being done on the periphery. But, spoke with an independent voice very much, which I think is very helpful as we sort of thought about this, in particular around the characteristics and added substantially to this.

But just to get to your point, there's no word "patient" up there. And I think it's for us to frame that this is a broad, we are the Patient-Centered Outcomes Research Institute, but the notion is that this is broadly applicable. And if you -- I think you can bring your own frame on this about patients. But if you think about it for a minute in terms of populations, it reads pretty well given my personal characteristics and condition preferences. What should I expect will happen to me? Well, that can be about your risk about whether you're going to get anything or what you're likely to be at risk for. And then, what are my options -- that options can be for

prevention, or they could be for treatment or diagnosis.

And what can I do to improve them? That's about self-determination, both with regard to your engagement in healthcare system as well as behavioral, lifestyle, a whole range of different things that might be important.

And I will say, in every time we -- we actually in the document that wasn't distributed, or maybe the one that was, it did say asterisked patients were struggling for how to use that word, because we're broadly speaking about people. Sometimes, about people who have conditions and sometimes about people who may be at risk for conditions, we're all at risk for something. But, you're just identifying an issue that I think the whole group, the Board and the Methodology Committee, may have to work together to message appropriately with communications about that we are talking about the whole spectrum. But keeping people healthy is certainly, I think, within that.

I don't know, Sherin --

DR. GABRIEL: No, I just wanted to underscore that. But I think I also take your point. It doesn't preclude it, it was part of the conversation but it doesn't jump out at you. And I think you're raising the point that maybe it should be highlighted a little bit more.

DR. WEISMAN: I'm not sure exactly how. But, no. I agree with what you said, Harlan. It's there. I mean, it's certainly compatible with it. Just didn't seem like maybe the words you would choose if you were talking about health maintenance or prevention. That was my only point. But maybe it's okay with everybody.

CHAIRMAN WASHINGTON: [Off microphone.]

DR. GABRIEL: Yeah.

CHAIRMAN WASHINGTON: Steve Lipstein, the Christine Goertz and then --

VICE CHAIRMAN LIPSTEIN: Within the charter and the working definition for the Methodology Committee, one of the questions I think I have is, do -- you know, where do we identify the data that we have versus the data that we need?

And so it gets back a little bit to Francis' point, and he said I made but I wasn't quite sure I made it. Which is, do we need patient-specific information? Or, are averages and population-based data sufficient?

So for example, when you look at the four questions and you say, you know, what is this -- you know, the first question is, you know, what can I expect? What does this mean to me? Typically, what you get in an encounter with the medical world is, well this is what happens to the average patient or the median patient or 20 percent of the population gets A, 20 percent of the population gets B, 40 percent gets C. And you say, well, where am I? So where do I fit in?

And a lot of the data analysis that comes out of outcomes research is based on evaluation of population-based metrics that look at averages and medians and statistical samples. But, is it the purview of the Methodology Committee to make recommendations about where we just don't have sufficient data to do patient-centered outcomes

research? Is my question.

DR. GABRIEL: So, I can try -- I was -- I had an answer prepared, but I think I misunderstood your question. But I'll give it a try. So the first bit, when you talked about patient-specific data. I guess, the purpose of proposing this definition is really as a target. Is this the right thing for us to -- the right collection of things for us to aim for? Is this the right scope? And then, within that, we're going to come back and actually the second half of my presentation gives you an idea of at least what we're thinking about how to get there. What kinds of data might be needed, and so on.

In terms of whether or not it's within our scope, I'm not sure. I mean, the statute says improve the science of patient-centered outcomes research. So, at least in my opinion it's within our scope to identify what is known regarding methodolgic standards, regarding methodology to answer these key questions that patients ask -- patients and people need to know.

And then, to identify those areas where we see there are critical gaps, but there really aren't good methods out there. And perhaps propose those to be considered among our collection of research priorities to do methodologic research to fill those gaps.

And so to me, that's how I understand improve the science and methods of patient-centered outcomes research.

CHAIRMAN WASHINGTON: We'll go to Christine. I saw Sharon-Lise Normand's hand.

DR. NORMAND: Yes, so I'd just like to add to that response that Sherine provided. And again, when Sherine gets to the second part of her discussion she's going to talk a little bit about -- and I don't know if you're going to get to all of that today. But we think about the organizational structure of how we're going to go about this task.

And part of it relates to this specific social background characteristic that people bring in. Another part of that relates to treatment heterogeneity. That is, does the effectiveness of

a particular treatment vary depending on patient characteristics? And you can hone that down to small sub-groups. And so, that's getting part of what you're asking.

And so, part of what we're going to be thinking about is that organizational structure about methods to help patient-centered outcomes research to be able to estimate in a valid, reliable, reproducible, feasible way -- estimates of the things that, Steve, that you're raising. So, that's sort of later, but that's sort of encompassed in sort of answering these particular questions.

CHAIRMAN WASHINGTON: Christine.

DR. GOERTZ: Just a thought and a question. I think getting back to Harlan W.'s comment about the fact that it seems more -- the definition seems more oriented towards people who are ill. You know, we might think about changing the healthcare, the word "healthcare" to "health". Because I think it's that "healthcare" that sort of leads us in that thought direction. So maybe there

are some ways to say healthcare and -- or just replace it with "health".

And also, I was really -- I think it is important to get public and stakeholder comment on this. And I'm just wondering if you've thought about how, you know, if the committee had thought about that or how we're going to proceed to make sure that we really do get it out for public comment. That's sort of beyond, you know, what we're doing right now. Is there a vehicle for that, or do we need to develop one quickly so that we can do that?

DR. GABRIEL: Well, I'm partly actually looking for guidance from the Board on how best to do that.

CHAIRMAN WASHINGTON: Yeah, that is one of the questions on the table for the day. Okay.

Well, let's -- we're going to come back to that, Christine. So, now it's on the table and the Board members are cogitating over that question. We will come back to it.

DR. SIGAL: So, I like it a lot because to

me, it does speak to patients. Because you don't have to say it, first of all, it's the first word. You say what works for me. You talk about intent, you talk about personalized medicine. You have a metric that is important to all of us. And to me, it even speaks -- I guess maybe we need more clarity to risk. Because you know, what risk do I have?

So, I think it's captured. Maybe we need to wordsmith a little bit more, but I think it's a really good definition.

And what I like about it is, it's pretty clean. It's pretty clear on, you know -- and maybe we need a few more words here and there. But I think, you know, these are the issues that PCORI are about. This is what personalized medicine is about, and these are the answers that patients want. So, you know, for what it's worth I think it's pretty good.

CHAIRMAN WASHINGTON: Lean Hole-Curry.

MS. HOLE-CURRY: Thanks. My question is on the -- there were four questions under the

Program Development Committee's working definition, and three under yours. And that actually was an evolution in thought process, being on the Program Development Committee. So I wondered if you had had a chance to review that fourth question and decided against including it in your working definition, or whether that's just due to the evolution on both sides?

DR. GABRIEL: It's the latter. And so again, that's why we're brining it back. And I think one of the issues that we had was, we went through a little bit of a process and had input from the PDC. And then, we were getting e-mails from a bunch of different people. And we decided we really need to do this in a systematic way. And so, we're asking for input from everybody, and we will synthesize it and come back.

And so -- and we did think, also, that the second part of the definition does speak a little bit to some of those points. But again, we're looking for input.

MS. HOLE-CURRY: Thank you.

DR. NORMAND: I just want to add that the fourth question from the PDC, I think it's actually captured in the last bullet. A wide variety of settings. And that was sort of the delivery settings point that was part of a separate bullet, you know, item in the PDC. Just for clarity.

CHAIRMAN WASHINGTON: Francis, please. Collins.

DR. COLLINS: Leah basically asked the same question I was going to, so let me just comment. I really think it would be helpful to have that fourth question about health systems in the top part to make it clear that that is part of PCOR, the definition that we are interested in understanding the role of health systems in achieving good outcomes.

It may be sort of covered a bit lower down, but it seems sort of odd not to mention it explicitly, especially if we're going to have a fully-coordinated, integrated PCORI where we cross-reference each other.

DR. GABRIEL: And you know, as I said it

was a timing issue. And I think you bring up a good point, especially if we use the top part separately from the bottom half, which may very well do.

CHAIRMAN WASHINGTON: Leah.

MS. HOLE-CURRY: The other differences that that fourth bullet actually speaks to what patients or empowering patients to ask questions of the system, rather than we're just going to focus on the system itself and improvements to the system. So, it changes the focus a bit even though the question is the same.

CHAIRMAN WASHINGTON: Harlan Weisman.

DR. WEISMAN: Yeah. I wanted to just comment or on what Steve's earlier comment was about what methods are used. You know, on the personalized basis of -- how can an individual patient make comment. But before I do, let me just say that my previous comments on the definition. If I were reviewing this in a peer review kind of way, I would call that a minor comment, and I would accept it with the minor comment for the authors to

consider, as opposed to rejected. Something that would lead to a rejection on my part.

Okay. Just for context.

DR. GABRIEL: I'll note that.

DR. WEISMAN: You know, we were talking, the Board had a previous conversation about, it's one thing to have information that is going to help us get through your methods, through the methodology. Because there's some important research questions where there's uncertain methodology and outcomes research. And that's really important. And then that's going to be a piece of information.

But we were also talking about -- and this goes, I think, to Steve's question about -- or, comment, about when the patient is sitting down with their doctor or nurse, whoever is making -- helping them make a decision. It's within a complexity of their individual circumstances. And it comes down to not just knowing the information, but also assessing the quality of information and a lot of incomplete information because quite

frankly, a lot of times we're not going to know things. But you still have to make a call on it.

And it would seem worth, maybe, a research question -- this is where I think the Methodology Committee could help us think about it. How -- I'm struggling with how to say it. But it's really decision support. How do people actually make high-quality decisions, either with pieces of information that may not exactly fit them, or incomplete information? Yet, a decision still has to be made. They have to be guided by what can be presented to them. They also have to be guided by, you know, their own sense of their values and so forth.

But still, they've got to come to decisions. And that's, I think, a really under-studied area to -- some of it is, you know, Bayesian approaches to decision-making. I'm not really sure. I don't know if you guys have thought about that. Do you think it's out of scope?

DR. GABRIEL: We actually had some of that very discussion this morning, that -- how important

it is as we reframe the work of the Methods Committee to fit it into a framework that starts with, what are those decisions that are important to patients? And also, how do patients and people make the deacons that they need to make regarding their healthcare?

And then downstream somewhere is the methods. But it's very important to understand that full framework. And again, you're all pre-empting the second half of my discussion. But we've really only started to think about that, really. The work of the Methodology Committee is mid-stream to that process, but we have to understand that full framework that starts with the decision-making on the part of the patient.

CHAIRMAN WASHINGTON: So, I had been asked at the intermission to remember to call out your whole name, both for those participating on the phone as well as for the recording here. But I confess, I'm tired of calling out your names. So, you are going to raise your hand. I'm going to point at you, and you're going to call out your own

name.

[Laughter.]

CHAIRMAN WASHINGTON: I think it's more efficient, too.

So, Mark? Full name.

DR. HELFAND: Mark Helfand. And Harlan, so I just wanted to say that we, as Sherine said, we have really discussed that.

And the question in the definition group was, how much of that to get in there? And if you notice, you can't talk about decision-making without talking about preferences and how people value those different preferences, what it means to them. But you also can't talk about it without considering the chances. That is, some aspect of I expect what will happen to me is uncertain. And that's, I think, what you're getting at.

So, you know, I'm the editor of the journal *Medical Decision Making* and this is like what we're most interested in, is how to make good decisions. And so, we -- I think we had to settle on the definition for the term "informed decision-

making." But to me, that has connotations of how do you communicate about risk? How do you weigh things? How do individuals -- how are individuals supposed to make that, or in fact, any decision-makers?

So again, it's another thing that, you know—definition -- more words? Or some word that we can later elaborate and say, this is really important to us.

CHAIRMAN WASHINGTON: Yes, Bob?

DR. ZWOLAK: Bob Zwolak. I like this definition, too. And given the discussion we've had in the last few minutes, it seems that every single day we meet patients in our practices who have a different number and combination of disorders and different personal preferences and different drivers that the complexity we're already introducing by these new variables, we're going to consider. In PCORI, that we're going to -- as you work your way down the decision trail, you run out of science before you run out of the number of different patients that you're going to see each

day. So, there is -- there has to be a limit. And we just need to go as far as we can go to help the people and help the patients and to help the providers.

CHAIRMAN WASHINGTON: This is a working definition, and it is an evolution. Having started with the Methodology Committee, but also having gone through an iteration that involved input from the Program Development Committee. It's now at a point where it's also benefited from a -- or, will benefit from input from the board. And the question on the table is, beyond the board how will we now solicit and incorporate input from a broader array of stakeholders and constituents?

At a minimum, we will put it on the Website and we'll invite comments. But I don't think anyone on the Board would feel that that's sufficient. And so, Sharon, I would ask that we, in fact, have you and your group take this under consideration and propose a plan for us.

DR. LEVINE: I can do that now.

CHAIRMAN WASHINGTON: Okay, please.

DR. LEVINE: I was going to say, we have a growing list of interested --

CHAIRMAN WASHINGTON: Your full name. In your case, you have to say why we're asking you to take it on. Okay.

DR. LEVINE: Sharon Levine. And I'm the chair of the committee whose name, hopefully, will be changed tomorrow, but the committee currently known as the Public Affairs and Communication Committee.

And I was going to say, we have a growing list, I think it's over 400 interested parties today who have signed up for communication from PCORI. And I wonder if we might not send an e-mail distribution to 400 people and say, here's the proposed working definition. It is on the Website, here's how you access the Website. And, please comment if you have comments to offer.

DR. GABRIEL: I would just suggest that we also --

CHAIRMAN WASHINGTON: Name?

DR. GABRIEL: Oh, pardon me. Sherine

Gabriel, chair of the Methodology Committee. I was also going to suggest that we have the rationale document on there as well, because every word of this was carefully vetted in that document I think nicely and succinctly explains how we got to this definition.

CHAIRMAN WASHINGTON: I think that's a terrific suggestion. So, we will proceed to post it and to disseminate it to this list of 400-plus. But at the same time, we'll also ask your committee to consider what additional steps we might take to ensure that we have effective input.

DR. LEVINE: And Sherine, if -- just cut one paragraph describing the relationship of the rationale document to the definition, so when people log on it's really clear.

DR. GABRIEL: Okay. Yeah, it should be. And I don't know if it's reasonable, but if we let folks know that our next deadline is whenever it's going to be to bring comments back to the board, that will help us synthesize what we get back.

CHAIRMAN WASHINGTON: Bob?

DR. ZWOLAK: Bob Zwolak. Just a quick point of clarification. Will the last bullet, the question about healthcare systems, be added to the definition at this point?

DR. GABRIEL: I'm almost certain that it will, yeah. I mean, we have to bring the group together. And I mean, I think it makes very good sense. And I'm hearing a lot of -- seeing a lot of head-nodding around the Board table. So I think we'll do that.

CHAIRMAN WASHINGTON: Mark?

DR. HELFAND: I want to --

CHAIRMAN WASHINGTON: Name.

DR. HELFAND: Mark Helfand, sorry. I did want to restate, though, what Sherine said before. We do get a lot of individuals who, you know -- I mean, people have made their comments. And what we'd rather do is, have all of the input before making changes. And I think that's -- you know, just to be fair to the public and everyone else to say, you know, that's how we want to incorporate the feedback.

CHAIRMAN WASHINGTON: I -- you know, I only get one vote in this. But I think this is fundamentally a different kind of comment that's being made that changes the way it's laid out. Most of the other comments that I've heard relate to words here, there. But this brings to another level of attention a dimension that we want to advance and it's quite consistent with the PDC. So, I think to some degree we are also asking, you know, are the partners to comment on that while we comment -- and that's a different level.

So, I would ask for the comments if others feel similarly.

DR. HELFAND: Yeah, so Gene, can I just say --

CHAIRMAN WASHINGTON: Sure, Mark.

DR. HELFAND: In our deliberations -- and I think this is reflected in the rationale document -- this is a lot of what happened is that, should things be promoted to the top or below, and does the message of the top really get through best? Depending on which characteristics or which things

go up there and go below.

And I'm just seeing if there's -- so I think it's similar in the sense that if you got feedback that says, oh, this, this, and this should also go above, then the above part, you start to have to prioritize so it has a message.

And so, that's what I really mean. Is that changes should be made after all the feedback is back. Not to say this isn't a different level, but we might get similar things that are like that. You know, put this aspect of it up there instead of below. And I think this part one and part two thing, that's really the dynamic there. What goes in the top part, what goes in the bottom.

CHAIRMAN WASHINGTON: Any other members of the Board? Christine?

CHAIRMAN WASHINGTON: Name.

DR. GOERTZ: Oh, I'm sorry. Christine Goertz, a member of the Program Development Committee.

I agree with you in concept. But I'm going to argue with you about this specific point.

And the reason why is because it begs the question why isn't it there when all the rest of the bullets are there? So, if it was a more general comment or you had, for example, one, then I would agree with you completely. But just my concern is that you have all the other bullets, more or less word for word. And then that one is missing. So that's my concern about putting it out the way that it is, is it just puts the question in people's mind, why was that one thing not included?

DR. GABRIEL: I don't want to draw this out longer -- more than it deserves --

CHAIRMAN WASHINGTON: Her name is Sherine Gabriel.

DR. GABRIEL: Oh, Sharin Gabriel. Pardon me.

But, when we first had the discussion, that bullet wasn't there. So it wasn't like, oh we see these four bullets and we're taking this one out, but I might suggest to sort of short-circuit this is that the comments from the Board are perhaps a little bit different than the comments

we're going to get elsewhere.

And so, I might suggest that we get -- we collate the comments that we hear today, we take it back, and then we go through perhaps one other revision before it's publicly posted. And then, so -- do it in a two-stage process. Gather the comments that we get here, and perhaps others that you might have -- that you might think about, you know, tomorrow or whatever. And then, we'll post what we get with your permission, and then try and get additional comments thereafter.

What do you think Sharon? We'll look at Sharon for advice on how best to do --

DR. LEVINE: Sharon Levine. I had a comment, but it was more about -- I disagree that what's below in the bottom is the same as that fourth bullet. I actually think it's looking at two different things.

What's -- that fourth bullet is about actually doing research on the impact of different models of delivery on health outcomes. And what's below is including research subjects from -- in

different settings. And I think those are two different things.

So, as you work this and mug Mark to get the outcome you want, I think we need to think about that, also. And I think your proposal is fine.

CHAIRMAN WASHINGTON: And so, we are going to follow your proposal that this -- these comments be passed on to the Methodology Committee, who is already here And that you will make a decision about the next draft and post it.

DR. GABRIEL: Yes, we do want comments from the Board. Dr. Epstein, were you going to say something?

DR. EPSTEIN: Nope. Holding my fire.

DR. GABRIEL: You're holding your fire?

CHAIRMAN WASHINGTON: Gail?

MS. HUNT: Yeah, Gail Hunt. I just wanted to agree with Christine, Sharon, and Gene really strongly that I think that the fourth bullet should be included. I think it really is quite different than what you have in the bottom half. It's not

picked up by using the terms of the variety of settings. It's not the same thing.

And so, and I can't see any reason that we wouldn't have, eventually, the PDC is -- has a definition. And the Methodology Committee wouldn't have -- couldn't have, really, a different definition. You could have maybe an expanded definition or more bullets under it or something like that, but the basic concept of the definition being different between the Board and the Methodology Committee -- just a minute, Mark. I can see you, like, leaping out.

I think they have to be consistent. And so, that's what I'm suggesting.

DR. HELFAND: Yeah, I think they're -- I don't think it's a conceptual thing. I think that the intention of both definitions is to include those interventions. And that the top part of the definition says, you know -- I mean, it depends on what we call top and bottom. But it's not up right now. It definitely says and includes in the scope, comparing healthcare system interventions.

And so, I don't think it's going to be a big problem. It's a matter of emphasis, but I don't think it was any idea to not have healthcare interventions or health system interventions play a prominent role.

UNIDENTIFIED SPEAKER: For our guests, that was Mark Helfand of the Methodology Committee.

DR. KRUMHOLZ: This is Harlan Krumholz.

Let me just suggest that we allow the Methodology Committee to mull over that. I think they've heard a message on this. They've done a great job on the definition. They can synthesize these things. It's up to us, I think, to allow them latitude and to, you know, absorb some of the comments they've gotten and come back best they can.

So, I just think it's -- we're talking a lot -- we're all in agreement -- violent agreement, some a little bit. But, we're all in agreement. Just allow that to proceed.

CHAIRMAN WASHINGTON: Sounds great.

DR. GABRIEL: So, on that note, I was just

going to make one final comment --

UNIDENTIFIED SPEAKER: Sherine Gabriel.

DR. GABRIEL: Sherine Gabriel. Mark is really speaking to the integrity of the process, not really in dispute about the content or bullet four or the importance of healthcare delivery system research at all here.

And so, we will take the comments under advisement and come back to you with a revised definition for posting for public comment.

CHAIRMAN WASHINGTON: Okay. Actually, I was proposing that once it goes to your group, your group is going to proceed with the posting. I don't see you coming back to this group. You've incorporated, you will have taken this on advisement, you will have incorporated it, and we're charging you to proceed.

DR. GABRIEL: Even better, thank you.

CHAIRMAN WASHINGTON: Okay.

DR. GABRIEL: So, can I go forward? Or do you need to take a vote or anything at this point?

CHAIRMAN WASHINGTON: No.

DR. GABRIEL: Okay.

CHAIRMAN WASHINGTON: Working definition.

DR. GABRIEL: All right. The consolidated work plan, not looking for a vote here.

But again, just to highlight the team that worked on this and the goal of this group was really to pull together all of the work and thinking across all of our various -- our work groups within the Methodology Committee and create a consolidated work plan that itemizes who is going to do what by when, and so on. We are not ready to bring this forward, we need a little more time, particularly with our staff to flesh out the budget before we bring it forward for final approval. And we expect that that will be a couple, two, three weeks.

But again, just to remind you that the work plan covers these foundational tasks, covers our core tasks, and the other two items that I spoke to before continuing to improve the product. And then, additional input and guidance to the Board on any matters where you see us bringing

value.

This is our work plan calendar. What I can guarantee for sure is some of these dates will change. But again, to give you a sense of what you can expect from us at the July meeting, we hope to have an early review of standards and what some of call an evidence map. And a final work plan and budget, and some criteria to classify the standards, and so on. And then, you can just get a sense of the work going forward, but I'll discuss that more in upcoming slides.

So, what I'd like to do in the next few minutes here or the next 30 or so minutes is give you a sense of our thinking about the strategy to accomplish what we refer to as our core tasks. Now, I put these slides together three or four days ago. As a result of our wonderful meeting this morning, these slides are already way outdated because the group had terrific suggestions for how to push this even farther this morning. But I'll give you a sense of at least what we've been thinking.

Before I do that -- and I added this slide, I think, in response to something Ellen asked at the last Board conference call when I was talking about proposing Tier 1 methodological research questions. And I think it was you, Ellen, who said, well how do those differ from the other research priorities? And just to remind everybody listening that Methodology and the work that the Methodology Committee will be focused on really addresses the how of patient-centered outcomes research.

So, we talk about the importance of patient values, but how do we exactly assess that? What are the methods? Are those methods standardized so that we can interpret data or cross a variety of studies? How do we operationalize valid, reliable, and useful instruments? And I think that actually also speaks to a point that Ellen made a bit earlier. They could be survey tools. How do these outcomes triangulate with conventional outcomes of things -- laboratory tests, or things that we conventionally use as

measures? How do we quantify a clinically meaningful increment of change to know someone is better from a patient perspective? What does that really mean?

And then, Patients Like Me, measuring patient differences, identifying characteristics that predict those differences, and incorporating complexities of care delivery settings. I mean, even things like nurse staffing. How does that influence outcomes?

And then, finally, some more analytical thoughts, perhaps, on how to minimize bias, particularly in observational data and addressing tradeoffs. So, these are just some examples to give you a sense of the kind of questions we think about at the Methodology Committee.

This is, again, just that work cycle where we start with reviewing and then later updating the landscape with respect to methodological standards for PCOR. Using what we learn from that landscape review to devise standards and a table, identifying gaps, proposing methodological studies to advance

research and innovation in this arena.

And as time goes on, the foundational tasks will be much more of a staff function and will be largely focused on that other stuff, that core work.

This will also probably change a little bit, but it gives you our thinking as of four days ago on how we would go about doing this. And I'm going to speak a little bit about each of those six points in upcoming slides, and try and sprinkle in, hopefully, with input from my colleagues here some of the discussions that we had this morning.

And so, our first step was to review what we could in the literature. And from talking to individuals and re-reading and re-reading the statute, what is the intent here of our work? Of our task?

Second, to conduct a landscape review and we'll do this along with other things in alignment with the PDC. And that landscape review has -- maybe you'd call it a face-to-face piece and a pen and paper piece. Part of that is going to be

actually engaging groups and individuals who have done this work in a workshop or really engaging them one-on-one, face-to-face to understand what the challenges were in devising methodologic standards in certain areas.

So, again, we'll need expert stakeholder and public input to understand the landscape. And also, do more standard review of standards and guidance related to methodology.

There's also the third bullet under number two there, some relevant literature that isn't specifically standards and guidance but sort of surrounds that arena, which we felt we need to summarize to understand. And these include not only published literature, but things that are commissioned, white papers, and so on. So, that's a second step.

Some approach to categorizing the methods, not only categorizing the quality of the methods which you don't see there, but putting them into buckets. So, one bucket might be there is a methodologic standard that exists in a particular

domain. There's good, strong evidence that we can rely on that standard. It's widely implemented, and you might call that best practice. And perhaps, those best practices would be our first set of -- the first set of standards that we propose.

Other categories might be a methodologic standard exists, there's good, strong evidence, but for some reason it isn't widely implemented in the research community. And we might need to understand why that is, that might be an implementation gap. And the third might be an area where we see there are important questions. And some important clinical questions, important questions for patients and people. And some of these were raised, actually, earlier this afternoon. But there really isn't a defensible methodology to answer those questions. And those might constitute true gaps where we would propose methodological research.

So again, the first set of standards in the cycle might be based -- that would be based on

best practices. And as we learn more and more about the gaps, we'll propose methodological research to fill those gaps. And the translation table will incorporate both the best practices and the gaps as a guidance tool. And then, you see the feedback loop there.

So, just a couple of comments on some of the thinking and reading and discussion that's occurred with respect to each of these. So, review and understand intent.

This is just one of many papers, and this is by Sean Tunis, Joshua Benner, and Mark McClellan on comparative effectiveness research, policy context, methods, development, and research infrastructure. Again, one of the things that we read to help us try and understand the intent behind what we're doing.

And if you look at some of the language there, it sort of reflects some of the language that we've read in the statute. Meaningful involvement of patients, consumers, clinicians, payers, and policymakers in the key phases of

design and implementation, development of methodological best practices for the design of these studies, improvements in research infrastructure.

And again, there were some discussions about research infrastructure today and the notion that all of this would lead to better-informed clinical decisions and health policy decisions.

So, you know, one place where we looked that developing -- trying to understand the intent behind our charge to develop methodological guidance for CER. Again, these are just some quotes from this particular paper. A crucial requirement will be to employ the best analytic methods and data. And again, a lot of the questions that came up in the last couple of hours spoke to the lack of really good analytic methods and data to answer some of the questions that are most important to people and to patients.

And some of this literature speaks to the importance of having a translation table to help guide users in determining which methods to use to

answer which questions.

So, with respect to our second major task, conducting a landscape review. Again, we see two pieces there. And the first part of the landscape review, obtaining expert stakeholder and public input really speaks to, again, the discussion that we heard from the PDC and also from Sharon Levine about the importance of understanding the science of stakeholder engagement, if you will. What is really the best way of bringing in that kind of input? And I think the answer is, we don't quite know but we need to bring folks together, perhaps across all three committees, to really figure out how to do that most effectively.

There are other resources out there. The AHRQ community forum that Gene oversees is one useful initiative that we might turn to, to help understand how we can most efficiently and effectively bring in that kind of input. And you can see there that its stated purpose is to improve and expand public stakeholder engagement in PCOR and CER.

As part of our process, we have across the Methods Committee -- and we'll invite others to send us ideas also -- started to put together a list of organizations and individuals who we think would be -- whose input we think could be quite useful to our work. And we've got kind of a growing list of 22 organizations and 53 individuals. We're not going to invite all of them by any means, but we're starting to kind of develop a list of who could help us with our work so that as we move forward with the landscape review, we can bring some of those key individuals and groups together to advise us.

DR. WEISMAN: Sherine?

DR. GABRIEL: Yes.

DR. WEISMAN: Just a quick -- you know, this was -- this was also true this morning, but I didn't ask it then, either.

So, who are we talking about? And it makes sense in terms of getting stakeholder feedback, is from other organizations in the healthcare community. But there are, you know,

organizations that get -- are routinely find out what do people think? You know, whether it's businesses and they do quantitative market analyses or polling people and other things.

Do we feel that that -- I don't know anything about the methodology, but I know in business schools and otherwise, they do teach, you know, how to get this kind of information from -- and businesses make, you know, multi-million dollar to billion dollar bets based on this kind of quantitative customer insights.

And I'm just wondering whether there's something to be learned there from them that would be beneficial here.

DR. GABRIEL: I mean, I think the answer is quite possibly. We'll never know unless we pursue it. And so, again to invite members of the board to give us ideas as to where we could go to learn from others, there could be some very useful lessons from the private sector.

CHAIRMAN WASHINGTON: The other point I would make here, Sherine, is that while I expect --

DR. GABRIEL: Gene Washington.

[Laughter.]

CHAIRMAN WASHINGTON: Touché. Okay. Well done. Gene Washington.

The point that I wanted to make here is that, while I suspect these meetings will be quite technical, nevertheless it might still provide an opportunity to have what we're calling a non-traditional stakeholder somewhere in the room. If not for input, if -- as a primary objective, as a secondary one, it would begin to build some bridges and communicate what some of the issues are to stakeholders that we want to engage over a longer period of time.

DR. GABRIEL: So, the second part of the landscape review is perhaps the more traditional piece of reviewing existing standards and guidance, regarding methodology for this kind of research and summarizing literature, commissioned white papers, as I mentioned.

The third part, which I also alluded to, kind of categorizing the methods. Identifying

standards and critical gaps, identifying best practices, implementation gaps, and perhaps what we might define as true gaps. We have around the Methodology Committee already gone through a process where we started identifying what those gaps might be and, is there some low-hanging fruit? And what we're hoping is that low-hanging fruit is going to lead to our proposals for Tier 1 grants with respect to methodology in the short term. And, again, we've got a growing list of 64 gaps, all the way from, you know, how do you effectively communicate with patients regarding research to gaps involving analytic tousle and bias, and so on. So, again. That's another area that we're actively producing work.

The last three I'll just share there. Again, as I mentioned, the first set of standards will be based on what's known in terms of best practices today. We'll be proposing Tier 1 methodologic research based on our current understanding of the gaps in methodology for patient-centered outcomes research. That will be a

growing effort, but we probably know enough to be able to recommend something in the short-term that will help get the Tier 1 process moving.

And then the last step is creating a translation table, incorporating best practices and gaps as a guidance tool. And to be honest, we kind of got stuck there because we realized that all of us around the methodology table had a different image in our heads as to what that translation table looks like. And we decided that before we -- before we went any further, we had to engage in a discussion and really kind of a brainstorming session to visualize what that end product might look like before we start building it out. And we've done that in a couple of meetings and spent this morning doing that -- completing that process.

And you'll see the results of that in the near future. But just to give you a sense of when you try and understand, at least from the literature, what translation tables look like, they vary all over the place from someplace -- I'll call this something relatively simple even though it's

got lots and lots of words on it. But basically, you have methods on the left-hand side, the description of what -- you know, what is a cluster of randomized control clinical trial, what's an example, what are advantages and disadvantages, and some very brief ideas about its uses.

It's almost something you could get from a textbook, I might say. It's more than that. There is some guidance there. To tools -- and there are many, many more. I'm just sharing with you a couple. To tools like Mini-Sentinel, which is part of the Sentinel Initiative. And for those of you who aren't familiar with the Sentinel Initiative, aims to build a national post-marketing data surveillance system for drug safety. And Mini-Sentinel really looks at building the methods behind that large initiative. And Sebastian Schneeweiss, who is a member of our Methodology Committee, is also one of the members of this group.

And that's what their translation table looks like. It's really a decision tree put into a

table. So, a structured decision table to facilitate method selection for active medical product monitoring scenarios. So they look at potential drug exposure, and a potential health outcome of interest -- at least the link between those two. And then, consider various approaches to trying to answer some of those questions.

So again, I don't need to get into the detail of that, but only to share that just saying translation table wasn't enough. We had to engage in a serious kind of long discussion about what that really means and what would make the most sense for PCORI.

And that's, again, what we did this morning. Starting with a discussion about the central organizing principle and we all agreed that it really needs to stem from those decisions that patients, that are questions that are most important to patients, and the decisions around those questions that patients need to make. And then build out that framework, that architecture, in order to understand how best to build a

translation table that might be a bit downstream to provide -- to serve as a guidance tool for groups and individuals trying to design those questions, trying to fund those questions, or even trying to understand or interpret the results once such research is done.

So, I'll actually ask my colleagues to jump in, too. One of the suggestions this morning, for example, was building an interactive tool where depending on the kind of user -- so if you're a patient, you put in your characteristics and your questions. You get a different output than if you were an epidemiologist trying to figure out how to design a particular study, than if you were a reviewer trying to review certain research studies.

So, it becomes very complicated and we are looking at the term "translation table" very loosely. We're really thinking about it as a translation tool. It could be, you know, part decision tree, part table, part interactive electronic tool. Somebody this mooring suggested, I think, a video game But again, we're in the

process of really trying to visualizes what that end product looks like so that we can devise our methodology around it.

Sharon-Lise?

DR. NORMAND: This is Sharon-Lise Normand.

So, I just want to add two comments onto what Sherine has described. So, you know, we have some constraints because we want to talk about patient-centered outcomes research. And so part of the measure -- part of the process that we're thinking about is much more complex than the example of the translation table that you've seen earlier.

And that relates to sort of the first thing, it has to be an outcome that matters to patients. And so even if you're a -- perhaps you're a hospital or a certain delivery -- healthcare delivery system, you may want to look at rates of some things. But prerequisite is, you definitely need to be -- need to include -- it has to be a patient-centered outcome. So we have constraints in the way we're looking at things.

And then, I think, the other point I'd like to emphasize is the complexity that we're envisioning here and that relates to sort of the -- I might call it the unit of experiment whether we're talking about interventions that are delivered for behavioral interventions where they're delivered within a group. So, that's very different than the work of the Sentinel, where we're talking about a drug exposure where it's given directly to the particular patient. We're talking about much broader interventions, and so it's much more complex.

And so I just wanted to add those two other comments.

DR. GABRIEL: And the complexity goes even one or several stages more if you're talking about health system interventions, which is also within our scope.

So, I might just stop and see if other members of the Methodology Committee who were part of that discussion this morning? If it's all right, wanted to add?

DR. LAUER: Hi, Mike Lauer. We were thinking that this could be an enormously valuable product of PCORI. This would be a user-friendly, instructive, interactive tool which would provide advice on tradeoffs regarding data sources, design, and analyses for questions that are very much patient-centered. And it's -- we can get this thing started at a certain level of complexity, and it could continue to grow and develop over time, both in terms of sophistication and also grow with changes in scientific knowledge. So this is something that we're really very excited about. And it could be -- this is definitely would be a unique contribution from this group.

CHAIRMAN WASHINGTON: Terrific.

DR. GABRIEL: Ethan wanted to make a comment?

DR. BASCH: Yeah, just a comment. That one thing that emerged on a --

CHAIRMAN WASHINGTON: Name.

DR. BASCH: Ethan Basch. Tough crowd.

One thing that emerged out of our

discussion this morning was that the inclusion of patient-centeredness happens before it comes to the point of the translation table, perhaps. That the research question itself, by its nature, needs to be patient-centered such that the methods that are being applied to answer that particular question can be appropriate to what we are defining as being patient-centered outcomes research.

So, in that vein it became clear to us that the essential elements of the approach to answering the question had to actually be imbedded within the question itself, both in terms of patient-centeredness and in terms of the various levels of evidence that would be appropriate to answering the question that's being asked.

DR. GABRIEL: We're going to end early. I think this is my second to last slide.

DR. COLLINS: I won't -- I'm just curious.

CHAIRMAN WASHINGTON: You just jinxed us.

DR. GABRIEL: In my culture of origin, that's called the evil eye. So I just gave it to myself.

DR. COLLINS: So, Francis Collins. I'm just curious, as somebody who is not a methodology expert. This whole concept of the translation table is only vaguely familiar. And I must confess when I saw it in the statute I thought that was a remarkably sort of detailed kind of assignment to give the Methodology Committee.

So, is this the sort of thing which, had it not been in the statute, you would be doing anyway? Or it would have been sort of downstream and you would not be right now focusing on that? Just educate us a little bit about the role that this plays in the midst of all the other responsibilities you're trying to shoulder.

DR. GABRIEL: I think the key words in what you just asked was, sort of thing. So, yeah. This is the sort of thing we would be doing in terms of providing guidance for the use of certain methods and certain -- under circumstances and in certain populations.

Translation table isn't, you know, common parlance. But that's why we had to go back and,

you know, talk to folks and see what examples existed out there.

But I think the intent makes good sense for Methodology Committee for, again -- and guidance for a number of different users from the patient to the investigator to a reviewer, to a policymaker. The information would be framed a little bit differently, and I think that's why we're imagining this interactive tool this morning.

But kind of like you're furrowing your brow. So kind of like -- and I don't want to use this as an example, but you know when you go into Amazon they know what kind of books you like and things are served up to you based on who you are and what your needs are. And we learned -- I learned this morning -- I wasn't familiar with it that there are some tools out there; was it Academy Health that Mike Lauer shared with us? That have actually gone partway down the path to building a tool like CHAIRMAN WASHINGTON: Dr. Joe Selby.

DR. SELBY: Future PCORI staff. I can't

quite remember now, and excuse me for maybe revealing how little time I've been engaged in this thinking.

Whether you called the prior section of your presentation, Sherine, whether you called it patient engagement or stakeholder engagement, but it occurred to me that patients are both stakeholders in elaborating the research agenda of patient-centered outcomes research, and then somewhat later in the process they are the participants in much of this research.

And I've -- I felt like we were going back and forth between engaging patients as participants in outcome studies, and assessing their preferences or their utilities, if you will, for certain outcomes. And then, talking about engaging patients at an earlier stage in the process as stakeholders, along with other stakeholdlers, but I wondered if that was in some ways intentional that we need methods for both types of engagement?

And we need to do a landscape survey of the methods that we use, both to elicit the

preferences, if you will, of patients for the kinds of research we do, as well as the preferences for, you know, specific approaches to care in a group of patients with a particular condition when we do the research.

DR. GABRIEL: Yeah. And I think, again, we -- that came up this morning and the importance of having patient input, stakeholder input. At both of those levels, I think, is going to be important.

So --

CHAIRMAN WASHINGTON: Proceed.

DR. GABRIEL: So, this really is almost my last slide. So, really just in summary, the methodology committee is off and running. We've established some operating principles and completed some -- what we call key foundational tasks. And we're starting to create this organizational framework that will guide the bulk of our work, which will be driving towards completing the two deliverables that are in the statute. But really, addressing what we understand as our core function, providing methodologic guidance and promoting

methodologic innovation in patient-centered outcomes research.

And with that, I really just wanted to remind you -- not that any of you have forgotten who we are. This is the Methodology Committee, again. And many -- I think 10 of us are here today. And they are an incredible group of individuals, not only in terms of deep expertise in methodology, but their commitment to this cause.

And to thank you all for your attention.

CHAIRMAN WASHINGTON: I also want to -- Gene Washington.

[Laughter.]

CHAIRMAN WASHINGTON: And before we comment further, I want to thank each and every member of the Methodology Committee for really -- I'm overwhelmed by -- you said you're off and running. You're off and running, you know, quickly. But you also -- quite effectively are moving a major agenda forward in a short period of time. And so, on behalf of everyone on the Board, thank you. And I want to just --

[Applause.]

CHAIRMAN WASHINGTON: Final thoughts, comments? We have Kerry.

MR. BARNETT: Kerry Barnett. I echo those comments. Wonderful work. But it's also clear that you have an awful lot of work ahead of you. And you're on a deadline that, if my math is correct, is about 11 months from now.

DR. GABRIEL: That's May 20th, 2012. Not that I have that, you know, emblazed in my mind.

[Laughter.]

MR. BARNETT: Fair enough. And so my question is, as you chart this work going forward, does it feel like you can get it all done? Kind of given existing resources and given the existing work plan? Or, do we need to be rethinking staffing support and other ways that we might be able to support the committee to help you meet that deadline?

DR. GABRIEL: So, I guess, yes and yes. So, two points. The first one is, it's very clear. It's clear from the statute and it's--we're

grateful for that -- that we can't do it all alone. And the statute says, you know, consult, contract, whatever with groups who can help us. And so, we're going to be doing that as soon as we have these tasks a little bit more solidified and crystallized to know exactly what kind of help we're looking for and with whom we can consult to bring it in.

But -- and like the PDC, we've also had a project manager, Jane, who is sitting back there, who we've had for a week and that's been tremendously helpful. But as we look forward, I think -- and we've talked about some of this. Having a researcher, you know? Somebody who could actually do a lot of the leg work, if you will, in pulling together the landscape review, doing some of the literature stuff and some of the scientific work that is perhaps a little bit less strategic than what we need to do, but would really be important to moving us forward. And so, you will see some of that in the budget that we hope to bring forward in two to three weeks.

So, I think it's doable -- and actually, the third comment is, it's doable because we're not going to do it all on step one. And I think perhaps Mike alluded to this. You know, the first step won't be everything, it'll hopefully be something useful and a framework that we can build on.

UNIDENTIFIED SPEAKER: Steve Lipstein, I think you're the next commenter and for the time being, the chair of the meeting.

VICE CHAIRMAN LIPSTEIN: Gene Washington, Jr., oh, just returned.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: I wanted to echo what Gene said. First of all, I don't know that many people in the public audience know that the Methodology Committee was named at the end of January. So, this represents just February, March, and April. So, Kerry, in answer to your question, I expect that their work will be done by the end of July.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: But what I was going to mention and I think Sherine brought it up was that in the consolidated work plan, there's a list of resource requirements. And so, at some point we have to marry that up with your budgeting process. And so my question was, how is that going to happen?

MR. BARNETT: I'm just very cognizant that if it takes us 6 or 8 weeks to do that, that's a critical period of time that you guys will have lost against your 11 month, 12 month deadline. So it is worth us putting our heads together and making sure that happens.

DR. GABRIEL: And I'm very -- I mean, as I said, I was hoping we'd get that done by now, but it was just too much, too big a chunk to take on. But, I think all we really need is a little bit more staff time and we can get it done and I don't know. One to two weeks, maybe?

DR. NORMAND: This is Sharon-Lise Normans. I think whatever we ask for, you should just give it to us. And that would expedite things.

UNIDENTIFIED SPEAKER: I'll move that one.

CHAIRMAN WASHINGTON: Okay. Bob Z.

DR. ZWOLAK: Bob Zwolak. Sherine, that was a tremendously comprehensive report and a staggering challenge in front of you. I have a question related to the Tier 1 grants that the PDC has been working on for some time now.

I wonder if you might describe your collaboration with PDC and particularly, does your involvement with PDC sort of take your eye -- does your involvement with the Tier 1 grants sort of take your eye off the ball for these bigger goals? Or does it expedite or facilitate what you have to do?

DR. GABRIEL: Well, I'll take the second one first, maybe. So in our work cycle, at least the way I've imagined it, the Tier 1 grants are part of that. So, it addresses some of the most critical gaps in methodology that will hopefully inform the second set of methodologic standards that we produce, the results of which would hopefully inform the second set of standards.

So I don't think it really, you know, takes our mind off. I think it's important that as we come up with standards based on best practices, we're also promoting research and innovation to create better methods and to implement -- and to identify implementation and methodologic gaps, and address those in order to come up with a better set of standards the next time. So, I don't think it does.

In terms of working with the PDC, we probably have to do a better job of that. We have only been in place a couple of months. One of the reasons that we, that Rick and I pushed to have a project manager kind of close to us, is to take advantage, at least, of the geographic proximity. And the two of them have already been meeting in the last week that they've been onboard and the two of them and the four of us worked together to try and align our work even more closely.

So, the spirit is willing but the body's been a little tired lately, I think is the short answer.

CHAIRMAN WASHINGTON: Okay. Ellen?

DR. SIGAL: Ellen Sigal. Just a short comment.

I, too, echo what Kerry said and others have said. I really do think we have to really look at the resources that are going to be needed for this committee and the other committees, because I don't know how this committee can sustain that level of work, even with experts.

So we really have to, you know, with the ability to outsource some of it because I don't know how you're doing it now and maintaining a full-time job. So, I mean, we do have to look at the longer-term in terms of how much time all of this committee, and also that would be the same for the PDC, can put into this. And what resources we need in-house, what we need to contract out for, because it's a lot of work. I mean, it's huge and large expectations and we need to fulfill them.

DR. GABRIEL: I couldn't agree more. And I think, again, we just need to move as quickly as we can to have a proper budget to incorporate into

the overall budget.

DR. SIGAL: I do want to -- I neglected to say thank you, because it's really good work. Thank you.

CHAIRMAN WASHINGTON: Kerry, are you?

MR. BARNETT: No.

CHAIRMAN WASHINGTON: I think we've heard from everyone. Freda has been a little quiet today, but that's all right. We'll give here -- we expect that.

[Laughter.]

MS. LEWIS-HALL: I'll be noisier tomorrow.

CHAIRMAN WASHINGTON: We expect that.

MR. BARNETT: [Off microphone.]

[Laughter.]

CHAIRMAN WASHINGTON: After that, Kerry, your voracity is definitely in question.

Again, I want to thank all who joined us and spent the entire afternoon with us, both here in the conference room as well as those who are on the telephone.

And just a couple of announcements before

concluding. One is that we do have a public session this evening from 7 to 9 that we are entitling the Stakeholder Discussion Forum. And it's right -- where is it, Pat? Is it in this room?

MR. NICHOLS: It's on this floor.

CHAIRMAN WASHINGTON: It's on this floor, across the hall. So if some of you are listening to this announcement and you are in the area, it starts at 7. And then the final announcement, Pat, is?

UNIDENTIFIED SPEAKER: But, Gene, but it won't be Webcast, right?

CHAIRMAN WASHINGTON: No.

MR. NICHOLS: It will not be Webcast, it will be --

CHAIRMAN WASHINGTON: It will not be broadcast.

MR. NICHOLS: It will be roundtable conversations, and it will be an engagement of our colleagues fully. Very different. There will be no presentational quality about it. It's a

dialogue with stakeholders. So, we'd be delighted to have you join us.

There's time for our guests between now and then to go out and grab a bite to eat. For the Board members and the Methodology Committee members, there's a grab and go meal available on the second floor, where we were earlier. And it's available now.

CHAIRMAN WASHINGTON: Okay. So with that, today's session is concluded.

Thank you again, everyone. Cameras off, please.

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