PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday, September 14, 2020

Teleconference/Webinar

[Transcribed from PCORI teleconference.]

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BOARD OF GOVERNORS

Kara Ayers, PhD
Lawrence Becker
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Alicia Fernandez, MD
Christopher Friese, PhD, RN, AOCN, FAAN
Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
Gail Hunt
Michael Lauer, MD [alternate for Francis Collins, MD, PhD]
Sharon Levine, MD [Vice Chairperson]
Freda Lewis-Hall, MD
Michelle McMurry-Heath, MD, PhD
Barbara J. McNeil, MD, PhD
David Myers, MD [alternate for Gopal Khanna, MBA]
Kathleen Troeger, MPH
Robert Zwolak, MD, PhD

AGENDA

AGENDA [continued]

P R O C E E D I N G S

[1:32 p.m.]

MS. JACKSTADT: Dr. Goertz the floor is yours.

CHAIRPERSON GOERTZ: Thank you.

Good afternoon and welcome to the September 14, 2020 meeting of the PCORI Board of Governors. I'm Christine Goertz, Chairperson. I want to welcome those of you who are joining us for today's board meeting by teleconference and webinar. Thank you to everyone who's joined us virtually online and on the phone. We're very pleased to have you here for the first of two days of meetings.

I want to remind everyone that conflict of interest disclosures of Board members are publicly available on PCORI's website and are required to be updated annually and if the information changes. If the Board will deliberate or take action on a matter that presents a conflict of interest for you, please recuse yourself or inform me if you have any questions.

If you have questions about disclosures or

recusals relating to you, or others, contact your staff representative. All materials that were presented to the Board for consideration today will be available during the webinar and then after the webinar will be posted on our website: www.PCORI.org.

The webinar is being recorded and the archive will be posted within a week or so.

Finally, a reminder that we are live Tweeting today's activities on Twitter, join the conversation with @PCORI.

Kat, can you please do a roll call?

MS. JACKSTADT: Certainly.

Kara Ayers.

DR. AYERS: Present.

MS. JACKSTADT: Larry Becker.

MR. BECKER: Here.

MS. JACKSTADT: Michael Lauer, filling in for Francis Collins or Francis Collins.

[No response.]

MS. JACKSTADT: Jennifer DeVoe.

DR. DeVOE: Present.

MS. JACKSTADT: Alicia Fernandez.

DR. FERNANDEZ: Here.

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Here.

MS. JACKSTADT: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. JACKSTADT: Mike Herndon.

[No response.]

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Present.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Here.

MS. JACKSTADT: David Myers filling in for Gopal Khanna.

DR. MYERS: Here.

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Here.

MS. JACKSTADT: Freda Lewis-Hall.

[No response.]

MS. JACKSTADT: Michelle McMurry-Heath.

DR. McMURRY-HEATH: Here.

MS. JACKSTADT: Barbara McNeil.

DR. McNEIL: Here.

MS. JACKSTADT: Gray Norquist.

DR. NORQUIST: Here.

MS. JACKSTADT: Ellen Sigal.

[No response.]

MS. JACKSTADT: Kathleen Troeger.

[No response.]

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: Robert Zwolak.

DR. ZWOLAK: Here.

MS. JACKSTADT: Dr. Goertz, we have a quorum.

CHAIRPERSON GOERTZ: Thank you so much Kat. All right, can we have the next slide please? We have a very full agenda today.

We're going to start out with our Consent Agenda where we'll consider for approval both the minutes from our July 21st meeting as well as committee leadership nominations for the Board. We will next consider for approval new advisory panelists, chairs, and co-chairs, our revised

Methodology Committee and Governance Committee charters, and our Cycle 1 2020 Dissemination and Implementation Awards slate.

Followed by that we'll have the Executive Director's report, which includes both highlights from her first five months with us, as well as an update on the -- our COVID-19 initiatives. We'll then consider for approval for posting for public comment our cost data principles for researchers before we wrap-up and adjourn.

So our first item on the agenda then is our is our Consent Agenda. Again, with both the minutes from our July 21st meeting and our nominations for chairs and Board chairs.

Do we have slides on the nominations?

Okay, thank you.

So this -- this slide outlines are our recommendations of the Governance Committee on Chair and Vice Chair for Engagement, Dissemination, and Implementation Committee, the Research Transformation Committee, our Science Oversight Committee, as well as our Finance and Administration

Committee.

Any questions at all about that?

Gail?

MS. HUNT: Yeah, I didn't see the Selection Committee on that list.

CHAIRPERSON GOERTZ: The Selection Committee actually goes through a different process, which is why it's not on that on that particular list.

MS. HUNT: Okay. Are you going to talk about that later on?

CHAIRPERSON GOERTZ: I don't think the Selection Committee is on this slate, is it Nakela? Do you --

DR. COOK: Hi, Christine. No, the Selection Committee is not on the slate for this today. And we will have to go back and take a look, I believe the Selection Committee would be approved through a later process in terms of the timing of rotation off.

MS. HENNESSY: Yeah, this is Mary Hennessy.

MS. HUNT: Let me just mention Mary, I read

through all of the materials that were sent out. And I realized that while there are vice chairs mentioned or put forward for each of the other committees, there was no vice chair for the Selection Committee, which would be is, since I've been on that committee, it's where you stand in when Barbara, who's the chair, has a conflict of interest. So they really need a vice chair identified.

CHAIRPERSON GOERTZ: Thank you Gail, we will absolutely make sure that that we have a vice chair for the Selection Committee. It's just something that we're not addressing at this -- under the umbrella of this particular motion.

But we certainly understand how important that role is.

All right. So, I would then like to ask for a motion to approve this Consent Agenda, which again, includes both our minutes and our leadership, committee leadership nominations.

MR. BECKER: I'll make that motion.

CHAIRPERSON GOERTZ: Okay, Larry is and

then who was the second?

MS. HUNT: I'll second.

CHAIRPERSON GOERTZ: Is that Gail?

MS. HUNT: Yep.

CHAIRPERSON GOERTZ: Okay. Thank you very much. Thank you.

All right. Is there any, any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. I'd like to call for a voice vote, then all those in favor?

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right, the Motion passes. Thanks so much.

Now I'd like to, I'd like our next agenda item, I'd like to turn it over to Kristin Carman, Steve Clauser, and Stanley Ip.

DR. CARMAN: Hi, good afternoon. My

colleagues and I, Steve Clauser and Stanley Ip, are genuinely excited to share with you and to present the advisory panelists proposed for the various PCORI advisory panel groups today.

As you all know, the advisory panels are just one of many ways that PCORI insures really deep and valuable input from our patient, caregiver, and stakeholder communities. Can we go to the next slide, please?

This is just to remind you of the review on the approval process, this occurs every year, and every year we receive remarkable applications. And even this year, what was obviously a truly challenging context.

I want to remind you of the basic deadlines, but deadlines usually close the last Friday in March, but we actually extended it by two weeks as this coincided, unfortunately, this year with the onset of the COVID-19 pandemic. Now the applicant pool undergoes a three-tiered review process with an eye towards really creating a balance of stakeholder types, that as well as

representation demographically, and otherwise across the five panels.

The proposed slates are then approved by the Executive Director, and the subcommittees of the Board before they are presented to you here today, which is what we're doing.

And I do want to take a moment here to thank all the staff for their support. This really is an all-organization effort.

Can we go to the next slide, please?

So this table shows you the number of applications received versus the number of seats we were looking to fill on each panel, this information you like have every year. And while we did extend the advisory panel application by two weeks this year, which was as long as we could do it and keep up with our mandated timelines. The number of applications were down across all advisory panels this year about 30 percent.

We did see that many of the applications from our patient applications, from really underserved and challenged communities, is where we

saw some real drop-off. We had about 42 applications that were left in draft status April 10th.

Having said that, I do want to note as ever, while our numbers were down a little bit this year, we still received many, many strong applications and as you know, from year-to-year, we have an embarrassment of riches of people wanting to participate in our processes.

And as ever, in what you're about to have discussed with you today, is we have made a conscious effort to include sort of multiple dimensions of diversity, as I mentioned. And I do want to note that while each applicant has to self-identify with a particular stakeholder category, we're very careful to include people who can bring multiple types of perspectives to what they're going to be talking about as members.

And, of course, as ever, we made sure that we met charter requirements.

With that, I would like to turn it over to my colleagues to introduce the science panels, and

then I'll come back and talk to you about the Patient Engagement Advisory Panel.

So can we go to the next slide, please?

DR. IP: Hi, Kristin, thank you very much.

I'd like to present the panel proposed by the SOC and the MC. This is Stanley Ip. Next slide.

So, we are very excited about the individuals we hope to bring onto the Advisory Panel on Clinical Trials. We're nominating six new members with diverse expertise and demographics to replace the six departing panelists. While their primary stakeholder designations listed on this slide denote only one self-identified affiliation. These proposed panelists also identified with additional stakeholder experience as clinicians, consumers, patients, caregivers, payers, representatives of training institutions, hospitals and health systems.

Next slide.

The proposed Chair, Catherine Crespi-Chun has served on the panel for two years and is the

current panel co-chair. She's a Professor of Biostatistics at UCLA, Fielding School of Public Health.

Next slide.

So we are similarly excited about the individuals we hope to bring on to the Advisory Panel on Rare Disease. We are nominating six new members with diverse clinical research and lived experience to replace the four departing panelists. While you see the primary stakeholder explanations on the slide, three of these proposed members also identify themselves as researchers.

Next slide.

The proposed co-chair Doug Lindsay, has served on the panel for one year and represents patients, caregivers, and stakeholders. He is an innovator and a nationally recognized speaker who understands the challenges faced by patients with rare diseases through his own 14-year journey with a rare condition.

Next slide.

For the Advisory Panel on Clinical

Effectiveness and Decision Science, we are proposing to bring on 14 new members to satisfy the requirements of the charter for size, stakeholder representation, and expertise as 10 panelists are rolling off this fall. The proposed nominations will not only replace the expertise of individuals rolling off, but creating new ones not previously included, such as intellectual and developmental disabilities, health economics, and mind and body practices. No new chair and co-chair are being nominated at this time.

Next slide.

Next slide.

So Steve.

DR. CLAUSER: Thank you, Stanley. This is the slate for the new nominees to serve on the Advisory Committee for Healthcare Delivery and Disparities. We're proposing to add four new members to replace the six members who rolled off the committee this year. You can see the stakeholder designation that they identified in their applications, they cross several stakeholder

categories with their lived and professional experience, and these new members add important expertise to our panel, including expertise in two of our Congressionally-mandated priority areas, maternal mortality, and intellectual developmental disabilities as well as expertise in rural health care.

Next slide.

We are nominating two existing panelists to serve as Advisory Committee co-chairs for the coming years to replace the two co-chairs who rolled off this year. Alicia Arbaje is Associate Professor of Medicine at John Hopkins University's Center for Transformative Geriatric Research. And Jane Kogan, who is the Associate Chief Research and Translation Officer for Insurance Services in High Value Health Care at the University of Pittsburgh's Medical Center. And they will be serving two-year terms.

Next slide.

Kristin, I'll turn it back to you.

DR. CARMAN: Fantastic. Thank you, Steve. And I will go ahead and present the Patient

Engagement Advisory Panel on behalf of Larry and EDIC.

So can we go to the next slide, please?

We are in -- I know I say this every year, but it's very, very true. We're really excited and energized by the individuals we hope to bring on the PEAP this year.

While we did have seven members roll off, we are nominating four members this year. And that's because our previous panel we had enlarged quite a bit to ensure that we really increased our diversity and inclusion. And we've been able to maintain that and create a panel that I think is a little bit more right-sized from the perspective of the panel as well.

These new members ensure that the panel maintains a very, very strong commitment to addressing inequities and the issues that really are so important to our communities right now. It also maintains a balance between individuals who both are very experienced with PCORI but also bring a fresh perspective on our work and can help us think about

the critical issues around engagement.

If we can go to the next slide, please, I want to mention our new chair and co-chairs.

Gwen Darien is our current co-chair and we are nominating her to become our chair. She's been on the PEAP for two years, she serves as the Executive Director of the National Patient Advocacy Foundation -- really important as her co-chair, she's really led a lot of our efforts around improving our engagement principles around equity and diversity, and those values in thinking about some future state activities.

Our new co-chair is Neely Williams, she is a very familiar name to PCORI, although newer to the PEAP. She's been a very active member on PCORnet since its inception and she's served in multiple capacities. And we're very excited to have her serving in our co-chair role.

So with that, I will open it up for Stanley, Steve, and myself, if there's any questions or obviously turn it over to Christine to decide on next steps and calling for a motion.

CHAIRPERSON GOERTZ: Great, thank you. Thank you so much to all of you. It's incredibly exciting to see this with so many people with such amazing expertise who are willing to either continue serving PCORI or to begin serving PCORI in these absolutely critical roles. So are there any -- is there any discussion on the part of the Board before we call for a motion?

Gail, did you want to make a comment?

MS. HUNT: Yep. I think that it's important that we [inaudible] for these committees. And I have [inaudible] that's been pretty weak in the whole time that I have been on PCORI. That I, for example, went to the PEAP meetings, and I would be the only person, the only Board member, and they would sit talk about that. Why aren't there other Board members that come?

And so, I think that with the new people coming on, the seven new Board members, we should encourage them if they can, to participate in the advisory panels as they can. I think that's a great idea. And it would really improve the new members

understanding of PCORI by participating in these -- in the advisory panels.

CHAIRPERSON GOERTZ: Thank you. Thank you, Gail, for that, that suggestion. I think that's something that we really need to -- need to take to heart.

Any others who'd like to make a comment?

DR. TROEGER: This is Kathleen.

CHAIRPERSON GOERTZ: Yes, Kathleen.

DR. TROEGER: I'd just like to echo what Gail mentioned about these committees and publicly broadcasting and making available or more available, potentially that the meetings -- I know they're posted on the website, but I think it is particularly important for those of us that aren't following that to perhaps get a reminder. So that would be a great -- that'd be a great thing to have.

CHAIRPERSON GOERTZ: All right, we'll definitely follow up with Nakela about how to how to make sure that Board members are more keyed in these to these committees and so that there is an opportunity for people to attend if they're able.

Larry, did you want to make a comment? I

MR. BECKER: Yeah, I wondered if you could display all of the diversity of these panels in total, just so that we know what we're doing here.

DR. CARMAN: Larry, if you'll forgive me, I cannot display but I can read it to you. Does that suffice if I give it to you verbally?

MR. BECKER: Sure.

DR. CARMAN: Okay, fantastic.

So, Larry's question is the demographics of the application pool. So I'm going to give you demographics in the variety of ways we think about it. So for the entire applicant pool, 51 percent are patients, 24 percent are researcher, 10 percent are clinician, one percent payer, one percent policymaker. And do remember, 11 percent didn't report.

So lots of folks actually don't articulate and want to articulate exactly what their demographic is in terms of that. Sixty-one percent are white, that's non-Hispanic. Eighteen percent are Black or African American, eight percent Asian

Pacific Islander, one percent Indian/Alaska Native, two percent Hispanic-LatinX, and 10 percent did not report.

I do want to note, and we actually had this conversation, as you recall on the EDIC Larry, that there is I think, and continues to be a real fluidity in how people report their demographic background in terms of race and ethnicity. And so, we've seen some real shifts, particularly around Hispanic-LatinX in terms of how much people want to declare that.

And the only other thing I wish to note and it's quite fascinating this year. I'm going to tell you, it's 38 percent female, 11 percent male, but I will tell you that 51 percent this year did not wish to report compared to the last year where more people are willing to report that information.

MR. BECKER: Thank you very much.

CHAIRPERSON GOERTZ: Thank you. Any other questions or discussion points?

[No response.]

CHAIRPERSON GOERTZ: All right, I'm going

to ask for a motion then to approve the proposed slates of members positions and terms for the advisory panels that are listed on this motion?

DR. ZWOLAK: Zwolak, so moved.

DR. AYERS: Kara --

DR. HOWERTON: Russ --

CHAIRPERSON GOERTZ: I'm sorry. Okay, I'm sorry. I hear Russ. I'm going to go with Russ for that motion.

Can I have a second?

DR. LEVINE: So moved. Second.

CHAIRPERSON GOERTZ: Thank you, Sharon. All right. Any further discussion?

Mary, did you have a point of clarification you wanted to comment on this before we vote?

MS. HENNESSY: No, I'm just activating my camera because I'm the next agenda items and I don't want you to have to wait for me.

CHAIRPERSON GOERTZ: Okay. Thank you. Thank you for that.

All right. Any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm going to ask for a voice vote then to approve the motion.

So all those in favor?

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: Wonderful. Again, well, congratulations to all of our new advisory panel members and leaders. We really appreciate your service.

Now I am going to turn the agenda over to Sharon Levine and Mary Hennessy.

DR. LEVINE: Thanks, Christine. And this agenda item is to present to the Board and to get your approval for amendments the Governance Committees putting before you, the Methodology Committee charter and the Governance Committee charters.

As you may remember, PCORI's reauthorizing legislation shifted the authority for appointing

members of the Methodology Committee from the GAO to the Board of Governors. At the Governance Committees meetings on March 20th, May 29th, June 22nd, and July 10th, the Committee discussed and developed a proposed governance framework that will enable the Board to appoint Methodology Committee members and saw the input and agreement of the Methodology Committee which supports the proposed Governance structure. And we are very grateful to Robin Newhouse for her continued participation -- active participation in the Governance Committee.

The Committee is recommending that the Board approve the proposed amendments to the Methodology Committee charter that reflects a governance framework. Once that is approved, the amended charter is approved, the Methodology Committee will be able to work with the Governance Committee in implementing the new Board authority and putting together an implementation plan.

And the plan includes the fact that appointments to the Methodology Committee will occur, appointments and reappointments, on odd

years. So that -- and given that Board member appointments are in the even years.

And we're also recommending today that the Governance Committee approve amendments to the I'm sorry, that the Board approve Governance Committee recommended amendments to the Governance Committee charter, which simply aligns the language in the reauthorizing legislation by deleting one of the responsibilities of the Governance Committee, which was to advise the GAO regarding the appointment process of Methodology Committee members.

Now that PCORI has that authority, that Governance Committee no longer has to advise the GAO, who is happy to have shifted that responsibility to us. And as I said, once the Methodology Committee charter is approved, we will develop a plan to implement the approved governance structure.

Mary is going to go through the amendments with you.

MS. HENNESSY: Thanks so much, Sharon. Can I have you move the slide forward and move it again

forward?

Sharon's already given a great background to what is led to the proposed amendments, and I'm just happy to briefly summarize what the proposed amendments are, and how they reflect the proposed governance framework for the methodology Committee.

The amendments to the charter would implement six-year terms for Methodology Committee members with staggered term structure. This is similar to the way the Board is structured, and is a highly recognized governance best practice because it provides ample support for the committee to at any given time be equally divided among members who are new, those who are experienced, and those who are highly experienced.

An additional part of the governance framework is that a Methodology Committee member could be appointed to an additional six-year term to the extent it's necessary to fulfill the functions of the committee or the requirements of the law or the needs of PCORI, but in any event, would serve no more than two, full, consecutive six-year terms,

similar to the way that most boards work, and in the way that this board works.

For this committee appointments to the MC that were to fill a premature vacancy. So if a member prematurely resigned or departed the Methodology Committee, the Board could consider appointing someone for the remainder of that predecessor's term which is a function that's used to try to retain the staggered term nature of the committee.

And then similar to committees and to boards, the charter reflects a model that confirms that the appointed MC members are eligible to serve until their successor is appointed. And that's really designed to prevent against an inadvertent gap and valid membership in the event, for example, that the Board didn't approved and the Board scheduled was two weeks later than the appointment had been six years earlier.

So that summarizes the structure. Can you move to the next slide, please?

Sharon's already explained, the proposed

amendments to the Governance Committee charter, which really is designed to reflect the reauthorizing law.

Next slide, please.

And Sharon has also walked through the significant next steps that would follow if the Board approves the charters. There'll be ongoing planning to develop an implementation plan with the major points outlined here on the slides.

Next slide.

I'll turn it back to Sharon if you have any other comments or turn it back to Christine for managing a Board discussion and vote.

CHAIRPERSON GOERTZ: You're on mute Sharon.

DR. LEVINE: Sorry, I just wanted to see if Robin had any comments she wanted to make or add to this.

DR. NEWHOUSE: No, Sharon. Thank you so much. Perfect.

DR. LEVINE: All yours, Christine.

CHAIRPERSON GOERTZ: Great, thanks.

Thanks so much to both the Governance

Committee and Mary and the Methodology Committee for the hard work in making these amendments that we're able to fulfill this new and incredibly important obligation.

So do -- there any? Does anybody have any questions or are there further discussion points?

Larry?

MR. BECKER: Just a quick question. How are the current Methodology Committee members going to be assigned relative to terms?

MS. HENNESSY: Larry, that's exactly the type of next steps where they'll be a plan for figuring out transitions for current Methodology Committee members and with the plan for the Board to appoint in odd years. There'll be really good time to think through working with the Methodology Committee and its current membership on plans for those members.

MR. BECKER: Thank you.

CHAIRPERSON GOERTZ: All right. Are there any other questions or comments?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to ask for a motion to approve the proposed amended Methodology Committee charter and the proposed amended Governance Committee charter.

DR. LEVINE: So moved.

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: All right, Sharon -- I heard Sharon and Barbara, was that you for -- are you willing to second?

DR. McNEIL: It was.

CHAIRPERSON GOERTZ: Okay, great. Thank you. Thank you so much. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, I'm going to ask for a voice vote then to approve the approve the motion.

All those in favor please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: Great, thank you very much.

All right. Next up is Larry Becker, who will be giving some introductory remarks regarding our Cycle 1 2020 Dissemination and Implementation Award slate. And then I think he'll be turning it over to Joanna. So Larry.

MR. BECKER: Yeah, thank you very much. Let me get my camera on. There we go.

So thank you very much the EDIC spoke of all of these awards you're about to see, we support the moving forward of these awards, and I'd like to turn it over to Joanna to give you the details.

DR. SIEGEL: Thank you, Larry.

As Larry said, I'd like to present to you the proposed funding slate for the D&I Limited Competition PFA. And just as a reminder, this is the funding initiative that we have that provides an opportunity for awardee teams who've completed their PCORI-funded study, to take next steps in promoting uptake of the evidence into practice, in the context

of related evidence to lay the groundwork for broader uptake.

First slide, please.

Here you see our merit review criteria. And as you know, these resemble very much the ones are used for review of research studies in science, with some tweaks for better applicability to implementation needs.

Next slide, please.

This is a review of the current cycle. We had ten Letters of Intent submitted, we had seven Letters of Intent invited. Of these, four submitted an application.

This is not the usual number of applications that we receive, we did have some drop-off, related to the timing with respect to COVID. In fact, a couple of the Letters of Intent that did not respond, have responded to the next cycle.

The proposed funding slate recommended by the EDIC is one application out of the four received for a funding rate of 25 percent.

Next slide, please.

This is the title of the proposed slate project; it's called the Implementation of Effective Home Oxygen Weaning Strategies in Premature Infants.

This proposed project will incorporate a recorded home oximetry program, that was tested in a PCORI-funded study, into standard practice in 12 hospitals located across the US. The program was found to be safe and effective in terms of managing home oxygen therapy for premature infants. It shortened the duration of home oxygen therapy and it also increased patient satisfaction.

The implementation sites include diverse medical centers of different sizes, which use different care teams, workflows, and processes for working with families with premature infants to demonstrate feasibility of uptake in this range of sites. The project will reach approximately 600 families each year.

Next slide, please.

The proposed budget is $1.3 million. The budgeted annual amount for this PFA is $9 million and this is the first cycle of 2020 for this PFA.

Next slide.

I'll turn this back over to Christine.

CHAIRPERSON GOERTZ: Sorry about that, I have trouble getting myself off mute.

So, this is before we before we have our discussion. I'd like to let you know that we've had two of our Board members who have notified us of their intention to recuse themselves from the deliberative discussion and vote on this particular slate. Those are Bob Zwolak and Kara Ayres.

Now, if there are any other Board members who believe they should recuse themselves. Please, do so.

[No response.]

CHAIRPERSON GOERTZ: All right. Any questions or comments for Joanna?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I am going to ask for a motion to approve the slide as outlined.

MS. HUNT: I so move, Gail.

CHAIRPERSON GOERTZ: Gail, thank you.

DR. DeVOE: Second, Jen.

CHAIRPERSON GOERTZ: Jen, thank you.

All right. Any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, we're going to ask for -- do a roll call vote then, Kat.

MS. JACKSTADT: Kara Ayres is recused. Larry Becker.

MR. BECKER: Approve.

MS. JACKSTADT: Francis Collins or Mike Lauer filling in for Francis Collins.

[No response.]

MS. JACKSTADT: Jennifer DeVoe.

DR. DeVOE: Approve.

MS. JACKSTADT: Alicia Fernandez.

DR. FERNANDEZ: Approve.

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Approve.

MS. JACKSTADT: Christine Goertz.

CHAIRPERSON GOERTZ: Approve.

MS. JACKSTADT: Mike Herndon.

DR. HERNDON: Approve.

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Approve.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Approve.

MS. JACKSTADT: David Myers. David Myers filling in for Gopal Khanna.

[No response.]

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Approve.

MS. JACKSTADT: Freda Lewis-Hall.

DR. LEWIS-HALL: Approve.

MS. JACKSTADT: Michelle McMurry-Heath. Michelle McMurry-Heath?

[No response.]

MS. JACKSTADT: Barbara McNeil.

DR. McNEIL: Approve.

MS. JACKSTADT: Gray Norquist. Gray Norquist?

DR. NORQUIST: Approve.

MS. JACKSTADT: Thank you, Gray. Ellen Sigal.

[No response.]

MS. JACKSTADT: Kathleen Troeger.

DR. TROEGER: Approve.

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: And Robert Zwolak is recused. Dr. Goertz, the motion passes.

CHAIRPERSON GOERTZ: Thank you very much Kat.

DR. SIEGEL: Thank you.

CHAIRPERSON GOERTZ: All right. Our next agenda item then is our Executive Director's report. So I would like to turn the podium over to Nakela.

DR. COOK: Thanks Christine. It's a pleasure to join you all this afternoon and present this report, which has two major areas of focus for our discussion today. The first is a reflection on my first 150 days at PCORI and I'd also like to give you some updates on our COVID-19-related work.

Next slide.

This board meeting, we're actually celebrating the 10-year service a four of our Board members whose terms are coming to an end and I just

wanted to say on behalf of all the staff at PCORI that we thank you for your vision, your commitment, and your dedication and tomorrow we look forward to hearing your reflections on the past 10-years and opportunities for PCORI's future.

Next slide.

I'll jump right in and begin with some highlights from my 150 days.

Next slide.

So I just passed my five-month mark and milestone at PCORI and I must say it's been a really exciting journey thus far and I wanted to provide a few highlights of these first five months. I've been focused on several things including PCORI's operations, particularly as it relates to remote work as well as a return to work plan and our COVID-19 environment, establishing a leadership team, as well as focusing on issues of diversity, equity, and inclusion and resuming full operations post our reauthorization.

Another intense area of focus has been related to the Board of Governors and several

committees, and I have been working to engage with the committee's and start the launch of the strategic planning process which you'll hear a report about tomorrow. I've also been very interested in engaging with our stakeholders and virtually trying to touch base with many of them through a modified version of a listening tour, and also representing PCORI at several diverse venues.

Reauthorization priorities have been high on our list of activities in the first five months, and you'll hear more about our COVID-19 response activities.

Next slide.

I wanted to begin with our PCORI operations and just take each of these in turn.

Next slide.

We're really fortunate at PCORI, to have a remarkable health emergency preparedness planning team. That's basically been working with us to keep us operational, even in a remote environment and our staff at PCORI continue to work remotely for the foreseeable future and have been functioning very

well remotely, with a remarkably accelerated case workload in the face of COVID-19.

We're also benchmarking and communicating with other organizations and gathering information from local health departments and public officials to inform our decisions around working from home as well as returning to the office, eventually. And several principles guide our COVID-19 reopening plan which we released to our staff last month, and we used a few guiding principles as it relates to our reopening plan.

And some of those are listed here including the safety and well-being of PCORI's workforce, as well as considering a very flexible approach that would consider the needs and circumstances of our staff and the COVID-19 environment in this local area. We also recognized the importance of complying with requirements set forth by local and federal authorities, and we anticipate providing far advance notice before the start of any of the phases and our reopening plan, so that also recognizing that if appropriate, we may need to backtrack on

some of the phases, depending upon the local situation.

The plan that we've laid out follows a very deliberate and gradual multi-phased approach to return to PCORI's worksite and considers lots of factors including access to COVID-19 testing, even the scenario of number of cases and availability as it relates to public transportation and government requirements as I mentioned before. And with this type of multi-phased approach we're looking at a gradual increase in staff access to the worksite, beginning with those who really have a need to be in the office on some interim basis, or those who just prefer to work in the office, and only after our offices are ready for any staff to return to the workspace.

We're in the process of making several modifications to the workspace to account for the social distancing requirements and limiting the overall numbers of individuals in the space. So this does mean that the majority of PCORI's workforce will continue to work remotely for the

foreseeable future. But as we move to phase four that that would be the time where we'd have a full return to the office and that would be really after there's widely available or effective prevention or treatment strategies or a change in the virus virulence or even transmissibility.

Next slide.

I've also been very focused over the last five months to make sure that we had a functioning, cohesive leadership team, and given several of the leadership vacancies that we have it at PCORI, I focused on knitting together this leadership team that would identify senior leaders across PCORI who have stepped up to take on some additional responsibilities, or bringing in additional leadership in an interim period while we work toward our goals of building out an operational model for PCORI of the future.

And I'd like to take this opportunity to thank those who have stepped in to do so as well as to introduce a couple of new staff to PCORI. Tasha Parker joined us from her prior role at the American

College of Obstetrics and Gynecology, and she's our new Communications Director and Laura Lyman Rodriguez joined us as our Interim Program Support Officer and a Senior Adviser to me, following many of her years at the NIH and at Geisinger Health.

Next slide.

Diversity, equity, and inclusion has also been a very prominent focus for us in the last several months punctuated really by what's happening all around us in the United States as it relates to issues of social and racial justice and this slide shares a snapshot of several of the activities of focus both internal and external to PCORI. In late July, Josie Briggs and I had an honest conversation about race diversity, equity, and inclusion for all the staff within PCORI to hear. And it was really to demonstrate that these dialogues can happen. And I followed this conversation with an invitation to staff to join me for roundtables that are focused on diversity, equity, and inclusion, and then visioning the culture for PCORI that we would like to create for the future.

And our staff and leadership are embarking on an effort to formulate a comprehensive initiative, both internally and externally focused on PCORI as a workplace as well as a funder that's really a microcosm of the broader research funding environment. We know we have some of the similar challenges related to diversity in applicant awardee or even participant pools, and we look forward to continuing to work on this and advance our efforts.

Our Engagement team has also begun the process of considering and updating our engagement rubric from a diversity and equity lens. And I've been participating in discussions and other venues and with stakeholders who are hosting meetings to tackle issues of racism, discrimination, as well as diversity, equity, and inclusion in our work. And a few examples are the Academy Health Research Conference, which had a special plenary on racism and health services research, and a recent roundtable that was hosted by two key PCORI stakeholder organizations, where they were having discussions about diversity, equity, and inclusion

in the work that we carry out.

And discussions about diversity, equity, and inclusion have come to the fore in my meeting with the advisory panels, as well, so a very prominent issue on people's minds.

And at the upcoming PCORI Virtual Annual Meeting we will have a keynote speaker who's focused on addressing discrimination and bias as root causes of health disparities, as well as a panel that will follow to help identify some concrete actionable solutions to addressing some of these issues in the pursuit of health and healthcare equity.

Next.

And we anticipate that we'll have more to come when we talk with you in October, where I can give you an update on several of these ongoing activities.

Next slide.

So my first five months I've been fortunate to engage with four committees and the Methodology Committee to prepare for several topics that we're going to be discussing in the meeting today and

tomorrow and have been working to build relationships with Board members and establish regular communications with updates at the meetings as well as interim updates between meetings, and also have been focused on launching PCORI's strategic planning effort with the Board Committee for Strategic Planning, and tomorrow you'll hear their report from the first meeting of the Strategic Planning Committee.

Next slide.

As I've begun going around and listening to the stakeholders in the virtual format, I've been hearing a lot about what's on their minds, and several topics of discussions were brought up across stakeholder groups including the priorities in our legislation, but I thought I'd give you a flavor of what I've been hearing from some of the groups.

Our advisory panels have been discussing the establishment of our national priorities for the future and I know you've seen some of their comments in our prior meeting and we'll have a chance to look at those again tomorrow when we talk about strategic

planning, and I've also heard the importance from the advisory panels related to eliminating health disparities and addressing broader issues such as social determinants of health, as well as a focus on our priorities in our legislation including maternal mortality, intellectual and developmental disability, and the cost data provision.

The payers that I've been speaking with have been interested in the implementation of our cost data provision in our legislation, as well as how we anticipate collecting data that would help inform their decision-making. I would also say that payers and purchasers have been interested in issues of social determinants of health and have even talked about the issue of maternal mortality as it relates to those social determinants.

And our purchaser community has been raising the issue of collecting data that will actually support the value in healthcare and data that can be of use to them as they think about value and value assessments.

Our congressional leaders have also

signaled their interest in efforts to eliminate disparities and, as well as priorities and legislation, and our COVID-19 response.

And patients that I've been meeting with and the Patient Advisory Panel have focused on diversity and inclusion quite a bit as well as priorities in legislation and how to advance engagement and research to more of a patient-driven research agenda. All very interesting topics for us to pursue in our next phase for PCORI.

Next slide.

Another intense area focus of the first five months has been related to our reauthorization and the several new areas of focus in the legislation, and we've been diligently working to make progress to meet our congressional priorities, including implementing the provision on cost and economic data, which will be discussed later today as well as developing our new priority topics in legislation; maternal mortality and intellectual and developmental disability, and I'd like to talk a little bit more about those latter two priorities.

Next slide.

So to implement the priorities related to maternal mortality and intellectual and developmental disabilities, PCORI actually began engaging stakeholders in 2019 with maternal mortality as a forerunner, knowing that that may be important in our reauthorization legislation, And intellectual and developmental disabilities followed shortly behind that, and we continue to plan multi-stakeholder engagements to articulate a longer term vision for these areas which will be priorities for us over the next decade.

And we anticipate a combination of short- and long-term efforts from funding opportunity announcements to other types of evidence products and plans for collecting data, it's all important to the analyses that may be supported with PCORI's work.

And our first effort has been a focus in the broad Cycle 3 2020 announcement, which was a special area of emphasis to set aside funding, where we took our first stab at reflecting some of what

we've been hearing from our stakeholder communities, and incorporated areas related to maternal mortality focused on the care coordination -- maternal health issues and care coordination, as well as improving the care for individuals with intellectual and developmental disabilities as they go through transitions from childhood to adulthood care and recognizing the challenge that that brings in that scenario.

Next slide.

As I mentioned, the legislation emphasized a range of short- and long-term activities as priority for PCORI as we move forward into our next phase. And we have been focused on an array of evidence products that are shorter- and longer-term activities and we'll continue to hone this and have been talking about this in the last five months as well.

So along with other sources we've used horizon scanning to inform research questions, and in fact, horizon scanning is being used as it relates to COVID-19 to inform research priorities.

And the spectrum that's displayed here represents some of those trade-offs between speed and rigor. On the left are summary products that can be completed maybe in about a year but represent less -- present less rigorous evidence. And as you move to the right on this slide, towards our large multi-phase research trials, the rigor increases, but so does the time required to complete these types of projects.

And so, the newest and more rigorous research products that PCORI funds are a form of these large pragmatic study designs that you see on the very far right. But dissemination and implementation activities really span the entire timeframe. And so, we'll continue to hone this range of activities from short- and long-term products that can help fulfill our goals and mandates for our next phase.

Next slide.

Our reauthorization language also shifted the authority to appoint the Methodology Committee members to the PCORI board from the GAO, and we just

finished a dialogue about that but that's been part of the focus of these first months. And earlier you approve the amendments to the charter to support this process and consistency of the language.

We've also begun with the chairs of the Methodology Committee, and we'll continue to work with the Methodology Committee and Board to think about the future focus of the Methodology Committee in alignment with the vision for PCORI 2.0, that will help to continue to tap into the expertise this unique expertise of this committee, in pursuit of our priorities moving forward.

Next slide.

And lastly, COVID-19 response has remained front and center for me over the last five months as we've been focused on funding, tracking and learning. And we'll talk a little bit about funding and some of the products and support that we've provided as it relates to our COVID-19 response, as well as the tracking that we're doing of our portfolio and learning because in this dynamic environment we're learning a lot about operational

innovations as well its implications longer term beyond even the pandemic.

Next slide.

So I'd like to shift gears and talk a little bit about our COVID-19 activities and give you an update on those activities.

Next slide.

This slide just demonstrates PCORI's multi-pronged approach to its COVID-19 response activities and many of the approaches that we've taken at the PCORI for critical work in the areas of our awards portfolio where we've been supporting enhancements of existing awards, to adapt to the issues of the coronavirus pandemic. We've also solicited new awards through targeted solicitation and funded the HERO Healthcare Worker Registry to facilitate trials.

We have promoted information sharing in a variety of different venues and I mentioned the horizon scanning effort that was focused on COVID-19 that continues today. We also have at our annual meeting sessions devoted to our COVID-19 response.

And we hosted a webinar series that was very popular and well-attended. And these webinars are posted on our website for future viewing. But some of these focused on issues like discharging patients recovering from COVID-19 or even the changing role of telehealth and we're working with other federal agencies and organizations for coordination of our efforts.

And lastly, we continue to maintain this focus on adapting in the environment for awardees and applicants and we are starting to see those needed adaptations to existing projects rolling into PCORI now. I think investigators are starting to understand the longer-term impacts to their study and are starting to raise some of the issues that will be important for us to understand more fully.

Next slide.

So this slide is just a refresher that in March and July the Board of Governors approved a combined total of about $160 million in COVID-19 funding for projects, enhancements, and adaptations, and also gives you an update as it relates to our

commitments within that $160 million.

So $114 million has been committed. And this is a combination of $80 million in targeted awards including the HERO Registry and Trial, as well as the nine awards, which I will report to you today under the COVID-19 Targeted PFA.

It includes $33 million toward our enhancement projects, about 100 or more projects in this phase, and about $500,000 in adaptations. As I mentioned, we've just started to see the adaptations roll in to PCORI in terms of what may be needed for the researchers to adapt their programs to continue to conduct the work in our COVID-19 environment.

Next slide.

I wanted to focus just a little bit on our research funding, and we'll walk through a little bit around the updates on the Healthcare Worker Exposure Response and Outcomes or HERO Registry and Trial. I'll also give you an update on our targeted funding announcement which you may remember focused on three areas of priority, including adaptations to healthcare delivery, the impact on vulnerable

populations, and the healthcare workforce -- its well-being management and training.

And also, I'll give you an update on our Enhancement Program, where awardees could adapt or add aims to address COVID-19 outcomes and implications.

Next slide.

So let's take each in turn and begin with the HERO Program and I'll start with an update there.

The HERO Research Program, as you recall, is being conducted by investigators at Duke University through an award to Duke, and the registry continues to be a really important focus. It's designed, as you may remember, to create a community of healthcare workers at-risk for infection and has an approach that is participant-driven in terms of what matters most and is most important to the participants and the healthcare workers that are in the registry. And this is a really unique component for this registry as compared to others that are existing in this space.

It was also designed to identify those healthcare workers who were interested in clinical trials and create a data set of clinical and environmental risk factors as well as emotional outcomes for those responding on the front lines.

And almost 17,000 healthcare workers are enrolled, and you may remember this is medical and non-medical healthcare workers. And surveys are being conducted within this registry related to the healthcare worker well-being.

We are -- the investigators are also receiving regular queries about questions of interest to pursue using this data set. And so, it's going to end up being a very rich resource in terms of understanding the experience of healthcare workers during the pandemic.

You may also recall that the hydroxychloroquine trial is evaluating the efficacy of hydroxychloroquine to prevent COVID-19 infection in at-risk healthcare workers, and the targeted enrollment has been revised to 2,000 participants as the target in response to some changes and assessing

what really is a clinically meaningful effect size with more data and publications from other studies being able to inform this. It still preserves 80 percent power to detect a difference in prevention of infections and will still remain one of the largest and most rigorous hydroxychloroquine prevention studies, and there's been some ongoing and renewed scientific and even debate in the media as well, that really reiterates for us the importance of finding a definitive answer. This renewed debate has really arisen in the last few weeks and makes it even, I think more compelling for us to be able to answer the question.

Thus far 1,300 healthcare workers have been enrolled of the 2,000 targeted.

Next slide.

I thought it would be important just as a reminder to mention the several oversight mechanisms that are still in play related to the HERO Hydroxychloroquine Trial and you may remember that this trial is being conducted under an IND, and there's a data safety and monitoring board

established by Duke that meets regularly, approximately every other week, and its reviewing safety data and other trial data, and actively reviewing the scientific and media information -- both published as well as unpublished information, through connections that they have with other COVID-19 related studies.

And they've engaged the DSMBs of several other COVID-19 related trials to ensure that they have the active flow of information to assess very broadly the implications for the trial that PCORI is funding. They have recommended continuation of the protocol at the revised targeted enrollment sample size.

The DSMB also continues to monitor processes to make sure that we are ensuring effectiveness, safety, or futility issues are addressed very promptly. We also have a PCORI advisory panel and I'd like to thank both Alicia Fernandez and Mike Lauer, who serve on the panel, that advises me related to the overall funding and monitoring questions, and provide some insights to

the investigators as well who often are able to take those insights into their dialogues with the DSMB.

And lastly, I'll just mention that PCORI's contractual mechanism and processes are cost reimbursed, and so it does allow us to have a reduction in the financial impact if there is a scenario where we need to stop the study early.

Next slide.

I next wanted to give you an update on our enhancement program, and you may remember that the enhancement awards allow for current awardees to submit proposals that can leverage their existing awards to address the COVID-19 health crisis. And applications were accepted on a rolling basis and we've now closed our applications for this program, and we received approximately 250 proposals in this enhancement process and it was really a remarkable effort by our staff to review them all with a very quick eye, and we've approved about $33 million to-date across research, dissemination, implementation, and engagement awards.

And this slide just shows you the breakdown

of the improved enhancements by the programmatic area.

Next slide.

And this slide should be familiar to you but it's updated in order to be able to demonstrate that the approved research enhancements as well as the dissemination, implementation, and engagement enhancements really span a broad array of intervention strategies as well as health conditions, not just to understand the impact of COVID-19, but also to generate some actionable outcomes related to the pandemic.

And we found this program to allow for some timely research across these broad arrays of conditions and strategies as well as emerging topics related to COVID-19. It was really, I think, an effective approach to be able to leverage awards that may have been working in certain areas to then be able to understand the implications of COVID-19 in that area, in a very rapid fashion.

I'll give you a couple of examples that may demonstrate this.

Next slide.

So this is an example from one of the enhancements to a Research award that compares the benefits and harms of five different treatment options for extended treatment of venous thromboembolism. It compares warfarin and five of the newer oral anticoagulants. And the Enhancement award allows the researchers to address COVID-19 associated coagulopathy, and the increased risk for venous thromboembolism in the setting of COVID-19 by leveraging the parent study to understand the prevalence of post-hospitalization venous thromboembolism as well as the risk in key subgroups.

Next slide.

This is just another example from -- this time from our Dissemination and Implementation awards program, where the existing parent project is integrating a proven decision aid as part of patient care at 15 different lupus clinics, and the Enhancement award addresses the fact that individuals with lupus have a higher risk for

serious complications from COVID-19, and that the care that they're receiving has primarily shifted toward telehealth. So the enhancement adapts the decision aid for use in telehealth appointments by adding two new modalities: a smartphone app and a website for patients to use in advance of a telehealth visit, in order to make sure that they're able to share in the decision-making at that visit.

Next slide.

And this last example is an Engagement award that reaches African immigrant populations including patients, caregivers, and groups to engage in patient-centered outcomes research or comparative effectiveness research. And the enhancement is to capture their points of view to produce some knowledge to inform interventions that engage African immigrant patients in COVID-19 prevention testing and treatment. So this is a really unique opportunity for a population that we were already working with to now be able to assess the best ways to engage them as we're thinking about COVID-19 related strategies.

And next slide.

I also want to give you an update on our targeted PCORI funding announcement that underwent this expedited process, that you may recall, on the three priority areas related to adaptations, to healthcare delivery, to healthcare worker well-being, and vulnerable populations. Nine awards have been made and they cover all three of those priority areas, and they've been focused in a broad array of activities including congregate and group homes. The impact of mitigation strategies on vulnerable populations, mental health in underserved communities, the nursing home population where we know so many on the front line put themselves at risk on a regular basis. Telemedicine in primary care which has just been an adaptation, out of necessity, as well as remote monitoring in opioid use disorders and the implications of COVID-19 on treatment for opioid use disorders, and physical and mental health of our frontline health care workers.

So a very broad array of awards from this targeted announcement.

Next slide.

These nine awards that I just mentioned represent about $30 million in funding. And this slide just shows you the distribution of the projects amongst the three priority areas that we delineated. And there's one project that really crosses two priority areas, an intersection that was quite unique in terms of thinking about both the impact of COVID-19 on the healthcare workforce as well as vulnerable populations and this is one in the group home setting where they're examining the impact of COVID-19 on both staff and those living in that setting.

Next slide.

As I mentioned in the beginning, we're also actively monitoring projects to support their success and that's done pretty routinely at PCORI. But we also want to monitor the disruptions and delays related to COVID-19. And in Quarter-3 2020, we had about 241 studies that were eligible for evaluation and 75 of these projects were found to be in what we call the yellow, orange, or red zones

where they may or cannot meet their original objectives.

And so, we thought it would be important for us to take a deep dive and understand if there were any COVID-19 related impacts in those amongst those studies.

Next slide.

So this slide just shows you the status of projects over the past eight quarters, and we are just now at the point that we may start to see some COVID-19 related impacts on our studies in Quarter-3 2020. So the Quarter-3 data is really the first quarter that's going to reflect some of the COVID-19 impact across our portfolio. And I have a feeling it'll become much more evident with our tracking, given that we know COVID-19 has impacts across the research enterprise. So we're just really at the tip of the iceberg.

And the Quarter-3 data demonstrates that we have generally a very slight decrease in the green zone projects or those that are on track, and an increase in projects in the yellow zone, but overall

not much different so far and the percentage of projects that are off-track in the orange or red zones.

And I wanted to mention that this data really represents studies across our full portfolio and not necessarily just the ones that are recruiting, and if we looked at that subset we probably would see more dramatic shifts, but it does represent some of the earliest indications and we'll wait and see how we continue to track, but also hear from our researchers in terms of their need for adaptations which will give us some indication of how COVID-19 is affecting their work.

We also anticipate that the percentage of those off-track may go up over time, related to some of the disruptions that we're starting to hear about, but we'll continue to closely monitor both our project status as well as some of the COVID-19 related disruptions and delays that I'll show you on the next slide, which we anticipate we'll be able to provide you some updates on over time.

So let's go to the next slide.

This slide is going to show you a little bit more detail around the type of COVID-19 disruptions and delays we're starting to hear about.

So over half of our projects with COVID-19 related disruptions report that their disruptions are recruitment activities that are significantly decreased, and about 20 percent of those that report COVID-19 related disruption or delay report that their award is completely paused; 20 percent are reporting that the intervention needs to be adapted; and 16 percent are reporting that no new recruitment is occurring.

So these are the types of things that we think are important for us to learn more about as we continue to work with the awardees to garner the most that we can out of the studies and the investments that have been made, and we're continuing to track and monitor these awards closely and share more data when we bring the full Quarter3 2020 dashboard materials to the Board.

Next slide.

So as I wrap-up, I just wanted to end on

the note of looking forward to my next 150 days in mentioning a few areas that I know are on the horizon, as we continue to work on our future funding opportunities, we anticipate that we'll be thinking about this next phase of the COVID-19 response. And we're recognizing that there are areas of still emerging importance including longer term complications of disease in other areas.

We continue to recognize the importance of continuing our work in health disparities and thinking about that emphasis and doubling down on the issues of health disparities that I've been hearing about in several of my meetings with our stakeholders. And we also anticipate spending some time with the Board in terms of thinking about the strategic vision for the next phase for PCORnet, as it moves into Phase 3, and we'll -- you'll hear a little bit more tomorrow from Dr. Briggs who will be talking a little bit about the evaluation, and how we can incorporate that in terms of thinking about our strategic plans for PCORnet and Phase 3.

We also are looking forward to the awards

through our Large Phased Clinical Trial Program, and anticipate that this will be an important focus of both our work in terms of making sure we have the robust applications that we intended to solicit, as well as the oversight and monitoring of those awards that we make.

I look forward to continuing to work with all of you, as we continue to think about our strategic planning for the future and welcoming our new board members to PCORI. I also look forward to continuing to engage with our stakeholders, as we continue to talk about our national priorities and hearing what's on their mind related to the opportunities for PCORI for the future, and setting that research agenda.

We also are looking to our stakeholders to help inform our approaches related to maternal mortality, intellectual and developmental disabilities, and how we will interpret and respond to the legislation related to our cost data outcomes. And we are really excited to continue our work in terms of thinking about operational

innovations, where we have the opportunity to continue some of the evaluation that we've started around PCORI operations and enhance it for the future given the opportunity to really scale up post-reauthorization, and we anticipate that we're going to learn a lot from some operational pilots that we've put in place even as in terms of our COVID-19 response.

For example, we've learned from our Virtual Merit Review that we've been conducting that Merit Review has received actually overwhelmingly positive feedback from the panels, and we worried about how that would play out and the staff have really skillfully created and adapted, creatively adapted, while maintaining high standards and we anticipate that there could be robust virtual collaboration amongst staff with external audiences using this as an opportunity to learn from. We've also had some opportunities to expedite solicitation cycles which we think are opportunities for learning as well.

And lastly, we look forward to thinking

about our operating models for the future that build on the practices that have been successful over the last 10 years and try to set us up for success over the next 10.

So with that I'd like to thank you for your attention and I'm happy to answer any questions or hear any comments that you may have.

CHAIRPERSON GOERTZ: Thank you so much Nakela for that excellent presentation.

Any questions for Nakela or discussion points? Remember to please put yourself on webcam if you do want to make a comment or have a question.

So while we're waiting Nakela, I'm wondering if you could let us know what your strategy is for prioritization of -- I mean this is, you certainly have -- you've been, I'd say drinking from a fire hose in a lot of ways over the last 150 days and just, you know, I think -- I know I'm speaking for the entire Board when we say we're just so excited to have you with us, and we think you've done a terrific job in the last 150 days and very much looking forward to the future.

But we recognize that there's so much work to do and all of it is critically important, and you know we've talked, you know, for many years about the fact that PCORI has continually been, you know, painting the boat as we row it, and, and I think you're still even 10 years later given everything that's going on, you know, you're now the one that is, you know, doing all of those things and what is your plan to prioritize and how are you how are you handling that?

DR. COOK: Christine, it's a great question and I have been going through some exercises of prioritization myself in terms of thinking about the things that are pretty urgent versus those that are important and have a longer runway for them. And so, some of the things that I anticipate is that there are -- there is this jumpstart post-reauthorization, as well as some responses for COVID-19, and the activities are happening in our current environment that I think have some urgency to them, but they also have a long runway and they're not a sprint, they're marathons.

And so, starting to think about how we bite off the pieces that are most important to get things started and start to put plans in place that allow us to continue to evolve and add to and refine over time, is how I'm kind of thinking about the prioritization because to fully take on all of these things in full depth, early on, I think will be a challenge and so there definitely are pieces of all of them though that we can get started, knowing that they have these components that will continue over time.

I mentioned maternal mortality and intellectual and developmental disabilities as one example where we are starting to think about this and the 10-year runway, in terms of how -- what are we going to be doing over this year, next year, or the following year, and making the plans for the short-term that may be in this first one-to-three years and then knowing that we'll continually evolve it and build on it. And it allows us to bite it off in, I think, bite-sized chunks, that we're able to prioritize that work while we're recognizing that

there's going to be longer term planning.

So I appreciate the question because we certainly are recognizing it as well and there's another component to thinking about this, which I think relates to being able to find efficiencies and opportunities to do things at scale that would allow us to support our work a little bit differently so that perhaps we can learn from processes that are working well and apply them across in a way that would allow some of the focus to shift to give people some bandwidth for the new things that are coming down the pike.

CHAIRPERSON GOERTZ: Great, thank you that's really helpful.

Any other questions or comments?

Jennifer?

DR. DeVOE: Hey, Jen DeVoe here, thanks.

I just wanted to say how much I appreciate you Dr. Cook, this is an amazing amount of work in the first 150 days. It feels like the perfect storm starting this new role and COVID and everything else that hit, so, just super impressed and really

excited about the next 150 days and thank you for your service and all this wonderful work.

And this presentation was fabulous and getting to see everything that's going on. So I appreciate it very, very much. Thanks.

DR. COOK: Thank you so much, Jen. I really appreciate that.

CHAIRPERSON GOERTZ: Bob.

DR. ZWOLAK: Nakela, also, my congratulations on a fabulous first 150 days.

I was wondering if we're seeing -- if you're seeing signs that research recruiting is starting to come out of the dive.

DR. COOK: Yes, Bob, I may not yet be able to fully answer that one. And, you know, I think that one of the things that we're still seeing is that the recruiting of participants in the studies has really shifted in terms of how it's being done and how to reach participants and the interaction that it's happening with the interventions are more remote and done differently. And so, what we've really been focused on and been hearing from our

communities how to support that.

So it seems it's been a little bit of a focus of how do we continue supporting that effort, but yet thinking about the implications it may have on your research design, your analytic plan, and things of that nature. So that's been what we've been more hearing right now and, but I do hope to see, and you saw that on the kind of reasons for COVID-19 delays. I do hope to see that eventually we can see less of the recruitment halted or, you know, the idea that recruitment has slowed down, but we're still collecting the data in the other way that it's still taken up for us as opposed to plateaued or coming down.

And we do lag a few months in our collection of data so that was Quarter-3 2020 we're looking at, so when we see our Quarter-4 data, we may see something look a little bit better, but I think we may see it a little worse before better.

DR. ZWOLAK: Thank you.

CHAIRPERSON GOERTZ: Any other questions or discussion points?

[No response.]

CHAIRPERSON GOERTZ: I have one last question. Just I'm just about a year ago, Sharon and I had an opportunity to meet with each of the Board members and ask what challenges they saw facing PCORI and what are the things that they felt were more most pressing and not surprisingly, you know, two of the things that they thought were, you know, found to be the biggest challenges ahead were reauthorization and making sure we got the right Executive Director.

And I think we now have those, both in the in the rearview mirror and really excited about the the opportunity, and we're just wondering what you see as some of the big challenges that we'll be facing over the next -- over the next really six months?

DR. COOK: Yeah, that's a great question because I do think that some of the big challenges are probably in this kind of looking forward to my next 150 days, while they're great opportunities, I think there are challenges in them.

So, the idea of thinking about what we need to do in the second phase of our COVID-19 response, we had the challenge in the first phase and now I think we're here in our second phase.

There are some real challenges and thinking about how we start to tackle the problem of health disparities differently because we have been an organization focused on health disparities since the inception of our national priorities and the organization itself, but I think what we're starting to recognize as we're having a lot of these dialogues around issues of racism, discrimination, health disparities, this/that, we may have to redefine the problem differently and it's a really difficult one to deal with and crack. And I think we have an opportunity to focus on it, but to me it's a huge challenge.

And then I'd also think that the opportunities in our legislative mandates present the challenge in making sure that we are doing this in a way that engages with the stakeholders and is responsive to what we're hearing and brings us all

together around the planning that we create for the future. So I think many of these things kind of wrap into thinking about the PCORI 2.0 in some way, shape, or form.

And then the last one I'll mention is making sure that we're thinking about the operational effectiveness to support all of those activities because there is, I think, this idea of a kind of jumpstarting post-reorganization in the midst of the challenges of COVID-19 with some pretty sizable tasks that we want to take on, and so, trying to do that all together I think is a challenge, but I think we're up to the task.

So, I feel hopeful about it but there are definitely challenges in them.

CHAIRPERSON GOERTZ: Great, thank you that's really helpful.

Sharon?

DR. LEVINE: Yeah, thanks so much for that and Christine for your question. It prompted me to think about Ellen's comment this morning about the pandemic and the country facing a public health

challenge and the public health crisis.

And I think that the opportunity this presents PCORI, and it's timely given that we're beginning a strategic planning process, is to look at PCORI's potential role in the public health sphere and the public health system, and certainly there are many voices saying that racism, social justice are public health issues.

And we have, in our first decade, played on a smaller playing field and been focused on the healthcare delivery and very much so on, as was our mandate -- as is our mandate, that that clinician-patient-caregiver triad.

And I think we have an opportunity as we look at our national priorities and our goal setting, long-term goal setting, to incorporate more of a public health perspective in our research. And, I think that's a way of incorporating your comments around whether it's the next pandemic or disparities. And I think our language needs to shift from "addressing" to "eliminating" disparities. But that isn't going to happen within

the dyad of the care delivery experience it's really going to happen by taking the larger systems view.

And I think it creates for us an opportunity to think about what role PCORI and its research engine can play in addressing the public health challenges that face the country.

CHAIRPERSON GOERTZ: Thanks for sharing that Sharon and it, in many ways, echoes some of what we've heard in our discussions with panels and particularly the PEAP, the Patient Engagement Advisory Panel, where this issue of thinking about the broader kind of social determinants and public health issues that are really an interplay to what we're seeing and related to health disparities was going to be important for us to take on. So I know that that's something that will come into the strategic planning discussions, but it certainly is reflective of other conversations I've heard.

Thank you. Any other comments or discussion points?

[No response.]

CHAIRPERSON GOERTZ: All right. In that

case, Nakela, thank you once again for such an excellent presentation.

It's now time for a break we're going to -- we are going to reconvene at 3:30, so we have just about a half an hour. I look forward to seeing everybody back at 3:30 Eastern time.

[Recess.]

MS. JACKSTADT: Hello. Welcome back. It's 3:31.

DR. McNEIL: Barbara's here.

MS. JACKSTADT: Terrific, thank you so much Barbara.

MS. HUNT: I'm here.

MS. JACKSTADT: Thank you, Gail. And just a reminder the lines are open for all to hear. Thank you all for joining us and Christine if you're on.

CHAIRPERSON GOERTZ: I am. Thank you.

Why don't we go ahead and get started again. Welcome back everyone. Just a reminder to please mute your microphone when you're not speaking.

I'd now like to turn the meeting over to Andrew and Joanna to present on our cost data principles for researchers, which we will consider for approval today.

Andrew and Joanna?

MR. HU: Thank you, Christine and good afternoon everybody. For this session Joanna and I will be presenting to the Board an update on PCORI's plans to implements -- sorry, let me turn on my camera so you can see me. There you go.

As I mentioned, Joanna and I will be presenting to the Board an update on the PCORI's plan to implement our new mandate to collect the full range of outcomes data, now including cost and economic data as well. But before getting into the presentation I know, both Joanna and I would like acknowledge and thank our teams for the work they put into this, this has= truly been an institute-wide effort.

Next slide.

So for today's conversation, we will be discussing our broader implementation plan as it

relates to this new mandate, but more specifically, we'll be talking about the proposed principles for the consideration of the full range of outcomes that we hope to release for public comment today. But before we get to that, we want to make sure we set the context with a quick reminder and update on what's included in the law, as well as the stakeholder and Congressional intent behind this provision.

We'll also present on our current plans on how PCORI will implement and operationalize this new mandate and the next steps that will go into that.

And lastly, we will talk to the principles and the evolution following conversations with the PCORI's advisory panels, the Methodology Committee, as well as the strategic committees on the Board.

Next slide.

And so, for some initial contacts and an overview of the reauthorizing law. We wanted to remind folks that our reauthorizing law did include a new mandate to direct PCORI to capture "as appropriate" the full range of outcomes data in the

course our research. This new mandate expands the range of outcomes data PCORI had already been collecting to now, included cost burdens and economic impacts related to the utilization of healthcare services, and more patient-centered perspectives on cost burdens as well.

This includes medical out-of-pocket costs, health plan benefit and formulary design; non-medical costs important to patients, families, including caregiver burden; effects on future cost of care workplace productivity and absenteeism; and costs associated to healthcare utilization. While this new mandate does expand the type of data PCORI can collect, we are still prohibited from developing quality adjusted life year or quality thresholds, or from conducting cost-effectiveness analysis.

To strike a balance between all the positions raised by our stakeholders, Congress directed PCORI to capture both traditional economic measures and cost and economic outcomes that are important to patients.

Next slide.

So as I noted in the last slide, Congress, when debating PCORI's reauthorization last year it heard from a wide range of stakeholders on this topic. And this is -- the topic of addressing cost and value continues to be a sensitive subject amongst the broader healthcare community, as it had been during the debate around PCORI's establishment.

So to make sure that that there was a balance between those who had advocated PCORI to conduct cost-effectiveness analysis, and those who believed PCORI's focus should be purely clinical, Congress settled on a new mandate from PCORI to consider a broader range of outcomes data as applied to now include costs and economic impacts, but maintain the prior revisions on cost-effectiveness and established a quality adjusted life impressions.

Next slide.

So earlier this year, as you begin thinking about how PCORI should approach implementation of this new mandate, the Public Policy team as well as the Public and Patient Engagement teams did reach out to a number of our stakeholders and partners for

some early input. And this is a summary of the info received, it's by no means a comprehensive list. But I think the main takeaways were that PCORI must ensure transparency, most notably patient engagement throughout implementation. And PCORI should consider the full range of treatment options, not focused on a single technology for therapy.

Others noted that this is a great opportunity for PCORI to help develop standards around identify and capturing costs and economic impact data important to patients. There were still concerns about the use and misuse of this data that could lead to cost-effectiveness or inappropriate value assessments.

And lastly, we heard that there was hope that this effort could expand beyond traditional health economic perspectives on cost and value.

Next slide.

So given the complexity of this topic, we are proposing to take a very deliberate and transparent approach to implementation. And we've broken this into three separate pillars:

Pillar 1 is meant to serve two separate, but related goals. The first is the establishment of high-level principles, which will inform the public on how PCORI is interpreting this mandate. And the second is, based on the principles and the input received on them, to develop guidance for future applicants on how they can incorporate this mandate into their research proposals. And we're hoping to be able to finalize the principles and develop the guidelines for applicants by early March -- by February or March of next year.

Next slide.

Pillar 2 is more focused on the establishment and update on methodology standards to further inform how PCORI-funded studies should capture relevant data. We fully expect the Methodology Committee to play a leading role in this, though we expect this will be a longer process that will ultimately result in an update to PCORI's methodology standards.

And lastly, Pillar 3 is focused on PCORI's role in discussions on how this information can and

should be used. We expect this one to be an ongoing discussion, as it relates to broader policy and clinical decisions.

Of an important note, these pillars do not have to happen sequentially, and we are already working through each one to identify opportunities for PCORI and how we can play an impactful role.

Next slide.

So this slide shows a proposed timeline for implementation. With Pillar 1 being the most immediate. The next steps include, obviously if the Board approves today, the proposed principles that will be released for public comment. It'll be a 60-day public comment period.

We also plan to host a series of webinars to provide patients, consumers, and other healthcare stakeholders a platform to discuss their perspectives on this mandate and our principles. Those are currently scheduled for October 5th and 6th, and then based off the input that we received from both the principals and from the webinars, we will use them as basis to develop guidance and for

future applicants. And lastly, we will be sure to present a revised set of principles for the Board to approve in February or March of next year.

In terms of implementing Pillar 2, we hope to be able to launch efforts to update the PCORI's methodology standards at the end of this year, early next.

And as I mentioned for Pillar 3, we are working to develop plans and opportunities for PCORI, you know, whether it's leveraging our role as a funder or a convener to be more proactively engaged on the topic of healthcare cost and value and these are ongoing activities.

Next slide.

So getting to the principles. This slide is meant to highlight what they are, why we developed them, and how we expect them to be used. In terms of the what, the principles are a high-level framework to describe PCORI's interpretation of the new mandate. In terms of why, we felt it was important for PCORI to provide the public and future applicants with an understanding of that

interpretation.

And lastly, on how they will be used. We took these principles to serve as a point of reference for PCORI as a basis of developing future guidance to potential applicants, and for updating PCORI's methodology standards. These principles themselves are not meant to be the standards or the methods for research.

Next slide.

So before getting to this point, we did seek input from our stakeholders, PCORI's advisory panels, the Methodology Committee as well as the EDIC, RTC, and SOC throughout the spring and summer. This included providing updates on the provision during the June cycle advisory panel meetings. We presented early drafts of the principles the EDIC and RTC in July, and had a follow up meeting with EDIC in August and presented to the SOC in their August meeting, as well.

These conversations were extremely helpful as we worked through to refine these principles and prepare them for public comment.

Next slide.

The main themes of the input we received was that we needed to be clear in our definitions of outcomes and provide clarity on what types of analyses may be allowable under the interpretation of this mandate. And as for the definitions, we heard comments that the costs and economic impacts will be felt very differently by patients due to a number of factors, such as insurance coverage.

We also heard that we needed to clarify that that payers and providers, as well as patients, face a wide range of decisions for their consideration of the full range of outcomes may be important. And we heard that there is a desire to make sure that the data that is captured through the course of our studies be made public and the results. As for clarifying what types of analyses are allowable. We heard that we needed to clarify and provide a distinction between the capture of data, allowable cost analyses, as well as how we define the conduct of cost effectiveness.

More specifically, we received input about

needing to define the scope of the data that is permissible to collect and what, if any analyses would be allowable, and also provide some examples of what is allowable and what isn't. And we heard questions about whether or not all PCORI-funded should capture this type of data.

Next slide.

So, while the principles will help inform the public on PCORI's interpretation of the mandate, they will also serve as the basis of guidance that PCORI with develop with future applicants. So at this initial phase and step, we're hoping to solicit input on the principles, but also on a couple of questions that will help inform our work as we develop guidance for future applicants.

The first gets at whether all PCORI-funded studies should be captured this type of data. We felt it was important to ask this to help us better understand the advantages or disadvantages to such a requirement, and to see if there are any reliable indicators, where the capture of this data may or may not be helpful to the overall importance of

findings.

The second question seeks input on what types of analyses, understanding the limitations of our law, may benefit stakeholders and their perspectives on specific uses and advantages of each type.

So after walking through the proposed principles, we'll come back to these questions again.

Next slide.

So getting to the principles themselves. And we will give it a little bit more detail in each one, and of each one in subsequent slides. We'll also share the four principles with you in materials, but here's just a proposed list of our four principles that we're looking at.

With Principles 1 and 2, kind of more focus on defining the types of outcomes that we're trying to capture. So Principle 1, PCORI-funded research may consider the full range of outcomes important to patients and caregivers, including the burdens and economic impacts.

Principle 2, directs the researchers to consider the outcomes that are important to respective stakeholders when those outcomes have a near-term or longer-term impact on patients.

Principle 3, gets to the collection of data and noting that they must be appropriate and relevant to the clinical aims of the study.

And Principle 4, acknowledges that beyond the collection of data, PCORI may support the conduct of certain types of economic analyses, as part of a funded study to enhance the relevance and value of the information to healthcare decision-makers.

Next slide.

So we'll get into each principle a little bit -- with a little bit more detail.

So, Principle 1, as I mentioned focuses on providing some directions for collecting and examples of potential outcomes that may be important to patients and caregivers. Notably, this principle reiterates the need for patient/caregiver engagement when identifying those outcomes. And we also, in

the document, include a list of possible economic and cost components that may be relevant and important to our patient/caregivers and these are built out a little bit more than what was included in our mandate -- in our statute.

Next slide.

Similar to Principle 1, Principle 2 also focus on outcomes and relevant data, but this one is more focused on the stakeholders. And especially when those outcomes have a near-term and long-term impact on patients.

The language in this principle differentiates the outcomes of relevant to stakeholders from those relative and important to patients and caregivers, as well as provides a couple of examples as to why certain -- why capturing certain costs and economic data may be useful for stakeholder communities and decision-makers. And similarly to Principle 1, we included a possible list of economic and cost components that may be relevant to stakeholders. Again, building this out a little bit more from what was included in

our statute.

Next slide.

Principle 3 focuses on certain directions related to the collection of data, on the burdens and economic impacts. I think most importantly in this principle, we state that PCORI will not fund studies where cost and economic impacts are the primary aims and outcomes of the study. We also asked to ensure that applicants are not capturing data for the sake of capturing data, we direct applicants to justify why they choose to or not choose to collect relevant cost impact data in their studies.

And as part of that we do instruct applicants to consider the feasibility of capturing this data when submitting their research proposals.

Next slide.

And lastly, Principle 4 focuses on the analysis of the collected data. We use this principle to acknowledge that there may be times when the conduct of certain types of limited economic analyses may be allowable as part of a

PCORI-funded study or when those analyses enhance the relevance and value of the study for healthcare decision-makers.

And while we hope to hear from the public on this, we have seen limited examples where researchers are already building on research results from PCORI-funded studies and conducting their own analyses to identify possible returns on investment and other cost-related analyses.

A couple of examples include Dr. Schuster's project focused on behavioral health homes, as well as the PCORI-funded study that was recently published in Health Affairs, looking at the return on investment of community healthcare worker programs. While this principle does lay out certain circumstances where limited economic analyses may be allowable. We do hope to hear from the public on what analyses may be most relevant and a value to decision-makers.

But we do want to make sure and clarify that there are still hard limitations on what's allowable here. Our statute still, as I mentioned,

includes prohibitions on cost-effectiveness and establishment of quality adjusted life year thresholds. So, those type of analyses are still are not permissible.

Next slide.

So as I mentioned coming back to these questions. Our goal with the principles is two-fold. The first is provide the public and stakeholders with an understanding of how PCORI interprets the mandate and to seek input on interpretation. The second is to use the principles and the input received on them as the basis of guidance, PCORI will develop with future applicants how best to incorporate this mandate into their recent proposals.

So, you know, we hope that we will receive good comments on the principles themselves, but also receive input to these specific questions that we have posed to the public, as they will definitely inform and our guide our applicants.

Next slide please.

So this slide highlights the next steps in

terms of the principles, only. We want to lay out a very transparent and deliberative process moving forward. As noted earlier, we've received input from some of our key stakeholders, PCORI's advisory panels, and Methodology Committee, and Board committees, but we also plan for plenty of opportunities in time for the public to weigh-in via a public comment period on these principles and a series of webinars that we're hosting in October.

This will allow -- there will be some time for us to collect and analyze that input we received and we will -- that will result in a set of revised principles that we'll bring back to the Board for final approval in February or March of next year.

Next slide.

Lastly, some details on those webinars that we mentioned, we do plan on holding two public sessions on October 5th, and 6th. The first panel will be focused on patients, caregivers, and consumers.

The second will be with other stakeholders, payers, purchasers, the life science industry

providers and health system representatives. Both panels will be 90 minutes, running from 2:30 p.m. to 4 p.m. Eastern, and we'll include some introductions of PCORI's work on this topic, some legislative context for all of the discussion amongst the respective panelists.

Invitations to these webinars have already been sent to the Board and Methodology Committee earlier, but as the events are made public in the next day or so, we will make sure you guys see them again.

Next slide.

So, we'll pause there before we move to votes and discussion for some discussion amongst the Board.

CHAIRPERSON GOERTZ: Great. Thank you, Andrew.

Any questions or discussion points for either Andrew or Joanna.

MS. HUNT: Christine.

CHAIRPERSON GOERTZ: Yes, Gail.

MS. HUNT: Principle No. 1, it includes --

you sort of had a drop down after kind of talking in more depth, but what you didn't include was really out-of-pocket cost for the family. Work you did have something about work. But I think we should think a little more carefully about those impacts that the family deals with.

So for example, flying with the person to the Mayo Clinic or [inaudible] Johns Hopkins, some of those things you captured for patients are clearly things that also need to be thought of for caregivers. So, I just noted that, and that's something that you should just put in there somewhere. Thanks.

MR. HU: Thanks. That's a good point.

CHAIRPERSON GOERTZ: Thank you Gail. Any other comments or questions.

I know that a tremendous amount of work has gone into getting us to this, this point and we really appreciate that, Bob.

DR. ZWOLAK: I'd like to congratulate Andrew and his team. I think, I'd also like to congratulate Congress for writing these provisions

and passing them. I think this gives us an enormous opportunity to finally address the economic impacts with tools that are much more relevant than QALYs.

I've always thought that QALYs missed the mark when it comes to assessing the true real world, relevant, economic impact. So I applaud the approach. I think the work that's been done so far is excellent, and this gives PCORI, I think, an immense opportunity to bring to the research and clinical world a real representation of what economic impacts are.

So congratulations and Godspeed.

CHAIRPERSON GOERTZ: Thank you, Bob. Any other questions or comments?

[No response.]

CHAIRPERSON GOERTZ: Okay, well thank you Andrew and Joanna. We're now going to ask for a motion to approve the draft principles for the consideration of the full range of outcomes data for posting for public comment.

DR. DeVOE: So moved, Jen.

MR. BECKER: Second

CHAIRPERSON GOERTZ: Jen. Okay, thank you, Jen. And Larry as a second -- I heard. Okay, is there is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, then.

Are we -- can we do this as a voice vote?

MS. JACKSTADT: It's a roll call vote, Christine.

CHAIRPERSON GOERTZ: Okay. All right, let's go ahead and do that, do a roll call vote then.

MS. JACKSTADT: Certainly. Kara Ayers.

DR. AYERS: Approve.

MS. JACKSTADT: Larry Becker.

MR. BECKER: Approve.

MS. JACKSTADT: Francis Collins or Mike Lauer filling in for Francis Collins.

DR. LAUER: Approve.

MS. JACKSTADT: Jennifer DeVoe.

DR. DeVOE: Approve.

MS. JACKSTADT: Alicia Fernandez.

DR. FERNANDEZ: Approve.

MS. JACKSTADT: Christopher Friese.

DR. FRIESE: Approve.

MS. JACKSTADT: Christine Goertz.

CHAIRPERSON GOERTZ: Approve.

MS. JACKSTADT: Mike Herndon.

DR. HERNDON: Approve.

MS. JACKSTADT: Russell Howerton.

DR. HOWERTON: Approve.

MS. JACKSTADT: Gail Hunt.

MS. HUNT: Approve.

MS. JACKSTADT: David Myers filling in for Gopal Khanna. David Myers?

[No response.]

MS. JACKSTADT: Sharon Levine.

DR. LEVINE: Approve.

MS. JACKSTADT: Freda Lewis-Hall.

DR. LEWIS-HALL: Approve.

MS. JACKSTADT: Michelle McMurry-Heath.

DR. McMURRY-HEATH: Approve.

MS. JACKSTADT: Barbara McNeil.

DR. McNEIL: Approve.

MS. JACKSTADT: Gray Norquist.

DR. NORQUIST: Approve.

MS. JACKSTADT: Ellen Sigal.

[No response.]

MS. JACKSTADT: Kathleen Troeger.

DR. TROEGER: Approve.

MS. JACKSTADT: Janet Woodcock.

[No response.]

MS. JACKSTADT: Roberts Zwolak.

DR. ZWOLAK: Approve.

MS. JACKSTADT: Dr. Goertz. The motion passes.

CHAIRPERSON GOERTZ: Thank you. And thanks once again Andrew and Joanna and the entire team for getting us to this point, we really look forward to learning more as we go through the next steps of this process.

MR. HU: Thank you.

CHAIRPERSON GOERTZ: Thank you. All right. We're getting ready to conclude our meeting for today's portion anyways.

Before we do close. Nakela, I'd like to turn the agenda back to you to see if you have any

final remarks from today.

DR. COOK: I just would like to thank the Board, again for the input on several important topics today and we look forward to continuing the discussions tomorrow. It's been a very helpful meeting, and the preparations and leading up to it has been quite helpful. I'd like to thank the staff and the PCORI committees who helped to prepare for these discussions. Thank you so much.

CHAIRPERSON GOERTZ: Thanks. Thank you Nakela.

So let me close by, by thanking all of those who joined us today via webinar and teleconference, we hope you're also able to join us for tomorrow's meeting. A reminder that all materials presented to the Board today will soon be available on our website. And today's webinar was recorded and the archive will be posted within a week or so.

We always welcome your feedback at info@PCORI.org, or through our website at www.PCORI.org.

Thanks again for joining us. Enjoy the rest of your afternoon.

MS. HUNT: Thank you.

CHAIRPERSON GOERTZ: Take care everyone.

[Whereupon, at 3:58 p.m., the Board of Governors meeting was adjourned.]