PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday, March 8, 2022

Webinar

[Transcribed from the PCORI webinar.]

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Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
James Huffman
Connie Hwang, MD, MPH
Michael Lauer, MD, NIH Director Designee
Sharon Levine, MD [Vice Chairperson]
Barbara J. McNeil, MD, PhD
David Myers, MD, FAAFP
Eboni Price-Haywood, MD, MPH, FACP
Karin Rhodes, MD, AHRQ Director Designee
James Schuster, MD, MBA
Kathleen Troeger, MPH
Danny van Leeuwen, MPH, RN
Robert Zwolak, MD, PhD

AGENDA

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AGENDA [CONTINUED]

P R O C E E D I N G S

[9:01 a.m. EST]

MS. THOMPSON: Dr. Goertz, the floor is yours.

CHAIRPERSON GOERTZ: Thank you so much, Maureen. Good morning and welcome to the March 8th, 2022 meeting of the PCORI Board of Governors. I'm Christine Goertz, Chairperson. Welcome to everyone who's joined us for today's Board meeting. We're very pleased to have you.

Before we turn to our agenda. I'm very excited to welcome Dr. Robert Otto Valdez to PCORI. Bob was named as Director of the Agency for Healthcare Research and Quality on February 22nd is therefore a member of the PCORI Board of Governors by virtue of his new position.

We'd also like to thank David Myers, who has been serving on the PCORI Board while he was the Acting Director of AHRQ. It was a pleasure working with David and we wish him all the best as he resumes his role as Deputy Director at AHRQ, we look forward to working with Bob. We're also pleased

that we will continue to have the opportunity to work with Karin Rhodes as the Designee for the AHRQ Director. Thank you, Karin.

Now to our agenda. As a reminder, Board Members' conflict of interest disclosures are available on PCORI's website. These disclosures are required to be updated annually and when the information changes. If the Board will deliberate or act on a matter that represents 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 related to you or others, contact your staff representative.

Today's meeting is being recorded. Members of the public who have logged into the webinar will see the slides that have been prepared for the Board meeting. The agenda for today's meeting, the approved minutes from the Board's prior meeting, and an archived webinar will be posted on PCORI's website within a week.

Board members participating onsite who wish

to speak should turn their tent card up. Board members participating remotely should indicate they wish to speak by sending a chat message to organizers and panelists.

Maureen, would you please call roll?

MS. THOMPSON: Kara Ayers.

DR. AYERS: Present.

MS. THOMPSON: Kate Berry.

MS. BERRY: Here.

MS. THOMPSON: Jennifer DeVoe.

DR. DEVOE: Present.

MS. THOMPSON: Alicia Fernandez.

DR. FERNANDEZ: Present.

MS. THOMPSON: Christopher Friese.

DR. FRIESE: Present.

MS. THOMPSON: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. THOMPSON: Mike Herndon.

DR. HERNDON: Present.

MS. THOMPSON: Russell Howerton.

DR. HOWERTON: Present.

MS. THOMPSON: James Huffman.

MR. HUFFMAN: Present.

MS. THOMPSON: Connie Hwang.

DR. HWANG: Present.

MS. THOMPSON: Sharon Levine.

DR. LEVINE: Present.

MS. THOMPSON: Barbara McNeil.

DR. McNEIL: Present.

MS. THOMPSON: Eboni Price-Haywood.

[No response.]

MS. THOMPSON: James Schuster.

DR. SCHUSTER: Present.

MS. THOMPSON: Ellen Segal.

[No response.]

MS. THOMPSON: Larry Tabak or Mike Lauer, Designee of the NIH Director.

DR. LAUER: Present.

MS. THOMPSON: Kathleen Troeger.

MS. TROEGER: Present.

MS. THOMPSON: Robert Valdez, or Karin Rhodes, Designee of the AHRQ Director.

DR. RHODES: Karin Rhodes is here.

MS. THOMPSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Present.

MS. THOMPSON: Janet Woodcock.

[No response.]

MS. THOMPSON: Robert Zwolak.

DR. ZWOLAK: Present.

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

CHAIRPERSON GOERTZ: Thank you. Can we have the next slide please?

All right. As, as you can see, we have a very full and exciting agenda today. We're going to start out with our approval of the minutes and then Nakela will give her Executive Director's report. Following that we will consider a number of issues for adoption.

The first is our research agenda. I'm very excited to be at this point, as I know, all of you are. We'll also consider for approval a new Methodology Committee framework, and then we'll be looking at a number of awards -- our Cycle 2 2021 award slates. We'll look at the development of some targeted PFAs. We'll have an overview of our work

on maternal morbidity and mortality and a discussion on maternal health.

This will be followed by consideration for approval of the PCORI/AHRQ Learning Health Systems 2.0 Initiative, and then we'll have our public comment before we wrap up for the day.

Next slide please.

So our first order of business then is to approve the minutes for our February 15th, 2022 Board of Governors meeting. I'd like to ask for a motion to approve, just please remember to identify yourself and use the microphone.

DR. HOWERTON: Motion to approve.

CHAIRPERSON GOERTZ: Thank you, Russ. Second?

DR. McNEIL: Second, Barbara McNeil.

CHAIRPERSON GOERTZ: Thank you, Barbara.

Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions.

[No response.]

CHAIRPERSON GOERTZ: All right. We have we have minutes then.

Just a reminder to turn off your microphones if you are not speaking.

I'd now like to invite our Executive Director, Nakela Cook, to present her ED report.

DR. COOK: Good morning, everyone. It's great to see you today and looking forward to covering a few topics with you in this report.

I'll have a few announcements for the Board and the public, I want to do a few introductions of some new leaders at PCORI, but then I'll take you through an update on some of our ad hoc working groups and committees relating to the Board, and I'll give you some highlights as well from our COVID-19 portfolio.

So to start off, I wanted to begin my updates this morning to acknowledge and an upcoming

important announcement. The Comptroller General of the United States, or the GAO, you know, has the responsibility for appointing up to 21 members of the Board of Governors. And we know that as a result of some terms ending in September of 2022 this year, and some openings due to resignation, that they're going to be several open positions on the PCORI Board of Governors in September.

So the GAO is gearing up to announce in a notice in the Federal Register in the coming months, a call for nominations in relevant categories. And we want to make sure that we have an opportunity to spread the word about that in order to have a robust response for potential members of the PCORI Board.

We can go ahead to the next slide.

So there are a couple of other important announcements that relate to our ongoing implementation of PCORI *Next*, and as you may recall, from one of my prior Executive Director updates PCORI *Next* is really our organizational transformation initiative that invests in our operational, cultural, and professional excellence.

And ultimately the goal is to help us accelerate delivery on our mission.

We can go to the next slide.

So I'm pleased to announce as part of PCORI *Next*, the arrival of four new leaders at PCORI. And we'll just briefly touch base about each of them. We can go to our next slide.

Maureen Thompson comes to PCORI as our first Director of Board Governance, Operations and Relations from the American Nursing Association, where she served as the Vice President of Governance and Planning. Maureen is a very seasoned executive with over 15 years of experience in board governance, strategic planning, and volunteer administration.

She's also an audiologist by training and has her Masters of Arts in Audiology at George Washington University. She is supporting her first in-person and hybrid board meeting today. So excited to have Maureen at PCORI.

You can go to the next slide.

We're also welcoming Brian Trent. Back

one, if you don't mind.

As our incoming Deputy for Operations, Brian will join us in March -- a little bit later in March of this year. And he is joining us from the National Institutes of Health, the Eye Institute, specifically, where he served as the Deputy Institute Director for Management. He also has a history of working at the Food and Drug Administration where he spearheaded the administration's operations of the Center for Tobacco Products and was previously, as well, the Chief Operating Officer in the Immediate Office of the Assistant Secretary for Preparedness and Response.

He has 25 years of experience in financial management and operational leadership, and will bring a wealth of experience to PCORI.

You can go the next slide.

Next, I'd like to introduce Harold, or Harv, Feldman. Who is our incoming Deputy for Patient-Centered Research Programs? He's currently the George Pepper Professor of Public Health and

Preventive Medicine at University of Pennsylvania, where he leads and directs a Center for Clinical Epidemiology and Biostatistics, and previously was the Chair of Epidemiology, Biostatistics, and Informatics.

He's a nephrologist by training and is also the editor-in-chief of the *American Journal of Kidney Diseases*. And we couldn't be more excited to welcome Harv full-time with us at PCORI beginning in July of this year. You can go to the next slide.

And last, Erin Holve is our new Chief for Research Infrastructure, and she joins us from the District of Columbia's government, where she served as the Director of the Department of Health Care Finance's Health Care Reform and Innovation Administration. And she also served as the chair of the Mayor's Health Information Exchange Policy Board and led the District's investments on digital health.

Previously, she was at Academy Health where she intersected with the PCORnet and has a great deal of background there. She also has a background

in working with electronic health data records and worked at the Kaiser Family Foundation and at HHS in the past. We couldn't be more excited to welcome Erin at PCORI in her new role.

We can go ahead to the next slide.

And here, I want to go ahead and transition to update you a bit on some of the ad hoc committee and work group activities. During this some next part of my update, what you'll see is that we really wanted to demonstrate how all of these committees and work groups really work together in fulfilling a lot of the strategic planning activities that are going on at PCORI right now.

And they really do have a defined scope of work for a defined period of time that's contributing to us setting some of the strategic directions for the organization, and they bring in many ways an integrated approach to thinking about several high priority issues at PCORI.

We can go to the next slide.

So this slide just gives you an overview of several of those activities at a glance, and you can

see here the charge, the composition, the timelines, and some of the outcomes of these activities to-date. And across the top here is the Strategic Planning Committee and you see that the charge for that committee was to work on behalf of the Board to develop an oversee the conduct of a strategic planning process and development of a strategic plan for approval by the Board. And it's composed of Board of Governors members, Methodology Committee, and staff leadership, and has been active since July of last year. And will continue through the presentation of the strategic plan to the Board for consideration.

And thus far, some of the key outcomes include the national priorities for health research agenda and strategic plan that will be forthcoming.

Our PCORnet priorities Work Group, in its Stage 2 formulation, is building on the work of the Stage 1 Priorities group that identified prioritizing principles for funding infrastructure related to PCORnet's next phase. And the work from the Stage 1 group was conducted between November of

2020 and January of 2021.

And the Stage 2 group has just convened in February of this year and anticipates working through August or September. And we're going to talk a little bit more about this work group, because it's just starting and thought that we could give a greater degree of update to the Board on future slides.

You heard last time around, in February, when the Board met and update from the Healthcare Cost and Value Work Group. And here's just a snapshot of that charge around developing a framework of activities to support for PCORI's approach to collecting the full range of outcomes that can help inform the value conversation and support policy priorities.

And again, this is a cross-cutting group of Board of Governors members, Methodology Committee members, and staff leadership. And we look forward to other Board members joining the group that have indicated interest.

You can see the timeline of that work is

anticipated to go through the end of this year and already that group has delivered a framework for activities and the charge for a landscape review that's about to begin.

And we're going to talk a lot more in detail later on today about the Methodology Committee 2.0 Work Group that's working to envision the future focus of the Methodology Committee. And you can see a cross-sectional group of members that from the Board of Governors, the Methodology Committee, and staff that are involved here. And we're wrapping up the work of that group. And they've already worked through a vision, as well as implementation approaches. So we'll talk about that in more detail later today.

We can go to the next slide.

I just wanted to pause before going through each of these a little bit more and to thank all of the Board members, as well as the Methodology Committee members, and the staff of PCORI who've participated in these groups. We've heard that they've been incredibly effective in terms of

identifying our next steps in setting a direction. And so, I really want to applaud all of you for your time and effort that you spent in helping to bring these groups to where they are.

So, as I talk about the strategic planning update, I'm also going to be relatively brief here, but let's go to the next slide because I wanted to use this familiar slide that you've seen before to highlight all of the ad hoc working groups and committee activities and how they relate to being an integral part of the strategic planning activities. And we'll take deeper dives into these areas, but as you can see here, they really do correspond to the different ad hoc groups and committees that we've stood up over the last year or so.

Let's go to the next. So here's a snapshot of our anticipated timeline for the final stages of strategic planning. And as you can see over the past year or so, a lot of stakeholder input, a healthcare landscape review that included the priorities on the Horizon Report from the National Academies, as well as our Congressional

Reauthorization, fed into several big milestones for us around strategic planning, including the proposed National Priorities for Health that went through a public comment phase, the Board adoption of those priorities, and now we're in that stage of integrating the public comment on the research agenda.

And as you see, moving forward from March to the July timeframe here, we'll be working on drafting the strategic plan and refining that strategic plan, and July through December will really be that ongoing work to begin the implementation strategies of plan.

You can go to the next slide.

So I'm just going to transition to the PCORnet Priorities Work Group. And I'm going to go over this one in a little more detail, given it's just started up and I wanted to go to the next slide and begin with just the composition of the group. So I wanted to begin by thanking both Bob Zwolak and Kara Ayers for their leadership of this group. Bob also chaired the Stage 1 group of the PCORnet

Priorities Work Group. And as you can see, we really strive to achieve a cross-sectional kind of representation of the different stakeholder groups represented on the Board in pulling this group together.

We can go to the next slide.

So the first Stage 1 group was focused on thinking about the prioritizing principles for PCORnet that would really align to ongoing strategic planning activities and would guide the funding of the next phase for PCORnet. And the group came together in 2020, and the principles were approved by the Board in January of 2021. And the principals themselves were intended to actually inform a number of activities at PCORI, including the priorities and performance metrics that we may review from PCORnet, as well as requirements and metrics for the selection of the awardees, even in Phase 3, and the oversight for performance monitoring of the contracts that we do within PCORI, as well as a framework for decisions and future funding.

We can go ahead to the next slide.

So here are those principles, just to remind you of the ones that were seen back in January of last year. And they were grouped around three major areas: patient-centeredness, national scope of work, as well as governance and partnerships. And I show these to you again, because the Stage 2 work is really building on these principles.

We can go to the next slide.

This is a snapshot of some of the goals that were articulated in the Phase 3 PCORnet -- PCORI funding announcement. And what I wanted to highlight here is that the principles really informed exactly what we ask of those that were applying to the PCORnet funding opportunity. And here you can see that there really was a focus in the PFA on increasing the utilization of PCORnet for definitive research studies that are national in scope, building off of that set of principles around national in scope.

There was also in order to support those national in scope studies, a focus on optimizing

infrastructure that increased diversity of populations in care settings and efficiently implemented research studies that address PCORI's strategic research priorities and strengthen that patient stakeholder engagement and deliver that high fidelity, high integrity data for research. This is really consistent with what we saw on the prior slide related to the PCORnet prioritizing principles.

We can move to the next slide.

So we also focus pretty heavily as we thought about the Priorities Work Group Stage 2, about how the Stage 2 work group could build on those principles in the next phase of this work. And so, the contributions of this work group will really support the Board's governance role for PCORI's infrastructure investments related to be PCORnet by proposing some strategies that will help us assess the return on investment as well as evaluate program accomplishments. And we heard pretty clearly from the Board that this would be an important next step.

So some of the topics that the group is looking forward to discussing relate to research, implementation, and efficiency, stakeholder engagement and partnerships, relationships with other federal health agencies, as well as network accessibility.

And let's look at the goals specifically for the Stage 2 group, if we can move to the next slide.

And here you see the goals really are to build on those principles that were formulated in the Stage 1 group and helped us in terms of proposing strategies to inform a PCORnet evaluation framework and guide the Board's future consideration of accomplishments that can be attributable to the infrastructure funding and decisions about the PCORnet investments. There's also a goal to propose strategies, to help us integrate and leverage for PCORnet assets to help advance the national priorities for health and research agenda.

So really trying to understand the opportunities for PCORnet to help advance the

strategic plan.

And the last goal here is around providing information and reports and recommendations that can help inform a lot of the deliberations of strategy committees, the Board strategic planning activities, and the Board as a whole.

We can go to the next slide.

Here's a quick snapshot of the timeline. So the group met back in February for some goals setting and to organize and work on the goals as well as what the group would like to cover. And then between March and May, there'll be several work group meetings that focus on things like the evaluation, governance and research implementation and engagement, and advancement of the strategic plan.

We hope that as we move to June and July, we'll be ready to work on some deliberations in terms of strategies and develop draft strategies that can then be brought to the Board. And we anticipate a June update with the Board at our next meeting. And then by September being able to bring

some proposed strategies to the Board for consideration for adoption.

So we'll shift gears and talk about the Healthcare Cost and Value Work Group. And this is one that you had a recent update on, so I'm going to be relatively brief here. We can go to the next slide.

I wanted to begin just with a snapshot of the work group membership. And as I mentioned before, the membership includes Board and Methodology Committee and staff, and we convened this worker to help us continue to refine our approach to the important conversation about cost and value. And we have had a few Board Members that have asked to join this work group subsequently, and so, we look forward to being able to add them to the group.

The work group is working to identify some approaches that can help PCORI position itself as a trustworthy informant in cost and value conversations. And they really emphasized how important it is to have a situational awareness

about these activities at the intersection of cost and value. And that we have to have an understanding and acknowledgement of a lot of the complexities of the healthcare system and stay focused though on what PCORI can accomplish within that.

And the work group has really emphasized to be sensitive to being timely with our work and responsive to the current environment, and there's a large waterfront to cover. And so, we're taking a phased approach and we're really in that first phase of efforts, let's go to the next slide.

So one of the first things that the work group took on was establishing a framework of activity in this space, emphasizing for PCORI's patient-centered approach in its role as a trusted convener. And what you see here is not a value framework. It's actually a framework for the organization of PCORI's activities that'll help us inform some of the health care cost and value discussions.

And you can see that the work group really

identified an approach that supports PCORI's role in not arbitrating value, but actually really using convening power to bring stakeholders together and better understand how different communities define the value and consider important attributes or components of patient-centered value. And there are a couple of complimentary and interrelated activities that are going to help us with pursuing this approach.

So let's look at the next slide around some of the upcoming activities.

So these are the three pillars of activities or the first around the collection of the full range of outcomes data, the second around informing the value conversation, and the third around supporting policy priorities. And for the immediate work, we're focusing on this informing the value conversation component and with this upcoming landscape review, and we're going to be listening to the stakeholders in those sessions and iterating as we go. But I'm hopefully snowballing with a number of stakeholders in order to really get input and

advice on how we think about the value conversation.

And many Board Members actually contributed back in February to some thoughts that we are incorporating in our way of moving forward around thinking about this and are bringing that back to the next real group discussion. So greatly appreciate that.

Let's go to the next slide.

And I'm going to transition here to talking about the Methodology Committee 2.0 Work Group, and because we have a full update coming, I'm not going to spend a lot of time here either, but let's go to the next slide.

So the Methodology Committee 2.0 Work Group was launched as part of PCORI strategic planning process and also taking into account the shift of the appointments to the Methodology Committee to PCORI Board of Governors, thinking about how to prepare for that. And the charge was to propose a future vision and focus for the Methodology Committee as part of our strategic planning process that leverages this rich and unique group of

expertise that we have in the committee. And the composition of the work group has individuals from the Board of Governors, the Methodology Committee and staff. And we mentioned that that timeline is going through about March of this year.

We can go to the next slide.

So there were several things that were really relevant in terms of PCORI's near-term priorities to the Methodology Committee, and this served as a framework for how they have taken on their work, the strategic planning, the focus on key areas in our reauthorizing legislation are informing the way in which that work group took on thinking about that future vision.

And we'll be excited to share that with you in a little bit. Let's go to the next slide.

So I'm going to transition to the last part of my update which is really around giving you some of the exciting results I think that are coming from our COVID-19 funding investments in that portfolio, just so that you have a snapshot of some of the ways in which we're starting to see results come to

fruition.

This slide should look a bit familiar, although it's been updated a little. It's summary of PCORI's response to COVID-19 pandemic. And you know, this has been a heavy area of focus for us in multiple ways. And our efforts have focused around thinking about new award funding, where you can see that we've funded over 150 awards at about $94 million.

And we've also had information sharing where we've had COVID-19 horizon scanning updates on a regular basis that we share with our public and other communities. We've been focused on collaboration with other federal entities, as well as and the collaboration and the funded investigator space, as well as embedding COVID-19 special areas of emphasis in our PCORI funding announcements.

We can go the next slide.

So this slide summarizes the funded portfolio from enhancements, as well as the new awards and research and engagement. And you can see the PCORI made about 158 of these awards to-date

related to a lot of issues of relevance to the pandemic; 122 of them were enhancement awards and 36 of them were new awards in the research and engagement space.

We can go to the next slide.

So these are a few publications that are just snapshots from our COVID-19 enhancement publications, and I'm not going to go over all of them, but I'll highlight a couple on the next few slides, but you may recall that the enhancement projects were across research, dissemination and implementation, as well as engagement projects. And they covered a lot of different strategies, including -- and several health conditions, really, including things like heart failure, sickle cell disease, multiple sclerosis, and how interventions and treatments or even communities for responding and managing in the COVID-19 environment.

Let’s go to the next slide.

So let's delve into a couple of examples. This is one that was a PCORI-funded project that received an enhancement and the subsequent results

paper is represented here and the original PCORI-funded study sought to compare safety and efficacy of rituximab and other medications in patients with multiple sclerosis. And when the pandemic hit, the researchers really wanted to learn more about how COVID-19 affected multiple sclerosis patients and how multiple sclerosis medications could actually affect outcomes.

And so, they received an enhancement award to conduct three substudies and investigate the risks and benefits of disease modifying multiple sclerosis therapies, the severity of infections, as well as patient outcomes before and after COVID-19. And so, the publication that you see here is a result from one part of that enhancement.

This is the one that is yielding some of the findings and papers that we thought were of significance. So the researchers here found that multiple sclerosis patients who were on rituximab were more likely to be hospitalized from COVID-19 compared to the general population. And what was really important about this finding is that it led

to our recommendations that patients needed to take extra precautions following infusions, and that the extended dosing intervals or lower doses also needed to be considered in order to protect patients from potential COVID-19 infection complications.

We can go to the next slide.

So, this is an example from our dissemination and implementation COVID-19 enhancement portfolio. And this one is really focused on supporting families and children with autism spectrum disorder and ADHD during the COVID-19 pandemic. And many schools, as you may know, stopped providing in-person special education services in response to the pandemic. And so, this enhancement had to adapt resources for patients and parents and caregivers to use at home, online, and in a series of short videos.

And early results actually revealed that the dissemination of the videos, as well as through evaluation of the caregivers, that the videos were really quite helpful. And they were thought to modestly reduce the interference and frequency of

executive function problems in children and reduced caregiver strain.

We can go to the next slide.

We also want it to highlight another example of a publication from a PCORI-funded COVID-19 award that responded to the question about effective ways to prevent or reduce the impact of COVID-19, especially on vulnerable populations in the healthcare workforce.

And although most patients with SARS-CoV-2 infection can be managed safely at home, that the need for hospitalization can arise quite suddenly. And so, the findings from this paper actually showed that enrollment of outpatients with COVID-19 in an automated remote monitoring service that actually reached out to patients following their presentation was associated with reduced mortality and potentially was explained by more frequent telemedicine encounters and more frequent and earlier presentation to the emergency department.

You can go to the next slide.

I also want to provide you with an example

of a result that's coming to fruition from one of the collaboration efforts, and this is the collaboration between PCORnet and the CDC. And you may remember that the CDC leveraged PCORnet infrastructure and supported further infrastructure development to enable a PCORnet common data model that was able to be updated rather frequently in order to support surveillance efforts.

And this specific project was focused on racial and ethnic disparities in receipt of medications for COVID-19. And the analysis was able to leverage the 41 healthcare systems that are participating in PCORnet. And it suggested that there was lower use of monoclonal antibody treatment amongst Black, Asian, and other race and Hispanic patients with positive SARS-CoV-2 test results as related to white and non-Hispanic patients.

And they also found that these differences were similar to other administration of inpatient medicines for like remdesivir and dexamethasone for COVID-19.

So I wanted to use that slide to kind of

transition a little bit to some of the other ways that the PCORnet team has been involved in the COVID-19 response. And this is just a reminder slide about the PCORnet HERO Research Program, which had a component of a registry as well as the hydroxychloroquine trial.

We can go to the next slide.

So as you may recall, the trial was funded in April of 2020 and leveraged PCORnet's infrastructure and completed in February of 2021. And there were about 1,300 healthcare workers enrolled in the clinical trial. There were a lot of challenges related to enrollment and emerging evidence under the advice of the DSMV. The enrollment was actually ended prior to reaching the original target, given all the transitions that were happening in the larger landscape.

And you may remember as well that early in the pandemic, there was just a proliferation of some small studies and a number of larger ones that focused on hydroxychloroquine. And many of these studies really stalled and ended enrollment early

due to some of the same types of challenges.

While the results did show that hydroxychloroquine appear to be safe, but without significant benefits in a group of healthcare workers and the study was ultimately underpowered to really determine if some of the small signal that was seen around hydroxychloroquine could prevent COVID-19 infection in healthcare workers. And just to get the results out to the public, they were published in MedRx for rapid dissemination.

And a meta-analysis has been completed and is on its way to be published with other hydroxy-chloroquine studies that were focused on pre-exposure prophylaxis just to aggregate information as many of these studies were underpowered and thought to have at least a benefit of aggregating the results for publication.

Let's go to the next slide.

The registry component of the HERO Research Program has over about 55,000 participants that have been enrolled as of January of 2022. And there are healthcare workers, as well as family members and

surrounding community members that are enrolled in the registry now. And it really has two components, an intake survey that collects some basic information like demographics and employment characteristics, and exposure and diagnosis status as well as vaccine status.

And the registry has taken on an approach in its second component, which is really around monthly hot topic polls or surveys that help try to gauge the healthcare workers perspectives on evolving issues. And you see a few examples of some of the types of polls that they focused on in terms of things like vaccine confidence, financial burden, or healthcare worker burnout.

And there's a future survey that's planned on post-acute sequelae of COVID-19.

And I also want it to highlight that the here the registry has also served as a resource for essentially information related to vaccines. And so the HERO Together Program embedded within the registry is a Pfizer-funded study that's studying various vaccine side effects. And this registry has

been used to recruit over 20,000 participants for HERO Together, which is the largest U.S. COVID-19 vaccine registry study. And the only one that submitted safety data to the FDA, including mostly adjudicated medical events.

And what I want to show you on the right here is that coming out of the registry, we've seen some publications that are starting to emerge, and here's one on the impact of the early phase of the COVID-19 pandemic on healthcare workers. And it informed a special area of interest in PCORI's funding announcements around burnout for healthcare workers.

We can go ahead to the next slide.

So just as a funding update related to the HERO program, you can see here that in March of 2020, the Board approved about $50 million for the HERO research program, and then PCORI approved an initial investment of about 40.8 million in the HERO research program. And the way that the contracts were awarded, they are milestone driven and cost reimbursable, which basically means that expenses

must be sent to PCORI before they're paid.

And then current cumulative expenses for the registry and the trial are 13.9 million, which is actually what was spent of the commitments that were approved by the Board.

We do anticipate that there are still some close out that will happen with the registry as those contracts go through March of next year, to make sure that we are able to go through the final peer-review process.

We can go to the next slide.

And here's a snapshot of some of the publications. I mentioned that the hydroxy-chloroquine trial had a pre-print publication. The research platform design was published in contemporary clinical trials. And the early phase impacts that I mentioned from the Hero registry was published in the *Journal of General Internal Medicine*.

And there are several other areas of focus for which publications are being worked on, including racial differences in healthcare workers

experiences and outcomes, healthcare worker burnout, as well as the meta-analysis of the pre-exposure prophylaxis trials that I mentioned, and stakeholder engagement, and other nursing home healthcare workers as another area of focus.

We can go to the last slide.

So here, I just wanted to wrap up our -- my report on our COVID-19 response summary, to mention that all of these different areas around award funding and information sharing and collaborating and embedding have really comprised the major way in which we've been thinking about our pillars of our COVID-19 related efforts.

And I believe we're going to continue to see these types of publications and outputs from some of those investments. I wanted to take the opportunity to give you an update on them today.

So that's all I had for the Executive Director report this morning and I wanted to pause for any questions or comments.

CHAIRPERSON GOERTZ: Thank you. Thank you, Nakela. Any comments or questions for Nakela?

Danny?

MR. VAN LEEUWEN: Yeah, I was wondering in the COVID arena, if the, sort of our aggregate learning across these efforts told -- pointed out anything about people's growing ambivalence or suspicions of science. And if -- like, how did that impact anything that we did?

What were those challenges? Did people face those challenges in our portfolio?

DR. COOK: I may not have the exact answer to that Danny, and it may require a little bit of some qualitative work with some of those that we funded in order to get a sense of that.

I probably would say that, you know, we certainly would anecdotally think that there may have been some issues related to the hydroxy-chloroquine trial that may have contributed in some of the ways that you're describing, but I may not have a systematic understanding of that.

One of the other activities is going on around looking at the COVID-19 portfolio is an evaluation of a COVID-19 on the impact of the funded

research conduct. And that's not something that we yet have ready in a way that we can present, but we're working on that for perhaps the next time we do our update from the dashboard and other ways that we can talk about impacts on the funded work itself, the conduct of that work.

MR. VAN LEEUWEN: Thank you.

CHAIRPERSON GOERTZ: Mike.

DR. HERNDON: Thank you Nakela. Again, very good presentation and good synopsis. And I'm personally beginning to kind of see the efforts of your work come together, to make this a little easier for all of us to understand when we're not completely entrenched in all of intimate details from these committees. And special thanks to Bob and others on your work with PCORnet.

I was particularly thankful -- that, that they were interested in you know, in Phase 2 of reaching out and expanding kind of the potential horizon for data in like with Medicaid and Medicare, you know, and seeing CMS. And, you know, there's just so much data that is yet to be tapped.

And so, I had the opportunity to meet with them and to discuss, you know the use of, you know, statewide HIEs and the use of data. And of course, claims data is not all that, all that, but it is that, but there's stuff there.

So anyway, that's -- I think the PCORnet has kind of been an area of question mark for some of us Board Members for a few years, and it's starting not to be, and I just appreciate the work, Bob, that you've done leading that and Nakela your work on PCORnet, I think that's incredibly important and that, that just stuck out during the presentation as well. So thank you.

CHAIRPERSON GOERTZ: Thank you, Mike. Kara.

DR. AYERS: Thank you. Well done, Nakela, you explained a lot in a little bit of time. I have a question way back in the umbrella slide. When we think about like the structuring of the working groups, our two kind of newer priority areas specified by the reauthorization. I know those aren't working groups and I know PCORI has built

out. There's a great website on the page that summarizes the work around intellectual and developmental disabilities, as well as maternal mortality.

And I've gotten familiar with PCORI staff that works on these issues. But I wondered if there was a structural way that those two focus areas are worked in? I know they're not working groups. Is there another mechanism that ensures that they're kind of built into the overall structure?

DR. COOK: That's a wonderful question, Kara and I was highlighting several of the groups that have been working related to the Board and where we have board engagement on those groups and committees. We also have an approach internal to PCORI where we've been using cross-functional groups to address high priority areas.

And we've particularly set up two that are working on maternal morbidity and mortality, and one that's focused on intellectual and developmental disabilities to integrate our work across engagement, research, dissemination, and

implementation, all the different types of evidence products we can use as well as touching base with the relevant communities like the Methodology Committee and others on those areas.

And, you know, it's been an incredibly rewarding to see this happen. And as you see things that come forward to the Board related to PCORI funding announcements, or different types of workshops and things of that nature we're conducting, they're really stemming from the work of that cross-functional group.

So probably something that we can talk about further and bring that kind of some of the logic models and other things that they've put together to the Board in order to be able to see that.

DR. AYERS: Yeah, that's great. That's exactly what I was hoping to hear. That there was -- it was evident by the products that are, you know, creative, but it's great to hear. Thank you.

CHAIRPERSON GOERTZ: Thanks Kara, Jen.

DR. DEVOE: Thank you. Wonderful

presentation and I'm really excited to hear about, especially the HERO Registry.

Given that our healthcare workforce has taken the biggest hit I've seen in my lifetime and probably in this last century. Is there a plan to extend the registry beyond the period that you described? Because I really feel like I don't know that there are other registries, this large, that could be as informative for the next 20 or 30 years about our healthcare workforce, which is essential to our society, in my opinion. If course, I'm biased as a member of that workforce.

But it's very impressive, the amount of people that are enrolled and I'd love to see it continue in a longitudinal fashion if possible.

DR. COOK: One of the things that we've talked about internally is that if there are projects that are really kind of equipped to leverage the registry that there are certainly a minimal amount of investment that it would take in order for us to continue and for those projects to come to fruition. I believe in, in general, the

infrastructure costs on the registry are about 4 million a year or something like that.

So some of it really is about having the types of projects that would come forward to leverage the registry and be able to use it in a way that would be productive. And we certainly are willing to think about what kinds of things maybe we could even solicit or other things that may be of importance to the community that would be important.

And we have right now that contract opened through March. And so, they're still -- March of next year, so there's still time.

DR. DEVOE: It's an amazing cohort. Anyone wants to do a cohort study over the next 20 years should speak up.

CHAIRPERSON GOERTZ: Thanks, Jen.

Nakela, I have a quick question. I know that one of the goals that we had from our COVID portfolio was to use it as a learning laboratory to see how we might be able to think about new ways to review and select grants, to be able to accelerate the timeline from basically from TPFA to award and

contracting for the studies. And I wonder if you could just let us know what are the key lessons you think we've learned from that experience?

DR. COOK: Well, we had two targeted funding announcements that went through an expedited process. And you may remember those and they both piloted different approaches because we learned a lot from the first one that informed the second approach.

And the second one was one that we used a lot of different ways in which we solicited as well as reviewed. And one of the interesting review approaches was a reverse site visit type of review. That was an interactive review opportunity with reviewers having the research team present in order to be able to ask and answer questions about the project. In addition to having had the offline review of the application.

And that's one example of something that was thought to be an incredibly rich opportunity and narrowed the timeline of what usually it would take for getting a summary statement and then going back

to a research team to get clarifications on questions, having revisions that are necessary before you get to the final stage of being prepared for a contract award. And so, that's something that we're really interested in exploring further as the types of projects that may be amenable to that.

We called that our fast approach, you know, it was kind of fast approach award where we may actually want to try out some other topics in that fast approach and see if we can expand it beyond what we used in COVID-19.

One of the things we learned that didn't work as well, was in the first targeted PFA where we eliminated completely the letter of intent phase to try to streamline some of the upfront timing and seeing if we could just go to an application for review. And why that didn't work well for us is because there are so many things that are different for a PCORI award as compared to other research funders. And that letter of intent stage is really an important way to help people understand what PCORI funding is about in order to make their

applications more successful.

So we got a large number of applications, ended up reviewing a very large number of them. Whereas with letter of intent, we would've been able to tell people before they went to an application stage, what really worked or not.

The other thing we did is we shortened application length in both opportunities. And we did find that application length has a sweet spot. And we were probably too short in the first one. We allowed for a little bit longer in the second one, and we probably have some ways that we could streamline application length.

So we're learning about those kinds of things.

CHAIRPERSON GOERTZ: Great. Thank you, Sharon.

DR. LEVINE: I have a statistics question for -- from coming from a non-statistician. I'm trying to understand the reliability of doing a meta-analysis of a lot of underpowered studies and how confident you can be in the results of that, or

what kind of conclusions you can draw with confidence from a meta-analysis of a lot of studies, each of which is underpowered and probably very differently constructed.

DR. COOK: I'll have a non-statistical response for you, too, Sharon. But I will say that these studies actually work together up front and an interesting way.

So there was a lot of harmonization of the approaches and outcomes in ways that would allow for such a meta-analysis. And I recall that as part of, even in the design stage and early phases of these studies coming out. The pre-exposure prophylaxis one, they had a lot of communication amongst each other, and we're already thinking about the opportunities for combining data from the beginning. So that made a big difference.

CHAIRPERSON GOERTZ: Danny, did you have another comment or question?

MR. VAN LEEUWEN: Nakela, I want to thank you for including what you learned didn't work in your report, because I think in the research world,

we don't hear enough about what didn't pan out as we expected. So thank you.

CHAIRPERSON GOERTZ: All right. Any other comments or questions?

Anyone on -- who's joining us virtually, any Board Members.

[No response.]

CHAIRPERSON GOERTZ: All right. Well, Nakela, thank you for that excellent report. It's exciting to see us moving forward in so many ways.

Now I am really pleased to introduce our next topic on the agenda, which is to consider our research agenda for adoption. There's so much work has gone into the development of this and so many of you -- and so many of our stakeholders have been involved in helping us get to this point.

And so, I'm going to now invite our co-chairs of the Strategic Planning Committee, both Sharon Levine and Nakela to present the proposed agenda.

DR. LEVINE: Thanks so much, Christine.

And as Christine said, today is really the

second important milestone in our strategic planning process. And we are bringing forward for the Board's consideration today, the proposed research agenda for review. And if there is concurrence for adoption.

This research agenda as we defined it, sets the framework for delivering progress on our national priorities for health, specifically through funding comparative clinical effectiveness research projects. We've had multiple discussions at the Board level, multiple opportunities at the Strategic Planning Committee to go through this, and multiple opportunities for both Board Members, as well as stakeholders to provide feedback.

We've convened multiple stakeholder convenings and have had an open public comment period. We're very grateful for the stakeholders and members of the public who took the time and showed enough interest to provide comments to PCORI on the research agenda.

And I also, if I could have the next slide, first slide -- thank you.

Also I want to thank the members, both Board Members and staff, who have constituted the Strategic Planning Committee and in particular Katherine Jackstadt, who has provided incredible support to all of us as we've gone through this process.

I'm going to turn it over to Nakela now to go through the details and where we are.

DR. COOK: Thanks so much Sharon. And again, just, couldn't be delighted to be at the point where as you can see on this slide, we're talking about the adoption of the research agenda.

This is a slide that you've seen many times before and just shows our journey and strategic planning and where we're going. And I just wanted to reiterate that the research agenda's purpose is to provide the framework for achieving progress on the recently adopted national priorities for health. And specifically through the strategy of funding comparative clinical effectiveness research and it's going to support for PCORI's unique space in that health research landscape.

Let's go ahead to the next slide.

This slide is just meant to remind us of the importance of public input and public comments and informing the national priorities for health, as well as the research agenda. And the graphic also serves to highlight where we are in the process of establishing the research agenda, namely at that adoption phase.

And the research agenda, as many of you will recall is going to then help to guide the development of the continuously relevant research project agenda. And that's at that stage where the topics of focus are identified.

And engagement, in all of this, continues to be an important aspect of strategic planning. And we continue to collate that feedback to inform our forthcoming research project agenda, which is going to outline that process for funding around the specific topics and will be updated with ongoing and regular stakeholder engagement to ensure that it remains relevant to the evidence needs of patients, as well as stakeholders.

We can go to the next slide.

Since we've demonstrated from the last slide throughout the strategic planning process, we sought to get and gather input from a range of stakeholders. And the input was really important and we've been hearing feedback related to the research agenda even before the formal comment period. But in addition to the comment period for the research agenda, stakeholders have provided input to us via a lot of different avenues, such as meetings and surveys.

And this approach helped us to hear from multiple stakeholders, including patients and caregivers, purchasers and payers, researchers and clinicians in a variety of venues.

I'll go ahead to the next slide.

So before we discuss exactly what we heard from the public feedback, I wanted to give you just this brief reminder of what was included in the proposed research agenda that was posted for public comment and it's comprised of the six statements that you see here. And I'm not going to go over

each one individually because we'll talk about some of the revisions and the final proposed group of statements for the research agenda for consideration for adoption in a moment. Okay.

So the analysis of the public feedback, which is comprised of both the public input that we received through the meetings and other types of surveys, as well as the public comment suggested overall really strong support for the research agenda. And PCORI's extensive feedback was also synthesized into five key takeaways that summarize the overarching inputs that we heard from stakeholders on the research agenda and the takeaways that are supported by several insights that help further explain each of those takeaways.

And the takeaways and insights resulted in different types of considerations for PCORI that were relevant in different components of the strategic planning process. So it includes considerations that need to be addressed in the research agenda, considerations that could be addressed in the research project agenda or

considerations that could be addressed in the strategic plan, as well as considerations that could be addressed in action plans.

And some of the different descriptive information about the research agenda will be reflected in the strategic plan that aims to describe all those various components and really present a more cohesive vision for PCORI's future activities.

And while the feedback did really apply to different components, we're going to focus in first on the considerations that we thought would be addressed in the research agenda and the six statements themselves.

So here are the five key takeaways that we heard in our public feedback. The first takeaway was that the research agenda has broad support that can be further enhanced with minor clarifications and additions. The second is that stakeholders are really engaged by the research agenda's focus on health equity and are eager for PCORI to address systemic issues that perpetuate disparities.

The third is that enhancing alternatives to traditional research teams, methodologies, and contexts could improve equity and representation in research. The fourth takeaway is that technology and data sharing innovations are central to the future of CER. And the fifth, is that a deficit of trust and health information poses a significant barrier to improving health outcomes.

We can go to the next.

So amongst all the insights that supported the key takeaways, there were two that flow directly to informing edits to the research agenda, and you can see them here. Other insights are still going to be addressed there just to be addressed elsewhere as we just talked about on the prior slide.

So these other areas that we'll address some aren't just necessarily specific to being considered for the research agenda and they'll inform those other areas like the research project agenda, the strategic plan, or the action plans.

But these are the two that we thought and hearing from stakeholders -- that we heard from

stakeholders were really relevant to consideration of potential revisions to the research agenda. And the first insight here is that the research agenda could be more explicit about the need to impact structural racism and its effect on health. And the second was that the research agenda statements could be more inclusive of a broad range of historically excluded populations, such as rare disease communities, people with disabilities, and those who are homebound.

So let's go to the next slide and we'll talk about how we were addressing those in the research agenda.

So based on these insights that were relevant to the actual six statements themselves in the research agenda, we're suggesting a few changes to two of the statements. And so, I'll go through the suggested edits because I think it's not lined up just perfectly on the slide, but hopefully you can see it here.

So the first edit pertains to the first bullet and the statement's been revised by adding in

inclusive and underrepresented, as well as to clarify that the research agenda is really intended to be applicable to many populations. And the statement now reads, "Fund research that fills patient and stakeholder prioritized evidence gaps and is representative and inclusive of diverse and underrepresented patient populations and settings."

And the second edit pertains to that second bullet and the statement's been revised here to try to reflect that research is one aspect for achieving health equity and to underscore the importance of research to generate findings that counteract the impact of racism, discrimination, and bias on health. So the statement now reads, "Fund research that advances the achievement of health equity and elimination of disparities with an emphasis on overcoming the effects of health and healthcare outcomes of racism, discrimination, and bias."

And given how important both of these statements really were and the concepts that they represent, we intend to address them in other areas of the strategic plan to including, for example,

language around the importance of inclusive and representative research and the context of longstanding racism of all kinds, including structural, institutional, interpersonal, and the impacts on health that they may have.

We can go the next slide.

So there were several other additional insights that were garnered from the public feedback and these insights are what PCORI heard from public comment, the meetings, and the surveys, and events. And it's not a what PCORI is asserting. It's what we've heard. And I'm just going to highlight a few of the insights from the five key takeaways and where those insights from stakeholders will be considered in the strategic planning process, including the research agenda, the strategic plan or the research project agenda or action plans.

So the first takeaway you can see here is that the research agenda has broad support that can be further enhanced with minor clarifications or additions and the first two insights that support that takeaway we've already talked about. Those are

informing revisions to the research agenda itself.

The other three represents insights, including concrete examples that could be helpful in clarifying the relationship between underlying drivers of health disparities and funding goals, and another that's focused on supporting high quality research that prioritizes patient perspectives, especially those underrepresented in research and a last insight there around the specific mention of health systems in public policy and achieving the goals in the stated research agenda.

There's not really a one-to-one relationship in terms of how we're thinking about the insights and where there'll be addressed, but we think those other three insights will be addressed in the research project agenda, the strategic plan, and action plan.

We can go to the next slide.

So this is the second key takeaway, which is that stakeholders are energized by the research agenda's focuse on health equity, and eager for PCORI to address systemic issues that perpetuate

disparities and you can see that takeaway was supported by several insights. And I'll just highlight one for you. And that's related to barriers to care that are rooted in social racial and economic inequities created by policy decisions are drivers of health inequities and stress, and they stress the need for research that examines how these factors in the social determinants of health lead to different health outcomes.

This takeaway specifically is -- and the insights here, are thought not to be directly applicable to the research agenda statements themselves, but that they could be addressed in other areas like the research project agenda, the strategic plan, and our action plans.

Let's look at takeaway number three.

So takeaway number three is embracing alternatives to traditional research teams, methodologies, and contexts that could improve equity and representation in research. You see the several insights here that actually support that takeaway. And one that I'll highlight is that

community-based participatory research approaches in which community organizations have sufficient authority and resources to be full partners in the research process can help diversify research participation and expand the relevance of research results.

And another insight that informed this takeaway was around standardized metrics that are needed to measure the clinical and nonclinical outcomes that are most important to patients. And you can see that these insights are thought to be most relevant to our action plans, as well as our research project agenda. And so, will be considered in those spaces as we move forward.

We can go to the next slide.

The fourth takeaway is around technology and technology and data sharing and innovations that are central to this through the future of CER, and these takeaways were also thought to be considerations that can be addressed in the research project agenda and action plans. And I'll highlight one of the insights that support this takeaway. And

it's the insight around evaluating the efficacy and equity of telemedicine visits for different populations.

Let's go to the fifth one.

So this is takeaway number five. That focuses on a deficit of trust and health information that poses a significant barrier to improving health outcomes. And here you can see that there were five different insights that informed this takeaway. And perhaps I'll just highlight a couple here around evidence-based practice that's needed to select messages and messengers to disseminate strategies, tailored to different audiences.

And another that's focused around effective implementation science that's going to require new standards and procedures as well as training for researchers related to the field of implementation science.

So the insights on this slide and this takeaway overall were thought to be most applicable for being addressed in the research project agenda, the strategic plan, and our action plans.

So here is the proposed research agenda for the Board's consideration for adoption. And this includes the prior revisions that were shown on one of the earlier slides, but it also has a structure that's been revised now to streamline the text. Previously, each of the statements were structured and worded so that they could stand alone when public comment was open. But now we have a header that says fund comparative clinical effectiveness research that, and then sub-bullets that focus on the language that we've just looked at that was revised related to the research agenda statements.

So this is the summary of what we've heard, where we think those considerations can be addressed in the final proposed research agenda that's put forward to the Board.

Thanks. I'll turn it back to you, Christine, for discussion.

CHAIRPERSON GOERTZ: Thank you so much. Nakela. I'd like to open it up for discussion. Yeah, we can actually, we can do a -- why don't we do some brief discussion and then we'll have a

motion. All right, James?

DR. SCHUSTER: Yeah. Thank you, Nakela. It was a great overview. It looks like you've got really powerful input from the stakeholders. I was wondering if you could just say a couple words about the input process, a little more about the process used to get input from stakeholders, just because it sounds like it was so successful. It would be helpful to understand a little more about it.

DR. COOK: I certainly can. So there were two components here. There was the component of putting things up for public comment and then a robust outreach to make sure that stakeholders that have replied before and were interested in PCORI's work were aware of what was up for public comment.

But we also took on the opportunity to have several convenings. We have advisory panels that already convene on a regular basis and we utilized our advisory panels as a way to get input on what was being proposed for the research agenda, touching base at each of those. And the ones that we couldn't reach, we were reaching out via survey.

We also convened different stakeholder groups like our payers and others. And so, because we didn't have a natural convening opportunity, we went by survey to the payers that have typically interacted with PCORI. We also had clinician and convenings, both physician and non-physician convenings, where we had an opportunity to go over what we were thinking about with a research agenda and directly hear feedback in breakout sessions, even in order to get some rich input.

So the way that all this input was synthesized was sent through a very methodical method in terms of having both a public comment input, as well as what we were hearing from the surveys and those convenings coming together in a way that we could actually kind of summarize the key takeaways as themes, and then support it with these insights that you are seeing.

We also had input from our national priorities process with public comment and different convenings that we, at that time, you may remember when we got the stakeholder feedback, we did

something similar, or we said there were certain considerations that were relevant to the national priorities and other considerations that may be relevant to the research agenda.

So we went back and captured all of those as well, so that they weren't lost and brought them into the synthesis.

So hopefully that helps in terms of thinking about the robustness of what we've heard, but it really was quite an effort to try to reach as many of the communities that work with PCORI as possible.

DR. SCHUSTER: Thank you.

CHAIRPERSON GOERTZ: Kara and Bob.

DR. AYERS: Yeah. Thank you. I'm also commending the rich stakeholder impact that you got and also how you synthesized it.

I just wanted to mention on the revision for research agenda side were actually like wordsmithing that, and I'm not suggesting this as a revision for the actual wording, because I respect the stakeholder process that went into that. But

you mentioned that you're going to be addressing this in other, you know, many other longstanding projects.

DR. COOK: Yes.

DR. AYERS: So I think when we use underrepresented, it is a little bit passive in this case. So I think sometimes it's important to specify historical exclusion of groups. And so, when we lack diversity in some of our research. So just thinking of kind of another word that would be important in addition to underrepresented, because I think that's accurate as well, but also kind of the historical picture of this.

And I think it would address as well that stakeholders wanting that more explicit connection to structural racism. Thanks.

DR. COOK: Thank you. I may have mentioned Kara that there definitely is opportunity for us. And as I commented, there's going to be quite a bit of a language that goes around the way in which we present the six statements. And so, it provides us an opportunity to use more words, to kind of explain

the fuller context. And so, I appreciate that we could probably work something like that into that language. So very important comments. And thank you for that.

And if I'm understanding you correctly, you were saying not to edit it here, but to keep it in that broader context.

DR. AYERS: Yeah, totally. And I think even broader context and maybe what we've talked about here too, in terms of structural racism as well, but also structural oppression. I think some of our work on the rare disease panel has talked about literal exclusion from clinical trials, and the result of that over time has been, you know, populations like people with intellectual and developmental disabilities, really not being able to find themselves reflected in research.

So it does connect to structural racism and structural oppression, but also kind of the way that we've conducted research in some ways is inadvertently, but, you know, has had an impact on different groups.

CHAIRPERSON GOERTZ: Thank you, Kara. Bob.

DR. ZWOLAK: Thank you. I'm still a bit troubled by the second statement in the research agenda. Not because I disagree with the goal because I absolutely agree with the goal, but for the following reason, the statement says fund research that advances the achievement of healthcare equity and elimination of disparities.

And my point is that research provides scientific data to inform and clarify those disparities and if we fund good comparative effectiveness research, we may actually identify solutions that actually work in our sort of complex and oftentimes dysfunctional healthcare system. But research alone really can't directly achieve health equity and eliminate disparities. It can only provide evidence and potential solutions.

Achievement of healthcare equity and elimination of disparities is really above the pay grade of PCORI and beyond the scope of research alone, we, you know, we need the engagement of our political leaders and community leaders and payers

and the healthcare systems leaders to accomplish those goals.

So to me, the research is very important, but a small step and this statement almost seems to overstep our ability -- exceed our ability to accomplish that terribly important goal. And again, as, as Kara, I don't at this point, suggest that we change the wording because I respect the pathway by which we got here.

But I do think we can't pass up the opportunity to say that research alone can't get us where we need to go.

DR. COOK: Bob, I would agree with you if that sentence started with that, you know, achievement, but from my perspective, research actually can advance the achievement.

DR. ZWOLAK: That was going to be my comment as well.

CHAIRPERSON GOERTZ: And maybe we need to have this discussion offline, but --

DR. ZWOLAK: So I'm not, as I say, I'm not, I'm not I'm not suggesting we change this wording.

CHAIRPERSON GOERTZ: Right.

DR. ZWOLAK: We got through a very complex process to get here, but I just, I do think that point needs to be made.

CHAIRPERSON GOERTZ: Okay. No, thank you. I appreciate it.

All right. Are there any other comments or questions for either Nakela or Sharon?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to ask for the next slide and I am going to -- I'm sorry Sharon. Did you want to say something? I'm not looking far enough over to my left.

DR. LEVINE: Peripheral vision problems.

CHAIRPERSON GOERTZ: It is.

DR. LEVINE: My only comment was that I think Bob's -- if I'm hearing you, right Bob. What's missing is the instrumentality. So how does comparative clinical effectiveness research advance the achievement? And it's through providing evidence, which I think is implied in the statement.

And certainly I think comparable to Kara's comment as we use the research agenda to fund, to identify research projects, clarifying that may be helpful for researchers who understand they aren't being asked to solve problems that research can't solve. So I think it's an important comment.

CHAIRPERSON GOERTZ: Good. Thank you. Thank you, Sharon. I agree.

All right. What I'd like to do then is ask for a motion to adopt the research agenda as presented.

DR. HERNDON: So moved, Mike.

DR. MCNEIL: Barbara, so moved.

CHAIRPERSON GOERTZ: Thank you, Mike.

Barbara, are you willing to be a second on that?

DR. McNEIL: Yes, I am Sharon -- I mean --

CHAIRPERSON GOERTZ: Christine, that's okay.

DR. McNEIL: Christine.

[Laughter.]

CHAIRPERSON GOERTZ: All right. Is there

any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, that I'm going to ask Maureen to lead us through a roll call vote on this.

MS. THOMPSON: Thank you, Dr. Goertz. When I call your name, if you would indicate approve, oppose, or abstain. Thank you.

MS. THOMPSON: Kara.

DR. AYERS: Approve

MS. THOMPSON: Kate Berry.

MS. BERRY: Approve.

MS. THOMPSON: Jennifer DeVoe.

DR. DEVOE: Approve.

MS. THOMPSON: Alicia Fernandez.

DR. FERNANDEZ: Approve.

MS. THOMPSON: Christopher Friese.

DR. FRIESE: Approve.

MS. THOMPSON: Christine Goertz.

CHAIRPERSON GOERTZ: Approve.

MS. THOMPSON: Mike Herndon.

DR. HERNDON: Approve.

MS. THOMPSON: Russell Howerton.

DR. HOWERTON: Approve.

MS. THOMPSON: James Huffman.

MR. HUFFMAN: Approve.

MS. THOMPSON: Connie Hwang.

DR. HWANG: Approve.

MS. THOMPSON: Sharon Levine.

DR. LEVINE: Approve.

MS. THOMPSON: Barbara McNeil.

DR. McNEIL: Approve.

MS. THOMPSON: Eboni Price-Haywood.

DR. PRICE-HAYWOOD: Approve.

MS. THOMPSON: James Schuster.

DR. SCHUSTER: Approve.

MS. THOMPSON: Ellen Segal.

[No response.]

MS. THOMPSON: Michael Lauer.

DR. LAUER: Approve.

MS. THOMPSON: Kathleen Troeger.

MS. TROEGER: Approve.

MS. THOMPSON: Karin Rhodes.

DR. RHODES: Approve.

MS. THOMPSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Approve.

MS. THOMPSON: Janet Woodcock.

[No response.]

MS. THOMPSON: Robert Zwolak.

DR. ZWOLAK: Approve.

MS. THOMPSON: And Dr. Goertz the motion passes.

CHAIRPERSON GOERTZ: Thank you so much. And again, thank you to Sharon and Nakela and the other members of the group that -- the Strategic Planning Committee that have helped us get to this point, all of the stakeholders that really made such important contributions to our research agenda. I think this is a historic moment in our strategic planning process and I'm really pleased to be at this point and to see what happens next.

And we're going to now move to our next agenda item, which is to talk a little bit about the Methodology Committee framework. We're going to get an update from the MC 2.0 Work Group, as well as discuss the Governance Committee's recommendation on

conflict of interest and the governance framework for the Methodology Committee.

Now, as reflected in so many of our board agenda items today, PCORI is advancing its strategic direction in multiple ways. And one area of focus is considering how the role of the Methodology Committee and how it can support PCORI's strategic direction. I think that the Methodology Committee is truly an incredible resource that PCORI has to help further our work. And we want to make sure that we are maximizing the opportunity to get input from members of the Methodology Committee as we advance our work in multiple ways. And that's really what -- the ways to broaden the influence and scope and work at the Methodology Committee is really what we're going to be talking about today.

And we're going to consider two different areas of focus related to the MC in our discussion today.

The first is to consider an update from the Methodology Committee 2.0 Work Group, which includes members of the Board, the Methodology Committee, and

PCORI staff. And this group has been considering a future state vision for the Methodology Committee. So I'm looking forward to hearing an update on that work and we'll have an opportunity to discuss and provide comments and future direction.

Secondly, we'll consider recommendation from the Governance Committee about the conflict of interest in government's framework for the Methodology Committee going forward. We'll consider the recommendation of the Governance Committee, discuss, ask questions, and consider whether or not to approve the recommended framework.

We're going to start out with Nakela, who will provide the update regarding the MC 2.0 Work Group. And after that discussion, Sharon who chairs the Governance Committee, and Mary Hennessey, our General Counsel, will provide an overview of the Governance Committee's deliberations and recommendations.

So Nakela, I'd like to start by turning it over to you.

DR. COOK: Great. It's really an exciting

opportunity to talk about the Methodology Committee 2.0 Work Group on behalf of the larger group. And one of the elements, as Christine mentioned in the strategic plan and activities was really to establish this vision and focus for the Methodology Committee that was aligned with PCORI's strategic direction. So taking the opportunity of what we were thinking about in the strategic plan and how could we really enable the work of the Methodology Committee in order to advance that.

And furthermore, we also have this adjustment that we want it to take into consideration of the fact that the reauthorizing law shifted that establishment of appointments to the members of the Board of Governors and want it to think about that as we were moving forward with our work.

So I'll walk you through the way in which we approached this, and I think an exciting vision for the future. Let's go ahead to the next slide.

So just a little bit of background and rationale. I mentioned some of it already. We want

it to advance PCORI's strategic planning by thinking about the Methodology Committee as an integral part of that and leverage the expertise of the Methodology Committee, identifying intersections with some of PCORI's priorities for the future. And earlier in my Executive Director report, I mentioned a few of those priorities for the future that had a natural opportunity to align with Methodology Committee work.

And we also were thinking about how we wanted to enhance relationships with Board, staff, and other committees and panels, and particularly increasing the opportunities for exchange with the Board on relevant items and intersections with the work of other committees and panels where the Methodology Committee could really be leveraged for input.

Let's go ahead to the next slide.

So here are the purpose and outcomes that we identified together as a work group, including the statement around envisioning that future focus of the Methodology Committee is one that advances

PCORI's evolving strategic directions, leverage the member's expertise, and fulfill the legislative intent for the Methodology Committee role. And we had several outcomes that kept us focused, including outcomes related to the roles and responsibilities of the committee and relationships with the staff, Board, and other committees and panels, as well as the broader methods community.

And we also want it to think about the composition of the future for the Methodology Committee. Let's go to the next slide.

So in discussing the future state vision for the Methodology Committee, the work group considered a lot of potential areas for future focus, including the important work laid out in the legislation around methodology standards, but expanding to areas related to consultation, as well as the methods components and our national priorities for health research agenda and research project agenda, there are a lot of complex issues in those areas of our strategic plan, as well as thinking about the methodological issues for

priority topics related to our legislation from maternal morbidity and mortality, intellectual and developmental disabilities, and the full range of outcomes data. And the committee's already engaged in several of these areas.

We also want it to think about opportunities to understand our current methods portfolio and the generation of methods from PCORI awards that could help inform future directions and think about as well the future needs for the Methodology Committee to really enable their success both through PCORI staff leadership and support for the Methodology Committee.

Go to the next slide.

This is the working group membership. As you can see here, and really a robust group of individuals across broad representation from the Board of Governors, the committee, and staff.

I also just if you don't mind going back for one moment, just wanted to note as well that I think important to this composition was that the Board Chairperson and Vice Chairperson participated

and the Methodology Committee Chairperson and Vice Chairperson as part of the group.

We can move forward.

So I'm going to transition now and talk a little bit about the future state vision. So this is the exciting component here and the roles and functions that were envisioned within it.

You can go to the next slide.

So the working group developed really a shared vision for the future state and the Methodology Committee consisting of six major domains. And you can see the first three that are represented here on this slide. One around development and updated standards consistent with the legislation. Innovation and best practices is another domain. And then the third, around opportunities on the horizon.

And I'm just going to talk you through what we meant by these areas or domains and under developing and updating standards, really wasn't a focus on developing a PCORI prioritized inclusive high-quality standards as mandated by authorizing

law for CER. And there was some real intent around for PCORI prioritized in the sense that the Methodology Committee is really interested in developing those standards that are going to be most helpful for PCORI and PCORI's broader community, and utilizing flexible and transparent approaches to do this.

And in that statement, we were really thinking about the fact that how we get to the standards can actually engage that intellectual contribution of the Methodology Committee members, but that we may be able to support that a little bit differently and more effectively than we had in the past.

Innovation and best practices focused on facilitating the utilization of standards as well as cross-cutting really cutting-edge methods for CER through the guidance for the research community. And so, this point focused on the fact that while standards may provide one degree of a leveling playing field in terms of the types of methods approaches that we would anticipate in our funded

portfolio, that they're cutting-edge methods that we also want to be thinking about. And how do we think about how we incorporate that into guidances for the research community, and perhaps even thinking about some things that others utilize like FDA, which creates guidances in areas that may be in that cutting edge space.

There was also the point underlying the innovation and best practices, domain around convening and advancing methods for the use of real-world evidence in new areas of PCORI's focus, such as those like science and engagement work, which you're going to hear about a little later today, where there are a lot of methods questions that could be really talked about in a more robust way.

In the domain that was focused on opportunities on the horizon, we were focusing on serving as a resource to PCORI on methodological approaches related to the national priorities for health and research agenda. And just a couple of examples here of those areas that could be included are methods that relate to something like

implementation science, which we know is a newer area included in our priorities for health as an area of emphasis for PCORI, as well as some of the priority areas that are included in reauthorizing legislation.

And particularly, when we think about areas such as intellectual and developmental disability, the Methodology Committees has already had a workshop in this space and identified the complexities of that work, especially when we're dealing with certain rare diseases and a smaller population sizes.

Let's go to the next slide.

So the other three domains in the vision included a focus around expertise in diversity of perspectives, as well as engagement with the broader methodology community and relationships with PCORI bodies and supporting the integrity of the work. So under expertise and diversity of perspectives, the vision contributed that we needed to provide diverse perspectives, intellectual talent, and methodological expertise that's really leveraged

toward for PCORI's strategic directions.

And there are new areas that are emerging in strategic directions that may actually be important for consideration of membership in the future for the Methodology Committees, such as expertise in the field of equity.

There was a domain around engagement with the methodology community, which focused on engaging with the broader research community about rigorous methodological approaches for the conduct of CER through convenings and other types of exchanges with the broader community of methodologists. And I think this is a really important component in terms of thinking about the Methodology Committee as a resource more broadly to those that are engaged with PCORI.

And then there was the last domain here around relationships with other PCORI bodies and supporting integrity. And this one focused on revitalizing and fortifying relationships with other PCORI bodies to help strengthen outcomes related to PCORI's strategic directions, including being able

to have an interaction at a strategic and deep level with PCORI leadership, as well as with the Board of Governors and advisory panels and thinking about ways that we can do that more effectively.

We also brainstormed actions to implement the shared vision and a few key areas and continued that we articulated several of those goals and actions that needed to move the Methodology Committee forward. And you can see that there were several themes, even in what I just talked about, including increasing engagement and communication with the methodological community more widely, keeping up with changing practices in the field and updating standards, but also thinking about cutting edge methods and what's coming out of the portfolio and further increasing the diversity of that expertise on the Methodology Committee.

And we heard from the work group, a real emphasis on innovation and best practices as well as engagement of the community and that the Methodology Committee can play a really critical and key role and identifying methods for the field. And so, we

greatly appreciated that.

We also heard the importance of really being grounded and PCORI strategic direction and several components of that vision.

So there were three key areas when we started to talk about discussions that would really enable that vision, and one of them was enhancing the PCORI staff and Methodology Committee partnership. And here we actually identified a need to increase some of the infrastructure support and capacity of PCORI staff to partner with the Methodology Committee so that there really could be an increased focus on intellectual contributions with the support of that ongoing activity being carried out by staff partnership.

We also heard about the importance of enhancing the staff partnership with the Methodology Committee at multiple levels of connections at PCORI, both a strategic level, as well as one that enabled the activities for implementation, and connecting with as well the enablement of Methodology Committee activities with ongoing staff

support was something that was thought to need a more robust connection with the committee and opportunities for us to enhance that as well.

We can go to the next slide.

So given really the scope of the future state vision that enables the Methodology Committee to serve as a critical resource, the Board and staff, and in many ways, positions the committee closer to PCORI's funded portfolio. The working group also embraced the need to think about a requirement for all Methodology Committee members to forgo eligibility to apply for PCORI funding.

And the group really recognized that this would allow all of the Methodology Committee members to be able to contribute and advance the Methodology Committee's work and advise on even funding priorities and plans and concurred that maybe we needed to think about a shorter term that may be more acceptable in terms of the time period for interested candidates to forgo eligibility for PCORI funding, rather than the six-year term that had been previously approved by the Board.

We can move forward.

So we wanted to pause at this part of the discussion related to the Methodology Committee future state vision, and just ask if the vision really resonates with you, or if there are other implementation ideas that we should consider as we're refining the focus within the domains of the future state vision.

And we have another meeting with the committee that we wanted to bring back any input to the Board for final revisions. And you can see the six domains that are listed here. Again, just as a recap, to refresh your memory as we are walking through this discussion.

So looking forward to your comments, and I may even ask if Christine it's okay if Robin or Steve had anything they wanted to add and contribute.

CHAIRPERSON GOERTZ: Yes, absolutely. I was going to go there myself. So I know that we have Steve Goodman, who is the Chair of the Methodology Committee is with us virtually and Robin

is the Vice Chair is here with us in-person. So I'd love to get your input. Steve, might we start with you?

DR. GOODMAN: Well, I'll mainly cede the floor to Robin since she's there physically, and she's been completely a part of all these conversations. I think Nakela has captured it beautifully. We're of a single mind about getting the Methodology Committee working to its maximum capacity. I heard yesterday the metaphor that we were in a gift in a wrapper that hadn't been quite unwrapped. And I think we sort of agree with that and, and we think that what's been outlined really will be key to getting us fully engaged.

And in addition to the new staff changes that are occurring in the new -- this also interfaces with the new things that are happening at PCORI. So all of these things are of a piece.

I don't have anything really materially to add because Nakela has covered the territory pretty well. Just that we're all in alignment about making the most out of what we think is really a very, very

special resource for a funding agency like this. There's no other funding agency that has any resource like this and maximizing its effectiveness will be, I think, a value to PCORI and also of tremendous professional -- greater professional satisfaction to the members themselves, of the MC.

So that's all I really have to add, but I, again, I defer to our onsite member and thank you for the opportunity to speak on this.

CHAIRPERSON GOERTZ: Thank you, Steve. Robin.

DR. NEWHOUSE: I agree with everything Steve said, but not only does it resonate, it feels exactly right at this point in time. I would say that over time having conversations with the limited people, don't give us the opportunity as a full committee to be able to contribute everyone's specific expertise. We're all incredibly different.

So this is perfect, particularly given the direction of PCORI and their strategic initiatives and the change in some of the research goals. It's exciting. It will enable us to be able to be part

of that in a full way and fully embrace our wonderful staff from PCORI that have been so helpful in developing not only our standards, but supporting us in a lot of innovative ways.

And also to say this whole conversation has taken place over time. The Methodology Committee had rich dialogue under Steve's leadership and I completely agree with this direction. So it all aligns incredibly well. The committee made a -- I think great recommendation, and we all agree with that recommendation.

CHAIRPERSON GOERTZ: Thank you so much, Robin. Barbara, I know you wanted to make --

DR. McNEIL: I actually had two comments.

I thought this was a wonderful presentation by wonderful group, but I wonder Nakela, could you go back several slides to the one that has three columns? It says future state vision, maybe four or five slides back.

Keep going one more.

That one.

So this has always bothered me. This left

hand one, it says developing PCORI high quality standards. Now the issue here is there a zillion approaches and methodologic approaches for statistical analysis and comparative research. And we were not developing them.

This implies is if there's a brand-new field of there and by God, we're going to develop approaches for comparative effectiveness research. We're not. There are textbooks on this project.

And I think this statement is just not quite right. We may be trying to improve those standards, but we're certainly not developing all of them. We may be developing some new ones, but when I looked at the methods handbook a while ago, they really weren't too many new ones that we're developing. So I think we want to be very humble here in what wording we use in that left-hand column. I don't think it's quite right.

And then I'll just give you my second comment or maybe Steve wants to comment.

DR. GOODMAN: I did just a very quickly, this is actually really technical language. This

isn't talking about standards in the field. This is talking about the official method. You know, PCORI methodology standards, which are a statement about how research has to be conducted. It is not that we are necessarily at the forefront, although we hope our funders -- or our grantees are of establishing the standards in the field.

We're not using standards in a generic way. This is a very technical use of the term. So that that's all it means. And in fact, we've aimed not for having standards that are always at the cutting edge because that cutting edge changes every day. We want them to be high quality.

DR. McNEIL: Is that a difference in language entirely clear?

Am I the only one that was confused about it? Because I've been confused for months about this.

DR. GOODMAN: It's standard within PCORI, but I can't speak to it. I'll have others speak to that. When we talk about new standards, we're talking about new sections of the methodology report

and new standards that are listed on our website.

CHAIRPERSON GOERTZ: I think Nakela wanted to make a comment.

DR. COOK: Steve, you really summarized that. Well, I thought one other thing that may resonate with the Board members and with you Barbara, is that the terminology standards and the way we use it in define it is based off of the authorizing legislation and how it was defined for us at PCORI.

And so, we do reference that both, you know, on our website for when we're talking about standards, et cetera, but it is different than perhaps the way that you may think about that the cutting-edge work, et cetera, like Steve was saying.

So I just wanted to add the point around the terminology coming from the authorizing law and that we try to reference it when we are when we have the standards reports out on our website.

DR. McNEIL: I buy that in a Nakela and against the question is if this slide was shown to a generic audience, would it be easy for them to see

that distinction?

DR. COOK: We can certainly make that clearer in such a slide like this, particularly talking about the utilization of the terminology related to, and have a definition or something like that.

DR. McNEIL: I wish you would, because this has bothered me for a long time and I realize it's in discussion now, as Steve has described it, but I would, I think for the greater community that's listening to your talk or Steve's talk, that it would be good to have that a little bit clearer.

And then my only second comment was that you indicated that there was potentially a drop in the ability of methods -- and members of the standard -- of the methods committee to apply from grants from PCORI from six years to four years.

Why is there any limitation?

CHAIRPERSON GOERTZ: Barbara, that may be a misunderstanding. What they're saying is right now, the length of time that a methodology, the time of service on the Methodology Committee is six years.

And we're talking about shortening that term of service to four years --

DR. McNEIL: Why would we do that?

CHAIRPERSON GOERTZ: -- with an option for a reappointment.

And the reason why is because as we change our conflict-of-interest standards, if in fact we do vote to change that today, then our thought is that six years is a long time for a scientist to forego the opportunity to apply for PCORI funding. That for four years is not quite as long.

DR. McNEIL: I see, okay.

CHAIRPERSON GOERTZ: It's not quite as long. And Steve or Robin, if you wanted to make any additional comments on.

DR. NEWHOUSE: No, the only comment is it's actually a year longer than the term. So there's a washout period.

CHAIRPERSON GOERTZ: Okay. Thanks. Yeah. Thanks for that clarification.

DR. McNEIL: I'm sorry. What's the washout period mean? Functionally? Why a washout period?

DR. NEWHOUSE: So even after six years, they still have a period of time where they cannot apply, to Board Members --

DR. GOODMAN: -- after four years.

CHAIRPERSON GOERTZ: So the same is true for Board Members that were not able to apply for PCORI funding for one year after the end of our term of service on the Board.

DR. McNEIL: I that logical?

CHAIRPERSON GOERTZ: Pardon? It's similar to NIH and other funding agencies as well.

And we can talk more in detail about this if you would like.

DR. McNEIL: We talk offline.

CHAIRPERSON GOERTZ: All right. Thanks Barbara. Anything else?

[No response.]

CHAIRPERSON GOERTZ: All right. Russ, did you want to make a comment?

DR. HOWERTON: My only comment is that would be pretty normal in almost any kind of fiduciary thing. You know, government service, you

can't walk out of somewhere and two days later -- we need that year.

CHAIRPERSON GOERTZ: Sadly to those of us who are going off the Board soon.

All right. But I agree completely. Are there any other -- Alicia?

DR. FERNANDEZ: I was wanting to make a comment and about how well I thought Steve Goodman and Robin and the PCORI staff and the members of the committee handled the conflict-of-interest discussion and it's a difficult area. And they were -- we were balancing lots of really compelling arguments around how to get the Methodology Committee more involved, and yet how to handle that with integrity.

And I'm happy where we ended up and I feel that it was really a robust, careful discussion. And I am appreciative of the leadership of everyone who was there. Thank you.

CHAIRPERSON GOERTZ: Thank you for making that important comment. I agree completely. We have Danny, and then I think I'd like to move onto

the next component of this discussion. Danny.

MR. VAN LEEUWEN: I want to appreciate the expertise and diversity of perspectives. I thought for quite some time that we needed to include patients and caregivers on the Methodology Committee and more interaction with our advisory panels, like the patient engagement panel and the rare disease panel. And I really appreciate that. That's been included. Thank you.

CHAIRPERSON GOERTZ: Thank you, Danny.

All right. Now I'd like to ask Sharon and Mary to present the Governance Committee's, you know, recommendation regarding the MC's conflict of interest. So we've been talking about in generalities, we're going to talk about it in a specific manner now.

So, Sharon.

DR. LEVINE: Thanks. And can I have the next slide?

Great. Thanks so much. So I'm not going to repeat much of what has been said, but just in brief, the work that you just heard presented and

the recommendation that we're bringing forward from the Governance Committee, and I also want to thank both Robin and Steve for their commitment to this work and Robin in particular for her longstanding participation in our Governance Committee and the valuable contributions she's made.

Steve Goodman has been saying for a long time, we could do so much more for PCORI. And the recommendation we're bringing forward today, to revise the conflict-of-interest policy and governance framework is a partial answer to how can that happen. And one of the things that has inhibited PCORI's ability to fully utilize and benefit from the expertise in the Methodology Committee is that Methodology Committee members have had the option of either agreeing upfront to not apply for PCORI grants or maintaining that privilege.

And we are left with a very small number of a Methodology Committee members who have the ability to participate more fully in PCORI's work. And so, as Alicia referenced, we spent a fair amount of time

over multiple Governance Committee meetings and Robin and Steve led this conversation with the Methodology Committee and we are bringing forward for your consideration a revision to the current conflict of interest approach in governance framework.

And I'm going -- I'll lead with the conclusion, which is that -- and then Mary will go through the context and the details, but that in the future Methodology Committee members will be required to forego the opportunity to apply for PCORI funding during their term on the Methodology Committee and thereafter -- and that's the washout period that Robin referred to, consistent with PCORI's conflict of interest policies.

In order to make this potentially more palatable that medic Methodology Committee appointment will be a four-year term. And the term and appointments will be staggered every two years to allow for continuity. The Board will be authorized to appoint Methodology Committee members to a second four-year term to the extent necessary.

And I would add desirable, to fulfill the functions of the Methodology Committee requirements of the authorizing law or needs of PCORI. And no Methodology Committee member can be appointed to serve more than two full consecutive four-year terms.

And as you all know, as Board Members, we are limited to two six-year terms on the PCORI Board. Mary, I think -- over to you.

MS. HENNESSEY: Yeah. Thanks so much, Sharon. We thought it'd be helpful to put the Governance Committee's recommendation in some context so that you could understand what the Governance Committee work has been over the past couple years, what the Board has already considered and how the work of the work group and the recent discussions of the Governance Committee, it will move PCORI or is envisioned to move for PCORI to the next level.

And so as has been mentioned, we all know that the reauthorizing law shifted authority to appoint the Methodology Committee members from the

GAO to the Board. And very soon after the reauthorizing law, the Governance Committee began to think about how would PCORI implement this shift in authority? What kind of structure would be helpful to have?

And it had initial discussions and after thinking through a possible framework, made a recommendation to the Board which was taken, and that was to develop the framework that could be ready to appoint Methodology Committee members. And at that time with the Governance Committee's recommendation, the Board approved a six-year staggered term structure. But at that time, the Governance Committee recognized that there would be a need to discuss a conflict-of-interest framework, but it was premature to do that at that time, because it was not yet clear exactly what the Methodology Committee's role would be, how it could contribute to PCORI's strategic direction and the like.

And so, the Governance Committee's initial stage of work did not incorporate a recommendation

on that. Next slide, please.

So for background purposes and to get grounding, we thought it would be helpful to understand what the historic conflict of interest framework has been. And that is that the Methodology Committee has been composed of both members who have decided to maintain their eligibility for PCORI funding and those who have chosen to forego eligibility for PCORI funding.

And this framework resulted in ensuring that there was a structure so that members who maintain their eligibility for PCORI funding are firewalled from receiving advanced information about PCORI funding opportunities. And they could not serve as Methodology Committee leadership or on various committees or work group because of that role enabled them, or potentially gave them access or advance access to information about funding opportunities and the like.

In contrast, Methodology Committee members who decided to forego opportunity for applying for PCORI funding could serve in MC leadership roles,

could serve on strategy committees, and could serve as a resource across PCORI relating to funding priorities and the like.

Next slide, please.

And so, as has been discussed already, there's just a tremendous recognition and the Governance Committee has recognized the tremendous value that the Methodology Committee brings to PCORI in advancing PCORI's research direction, including relating to funding priorities. And that PCORI will benefit from having the full MC membership available to advise PCORI in this area.

And so, as has been discussed the Governance Committee reached out and got feedback from both the Methodology Committee and from the Methodology Committee 2.0 Work Group. And after deliberating on that, getting that feedback has advised -- that the Governance Committee is advising that the Board adopt a revised conflict of interest framework under which all future MC members forego the opportunity to apply for PCORI funding.

And as described, given that shift in

eligibility expectation to forego eligibility to apply for PCORI funding, the Governance Committee is now recommending that the framework, appointment framework shift to a four-year staggered term rather than a six-year staggered term.

Next slide, please.

And so, Sharon already reviewed the specifics of the recommendation of the Governance Committee. If the Board approves this recommended framework of the Governance Committee, then what will happen is with that recommendation approved by the Board, there would be proposed revisions developed to some key governing and conflict of interest documents, including for example, the Methodology Committee charter that would be developed and brought back to the Board for approval to implement the recommended structure.

So I'll turn it back to Christine and Sharon to see if there are any questions or comments.

DR. LEVINE: Just one other comment. We, you know, we are hoping to proceed with this

expeditiously so that we can begin the process then over recruiting additional Methodology Committee members, too, because we do have openings and space and we would love to be able to augment the membership of the committee with other members who can support PCORI and who can offload some of the leadership responsibilities that Robin and Steve have been sharing for a long time now.

CHAIRPERSON GOERTZ: Okay. Thank you. Thank you, Mary. Thank you, Sharon.

All right. Danny, I see your tent is up -- okay, down. Okay, Mike.

DR. HERNDON: Does the conflict of interest preclude Methodology Committee members for being consultants to people, researchers who apply for grants?

MS. HENNESSEY: If I'm understanding your question, you're asking whether it would preclude Methodology Committee members from serving as consultants on research projects funded by PCORI. Is that what your question is? I'm sorry.

DR. HERNDON: So if, I mean, there's so

much expertise and, you know, from the members, if a researcher has a relationship with the Methodology Committee member and wanted to use their expertise and the Methodology Committee member was not the applier, if you will, for the grant, but would be a consultant to and receive renumeration for their consulting activities, that would be precluded as well.

MS. HENNESSEY: Yes. What would be precluded as a Methodology Committee members, similar to Board Members being included in a research project plan and receiving remuneration for that and the like. What it does not preclude is Methodology Committee members, or for example, Board Members, PCORI has tremendous amounts of publicly available information. It does not preclude a Methodology Committee member or a Board Member from pointing research -- the research community to publicly available information about the field about PCORI and the like.

DR. HERNDON: Yeah. I thought so. I just wanted to make that crystal clear. Thank you.

CHAIRPERSON GOERTZ: Thank you. Thank you, Mike.

Any other comments or questions before we move to a vote.

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to, before asking for a motion, I'm going to ask Maureen if there are any updates to Board Member attendance.

MS. THOMPSON: Dr. Goertz, James Huffman has dropped off the call.

CHAIRPERSON GOERTZ: We still have a quorum?

MS. THOMPSON: Yes.

CHAIRPERSON GOERTZ: All right. in that case, I'm going to ask for a motion to approve the revised conflict of interest and governance framework for the Methodology Committee as recommended by the Governance Committee.

DR. ZWOLAK: Zwolak, so moved.

CHAIRPERSON GOERTZ: Thank you, Bob. I need a second.

DR. McNEIL: Barbara.

CHAIRPERSON GOERTZ: Thank you for that. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm now going to call for a voice vote. So all those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions.

[No response.]

CHAIRPERSON GOERTZ: All right. The motion passes. I am incredibly excited to be at this point. I think there's some of us on the Board that have been trying to make this happen for 11-and-a-half years. So it is truly a moment to celebrate and Steve and Robin are really thrilled that we'll have this additional opportunity to access the true, the talents and skills of the members of the Methodology Committee as we, you know, woven throughout our work as we move forward.

And I just want to want to thank you again for everybody that members of the Methodology 2.0 Committee, all the members of the Methodology Committee, and both of you in particular for helping us to get to this point.

All right, we are now going to take a 30-minute break and believe it or not, we are two minutes over. So we're doing great on time today. We'll return at 11:30 a.m. Eastern time.

Just a reminder to those of you who are joining us virtually that the line will remain open. So if you leave you may want to make sure that you are on mute during our break. We'll be back in just a few minutes.

[Recess.]

CHAIRPERSON GOERTZ: All right. Why don't we go ahead and get started?

So the next item on our agenda is our award slates. And we're going to start out with Nakela's overview of the awards that we're going to consider today for approval. Nakela.

DR. COOK: Thank you. You may recall that

as we look at award slates together to monitor progress against what's laid out in the Board approved commitment plan. I usually go through a few slides to give you some context. And so, I'll do that now related to the slates that are under consideration for approval by the Board.

And I want to begin today with a review of the slates are under consideration that are from Cycle 2 of 2021 with just some overarching contextual comments. The first is that just to recall that the slates that are presented today have gone through the multi-step process of merit review and staff review, as well as the relevant selection committee. And at the Board level, the focus really is for consideration of approval of the slates is on the alignment of the slate with the overall goals and priorities of the PCOORI funding announcement.

[Microphone feedback.]

CHAIRPERSON GOERTZ: Everybody turn off your mic and mute yourself. Thank you.

DR. COOK: Okay, great. So the focus today for the Board is really on the alignment of the

slate with the overall goals and priorities of the PCORI funding announcement, as well as the commitment plan.

We can go ahead to the next slide.

So today the Board is going to take a look at slates for consideration for approval. There are six of them. Two of them are from the dissemination and implementation PFAs from Cycle 2 and four are from research-related PFAs from Cycle 2 2021.

And the total amount of funding is 80.4 million across these different slates. There was also a targeted funding announcement in Cycle 2 of 2021 that was focused on intellectual and developmental disability. However, we don't have a slate resulting from that announcement. And I'll mention that in my other remarks in just a moment.

We can go to the next slide.

So let's begin by looking at the dissemination and implementation award slates that are being considered today for Cycle 2 of 2021. These come from a limited competition PCORI funding announcement, as well as a funding announcement

focused on implementing findings from PCORI research investments. And this slide shows how those slates fit into a larger context and how they compare to a historical average. And this historical average is based off the prior three cycles.

So with the approval of the slate, that's highlighted in the lighter blue here for Cycle 2 of 2021, you can see a few things. You can see that we have an increased number of letters of intent and applications, and a greater success in conversion of those letter of intents to invite applications and a higher funding rate as well.

But the absolute numbers are still low. A little larger than they have been in Cycle 1 of 2021.

And as we move out into the future cycle that you see here on Cycle 3 of 2021, those will come in to the Board in the summer timeframe.

Then we have four applications in which has promising in terms of being able to think about having a slate for Cycle 3 of 2021. But you may also recall the limited funding announcement is

limited to findings that come from research funding that are prime for D&I awards. And so, this comes in waves and is really based on what's coming to fruition and coming out of our completed projects from historical funding to make those eligible for one of the PFAs that's listed here.

We can go to that next slide.

So this slide demonstrates how the Cycle 2 2021 slates for the pragmatic clinical studies slate's fit into the larger context. And here you can also see comparison to a historical average. So with the approval of the Cycle 2 slates, there are a couple of things you can see here. That we had fewer letter of intents and applications for the cycle. And we do see that Cycle 2 does have a dip in our applications and awards in general, and we've never fully figured out why that's the case, but we did also issue this in Cycle 1, as you can see here. And so, sometimes having multiple solicitations back-to-back, we've dealt with the pent-up demand.

We have also had, I think given -- and as we're thinking about the PCS for the future, we're

now combining that with our broad announcement. And so, that will be in the first issue of Cycle 1 of 2022. So we're going to have to watch the trends differently moving forward. And so, when we bring slates forward from that new merged announcement, we'll be able to think about it independently, but also have some sense of historical averages between the broads and the PCS slates that we'll bring together for you at that time.

Okay. We can go to the next slide.

So this slide puts the targeted award slates in context for you. And there are three that were issued and the slates that are presented to the Board for consideration today relate to maternal morbidity and mortality, as well as urinary incontinence in women. So the ones that are on the right side of the slide that are bolded. The intellectual and developmental disabilities PFA was one that focused on targeting interventions related to mental health conditions in individuals with intellectual and developmental disabilities.

And in Cycle 2, we did receive LOIs and two

were thought to be meritorious to move on to submission of application. But only one application was submitted and unfortunately wasn't funded.

But it's important to note that while we don't have a slate today for this one, you'll hear about another application that's being funded under the pragmatic clinical studies PFA that actually does hit the target that we were looking for under this PCORI funding announcement. It's focused on ADHD amongst individuals with autism.

And so, the pragmatic clinical studies announcement had a way in which we emphasized some of these areas of interests that we had also identified in this targeted PFA. And that seemed to have been effective.

As we also think about our targeted award slates, one of the things that we did differently with these PCORI funding announcements is that we indicated an opportunity for resubmission and reissue of these funding announcements. And so, the other thing that we're working on is thinking about how we clarify certain areas in order to make sure

that we provide an opportunity and resubmission a reissue.

And we particularly think this is going to be important as well for our maternal morbidity and mortality specified PFA. So I'll talk about that one a little bit next.

We had a really robust response, as you can see, with 26 letters of intent that came in and 12 applications that were submitted. One has been proposed for funding on the slate here. Again, this is an area where we're working on some clarifications of this PFA and anticipate seeing resubmissions. And so, the targeted funds that we had, or the level of committed funds that we had available for these PFAs took into account multiple cycles.

And so, this is an exciting opportunity for us to build on the possibility of responses to these PFAs through those reissues of the PFA.

And then our urinary incontinence PFA, can we go back a slide for a moment?

We had 10 applications that came in for

this one and three are being proposed for funding. And we feel that these three really fulfill the objective of the PFA and we plan to reissue this one.

Let's go ahead.

So I also want to take a moment to look at the broad award slates. And you can see here that the Cycle 2 2021 slate does have that same kind of dip in Cycle 2 for letters of intents and applications. And as I previously mentioned, we tend to see that dip with unclear reasons, perhaps because it's flanked by issues. I'm sorry. Issues of the PFA in Cycle 1 and Cycle 3. So we may not have as much demand in the middle cycle.

But Cycle 3 does look promising with 65 applications submitted and starting again in Cycle 1 of 2021, we'll have the PCS and broad combined. And so, we'll have to track those trends different.

Let's go the last slide and kind of bring it all together.

So this slide provides that context of the proposed commitment plan and the targets and the

commitment plans that you're seeing as well as what we actually have in terms of cumulative commitments against that target with today's slates. And so, on this, on the left here, you can see that for D&I, there was a plan commitment target for $40 million for all D&I awards for fiscal year 2022. And we knew those were ambitious targets. But we have today ahead of us, $9 million worth of cumulative commitments for fiscal year 2022.

And again, slates that will be coming forward in Cycle 3 as well.

And under our research line here, the bottom row here on the table, you can see that we had a commitment target in FY '22 of 500 million for all research awards. And we're at about 121 million with our cumulative commitments with today's slates. But we also recognize that we have a robust Cycle 3 and research awards, including the PLACER PFA, which is a large one for us and was intended to be the larger bulk of funding for fiscal year 2020.

So we do think that we won't recommend at this time revision in our anticipated commitment

plan, but think that we may get close to what were really ambitious targets. But we are hopeful that we can get close to them, given Cycle 3 has many PFAs that will be coming forward before the Board.

And I believe that's where I'll pause and see if anyone has any comments.

CHAIRPERSON GOERTZ: Thank you and Nakela.

Any comments or questions on these general issues before we turn to the specific slates? I see Bob and then Russ.

DR. ZWOLAK: Nakela, any lessons learned from the seeming lack of a successful response to the two new Congressionally mandated areas of interest? Anything that we can take home from the applications or LOIs that didn't make it, that will fashion a more successful solicitation next time?

DR. COOK: Yes. And in fact some of those things have happened already in terms of speaking with those that applied and understanding some of the issues that needed both clarification in reissues of the PFA, as well as I think in some being relatively new to applying to this type of

approach, having that opportunity for resubmission was thought to be a really promising one because after our first application getting reviews and feedback, being able to incorporate that in a resubmission, we think is going to be extremely helpful.

So I think we have a couple of approaches that we're hoping will help us with the second issue already. And hopefully that those lessons learned will help us, even as we're thinking about other PFAs.

CHAIRPERSON GOERTZ: Thanks Bob. Russ.

DR. HOWERTON: I just have an editorial. Am I misremembering or misunderstanding or should the second row in most of those slides under LOIs submitted have been applications invited? Because it said LOIs invited in the second row.

DR. COOK: LOIs invited for --

DR. HOWERTON: Can you go back one or two more.

DR. COOK: Yes, I think I know what you're -- so --

DR. HOWERTON: Wouldn't it be applications invited in the second row and then applications submitted?

DR. COOK: It should be LOIs invited to submit applications. Yes. So the LOI --

DR. HOWERTON: Oh, I'm just forgetting the second -- I mean it -- just, to me, it reads we've asked you, we've invited you to send an LOI after you've sent an LOI.

DR. COOK: I'm understanding we can make some clarifications on that for the future.

DR. HOWERTON: Thanks.

CHAIRPERSON GOERTZ: Yeah. Good point, Danny.

MR. VAN LEEUWEN: How much is methodology an issue in terms of the challenges of successful applications for these new arenas of applications?

DR. COOK: Particularly, in the ones related to intellectual developmental disabilities, we do see that as an issue. And that was something I think that came up when we were talking about the Methodology Committee 2.0 framework.

And we've had some workshops in thinking about that and are recognizing that's an area where we probably have to work, even in some of the questions that we put out for CER questions, what really can be answered with some of the methods that are available.

Targeting certain populations has been one approach, but, you know, we were also looking at are there cross-cutting questions across, and that's where we run into a lot of methods issues.

CHAIRPERSON GOERTZ: Thank you, Danny.

Are there any -- is there anyone who's joining us virtually who'd like to make a comment or has a question?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case we were going to move to the specific slates themselves. I'm going to ask Mike Herndon, Chair of the Engagement, Dissemination, and Implementation Committee to introduce the D&I awards slates.

DR. HERNDON: Thank you, Christine.

So during this session, this portion of the

session we'll present the two proposed D&I award funding slates for Cycle 2 2021. As a reminder, PCORI's Engagement, Dissemination, and Implementation Committee is responsible for recommending funding slates to the Board of Governors for all D&I awards having a budget larger than $500,000.

So in February the EDIC endorsed both slates that you'll hear about today. I'm going to now go ahead and turn this over to Joanna Siegel, who will present the Cycle 2 2021 award slates that the EDIC is recommending to the Board for approval. Joanna.

DR. SIEGEL: Thank you, Mike. As Mike said, I'm going to be presenting two proposed D&I slates today.

The first that you see here is for our limited competition funding initiative, which is designed to provide the opportunity for awardee teams who've completed PCORI-funded research to take the next steps in promoting the uptake of the evidence into practice and to lay groundwork for

broader future uptake.

This slate today includes two projects, both of which are proposing to implement findings from studies funded through PCORI's improving health systems or IHS research priority area.

The first project will optimize sickle cell disease care at infusion centers in nine health systems increasing access to specialized pain management services for patients with sickle cell disease. The original PCORI-funded research saw that effective infusion center care halved wait times for these patients as compared to patients receiving care in the emergency department. This project will improve both care experience and patient-centered outcomes for patients with sickle cell disease.

The second project will implement a program that uses therapist's report cards to pair patients with therapists based on patient's primary health concerns and therapists' strengths. The project is putting this program into place at nine mental health clinics in Pennsylvania. And then rapidly

scaling to more than 50 additional centers in 12 states.

The total funds requested for these two proposed projects is $6.4 million.

The second slate is for our implementation of findings from PCORI's major research investments PFA, which is an open competition funding initiative that has the goal of promoting the uptake of findings from specific PCORI-funded research topics in the context of the body of related evidence. The project being recommended for funding today will increase access to and delivery of evidence-based first-line conservative management treatment for urinary incontinence in women aged 60 and over as you know, most women with UI do not seek and do not receive care for UI despite findings from a recent PCORI-funded systematic review update conducted in partnership with AHRQ that documents the evidence in support of effective non-surgical treatment approaches.

This project we'll use a virtual approach to screen, treat, and provide referrals as needed

for more than 26,000 women in Southern California.

The total funds for this proposed project are $2.5 million.

And one additional note on this project is that it compliments a recent AHRQ funding initiative on the same topic, following the PCORI-AHRQ collaboration around both of our implementation efforts. Next slide please.

So this slide shows the motions that you'll be asked to vote on in the next slide, which is the formal voting slide. And we can go to that next slide and I'll turn it back to you, Dr. Goertz for any questions and for the vote.

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

Before we begin any discussions? Jennifer DeVoe and Jim Schuster have notified us of their intent to recuse themselves from the deliberative discussion and vote on the D&I award slates.

If any other Board Member feels that they should recuse themselves from this discussion and vote, please feel free to do so.

The floor is now open for discussion. Any comments or questions for either Joanna or Mike?

Russ.

DR. HOWERTON: Do you share the optimism that the next cycle we'll hit our goal for D&I for this year?

DR. HERNDON: Well, you know, the role of the EDIC really is to put forward recommendations for what to proposed to us. And these limited competition awards, just as a reminder to everyone, is for researchers that have done a research project for us.

And so, the first two, they have to number one, be interested in the dissemination phase of what their research project was. And so, you know, we have discussed that Russ and missing the mark, you know, for the number of meritorious awards. But I think there was one, for example, I'll be candid that just did not meet the standards that was presented and met some of the criteria, but did not meet the criteria.

So again, if it's meritorious, we want to

effectively get the evidence disseminated, but I'll let Joanna answer any questions, Russ, more input to answer Russ's question.

Joanna, do you have further comments?

DR. SIEGEL: Thanks, Mike. You know, it's hard to predict any specific cycle, but we certainly are seeing plenty of interests in terms of calls coming in. And in terms of the increasing number of findings that are arriving at peer-review and then becoming eligible for funding.

So we are optimistic, I can't say specific numbers, but I'm certainly seeing the program strengthened over time.

DR. HOWERTON: Okay. Thank you. I'm not judging any of the actions, I just will say vis-à-vie our discussions yesterday, creating knowledge, demonstrating that we can then invest in implementing and disseminating it and having turned out, that is our reauthorization discussion. I mean, that, that virtuous cycle will self-reauthorize if we can do that.

DR. SIEGEL: We very much appreciate that,

thank you.

CHAIRPERSON GOERTZ: Yeah, thank you, Russ.

Nakela did you want to make any comments?

DR. COOK: I would just maybe say overall, I think Joanna is spot on and that we're starting to see more results come to fruition that may be ripe and ready for thinking about dissemination and implementation.

But I think to your specific question about Cycle 3, I do think that's an ambitious goal for Cycle 3 for our dissemination and implementation slates trying to move to the 40 million from the 9 million commitments we have currently. And I'm not sure one cycle will do that for us, but we were seeing that trajectory overall.

CHAIRPERSON GOERTZ: Okay. Any other comments or questions?

[No response.]

CHAIRPERSON GOERTZ: In that case? I'm going to ask Maureen if there are any updates to Board Member attendance.

MS. THOMPSON: Yes, Dr. Goertz, Kara Ayers

has left the meeting. James Huffman has left the meeting. And we still have a quorum.

CHAIRPERSON GOERTZ: Okay. Thank you, Maureen.

All right, I'm going to then ask for a motion to approve funding for the two recommends slates of awards from the Cycle 2 2021 dissemination and implementation PFAs.

DR. HWANG: Motion to approve. Connie Hwang.

CHAIRPERSON GOERTZ: Thank you, Connie.

DR. LEVINE: Second. Sharon Levine.

DR. FRIESE: Chris Friese, Second.

CHAIRPERSON GOERTZ: Okay. I heard Sharon first, but thank you, Chris.

All right. Are there -- I'm going to ask all those in favor then to please say -- is there any further discussion first?

[No response.]

CHAIRPERSON GOERTZ: All right. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. The motion passes. Thank you. Congratulations to the investigators on these awards.

I am now going to turn the meeting over to Vice Chairperson, Sharon Levine to chair the next agenda item.

DR. LEVINE: Thanks Christine. And as we move to the next item, I'm going to invite Barbara McNeil, Chair of the Selection Committee to introduce the research awards slates.

DR. McNEIL: Oh, hi. So the Selection Committee met in February and we reviewed two PFAs from the broad and pragmatic clinical studies. One involved improving postpartum maternal outcomes for populations experiencing disparities. And we also reviewed non-surgical options for women with urinary incontinence. Those were targeted PFAs.

The committee did their work by reviewing

the merit review panels, the scores from the merit review panels, and then quite importantly, we reviewed and considered the scientific program staff recommendations.

And in this case, we looked upon their reviews of issues that had been raised in the review process. We looked at the programmatic fit of these applications, the portfolio balance, and whether these applications were consistent with funding announcements.

So Carly Khan will now present the slate, this first slate.

DR. KHAN: Great. Thank you, Barbara. Hi everyone. My name is Carly Khan. I'm an associate director in PCORI's Healthcare Delivery and Disparities Research Program. And I'm pleased to present the pragmatic clinical studies overview and slate recommendations for your consideration today.

So again, briefly, just a reminder, the pragmatic clinical studies funding announcement has a direct cost cap per study of $10 million and seeks to fund clinical trials, large simple trials, or

large-scale observational studies.

Next slide please.

Okay. So these Cycle 2 studies are being recommended for funding by the Selection Committee. Each study proposed for funding is a multi-site randomized trial. And very broadly, the studies will examine the comparative effectiveness of pharmacologic management of attention deficit hyperactivity disorder, or ADHD, in children and youth with autism.

And the second will compare population management approaches for chronic obstructive pulmonary disease, or COPD, patients in primary care.

And the total requested funds for these two studies is $18.9 million. And now I'll turn it over to Els Houtsmuller to present the next slate. Thank you.

DR. LEVINE: Els, are you there?

DR. HOUTSMULLER: Yes, I am. I'm sorry. I had a little bit of trouble.

Thank you, Carly. Hi everyone. I'm an

associate director in the Healthcare Delivery and Disparities Research Program at PCORI. And I will be introducing the proposed slate for our targeted funding announcement that focused on improving postpartum outcomes, maternal outcomes for populations that are really experiencing the worst disparities.

Next slide, please.

Okay. We are proposing to fund one study that is a large multi-site cluster randomized study that looks at a trauma informed approach to timely detection and management of early postpartum hypertension. The total funds requested are a little over 20 million. And with that, I want to hand it over to my colleague Nora. Sorry, with that I want to end this presentation.

DR. McGHEE: Thank you Els. Hello everyone. My name is Nora McGhee and I'm a senior program officer with the Clinical Effectiveness and Decision Science Program at PCORI.

I'm pleased to present the Cycle 2 2021 non-surgical options for women with urinary

incontinence funding announcement overview and slate recommendations for your consideration today.

With this targeted announcement, we sought studies that address the comparative effectiveness of various non-surgical approaches to address urinary incontinence in women. This announcement was developed in consultation with those working on the related implementation announcement that you heard about earlier, and they are complimentary to one another.

The funding announcement has direct cost cap of $5 million per study. And studies can last up to five years. Next slide.

This cycle, three applications are being recommended for funding by the selection committee. They are all randomized multi-site trials. These studies will collectively compare both clinical and systems approaches to address the needs of women with the three main types of urinary incontinence: urge, stress, and the mix of both.

The first study will compare or reduce those to standard dose of Onabotulinum Toxin A. The

second compares two methods of care delivery: advanced practice provider co-management versus electronic co-management. And the third compares oral use of the beta adrenergic Mirabegron to Onabotulinum Toxin A.

They will all examine the impact on both symptom severity and a range of quality-of-life measures for this common challenging condition. The total funds requested are $19.5 million.

I'll turn it over to Steve Clauser now to start the presentation of the broad slate.

DR. CLAUSER: Thank you very much, Nora.

We'll now transition to consideration of our broad funding announcements slates. I'm joined by Stanley Ip who will present the methods slate. Next slide.

You know, this is a consensus slate for the improving healthcare systems broad funding announcement. This announcement seeks to fund investigator-initiated research that compares the effectiveness of alternative evidence-based delivery strategies and policies that are intended to

optimize quality outcomes and efficiency of patient-centered care and have great potential for sustained impact and replication.

Interventions response to this PFA tend to emphasize technology workforce incentives, organizational policies that are important to patients and other stakeholders, including payers and employers.

Now this slate on this slide is proposed for the Cycle 2 2021 announcement. Both are clinical trials. The first study compares options for improving outcomes for hospital and home transitions among children with complex diseases. And the second study compares alternative strategies for improving symptom monitoring with supported clinical follow-up among adult patients with kidney failure who are treated with hemodialysis.

We're requesting 8.6 million to support these two projects. Next slide.

Now I'll turn it over to Stanley to discuss the methods slate.

DR. IP: Thank you, Steve. Hello everyone.

My name is Stanley Ip. I'm Interim Program Director for Clinical Effectiveness and Decision Science.

I'm pleased to present to the Board for consideration the methods awards slate. As you can see on this slide, there are a total of four studies on this slate and all of them aimed to improve different aspects of conducting comparative effectiveness research. Two focus on the use of machine learning and two focus on the use of observation of data.

The total amount of this is $4.1 million. And thank you. Now I turn it back to you, Dr. Levine. Next slide.

DR. LEVINE: Thanks Stanley. And before we begin any discussion, I want to let the Board know that the following Board Members have asked to be, or have indicated their intention to recuse themselves from the discussion and the vote on the research award slates. Kara Ayers, Jen DeVoe, Christine Goertz, Mike Lauer, Barbara McNeil, and James Schuster are all recusing themselves.

And if there is any other Board Member who

believes they should add their name to the recusal, please free to let us know right now.

And I assume we still have a quorum, Maureen?

MS. THOMPSON: Yes, we do Dr. Levine.

DR. LEVINE: Okay. Great. The floor is now open for discussion. Please identify yourself before making a comment. Alicia.

DR. FERNANDEZ: I don't want it to make a comment about the maternal mortality because what got approved is about the management of hyper-tension. Obviously, that's a really important deal -- a really important area.

I think that it's taken me as someone who doesn't know very much about maternal mortality, it's taken me a while to sort of even just grasp one really important fact that I thought I would share with folks, because I think it'll inform our discussions going forward.

And that is that while maternal mortality in the U.S. is twice that of other developed countries there -- the U.S. -- in most years loses

around 600 women under maternal mortality. And that's you know, unacceptably a large number, but that said just to put it into context. It is last year, San Francisco had 800 deaths from opiate overdose in one city alone.

The reason I compared this is just to give a sense of order of magnitude, which I think can be really hard to grasp. And it's really made me start thinking about how hard it will be to do research that will end up lowering this unacceptable high death rate because of the difficulties of doing research and that is in a large country, with relatively few outcomes.

And I just wanted to -- I have nothing more interesting to say, except to put that on the table for all of us to think about as we move forward. And to say that many of the things that were going to be seeing, like this thing about improving hypertension, are still extraordinarily important in as much as it may result in providing evidence to improve care for many women who will suffer morbidity from their pregnancy irrespective of

maternal mortality. I hope this is helpful.

DR. LEVINE: Thanks, Alicia. And I would add to that, that average number doesn't represent the enormous range across the country and even within for example, California, where there's a huge difference between counties in terms of the rate of maternal mortality. Access to quality of care, institutional bias, all go a long way to -- the last time I looked at it, I think the state of Georgia had something like 10 times the number of women dying in the postpartum period compared to California, for example. And within California, an eight-fold difference between counties.

So on average it's a small number, but certainly there are geographic locations and where the numbers are on an unacceptably large.

Any other comments, any other points of discussion?

[No response.]

DR. LEVINE: If not, can I have a motion to approve the Cycle 2 research awards slate?

Oh, sorry.

DR. HWANG: Sorry, Sharon. I was slow on the flip of this, but it's just a comment. I'm excited actually to see in these in the pragmatic category some work on machine learning. And so, looking at that, it looks like starting to think about how to look at comparative effectiveness, you know, treatment effects.

My only comment is I see from where I stand seeing the landscape, a lot of population health solutions that are leaning further on AI and machine learning. And I think some of the challenges out there is to understand what sometimes appears to be a black box about, you know, whether this is really going to deliver the outcomes and how you know, how does it actually do that -- how does it work? How consistent is it?

So I'm excited to see PICORI funding some projects in the space and hopefully to expand that further.

DR. LEVINE: Thanks Connie.

Anything else?

[No response.]

DR. LEVINE: Okay. Can I get a motion to approve the Cycle 2 research award slate?

DR. RHODES: So moved.

DR. LEVINE: Thank you Karin. Can I get a second?

DR. ZWOLAK: Second

DR. LEVINE: Thanks Bob. And I'll call now for a voice vote. All those in favor, say aye.

[Ayes.]

DR. LEVINE: Any opposed?

[No response.]

DR. LEVINE: Any abstentions?

[No response.]

DR. LEVINE: The motion passes and I will turn it back to Dr. Goertz to chair the remainder of the meeting.

CHAIRPERSON GOERTZ: Thank you, Dr. Levine.

All right. I'm now going to ask Dr. Cook to provide an overview of our targeted PFAs.

DR. COOK: Excellent. Well, I'm excited to talk with you a little bit about where we are with our process for development PFAs, developing PFAs

while our strategic planning's been underway. And we can go ahead to our next slide.

You can see here that we've released eight targeted PFAs to-date, since we talked with you about a candidate -- a set of topics that we wanted to advance for targeted PFA development while strategic planning was underway.

And the ones that are italicized on the table and the Boards just considered approving the funding for the resulting slates that come from those PFAs. And in addition to what you see here over this time period, we've also released two special areas of emphasis for topics in our broad PFA. And we've been using those special areas of emphasis to also kind of tee up or prime the community for applications related to what may come later in terms of targeted announcements.

And the two topics related to special areas of emphasis for one around telehealth for chronic disease management amongst from vulnerable populations with complex needs. And we released that as a special area of emphasis in the broad

announcement to expedite some of the opportunities related to COVID-19.

We also had a special area of emphasis around addressing racism, discrimination, and bias in healthcare systems and care delivery, which we think will also help us with getting some footing related to some of the things that may come forward around the health equity initiatives.

Let's go to the next slide.

So in April of last year, the Board approved a large set of candidate topics for targeted PFA development or special areas of emphasis through the 2022 funding slates or funding cycles. And on the left are the topics that have moved forward as targeted PFAs or special areas of emphasis. And you can see the two special areas of emphasis that I mentioned there. The last two at the bottom with an asterisk.

And one of the things that as you look going forward into the Cycle 2 2022 and Cycle 3 2022, you see that areas that we're continuing to work on. And today you're going to see the

hypertension control targeted PFA.

But I want you to also remember that these are in addition to PCORI funding announcements related to COVID-19 maternal morbidity and mortality and intellectual and developmental disabilities. And we always thought that those would be ongoing in addition to those that were on this list of candidate topics that were approved by the Board.

And for maternal morbidity and mortality and intellectual developmental disabilities. There are three special areas of emphasis that are planned for Cycle 2 2022 that you don't see here. So just to mention them. One's related to aspirin use and preeclampsia and other related to postpartum hemorrhage, and a third related to caregiver-mediated interventions for individuals with intellectual and developmental disabilities.

One of the things that I think this candidate set of topics did for us, is it allowed for some longer-range planning, as well as a focus on some of the staff resource, providing as well that greater lead time for research teams that want

it to come together around these different areas. And we were hopeful that it would increase applications and submissions, and we'll track that in order to report back on this kind of experimentation that we had this year with the support.

I think we can -- one other thing I may mention is -- can we go back for one point.

I just wanted to add that while you see the timelines that we've added for the future cycles for Cycle 2 2022 and Cycle 3 2022 here, they are tentative. But we wanted to make sure that we're ready for the release and these time periods, but they give us targets. And that's part of what we want to set out with this candidate set of topics.

And then the last thing I'll mention is that you're going to see before you, in addition to the hypertension control PCORI funding announcement today, science of engagement for PCORI funding announcement, and it wasn't originally on this list of candidate topics. Partly because of that time, it wasn't anticipated that it would come in as it is

now ready to come forward to the Board, but we certainly wanted to make sure that we bring that important topic to you.

You can go to the next slide.

So here you say that the Board is going to consider two targeted PFAs that have been recommended by the Science Oversight Committee for Cycle 2 of 2020 to the health system strategies to address disparities in hypertension management and control PCORI funding announcement and the one around advancing the science of engagement. And again, these two total up to $86 million in terms of thinking about potential funding commitments, and we have opened or anticipate opening these PFAs for multiple cycles similar to the way we talked about in the past with some of the PFAs that came forward to the Board previously to allow for the resubmissions that may need to come forward, as well as reissues for more opportunities for new research teams to come together around awards.

We can go ahead to the next slide.

And I think that's where I pause to see if

there are any questions or comments related to these and then we'll go into the specific announcements.

CHAIRPERSON GOERTZ: Thank you Nakela, any general questions before we move into the specific PFAs?

[No response.]

CHAIRPERSON GOERTZ: All right. Seeing none. I'm going to ask our Science Oversight Committee Chair Alicia, to introduce the targeted PFAs proposed.

DR. FERNANDEZ: So on behalf of the Science Oversight Committee, I'm pleased to recommend to the Board, the development and funding of two targeted PFAs that Nakela has just highlighted and set into context for us. The SOC has discussed and approved these topics for the Board's consideration today. And we look forward to recommending additional topics to the Board in the future.

So today's topics or the health system strategies to address disparities in hypertension management and control and the science of engagement.

And I turn now to Els Houtsmuller and Hillary Bracken to describe the first topic.

DR. HOUTSMULLER: Thank you. Alicia, so this first targeted PFA focuses on the research question of the comparative effectiveness of health system strategies to improve blood pressure control for those populations that are experiencing the disparities in outcomes.

And some of the examples of those populations are listed on this slide. So these are Black, Hispanic people, people who live in rural areas and also people who are uninsured.

Next slide, please.

So for this targeted funding announcement, we are asking for studies that include populations, adults with hypertension, and then especially in those populations that are experiencing disparities. The interventions and comparators are listed on this slide and they really are -- these are examples of interventions that have evidence or are in use to -- and they have evidence regarding management of blood pressure, et cetera, and/or are in use.

So we are asking for a number of these interventions, and they can be combined as well.

The outcomes are a blood pressure. And there are specific parameters that we're using that are in use. Also the patient experience of care and patient engagement in care. Also self-management, health-related quality of life, and costs.

We are asking for follow up of 18 months or more. And the settings we're interested in are really community settings, primary care, and safety net settings.

Next slide, please.

The total that we're requesting for this PFA is 50 million. We are estimating -- we are thinking that we will release this funding announcement in two to three cycles in order to really make sure that we get the studies that can address this evidence gap. And so, we are estimating that that would be about four or five studies.

The direct cost per study will be up to 10 million for small studies and up to 15 million for

larger studies with a project duration of up to five years.

Next slide, please.

And I will now hand it back over to Alicia.

DR. FERNANDEZ: Can I call for a motion to approve --

CHAIRPERSON GOERTZ: Wait, I'm going to -- I'll take --

DR. FERNANDEZ: Oh, that's what I was asking.

CHAIRPERSON GOERTZ: Okay. That's great.

All right. Thank you. Thank you, Els and Alicia. Now I'd like to open it up for discussion. Any comments or questions for either Els or Alicia on this motion?

We'll actually be voting on these two PFAs separately. So the first one will be that the one on hypertension.

[No response.]

CHAIRPERSON GOERTZ: All right. I am not seeing anything. So I'll Maureen, are there any updates to Board Member attendance that I need to be

aware of?

MS. THOMPSON: No.

CHAIRPERSON GOERTZ: Thank you. All right.

In that case, I'd like to ask for a motion to approve the development of a health system strategies to address disparities in hypertension management and control targeted PFA with funding up to $50 million in total costs.

DR. HERNDON: Mike, so moved.

CHAIRPERSON GOERTZ: Thank you, Mike.

MR. VAN LEEUWEN: Second, Danny.

CHAIRPERSON GOERTZ: Danny is second, and thank you. Any further discussion.

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'd like to call for a voice vote. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: Okay. Thank you. I'd now like to invite Kristin Carman and Laura Forsythe to present on the development and funding of the targeted PFA and advancing the science of engagement.

DR. CARMAN: Thank you so much, Dr. Goertz. My name is Kristin Carmen, and I'm the Director of Public and Patient Engagement. I'm very pleased to be presenting this initiative with my colleague, Laura Forsythe, who you can see here, who's the Director of Evaluation and Analysis.

This initiative really builds on the activities and information shared in previous board meetings. And we're really here to talk about the science and the study of engagement and research, which is, you know, the engagement in research is the meaningful involvement and partnership of stakeholders throughout the entire research process, ultimately to improve the comparative effectiveness research we fund, as well as the uptake in the use.

Can we go to the next slide please?

So what we're recommending for this PFA is

we really have arrived at these questions of interest based on critical evidence gaps. We've identified in the literature and pulled it from the relative strategic committees, external parties who responded to the request for information, as well as really external funders perspectives.

Now the activities that we're outlining here for the PFA are to address near-term priorities and truly foundational work that's necessary to move this field forward. So a key feature of these efforts will also to be ensure relevance to diverse populations.

Our first area of focus you see on this slide is the development of validation of measures with a particular emphasis on rapid measure development. At a high level of the gaps we hope to fill, include new measures, strengthening and validating measures that have already been developed, as well as adapting measures from really adjacent fields. Engagement in health care or community health promotion, things like.

Our second recommended area of focus is

development of new and testing of commonly used engagement approaches, particularly for historically underrepresented populations.

Now, while the practice of engagement is increasingly common engagement as an intervention has really been less systematically studied. And what has become increasingly clear is that we need to develop the rigorous evidence both investigators and their stakeholders are calling for.

Next slide, please.

Today we're asking for the Board to approve $36 million for research on the science of engagement over three years. That's an estimated nine cycles over those three years, as you can see, there are two levels of direct cost per study. The studies up to 500,000 are for awards that will develop or validate engagement measures. The studies up to 1.5 million are for awards to test engagement methods.

Over time, we do anticipate a shift in emphasis from measure development towards growing the evidence-based and effective approaches to

engagement. Next slide, please.

With that, I will turn it back over to Dr. Goertz for any questions and the Board vote.

CHAIRPERSON GOERTZ: Okay. Thank you so much, Kristin and Laura. All right. Are there are there any questions. Mike.

DR. HERNDON: A comment, not a question.

Yeah, I just wanted to be one of the first to put my support behind this. And the EDIC has had several conversations with Kristin and Laura. And you know, as representative for the EDIC and as a representative for the states, specifically as payer and policymaker, I wanted to just voice my support because this science of engagement PFA has the potential to be a game changer. I believe.

It was obvious to the EDIC from the responses we got from the letter of interests that we -- or the request for interest in we had from our research community and partners that, you know, there's a paucity in evidence around engagement. It just does not really exist, especially on the measurement.

And so, I think the research community is very interested in this and will be very supportive of this effort. And I'll only wish that, you know, I had had, you know, some evidence for engagement in some of the programs and things that we were trying to implement, especially from a quality improvement perspective, you know, as a policymaker.

So I really do think that, you know, from building, you know, more and stronger evidence on the sites of engagement on engagement itself, that PCORI will, number one, we'll be better prepared -- ourselves, and as an organization and other organizations and individuals will be better prepared for this, for the engagement that is necessary for effective research.

I think secondly, that we will be able to support evidence-based approaches to engagement that our researchers and partners will need to have more meaningful influence on the research design and conduct.

And then lastly, just that the research is going to be more meaningful. We'll have better

recruitment. You know, Nakela talked about one of the barriers, you know, to the HERO trial. You know, I think this is a good example of how this science and engagement could really lead to a large impact and some of our more important studies.

So with all of that, I just feel like it, this is something that PCORI needs to do to support our long-term and short-term goals. You know, the research and the findings that we generate. So thank you, Dr. Goertz. Thank you.

CHAIRPERSON GOERTZ: Thank you, Mike Connie, did you -- okay? All right. Any other comments or -- Bob?

DR. ZWOLAK: Thank you. I'd like to ask the staff or perhaps Robin or anyone who may know this, whether we have a sense through our preparations of whether there are sufficient scientists who are experts in the science of engagement to take advantage of this.

I know that from time to time, some of us have speculated that one of the reasons that our comparative effectiveness funds have not been

totally used is potentially the lack of highly qualified comparative effectiveness scientists. I think that several years ago, we looked into that and thought that wasn't the case, but the science of engagement -- relatively new, are there enough trained scientists out there to take advantage of our offer? And should this be an area where we should think about funding education in the science of engagement?

DR. FORSYTHE: Yeah, that's a great question. And I will say that we believe there are people out there who are ready and eager to have this opportunity and they just need the resources to get the work done. We heard a robust response in our requests for information that there's people out there that want to do this work. And from other funders that this is really a gap that PCORI can uniquely fill to give people the resources.

At the same time, I will say we are also aware of the work we need to do to do some capacity building and field building. And we are thinking about the opportunities that we need to put in place

to provide that support for applicants, for the people we award, and for the communities that will participate.

And that's one reason that we are asking for this funding to be over three years so that we can build a program and let the community know that this will be available as they, you know, get prepared to submit some robust applications. So we're looking for this to grow over time over, over those years.

CHAIRPERSON GOERTZ: Thank you. Thank you, Laura. Any other further questions? Oh, Robin.

DR. NEWHOUSE: I just wanted to mention that Agency for Healthcare Research and Quality had R24s, and there were, I want to say about 13, which were broad that included methods related to engagement or PCORI methods, I would say.

But in addition anyone that has a Clinical Translation Science Institute has an engagement core. So I can't tell you if there's a right number for submission, but I would say that this is something on the radar that might need some focusing

and refinements in terms of the training. You know, I think methods transcend -- qualitative and quantitative methods transcend the content of what you're studying.

So I think that's good, but it will give the opportunity to really refine that science to a community of scholars with an expertise in this area if there are fewer than we anticipate.

DR. CARMAN: I would just amplify that there are many scholars and individuals who have been conducting work in this area and research sometimes under-resourced, we might suggest because there hasn't been as much funding in this area. We actually think there is. I don't know if the word is a pent-up demand, but I think there are a lot of individuals who are going to be very interested in this. And we certainly found that out in the request for information, and as Laura mentioned, our approach to this really is to think about how do we build the field and these methods.

And also got a lot of great advice from the Methodology Committee on how to think about this as

well. So very grateful for that, too.

CHAIRPERSON GOERTZ: All right. Thank you. Anything else?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case --

DR. HERNDON: I might just mention -- just lastly, that I think when I was talking about the kind of positive evidence and stuff, it's a lot of it's around the measurement of engagement. And I kind of mentioned that, but I don't know if I stressed that enough. That is where I think there's -- not only do we want the science, but that was one of the things that the EDIC members, we were asked to respond to. That was one of the things that we really felt like there was a significant need.

So just to put a little extra focus on that need as well, specifically on how to measure engagement.

CHAIRPERSON GOERTZ: Thank you for that additional point.

All right, Maureen, I am assuming that we

that we still have a quorum, correct?

MS. THOMPSON: Correct.

CHAIRPERSON GOERTZ: All right. In that case, I'm going to call for a motion to approve the development of the advancing the science of engagement targeted PFA with funding up to $36 million in total costs.

DR. RHODES: So moved.

CHAIRPERSON GOERTZ: Thank you, Karin. I appreciate it.

DR. HERNDON: Second.

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

[No response.]

CHAIRPERSON GOERTZ: All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: Great. Thank you.

Thanks to both the SOC and the staff for the incredible amount of work that goes into developing these two really exciting PFAs. We are just a little bit ahead of time, and I'm wondering if the Board would like to move forward with our next agenda item.

We do not have any public comment scheduled, so we'll be able to we have the potential to finish a little bit early today and we may have to push it into our one-hour lunch period, just a little bit, but if you're okay with that, we can move forward with our Learning Health Systems 2.0 discussion.

Anyone who has any concerns about that?

[No response.]

CHAIRPERSON GOERTZ: All right. Anyone online who would prefer that we did not do that.

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to invite our Research Trans-formation Committee Chair Kathleen, to introduce our next agenda item, which is the PCORI/AHRQ Learning

Health Systems 2.0 Initiative, Kathleen.

MS. TROEGER: Thank you, Dr. Goertz.

Sound check?

CHAIRPERSON GOERTZ: Yes, we can hear you fine. Thank you.

MS. TROEGER: Thank you very much. So on behalf of the Research Transformation Committee, it's my privilege today to both introduce and recommend the following initiative to the Board, which is the PCORI/AHRQ Learning Health Systems Initiative.

This initiative builds on the success of the Learning Health System 1.0 program, and it's really been both informed and reviewed with feedback from the Science Oversight Committee and has been the subject of really robust discussions and review from the Research Transformation Committee back in February. Following the February deliberations of the Research Transformation Committee recommended that the Board move forward and approve this initiative after the presentation and deliberations today. And as well as the collaborative initiative

with AHRQ.

So I look forward to comments both from Chris Friese, I believe. And I will turn this over to Steve Clauser to really walk us through the PCORI/AHRQ Learning Health System Initiative from here. Thank you.

DR. CLAUSER: Thank you very much, Kathleen. I'm pleased to be here to present our concept for the LHS 2.0 Training Initiative. But before I describe the concept, I did want to emphasize. That the LHS 2.0 is the first of several funding concepts.

We plan to bring to the Board to set a strong foundation for training opportunities in clinical and patient-centered outcomes research that will strengthen the clinical and health systems research in learning health systems, as well as develop new pathways for these scholars and other researchers to obtain training, to perform clinical effectiveness research, and participate in our dissemination implementation research in response to PCORI and AHRQ funding opportunity announcements.

And as you'll see some of the innovations in LHS 2.0 are designed to begin that process.

Next slide.

You know, Ms. Troeger went over some of the information that we had on the nature of the program. And I just want to make a couple additional comments.

First of all LHS 1.0, which is the current training program, is a collaborative effort between AHRQ and PCORI where PCORI provided significant funding for the initiative AHRQ administers the program and staff from both organizations jointly monitor and oversee the program.

AHRQ has been an invaluable partner in supporting this program, given their extensive expertise in training programs and their willingness to work together with us to meet both organizational goals. And they have been a great collaboration in this process. And we propose to continue this partnership for LHS 2.0.

And second, the Learning Health Systems Training Program 2.0 is going to be a new training

program that's distinctly different from other training programs that AHRQ supports. In our new program, we are presenting today we are going to build on the successes and lessons learned from the current training program to expand opportunities for training, research, and career opportunities for embedded health systems researchers.

Next slide.

Now this slide summarizes the purposes and objectives of the current LHS training program, utilizing the K-12 training mechanism. The purpose of the current program is to prepare newly trained clinicians and research scientists as embedded health systems researchers by supporting research in the partnering systems themselves. And supporting this goal was a set of objectives that are the focus of the current program.

A curriculum was needed for training investigators and embedded health systems research, as well as training in patient-centered outcomes research, do activities that involved engagement of patients and stakeholders in research and our PCORI

methodology standards. Also clinicians and research scientists and mentors were needed to be identified and recruited into the training program who are committed to conducting this research in health settings with the goal of improving quality of care and patient-centered outcomes.

Also centers of excellence need to be established that linked research training programs with health delivery systems to support the training of scholars in research competencies that were meaningful and supported by health systems.

And finally, learning collaboratives that needed to be developed across centers to promote development, but shared curricula to support scholar-mentor interactions across centers.

Next slide.

Now we actually commissioned an interim evaluation to the program to assess our progress in meeting the goals of the program. And some of this detail was presented, available in the briefing book and Ms. Troeger highlighted some of them in her opening remarks, so I'm just going to touch on a few

highlights.

Ms. Troeger mentioned the strong participation of scholars and mentors in the program, but another success for us that came from the evaluation was the diverse professional backgrounds of the participants. Scholars included primary care physicians, surgeons, nurses, psychologists, pharmacists, health systems, researcher, and even a system engineer.

The 11 centers who have collaborated in developing a robust training curriculum and program relevant to learning health systems competencies central to embedded health system research and competencies, the domains were developed in seven areas.

And I'm just going to summarize the three domains that they fall in. One is defining attributes and competencies about LHS scientists and researchers and trying to match them into very specific learning activities with an emphasis on experiential learning within the systems themselves.

Communicating the value proposition of

healthcare delivery organizations, to sustain the embedded researchers.

And finally, building a learning community largely through scholar forums, to enable scholar to share their experiences to accelerate learning and implementation of best practices.

And all of this has been enhanced with strong academic and health systems partnerships that produced health systems research across diverse clinical and health system topics. This experience contributed to scholar satisfaction of the program and career advancement for scholars through publications and employment.

And health systems partners also report satisfaction with the program thus far.

First, centers responded to the need expressed by scholars and systems to develop a new competency domain in the program related to health, equity, and justice. And the development of this domain and the strong receptivity among the center scholars and health systems really contributed to our thinking about LHS 2.0. And second, every

scholar projects have impacted clinical care delivery.

For example, one scholar project resulted in changing protocols where pharmacists now interview patients about their penicillin allergies. And if the penicillin allergy is low risk, they were allowed to offer the patient a change with amoxicillin when the patient and treating provider agree. And all of this has happened during a period of COVID-19. When system partners were willing to work with scholars to get studies that were delayed by the pandemic back on track, when conditions allowed.

Next slide.

Now, this is the approach for proposing for LHS 2.0, it reflects both acknowledgement of the strengths of LHS 1.0, but also some lessons learned from the program to-date. First, we'll be moving away from the K award mechanism to adopt a more flexible program award mechanism that will provide clear course of activities, such as governance, research, and training that can be assessed more

specifically in the review process.

This also responds to the feedback we've heard from scholars, mentors, center PIs and health systems partners that the K award was not flexible enough to meet their needs, allowing such things as different types of appointments, tailoring training requirements, flexibility, and size of projects, and the potential for co-funding by system partners.

And we propose to develop research cores that will be more aligned with AHRQ and PCORI's priorities and resources to include health equity, primary care, maternal mortality and morbidity, and intellectual and developmental disabilities. And this will include, for example, making PCORI's research portfolio of funded interventions available to scholars for consideration in the project selection. We'll also provide closer connections to PCORnet through, for example, possibly making available data queries to assist in the development of research projects.

And program diversity will be increased in three ways.

First, we'll open the program to early and mid-career investigators to enable mid-career investigators interested in patient-centered outcomes research and embedded health systems research to participate in the program. This might allow more sophisticated projects and will prepare them to consider PCORI and AHRQ research funding priorities.

Second, scholar diversity will increase with increased participation by individuals who are from populations underrepresented in research, such as individuals of color or persons with disabilities.

And finally, system partners will be extended to include minority serving institutions, federally qualified health centers, and other health systems that are committed to serve underserved populations.

Now we believe LHS 2.0 will yield greater opportunities for achievement and career enhancement by creating a program model that will enable awardees to execute robust embedded health systems

research that will begin to create a pathway to PCORI and AHRQ funding mechanisms and directly leverage the interest of health systems and others who may be interested in co-sponsorship.

Next slide.

So the total funds we're requesting from PCORI today is 25 million, which is an amount that AHRQ will match. We will have one cycle and participate 10 awards each with a project duration of five years. And if approved, PCORI will begin transfer of funds to AHRQ in fiscal year 2023. The details of which would be subject to a memorandum of understanding signed by both AHRQ and PCORI leadership.

Now a return meeting back to Ms. Troeger.

CHAIRPERSON GOERTZ: Thank you so much, Steve. Before we begin our discussion, Karin Rhodes has agreed to accuse herself from the deliberative discussion and vote on the proposed motion.

If any other Board Member feels that they should recuse themselves, please do so.

Any comments or questions for either Steve

or Kathleen?

[No response.]

CHAIRPERSON GOERTZ: I have a question.

Steve, could you provide just a little bit more detail about the, you know, what the product has been from the first initiative? You know, how many people have been trained or what -- have we asked their opinion on what they've learned it, et cetera.

DR. CLAUSER: Yes, thank you for that question. I went over that briefly in my prepared remarks, but I'm more than happy to amplify on it.

We currently have -- at the end of our evaluation, which occurred near the end of last year, we had about 82 scholars that were in the program. We have, I want to say 30 -- I'm trying to remember by memory, but it's like 30 or 32 who have actually completed the program and have kind of matured on to other positions.

And the research really is a wide variety of things. Some involving data development and data analysis that studies that health systems were

interested in, particularly studies related, for example, how to build in better data about social determinants of health or information related to characteristics of underserved populations. But some of it was really related to actually doing research that actually impacted practice.

I mentioned the one about you know pharmacist intervention, but we also had studies that really tried to refine websites to make them more patient facing and familiar for patients that were being prepared to go into transplantation.

And there are a number of other those studies I could remark on time permitting, but they really ranged a variety of approaches. Remember they only have two or three years in the program, but we were very, very impressed with the number of studies that were really trying to impact the delivery questions that many of these health systems are struggling with.

CHAIRPERSON GOERTZ: Thanks, Steve. That's really that's really helpful. I have Kathleen, Chris and then Bob.

MS. TROEGER: So I added a note to the chat Steve, just to build on your comments in terms of the success, that there've been in an additional 300 publications or so, right, that have also emerged.

So it's not just people that have been trained, it's that the information I think is being digested and out there disseminated and with some hope implemented as well.

My comment is really general it's to thank both Steve and the staff and team at AHRQ that have pulled together, not just this presentation, but really a successful program from its initiative several years ago, that allows us to see what the deliverables have been, the impact and the potential. And also to think other members of the Board and the various committees that have been involved in getting us to this point.

So I think Chris is going to follow up.

CHAIRPERSON GOERTZ: Great. Thank you, Kathleen. Chris?

DR. FRIESE: Yes. Hi, can you hear me?

CHAIRPERSON GOERTZ: Yes, we can. Thank

you.

DR. FRIESE: Great, good afternoon. I won't repeat everything that's been said, other than to underscore what both Kathleen and Steve has said.

As a training program director, myself, it's often difficult to evaluate in real time. And so what I like about this proposal is that we're rapidly learning as we go and we're positioned to continue this work in a seamless fashion. So I appreciate our colleagues at AHRQ and Steve and his team for moving that forward.

I also just wanted to briefly summarize the SOC discussion because this did come forward to SOC. And I think that a lot of what we saw in terms of programmatic changes were informed by that interim sort of rapid evaluation analysis. I also think that this approach in 2.0 really aligns quite nicely with our strategic plan moving forward.

And I especially appreciate the ability for a more flexible and adaptive model so that as the needs of the field change which some we can predict and some we can't. I think this mechanism will

position us better.

And then finally, I'm particularly excited of the lens of health equity coming into this work that we can both prepare individuals from under-served and historically excluded communities as well as conduct robust research that affects and improves care for those communities.

So I think a lot of strengths here and again, thank the team for their hard work and that's all.

CHAIRPERSON GOERTZ: Thank you, Chris. Bob?

DR. ZWOLAK: As a lifelong medical educator, I totally endorsed this proposal. But to follow up on my prior question, is there anything that we've done thus far with our LHS that has involved education or mentoring and engagement?

And is there anything that would, in this proposal, either emphasize or possibly exclude learning in the realm of engagement science?

DR. CLAUSER: Thank you Bob, for that question. Early on in the LHS program, we realized

there was a deficit in terms of the kinds of material and information we had available to really embed principles of patient-centered research into the training curricula. And we had individuals from our engagement department work collaboratively with us to prepare a training program that the centers themselves picked up to try to do that.

Largely that is training the researchers themselves in how to do patient-centered outcomes research, but through that curricula, that is something I think we could share. And also, we should begin thinking about that with future initiatives as kind of a springboard to provide really specialized training, especially to specialists who want to get into this patient-centered outcomes research arena, but are unfamiliar, you know, with kind of working in that kind of environment.

I think that's a real opportunity that we can build from, and we've got the start of a curricula within this program to do it.

CHAIRPERSON GOERTZ: Great. Thank you.

Any other comments or questions?

[No response.]

In that case? Can I have the next slide, please?

I'm going to ask for a motion to approve funding of up to $25 million to AHRQ.

DR. FERNANDEZ: So moved.

CHAIRPERSON GOERTZ: All right, thank you Alicia. Everybody can read and knows what we are talking about. Can I ask for a second?

DR. FRIESE: Chris, second.

CHAIRPERSON GOERTZ: Okay. Thanks Chris.

Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. Thank you.

I'm very excited to see this next iteration of this important project move forward. So we will be reconvening right at 1:45.

We have a very exciting afternoon ahead of us. Nakela will be providing an update on our current and proposed work on reducing maternal morbidity and mortality. And then we'll be joined by Representative Underwood who will speak on her experiences in leading this effort in Congress.

And we do not have -- we will not have a public comment period today. Nobody has signed up. So we -- it looks like well after Representative Underwood is with us, we'll be able to move towards, and Nakela can provide a wrap up and we should be able to adjourn just a little bit early, but we will see everybody at 1:45.

Just a reminder for those of you who are joining us virtually to please stay online, you know, mute your camera and your microphone, but don't hang up and we'll see you again at 1:45. Thank you.

[Whereupon, at 12:51 p.m. EST, a luncheon

break was taken, and at 1:45 p.m. EST the meeting resumed.]

AFTERNOON SESSION

[1:45 p.m.]

CHAIRPERSON GOERTZ: All right. Why don't we go ahead and get started? I hope everyone had a nice lunch break. I'm incredibly excited about the session to come. We're going to start with Nakela, as I said before, we'll provide an overview of our work on reducing maternal morbidity and mortality and then we'll be joined by Representative Underwood.

I ask for your indulgence with, we want to have a little bit, there may be a little bit of flexibility here in our schedule if Representative Underwood joins us early, I think we'll probably transition to her right away. If she's a little bit late, we'll be able to have a little bit longer discussion.

But basically the plan is to pivot, given her schedule to pivot to her as soon as she's able to join us.

So Nakela, if you want to get us started.

DR. COOK: Excellent. Well, we've begun

already today, talking a bit about PCORI's work to reduce maternal morbidity and mortality. We saw a slate that had awards that were focused in this space, but what I was going to do is just try to give you a little bit of an overview of the work in the area, and then we can have an opportunity for any comments and discussion from the Board.

You can go to the next slide.

So I'll just begin by mentioning as all of you know, that maternal mortality was identified as a new priority research area in the reauthorization law in 2019, as well as a research topic area related to individuals with intellectual and developmental disabilities. But I think what this means for us is that maternal morbidity and mortality and research related to individuals with intellectual and developmental disabilities are going to be long-term areas of the focus.

So we anticipate that both PCORI funding, as well as the ongoing eight engagement efforts are going to be critical to help us identify the stakeholder driven topics within these areas that we

really focus on.

Let's go ahead to the next slide.

So as we've started to hear earlier, and even some of the background discussion about this important topic area, that the United States really ranks lowest amongst high-income countries and parameters related to maternal health. And there are significant disparities, as we know, related to maternal outcomes that have been reported with Black women being three to four times more likely to die from pregnancy as compared to white women. And American Indian and Alaska Native, as well as Hispanic, rural, and populations with lower socioeconomic status, also face significant disparities in outcomes.

And if we're really going to address the issues of maternal mortality in the United States, it's going to require us focusing on research that helps to advance strategies to eliminate health disparities and strategies that will help us think about how we can achieve equity in the United States.

So this framework is one of the ways we've been trying to start thinking about this problem in a bigger context. And so, what you can see here as a slide that points to several opportunities for interventions in the healthcare arena, thinking about things from various risk factors to social needs, clinical and healthcare variables amongst others, that really impact pregnancy outcomes.

And the frame here is from a preconception stage all the way through to the postpartum arena. And we also see here that the majority of the deaths occur during the pregnancy and postpartum period with about 60 percent of the deaths being preventable, which I think is a really important concept for us in thinking about the opportunity for interventions.

Let's go ahead to the next slide.

So PCORI has actually been funding work related to reducing maternal morbidity and mortality since 2013. And as you can see here, we've funded about 63 comparative clinical effectiveness research and engagement projects that focused on maternal

morbidity and mortality to a total investment of about $91 million. And if you count what we just recently had -- with the Board just approved, it's really around $110 million now and 64 projects. So we're continuing to make some headway in that investment.

Go forward to the next slide.

And after the reauthorizing legislation in 2019, there was an enhanced focused on thinking about ongoing engagement opportunities to guide the efforts around maternal health. And here you can see that we've had about 28 different meetings with stakeholders in the maternal morbidity and mortality community to help inform the development of the topics that you've seen in the pipeline related to PCORI funding opportunities.

There was also been some survey feedback in terms of reaching out to diverse stakeholder representatives through a survey mechanism to help in identifying priority areas and topics that will be relevant to help inform our plans and decisions. And at our annual meeting in 2021, we also had a

panel that provided great insights on stakeholder engagement for equitable maternal health outcomes.

And we hosted some webinars as well to help inform a PCORI/AHRQ evidence review, which we think is going to be helpful as we continue to move forward with other project opportunities.

There has been, in another part of PCORI's portfolio, we also think about the synthesis of evidence. And there's an approach here that I'm showing you around evidence synthesis that entails this combination of thinking about both those short-term opportunities and the long-term ones. Like the studies that we talked about that are funded through PCORI funding announcements.

But here you can see PCORI's funded three systematic reviews and one rapid review in the maternal health space. And some of the systematic reviews focus on things like cervical ripening or the peripartum and postpartum management of hypertensive disorders of pregnancy, as well as postpartum care for women up to one year after birth. So honing in on those areas that we see the

great degree of deaths and where we have an opportunity to learn more about potential interventions.

And we've also funded a rapid review related to telehealth strategies for the delivery of maternal healthcare.

So I'm going to go ahead and pause and turn it back to Christine.

CHAIRPERSON GOERTZ: Thank you so much, Nakela for that brief overview of our portfolio in this incredibly important area.

Representative Underwood, I understand you have been able to join us and have left us.

[Laughter.]

CHAIRPERSON GOERTZ: So we will assume that she is going to -- oh, she was doing a check.

All right, well, why don't we go ahead and why don't we -- is there someone who's able to interact with her and ask her to put on her camera when she's ready?

STAFF: Yes --

CHAIRPERSON GOERTZ: Okay. All right.

DR. COOK: I could go ahead and finish --

CHAIRPERSON GOERTZ: Why don't you go ahead.

DR. COOK: Okay, great. There's really only one other update and that around PCORI funding announcements. So we can go to the next slide.

So here, I just wanted to give you that update around some of the targeted funding and the special areas of emphasis that we focused on just to kind of consolidate your knowledge here.

In the recent targeted funding announcement that we just looked at a slate, was the improving postpartum maternal outcomes for populations experiencing disparities. And prior to that, there was a special area of emphasis that was focused on the continuity of care in terms of thinking about maternal care and a broad funding announcement. And there were two awards made from that special area of emphasis as well.

You may recall when we talked about the PFA on the left, we mentioned that it would be posted again in future cycles for additional applications

to come in. And we think we're really cultivating some applications that are going to come through that reposting and reissuing.

We can go ahead to the next slide.

So we continue to work on thinking about these new funding opportunities and we have a pipeline of topics that we've heard about through some of the engagement opportunities that we've been hosting and thinking about how we can intersect this work with some of the other efforts that we're thinking about around health equity. And you'll be hearing about that in a future Board meeting.

We also think that there are a lot of opportunities to continue to talk with the stakeholders, to help inform and guide a lot of our ongoing efforts and engaging with communities is a key component of how we've been thinking about this work, given the nature of the types of interventions that may be most effective here.

And we're also thinking about the intersections with interventions that address social determinants of health because of the ways in which

those issues really underpin a lot of the challenges that we're seeing in this arena.

So these are just some broad strokes to kind of give you a little bit of background in terms of where we are on some of these activities, but I look forward to having a lot more discussion over time with the Board here. And this again is a long-term commitment area for us.

CHAIRPERSON GOERTZ: All right. Thank you, Nakela. Representative Underwood will be joining us right at two o'clock. So we do have a moment or two, if anybody has any questions at this time,

Okay, Bob and then Mike.

DR. ZWOLAK: So thanks Nakela. It's a nice overview. My simple question is can PCORI win this battle? Can we put these points on the Board?

I don't think, and I'm not an expert, but I don't think our poor maternal mortality is due to lack of high-quality care in places where there is high quality care. In Sharon's comments apropos an eight eight-fold difference in maternal mortality from one county to the next in California.

We can do lots of research, but I think that in order to win this battle we need dissemination and more uniform, high quality care implementation of whatever we find.

Is that something we can accomplish? I mean, we can spend a lot of money on research, but can we impact the numbers?

CHAIRPERSON GOERTZ: Perhaps that's a question for Representative Underwood.

Sharon, and then Mike.

DR. LEVINE: So Bob sent me an article from *Health Affairs* on Monday, I guess it was. And if you look at what University of Pennsylvania did, I mean, they had a significant impact in a relatively short period of time by looking at the evidence and implementing, you know, specific practices and also addressing that, you know, what they found in terms of embedded practices that were based in unconscious bias.

And, you know, I think highlighting -- the evidence that highlights practices that actually address issues like speed to treat hemorrhage

certainly will have an impact if there is a willingness to adopt them.

But the other opportunity, and which is why I'm excited about Representative Underwood, is to influence policymakers. I mean, there's a lot of belief and we don't control this, that expanding Medicaid to wait a year postpartum would have a huge impact on both morbidity and mortality, maternal morbidity and mortality. That's a policymaker issue. There's been a lot of energy behind it. And if there is evidence to support that, that makes a difference, then, you know, perhaps we can see movement on that.

CHAIRPERSON GOERTZ: Thank you, Sharon.

Mike, we have just a couple of minutes.

DR. HERNDON: A critical topic. As a former chief medical officer for Medicaid, this is a huge issue. And I think deserves a lot of collaboration with ACOG, Medicaid, CMS, and all that. And I'm just wondering how much of the discussions that we've had and convenings included those sorts of folks.

The biggest issue -- early elective deliveries, C-sections, and inductions social determinants of health, rural versus urban. And then just the -- all the potential morbidity issues; the postpartum bleeding, the clots, it is a tough nut to crack. And I think this could get big and I'm wondering how we're going to put it, you know, into a doable research project.

And then the last thing is just PCORnet. You know, surely there's some great work that could be done with PCORnet from the perspective of electronic medical records.

CHAIRPERSON GOERTZ: Thank you, Mike. I think what we'll do is -- Representative Underwood, are you with us?

Barbara, I've got Russ and then Connie, and then I'm going to put Barbara, I believe Representative Underwood was going to join us at 2:00. My understanding is that she is on the line.

STAFF: No.

CHAIRPERSON GOERTZ: She's not on the line yet. Okay. Did you want to respond to Mike, then?

DR. COOK: One thing I was going to say, Mike, is that I love your comment about the stakeholder communities to engage. So we'll certainly look at that and make sure we're reaching. And we'll reach out to you for some clarity.

The other thing I was going to say in terms of PCORI nation, how we're going to prioritize that some of the things like the systematic reviews and things of that nature are going to reveal to us some of the evidence gaps where we think comparative research will be helpful.

And then I also was just going to mention that the other way that we're trying to do this is looking at that intersection of where we see the burden, as well as the clinical question kind of and that that intersection is going to help us narrow down the PCORI space.

CHAIRPERSON GOERTZ: Thank you. First Russ.

STAFF: She's on.

CHAIRPERSON GOERTZ: Okay. Representative Underwood, are you able to see us and hear us today?

REPRESENTATIVE UNDERWOOD: Hello?

CHAIRPERSON GOERTZ: Hello? Yes, we can -- we are not able to see you, but we can hear you.

REPRESENTATIVE UNDERWOOD: Okay. I'm not familiar with this platform. So let me orient myself here.

CHAIRPERSON GOERTZ: Yes, absolutely. Please take your time.

REPRESENTATIVE UNDERWOOD: Hi.

CHAIRPERSON GOERTZ: Hey, we can see you.

Welcome to the PCORI Board of Governors meeting today. I'm Christine Goertz, I'm the Chairperson. On behalf of the entire board, I want to let you know how grateful we are for your time today.

Just a quick note Representative Lauren Underwood is a Democrat from Illinois. She is taking time from her very busy schedule to speak with us today about maternal mortality.

Congresswoman Underwood serves Illinois 14th Congressional District and was sworn into the a 116th U.S. Congress in 2019. She's the first woman

and the first person of color to represent her community in Congress. Congratulations for that.

She's also the youngest African American to serve in the United States House of Representatives.

Representative Underwood co-chairs the Black Maternal Health Caucus together with Congresswoman Alma Adams. They launched the caucus in 2019 to address one of the most urgent crisis is in the United States today. Maternal mortality rates in the United States are the worst in the developed world with 26.4 deaths per 100,000 live births. The goal of the caucus is to increase awareness of the Black maternal mortality crisis and to effectuate policy change to improve birth outcomes for Black families.

It's our goal here at PCORI to advance these goals by exploring CER questions on how to best reduce maternal mortality and to improve birth outcomes. We're incredibly excited to have you join us today. And Representative Underwood, the floor is yours.

REPRESENTATIVE UNDERWOOD: Well, thank you,

Dr. Goertz and to the whole PCORI Board. I really appreciate the invitation to join you today. It feels, you know, like this is the last week before COVID happened two years ago, and I just keep thinking about what was going on in early 2020. And I think, but I'm not completely positive on the timeline, but I think that the whole genesis of the Black Maternal Health Collaboration with PCORI started because I was sitting next to Dr. Friese at the Nightingale, I think, is what happened.

And I'm so excited that we have this opportunity to talk today because PCORI has such a unique mission to be able to advance patient-centered research. And I so very much appreciate your emphasis on maternal mortality, morbidity, and disparities. It is huge. And I think that you all in particular are so well-equipped to offer kind of a unique perspective and lift up some policy solutions and advancements that will be able to be deployed so broadly in order to save lives. And that's really what this work is about to me.

I'm Lauren Underwood. I am a nurse. I co-founded, co-chair Black Maternal Health Caucus. I was motivated to work on this issue after a classmate of mine from my MPH program at Johns Hopkins, Dr. Shalon Irving, died in early 2017 three weeks after delivering a beautiful baby girl named Soleil. Shalon did everything right, as you know, right. These disparities persist and the protective factors that might help other groups are not protected for Black women.

And I knew that if I happen to win my Congressional campaign, that this will be a topic that I would want to work on. I am so blessed to be able to have the support of not only in partnership with Congresswoman Adams, but we -- the Black Maternal Health Caucus have grown to a bipartisan caucus over a hundred members. We have broad support the Senate as well, and this amazing stakeholder community across the country; providers you know, researchers, leading community-based groups that have this really hyper-local focus that are addressing disparities in their cities, towns,

and states. And then, you know, industry leaders and big brands are also part of our stakeholder community

And it's through being engaged, the big brands like Uber, Lyft, Huggies, Pampers, you know, like those kinds of folks. They're all really excited about putting our collective energy behind saving moms' lives.

And so, it was through the engagement with these stakeholders across the country that we were able to develop the Black Maternal Health Momnibus as a comprehensive solution to address every clinical and non-clinical driver of maternal mortality and those disparities that we see in this country.

We intentionally designed the Momnibus to not be duplicative of existing legislative efforts.

So what that means is for several years, we have seen legislation try to expand postpartum Medicaid coverage. For example, something that I wholeheartedly support, I will readily endorse, you know, mandatory postpartum year-long Medicaid

coverage as the single most important thing that we can do to save mom's lives. But that is not part of the Momnibus. What we have done is really advanced novel policy solutions to address, you know, everything from social determinants of health, housing, nutrition, transportation, environmental and climate change-related factors. We have a new grant program for mental health and substance use disorder treatment. We are growing and diversifying the perinatal workforce. We are trying to scale up the digital tools and make sure that they're equitably available to birthing people in this country.

You know, just, it's now 12 bills to comprehensively address our nation's maternal health crisis. And we've made a lot of progress so far this Congress.

In 2021, every eligible Momnibus provision was included in the House passed version of the Build Back Better Act, that’s the reconciliation bill that passed in the House, but has yet to advance in the Senate.

This investment in these eligible Momnibus provisions plus the permanent expansion of year-long postpartum Medicaid coverage in every state represents the largest maternal health equity investment in the United States history. We're talking about over a billion dollars to save mom's lives in this country, and that has passed the House of Representatives.

We've also seen in 2021, one of our Momnibus bills, the Protecting Moms Who Served Act, which is designed to help Veteran moms was signed into law by President Biden in November. This was a bi-partisan bill.

I worked with Gus Bilirakis in the House, Senator Duckworth worked with Susan Collins in the Senate in order to get that bill done, which we're excited about.

A second Momnibus bill, the Maternal Vaccination Act passed the House with unanimous bipartisan support.

So what we have right now is a strategy that allows us to pass individual Momnibus bills.

So, you know, each of the 12 individually, while also working on the larger package through any legislative vehicle, right? Like our point of view is let's just get it done. And so, we're looking to pass the Build Back Better agenda, which we're now calling the Building a Better America agenda in the Senate with these critical maternal health investments.

And I remain optimistic that we'll be able to get a deal done this calendar year.

So, you know, my expectation for next steps will be to take a look at, you know, what didn't advance through that process, which I expect to be things like the WIC expansion for mom and baby to 24 months. Our work with the Federal Bureau of Prisons, the Justice for Incarcerated Moms Act, you know, things like that, that weren't able to be included through this legislative vehicle called reconciliation.

And then identify opportunities that may be contributory to you know, maternal -- severe morbidity or existing disparities or opportunities

to make a difference in reproductive health, maternal health. So things like endometriosis, polycystic ovarian syndrome, you know, dealing with some of the IVF issues, stillbirths, you know, any kind of miscarriage-related policy issue, you know, things like that. That's what I'm sort of conventionalized -- fibroids -- conceptualizing Momnibus to kind of include.

And so, we are beginning to think about those provisions right now.

I really see our caucus' priorities as very much aligned with PCORI's maternal health research focus, as well as your broader emphasis on health equity. You know, my healthcare work and my health equity work is obviously more broad than just maternal health stuff. So we've been working to lower out-of-pocket healthcare costs.

You know, the American Rescue Plan included a provision to make the advanced premium tax credits for ACA plans, more generous and expanded the eligibility pool. You might've seen the open enrollment commercials touting that four out of five

people can get a plan for less than $10 a month. That was my bill. We did that and I'm excited, we're trying to make that permanent.

We are also focused on growing and diversifying the healthcare workforce to expand access to high quality care.

One noteworthy bill, I want to call out there is something called the FAAN Act. The Future Advancement for Academic Nursing Act. It's $1 billion for schools of nursing. We got $500 million of it in Build Back Better. It's huge.

And we're working to expand access to mental and behavioral health here. I want to call out my Primary and Behavioral Healthcare Access Act, which would eliminate out-of-pocket cost barriers for up to three outpatient mental and behavioral health care visits, and up to three primary care visits per year.

We know this is important because this time of year after folk's deductibles reset, we're seeing, you know, people who need care, but where that out-of-pocket cost is a real deterrent and with

rising rates of suicide attempts and completions, rising rates and overdoses. We know that the American people are in crisis in this kind of pandemic moment, and we want people to get the healthcare that they need.

President Biden has embraced the three outpatient mental health and behavioral health care visits without a co-payment. And that's part of his new Building a Better America agenda. So hopefully you'll hear more about that.

Anyways, I'm really excited to be able to work with you all. I'm so grateful for a few minutes for remarks this afternoon, and I look forward to continuing the conversation on these important topics. Thank you.

CHAIRPERSON GOERTZ: Thank you so much again, for spending some time with us today and for your inspiring remarks.

As a research generating organization, we sometimes have discussions about, you know, what is the true impact of the, you know, our end product and research. And I think you are inspiring us all

with the actions that you're taking to actually make change happen, which is obviously ultimately our goal is as well.

So again, thank you so much for all the work that you are doing in this space and in so many other spaces as well.

I'd like to -- do you have just a few more minutes because there are a number of Board Members that would like to have questions, and we'd like to have a discussion if we could.

I'm going to start with asking Board Member Alicia Fernandez to make some comments.

DR. FERNANDEZ: Representative Underwood, thank you so much for taking the time to talk with us today and thank you for your leadership on maternal mortality. I'm Alicia Fernandez. I'm an internist from San Francisco. And I am Chair of the Science Oversight Committee here at PCORI.

And as you know well, the United States has twice in maternal mortality as of that, of other developed nations. And as you also know that maternal mortality is distributed very unequally,

particular, both by regions of the country, but by areas even within states and most notably by race/ethnicity, with Black women, having more than three times the mortality and a Native American woman having almost three times the mortality of white and Latino women.

And this is of course a completely unacceptable and at PCORI, this is for us not only a statutory mandate but it also fits into our strategic priority on health equity.

So we have been doing work in this area and are really looking forward to doing more work. In 2020, we formed a work group committed to driving forward our maternal mortality research agenda. And as a February of this year, we have funded 23 research projects for a total of $84 million and 40 engagement projects for a total of $7 million leading with what we funded today, 110 million research dollars in this area.

Since reauthorization, we've included a special area of emphasis on increasing access and continuity of patient-centered maternal care. And

we released a targeted from the announcement on improving postpartum maternal outcomes for populations experiencing disparities. And we are continuing to work to put together more targeted announcements.

We are working very closely with a broad range of stakeholders to inform our efforts with communities to consider areas of importance and strategic areas for development. And throughout we are looking at the interplay between the healthcare system and social determinants of health to see how research at that intersection can inform better outcomes.

So with that very brief overview of where we are. I'd like to open the floor for questions for other Board Members. But let me take a minute personally to say thank you so much for your leadership in this area. We really need you.

REPRESENTATIVE UNDERWOOD: Thank you so much. And what your remarks just make me think of one thing. We are hopefully going to be able to vote on a federal funding bill this week. The

omnibus that you all are likely tracking on. In there, I hope is funding for every state to set up a perinatal quality collaborative. And I suspect that many of your grantees will find a very fruitful partnership with those perinatal quality collaboratives.

And so, I would just ask that you all keep an eye on that and work with your grantees to make sure that, and especially in those states where they're being established, that that link and data sharing or information sharing relationship is strong. Because I think that your grantees are going to be very well positioned to inform and influence the work of those quality collaboratives as they work with health systems in each state. Thank you.

DR. FERNANDEZ: That is wonderful news and something that has been sorely needed. So thank you for that. Christine, I'll turn it back to you for questions.

CHAIRPERSON GOERTZ: Okay. Thank you. I believe Chris Friese, is also on the line with us

and was hoping to be able to ask a question, make a comment.

REPRESENTATIVE UNDERWOOD: Hi.

DR. FRIESE: Representative Underwood, it's great to see you. How are you?

REPRESENTATIVE UNDERWOOD: Good, thank you.

DR. FRIESE: Good. Well, I send you greetings from the University of Michigan School of Nursing, your alma mater. Go blue.

REPRESENTATIVE UNDERWOOD: Go blue.

DR. FRIESE: Well, thank you so much for being with us today. Thanks for your leadership on this very important issue and we're excited to be partners with you and the caucus.

I wanted to turn to -- you've made some mention on the importance of workforce and I think you, and I would agree that a robust healthcare team is likely really important for us to achieve these goals, and I wanted you to think with us a little bit about how we can position that and generate the evidence we need for all members of the healthcare team; community health workers, doulas, nurse

midwives, et cetera, physicians, mental health services, et cetera.

How do you see the workforce being helpful to us and what do we need to do in that space?

REPRESENTATIVE UNDERWOOD: Okay. Thank you so much, Dr. Friese. So what we have done in the Momnibus and was also included in Build Back Better was $295 million to grow and diversify the perinatal workforce. So we're talking about more midwives, more nurse midwives, more nurses, more doulas, more physicians, more maternal mental and behavioral health professionals. And so, that's $295 million and we set aside $50 million of it explicitly for doulas.

What we know is that there are many communities that are unfamiliar with this type of provider. And so, as we really create the scale of pipeline or this workforce, I think it will be very important. Particularly as we work with, you know, licensing boards and creating some standards because all of these professions don't necessarily have that kind of robust system with it, the way that nursing

and medicine and, you know, I'll call it legacy clinical specialties do.

I think it will be important to make sure that we have probably the broadest set of abilities as possible. Particularly, just anticipating some challenges that we'll see with like doulas, lactation consultants, things like that.

And so, I know that, you know, nursing has been playing nicely in the sandbox with our midwifery colleagues and I would encourage you all to continue to investigate the importance of midwifery care in the broadest sense. And especially acknowledging some of the unique challenges in our rural communities, in our rural states.

I would also be clear in looking at the workforce intersections when there is maybe a diverse population in a rural community, but not a diverse healthcare workforce. And when we're talking about some of these clinical specialists that are not nurses and physicians, right? Which I feel like there is kind of a robust status set there

for some of these other professionals, it might be useful to explore opportunities to contribute to the evidence base.

I was trying to be diplomatic and polite, but I think you see where I was going there.

[Laughter.]

DR. FRIESE: Thank you so much.

CHAIRPERSON GOERTZ: Thank you. Our next Board Member that had a question was Jennifer DeVoe.

DR. DEVOE: Hello. Thank you so much Representative Underwood, it's wonderful to meet you virtually. I'm a family physician from the great state of Oregon, and just had a wonderful opportunity and privilege to chair a committee at the National Academies of Science, Engineering, and Medicine in 2019, really wanting to align science practice and policy for health equity, especially for moms and kids.

And that was very eye-opening as someone who does a lot of policy relevant research, it was really eye-opening and confirmed what Dr. Goertz was talking about as far as the research that exists and

how we translate it into practice and policy. So we're very eager here at PCORI to do more of that.

So I love your idea about connecting with the registries at the state level that you're hoping to get funded and supported, but we'd love any other ideas you have for how PCORI can be most helpful to you and other policymakers seeking to make additional policy changes in this area.

Specifically, are there interventions or outcomes that we should prioritize? How has research been helpful to you? What research do you need more of?

REPRESENTATIVE UNDERWOOD: Thank you so much. I would say that we have really had a lot of enthusiastic engagement with some state legislators and their legislatures. I think that they have fewer resources than we do in Congress. And so, it is very evident that which states are leaning in and I would highly recommend either PCORI as an organization offer your expertise to them or connect your grantees with those legislators.

And I think that there is a very rich

opportunity for synergy there. And a lot of those folks just don't have -- they would not know to call you. So that's one area.

The second, I think you all are familiar with the Morbidity and Mortality Review Committees that are around the country. I think that those entities have a variable level of support and resourcing. And I think that, you know, in some states like mine, where we're seeing some of the disparity narrow because white women's death rate is increasing.

And I know that Illinois is not alone in that.

I think that there might be an opportunity for some work to sort of level set around trends and what you're finding in that really local data. I think that some of the MMRCs have been overwhelmed with the work required to investigate each case. That they might be missing a little bit of an aerial view that your organization or the PQCs, the perinatal quality collaboratives, once they're stood up could be able to provide. And I would encourage

you to look there.

And then the other thing, just because of what's happened in Illinois with the rising rates among white women, and then the narrowing of the disparity and what we seen out of some of the COVID data, which has documented a real increase in deaths among Hispanic birthing people, in addition to African Americans. Is that we need to be clear in our research and in the conversation that like all maternal death is unacceptable. And whether or not it's driven by a racial inequity or that racial inequity changes over time, which I think some communities are really experiencing does not negate the need for action.

And I would just encourage you to design your, I don't know what you call your funding, like your grant program, to be as inclusive as possible. We changed the language within the Momnibus to be very explicitly about a multicultural coalition because what we've seen happen even in the few years that we've been doing this work is that, you know, a shift is happening in the way that the data and the

disparities present themselves.

Because I think that we know that, for example, when the Momnibus passes, it will help all birthing people in this country. And we will transform maternity care in this country and we will lift all boats. Right. We know that. But I think that part of that is also making a choice around the way that we word the legislation and structure, these grant programs.

CHAIRPERSON GOERTZ: Thank you so much Representative Underwood. I know you have a hard stop at 2:30, but we're going to try to sneak in one more question. I know that Kara Ayers had a question.

REPRESENTATIVE UNDERWOOD: Hi Kara.

DR. AYERS: Hi Representative Underwood. Thank you so much for being here. My question is what is the role of community in improving maternal outcomes?

And specifically, I wondered if you could touch on women with disabilities in pregnancy. I loved your last comment in terms of, you know,

lifting all boats and people with disabilities will definitely be in those boats. Thanks.

REPRESENTATIVE UNDERWOOD: Yes. I think that there is a tremendous role of communities and, you know, people who would not normally consider themselves stakeholders. And so, it's really important for all of us to be as inclusive and as welcoming as possible.

I consider the stakeholder community to be anyone who wants to be part of it. And we try not to have, you know, closed invitation only type participation. We try to be responsive and open to everybody while recognizing that certain communities don't have capacity to either be present, don't have the capacity to do the policy work. Don't have the capacity to independently analyze the data or, you know, whatever.

And so, I guess what I would say with respect to individuals with disabilities I have not seen -- maybe my staff has, this is a limitation, just my point of view, but I have not seen the leading disability advocacy organizations engage us

directly. And I think that there really is an opportunity for synergy and for improving health outcomes more broadly.

And I think that there is also an opportunity as we create space and pathways for some of these other workforce professionals to be part of everyone's clinical care team, to make sure that the needs of individuals of all abilities is kept in mind.

And so, we really invite any disability advocates that you are connected with to reach out to us, but also their state and local legislators if they're in one of these communities that are doing this work to make sure they're part of the conversation. I think that will be essential.

And I say that because of what I've seen happen here in the Congress and our work with Senator Duckworth and the bipartisan enthusiasm. And I don't use that word lightly, enthusiasm, for correcting some of what happens in the maternal health space for our moms and families with disabilities.

People want to solve these problems. And so, you know, I'd love to engage further.

DR. AYERS: Thank you some much. I appreciate it.

CHAIRPERSON GOERTZ: Well, Representative Underwood, we definitely want to take you up on that offer to engage further. We're hoping that this is just one of many conversations that we're able to have as we pursue our mutual commitment to advancing the healthcare needs of our nation and with a particular emphasis on maternal mortality.

Thank you so much for taking the time to speak with us today. And once again, reminding us why we do the work that we do because of the incredibly important work that you do. And thanks to you and your staff for making this time possible today.

REPRESENTATIVE UNDERWOOD: Thank you so much. If I can just make one other suggestion, you guys didn't ask for it, but how HHS works. Please do not assume that your colleagues at the Department understand all the work that you're doing and have

done. And so, as you know, that certain agencies are prioritizing this work CMS, HRSA, CDC. Be in touch with those agency directors to make sure that they know that you are a resource and the kind of grantmaking that you're doing.

Because I think that there's an opportunity for collaboration, particularly as we unlock this billion dollars. And what I don't want to see happen is that people start to miss each other. You know what I mean? Like how incredible the collaboration would be, it'd be huge and an incredible legacy from the ACA and all the work that you guys have been doing for so long. So not to say that you're not, but I just know that. We have new leaders and they might not be as familiar with the rich resource that you all are. Okay. Thank you.

CHAIRPERSON GOERTZ: Thank you so much. Take care.

REPRESENTATIVE UNDERWOOD: Bye.

[Applause.]

REPRESENTATIVE UNDERWOOD: I don't know how to exit out.

[Laughter.]

CHAIRPERSON GOERTZ: You're stuck with us.

REPRESENTATIVE UNDERWOOD: I figured it out. Bye.

CHAIRPERSON GOERTZ: Bye. All right. Okay. Now I well -- that was truly inspiring. How exciting.

So, Nakela, thanks to you and the staff for making this possible today. What I'd like to do is we had a couple of -- we had both Russ and Connie that had their tents up before we so first Russ and then Connie.

DR. HOWERTON: I'll just make a quick comment. She's very engaging.

CHAIRPERSON GOERTZ: Yeah. Just terrific.

DR. HOWERTON: Hopefully she'll have a long career. I wanted to say that I agreed with Bob, the overall set point of maternal morbidity mortality is probably bigger than us. I mean, if you pick a big homogenous country like Denmark, there are many factors that we aren't going to make the U.S. Denmark today, but to me, this looks like the safety

journey we undertook in healthcare for a couple of decades. And I'm very encouraged that this is something we could make progress on because every increment, particularly in maternal mortality, every single maternal mortality, assuming a child lives is a child without a mother, it's a mother who couldn't have another child. And if there was a child from before, there's a child without a mother.

It's a very discreet endpoint. It's rare, but profoundly negative when it occurs, just like the safety events that we had in hospitals. And there are strategies to make incremental progress on that. And I believe -- to your point, we won't make ourselves Denmark through the work of PCORI, but we could contribute to the evidence that makes incremental change that led like the safety journey we had in healthcare.

And I'm encouraged it could be discernible, more rapidly than many things we've changed. It's the beauty of already agreeing upon the measure. Maternal mortality does not need definition work, we know the measure. Right?

And so, I think it's a great focus for PCORI that we could make change in.

CHAIRPERSON GOERTZ: Thank you, Russ. Connie.

DR. HWANG: Yeah, I agree with Russ. What a treat to hear Representative Underwood. Thank you so much for allowing for that time with her. And you know, I think there's a lot to admire about PCORI's investments in so far in maternal health and looking forward to some of the new funding opportunities that Nakela outlined a little bit earlier. Particularly the intersection with health equity, engaging with communities, and SDOH.

This got me to thinking about how PCORI's new flexibilities on economic impacts, those that are really important to the patient how those might really figure into the new funding opportunities and particularly in relationship to folks on the Hill, like Representative Underwood, it might be worth probing a little bit further on what sort of cost insights would be most helpful in advancing maternal health policy moving forward.

I think it would be a nice sort of intersection of efforts at the PCORI. And I'd love to hear your thoughts on that.

CHAIRPERSON GOERTZ: Nakela.

DR. COOK: Connie, I think that's such a wonderful thought and something that we can continue to explore. And, you know, particularly we may have an opportunity as we're thinking about even our upcoming funding opportunities to embed some thoughts like this. And so, it's worth us kind of getting a little bit more understanding of the types of things that may be very important.

We heard things like out-of-pocket costs. We heard things about some of the coordination of care issues related to coverage. And so, there may be opportunities for us to capture and collect some information that could be quite informative. So thank you for sharing that contribution.

CHAIRPERSON GOERTZ: All right. Any other comments? Questions? Alicia.

DR. FERNANDEZ: I wanted to comment on Bob's question because it's something I've been

thinking a lot about, you know, can we really make a difference here? And I want to say that I think we can. And the example that that most comes to mind for me is the decade of research on every aspect of MI care from the EMS care to which hospital people should go to, to how the cath lab, the time in the ED, to how the cath lab needed to be structured, et cetera, et cetera, that led to a disappearance of racial disparities in acute MI and gender disparities in the treatment of acute MI.

And without making us Denmark, we were able to do that.

And when I think about maternal mortality, and again, this is like the internist baby version. It's 50 percent of the death is at the time of labor or within a week. And I think to the two deaths that I know about, one when I was a CCU resident and fortunately my co-resident was carrying the code pager when there was a code in labor and delivery, and a young woman died with a massive pulmonary embolism and that was not preventable.

Or the death three years ago when a woman

came in one week after delivering, a few days after delivering and seizing from essentially eclampsia and that was preventable.

So I think that what I think is there is a huge -- there is a real opportunity to improve healthcare delivery. I think it will be really important for PCORI to not try to boil the ocean and improve maternal healthcare.

But if we want to really -- because there's a lot to improve, but if we really want to focus on maternal morbidity we can. I think we can, I think we can probably make a difference, particularly with working with stakeholders from the start and with very targeted, thoughtful impetus.

And so, I'm feeling very optimistic about this. Thank you so much for inviting Representative Underwood. I think that these sorts of things keep us focused on where we're going. I completely agree with what Christine said. And so, yeah.

CHAIRPERSON GOERTZ: Thank you, Alicia.

I just wanted to comment on the article that Sharon mentioned earlier, the *Health Affairs*

article that Bob sent out. And Bob, I'm wondering if you could share that with Nakela and perhaps we could share that with the entire board, because it does give you hope that the right action can make a difference. And I think that would be -- I think that that would be something that we really want to be focusing on right now.

Are there any -- Jen and then Barbara.

DR. DEVOE: So I'm going to go all the way to boiling the ocean again. Sorry to bring that up. But I will say I'm very excited to connect the conversation about our Methodology Committee and the work we're going to continue to do together in creatively developing and utilizing methodologies that help us compare the effectiveness of some of the policy interventions that Representative Underwood was talking about.

And so again, I chaired this National Academies committee that produced a 650-page report on aligning science with policy and practice and made a lot of evidence-based policy recommendations based on really great scientific work. And there's

not enough of that scientific work out there. And maybe it's not PCORI's job to do it, but I really think that we have to broaden our horizons because these are the kinds of interventions that you cannot randomize.

Occasionally you have the unfortunate situation that Oregon was in, where we randomly gave some people Medicaid insurance, and some people did not receive that coverage, but in this case, and there may be some states doing things differently. So you can compare what's happening in some states versus others. But I think she's going to need our help to show and better understand which of those policy interventions are making the biggest difference.

Because what I worry about is then money gets spent, and there's no outcomes to show that it's making a difference or not making a difference and researchers haven't really been in those conversations. And we know that not all policy is made based on evidence. Politics is obviously a big factor, but the evidence is going to be super

important.

And so, I just kept thinking about like, how do we study these interventions? Many of them are going to be natural experiments. We're going to say that's not in PCORI's scope or, you know, we have to continue doing RCTs and comparing the effectiveness of one effective intervention versus another.

But we really need to broaden our scope of methods and broaden the studies that we see as within our scope to really move this needle.

CHAIRPERSON GOERTZ: Thank you, Jen. Those are really important comments, Barbara.

Barbara, you're on mute.

DR. McNEIL: Nakela, I had remembered that we had spent $91 million in this field since 2013. So it's likely that some of those studies were well-done with lots of patients and well-powered. And I wonder if we should go back and look at those results and see which of them really have any potential for being implemented largely -- in a much larger way than they had anticipated when the study

was done.

I mean, that would be an elevator speech that would be at the top of anybody's list.

DR. COOK: That's great, Barbara. I know that that it's the work group at PCORI that's been working on maternal morbidity and mortality has been looking at that portfolio and we can go back and ask that specific question around are there things there that may be worthwhile for us to think about from a dissemination and implementation perspective that maybe has an opportunity for some scale-up or other specific settings.

It's a great comment.

CHAIRPERSON GOERTZ: All right. Jen, did you still have your card up? Okay. Mike?

DR. HERNDON: Yeah, just very briefly.

Prevention of unplanned pregnancy, I think needs to be not overlooked as we look at disparities in this work as well. And, you know, the work that Representative Underwood is doing for getting expanded coverage of Medicaid, postpartum is wonderful, but there are some other policies that

could potentially be influenced by work done and proving that, you know, long-acting reversible contraceptives, better known as LARC, is paid outside the normal payment system. Especially for like Medicaid with bundle rates. Paying immediate postpartum placement, FQHCs won't put them in because they cost $400 and it doesn't -- it breaks their budget because they get paid a certain fee.

So yeah, I think prevention of unintended pregnancy needs to be at least put forth as a topic for some of our partners when we're looking at the opportunities.

CHAIRPERSON GOERTZ: Thank you, Mike.

We'll make sure to make note of that. All right, Karin.

DR. RHODES: Yeah. So I loved hearing from her. That was very inspiring and I think we need that kind of connection between policy and what we're doing. And we are definitely informing policy, but I would also be supportive and sort of throughout, comparing the effectiveness of interventions with, you know, thinking of policy

interventions as a great one, especially looking state-to-state.

Any case I just wanted to endorse that perspective and see what people thought.

CHAIRPERSON GOERTZ: Thank you, Karin.

Are you talking about like implementation science or what?

DR. RHODES: For comparative effectiveness research. The comparisons of one policy in one state compared to another around how they're addressing, you know, the various -- I really liked the way the Nakela sort of spelled it out, the preconception, the pregnancy, the delivery, and the postpartum.

And I think of, you know each of those we've funded in each area and I don't think we just need to focus on the delivery when that's where most of the deaths without considering the whole spectrum and policies vary across that too, including generosity of Medicaid or availability of, you know. birth control or LARCs, et cetera, et cetera.

So I don't think, you know, we need to shy

away from that on the PCORI side.

CHAIRPERSON GOERTZ: No, thank you, Karin. That's really, that's really helpful. Thanks for that clarification.

DR. RHODES: Yeah. And just like when we went after smoking, it's a multi-modality approach and we saw a big decrease. So continuing to look at the social determinants and the postpartum period, et cetera, et cetera, seems to be important.

CHAIRPERSON GOERTZ: Yeah, absolutely.

All right. Anything else before I turn it over to Nakela for closing remarks? Anyone on that's joined us virtually that like to make a comment?

[No response.]

CHAIRPERSON GOERTZ: All right, Nakela.

DR. COOK: Well, I think we've come to that time where we're wrapping up another day of, I think, exciting session with the Board. And you know, it's been one of those moments today that I think we can kind of acknowledge some big milestones so to speak, and the Board adopted the research

agenda today. That was a huge.

It's so exciting to see where we are on our strategic planning journey.

And, you know, I love that slide with the mountains that has the streams and the rivers flowing, and we've been slowly making our way down that river. And we're at the point now that we have our research agenda and are looking forward to bringing before the Board in June the draft of the strategic plan.

We also talked about today, a number of other exciting elements, including in the report that I gave earlier this morning where we touched base on some important announcements that may be worth just a quick reiteration and particularly the fact that we're going to be looking out for the GAO's posting and the notice in the Federal Register for open positions on the Board for September of 2022, and I want to make sure that we stay tuned into that.

I also highlighted for you several of the leaders that are joining PCORI. And so, we'll look

forward for you interacting and subsequent meetings with those individuals.

We did talk as well about all of the ad hoc working groups and committees that are convening right now and how that all kind of fits in our larger focus around strategic planning. And so, I loved seeing how that knits together and a strategy that we're working on as we're moving PCORI's work forward. And I highlighted some things coming out of our COVID-19 portfolio, which I think we'll continue to build on and be able to provide you with some of those great examples of how that works coming to fruition.

And there were some nice comments as well in terms of the opportunities to think about even the registry from the HERO program that was funded and perhaps opportunities to leverage that work moving forward. So we certainly appreciated that from the Board members.

I also thought it was worthwhile just to mention another important milestone that we crossed today in reporting out on the work from the

Methodology Committee working group, as well as the conflict-of-interest framework. And couldn't be more excited to start this opportunity with the Methodology Committee, where we have a lot more strategic engagement in all of the aspects of PCORI's work with the group. And we'll look forward to moving forward the process for appointments by the Board so that we can continue to move forward with that work together.

And was excited that both Robin Newhouse and Steve Goodman were able to join us for that discussion because it's been work of a lot of people to get us to where we were today. So thank you so much for that.

And maybe the very last thing that I'll mention is that, we couldn't have ended, I think on a more meaningful topic for PCORI. And, you know, I think it just in many ways encapsulates what PCORI is about in terms of the opportunities for us.

And I loved the discussion that happened amongst the Board members to really start to think about what are those niche spaces, where what we do

at PCORI actually can make a difference in such a big problem for this country and the fact that we were so inspired by what evidence does when we have it available for policymakers.

And so, thank you for the additional comments in terms of who we may want to reach out to, to involve in that work, as well as some of the particular opportunities, even thinking about policy strategies and things of that nature that may be important for us in our larger portfolio, in the space.

So another wonderful day with the Board and much appreciate all of the insights, the engagement, and all of your work offline as well and different committees and working groups that have gotten us to the place that we are.

CHAIRPERSON GOERTZ: Thank you Nakela, I'd like to close by thanking all of those who joined us today.

A reminder that today's meeting agenda the approved minutes from the February 15th, 2022 meeting, the slides and the archived webinar will be

posted on the course website within a week. As always, we welcome your feedback at info@PCORI.org or through our website at www.PCORI.org.

Thanks again for joining us and have a wonderful afternoon.

[Whereupon, at 2:50 p.m. EST, the Board of Governors meeting was adjourned.]