PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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[Transcribed from the PCORI webinar.]

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A P P E A R A N C E S

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AGENDA

AGENDA [continued]

P R O C E E D I N G S

[9:00 a.m. EST]

CHAIRMAN HOWERTON: Welcome to the March 7th, 2023, PCORI Board of Governor's meeting. I'm Russ Howerton, Chairperson, and I'd like to extend a welcome to all who have joined us today.

In the spirit of our new governance framework, we have a busy agenda today discussing multiple issues centered around strategy, including appointments to our Methodology Committee, information about our funding plan, and updates on both how we might use PCORnet to increase PCORI research, as well as advancing our themes for research.

We look forward to a busy day and welcome you to that day.

I would like to ask Maureen, if you can call roll for us now, please.

MS. THOMPSON: Of course, thank you. Kara Ayers.

DR. AYERS: Present.

MS. THOMPSON: Kate Berry.

MS. BERRY: Present.
MS. THOMPSON: Chris Boone.
DR. BOONE: Present.
MS. THOMPSON: Ryan Bradley.
DR. BRADLEY: Present.
MS. THOMPSON: Jen DeVoe.
DR. DeVOE: Present
MS. THOMPSON: Alicia Fernandez.
DR. FERNANDEZ: Present.
MS. THOMPSON: Chris Friese.
DR. FRIESE: Present.
MS. THOMPSON: Zo Ghogawala.
DR. GHOGAWALA: Present.
MS. THOMPSON: Mike Herndon.
DR. HERNDON: Present.
MS. THOMPSON: Russ Howerton.
CHAIRMAN HOWERTON: Present.
MS. THOMPSON: Jim Huffman.
[No response.]
MS. THOMPSON: Connie Hwang.
DR. HWANG: Present.
MS. THOMPSON: Mike Lauer, designee for the

NIH Director.

[No response.]

MS. THOMPSON: Barbara McNeil.

DR. McNEIL: I'm here.

MS. THOMPSON: Debbie Peikes.

[No response.]

MS. THOMPSON: Eboni Price-Haywood.

[No response.]

MS. THOMPSON: Kimberly Richardson.

MS. RICHARDSON: Present.

MS. THOMPSON: James Schuster.

DR. SCHUSTER: Present.

MS. THOMPSON: Kathleen Troeger.

MS. TROEGER: Present.

MS. THOMPSON: Bob Valdez, AHRQ Director.

DR. VALDEZ: Present.

MS. THOMPSON: Danny Van Lewin.

MR. VAN LEEUWEN: Present.

MS. THOMPSON: Chris White.

MR. WHITE: Present.

MS. THOMPSON: Janet Woodcock.

[No response.]

MS. THOMPSON: Dr. Howerton, you have a quorum.

CHAIRMAN HOWERTON: Thank you.

DR. McNEIL: I'm here, I'm not sure if you heard. It's Barbara.

CHAIRMAN HOWERTON: Thank you, Barbara, I think we had you. Thank you very much.

If the Board will deliberate or act on a matter that presents a conflict of interest for you, please recuse yourself or inform me if you have any questions.

If you have questions about disclosures or recusals relating to you or others, please contact your staff representative, Maureen.

Today's meeting is being recorded. The agenda for today's meeting, along with 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 please remember to raise your hand turn your tent card over if you are in the room and you wish to speak and identify yourself before

making a comment or making a motion. You may also indicate that you have a question by sending a chat to Maureen Thompson who will add you to the queue if you were online.

You have in front of you the meeting agenda and as mentioned earlier, we have many substantive issues to speak of today.

I would like to carry the first agenda item forward now and bring to your attention the minutes of the February 14th, 2023 meeting. We do ask that anyone not in the room, keep us informed of their attendance if they are leaving the meeting so we can keep track for our voice votes.

Does anyone have any additions, subtractions, corrections to the minutes of the February 14th meeting?

[No response.]

CHAIRMAN HOWERTON: If there are none, could I hear a motion to approve the minutes?

DR. McNEIL: So moved.

DR. VALDEZ: I make --

CHAIRMAN HOWERTON: So I think we have

Robert and Barbara as first and second.

Any further discussion?

[No response.]

CHAIRMAN HOWERTON: All those in favor say aye.

[Ayes.]

CHAIRMAN HOWERTON: Any in opposition or abstention?

[No response.]

CHAIRMAN HOWERTON: I believe at this point, Nakela, I will turn it over to you for the Executive Director's report.

DR. COOK: Thank you so much Russ, and good morning, everyone. It is my pleasure to present the Executive Director's report today, which really has two major areas of focus and update on our funding activities from fiscal year 2022, with an example of a recent outcome and also our funding solicitations, which are ongoing for fiscal year 2023. And I'll conclude by just giving you a high of a recent PCORI-funded research result that I thought would be interesting for all of you.

And following the Executive Director's report today, you're going to hear from several of my colleagues to tee up several important strategic discussions focused on our long-range commitment planning and our advancement of our portfolio and topic themes in three major areas related to cardiovascular health, sleep health, and maternal morbidity and mortality, as well as PCORnet.

So we'll have a very rich discussion over the course of the day.

Why don't we go ahead to the next slide.

I believe there should be another slide before this one, if you don't mind going back one. Excellent.

So in fiscal year 2022, we focused on posting several funding opportunity announcements to continue our efforts to increase funding in our early years of our commitment plan model, and to accelerate progress really on our mission, and we posted, as you can see here, 33 different funding announcements in fiscal year 2022.

And the largest number of these were for

our Dissemination and Implementation Awards, reflective of our efforts to really recognize the increasing results that are becoming available from PCORI-funded studies and innovative strategies to work with partners to bring PCORI evidence into practice where it can really be used.

We also offered our newly combined Broad Pragmatic Studies Funding Announcement, and the Improving Methods Funding Announcement. Three times or each cycle, during the fiscal year, there were several Engagement Awards Funding Announcements this past year. You can see seven here.

And we also had within that, in an addition of a new type of engagement award, one focused on building capacity for small organizations. It's really an innovative new engagement award that was designed to help community organizations develop the capacity that may be needed for patient-centered clinical comparative effectiveness research.

You can see that the focused research topics and the funding announcements related to those stemming from prior Board-approved topics to

advance, as well as included several that addressed the topic themes that were approved by the Board last year, including improving mental health in individuals with intellectual and developmental disabilities; healthy aging, as you can see here; and improving postpartum maternal outcomes.

So these PFAs will produce applications and awards that translate into fiscal year 2023 commitments, and in our upcoming discussion on the commitment plan, you'll see our first quarter commitments for fiscal year 2023 and how those compares to previous years, but those commitments release stem from these announcements that were placed in 2022.

Why don't we go ahead to the next slide.

And I just wanted to highlight one of the Innovative Initiatives that was embedded in those 2022 funding opportunities, and that's the Health Systems Implementation Initiative. Many of you have heard of the acronym HSII, and it relates to this initiative, and we really think this is a groundbreaking initiative. It's got the potential

to greatly reduce the lag time from the generation of evidence to the results being up taken in clinical practice and the participating health systems within the initiative. But we also hope to see a movement beyond these participating health systems as we move this initiative forward.

It's really designed to leverage the expertise and the enthusiasm of the different health systems to implement change in their systems and their communities through implementing practice changing results from PCORI-funded studies.

Earlier this month, we had the pleasure of doing a special media briefing and announced the 42 selected participants that you can see here on this slide. Congratulations to all the participants. This is really a remarkable showing of a different and variety of array of health systems across the country. So we're really proud to have all involved in making this initiative come to reality and we look forward to seeing the promise really, that it holds in watching it unfold over the coming years.

Let's go to the next slide.

So, as I mentioned, the diversity of the group awarded in the Health Systems Implementation Initiative is really remarkable.

The systems all over the country come from large and small size health systems, rural and urban systems, across many different settings and different patient populations, and there are 42 systems that'll participate in this initiative. And you can see 41 states, plus the District of Columbia are represented. More than 800 hospitals, over 145,000 hospital beds. Over 6,400 primary care locations serving over 80 million unique patients. Nearly one in four people in the United States.

So what comes next in the Phase 2 of this initiative?

We're starting to get that component underway and that'll begin with a Learning Network meeting of all of those systems next week. So there's a lot of planning going on at PCORI for that, and that's followed by the opportunity for the participating health systems to apply for funding for capacity building projects, which will really

help them develop the type of infrastructure that's needed and refine their expertise to conduct implementation projects. And we anticipate offering about $500,000 or up to $500,000 for each health system's capacity building activities.

And then Phase 3 kicks off.

In phase three, that's where the systems will propose the actual implementation projects to work on the implementation of results from PCORI-funded research. We anticipate those projects to be somewhere between $500,000 and $5 million dependent upon the project and the scale and scope.

So really in the longer term, our aim is for these successful projects to be scaled up, both at these health systems and then beyond. So hopefully, you're as excited as I am to follow this initiative along. We can go to our next slide.

So looking ahead, and I'm talking about 2023, we expect really to sustain the high level of solicitations that we were able to issue in 2022, posting at least 33 different funding announcements this year with additional ones that may stem from

some of the topic and discussions that we are planning to have with the Board. Many that you see on this slide will be familiar with our Broad Pragmatic Studies, the Improving Methods, Science of Engagement Initiative that we are planning to offer three times every cycle this year, along with nine Dissemination and Implementation Funding Announcements.

One notable change that you'll see here is that the Phased Large Awards for Comparative Effectiveness Research, or PLACER, opportunity will be offered twice this year. And we're anticipating being able to offer that range of smaller-to-large funding opportunities every cycle moving forward.

So the PLACER program, you know, has been particularly noted by staff, as well as the Selection Committee and the Board, to produce the types of applications on topics of great interest to our mission. So we're really excited to be able to offer that more.

We also have two opportunities as you can see here related to the Health Systems

Implementation Initiative. This is for the Capacity Building Awards and for the Implementation Awards that I just described.

You'll also note in the 2023 opportunities here, the Partner PFA, it's the last one on the bottom there, Partnering Research and Community Organizations, to address the systems factors as well as social determinants of maternal health.

And this is an innovative new opportunity as well that really doubles down on our commitments in several ways. It uniquely positions community organizations as full partners and co-leaders of the projects alongside research organizations, and it addresses both the clinical factors and social determinants of health, which are key focus areas in our strategic plan. And it clearly aligns as well with our National Priority for Health to achieve health equity, as well as the key research topic of maternal health that we will be talking about even more later today.

So it's notable that this announcement also talks about opportunities to address maternal

morbidity and mortality in a way that really starts to understand the complexity of the factors at play.

Through all of these opportunities that you can see on the slide, we're really building toward the funding commitments that we're going to make in fiscal year 2024, and that the Board will see in 2024. So again, the 2023 solicitations lead to the commitments that you see in 2024. Let's go to the next slide.

I also just wanted to draw your attention to some additional ways that we are continuing to make progress on priorities in our strategic plan as well. You know, for eligible funded projects that are in an appropriate stage, we're offering supplemental funding to increase diversity and/or health equity impact in PCORI-funded CER, as well as to improve the understanding of patient-centered economic outcomes. And the goal, really of the health equity and diversity supplement, is to increase the diversity and representativeness of study populations in our PCORI-funded studies, and part of our efforts to make progress toward national

priority on achieving health equity.

And the second supplement that you see here on the right around patient-centered economic outcomes, is really designed to help advance our understanding of costs and other economic burdens to patients and caregivers and other stakeholders in eligible funded awards, supporting our focus on the full range of outcomes and patient-centered outcomes.

And we recognize that generating this type of evidence on potential burdens and economic impacts of health conditions or interventions will help support patients and others in making the informed healthcare decisions that take these impacts into account.

So for both of these types of supplements will be notifying those eligible funded awardees of the opportunity to augment their current projects to generate this type of evidence related to diversity and health equity, as well as patient centered economic outcomes.

And they'll provide us as well with another

opportunity or tool to continue to make progress on these PCORI priorities related to these two key areas while certain studies are underway. And so, we're excited about that. Let's go ahead to the next slide.

So I did want to just give you a kind of summary look at the status of our research awards to date. And PCORI has now made about 813 total research awards, including our comparative clinical effectiveness research and methods projects, and systematic evidence reviews. And about 480 of these, or 481 of these have been completed, and another 332 are in progress with 39 that are currently in peer review.

So having nearly 500 completed projects is something really to celebrate at PCORI, and this growing pool of projects allows us to analyze the portfolio in different ways and as you'll see, even when we talk about the portfolio presentations today and the discussions that are being teed up, and you saw some of that even at the previous Board meetings, so it really provides a richness for us to

incorporate in our discussions.

I'm just going to pause and just check if you're logged into the webinar, and you don't mind making sure to mute your line, if you're here in the room. We just have a little feedback. Great.

Let me just try that again. Okay, good. It seems clear now.

So in addition to this growing portfolio, we also have dissemination and implementation projects that are continuing to develop with 13 new projects now complete and about 36 that are ongoing, and we're continuing to see that growth in that portfolio as well.

Why don't we go ahead to the next slide.

So I just wanted to conclude by highlighting a particular study with recent results just to keep all of you apprised of the type of activity we see coming out of the PCORI portfolio. And this is the Prevent Clot study that compared aspirin and low molecular weight heparin for patients receiving treatment at a trauma center for long bone or pelvic fractures.

And you can see that the trial was conducted at about 21 different trauma centers with more than 12,000 patients. And the primary outcome was a 90-day all-cause mortality, but secondary outcomes included non-fatal pulmonary embolism, deep venous thrombosis, and bleeding complications. And aspirin was found in this trial to be non-inferior to low molecular weight heparin in preventing death from any cause, and secondary outcomes were really comparable across the groups, although there were fewer blood clots in the deep veins of the lower legs noted in the low molecular weight heparin group.

So, you know, aspirin's easier to take than subcutaneous low molecular weight heparin and it's generally cheaper. And so, this was really a landmark study because it really can change the standard of care.

And while the findings were presented in or published in the *New England Journal of Medicine*, and you can see the type of attention that this study has garnered already, being in the top 5

percent of all research outputs scored by Altmetric for the journal.

We are also seeing changes in clinical practice tools, such as UptoDate, where two of the UptoDate pages have already been changed to uptake the evidence here that has been generated by this study on the prevention of venous thromboembolism in adults, and you know, those updates say that aspirin can be an alternative to low molecular weight heparin in select low-risk patients who undergo surgery for lower extremity trauma.

So this is a real success story of PCORI-funded research that is moving to that place of really influencing clinical practice and has the opportunity to change standard of care. I've noted, it also aligns with our improving cardiovascular health theme which is nice to note as well.

So that's really all I had for you today, just a little bit of a tour of where we are with our funding opportunities as well as some innovative initiatives we're excited about and closing on this wonderful research result.

CHAIRMAN HOWERTON: Thank you very much, Nakela. Let me open the floor to discussion.

Please Zo.

DR. GHOGAWALA: Nakela, thank you for that overview, which I think is terrific and highlights some of the great strengths of PCORI.

One of the questions that I had was on this implementation initiative. How were the 42 systems selected by PCORI?

DR. COOK: That's a great question. And you know, we have when we put out a funding announcement review criteria that we put together, but as you can tell, there was really an emphasis on making sure there was a breadth of diversity of health systems involved. And really the capacity to work in a space of implementation within the health system with the dedicated leadership that's really needed to make system-level change at such a health system.

So we really do have remarkable leadership of health systems leading these initiatives and that was part of the review criteria as well.

CHAIRMAN HOWERTON: Thank you. I think it's James, and then Connie. Am I correct in the order?

DR. SCHUSTER: Yeah, so Nakela thank you for that overview. Lots of highlights to be proud of for sure.

One question I had, and it's possible we talked about this before in some contexts or you all have already implemented. I missed it.

But, you know, you talked about the health equity supplements that are available and I wondered if we've thought about the idea of making that a requirement in all of our work going forward for investigators to address whenever possible, you know, within the context of what they're doing?

DR. COOK: Thanks so much, James. And I think these are great points.

One of the things that we really pride ourselves on with PCORI's learning from the experiences that we move forward with. And so, we think there's going to be a great opportunity to learn from how these studies are able to incorporate

some of these priorities, which may help inform how we would potentially alter, even the activities that we outline in funding announcements in the future. So it kind of provides this opportunity to catch up with some funded awards as we start to learn enough to plan for how we can move that forward in future awards.

So it's a great point that you raise.

CHAIRMAN HOWERTON: Thank you. Connie.

DR. HWANG: Great, thanks.

So one is a comment, then the second is a sort of related question to James' area, but I'm so excited about the HSII initiative.

I just remember you know, certainly with Mike here, too, but like two years ago when it was really just a concept. So the roster is fantastic and I'm excited to hear updates on that as it moves forward. So that's my first comment.

The second again, relates to what James was saying about the supplemental funding. So great to see the opportunity for both health equity as well as the economic impact. Something that we've been

talking about, a flexibility that really, I think PCORI can lean into as we think about value in healthcare and sort of opportunities that way.

And so, I would love for us as a board to see that tracking of how often that is going to be utilized, that supplemental space. And just want to get a sense, too, of what do you consider to be a target you want to aim for in terms of usage of that supplemental funding? So, I know James is making it automatic, but I'm just curious where PCORI is currently thinking.

You know, what are we aiming for in terms of the uptake of that? Because those areas are so critical.

DR. COOK: Well, we have that opportunity embedded in our funding announcements moving forward, and we have in the past as well, and really what we recognize is that the awardees may need something additional in order to really help us to achieve the outcomes of that priority.

And so, that's really what we were intending to do with the supplement as I understand

a little bit more about what's necessary in order to start to help with that type of data collection.

So I think the goal is that for those that are eligible, and we really are looking at the stage they are in their project, et cetera, that kind of helps with understanding that eligibility; that if they're able to put together something that is feasible that we really can learn from, et cetera, that we would want to be able to support those. So we anticipate for those that are eligible, that we may get the majority of them really focused in on these types of supplements.

DR. HWANG: That's great. I love where we can aim for something where you say it's actually more the exception that researchers are not taking advantage of this.

It'd be wonderful to sort of set a bar that is that high. So thank you.

DR. COOK: Thank you.

CHAIRMAN HOWERTON: Thank you. Before we go to Ryan, could I ask if we're having discussion, could you take the slides down so that people online

will have more visualization of us? And then I think it is you next, is that Ryan?

DR. BRADLEY: So thank you for, again, for that exciting report, HSII is just so impressive and has amazing potential.

I'm curious about overlap between the organizations in HSII and members of PCORnet, and if there might be future opportunities. I can see some in inherent potential efficiencies by improving the overlap between those two initiatives.

DR. COOK: Well, you know, one of the things that we hoped we would have with the Learning Network is that opportunity for communication and learning across the awardees and there may be opportunities for us to also think about how we included some related to PCORnet that may not be in the HSII activities.

I think the Learning Network really could offer that opportunity for that type of exchange and dialogue. So I appreciate that comment because perhaps that's something we can consider facilitating internally.

CHAIRMAN HOWERTON: Before we go to Danny, I would like to interject just a personal -- I'm a visual display of information curious person, and it does strike me that we need a geo map of the HSIIs with like circles that connote how many patients they have. And we probably need a corresponding geo map graphic of the PCORnet institutions just to convey to external audiences and ourselves, perhaps, what it looks like.

The thing you mentioned of a beautiful symbiosis of a research engine spread across the nation and then an implementation engine spread across the nation would strike me as a key attribute of the PCORI in the future.

Anyhow, personal bias. Danny, thank you.

MR. VAN LEEUWEN: I'll continue with the implementation theme.

So I really appreciate that we've gotten this far in focusing on implementation because research without implementation is ink on paper, and like who actually implements -- it's a partnership between doctors, nurses, patients, caregivers are

the people that actually implement stuff.

And so my question is like how -- this is a systems-oriented focus right now. And so, how does that partnership fit in how we select organizations and how is this going to evolve that we, you know, focus on this partnership, in addition to systems?

DR. COOK: I think, Danny, one of the things that we recognize that health systems will need to do is organize within the system in terms of how they've moved forward an implementation project. And one of the reasons we thought it was so critical to have health systems leaders as part of this initiative because they really do have to help think about within their system.

They know their structure, their staffing, their communities the best, and we really are looking forward to them leveraging, kind of the expertise they have within the system to address some of the implementation challenges.

So I think we will see those types of partnerships emerge across system leadership, clinicians, and even with patients and others, in

terms of thinking about the right models for their communities that they serve. And I think we'll have a different array of approaches within the initiative as well.

We have the fortune as part of the media briefing to hear from a couple of the systems that are participating and some that are safety net systems that do this incredibly well in terms of crossing different levels and kind of tiers of a very complex system. And so, I imagine those are the types of things they will bring to bear on some of these projects, and we're excited about that.

CHAIRMAN HOWERTON: Danny, thank you very much.

And actually, as I think about our visual display of information, the bubble for a given health system shouldn't only have the attribute of count of patients, but we needed to mention that captures what Danny says, how intense are there connections outside the walls of the citadel into the community?

If we can capture that and put it on our

visual display, we will incent them to show up better by having more of those and that will drive that research.

Bob, I think it is you -- we have an online question, I think, before we get to you Bob. Can we get Kimberly and then we'll go from there? I know it's hard to keep order online, and I feel bad that we sometimes keep them waiting longer. Kimberly.

MS. RICHARDSON: Good morning. I just want to piggyback on some of the comments that you made, and particularly you, Russ, in terms of that geo spacing.

I think it's so incredibly important that the initiative, the HSII initiative, really begins to look at not only what's happening internally at these institutions as they relate to the communities in their catchment area, but also how well they connect to, as you said, Nakela, safety net hospitals. How well do they connect to community-based hospitals in terms of care and treatment?

So it's going to be really important for us to sort of the bang for the buck to really look very

closely at these initiatives and how well we are bringing these synergies of healthcare to everyone within these individual catchment areas because sometimes they do have a tendency to overlap.

So as we want to celebrate these individual organizations, we still want to find out:

How well will a woman from a rural community be able to access something at one of these selected initiatives? How well is someone from an underserved community going to be able to access these in these organizations that we're funding? So, thanks.

CHAIRMAN HOWERTON: Thank you Kimberly. Bob, I believe you're next.

DR. VALDEZ: Thanks very much. I'm think I'm going to be crossing the two topics that we've just been talking about. One has to do with the institutional activities and the other has to do with the adversity supplements that are being made available to researchers to increase the diversity in their studies. And quite honestly, there are large numbers of researchers who normally look at

that as a criteria for making their studies more representative, so the populations that they serve or their institutions serve.

I know that there's been the argument that it costs more, and that's why we need the diversity supplements to recruit patients who are not part of our regular recruitment mechanisms or services because they're already placed in these particular areas and they recruit from the same groups of people, in the same populations.

But I think there's something to be learned from PCORI grantees who already do that and who in their populations already are more diverse and representatives without requesting a diversity supplement. And I think we should take a look at that and see is this just a cultural issue? Is it truly an economic issue? And figure out how we, in fact, build that into our requests or our criteria for inclusion into a study or funding the study.

And that goes both from the institutional organizational issues that Danny, raised to just simply the way the study design is created to be

inclusive or non-inclusive, to be convenient or not so convenient.

CHAIRMAN HOWERTON: Thank you. I think you're highlighting a traditional principle of performance improvement, which is look internally for islands of excellence before you go elsewhere. And if we think of ourselves as a PCORI community, we perhaps would want to make sure we're sharing that first.

Kathleen, I believe you are next. Is that right?

MS. TROEGER: I think so. This will be quick.

So tremendous to hear the enthusiasm around the HSII initiative, I think it just represents a tremendous advance for PCORI. I echo most of what I think Ryan started in terms of this chain and with regard to the geospatial, in addition to the diversity and I think the representation of insured/uninsured, public versus private in the mix that we've heard.

I would also add that I think there is

already a significant or an overlap with existing PCORnet sites and it would be good to see that on the map as well, because it's some certainly, but not the majority. Thanks.

CHAIRMAN HOWERTON: Okay.

DR. COOK: Can I reply? Because that's come up just a few times in terms of that overlap.

CHAIRMAN HOWERTON: Sure.

DR. COOK: So I just wanted to let you know that we do know that a third of systems that are in the Health Systems Implementation Initiative are represented in some way, shape, or form in PCORnet. And so, I think that's actually a good point for us to follow up on.

And the other piece that I just wanted to make sure that I mentioned, is that the health systems really that are represented across HSII are you know, they're systems that actually are diverse within themselves and have kind of that inclusion of safety net hospitals or even community care or critical access hospitals as part of their systems, too.

And so, I think that's another area that I was hearing a little bit about, that we have that opportunity to really bring out in terms of understanding the richness of contributions of those types of diversity of systems. So just wanted to add those points to the discussion given it's come up a few times.

CHAIRMAN HOWERTON: All right. Thank you very much. I'm pretty sure that Zo is next, and Chris is the last between Mike and Alicia, I don't know who is after that, but we'll start with Zo.

DR. GHOGAWALA: Nakela, I was thinking a little bit more about the implementation initiative and one of the potential barriers for implementation oftentimes in healthcare systems are the costs associated making some of the changes that might improve health.

And so, my question is how much have we engaged payers in some of these implementation efforts in healthcare systems? Because it seems to me that they would be able to help us think through these implementation goals.

DR. COOK: I really appreciate that comment. And you know, our broad engagement of payers, I think, reveals some insights for us and we certainly have that opportunity to do that crosstalk between those engagements. But we also have engaged with provider plans as well that have applied to HSII. And so, I think we're going to learn from those types of plans, too, in terms of how we may think about the change and the cost of change, et cetera.

Some of the capacity building opportunity is also to jump start some of the type of infrastructure change that may be important, to even show a proof of principle, for a lot of the kind of evidence-base that may be necessary to push toward the types of change that may be important for implementation.

CHAIRMAN HOWERTON: Thank you.

DR. HERNDON: Just a question for clarity.

Nakela, I probably should know the answer to this, but I can't remember the discussions around it. When it comes to implementation of the research

and the science are we only going to be giving awards for implementation to the HSII participants other networks and organizations who want to do implementation, be able to do it?

DR. COOK: Within this particular initiative, the awards for implementation would be within those that have been identified as participants and awarded as part of the HSII program.

We will continue our other components of our dissemination and implementation activities, which, as you know, reach a wide array of opportunities for those outside of HSII to continue to work to move PCORI-funded research results forward. So it's not exclusive to those other opportunities.

CHAIRMAN HOWERTON: Thank you. Alicia.

DR. FERNANDEZ: Yeah, thank you.

First that was so exciting. That was an incredible report. It's just incredible to see all the things that are happening and the Health Systems Initiative is particularly exciting. And I think

what it has left me with is a real desire to know more.

And I wonder whether in the future, the Chair and you, Nakela, could give us a little bit of a report on the health systems -- on the initiative side, there is of course issues of priorities and governance and scaling, and so on and so forth. And I think it would be great at some point to hear a little bit about that and I don't know whether or not you wish for Board input into that, but I think that would be really important.

The other issue is just a plea for all of us, that we're developing PCORI-unique vocabulary and we should just be -- I think it may become confusing over time. When do we mean we're going to fund an implementation science? When are we funding in the implementation initiative? When are we doing the dissemination implementation of PCORI-funded studies? So health equity, diversity supplements, all of these things.

And so, over time I wonder whether we want to think about that just to make it easier.

And along those lines I hope that we will think about implementing diversity supplements along the lines of traditional NIH diversity supplements, which is to say for capacity building among researchers, unless that is one of the things that's already in there and I missed it.

But as many of you know, that's been a very valuable mechanism for younger people launching their careers. It is relatively cheap and my understanding is that at NIH it has borne fruit, certainly among the people that I've seen. It's borne fruit.

So those are just observations, but my overall emotion is one real excitement that we're poised to do this and that you've been doing this so thoughtfully, so thank you.

DR. COOK: Thank you Alicia.

CHAIRMAN HOWERTON: Thank you. Can I tag onto that? Have we thought of a name -- HSII is confusing, even to us here. We barely remember it.

Have our branding experts thought of a name to go along with PCORnet. We need to think of what

we're going to call that, not HSII. Chris.

DR. FRIESE: Well, thank you very much and congratulations on the accomplishments and the progress that you've described Nakela. It's very impressive and very exciting to see the list of HSSI centers.

CHAIRMAN HOWERTON: Wait, time out. He said HSSI.

[Laughter.]

DR. FRIESE: Sorry.

CHAIRMAN HOWERTON: I rest my case that we have to come up with a name.

DR. FRIESE: I apologize. I admit I am ascending a learning curve on the PCORI vocabulary.

CHAIRMAN HOWERTON: Yeah, well, we're all, too, don't worry.

DR. FRIESE: And the alphabet soup.

So Dr. Fernandez, I certainly support your comment earlier. And as you can see, I'm learning as well. But relative to the HSII Centers of Excellence that you've that you've selected and that you shared with us, I wonder is there an element of

our work that would capture the impediments that they experience in their implementation?

So Zo referenced one, it could be payers. But there could be other types of impediments as well. The challenge then, certainly it could be scope of licensure, it could be other facility licensure, it could be state law, it could be just an array of other challenges, and it would be really powerful if in some way we could capture, you know, collectively the impediments that they experience, and then glean what lessons that we might learn from their collective experience.

So I just wondered, Nakela, is there an element of our work that captures collectively those impediments of the experience?

DR. COOK: Thanks for highlighting that. And I would say yes and yes. Because we're really excited about the Learning Network as that way to start to reveal even some of the themes that maybe successes as well as barriers in terms of our learning across systems, both for the systems engaged, as well as for PCORI. We're going to learn

a lot through the Learning Network and the cross talk with the networks.

And then the other components, there's a robust evaluation plan activity that will be part of the initiative. And so, that'll be another way in which we can really glean, both the barriers as well as the facilitators really for this type of work.

CHAIRMAN HOWERTON: Thank you. In the room, I don't see other questions. Are there any online questions that I have not attended to?

DR. COOK We don't see any.

CHAIRMAN HOWERTON: All right, well, I want to compliment our Board. I'm not sure if you're reading your schedule and have adjusted your comments to fit that. You have arrived at precisely the time allotted for this discussion.

So if there are no further comments, we will thank Nakela for a superb Executive Director's report.

[Applause.]

CHAIRMAN HOWERTON: And no doubt the team that helped her prepare that, as well. Our applause

is for them also.

And I believe we would then turn to our next agenda item, which is consideration of Methodology Committee Appointments, and I would like to turn it over to James Schuster, Chair of the Nominating Committee for Members of the Methodology Committee, and I believe he will introduce the agenda item and subsequent speakers.

DR. SCHUSTER: Thank you.

CHAIRMAN HOWERTON: And I'm sorry if I had asked to have the slides. Oh, somebody already did put the slides back up. Never mind. You're ahead of me. Thank you.

DR. SCHUSTER: Thank you. And Harv Feldman is going to be presenting with me and I certainly want to start out by thanking everybody who served on this group. There were several meetings, lots of thoughtful work and as well as lots of work by the staff to evaluate new members for the Committee. As you all may remember, we had lots of discussions over the last couple meetings. And certainly, the new folks don't remember, but historically, we'd had

members on the Methodology Committee who some agreed to forego PCORI funding and some did not. And for the ones who did not, they couldn't participate necessarily in all the discussions and there were some limitations.

So we're moving to a different model, which you'll hear more about. So that was certainly part of it. And then there's also folks rotating off the Committee, and so, we did a lot of really trying to identify the right tempo for people coming on and/or leaving. So you'll hear some more about that as well.

And we think that this will really, that the model that we worked, on will really maximize the positive impact from the Committee, really a broad depth of expertise in these areas. And these folks have also all had background checks and extensive vetting as well.

And lastly, just want to also thank everybody who served on the Methodology Committee. As you'll see, some of those folks are going to be continuing but some people are rotating off either

now or shortly, and they certainly made great contributions and we really appreciate all their work over the past.

So I'm now going to turn this over to Harv, who's going to walk us through some of these details.

DR. FELDMAN: Great. Thank you, James. Maybe we can advance to the next slide.

So I'll just start off by, first of all, by thanking James for his leadership of this nominating committee, and this slide depicts the six Board Members and two staff, myself and Erin Holve, who gathered together for multiple meetings for this nominating committee and did the work of vetting that we'll describe here that led to the recommendations that we're bringing to the Board.

So with that, can we maybe advance to the next slide, please?

So this slide is a reminder to some and perhaps new to others of the Methodology Committee governance framework that was revised back at the beginning, the early part of 2022.

And I'll note that in developing the slate of nominees we were very mindful of this framework and the slate fully aligns with the revised March 22 guidance here that you see. All of the nominees have agreed to adhere to PCORI's conflict of interest policies that are also depicted here. And the proposed terms provide for the staggered structure that is also specified in the revised governance framework for the Committee.

You can go on to the next slide, please.

So the Committee vetted a very strong set of nominees who represented a broad array of areas of expertise, including but not limited to those that are outlined in PCORI's authorizing law. These included areas such as program evaluation; research, rigor, and reproducibility; data science and informatics; health services research; analysis of potential burdens and economic impacts to patients and caregivers; implementation science; as well as a methodological focus on diversity, equity, and inclusion.

And after careful deliberation of all of

the nominees, and there were approximately 30 or so nominees that were brought forward to the Committee. The Committee recommends a slate of 15 individuals that is comprised of seven current Methodology Committee members and the recommendation is for an appointment for approximately a two-year term, and eight new Methodology Committee members for an appointment of approximately a four-year term.

And you'll see this in just a moment.

We anticipate future Methodology Committee appointments now to occur biannually, which will again allow us to fully conform to the governance framework that I shared with you just a minute ago.

So if we move on to the next, and the last slide that I have here. Shown are the individuals on the slate of nominees. And you see they're separated by virtue of the duration that is being recommended for their term. And you see on the left, these are individuals who are currently serving on the Methodology Committee, recommended for approximately a two-year term. And then new members on the right side of this slide, for

approximately a four-year term.

And it is also recommended that the terms begin on the first day of April of this year.

So with that, let me bring this back to you Russ. And the next slide, which we don't need to go to quite yet until you're ready after discussion, has the motion for approval, but let me turn it over to you to lead any discussion you'd like to have.

CHAIRMAN HOWERTON: Certainly. Let me thank all of you for the work that got us to this slate of candidates and I open the floor for discussion from any and all members of the Board about these candidates or about the structure and processes that were outlined.

All right, we're going to start first with our line members for a change. Chris, Chris Freeze?

DR. FRIESE: Yes. Hi. Good morning. Thank you for this work. I appreciate it, and it looks like a terrific slate.

Just -- and maybe I missed it. It looks like both the Chair and the Vice Chair would be terminating at the same time, and I wonder if there

had been thought of staggering it a little bit for leader transition or maybe we do that in the next round as new Chair and Vice Chair are appointed.

DR. FELDMAN: Maybe I can address that, and James, please chime in.

So Steve Goodman and Robin Newhouse are currently the Chair and Vice Chair of the Committee, and therefore, will continue in those roles until such time as when the Board makes a decision, potentially, to modify the leadership of the Committee. The action of evaluating and potentially revising leadership of the Committee needed to wait until the Committee was actually fully populated.

So that would then travel through a board process that, as I understand it, would involve the Governance Committee and then on through to the Board.

So this is really, for the moment, a depiction of leadership and then it's really up to the Board how that will evolve over time.

CHAIRMAN HOWERTON: Chris, did that answer your question?

DR. FRIESE: Yes. Thank you.

CHAIRMAN HOWERTON: All right. Thank you very much. I think, Bob, you were next then the Chris in the room and then Ryan, am I correct? I'm sorry I didn't keep the order. So we'll start with you and then you can help me --

DR. VALDEZ: Well, first of all, thanks very much to the Committee members who selected the candidates and worked through the process. And I'm particularly happy to see the geographic diversity that's represented by the new potential members. But I would encourage us to consider more issues of our diversity in our committees, both those that are standing committees as well as those that are ad hoc.

The other thing that was impressive is that we also have people from different kinds of institutions, which I think is important for institutional work.

In particular, the discussion that we had just a few minutes ago. But there's some concerns I have about the fact that we seem to do pretty well

on the male/female mix and some on the geographic mix, but not so much on the race/ethnicity mix. And for some of the issues that we were talking about with regard to diversity of study populations and others, I think it's very important for us to keep that in mind.

DR. SCHUSTER: We did discuss those issues in the selection process and we tried to look at look at those issues. There were relatively small number of candidates who represented diversity opportunities. We did talk about the fact that is undoubtedly, at least partly related, to how you reach out and recruit folks to be candidates and that's a learning opportunity for us going forward. So we, the group, agreed with that.

CHAIRMAN HOWERTON: Thank you. Chris Boone.

DR. BOONE: Thank you. Yeah, I mean, I think it's -- I agree that it's a very impressive group of candidates. But I am curious to see, I mean, I noticed that most of these individuals are affiliated with universities, and I wonder if is it

due to the fact that there weren't many candidates from industry that applied to be part of the Methodology Committee? Or is it just by design that we choose, or sort of prefer, if you will, individuals that are affiliated with universities?

DR. FELDMAN: Yeah, we did not limit this in any way in that fashion, Chris, and I certainly agree with your observation.

I think, again, coming back to the sort of learning opportunity, because we'll be doing this iteratively as the Committee continues to refresh. We need to think about how our, the criteria that the Committee members utilize to assess the methodological backgrounds of the individuals, how much of that aligned with, for example, positions within the academic sector as opposed to other types of areas within the Methodology Community.

But this is a reflection of who actually applied in this instance. So thank you for the comment.

CHAIRMAN HOWERTON: All right. I think that takes us to Danny.

MR. VAN LEEUWEN: So I support this slate, but I really hope that in the next round of this that we put some people with lived experience on the Methodology Committee.

I can't imagine how we're going to address the methodology priorities for maternal mortality and morbidity or intellectual and developmental disabilities without having people with lived experience on this committee.

CHAIRMAN HOWERTON: Thank you, Danny. Does anyone by chance know if any of these members would actually have any of those lived experiences in addition to their other qualifications?

DR. FELDMAN: I don't know actually about whether they have lived experiences. I think it's a really important point that you're making, Danny, and I would say that these Methodology Committee members, and by virtue of being part of this group, have the role of interacting with a whole host of other entities at PCORI, including our stakeholder groups, which is very explicitly identified within the authorization for PCORI and the depictions of

the Methodology Committee.

So there is strong opportunity to weave in individuals with lived experiences.

It doesn't diminish your point in the least, but this committee certainly will not, has not, in fact, in the past operated in isolation of communities that, in fact, are enriched with individuals who have those experiences --

DR. SCHUSTER: Could I just jump in.

CHAIRMAN HOWERTON: I think you are part of the Committee, so you get to

DR. SCHUSTER: I think it's a great point though, and I think you know, in the same way that Chris raised the point about trying to identify folks from outside academia to participate. I think in the same way we could, you know, there are lots of people undoubtedly, who have the required technical experience and also have lived experiences, and that would be something certainly to ask folks if they're comfortable to share when they apply and potentially do some outreach, kind of trying to specifically encourage applications for

those communities.

CHAIRMAN HOWERTON: Thank you. Ryan, would you be willing to defer for a moment? I think Kara wants to make a comment on this point and then we'll come to you.

DR. AYERS: Thank you Russ. Yeah, I agree, Danny, it's a great point and I really think that even broader than just this selection process, we need to look at the way that we assess lived experience. The fact that we really don't know tells me that we need to reevaluate the way that we assess, you know, many times asking about disability is kind of the uncharted demographic and that I've asked where's the disability graph data when we have other diversity variables and have been told that's sensitive information. But yet we ask about other things.

So we really need to look at what questions we ask in our recruitment process and make sure that we're including, I mean, as noted, some people will always, for a variety of reasons, many valid, not disclose. But if we're not asking, we'll never

know.

And then just reiterating, that even though these individuals may have connections with patient communities or lived experience communities, that doesn't, of course, it's not the same as direct representation. So, great points.

CHAIRMAN HOWERTON: Thank you, Kara.

Just a personal point, thank you to all of you who sent me obituaries on Ms. Humann [phonetic] yesterday. Truly a remarkable individual -- to have read those and increased my knowledge base greatly. Thank you. Ryan.

DR. BRADLEY: Yeah. Thank you. I think maybe my comment or question just speaks to the criteria used in the selection of this committee and I'm not clear on the backgrounds of all these candidates. If those materials were supplied to us, then I apologize for missing them.

But I'm curious about the inclusion of sort of the up-and-coming generation of methodologists, specifically in the area of emerging technologies such as AI, cooperative computing platforms,

analytical platforms, use of wearable devices, and other emerging technologies that are going to be critically important to the future of the research that we do.

And those skills are not always nested in those with the most experienced research careers in these methods. In fact, the youngest and the brightest are actually often the best in innovating these methodologies. So if not in the present selection, I'm hoping that these factors are considered in future candidates for this committee.

CHAIRMAN HOWERTON: Harv, would you like to comment on that?

DR. FELDMAN: Yeah, I would just -- thank you for that really insightful comment.

The Committee was aware of some of those interests within the slate that's before you here, but I think it's really a critical point that you're making, again, about the care that we take in identifying how we reach out and how we characterize the requirements for the Committee.

And I think your point and the other points

that have been made here really suggest strongly that there's great opportunity for us to engage with the Board in really discussing how we can best outreach as this process iterates, which it will every other year. So thank you.

CHAIRMAN HOWERTON: Thank you. James is your card up for a question and Danny, I think your card was up from before.

One comment to Ryan. I'll solicit hard, but the requirement to forego the PCORI-funding may be harder for younger investigators, I mean, younger methodology-type persons, more senior-established folks may feel very confident that they have a pathway. They may. They don't all, they may, but the younger you are, you may need to keep more of your opportunities open.

So we do need to think of a way to balance that. I don't really know what the answer to that is.

As a new member, I will say, I think over the years that's been one of the great challenges for the Methodology Committee, is understanding that

balance to be impartial without funding, but to be knowledgeable and experienced.

Are there online questions that I have not called upon? Are there any further questions in the room?

Debbie. Please go ahead.

DR. PEIKES: Sure. I just wanted to follow up on what Ryan said. I would find it very useful to have just a listing of what their particular expertise is, just to get a sense of what kind of methodological expertise is covered going forward.

I'll hold my comment for this round.

CHAIRMAN HOWERTON: Well, thank you. I would actually echo Ryan, because I thought the names were not submitted to anyone prior to the meeting. And then in the materials I had, it was all TBD. Was there demographic information circulated?

DR. FELDMAN: I don't believe there's demographic information, but it's certainly straightforward for us to share the affiliations and a brief depiction of backgrounds of the individuals

on the slate for the Board.

CHAIRMAN HOWERTON: Point of consideration in the future. I'm very familiar with this, having contributed to all of this for you as a board by sending you a slate at the very last minute before we did nominations at the last board meeting. But in general, we should not be expecting our Board to actually vote on a motion for names that they just saw now because the Board would reasonably be expected to have some time to opine on that.

So as we think about next year's process, we need to consider that. I will ask the Board if you are willing to go ahead and have us have a motion on this slate, even with the information content, time cycle as you have it today.

If you are not, and if anyone is not, we are more than happy to do something different.

Danny.

MR. VAN LEEUWEN: Yeah. I think that we did receive something, but today when I was like, this morning I was prepping for today. I couldn't find it.

So I did see -- the reason I started my comments with I support this slate is that I did see the detail about these people and it was really impressive.

But again, I couldn't find it when I went back to look for it because I, all I could find was the original TBD stuff.

CHAIRMAN HOWERTON: I'll retract my comment then if I missed it as well. I had printed the TBD stuff, also.

DR. COOK: Yes. Unfortunately, I think the addendum came a little later than the original package, so you hopefully received it on Thursday of last week, and it did have some summary information about each of the nominees.

CHAIRMAN HOWERTON: All right, I retract my comments. Probably then we should vote. Shall we move on to the next motion? All right.

Does anyone, I think this -- I'm so sorry. Go ahead.

DR. NEWHOUSE: No, I can very quickly give you the list that I have from my own notes, if

that's helpful.

CHAIRMAN HOWERTON: Sure.

DR. NEWHOUSE: For you to know the scope, and I know Steve's on the line. Steve Goodman, who's the Chair who can add anything else.

So the areas of expertise that I have recorded are data science, informatics, diversity, equity, and inclusion; analysis of potential burdens and economic impacts to patients and caregivers, data science, informatics program evaluation, research rigor and reproducibility, social determinants of health, health literacy, numeracy risk communication, implementation science, health system science program evaluation.

I'm not going to repeat some of the others.

Reliability of epidemiology research; data science; informatics; the qualitative/quantitative mixed method, design and evaluation techniques.

Some of them are redundant.

Let's see, bioethics, data science. More economic impact. Patient and caregivers, decision science, participatory research, mixed method,

health disparities, patient engagement, community-based participatory research, health system science.

And let's see. I think that's about it,

Steve, is there anything we missed here?

DR. GOODMAN: I'm sorry, you're asking me?

The only thing I would just observe from, and I was not on the Committee, but many of these while they might not be junior researchers, they're definitely not senior. They're very sort of mid-career, very much in the mix of contemporary issues.

So related to the previous comment, I do think we have folks, and I totally agree with this comment that are very much in the mix of current emerging both methodologies and technologies.

Of course, it's impossible in a committee of this size to cover everything. But we have a lot of people who are, you know, you might call in the prime of their careers and represent the next generation.

CHAIRMAN HOWERTON: Thank you both, Steve and Robin, that was an impressive list.

Bob, you have one more?

DR. VALDEZ: Yes, I spent the weekend checking out these folks because there wasn't enough information for me to understand what they brought. And I second the wonderful list you provided having done that for myself, trying to understand who I was going to be voting for today.

But I have to disagree, I don't think that some of the more cutting-edge methodological approaches are covered, the issues that Ryan raised earlier, but these are certainly people who are at the middle of their careers largely, who are doing some cutting-edge work and have some impressive publications under their belt and work under their belt. I'm very supportive of them, from a mix and methodological perspective.

But there are some shortcomings that Ryan pointed out and there are some issues about how we know who we're voting for or not.

CHAIRMAN HOWERTON: So I would thank you very much for that. And again, we welcome diversity of opinion and I would actually ask, while we are starting the day after this vote to prepare for two

years from today. And so, if there are gaps, and in particular if anyone here knows anyone who might be a plausible candidate. I'm willing to bet that Harv and James would welcome those names now for the act of soliciting and finding individuals to be ready for us in 2025 to when many of us, most of us will still be here to vote on this, and begin. And perhaps we can lessen that gap the next go-round.

Thank you for that, Mike.

DR. HERNDON: Just a point of clarification, the email containing them was sent March 1st. Amy sent it March 1st,at 7:30. If you all look in your inbox, March 1, 7:30 p.m., from Amy.

CHAIRMAN HOWERTON: All right. Well, I'll have to acknowledge my failing in that. Ryan.

DR. COOK: Can you turn your microphone on for us, Ryan?

DR. BRADLEY: Sorry about that. I also wanted to acknowledge my failing in that, and that I did just review my email inbox and found the addendum.

I think perhaps a request should that

circumstance happen in the future; the significance of the changes be highlighted in a little more detail on the fact that there was some biographical information included that was not previously circulated. I think that would've been helpful.

I take responsibility for not reviewing the most updated version, but I think if there's a way, and particularly on important points like that, to direct our attention to those changes a little more specifically that would be very helpful because I had previously reviewed the other materials.

So that's just a general request. Sometimes action steps get buried in communications and it'd be really nice to bring them to the forefront.

That said, I also just wanted to comment on the issue raised about the potential challenges in foregoing PCORI funding and the challenge that might bring with recruiting younger, potentially younger, I didn't mean to say younger. Those that are perhaps at the, you know, the more cutting edge of the distribution of innovation regardless of their age, that forgoing PCORI funding might be an issue.

I think this ties back to the previous comment about looking into industry and looking into other sectors that may not be dependent upon PCORI funding. I think we also have to acknowledge it's still a very small minority of individuals who are funded by PCORI.

The Methodology Committee commitment is not a super long-term commitment to where that might be a significant career compromise for them. And I just want to thank everyone for the discussion around the point. I do think it's important, so thank you.

CHAIRMAN HOWERTON: Thank you. Agreed.

I will say with regard to communication, I believe a future state will be that we are all on a BoardEffect program, and the source of truth will be what is current on the BoardEffect. And to your point, we might get notifications of changes in BoardEffect, but rather than filter through, most of you probably get what, two, three emails a day, filter through the five or 10 emails in your inbox. We will be going to the BoardEffect platform, which

will be constantly current. I hope that's our future state.

We will happily let you add something, Nakela.

DR. COOK: I just wanted to add a couple of things and one of the things that we did from a process perspective this time around, was really lean on input from the Methodology Committee about the types of expertise that could be helpful for us to recruit and think about for the new appointments moving forward.

And I think in several areas that were identified by both, the Methodology Committee and discussed with the Board previously, we were able to find that type of expertise in the pool of candidates that applied.

So I just wanted to mention that I think there's going to be an opportunity for us to look at that again, as we come back for the next round of appointments in two years to say, you know, given the state of the field and the where things are, what are the areas of expertise that may be most

important? And we were able to put that in the solicitations that were sent out asking people to apply for this opportunity.

And so again, we can do that in the future. And it's important, as Russ mentioned, that as we start to think about where we want to go down the line, starting to build some of that so that we can make sure that the robust outreach includes those areas that would be most important to reflect on the Committee. But that was part of the process leading to the slate of candidates as you see right now.

And the Committee did a lot of work to try to sift through different areas of expertise in order to really understand and kind of complement that would be rich for the Methodology Committee.

CHAIRMAN HOWERTON: Are there online comments or questions not attended to?

MS. THOMPSON: No, there are not.

CHAIRMAN HOWERTON: If there are no further in the room, would anyone be willing to make a motion to approve this slate?

DR. HERNDON: Mike, so moved.

DR. FERNANDEZ: So moved.

CHAIRMAN HOWERTON: I'm going to take Alicia, not you, since you were in the Committee that did it. How's that?

And then we'll take Mike as the second.

How is that?

Is there any further discussion?

Have there been any changes in our attendance, Maureen?

MS. THOMPSON: Yes, Barbara McNeil had to step away.

CHAIRMAN HOWERTON: We remain with a quorum, I believe. And so, all those in favor say aye.

[Ayes.]

CHAIRMAN HOWERTON: Anyone in opposition or abstention?

[No response.]

CHAIRMAN HOWERTON: Thank you. The motion carries.

We have an excellent slate that we look forward to working with and we look forward to

beginning to address some of the points raised here as we begin the 2025 process tomorrow morning.

I want to, again, commend this Board for reading your agenda because we have hit the mark precisely on our time.

I believe that we turn again to James in a different role as the Chair of the Finance and Administration Committee for him to begin the strategic discussion on our 2023 and beyond commitment plan. One of our very important tasks as a board.

DR. SCHUSTER: Thank you. I'm actually doing this at my capacity as the Vice Chair.

CHAIRMAN HOWERTON: Fair point. You're right. I realize that now.

DR. SCHUSTER: Our Chair is on vacation.

CHAIRMAN HOWERTON: Jim is overseas.

DR. SCHUSTER: Yes. And so, I'm doing it in his stead.

So thank you for the introduction. The Finance Committee met recently and reviewed certainly ongoing financial statements, looking at

expenditures, financial positions, et cetera, and that was really -- everything looked quite good and on point.

The issue that we're bringing here this morning is really focusing on our long-range planning in terms of committing our funds. So essentially, how much we'll commit when, and it's certainly significantly driven by what our revenues are. But there's some flexibility we have in terms of, you know, whether we commit the same amount every year or whether we want to kind of, to some degree, frontload that commitment to get out as much money as we have work for, you know, work that we approve and is valuable. Which I think has been PCORI's historical approach and the recommendation from this group was to continue the historical approach.

Brian is going to review the details of that. He and his team did extensive work to really try to evaluate what's feasible and safe while allowing us to be as kind of assertive in our approach in terms of generating work as we can.

So I'll turn this over to Brian to walk through the details.

MR. TRENT: Thank you James. And good morning to everyone. Can we move to the next slide, please? Thank you.

So at the Board's December meeting, we discussed a plan to have strategic discussions related to the commitment plan over the course of this year. Today is the first of those discussions, which will focus on the long-range commitment plan mode. In June, we plan on discussing the three-year commitment plan, which will include a discussion on three funding categories within the plan, which are research, dissemination and implementation and infrastructure.

And these discussions will culminate in September, with the Board's decision on the three-year commitment plan for fiscal years '24 through fiscal years '26. Next slide, please.

So in December of 2020, the Board-approved both a long-range model for commitment planning along with a rolling three-year commitment plan.

Both the three-year commitment plan and the long-range model are subject to annual review and updates by the Board.

The philosophy that the Board adopted at the time for the long-range model had higher targets for commitments in fiscal years '22 through fiscal years '24, with a dip in fiscal year '25, and leveling off through fiscal year 2030.

By frontloading the model, the goal was to rapidly increase funding for new research projects in the earlier years following reauthorization. Next slide, please.

Here's the picture that illustrates what the Board-approved in 2020. You can see in the graphic the philosophy that the Board adopted for this long-range plan, which frontloaded our commitments with us eventually moving to a steady state in the out years through fiscal year 2030.

The light blue range represents projected award commitments based on two different revenue assumptions for the PCOR fee. One assumption assumes 5 percent growth and the other assumes no

growth. The revenue assumptions are based on the projections by the Department of Treasury. Next slide, please.

The proposed updated model that we're sharing with the Board today has more funds available for commitments in the out years because of a combination of factors. These include rolling over funds that were not committed in fiscal year '22. A projected bump in revenues from interest from our Treasury-backed securities, and keeping our net balance of unobligated funds at a minimum.

One additional change that we made to the updated model based on discussions with the FAC is adding a target range for estimated commitments in fiscal years '23, '24, and '25. Next slide, please.

So some of the benefits of the proposed updated Commitment Plan Model include maintaining a high and predictable level of yearly commitments with a surge in the earlier years; maintaining a low unobligated fund balance in the areas of $200 million to $400 million to maximize commitments while cushioning variability in revenue sources;

maintaining the operating principles of not committing funds before curing revenues; and the target range versus point estimates for allowing natural variability from year to year. Next slide, please.

As Nakela mentioned in her Executive Director's report, we've seen some steady increase in terms of our first quarter actual commitments over the past four years. Despite not meeting our targets in fiscal year '22, as you can see, we made significant improvements in the first quarter of fiscal year '23 compared to the previous fiscal years' first quarter commitments.

We'll be providing regular updates to the Board or our actual commitments throughout the fiscal year.

This graph represents funding across all funding categories, including research, dissemination and implementation, and infrastructure. Next slide, please.

So for today's discussion, we want to focus on the long-range model, the trajectory for year-

over-year commitments.

Does the Board concur with the approach taken, which includes maximizing commitments and minimizing unobligated balances?

Is having a variety of yearly targets an effective way of accounting for variability along various dimensions?

Does the Board have suggestions in terms of alternate approaches to targets?

Is there anything different that the Board would like to see in terms of the long-range funding model?

And are there any additional considerations related to the long-range model that we should discuss at the upcoming Board meeting in June?

And with that, Russ, I will turn it back over to you for questions and discussion.

CHAIRMAN HOWERTON: Thank you so very much.

And as always, I remind you to raise your tent card if you want to speak in the room or chat, Maureen, if you wish to speak somewhere else.

But James, we'll come back to you directly

as a member of the Committee to speak before opening the floor to discussion. Go ahead James.

DR. SCHUSTER: Thank you. So I just had a question for Brian, actually, which is in light of the wind down of the Medicaid expansion as the public health emergency ends and some of the additional subsidies that were available for folks on the Exchange during that period, is either one of those you think likely to impact the number of people purchasing policies, whose policies contribute towards our funding?

MR. TRENT: I really don't know the answer to that. I don't know Nakela, if you have --

DR. SCHUSTER: I just thought about that while you were presenting. It would've been good if I thought about it sooner.

DR. COOK: Well, James, we certainly can look into it. I think one of the things that we were trying to accommodate in the updated model is the fact that there can be that variation.

And you may recall that in some of the discussions with the FAC, we talked about the fact

that there's kind of an upper limit projection that is based on some of the historical, and then we dropped down to what could be zero percent. So we think we're covering both the high limit and the low limit in that range that's presented in the long-range model.

So even if there is some fluctuation related to the ending of that emergency funding and changes on that Exchange, we hopefully, are accounting for high and low.

DR. SCHUSTER: Yeah, hopefully.

So it just might be another dynamic worth tracking, you know, and maybe bringing it back in June.

MR. TRENT: Sure.

DR. SCHUSTER: Because it might be, you know, it might be trivial, but it might be more substantive. It's just worth looking at.

CHAIRMAN HOWERTON: Before I open the floor to discussion, I would like to highlight for -- particularly, our new Board Members, that this is one of the most major responsibilities we have as a

board to decide how to allocate these funds that society has entrusted to us.

And just a free year thinking, and in no way to sort of -- the theoretical range is vast.

In theory, I believe, we could commit all of the future expected funding to a single study next week or we could operate the ongoing studies and commit to no new ones and do 10, one or single study, in 2030.

So, I mean, the range of choices is great and how we choose is very important to our society, PCORI's success. So this is a worthy topic for deep deliberation for us.

Mike, I open the floor to you.

I'm not advocating for either of those two positions, by the way. I'm just trying to free your thinking. We, as the Board, are empowered to think about this.

DR. HERNDON: I'll start the discussion by saying that my opinion to question number one, Brian, is yes, we concur with the approach, or I at least do.

Just for the new people who've joined us on the Board, there has been a lot of discussion about underspending and how we do need to be aggressive and spend the resources that we have. And we've worked very hard to do that, at least over the four years that I've been a part of the Board.

So this approach, I think, makes the most sense to be aggressive at maximizing our commitments and I think it also is incumbent upon us then to make the topics and the attractive, you know, to researchers and we have to do a good job of making it you know, attractive and palatable to those who do this research and to get the meritorious bids and all that.

So I'd say yes, be aggressive and continue to do the excellent job that we're doing. The infrastructure we've built to accommodate this growth is outstanding here with PCORI and PCORI staff.

So I think there's no reason to change the attitude and the philosophy that we've had over the past couple of years.

CHAIRMAN HOWERTON: Thank you very much. Danny, I believe it comes to you next.

MR. VAN LEEUWEN: Thank you.

In the light of our discussion in the Executive Director's report about implementation, I'd like to address the fourth bullet and that I would like to see us revisit the emphasis that we put on implementation and funding for implementation in our June meeting when we're talking about specifics. Thank you.

CHAIRMAN HOWERTON: Thank you. And yes, I do believe I'm looking, but that kind of subject would be June. Would that be right?

MR. TRENT: Yes.

CHAIRMAN HOWERTON: Okay. Thank you.

Ryan, I believe you're next.

DR. BRADLEY: Yeah, very quickly. I just wanted to respond to the questions. And so, I certainly agree with maximizing commitments. I do hope that we're being aggressive enough.

In some ways, I think we all are aware of this issue of underspending and would like to see

that change. Obviously, a range is a very comfortable approach and sort of realistic approach in terms of how to represent that information.

My only request for anything different is as we look at our quarterly actual commitments over the past several years that we see quarter-by-quarter and that the target range is actually represented on that figure.

MR. TENT: Sure.

DR. BRADLEY: I think it just helps from flipping back from slide-to-slide and shows our progress to reaching our target commitment, if you will.

And this might be a discussion for some other time, but I would like to see us talk about an approach where as we approach the fourth quarter, if we're anticipating a significant unobligated commitment, that we come up with some flexible ways to commit those funds. And maybe that's a high risk/high reward-type initiative. Maybe those are supplements to existing projects.

I'm not sure what the right mechanism is,

but I think there's a huge need and if we have the funds, we should use them.

MR. TRENT: Thank you.

CHAIRMAN HOWERTON: Thank you, Ryan.

Before I go to Kate, who's next, I would call out that one of the or newer PCORI members, one of the challenges is a machine that has the capacity to evaluate meritorious research.

Of course, who decides what is meritorious?

As well as the research community that brings forth them. You know, those of you familiar with administrative budgets, you can always spend your budget by the end of December 31st. But the question of whether you were doing things of the highest and greatest value for the entity you're budgeting for, if you have to hit that is a challenge.

And so, I think PCORI as a whole, has had to struggle with mixing a desire to bring forth valid things to a society and having the capacity to evaluate them and having the input to do that.

I would offer the hypothetical that if we

knew there were ten world-changing research questions that could be answered next week with a $100 million each, and we had the capacity to know that, we might do something different, but it's not so easy to come to know that.

Kate, thank you.

MS. BERRY: Thank you so much. And I think the direction is good.

I did just want to maybe go back to James Schuster's earlier comment, and you know, I think oftentimes it's not super clear that health insurers do contribute significantly to the PCORI budget. So not everyone typically knows that publicly or even on the Board, I think.

And so, it might be helpful, just to at some point, to make it clear which type of insurers and what the contribution is and how that process works. I realized James sort of mentioned like the shifting of potentially people moving from Medicaid to Affordable Care Act and other coverage, that that may have an implication, but just in terms of awareness, I think it might be helpful for folks to

understand sort of, you know, how that works. Thank you.

CHAIRMAN HOWERTON: Well, thank you. And you've highlighted some of that, but am I hearing you ask that the team bring forth a little bit more clarity on that as well as the comments you've just made?

MS. BERRY: I think that would be helpful. Thanks.

CHAIRMAN HOWERTON: Did you hear that Nakela and Brian?

DR. COOK: Yes. I think we did hear that in terms of bringing forth more information on the revenue sources and we can --

CHAIRMAN HOWERTON: For the clarity of the insurance plans.

And Bob, I apologize, I skipped you in the list.

DR. VALDEZ: No problem. I just want to build on something that Ryan also raised, and that is to have a strategy for unobligated funds.

And in particular, there was so much

enthusiasm in some of the discussion yesterday about the big projects that you just kind of described, just as one of your end areas, but also projects that potentially are interventions that require more than the three-year time limit. Things that take a little longer. So that we have a way of using our unobligated funds to build for those kinds of potentially larger projects with higher potential impact, but maybe riskier, or those that are interventions that require longer periods of time to demonstrate effect that don't fit within our current framework or fit within in the NIH framework, but allow us to do something quite unique.

And part of that can be done as a result of taking on obligated funds and building a pool for those kinds of higher risk issues or longer risk issues or whatever it happens to be.

CHAIRMAN HOWERTON: Thank you. And if I'm not mistaken, we are the people that would direct the team to do that or not do that. So we would need to deliberate that. It is our decisions that will influence how they are doing that. The process

they've outlined now reflects some of the Board's thinking over the last several years that directed this.

MR. TRENT: And I would just also add that we have a special initiatives category that is a part of our commitment planning process. So for those things that we're not planned, we could put them within that particular -- utilize that particular category for funding items.

CHAIRMAN HOWERTON: And I think Chris Friese is next. But I will comment, before we go to Chris, our challenge is the benefit to society that we hope to bring with these investments.

We have some considerations of when that benefit will accrue so that we are well situated to see if society wants to make this investment again in 2030. So there's multiple dimensions to that time. Chris.

DR. FRIESE: Sure. This is a great discussion. We're in such a fortunate spot because of the great leadership here, so thank you everyone.

I'm going to -- some of my comments were

already pulled in, but I think we probably have an approximate sweet spot.

What would help me from representing an investigator community is, you know, and PIs and science teams are looking at pay lines as a strategy to decide where to send their best work and where to send their work first. And I think having this conversation alongside the relative, I know pay line is slightly different in the PCORI context, but I think that's a helpful lens to make sure that we have a competitive pay line.

Of course, we only fund meritorious proposals, but we are open for business and we are working with investigators and our pay lines are positive and are seen positively by the community as an important part of our future success, number one.

Number two, I think going back to something I believe Dr. Valadez just said and the prior speaker, I think we can take, and we have recent experience of using supplements as a strategy. I'm familiar with other institutes that look at, you know, Q3 into Q4 and then are able to move

supplements in a relatively expeditious manner on various high impact well-aligned to our strategy, kind of effort. So I think that work can continue. And maybe we need to come back with a more explicit direction for those, they're not discretionary, but available funds that are not yet fully committed.

So I think that's our work ahead.

But I think we also want to make sure that while we do this work, we believe that we would support a positive pay line that would be attractive for investigators to look to PCORI first for their proposals.

CHAIRMAN HOWERTON: Thank you. I believe Kathleen, are you next?

MS. TROEGER: Thank you, Russ. Thinking just overall, I strongly support the targets are helpful, so I think that's really one of the questions here. Like how do we feel about this? So I think it's good to have a target.

I support the notion of frontloading. I think it's an affirmative and aggressive stance to take and it may help us attenuate and eliminate some

of the underspending just by, again, giving us that sort of a target.

One of the things I would find very helpful for June, is to see sort of the burn rate or the burden of the existing studies, Brian, tailed over time so that we know what our unobligated is and we've got those targets, but also to then, not just the delta, but sort of how we're doing against it.

Particularly, as studies may begin to -- if we're successful on this, right? The gap should close and we should be more fully funding out. But if we start to see studies either end early or coming under budget or whatever it is, we just want to keep an eye, I think, on what the gap is between what we forecast and where we are.

MR. TRENT: Thank you.

CHAIRMAN HOWERTON: Thank you. Are there other comments that I have not heard?

Now, Brian and James correct me, I believe there is not a specific action item today. We are informing and illuminating.

MR. TRENT: That's right.

CHAIRMAN HOWERTON: It's the June meeting, we'll see a specific action item about the three-year plan. Is that right?

MR. TRENT: No, that will be in December.

CHAIRMAN HOWERTON: I mean in September. I'm sorry.

MR. TRENT: Yes. In June, we'll just be discussing --

CHAIRMAN HOWERTON: Carrying a little bit deeper into what Danny was saying.

So today we just leave everyone with food for thought on this. This is our charge. We are a board meant to improve the outcomes in America with this resource. And how we do it is -- I mean, how we choose to allocate those funds is one of our most important topics.

I don't know if this means everyone wants to get to a break sooner, but you are ahead of the schedule now. Perhaps we should turn to our next agenda item early and we may get just a slightly longer break. Would that be correct?

DR. COOK: We could go to a break now.

CHAIRMAN HOWERTON: Or we could go to a break now. So let me consult with my colleague here and see what we should decide to do best.

[Pause.]

CHAIRMAN HOWERTON: How about right now? I think people are looking at me like the answer is clear. So break now. Resume at 11:00. Thank you very much.

For those online, if I'm not mistaken, you need to not disconnect from the webinar, but since you would be on camera you should probably mute and turn your camera off and then turn them back on when you return at 11:00.

Is that accurate?

DR. COOK: That's accurate.

CHAIRMAN HOWERTON: Okay. Thank you.

[Recess.]

MS. THOMPSON: Hello, we're going to have everybody sit down now. We're going to go ahead and reconvene. Thank you.

CHAIRMAN HOWERTON: Thank you. It’s almost 11:00, so we have just a moment more. Hopefully,

those online have returned back to their cameras and microphones.

I was telling my Co-Chair here, it's going to take me a moment to reorient since we've altered our script and we've stuck so close to it, I'm slightly confused.

But I believe, next up, we are at a very important strategic discussion about PCORnet and PCORnet infrastructure funding. Am I correct?

DR. COOK: Yes.

CHAIRMAN HOWERTON: All right. And I believe, Erin, are you taking the lead in presenting for us? She is our Chief Research Infrastructure Officer, and she's accompanied by Laura Forsythe, who is our Director of Evaluation and Analysis. And they are going to provide context to support the Board's strategy discussions around PCORnet.

Following the strategic discussion, the Board will be asked to consider approving the commitment of funding to advance enhancements and innovations in PCORnet infrastructure.

And now I'll turn it over to Erin. Thank

you.

DR. HOLVE: Thanks, Dr. Howerton.

Laura and I are really pleased to join you this morning to discuss our progress to-date on the Board's strategies to leverage PCORnet to advance PCORI's National Priorities for Health and Evaluate PCORnet Performance. Next slide, please.

So there are a lot of fantastic activities to share and I want to leave plenty of time for discussion and to hear feedback from the Board on future directions.

So in brief in this presentation, I'll provide a little bit of background on PCORnet and the Board-approved strategies, Laura Forsythe will provide an update on our evaluation efforts, and I will review work underway to further address the team's progress to-date, advancing the Board-approved strategies to leverage PCORnet for patient-centered comparative clinical effectiveness research.

And then we'll turn to discuss and consider approval of funding to support continued progress

towards Board-approved strategies to leverage PCORnet for CER.

As we'll discuss, this proposal is essentially an update on conversations regarding infrastructure commitments that were originally anticipated for FY '22 to support advancement of Board-approved prioritizing principles. The plan to propose $16 million in commitments was deferred as staff reengaged with the PCORI Priorities Work Group culminating in the approved PCORnet strategies in December. And of course, we'll leave plenty of time for discussion. Next slide, please.

As a brief reminder for members of the public participating today, PCORI funded PCORnet to support a national resource where high quality health data, patient partnership, and research expertise deliver fast, trustworthy answers that advance health outcomes.

PCORnet, as you can see on this slide, is comprised of eight clinical research networks and coordinating center activities, which collectively represent more than 40 participating health systems

and several thousand clinical sites. With more than 30 million patients available for clinical trial recruitment, PCORnet is comparable to the nation demographically.

As noted on this slide, more than 30 national scale PCORnet studies have been conducted, including adaptable a study, finding the best dose of aspirin for people with known or existing heart disease to prevent death or another heart attack or stroke. These large research projects are a subset of hundreds of research studies in more than 500 published manuscripts using PCORnet.

Between 2017 and 2021 alone, PCORI funded 28 studies using PCORnet for a total of $180 million in committed research funding. Next slide, please.

As mentioned earlier, the Board guided development of PCORnet through two key recent activities.

In 2021, the Board developed and approved the prioritizing principles for infrastructure funding relating to PCORnet, which was subsequently used to guide the structure and support for the

current Phase 3 of the network, which continues until December 2024.

In 2022, building upon these principles, the Board convened the PCORnet Strategies Work Group, which met regularly over a seven-month period to develop the strategies to leverage PCORnet to advance PCORI's National Priorities for Health and Evaluate PCORnet Performance, which guides future PCORI activities with PCORnet, including infrastructure funding and performance evaluation. These strategies were approved by the Board in September 2022, and both of these resources are publicly available on PCORI's website. Next slide, please.

Here you can see a summary of the dimensions of the Board strategies and a focus of our evaluation activities. Both emphasize the overarching goal to use PCORnet for CER by maintaining and expanding the infrastructure to support PCORI's National Priorities for Health and to facilitate effective use of the network by partnering research organizations.

It's a testament to the PCORI research data and technology team who manages the PCORnet program that strong progress has and continues to be made across all of the Board-approved. strategies.

We'll circle back to some highlights and next steps related to the work group's primary focus and activities to-date with respect to funding research using PCORnet, as well as efforts to enhance the PCORnet infrastructure to continuously learn and improve.

However, we're going to start with some important updates from Laura Forsythe regarding PCORnet evaluation. So, Laura.

DR. FORSYTHE: Thank you, Erin. And while we've made progress planning and implementing each of the strategies related to evaluation for PCORnet, I'm going to focus today on the strategies related to the development of a maturity model and also related to incorporation of needs and perspectives from a variety of PCORnet stakeholders, as those are the two where we've really had the most significant emphasis so far. Next slide, please.

We're implementing the evaluation strategies through a series of activities.

We're currently finalizing a complete maturity model that defines what success looks like for PCORnet performance at three stages of maturity in seven different domains, like those such as research and governance. The maturity model will be the foundation and guide for what we evaluate at the appropriate times, how we will go about that work, and also how we interpret what we discover through those evaluations.

This year, we're also focused on an interim assessment that is meant to address the key questions that the Board Work Group for PCORnet strategies, that Erin referred to, identified as being crucial for the Board to understand in order to consider and plan for both baseline functions of PCORnet as well as innovations and expansions.

A key element of the interim assessment is an external assessment of the user experience of PCORnet with a particular emphasis on experience with the front door. The front door is really the

one stop shop for information about using PCORnet.

We defined users broadly, including people who have used the front door or have used PCORnet data, as well as researchers who have not yet used PCORnet but are potential users, and also network partners.

In the assessment, we'll use a mixed methods approach, including individual and group interviews, surveys, and also a public stakeholder convening to gather input on successes, challenges, and opportunities for PCORnet. We will supplement that work with surveys of other stakeholders related to their awareness and perceptions of PCORnet. And also beginning to work with the coordinating center to revamp the PCORnet dashboard to more clearly showcase uses of PCORnet research resources and results of PCORnet-powered studies.

While the interim assessment is more focused on activities and signals of progress towards PCORI's goals for PCORnet, we are also planning for longer term, ongoing assessments of PCORnet performance, including a more summative

assessment of impact of infrastructure investments. And we will do that once there's been more adequate time and opportunity for those elements to really develop and manifest. Next slide, please.

This slide shows a timeline of the key activities related to that interim assessment. We've already launched and have underway a contract for the external assessment of user experience and we plan to have a preliminary discussion with you in June about what we're learning, and a more complete discussion in September after all of the components of that interim assessment are completed. And so, that we can then discuss those findings and use them to inform the ongoing planning for PCORnet.

I'm going to hand it back to Erin. Thank you.

DR. HOLVE: Great. Thanks so much, Laura.

It really has been fantastic to work with Laura and her terrific evaluation and analysis team on this effort. And you can already see the fantastic progress we're making to-date.

So I want to turn now on the next slide,

please, to highlight some of the work implementing the Board-approved PCORnet strategies. Hopefully, this list which is really a set of examples, will give you a flavor for the momentum generated by the Board work group and the activities it has catalyzed, which are helping to optimize the value of using PCORnet for CER.

First, the PCORI team has worked closely with our colleagues in the CER Division with leadership from Tracy Hwang, Steve Clauser, and Laura Reineck, and with Carolyn Best and the operations team, to highlight PCORnet capabilities in supporting PCORI's broad pragmatic studies.

We're very excited by this joint direction to explicitly promote the capabilities of the network to conduct national scale PCORnet studies in order to generate definitive findings to advance decision-making

Second, the network has built and continues to expand capacity to advance PCORI topic themes by engaging experts from across the country to provide perspectives on ways PCORnet may be used to support

PCORI's work in both preventing maternal morbidity and mortality, and improving outcomes for people with intellectual or developmental disabilities.

Third, the PCORnet Coordinating Center is leading efforts to build capacity to enhance the PCORnet data infrastructure by leveraging annual data updates to expand the PCORnet common data model to incorporate the most widely adopted patient reported outcomes, including measures of depression and food insecurity.

Last, but certainly not least, PCORI staff is enhancing PCORnet visibility and researcher engagement by bringing the front door where it's needed. Which work group members will recall, was a particularly popular exhortation by Bob Zwolak, who Chaired the PCORnet Priorities Work Group with Kara Ayers. So hence, the front door logo.

This was a key priority for our work in 2023, and we're continuing to develop some of these opportunities for new consultation and training for researchers to work directly with the coordinating center front door, as Laura mentioned, to serve as

that one stop shop for information on using PCORnet for research. Next slide, please.

So before turning to our next steps, I want to re-emphasize that our primary focus in this current phase of network development is using PCORnet for research.

The two recent studies on this slide demonstrate why PCORnet continues to generate attention and highlights the range of research opportunities using the network, as well as the reach and usefulness of PCORnet to conduct research on important health questions.

The first on racial and ethnic disparities in outpatient treatment of COVID-19, is powered by PCORnet. And I should note that even since the data was pulled with this Altmetric score, that Altmetric score has actually doubled since that time. So both of these are in the top 5 percent of all, you know, papers reviewed by Altmetric.

The second, which is detailing the development and identification of four subphenotypes for Long COVID is one of more than 30 national scale

PCORnet studies that have been developed using the network. These studies have the scale to generate the kind of definitive findings to guide decision-making and incorporate strong patient outcomes as directed by the Board. The depth of these approaches to fully leverage the capabilities of PCORnet as a national resource is apparent.

And again, as I mentioned, both papers which were published very recently have very high Altmetric scores and, you know, are in the top groups of their publications. And believe Nakela has shared some of this in the past as well.

So again, just a real reflection of the breadth and scope of research that can be done using PCORnet.

And of course, I'm happy to come back to any of these activities and other uses of the network for further discussion. Next slide, please.

So today you know, in planning commitments for the third phase of PCORnet, the Board made a distinction between funding to support ongoing maintenance of the network and a separate need to

support enhancements to promote ongoing innovation. This framework was reiterated in the Board-approved strategies.

In 2021, the Board considered how best to support ongoing innovation and plan funding in alignment with the Board-approved prioritizing principles. In FY '22, this activity was deferred to seek input from the Board leadership on the PCORnet strategies.

So since that time, PCORI's research data and technology team, led by Claudia Grossmann and Kim Marschhauser, has proposed a rich set of activities to promote achievement of the goals the Board outlined to continuously improve and enhance the network. The team today is proposing four activities of work for enhancement.

The first is supporting PCORnet coverage to enhance comparability to the United States population. The second is building support for PCORI's programs and national priorities for health. The third is enhancing data capacity with patient reported outcomes, including a deeper workflow

assessment and design pilot effort. And the fourth, are enhancements to promote efficiency in patient-centered CER using PCORnet. Next slide, please.

So for the first of these, I want to harken back to actually even the earlier conversation about the heat map. So here you have a nice heat map of PCORnet. And it's interesting, on a few of the slides some of the colors are showing up a little bit different. So I will just emphasize while there are a few sort of lighter spots on this map, you can see really that at least geographically from this depiction, PCORnet has quite good coverage again, and that's reflective of the 30 million patient encounters we see and then the 60 million, if you go back five years.

So the Board strategies directed PCORI to invest in PCORnet infrastructure to continuously learn and improve by accelerating participation of diverse, underrepresented, and underserved populations, and supporting PCORnet coverages comparable to the general United States population.

The approach proposed by staff will

leverage administrative efficiencies in the network by working with the clinical research networks to add data sites to enhance the demographic coverage of PCORnet. Dimensions of focus will include race, ethnicity, geography, including rurality and socioeconomic status.

Past experience has demonstrated that site expansion is by far the most efficient strategy to enhance participation in PCORnet, since the CRNs are both expert in onboarding new sites in transitioning health systems and clinical site data to the common data model, and they're also able to develop query capacity, as well as the capacity to identify and engage site-level community members and researchers to participate and conduct PCORnet. Next slide, please.

So turning to the second opportunity, the Board directed PCORI to use PCORnet to fund research that advances PCORI's National Priorities for Health with an explicit emphasis on intellectual or developmental disabilities, maternal morbidity and mortality, health equity, and rare disease research.

As I mentioned before, staff has already made substantial progress in this direction with the work with the IDD and M and M Capacity Building Project, and PCORnet queries underway with report-outs on both of these areas planned for the fall of 2023.

With the Board's approval of the topic themes, several of which will be discussed today, there are great opportunities to further leverage the network to enhance understanding of the characteristics of PCORI topic themes, which can support PCORI's operational and strategic priorities using PCORnet, again, as directed by the Board. Next slide, please.

In ongoing discussions with the Board, the Research Transformation Committee, the PCORnet Board Work Group, as well as feedback from PCORnet network partners and the broader set of PCORI stakeholders, expanding the network's capability with patient reported information continues to be a high priority.

In 2022, PCORI completed a set of data

enhancement discussion papers, working with the network to evaluate current capabilities and social determinants of health data, patient reported information, and CMS claims data. While we have ongoing efforts to incorporate SDOH data and CMS claims data in response, the discussion papers make it clear that there is a greater need to focus explicit attention on harmonizing data in PRO and rethinking the most effective approaches to collecting patient reported information.

Specifically, though patient reported information data collection, and particularly, patient reported outcomes data collection is common among health systems participating in PCORnet, there is substantial variation in the measures that are collected, as well as the way these data are collected across systems.

For this reason, the team is proposing a PRO infrastructure design project to dig deeper into operational factors influencing PROs, in particular.

Several Board Members have already offered helpful guidance on this approach, which aligns with

the network's interest in engaging patients, researchers, and health systems, and to conduct site-level analysis to better understand the current workflows for collection and use of common PROs as well as rethinking a design approach to most efficiently collect PROs across the PCORnet partner sites for prospective PCORnet studies based on the findings of the workflow analysis. Next slide, please.

Third, there are key areas of enhancement and opportunities to continuously learn and improve by enhancing data quality and network research capacity by promoting the efficiency of the network to conduct CER and PCOR with respect to administrative efficiency, technical capacity, and self-service to promote more engagement and also some of our workforce development goals.

I'm not going to go through some of these candidate projects in detail. However, the concepts of improving alignment between IRBs participating in PCORnet, potential enhancements to technical or server capacity, and so forth, will likely be

familiar.

All are important, align with the guidance the Board provided through the principles and strategies. And in addition, these reflect the feedback from network members, federal and other research partners, and all have been assessed to be feasible at this juncture.

So staff proposed to work with a network to further assess the priority order of each of these with respect to the timeliness of specific opportunities presented to support CER as well as budget. Next slide, please.

PCORI staff in sum, is pleased to report our substantial progress and come back to the Board, as we said we would this last September, to provide additional information on our tactics to implement the Board's strategies using PCORnet. This discussion picks up on prior conversations and planning to fund support to advance the Board-approved prioritizing principles, which was deferred in FY '22 to FY '23, as staff reengaged the Board Priorities Work Group to define cross-cutting

strategies to leverage PCORnet.

These incremental commitments will further support advancements of the Board's direction and I am very happy to take questions. Laura and I both are.

CHAIRMAN HOWERTON: Thank you very much Erin and Laura.

Before I open the floor up the questions from the Board, one housekeeping detail. Do you know if we were using the front door logo before Bob left the Board? And if we were not, could I ask that someone reach out and share it with him so that he is aware of that? That would be much appreciated.

DR. HOLVE: I'm happy to do so. I actually thought about trying to get Bob a front door pin before he left because I know he was particularly, you know, appreciated that logo.

CHAIRMAN HOWERTON: All right. I would appreciate that. And one more visual display of information question.

I think most of us have an intuitive sense

of the density of the population of the U.S. across a heat map like that, but you know, of course, North Dakota has very few people, so there will be very few patient encounters. We probably need to have a comparative display of the population density per square mile with the patient encounters in whatever geographic area you're having, because what looks like a gap is probably not a gap.

And our real metric is the difference between the national ratio of patient encounters in the population and the density in a given area and we may be overcovered in some areas. I don't know. It depends upon how small a unit.

Are you going to state level or HSA regions or what is the region you're picking there?

DR. HOLVE: So I believe these are down to the five-digit zip code level in the heat map. But I can confirm that. And I do actually have some of the state level encounter data in my trustee binder here.

But you're absolutely right, Russ. That's one of the main thing takeaways, I think, as I look

at the data is just how many people are in each of those locations and it can't almost get obscured by a heat map because you know, some of the --

CHAIRMAN HOWERTON: Yeah, we probably don't need, for macro purposes we're talking about states, but 30 million is like 10 percent of the U.S. population. So if we have encounters 10 percent everywhere, that's good if we have 50 percent in some places, 3 percent in others, it would inform the Committee's work.

DR. HOLVE: Right. And can I just add there's, and again, if anybody wants a list to see a list of the participating health systems and major sites, I'm happy to provide that, but it has a lot to do with, you know, which health systems, obviously.

CHAIRMAN HOWERTON: Yep. Well, thank you and I would open the floor up for discussion.

Jen and I are going to partner, and we established that I am not so good individually at keeping up with who asked what questions, and so Jen is going to chaperone me in this regard. I'm not

even good at who was first.

DR. DeVOE: I saw Mike, Bob, Zoher, Danny,

DR. HERNDON: Thanks. So what is the process for monitoring the appropriate use of funds with PCORnet?

I understand typical awards, how we run the grant process for our traditional awards. But for PCORnet, what is our process for monitoring the expenditures and making sure they're being used appropriately? That's the first question.

DR. HOLVE: Highly detailed. So I can go back and certainly share with you as well, Mike, if you want to look at sort of the flow down of different responsibilities and direction.

The staff manages the clinical research networks as they would any other contract, right? These are cost reimbursable contracts. The scopes are very clear. And then, before any funds go out the door at all, they take a very close look at the expense reports that have been provided and, you know, deliver those funds on an incremental basis, again, based on the work that has been performed.

So again, it's highly detailed and there's a lot of attention that goes into making sure all of the CRNs are meeting their milestones on the appropriate timelines.

DR. HERNDON: Perfect. Thank you. And then just a final comment, and more of a comment.

And as a non-researcher, so forgive my ignorance in not being able to use the proper terms, but we talked about an intervention, you know, some act or positive step that impacts an outcome. But I'm also interested in gap analysis of where people don't get a service that they need that impacts.

So as we talk in the future about PCORnet, I'd like for us to -- and it goes back to the value-based purchasing kind of, and the quality outcomes. You know, what type of research question is there for gap analysis and that payers can use to say how do we improve the treatment gaps and what is consistent among the different types of participants who are putting this data into the huge data that we compile through PCORnet to give us some grasp of what quality looks like and how to address the

treatment gaps.

So just, I don't know how to say that any smarter than that. Sorry.

DR. HOLVE: Yeah, I much appreciate that comment and it speaks to a longstanding set of research interests of mine as well. So I really hear you on that. I think this is where the Board's leadership and direction to us about as the work group and the strategies talk about how PCORI can use PCORnet to inform our thinking about these types of questions. Where there are gaps? Where there are opportunities to conduct some of the high impact research that was discussed the other day?

So I think there's a lot of excitement, not only I think among the Board Members that I've talked to, but also among the network members in using PCORnet in that way. But we will very much be looking for the Board's direction about the appropriate strategy to do that type of work, and certainly hear your point about gap analysis.

Nakela, do you want to add to that at all?

DR. COOK: I guess one of the things that

brings to mind is the opportunity for the types of queries that really can inform priority setting and as we move into thinking about discussions that lead to the next phase for PCORnet. This may be an opportunity to hear from the Board a little bit more about the types of embedded strategies that we'd want to have in Phase 4 that could provide opportunities like that.

DR. DeVOE: Bob was next, and then Debbie.

DR. VALDEZ: Mike, prevention is primary. And that's a great idea that we should look at using it to understand that issue and the value and the quality of care that people are receiving or not receiving.

And let me just come back. Is there an opportunity to learn more about the maturity model? You've described it in the materials, but I couldn't find it described in any kind of detail anywhere. So if that could be shared with us, so we can understand the evaluation that you're doing and what measures we're looking at.

DR. FORSYTHE: Yes. There's a few things

we can share. We can share more about the information in the document that came out of the work group that describes where we left off. And that work group articulated what we called the advanced vision, kind of the future state ideal across those seven domains of PCORnet.

So we can share that now and then as we are coming into the final stages, I think there'll be some additional information we can share. It's really going to be the foundation then for our structuring of our structuring of our key evaluation questions about PCORnet. We want to align them with the appropriate point on the maturity model and derive the metrics and measures that we would use in our tactical plans for doing that, really based on the maturity model.

DR. VALDEZ: Thanks. I wanted to be able to understand that when you present it.

DR. FORSYTHE: Great. Thank you.

DR. VALDEZ: And comparability is really the key here, I think, and I'm fully in favor of us trying to provide the support that's necessary to

make the comparable U.S. population.

But it gets to this issue that Russ raised at the beginning of this discussion about what do we mean by comparable and is it simply the encounters criteria? Is that adequate?

For me, it's not because we know there's this vast diversity in the way medicine is practiced east of the Mississippi and west of the Mississippi, north and south, and how we think about those geographic regions I think is really important.

From my own perspective, when I've been doing this kind of research, regional representation to get a comparable population, that's been extraordinarily important, even if it's means going to Montana. Because the borderlands north or south are very different from other parts of the country where you may have a single encounter, whereas in other parts of the country you might have three or four encounters for the same problem or issue.

And so, I think we have to think really hard about how we want that's comparable population to be built. For example, the heat map you showed,

for me before I joined the administration, I was doing a lot of work in the southeastern states and the southeastern states is really the home of the Stroke Belt, and I really couldn't study that sort of cardiovascular issues without having a recognition of where the populations at highest risk were located and having access to information about that.

So to the extent that we want to map this onto our national priorities, we need to understand where those risk populations are so that we actually have a comparable population to draw from that gives us some information about both, the social and economic circumstances, within which those populations live and work in which affect their care delivery and their ability to take advantage of the highest technologies available and treatments available for people to recover.

CHAIRMAN HOWERTON: Before you go to the next one, I'm interpreting you've asked for a more sophisticated heat map than I was. I was thinking of just raw population and you're really thinking of

for our National Priorities for Health, a separate heat map for the density of those problems across the nation. That's a wonderful increment.

And then one last, I think I heard you ask, there's something, Laura, you're going to forward after the meeting to all Board Members as a follow up to his request about the maturity model from the work group. Is that right?

DR. FORSYTHE: There is an existing document.

CHAIRMAN HOWERTON: That's what I mean.

There is an existing document, so that should be able to come in a few days after the Board meeting that we'll all get that.

DR. HOLVE: And Russ, can I just add real quickly yeah. Bob, I completely appreciate your point. And I think one thing I don't want to lose in this discussion is, this is going to be one of the first opportunities, I think for the network, as a whole, to think about this question of comparability together.

And so, I see really tremendous rich

discussions exactly along the lines that you're describing. As well as a dimension, I think, you know, I know from our work group discussions, really mattered to a lot of the work group members and the Board, which is research readiness. Right?

So, you know, critical to this whole effort is we want a network that can do both high-quality observational studies as well as be ready to do the pragmatic trials. So we have to have an eye on both of those objectives in thinking about these sites. So, I think we're going to learn a tremendous amount, even though, you know, one of the components that we've outlined here that we'll be able to bring back for further discussion with the Board.

And you know, and really, we are I think ready to move forward very rapidly on that on that piece of our effort. And so, I look forward to having those conversations with you all in the near-term.

DR. VALDEZ: Thank you.

DR. DeVOE: Debbie. And then, Zo.

DR. PEIKES: Thank you. So I'm probably

the perfect epitome of a researcher who should know more about PCORnet and does not.

And I'm just wondering if you've done any outreach work with places like Academy Health or CDC Foundation, Medicaid Directors, other broader users, but I think would find it very valuable to the research.

DR. HOLVE: So thanks so much, Debbie.

This is definitely a space to watch. We are in the process of developing more kind of workshop offerings to help folks get deeper with the data because we know that just hearing kind of a brief pitch, much less a 90 second overview of PCORnet only goes so far.

But we have a whole series of presentations planned. Obviously, the last several years of the pandemic put a damper on a lot of professional meetings, but we are going to kind of, you know, pound the pavement over the next year to do exactly that. And again, we'll welcome the Board's feedback on those strategies and spaces you think we should be because we know this is one of the huge efforts.

And again, something that Bob and Karen, others on the work group, you know, really indicated.

It's just essential to get the word out that PCORnet is an open resource that may be used by all researchers, whether or not you're affiliated with the PCORnet site, and it's just imperative that we get that word out there.

DR. PEIKES: Great. Happy to have help in any way I can. I have lots of ideas of potential stakeholders and avenues there.

I also had some questions about the race and ethnicity data. Obviously, our goal is to have gold standard self-reported data. I'm just wondering what we know about the providence of the data and how we convey that to researchers as we look for more work on disparities. I just want to make sure researchers can distinguish between data that may be, you know, a receptionist tag someone versus self-reported versus imputed.

And so, they can really consider that as they come up with equity measures.

DR. HOLVE: Yeah, absolutely. It's a great

question and I'm happy to share more information from the code book. I think as most of us are aware, race/ethnicity data in the EHR is notoriously messy. So I always want to offer that caveat, but happy to share more information and dig into the details on the coding with you by all means.

DR. PEIKES: Thank you.

DR. DeVOE: Zo, and then Danny.

DR. GHOGAWALA: Thanks so much for this overview of PCORnet and the opportunities. I'm particularly impressed by the efficiencies that PCORnet can offer and the opportunities with harmonization of patient reported outcome data and so forth.

And my specific question is, as we look at PCORnet, do you have plans or have you already looked at the cost of pragmatic trials using PCORnet versus not? Because it seems to me that would be a tremendous thing for us to be able to demonstrate that we can perform pragmatic studies more efficiently with PCORnet.

DR. HOLVE: So I really appreciate that

question, and it's one of the reasons that, again, as the Board directed us, we're emphasizing the use of PCORnet for these PCORnet studies. So there are specific characteristics of conducting a PCORnet study.

One that I'll just highlight a little different than your question, is the ability to use the brand and mark of PCORnet, which we, PCORI, have responsibility for maintaining.

But with respect to your question Zo, I think one of the critical issues of doing those PCORnet studies is that we require the investigators to report a pretty fine-grained set of metrics on time to first patient recruited, you know, a number of sort of key issues related to IRB approval, et cetera.

And so, you know, we have about 30 of those studies as I mentioned, that have been done and we're just starting to kind of look at that information and see what could be comparable to the way that we collect data for other PCORI-funded studies and others that are funded by some of the

federal partners who also use PCORI, or rather PCORnet, to conduct some of their large-scale studies, which fall into this designation.

So that's maybe a longer way of saying it's complicated but we are really looking at that information for the exact reason you asked your question.

Nakela, do you want to add?

DR. COOK: I just wanted to add one other thing, which the working group that really helped to establish the strategies that the Board approved, talked a lot about related to PCORnet and there was this kind of thinking and when PCORnet was developed that perhaps it would facilitate studies better, faster, and cheaper.

And the work group really came back and said, well, cheaper may not be one of the key things to be thinking about. Because as we start to move forward certain strategies that PCORI really wants to see in these trials and studies, such as the type of engagement, the type of reach to certain populations, that it's not always cheaper.

And so, that's something that we certainly wanted to make sure that we kept in mind as we moved these strategies forward.

So I just wanted to mention that because I do believe that there was a recognition of the work group and subsequently the Board, of some of the complexities of thinking about how you might do things cheaper, so to speak.

CHAIRMAN HOWERTON: Privilege of the Chair, I have one comment. But what you just said, it is still cheaper in that you're getting a better product because you're using the same resource base, no less money, but getting more things. So same concept.

DR. FORSYTHE: And if I may, I was just going to use this as an opportunity to make some connections to the maturity model we talked about. Efficiency is one of the core concepts that's reflected there in our domains about research and operations and the model will offer us a chance to articulate the path towards ultimately achieving those goals of efficient research as we think about

what was involved in standing up the network, and piloting it and starting to use it, and expanding it, and really at what points are most appropriate to then really get down to some of those numbers you're thinking about and in what context.

DR. DeVOE: Getting to value.

Okay. We have Danny, Connie, and then Ryan.

MR. VAN LEEUWEN: Thank you. Well, thank you for this presentation, Lauren and Erin. It's great.

I want to build on Mike talking about gaps and Bob talking about the expanded heat maps, that I think that PCORnet right now is based on data about individuals and that public health data can be gotten down to a nine-digit zip code level.

So we think about the maternal health and we think about IDD, and we start looking at, you know, violence -- rates of violence, air quality, public space, transportation, drinking water quality, access to fresh foods and vegetables, infections in waste.

You know, I mean the availability of looking at public health data that then can identify, help to say, well, you know, if something is low, something is high, something is medium, you know, what's the difference then? And then to integrate that with individual level data, I think we'll be more likely -- if we just have individual level data, we're not going to look -- identify gaps because you're just going to look at what you're looking at.

So how are you thinking about, like in increasing the integration of public health data into PCORnet?

DR. HOLVE: Thanks Danny. So this gives me a great opportunity to talk about the collaborative work that we've do been doing with our colleagues at the Agency for Healthcare Research and Quality, they have pulled together a very nice database on social determinants of health with funding from the PCOR Trust Fund, and we've been looking at the best way to really align that data with PCORnet.

So the principal question at the moment is

whether or not we can do that at the five-digit zip code level or the nine-digit level, which would obviously be more powerful. We're still waiting on a consult from the Office of Civil Rights to double check on all of the -- particularly, the privacy issues that are entailed in doing that. But again, we see this as a great opportunity to work with our colleagues at AHRQ and leverage the work they've done in that space to-date.

CHAIRMAN HOWERTON: Does that answer your question?

MR. VAN LEEUWEN: Sort of. Sort of because my experience with stuff that is called social determinants of health data is like a certain flavor, but if we're thinking about it as public health data, it's much broader.

And so -- yeah.

DR. HOLVE: So I can just say that we remain, at PCORI, in terms of the work that we fund as we're thinking about these enhancements, but also that the clinical research networks themselves and the coordinating center are actively interested in

those types of questions.

It often comes down to, you know, the availability of the data, the cleanliness of the data, those sorts of things. But certainly very interested in doing that mapping wherever it's possible.

Again, I think a critical technical distinction is going to be where that mapping is available at the five digit versus the nine digits of code level, which will obviously be much more precise and I think useful for the kinds of questions that PCORI and some of our other federal partners are most interested in.

MR. VAN LEEUWEN: So, you know, to me, like those are refinement. Like this is like a road to go down and then -- you know, it's going to, this kind of public health data is notoriously uneven, you know, it has its own set of challenges, but the whole idea of starting to integrate and what do we learn, and then we could do better here or whatever, you know? I think it's road. So thank you.

I want to just say one more thing and that

is about, I'm really delighted to hear about the work on the self-service query. Because, and I would encourage you to include what are the networks that are involved in the studies in the search feature, and I'm not sure which dates are important, like start of, completion of -- this is like, I don't really -- I leave it to you, but something about timing is part of the query.

And thanks for all you're doing. This is amazing.

DR. HOLVE: Noted. Thanks.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: Connie and then Ryan.

DR. HWANG: Great, thanks. Laura and Erin, excellent update on the enhancements and innovation for PCORnet. And I think what's more striking to me and exciting, is this incorporation of patient reported outcomes, social determinants of health, potentially with payer claims data, some things that are ahead and would love little early insight or a deeper dive in terms of the participating in clinical research networks.

I think, Erin, I think you said the other day that there's a lot of enthusiasm, but I would love to get a better sense of the opportunity and challenges those sites may be feeling about that kind of ambitious expansion and what ultimately PCORI can do to really help all of those groups be successful.

But I would love some of your thoughts on that.

DR. HOLVE: Thanks Connie. So I think it's fair to say that all of the network partners are very excited about both of these directions and probably some of them would love for us to go even faster. As I mentioned, you know, there are some genuine privacy questions right, that particularly come into play when we're talking about some of the social determinants of health data, and so forth.

I know Eboni couldn't join us today, but I had some great conversations with Eboni that reflect my own experience within systems regarding the way that patient reported information is collected and used.

And in my former role as a payer, in some instances we were able to say, well, you shall collect as a minimum set, X and Y and Z, and that makes things a lot easier. PCORnet does not.

PCORnet is a federated network, it does not exactly have that luxury, right. I sometimes say that, PCORnet really is holding up a mirror to facets of the U.S. healthcare system, and so I think it's always important for us to bear that in mind.

The discussion paper that I mentioned that was done both on social determinants of health data, as well as patient reported outcomes. I think it's so notable because it reflects that national landscape and you see a tremendous diversity of measures that are collected.

And again, I can also say that I know from lots of my colleagues and friends who have worked on implementation of PROs that, you know, the devil really is in the details. So I just don't want to undersell that and then that's a key reason that our proposal really is to do that deeper dive and think about some variety of strategies to resolve that

issue.

And that is exactly by the by, in our last face-to-face meeting with our network partners, what they said, too. They said, don't underestimate.

So I always want to make sure to reflect their perspective on some of those types of issues.

I think, again, you know, as Danny was just saying, with the social determinants of health data, there's patchiness in that data and the public health data as well. And so, I don't want to undersell the challenges there. But again, this is why, you know, I emphasize the collaborative discussions we're having with AHRQ and ASBE about using the social determinants of health database because they've done a lot of that spade work to look at some of the measures that really could be comparable across the country.

And I think, I'm never one to reinvent the wheel where we can work with partners. So hopefully that addresses some of those areas. But I think overall, just a lot of enthusiasm knowing these are, as you said, are very, very important aspects of the

picture that we need to understand health and support decision-making.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: Ryan.

DR. BRADLEY: Yeah, thanks for that overview. I have a couple of questions. So I hope if you guys can always just give me the hook if I ask too many.

But I hope the first one is the easiest, which is can you just, maybe give a little bit more detail about the distribution of the requested $16 million across those four enhancements, even if that's sort of back of the envelope.
Do you have an approximation?

DR. HOLVE: Yeah, so for the first, we're looking at about $4 to $5 million we think. For the second, about two, I think the remaining -- there's sort of a balance of the last two in terms of their scope. You know, I do want to reflect that I think, you know, the first two in particular are really we know exactly how to approach both of those.

For the other two, as I mentioned with the

workflow assessment, that may guide our strategy instead of the balance of funding and where we see priorities.

The same is true for some of the efficiency enhancements, right?

So if we, you know if the Board approves and we start having deeper conversations with the network, they may say we really think what we primarily need is more dedicated server capacity, right? In which case if that turns out to be the highest priority, you know, again, we might need to shuffle a few things around, but there are also some creative solutions technically, and so, just want to leave some possibilities open there.

DR. BRADLEY: Yeah, thanks for that. The second is really just more a reiteration of a point that came up early, and I understand there's about a 30-ish percent overlap between PCORnet and participating members in HSII.

Just as expansions are considered, just considering the efficiencies that might be captured through reaching out to those partners.

DR. HOLVE: Trust us. That was the first thing we did when we got the final list of --

DR. BRADLEY: Yeah. Wonderful. Okay, I just, I didn't hear that point specifically from you, so that's excellent.

The other one is a controversial issue, but I'm really curious if, or how, PCORnet might guide best practices in the area of gender identity.

And we talk a lot about patient reported outcomes and I'm really interested in patient reported exposures, and unfortunately, I don't think we can really look to NIH for best practices in this area. It's a complex epidemiological issue. I have students that go through the exercise of how to determine gender identity as an exposure in the context of cardiovascular risk. And it's very complicated and not really achievable with a single cardiovascular cohort study.

Whereas, an instrument like PCORnet could be very powerful if the right exposure questions are gathered.

DR. HOLVE: Yeah, it's a terrific point and

I have a 16-year-old and a 13-year-old, and gender identity is a huge topic of discussion in our household. So I really appreciate the complexity of the questions.

I think, you know, there are a couple of different approaches we could take. I think both in terms of thinking about comparability. Right? And as I mentioned, some of those discussions will occur.

As you all know, systems are collecting this information in very different ways across the country. So we are certainly, again, with this sort of mirror to the U.S. healthcare system going to undoubtedly have to wrestle with that issue.

I think the other thing that I would just note, is this may be an area where we should look at some of the opportunities with our methods portfolio as well to contemplate some more focused attention for a variety of researchers who may want to dive into this this issue for distributed networks overall.

So it's a fantastic point. Thanks, Ryan.

I don't know if you want to add anything.

DR. COOK: The one thing I was going to add was that their latter point, which I think the question you raise is probably even bigger than PCORnet itself and that there may be other opportunities that PCORI can talk about to really think about this specific issue across research.

DR. BRADLEY: Yeah, thanks for that. I think it's an important potential way to lever the power of PCORI, so thanks for that.

The last question is, I'm sort of putting on my hat as a complimentary integrative health practitioner and in my own past experience and frustrations, actually, with the fact that a lot of healthcare utilization -- and specifically with complimentary integrative health and related fields, happens in the community out-of-network, given that we know that approximately 67 percent of adults use some sort of complimentary integrative health, it's not captured by the data routinely collected within our health system.

It's actually a really important confounder

to consider, especially when we get into chronic health conditions where we know utilization is very high.

So I guess I'll pose it back to you, are there some creative ways that either have been used or may be used in the future moving forward to capture some more granular information on community delivered adjunctive care, supplemental care?

DR. HOLVE: I'm thinking. You've got me thinking about this question, particularly with respect to the sort of creative or new approaches. I think we'll have to continue contemplating some of those new approaches. I do think that the combination of integration of claim sources with EHRs may help.

I will also say that I do think that, you know, better integration of complimentary integrative medicine is happening in some places with implementation of other electronic systems. I saw that in my prior work in the District of Columbia. And, you know, I think they're going to be future opportunities in that space.

Again, I'll just have to keep thinking on your very thought-provoking question about whether there are new strategies to incorporate that information. It's a good one.

CHAIRMAN HOWERTON: Other questions?

DR. DeVOE: Oh, Alicia, I didn't see your name --

DR. FERNANDEZ: No problem. I just wanted to do two things.

One is offer thanks that I'm sure many of the Board Members are feeling for Laura, your and Erin, your leadership and your work and the degree of confidence that you give us in terms of how thoughtful and nuanced, and careful the approach that you're taking is. So thank you very much.

The other thing is, just as someone who's been here now, for a while, this is a great discussion because we're like, well, are we capturing SOGI data? Can we think about ways to capture CAM? And I'm like, are we actually capturing the creatinine?

And the reason for that is that I'm still

like two years behind or are 18 months behind in the quality of PCORnet data.

And the fact is, I thank you for showing us ways in which PCORnet is being used, and please do keep us apprised of all of that because it is extraordinarily complex and messy and many of us on the Board felt like, well, you know, maybe we're never going to get the creatinine, much less anything else.

So we've come a long way. It has been a very bumpy road and I'm so thrilled at the level of leadership on the staff side and I know that many people on the Board, did work on that. And Kathleen is not right here, but I know she did and others did. And it's a great area where if you, whenever you want to come back, you should come back for more.

Anyways, we can support you. Thank you very much.

DR. HOLVE: Thanks, Alicia. I just wanted to say thank you to the whole Board as well as a special thank you to all the work group members on

the prior two Board activities. You know, the direction and leadership of the Board and support, you know, despite the bumpiness, has really been extraordinary.

And I speak for the whole staff in thanking you again for your commitment to this important project.

CHAIRMAN HOWERTON: Thank you. Are there other questions or comments that we haven't --

DR. DeVOE: I may have missed some. I didn't get any more online.

CHAIRMAN HOWERTON: Can I ask one follow up question to Ryan? And I think is there, this may be for you, Ryan, is there any institution focused on complementary and alternative medicine that either has the inclination or capacity to serve as a coordinating center?

I don't think we've ever had such a thing. Have we?

DR. HOLVE: Super interesting question, Russ. I don't, there has not been a specific focus, but you're correct that there could, if the Board

provided this direction, could be some further thinking about that.

DR. BRADLEY: So I think OCHIN is a member.

DR. HOLVE: Yes.

DR. BRADLEY: So three academic medical centers are OCHIN members, actually four.

The two Bastyr University campuses, the National University of Natural Medicine, where I work, and the University of Western States. So one of those campuses in Seattle, two in Portland, one in San Diego; do use EPIC as an electronic health record. They're EPIC, OCHIN sublicensees.

Ironically, we've approached OCHIN on a couple occasions about querying the complimentary integrative health data and met some funding obstacles because they have their own internal research enterprise now and it's been a tough nut for us to crack, but there is a fairly robust collection of data resting within OCHIN. Now that's not community delivered, complimentary integrative health, it's still academic delivered, but there are data there.

CHAIRMAN HOWERTON: Thank you. Mike -- I'm good at this.

DR. HERNDON: So my question has to do with kind of growing PCORnet to certain -- you know, Oklahoma's just now implementing a statewide HIE and for states like Oklahoma who wanted to promote PCORnet and get our HIE into PCORnet, how does that work and what's the funding and the strategy to grow appropriate members joining PCORnet?

DR. HOLVE: Thanks, Mike. There certainly are strategies for organizations who want to transform their data into the common data model to participate without core support from PCORI and there are some who have chosen to do that.

One of the things I will confess that I would love to see, is more of this type of integration with some of the health information exchanges that might have some of that capability to transform data. I think, again, the Board's guidance, direction prioritization will really be what drives our pace there.

But I think making sure that we understand

how those integrations might happen particularly as fast healthcare interoperability resources, or the FHIR standard, comes on board. Because there, I think, will be more of a convergence and the ability to use data across some of these systems.

So it's a great sort of orientation to the future and I hope we'll be part of further conversations with the Board.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: Zo.

DR. GHOGAWALA: It's just a quick follow up and to highlight Ryan's point about complementary care because I think that this is something that we've really got to think about carefully because it may also represent an opportunity to understand gaps in care, and I'm just thinking about it from my vantage point as a neurosurgery person.

We see a lot of patients with spinal problems, and if you look at patients with back pain in the United States, you're talking about a hundred million office visits per year. So there's a very common reason to see doctors, and I would venture to

say that I would bet that the average patient is suffering from back pain is far more likely to also be seeking care from complementary types of health solutions.

And if we can't capture that, and that's just one example, we ought to think about ways that we could, because it might really help us understand who's getting the appropriate care or who's not getting care that they might otherwise be able to get.

CHAIRMAN HOWERTON: Thank you, Zo.

So You won't know, but the previous occupant of this chair, the Chair of our Board, Christine Goertz, you've hit upon one of her key career foci in life. And in many ways, I'm somewhat sad that she and your time, did not overlap on our board.

DR. DeVOE: Danny, I saw your tent go up and then down.

MR. VAN LEEUWEN: I just well -- because Zo brought it up. I don't know how we can do any pain studies of any sort without complementary data; it

would be just empty. So I just want to -- ditto. Thank you

CHAIRMAN HOWERTON: All right. Thank you.

I think our administrative team has heard that message very clearly, and we look forward -- I want to thank you both again for coming.

I believe though we have a motion before us, and we may want to move on to that topic.

So the specific motion is an approval of $16 million for funding opportunities to advance the enhancements and innovations in the PCORnet infrastructure in accordance with our Board-approved prioritizing principles.

Does any one --

DR. VALDEZ: I will move that motion,

CHAIRMAN HOWERTON: Bob will make that motion. Do I have a second?

DR. FERNANDEZ: Second.

CHAIRMAN HOWERTON: Alicia has the second.

Is there any further discussion?

Maureen, have there been any changes to attendance?

MS. THOMPSON: Yes, there has. Kate Berry has left the call; Chris Friese has left the call. Kathleen Troeger as left the call; as has Barbara McNeil. We still have a quorum.

CHAIRMAN HOWERTON: All right, thank you.

All those in favor, please say aye.

[Ayes.]

CHAIRMAN HOWERTON: Any in opposition or abstention.

[No response.]

CHAIRMAN HOWERTON: Excellent. The motion carries.

Again by the way, you -- the Board, have hit directly the time allotment for this item. It's remarkable, but we remain one-half an hour in advance.

However, the next items, I believe are an integrated whole and I think it might be better to keep them as an integrated whole as opposed to squeeze a part in before lunch and part after.

I guess the one question that comes to mind given that there may be the public or others

expecting the 1:15 afternoon start time, do we just have a longer lunch break or do we frame shift and resume sooner?

MS. THOMPSON: Resume a 1:00.

CHAIRMAN HOWERTON: Are we okay to resume at 1:00? We'll take 15 minutes. Everybody's plane connections may get just a little bit better.

So the logistics for lunch are, I believe, the same as the rest of our daytime meals.

All right. Thank you everyone. And for those online, are they logging off and logging on or are they remaining on as well?

DR. COOK: For those online, you can stay on and just turn your cameras and your microphones off.

CHAIRMAN HOWERTON: All right. Thank you everyone.

[Luncheon recess.]

CHAIRMAN HOWERTON: Welcome everyone. It's one o'clock and I would like to call us to order again a little bit at the chosen time of one o'clock early. We have a very important theme for this

afternoon and a bit of a complex choreography. We're going to have a discussion on advancing our topic themes and awards portfolio.

At our board meeting in February. We discussed an overview of our CER awards portfolio. Today, Harv Feldman, Deputy Executive Director for Patient-Centered Research Programs; Tracy Hwang, Chief of Comparative Clinical Effectiveness Research; and Greg Martin, Acting Chief of Engagement and Dissemination will set up discussions of three topic themes.

And I'll turn it over to you, Harv.

DR. FELDMAN: Thank you Russ very, very much. And I am very pleased to be joined by Greg and Tracy, and we will be covering some topic themes. Why don't we go ahead and move on to the next slide.

So when I last presented to the Board in February, I shared at that time a broad overview of our CER awards portfolio and the Board provided very helpful insights for additional analyses and discussions, and we very much look forward to

returning to those in upcoming board meetings. Also at our February meeting we heard a lot of enthusiasm to discuss and consider areas of focus within the portfolio.

So today you'll be hearing from two of my colleagues from the Patient-Centered Research Programs department, who will be sharing on components of the portfolio related to selected topics within the 12 endorsed topic themes that you're all aware of, and I'll remind you of in just a minute.

Our aim today is to solicit additional strategic input from the Board on opportunities to advance the portfolio broadly. We'll be discussing three topic themes:

First, improving cardiovascular health, the second preventing maternal morbidity and mortality; and the third theme, promoting sleep health.

And this approach is -- as I have already sort of indicated, to facilitate Board discussions and consideration for future funding strategies at its upcoming meeting in June and beyond, throughout

at least this calendar year.

We can go to the next slide, please.

The broad overview of our portfolio that you heard last month focused on our CER awards. And this slide highlights really the full scope of our awards, and you see them depicted here in this graphic on the right.

And while the majority of awards are for CER, we also, as I'm sure you all recognize, fund awards to promote engagement in research, to support dissemination and implementation projects, as well as for the development of research infrastructure. And our portfolio reflects PCORI's holistic approach to all topic themes supporting opportunities for CER as well as engagement, infrastructure building, D&I awards to generate and promote, importantly the use of evidence.

So in the topic themes and presentations later today, you'll hear about a variety of types of awards that relate to these topics. So we're not focused exclusively today on CER, but we're really presenting to you in alignment with the topic themes

and the three in particular that I mentioned.

We can go onto the next slide, please.

So today's presentation is going to be organized by topic theme, so I thought it would be good to take a moment just to revisit the process by which the topic themes were identified and developed and they are depicted on this slide.

So there has been an important combination of inputs including, of course, strategic guidance from the Board, patient and stakeholder input -- such as what we learned from engagement awardees and stakeholder convenings, information on the health and healthcare landscape, an assessment of evidence gaps, and the PCORI award portfolio. And all of these have led to the selection of topic themes, which have been categorized in to three different groups: health behaviors, health conditions, and populations.

And many of these same inputs are relevant to identifying funding opportunities also related to these topic themes. And today we'll continue to seek strategic input from the Board for that

process.

So the categorized themes are summarized on the following slide. If we can advance the slide.

You've seen this image before. So you see the 12 topic themes categorized into the three categorical theme bundles: populations, health behaviors, and health conditions.

Now practically, we can't sufficiently discuss at any one meeting all 12 of these Board-approved themes. So accordingly, we today, and in subsequent meetings, plan to discuss subsets with the Board in over the next several board meetings.

Now, the sequence in which these are discussed is not really intended, it is not at all intended to convey priority rankings. This initial set was selected largely for operational reasons. They represent a mix of perennial issues such as maternal morbidity and mortality, and some newer topic themes such as those related to sleep. They also comprise themes that are a mix in size and scope within our existing portfolio.

Also, it's important to note that we're

working on all of these themes in parallel and not just those that we've selected to talk about in more detail today.

Development of each topic theme is at a different stage and the approach needed for different themes may in fact vary.

And then finally, while the upcoming presentations are organized by topic theme, I note that components of the award portfolio and future funding opportunities may often align with more than one theme. And you'll see shortly that there are overlapping areas and there are opportunities to advance multiple topic themes, oftentimes related to a similar health issue.

So with that introduction, if it's okay, Russ, I'll hand off to Tracy to continue and make a presentation to you all on the theme of improving cardiovascular health.

CHAIRMAN HOWERTON: Thank you.

DR. WANG: Thank you very much for that introduction. So first we'll talk about cardiovascular health. The next slide, please.

Cardiovascular health is a broad topic theme area with many opportunities for impactful PCORI funding. If we take a look at our portfolio to-date, as you might expect, there's been extensive engagement of patients and other stakeholders in informing our activity to-date, 24 Engagement awards have been funded. On the CER side, 92 awards addressing cardiovascular health have been funded, totaling almost $500 million in research spending.

The majority of these are investigator initiated, meaning they started this in partnership with patient stakeholder communities and were funded under our broad funding announcement mechanisms.

But the largest financial commitments have been in larger trials that are funded under targeted or PLACER solicitations. If you move on to the graphics below, you can kind of see the distribution of awards by continuum of care, heaviest in the treatment phase, but also representation in the prevention, screening, and diagnosis phases. And PCORI's CER portfolio, currently on the right-hand side, also shows really good coverage of the

numerous cardiovascular diseases and conditions.

Cardiovascular health is also the topic theme with one of the most robust utilization of PCORnet. There have been 12 cardiovascular studies that uses PCORnet with seven of these being funded by PCORI. There have also been several Methods projects in this topic area, for example, there's one that's looking at adaptive enrichment designs to inform subpopulation treatment benefits.

And we've collaborated with the American Heart Association in supporting research on atrial fibrillation, with the NHLBI in funding studies focused on reducing disparities in hypertension, and collaborations with AHRQ and others have also resulted in several systematic reviews. Next slide, please.

Cardiovascular health remains a critical area of focus for PCORI stakeholders, and that includes patients, caregivers, payers, researchers, et cetera.

Cardiovascular disease, unfortunately, remains the leading cause of death in the U.S., and

despite the many medical advances, age-adjusted cardiovascular mortality really has not substantially declined.

As we think about trying to bend that curve, we can't ignore the fact that cardiovascular outcomes are heavily influenced by disparities, social determinants of health, and affordability, and in turn could modify behaviors such as diet, lifestyle, and medication adherence, and may further result in suboptimal health system interactions or care inertia.

So based on the landscape scans and conversations with a wide range of stakeholders, there are some common themes that have emerged.

The first is, while cardiovascular health is a field with the advantage of having a plethora of evidence-based care options, many of these are actually underutilized.

Second, in routine practice, many clinicians still do not routinely elicit patient health goals to help them make patient-centered care decisions.

Third, despite calls to increase diversity and representation in cardiovascular trials, there are some populations that are persistently underrepresented in pivotal trials.

Fourth, patient-centered strategies to improve medication adherence remains critical.

And if we look at the continuum of care, we've heard a strong desire to target as much, if not more efforts, to upstream prevention as to downstream treatment.

So these themes really form the pillars of the framework guiding PCORI's future work in cardiovascular health. Next slide, please.

Looking forward, we are very excited about the potential contributions PCORI might make in cardiovascular health, and this slide displays some of those opportunities based on the continuum of care. This time, I'm going to start on the right-hand side of the slide.

If you think about secondary prevention, peripheral arterial disease and heart failure have been identified as priority targets by many

stakeholder groups. Peripheral arterial disease, or PAD, is a disease that has a high burden of symptoms, profound impact on quality of life, and well-documented disparities in access and receipt of quality of care.

This is an area where practice guidelines have especially called out for its paucity of rigorous comparative effectiveness trials, and these are needed to determine the best therapies that will help patients avoid amputation, will help patients improve their functional status, as well as many other patient reported outcomes.

Heart failure in many ways is on the other end of the spectrum. This is a field that in recent years has actually exploded with new pharmacologic and device-based interventions. Yet, many gold standard therapies, your ACE inhibitors, your spironolactone, these are implemented only in 25 percent or fewer patients. Substantial investment is needed to close equity gaps and to enhance adoption of and adherence to these types of evidence-based care.

Furthermore, we don't really have a great understanding of whether or not these therapies are beneficial in specific conditions such as peripartum cardiomyopathy. This is understudied.

Now, as we shift more upstream to the left-hand side of the slide, stakeholders have reiterated the need for more CER guiding primary or even primordial prevention, and non-pharmacologic approaches to obesity has been a very common theme.

Here's where we think our researchers might be able to leverage policy changes. For example, federal coverage of school lunch programs were happening during the pandemic and ended last year, and these may be opportunities for some natural experiments in this area.

Going back to the middle of the slide.

System level approaches to facilitate earlier detection of risk factors such as diabetes or systematically reduced disparities in cardiovascular disease screening, are some of the very forward-facing opportunities for PCORI-funded CER research. In particular, there's been

substantial increase in studying how telehealth and how technology tools, such as wearables, may be leveraged to facilitate diagnosis and disease monitoring.

And you'll notice as I've been speaking, how the CV health topic matrixes really well with many of the other topic themes of interests; such as older adult health, children's health, paternal health, and also dovetails nicely with the national priority on achieving health equity here.

So with the goal of facilitating CER in cardiovascular health, we hope that PCORnet will continue to provide opportunities, especially to permit that seamless transition from observational studies to ready to launch randomized clinical trials and our PCORI team will continue to develop opportunities that support health systems' ability to accelerate CER evidence, adoption, and implementation, as well as to grow our community capacity to engage in CER.

So with that, next slide, please.

We'd really like to get your feedback on

the proposed direction for CV health. And we'll start by just asking a broad question, what are your thoughts on important directions for this portfolio?

And with that, I'll turn it back over to Russ.

CHAIRMAN HOWERTON: Thank you Harv and Tracy. Before I open the floor for discussion, I would like to invite Ryan Bradley to share his thoughts on the improving cardiovascular health.

DR. BRADLEY: Yeah, thanks for this opportunity. And I have to admit, I slightly misunderstood the activity. So this is going to be a little ad-libbed.

I think some of you have probably gotten a sense of my priorities to the discussion so far, and there's no question in my mind that primordial prevention is really the only way to effectively treat or reduce the burden of cardiovascular disease. I think there's pretty well-recognized evidence that by the time we're talking about primary prevention, individuals already have hypertension, dyslipidemia, there's already early-

stage disease, and in some cases despite our best intentions, we know that disease will progress.

This is also in the context of established treatment guidelines from organizations like the U.S. Preventative Services Task Force that we know are not widely implemented in practice. Less than 40 percent of Americans receive advice on health promoting diets, physical activity, stress management, for purposes of primordial prevention. These are adults that are at-risk.

The statistics are much better for primary prevention in our country.

I also think we have to think carefully about what does it mean to deliver health promotion counseling and care? And simply telling patients to change their diet and exercise is really inadequate and we know that is true. We know that is not an effective approach to changing behavior. It takes careful goal setting, motivational interviewing, reinforcement of goals, revisiting of goals, and really having a trusting relationship with a provider or healthcare team in order to facilitate

those changes.

So I think this is a critical area of cardiovascular health research that PCORI could support.

Some colleagues of mine at Oregon Health Sciences University published a paper proposing preventive cardiology as a cardiology subspecialty, and my mouth hit the floor and it just strikes me that is an approach that will reduce access, increase disparities, et cetera. And so, really looking at preventive cardiology within primary care, maybe within non-physician care teams, perhaps within community delivered health services models, other approaches would really be quite fascinating to compare.

And I think that this gets into potential comparative effectiveness research not only on service delivery, but also models of care delivery training in specific areas that we know that could be influential.

Another area, and I think it was just referenced, is related to adherence of effective

therapies. And obviously, there's a lot of room for improvement in that area as well.

My interest is the use of complementary therapies and not necessarily complementary integrative health therapies, or perhaps some complementary integrative health therapies, but just therapies that augment the prescription in terms of helping educate patients about their risk, the importance of adherence, giving them some more highly interpretable understanding of their absolute risk of having adverse response to medication, side effects to medications, things that might help them adhere just through the provision of improved information and informed consent.

However, I also think that there's opportunities for complementary medicine services such as mindfulness, other meditative practices, not only to improve adherence, but also to help maintain adequate blood pressure control.

Let's see. But you know, I could talk about this for a long time, but I won't.

I think two rather controversial areas.

One is de implementation, and I think nobody wants to talk about this and because there's obvious implications for payers and providers that do quite well with the status quo.

But I think, we also have to acknowledge that there is a lot of negative evidence for certain degrees of cardiovascular interventions. PCI, for example. Where we there is yet to be, to my knowledge, a study that has demonstrated a mortality benefit. And yet we know that there are hundreds, if not thousands, of stents placed every day.

So looking at these questions of de-implementation towards optimal medical management is an area that's going to be quite controversial, but I think is very important for patient health and patient values in terms of -- I've encountered many, many patients that they fully understand what they're signing up for when they go to get catheterized, they get stents planted, and they don't realize that they're going to be on anticoagulant therapy and platelet therapy for the rest of their lives in some cases.

So these are some important areas.

The final one that I'll touch is the overlap between environmental health and cardiovascular health, and I think this further underscores the importance of very detailed training in this area.

Not appreciating the consequences of environmental health contaminants to cardiovascular disease is routinely overlooked. Very few people know that endotoxemia is actually an important stimulus for the activation of PCSK9. Of course, anti-PCSK9 antibodies is an emerging -- you know, new, relatively new treatment for lipid management and very, very expensive. We know adherence is poor.

How many have traced that back to its origins? You know, dysbiotic guts, endotoxemia, and systemic inflammation is one of the key triggers for PCSK9, and yet we would rather sign people up for expensive therapies rather than talking to them about environmental contributions such as those that are encountered in their diet, in their air, in

their water quality. Issues that Danny brought up earlier today.

So I'll stop with those. I think that we have a lot of work that could be done in this area and thanks for the opportunity to contribute.

CHAIRMAN HOWERTON: Thank you Ryan, for a very provocative set of leading thoughts and I'll now open the floor for discussion. Please remember to turn your cards up, or if you're online to text Maureen.

Oh, Mike. We have another -- Mike, I didn't realize we had another commentary.

DR. HERNDON: So, first of all, I cannot help in my comments that be influenced by my 16 years in the Medicaid world and six years as Chief Medical Officer trying to address quality, trying to address disease burden to the State and one of the opportunities I had was to build a disease management program in the early-2000s for the State of Oklahoma, which we termed a health management program.

We did not call it disease management

because managing diseases gets you nowhere, managing and assisting patients in healthcare is what drives outcomes.

We worked with providers trying to teach them how to do evidence-based care in their practice, practice redesign, et cetera, and what we learned is that retraining providers with motivational interviewing and system delivery redesign will only get you so far. And the truth of the matter is, and I'm not the only person to think this, there are authors -- published literature that put payment system as the number one driver for poor health outcomes.

We pay providers for quantity. We do not pay them for quality.

And in the Medicaid program, two percent of the Medicaid population are responsible for 30 percent of the cost, 5 percent of the Medicaid population is responsible for 50 percent of the cost. And the number one condition in Medicaid, is the same for the number one condition in the United States, and that is cardiovascular health, including

MIs, heart failure, stroke, et cetera.

And not only is it the number one cost expenditure, it's also the number one cause of death. So this cardiovascular health has to be at the top of the list for PCORI.

So to the question, I think it is an important opportunity. The fact that we have 14 preventive studies compared to 73 treatment studies, I think is disparate enough. It's saying that we need to be focusing on prevention.

And so, if there's any way to come up with the comparative effectiveness research question that could address how payment impacts outcomes, that's what I would like to see. That's, I think, the number one thing -- and thank you for the opportunity to get on my soapbox again. That's helpful for me.

And as far as additional populations, the vulnerable populations, you know, I talked about Medicaid, but Medicare. The uninsured, the working poor. I come from a rural state. We're rural, we have a lot of rural people.

The nutrition is horrible. You know, people eat to survive. They eat what they can afford, and unfortunately, they cannot afford to eat healthy. That's just the way it is in my state.

The working poor eat poorly because they can't afford to eat healthy.

I don't know where a research question lies there, but there is a population that needs to be considered in the research and getting them to the table to participate, I realize is a problem, but I think we need to develop some sort capacity and opportunity for them to participate.

And then lastly, I really think we've got to get more primary care providers at the table to help us frame questions and the research question. And it needs to be not just -- I was an integrated hospital employed physician and so yeah, that's great. I think there's a lot of us that could have something to offer, but what about the providers at the federally qualified health centers?

What about the safety net providers? Where a lot of these people enter the system because they

cannot afford to enter the system at an academic institution. They don't know how to navigate an academic institution, so they go to the provider that they're best known to, and that many times is a federally qualified health center or primary care doc in a rural community or in their neighborhood.

So to integrate, common day providers to develop the research question, I think is important. Maybe they don't know how to do it, but I think what they could contribute if they were taught would be helpful. So those are my thoughts.

CHAIRMAN HOWERTON: Mike. Thank you for those similarly thought-provoking observations. I think now we will open the floor to Board input.

DR. DeVOE: I had Bob and then James, and it looks like Alicia

DR. VALDEZ: Well, I want to thank both Ryan and Mike for setting me up for saying what I was thinking. So I'm going to join your soapbox in the sense that my soapbox has always been the fact that as I've been training medical school students and residents and others in New Mexico, most

recently, my experience is that the patients who come in the door, don't come in to come see us for a condition.

They have some complaints, some issue, but they usually walk in that door with more than one chronic condition or one condition affecting them. And yet, we treat and we do our science around isolating a condition as if their care doesn't include the care for these other things that may be affecting them as well.

And so, I'd encourage us to think about, as we think about funding research, that we look at the constellation of conditions. So, for example, in cardiovascular disease, the risk of a cardiovascular incident rises dramatically once a patient has a cancer diagnosis, and yet we either think of it as a cancer issue or we think of it as a cardiovascular issue. We don't think of it as a constellation of these two, what in essence are chronic conditions, that need to be investigated as a set.

And so, my hobby horse has always been, how do we think about care for people with the

constellation of conditions that they bring to us?

And this is particularly true, Harv, as we cut across those dimensions or populations who are already seniors.

But for those of us who are going to become older, we're in an aging society. And increasingly patients are coming to us who have multiple chronic conditions.

And so, as we begin to think about how we transform care and make it better for people, recognizing that even for a research study, we can't just take our old approach of thinking of it as a risk factor, as was described earlier. If someone has diabetes, it's a risk factor for cardiovascular.

It's actually those two chronic issues that need to be thought of as a constellation. And so, I don't have a good way of figuring out how that affects, how we decide, how we seek proposals.

But it certainly needs to be in the mix of a new way of thinking about health services research that addresses the reality of patients coming to clinics seeking services.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: James, and then Alicia.

DR. SCHUSTER: Thank you. Tracy, nice presentation and all good comments, too.

So I had a question and then a comment.

So Tracy, since you're really kind of a subject matter expert in this arena, I was curious if you had a sense of if there's some specific areas of focus of other funders. So if we were looking across the prevention and treatment landscape, are there some areas that in your senses have been less attended to or supported in terms, and might that be one factor we want to think about?

DR. WANG: Yes, I think this is an area that is very rich in potential research opportunities. Where I think PCORI has a unique niche in it, are in several areas.

One is from a secondary prevention standpoint, there are a variety of conditions, and we highlighted a few of them that I think are areas where we were informed loud and clear from our stakeholders that there are outcomes that are

perhaps not the traditional MACE type of outcomes, major adverse cardiovascular event type of outcomes, that many other study sponsors tend to focus on. For example, in PAD with regards to symptom reduction and avoidance of amputation and functional status quality of life, these really play very strongly to PCORI's strengths.

In response to many of the other comments that have been raised already. Again, we are often looking at real world practice here, where things like payment, things like multiple chronic conditions, are completely disentangled from the disease condition that are often studied in RCTs funded by other funders, in that they usually have to have very specific inclusion and exclusion criteria that rules out the majority of those populations from those trials.

Whereas, here, I think we really have the opportunity to incorporate all of those conditions and considerations and movers and changing factors within these areas to really answer the question of how do we make healthcare choices or help patients

and stakeholders answer those questions about how to make healthcare choices.

So again, that's another niche area that PPCORI is particularly. poised -- [off microphone.]

My apologies.

To finalize the comment about prevention. I think you are absolutely -- you know, I think the comment's been raised. We've done some great work in prevention. We can do a lot. And perhaps this is, and I think this again, is another area where we may have a stronger mandate than most in focusing more upstream on this.

We are hearing from stakeholders who are coming from a more socioeconomically disadvantaged backgrounds. We're hearing from folks who are really passionate about how social determinants of health affects not only the selection, but the application of various diagnostic and treatment strategies in a complicated U.S. population.

So I think, again, we've got a mandate to work in this area as well.

DR. SCHUSTER: Thanks. I think that's all

really helpful.

And I guess the one other area that I just wanted to raise for consideration is, you know, we talked about the new recommendations for treatment of congestive heart failure and how poor the uptake has been, and I wonder if that, itself, is a theme that -- I don't know exactly how to design this study, but is a theme that might be worth asking people to help us explore, which is how can we use that as an example of a new practice that has incredibly positive benefits for members?

But I think you said 23 percent or something of the time -- it's only used, you know, 23 percent of the time.

So how do we speed up that 10-year, 15-year adoption cycle with this particular practice, which is you know, probably one of the most impactful new guidelines that's come out in a long time.

DR. WANG: Yeah, I think, again, you're speaking to an area that is near and dear to my heart. Alicia spoke to this as well, in terms of thinking about sequencing and selection of these

therapies.

On the other hand, we also know that in heart failure, we've now got an explosion of device-based therapies that are being applied. And I would be pretty frank in saying that many of these are not necessarily being applied in the most judicious manner.

And so, to Ryan's point, You know, studying this to de-implement in some ways is in a way that's concordant with patient-centered values and healthcare goals, is again, a strong mandate for us at PCORI to be able to fund research in that area.

DR. FERNANDEZ: Thank you for that really excellent presentation. I really liked it and was particularly struck by the 12 studies using PCORnet and that only about half of them are paid for by PCORI or are PCORI-funded studies. And that's just great.

So I only had two brief comments.

One is, I want to pile on the theme of pharmaco-equity. And in particular, think about -- I wonder whether they, the CER program, would like

to think about doing something looking at pharmaco-equity in the treatment of atrial fibrillation.

It is an area that one of, I know one of my mentees, Utibe Essien, has done a lot of work on it, but these are not new drugs. They are not more expensive, and they're more patient friendly. So we should be really looking at that.

And what I like about the idea of asking you to think about whether that's something you want to do, is that we could ask about that with respect to two of our infrastructures, three of our infrastructures. We need intervention studies that are implementation science. We may need learning collaboratives, which are new, I don't know what we're calling it -- IHS --

CHAIRMAN HOWERTON: HSII.

[Laughter.]

DR. FERNANDEZ: That one. We might be interested in.

And then, it is a great area obviously for observational studies, for all I know, we already have observational studies underway using PCORnet

and really raising this loud and clear.

And the issue here, obviously, is that atrial fibrillation is one of the most modifiable -- anticoagulation of atrial fibrillation is probably the most modifiable risk factor for large strokes. And it's appalling that, you know, this would be a great contribution. So think about that and I'm sure you already are.

And the second one, is along the same vein.

I think that we should think about whether or not we wanted to put out for some observational studies using PCORnet, if in fact PCORnet is ripe for that, around more of the variations and things like PCIUs or others, with a standard, let's appeal to the PhD, Academy Health, Health Services Research saying, and what are you guys doing? So that we can actually get a little bit more -- so that's it, more observation studies here.

DR. WANG: Alicia, thank you very much for your comments, and I really like this framework that you're sort of the cycle here of leveraging the full range of PCORI resources and infrastructure, to go

from surveillance to treatments and back to implementation and surveillance again. So thank you very much for that comment.

DR. DeVOE: Mike, did you have another one?

DR. HERNDON: Yeah. To kind of build on something that Bob said earlier, that in our data, in the predictive modeling analytic tool we had in Medicaid. We used the predictive modeling to find our highest risk patients and to find that top one percent to deploy nurse case managers to intercept.

And so, the data was so revealing and what we found is that, of the population that had one chronic health condition, which a lot of people, most people have one chronic condition, probably have two, but if you had one chronic condition, the prevalence of depression was 40 percent.

So, which Bob, you made me think there's got to be a good research question in there.

You know, if you treat the chronic condition and ignore the depression, the outcomes are going to be so much less.

And so, guess what slows a provider down

more than anything in a practice? Do a PHQ-9 and see what their score is and try and deal with it.

Depression, behavioral health impacts so many chronic health conditions, yet it is probably what providers are trained the least to address.

So somewhere perhaps that's a question that we should be looking at. Is what does the evidence show, you know, for comorbidities, particularly behavioral health comorbidities? And what's the outcomes when they're treated versus when they're not treated?

And then the last thing I want to say is just, I used to be anti-community health worker.

Full disclosure. I used to think it was potentially an abusive, I'm sorry -- well, and you know, it comes from an honest place of abuse of people coming to Medicaid wanting to be paid for things and doing nothing.

But now after getting into the weeds and seeing what community health workers do and the value that they've brought, I have done a 180. I believe, truly believe that probably some of the

most potentially impactful people to improve health outcomes are people who live and work in the community, who are trusted by the people in those communities to help them navigate and access healthcare.

You know, and unfortunately, many of the patients, by the time they hit an academic health center is when they're in crisis and they've had the MI, they've had the stroke.

So I think we've done research on community health workers and that's great, but how do we -- is there potential for more powerful research, and I know that power is a research term, but not to be applied here, but powerful to the provider community so that we get the naysayers and the people who would embrace, including our federal government, who does not recognize community health workers as a payer type. And so, we end up getting these community health workers getting end up paid through grants. They end up getting paid, you know, some alternative method.

And so, perhaps some research that was

meaningful enough to change the payer minds because I was one of them. You know, let's impact the private payers. Let's impact the public payers that community health worker interventions work.

So those were two things I had on my list and I cut them short, but I just, after Bob made his comment, I just said, man, I've got to bring up the comorbidity issue because if you just treat one -- if you're just looking at cardiovascular disease alone as research, it's probably missing the boat. We have to look at comorbidity.

CHAIRMAN HOWERTON: Thank you, Mike.

And perhaps we'll close this session with Zo.

DR. GHOGAWALA: My question is very simple-minded, but I was just curious to know what we've learned from patient stakeholders about the barriers in primary prevention. What do they say are the problems of primary prevention in cardiovascular disease?

DR. WANG: I think many of the themes that we've talked about before have been encapsulated on

one of those slides.

One of those is access. One of those is what are impactful interventions we can really introduce here? As mentioned before, just telling them, Oh, you need to lose weight, is not helpful. Blood pressure management, for example, is an iterative process. It's not a prescribe one drug and everything's fixed type of thing.

So we're hearing about many of these and incorporating many of these into our solicitations to try to be able to create, hopefully, impactful intervention studies that can evaluate what should be brought to the forefront in terms of trying to improve U.S. health that way.

CHAIRMAN HOWERTON: Well, thank you everyone. Tracy, I hope you feel as though you've gotten a lot of input from the Board on this topic to take away, and perhaps now we'll turn to Greg and our next topic theme.

MR. MARTIN: All right, good afternoon, everyone. It's good to be with you again. Before we get too far into this presentation, I think it's

worth taking a moment to just remind of what we already know.

Frankly, maternal mortality in the United States is a crisis. There's no other way to put it. Among industrialized nations, the U.S. maternal mortality rate of nearly 24 deaths per 100,000 live births nearly trebles that of the next highest nation, which is France.

The rate for Black birthing people is more than double the national rate, and it's still yet higher for our American Indian and Alaskan Native communities.

We also know that 80 percent, four out of five of all deaths are considered preventable. Now adding to the sorrow of maternal mortality each year, more than 50,000 women in the U.S. experience severe maternal morbidity or unexpected outcomes of labor and delivery.

So we recognize the interest and the need for evidence at federal and state and local levels and across the health sector. And so, PCORI has been and will continue to pursue evidence to address

this crisis and we're pursuing our funding approach with energy and with enthusiasm, which I hope you'll hear in this presentation. Next slide.

So to help us better approach our work, in both examining the literature and engaging with patients, with families, with the broader health and healthcare community, we developed a framework to help guide our work around maternal morbidity and mortality. Now, this framework includes specific conditions associated with mortality, examples of patient level risk factors, and social determinants of health.

And I'd be remiss, of course, not to note, as has been indicated earlier in this meeting, you know, the cross-pollination amongst some of these topic themes. We see cardiovascular prominently represented here in maternal morbidity and mortality.

Now we'll provide further detail on some of our work to-date as we go through this presentation, but I wanted to highlight that our activities aim to address the various parts of this framework. And

these activities are informed and driven by the many conversations that we've had and continue to have with the wide range of stakeholders and patients, families, patient advocates, environmental scans, and literature reviews. Next slide, please.

So it's important to reiterate this extensive engagement and how we try to bring patients, families, communities into this PCORI ecosystem. As noted on this slide, we've had significant interest from communities in building capacity to engage in CER to address maternal morbidity and mortality.

We've included a special area of interest in our Engagement Awards PFA since 2021. And we've seen project foci that include breast/chest feeding, chronic conditions, oral health, the maternal health workforce, substance use disorders, and so on. And the populations that have been engaged include Black, Indigenous, and persons of color, immigrant and refugee communities, LGTBQ+ communities, low-income, rural, and so on. So we're seeing the Engagement Awards continue to be a robust

opportunity for building capacity to participate in the type of work that PCORI funds. Next slide.

With research, we've taken a blended approach to our work that uses the myriad of tools available to PCORI. We've seen studies come in that address access to care, quality of care, respectful care, timely detection and treatment of postpartum conditions, the maternal health workforce, delivery of treatment for opioid use disorder, and populations experiencing disparities.

And we've recently encouraged applicants to focus on things like addressing challenges regarding access to care, but specifically access to quality care and respectful care.

We've also encouraged applications around the postpartum period. Specifically, the first six weeks postpartum, during which we know about 35 percent of all mortality occurs.

We also launched partner-soliciting applications that they'll have dual PIs, one researcher and someone representing the community, and the studies will address outcomes prioritized by

the community by employing at least one strategy to address those social determinants of health that we've identified and one health system strategy to address disparities from maternal.

We've also continued to be grateful for our strong partnership with AHRQ. We've commissioned systematic reviews that address topics like, as you see here, outpatient cervical ripening and postpartum care for up to one year. And again, the cross-pollination of cardiovascular postpartum hypertensive disorders.

So given all the data and all we've heard from communities about health inequity and the role of social determinants and their work in maternal morbidity and mortality, we continue to feel that we cannot fulsomely address this crisis without also incorporating considerations around social determinants. Next slide, please.

So, looking ahead. We continue to pursue this blended approach to addressing maternal morbidity and mortality. So based on stakeholder input, landscape assessments, national data. Again,

literature reviews. We're very interested in the potential contributions that PCORI might make around things like natural experiments to examine the effects of state and regional policies.

There have been many efforts across this country to address maternal morbidity/mortality at local, state, and regional levels. What can we learn from this innovation?

There's also a strong interest in achieving equity through focusing on those populations that are suffering disproportionately in this crisis, including American Indian and Alaska Native communities.

We're also looking at postpartum morbidity and mortality. Over 50 percent of mortality occurs in that first year postpartum after that first week.

And what are the factors that contribute to that? Including postpartum depression and suicide, overdose, car accident, and intimate partner violence, which is an under researched contributor to maternal morbidity and mortality.

So there's great intersectionality here.

Again, I've mentioned cardiovascular a couple of times. That's certainly there. But also if you think about the other topic themes that you've approved us to work on: mental health, substance use, and so on. There's tremendous intersectionality between maternal morbidity and mortality in those areas in which we'll continue to pursue.

As you heard earlier in Dr. Holve's remarks there's interest in using PCORnet. She mentioned that goal of strengthening the capacity of the PCORnet infrastructure to facilitate CER in maternal morbidity and mortality.

And we're also exploring potential Methods work, including with the Methodology Committee on composite outcomes.

So there's quite a number of different areas that we can continue to pursue, and of course, we're going to continue to support communities to build and enhance their capacity to engage in the work that PCORI funds, the work that PCORI does as a funder, and to use the evidence that we funded.

And so with that, we certainly look forward to your feedback on the framework and future opportunities for PCORI funding. Next slide, please.

And so with that, Dr. Howerton, I'll cede the floor back to the Chair.

CHAIRMAN HOWERTON: Thank you, Greg. And before I open the floor for discussion, I believe we have comments from Danny and Alicia. Danny, perhaps will you go first?

MR. VAN LEEUWEN: Thank you. And full disclosure that when MMM was designated as a legislative priority, I reached out to some experts to inform my understanding. So let me just tell you who they are so I'm cribbing their advice to me.

So one of them was Michele Whitt, who's an OB/GYN physician specializing in healthcare information systems of technology with OCHIN, the Oregon Community Health Information Network, and Dr. Lisa Masinter, who's an OB/GYN physician working with Alliance Chicago.

So let me pull together some of the

recommendations and suggestions they made to me.

One of them was that there are 1,000 out of 3,200 counties in this country that are OB deserts where there is no services, no OB services. So 54 percent of pregnant women are without proximate maternal care. They said that the fragmentation of services of primary care, family planning, prenatal delivery, postpartum, pediatric, and then back to primary care, that the transitions of care across that continuum are fraught because there's so many different nodes and the information does not cross all those different systems.

They really emphasized that the solutions are hyper-local, and that it's really important -- and then they drew in the public health data, and so, understanding what are the hyper-local conditions and situations that impact solutions.

I think they also -- well, the last thing that I learned from them is the issues of teen privacy, is a challenge in information about maternal health, that has already been said addiction in pregnancy, and pre-preeclampsia.

So I noticed in our what we've funded there was nothing before prenatal and that to me is, you know, something we really need to think about. Thank you.

CHAIRMAN HOWERTON: Thank you very much, Danny. Alicia.

DR. FERNANDEZ: Yeah. Thank you. I wanted to share three observations and a small plea. And I should say that I'm an internist. As soon as a woman is pregnant and wants to keep the pregnancy, I'm like, "Ahh," and send her off to OB/GYN. So I'm going to take a very -- my point of view is from someone who does equity research, who really strongly emphasizes the patient-doctor relationship and who is very hard-headed on this.

So if you could put up your second slide, Craig, preventing maternal morbidity and mortality. I thought I would share three observations. The framework slide.

Observation number one. There are a little bit under 800 deaths of -- in -- per year out of the millions of women who give birth. And to -- I said

this before, to put that number into some sort of context. That's a number of people that we have die in San Francisco pretty much each year from opioid overdose. It's a little lower now.

So what does that mean to me? What does that observation mean?

It means that our studies need to be large.

I really believe that we can impact maternal -- I should have started there. I see our goal as decreasing maternal mortality and severe maternal morbidity as mandated by the legislature and I really believe we can do that. But it requires units of analysis and units of intervention that are at least on the state level in some places will be on the regional level that take place -- and that take place over time. And the implication for that, for me, was about partnerships. That we needed partnerships in order to fund the large enough work that needs to be done.

And fortunately, there are now a lot of partnerships because almost all states now have a quality of maternal care collaborative. And so,

those have been stood up, partly by Congress and there's a lot of funding going into that, so that's one.

So observation number one, 800 deaths per year.

Observation number two.

I think goes to things that we've heard from both Greg and Danny, which is that preventing maternal morbidity/mortality necessarily spans two types of -- we need to have, to necessarily think about it as spanning two types of systems. One is within the clinical system because so many of the deaths occur postpartum, necessarily spans primary care and the other fields with -- and behavioral health, with a drop off in both access and of information flow. And so, we have to help people construct studies that are very intentional around that and so on.

And the second is that the other system that, the other area that we have to span, is the clinical area with the workforce area because particularly things like maternal hemorrhage. Like

in what country where women give birth in the hospital is maternal hemorrhage to death an acceptable outcome? And this is not because people were rude to the woman or racist or biased.

And so, how could that be? So that is a workforce question.

Many states have reduced maternal mortality a lot by putting into place protocols and workforces that addresses, so to a certain extent, these down steps of information sharing and down steps to a certain extent, they span political issues like Medicaid non-expansion states or regulatory issues that are beyond our pale as researchers to directly influence, but not beyond our pale as researchers to call out -- to understand better how these work, when they work, when they don't work, and so on.

So observation number two, it's about spanning systems.

Observation number three flows from that.

And here if you go to the California collaborative, the California Maternal Quality Care Collaborative. One of the articles featured there

by a group of California researchers was about the difficulties inherent in data definitions, that is about the lack of data definitions, that have made doing interstate or inter-regional collaboratives very difficult.

And this is where I think we do have a very important role to play through PCORnet by providing certain types of data and if PCORnet can be used in this way, then I'm so happy to see those comments that we are already thinking about using PCORnet in exactly this way. So maybe I'm way behind the boat. I think that those will be really important studies out of which we can do observational studies that could in turn inform medical societies, advocates, and policymakers who are looking at reducing maternal mortality and severe maternal morbidity.

So that third one was about definitions of data and use and making and investing in PCORI, as we are doing, to really be able to create good observational studies.

And my last is a plea.

I really hope we can focus on preventing

maternal mortality and severe maternal morbidity and not in the -- also incredibly worthwhile goal of improving the birth experience, and improving clinical care and reproductive health, or women's health, or however we want to call it. Maternal health all the way through.

So even though, and the reason I said I'm a disparities person and I focus on the clinician communication and I've written articles on bias and blah, blah, blah; but I don't want to hear it.

I don't want a study. I don't want PCORI to fund a study on OB/GYN bias, which we've done, and say that is our way that we're going to combat maternal morbidity and mortality. Because it isn't.

Because bias is too distal an outcome from hemorrhage. It's not too distal an outcome, it's too distal in exposure. Not true for everything.

If you have horrible systems, you don't go in for your hypertension. You will come in seizing and with eclampsia and you die, will clearly the bias system but that's actually an even small group of the 800.

So I think that if we want to reduce those 800 deaths and the 50,000 SMM, we have to keep our eyes on the prize. We have to be very, very hard-nosed and we have to make sure that the conceptual models, that the study is powered to look at the outcomes that we want to over regions and space and time, and that the conceptual models are sound and sufficiently proximate. Because at the end of the day, we won't do our patients any service by not focusing on that.

So I like some of where we're going and for some of it, I want to really encourage us to do the math and we may only need to fund large, large, large studies. Maybe one large study to get to Russ's point. But I do think we can reduce maternal morbid mortality and SMM, at least from the ignorant internist point of view. I don't see why we can't do that, so thank you.

CHAIRMAN HOWERTON: Well, thank you both, Alicia and Danny, for those thought-provoking comments for Greg and the team. I will now open the floor to the Board as a whole and I see various tent

cards up. I'll turn to my partner and colleague.

DR. DeVOE: I saw Bob and then Mike, and it looks like Ryan and James.

DR. VALDEZ: Thanks very much, and thanks for the comments and the presentation, and thank you for putting that framework up because I want to address the framework and get to these issues of how we think about both, mortality and morbidity.

The tendency has been to focus on the mortality and sometimes the severe morbidity, but childbirth is a natural event and we should be aiming towards minimizing any morbidity that occurs and it's part of the experience, but it's also part of the clinical aspects. So I think we really need to think about separating this notion of maternal mortality and maternal morbidity.

It's easy for a researcher to focus on mortality. There's a finite outcome measure, but it's not necessarily the one that informs us about how to improve or minimize morbidity.

The other thing that this particular framework points out to me, and the experience that

I've had over the last couple of decades working in Native American communities and in urban cities, is that the two populations that were raised as greatest risk, that is African American communities and Native American communities, have experienced some similar epidemiological situations.

And that is, preconception young women have increasingly become more obese, show up with hypertension, show up with developing diabetes, and have behavioral/mental health-related interactions. Sometimes addiction, sometimes not addiction, but that's all pre-conceptional.

And so our framework focuses our research on postpartum, and I think we have to get upstream a little bit if we're, in fact, going to deal with the morbidity aspects and even the mortality aspects that are raised here.

So let me just see if I can summarize.

I think we should separate mortality and morbidity so we have a clear framework for the endpoints that we want to achieve. We need to be clear about the fact that we want to minimize

maternal morbidity and not just severe morbidity. And that we not just focus on the postpartum aspects of this framework, but also look at the pre-conceptional piece of it that by and large is left empty here, even in the framework.

CHAIRMAN HOWERTON: Thank you very much.

DR. DeVOE: We have Kara and then Mike, Ryan, and James.

DR. AYERS: Thank you. As I think was briefly mentioned in the beginning, I'm really fascinated by the overlap of some of these focus areas like the cardiovascular disease on this slide here with MMM, and so, I'm wondering if there's anyone tasked -- I think while this is great, sometimes the risk of having overlap is that if kind of both sides are trying to consider that overlap, it can fall through the crack.

So I just wonder if there's any one role or person that is assigned to look at the ways these different focus areas overlap and almost liaise in a way -- you know, back and forth between them. I'm just concerned, I guess, about the limits of

siloization and missing that really valuable opportunity to see how they cross.

CHAIRMAN HOWERTON: Do we want a response from the team for that?

DR. AYERS: Yeah, that would be great.

DR. FELDMAN: Sure. Thank you for that really important point.

You know, I think it would be fair to say that we really are focusing on the ensemble of these themes as we consider health conditions, and regularly, and I think, continuously look at the intersectionality as Greg pointed to. The presentations, of course, are being presented in a more focused way just as an approach to sort of sharing with you insights and information about portfolio opportunities.

Now that said, I'm sure, and I think your point is still very well taken and it really represents, I think, an important emphasis for us, for us to redouble those efforts. But that intersectionality is something that's very clear to us and we recognize it.

And it links a bit, I think, to Bob's earlier point about multi-morbidity states, it's in the same fashion health conditions really align with multiple of the themes and we're very mindful of that.

Nakela, did you want to add?

DR. COOK: The only other thing I wanted to add is the intersectionality across the themes is one way of thinking about things, and then also within this theme, we're also looking at the intersectionality across this continuum that you see in the framework because there are components as identified here, in that preconception space that Bob Valdez raised around some of the risk factors, the healthy -- I guess I'd say the health state of a mother coming into pregnancy that also has interplay for some of the other adverse pregnancy outcomes and the kind of degrees of morbidity that may be experienced through a pregnancy.

And so, there's that intersectionality as well that I just wanted to point out that we're also thinking about.

CHAIRMAN HOWERTON: Thank you team.

DR. DeVOE: We have Mike, Ryan, James, and Kathleen.

DR. HERNDON: In response to the third bullet point, additional areas in opportunities.

I do believe sticking with the prevention of, has to do with preventing the unintended pregnancies, and especially the unintended high-risk pregnancies. And why are more primary care providers not providing services for prevention of unintended pregnancies?

I trained in the eighties and in my training, obstetrics was not just an elective. It was, and I know it's not to now either, but it is kind of breezed over and you end up getting these silos of primary care docs who have no clue whether they can safely give an antibiotic to a pregnant woman, and you know, which ones -- I think, also are not comfortable doing long-term irreversible contraceptives, or LARCs, you know, whether it be low-dose progesterone IUD versus a Nexplanon-type device. And in my training, that was not an option.

I mean, you learned how to do those things and I did those things.

So I'm not sure what the research question is in there, but I do think there's an additional opportunity to address prevention of high-risk pregnancies through the use of contraception and why our medical community is no longer doing that universally, and only doing it in an OB/GYN's office. I think, is something that perhaps PCORI could put something out that talks about competency and the need.

CHAIRMAN HOWERTON: Thank you very much.

DR. DeVOE: All right, Ryan. And then, we've got Kate jumping in the queue and James and Katheen.

DR. BRADLEY: Yeah. Thank you. I don't want to be overly redundant here. I think we've already heard the message about the importance of preconception and focusing on prevention as well as the intersectionality with cardiovascular disease.

Still I'm struck by it and it seems that we could go a long way by reducing the disparities in,

again, preventive cardiology care that many populations are deserving of, and that we don't necessarily know how to do well. We haven't done well as a healthcare delivery system.

But in a lot of ways I see this and I'm like, well, if we just did what we were supposed to be doing as a healthcare delivery system, then that would help with a lot of these outcomes quite a bit. Obviously, we can't affect maternal age, we can't affect the brief -- well, maybe we can affect the brief inter-pregnancy interval, but these other risk factors are clearly cardiovascular risk factors.

So that's just reiteration of the importance of prevention and preconception planning by giving patients what they deserve to receive.

The other point I would make is -- and I'm going to admit that this isn't my area at all. So excuse me if I'm not staying in my lane, but it strikes me that what's missing here, or at least I hypothesize is missing, in terms of risk factors. Are additional psychosocial risk factors that are very inconvenient to acknowledge.

Issues like PTSD. I would hypothesize that preconception depression is a significant risk factor. Other risk factors that we think of as myocardial infarction risk factors, low locus of control, persistent stress in the home and work. Substance abuse, you know, behavioral risk. Those aren't on this on this slide.

And obviously, there are huge disparities in delivering care for mental health and behavioral health services as well. Also, a very hard nut to crack.

But I think just for the sake of rounding out the bio/psycho/social conceptual model of risk, they deserve to be on the slide and considered for funding.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: Kate and then James, Kathleen, and Alicia.

MS. BERRY: Yeah. Thank you. I really appreciate all of the previous comments and a lot has been said, so just not to be redundant, but maybe to add a couple things.

One is I think that in this category of risk factors and really thinking about how can providers and other stakeholders sort of be really engage early with people who may be have a pregnancy that's of high-risk and trying to engage early to address those various risk factors as early as possible to try to ensure a more positive outcome.

So that's one.

I think the early intervention particularly targeting those people with high-risk factors.

Another, and I think others mentioned different partnerships. The various stakeholders that need to be engaged here.

I didn't hear hospitals. And I think, you know, the vast majority of babies are delivered in hospitals. And so, I think the idea of like making sure we engage hospitals and there is -- CMS has identified sort of this birthing-friendly designation. So maybe something to think about in terms of hospitals to engage in a study or in the process.

And then the third thing I wanted to

mention, also maybe a sort of a policy overlay, but there have been quite a number of states that have extended Medicaid coverage for moms after they deliver their babies instead of just three months to 12 months and that can have a really important impact on outcomes as well as we think about more of the post-partum timeframe around potential depression and other factors.

So I just wanted to kind of add that to the mix. Thank you so much.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: James.

DR. SCHUSTER: Thank you. I'll be brief. There's lots of great comments already.

Just one thought is, you know, you have a lot of social dynamics or psychosocial dynamics across the bottom of the slide and maybe a way to address the point that I think maybe Kathleen or others raised, was even thinking about those as risk factors. The challenges with those are all really risk factors and maybe the most important ones in terms of long-term impact.

The second item I just wanted to mention is, there's been a huge emphasis on value-based payment policies across medicine. It's often not clear how effective they are even with enhancing medical care, quality of direct medical services. But there's now a push to include an emphasis on ensuring that providers address what we think of as social determinants or a number -- preventive care, a lot of the themes highlighted here, including value-based payment models for maternity care.

So that would be, I think, a helpful thing to evaluate whether that's impactful or not, only because it's rapidly growing and there's this assumption that it'll work.

CHAIRMAN HOWERTON: Thank you very much and we'll close with those on the list now.

DR. DeVOE: Kathleen and Alicia.

MS. TROEGER: Thank you. Just to raise briefly that the area that's adjacent to maternal morbidity and mortality is really the impact on neonatal health outcomes.

And yet, data collection in this area is

incredibly challenging for anybody who's done any of that primary or secondary research as the neonatal record is often decoupled, whether it's in claims or HER, lab, or otherwise inpatient/outpatient from the maternal record.

So you're pretty good right up until delivery, and then post-Apgar and weight, the record for the neonate disappears, which also makes longitudinal research difficult to understand what happened in prior pregnancies and neonatal outcomes beyond demise.

So I think when we look at building infrastructure capacity, particularly maybe within the HSII program or other, one thing to just consider here is I would just urge us to really fund projects and investigators that are looking for ways to optimize that data collection and potentially link records, provide linkage or overcome that challenge right now for investigators.

CHAIRMAN HOWERTON: Thank you very much. And NOW our last question, I believe.

DR. FERNANDEZ: See I got called on twice.

So thank you for that and I hope it's not too much. I want to say to my very respected colleagues, everyone has contributed really important points that I by and large agree with, and that I think that my plea went completely unheard.

So I hope that Drs. Feldman, Wang, Cook heard me because I think leadership is going to have to come from the staff.

And I, for example, I favor doing a study on whether or not the provision of the of food vouchers for pregnant women results in a better outcome both for the woman and for the baby. That's a study that needs to be done. Really important study. Not about maternal mortality and severe maternal morbidity.

So it's an "and" comment, by all means, let's do all of these other studies.

In the meantime, we have a legislative outcome, and I find it striking the amount of conceptual confusion that we're evidencing in not thinking about these, and Bob to his credit, attacked that head on and said, yeah, I know what

you want to talk about. And he said, but I want to talk about something else. And that's exactly right. It's an "and."

But if you want to talk about decreasing maternal mortality and you want to talk about decreasing severe maternal morbidity, then run the numbers and run the proximate and think about statewide partnerships and think about really big expensive interventions where there's a will to do that. And maybe even put out a call for proposals in which the people who can apply would be the statewide collaboratives.

So let's do all this other stuff but not confuse --

CHAIRMAN HOWERTON: Thank you everyone.

And Greg, I hope you would feel similar to Tracy, that you have had a lot of diverse input to help you plan.

MR. MARTIN: Certainly. I definitely appreciate it as well.

CHAIRMAN HOWERTON: Thank you very much.

And I believe Tracy, it comes back to you

for a second bite of the apple.

DR. WANG: Thank you very much. Let's talk about sleep health here.

CHAIRMAN HOWERTON: And not by the way that we've all had lunch in the late afternoon, here. We're talking about a different sleep health.

[Laughter.]

DR. WANG: So sleep health is a high impact issue. It's also resonated very strongly with patients, caregivers, and other stakeholders that we've interacted with. Next slide.

The next two slides give you a sense of PCORI's portfolio in sleep health. There has been three Engagement Awards, two Dissemination and Implementation Awards funded, totaling about a million dollars. And in part, these have really helped us cultivate engagement and sleep research, bringing stakeholders and researchers together, and allowed PCORI to gather public input, informing our research agenda.

On the right-hand side of the slide, you see a topic brief has also been disseminated on

insomnia and other sleep disturbances in persons with developmental disabilities. And this has also informed our investigator community on opportunities for research in this area.

One award on the dissemination front compared -- was disseminating findings from a PCORI-funded study that compared acupuncture with cognitive behavioral therapy for patients with insomnia. Another is focused on disseminating an evidence-based peer support intervention to promote adherence to positive airway pressure treatment for patients with sleep apnea. Next slide, please.

On the CER-side, this slide shows that we funded about 10 CER awards, totaling $22 million to-date. These include, and I won't go over these in detail, but you can see this, and it's also very publicly displayed on our website.

Four Studies on sleep apnea treatment and diagnosis. Three studies comparing therapies for insomnia. One study focused on general patient-centered sleep health, and there also have been two Methods projects that are focused on assessing sleep

health in an adult primary care population and in pediatric healthcare settings as well. Next slide.

There's been growing recognition that sleep is an important facet of health-related quality of life. Sleep health is suboptimal and about 1-in-4 U.S. individuals, with insomnia and obstructive sleep apnea being the two most common sleep disorders.

Insomnia affecting about 10 percent of the U.S. population.

Sleep apnea is vastly underdiagnosed. So currently it's reported as making up five percent of the population.

Both of these conditions can negatively impact quality of life and productivity and can also increase healthcare utilization. Many, many, many sleep and health interventions have been put forth. You can see this on the right-hand side of the slide. You'll see that many of these are very pervasive in the consumer space as well as the healthcare space.

Rigorous CER has been rarely conducted

here. And in fact, gold standard treatments such as CPAP for sleep apnea or cognitive behavioral therapy, CBT, for insomnia are not widely accessible and they're often very poorly adhered to, and are often substituted for by vastly understudied remedies or purported quick fixes.

Racial and ethnic groups are disproportionately impacted by sleep disorders and also represent one of the highest need populations for sleep health research. The literature suggests that Black and Hispanic individuals tend to have worse sleep health, but are also less likely to report those sleep disturbances, which leads to under-diagnosis here.

And we've done prior landscape reviews. But you can see that one has identified patients with intellectual and developmental disability as another high need group. Persons who conduct shift work or who reside in rural settings are often underdiagnosed or have limited access to high quality care. And sleep has also been identified as a growing need in children and adolescent health as

well.

So based on the many conversations with a wide range of stakeholders, I think PCORI's future work in sleep health should strive to capture the full range of patient-centered outcomes. And these include things like quality of life, which makes a lot of sense here.

But also adverse health outcomes such as risks for mental health, predilection for substance abuse, an increased risk of cardiovascular and other -- often multiple, chronic health conditions.

Given the impact on productivity the economic impact of poor sleep health should also be carefully evaluated. One of our stakeholders put it to us this way, people don't go to a sleep doctor because of the nighttime problems. They go to sleep doctors because of daytime problems. Which I think makes a lot of sense.

Data relevant to potential burdens and economic impact should be collected and analyzed as research outcomes, and better understanding of these burdens and impact will inform not only the patient

and the caregiver in terms of decisions they make, but also by clinicians and payers and healthcare systems. Next slide, please.

So looking forward, we believe that sleep health has many exciting opportunities that are ripe for PCORI funding.

One key area is addressing disparities in the screening, diagnosis, and treatment of insomnia and sleep apnea. We would like to see our investigator community develop responsive high-quality proposals that consider either system-level or multi-level interventions that can help close care gaps here.

For example telehealth referral options or creative deployment of home-based sleep study resources or technology tools, can be used to supplement primary care practice resources and to try to increase access for patients residing in rural communities.

And then in support of that, there's also an opportunity here to rethink the methods for assessing sleep health, as well as to re-engineer

how to improve sleep health, particularly in underrepresented populations. We've had ongoing meetings with subject matter experts and stakeholders to discuss how to measure patient-centered outcomes of interest, as well as what the challenges are and the best practices are in incorporating these measurements into what we hope are pragmatic clinical trials.

Often here, one of the things we hear about is the difference in treatment goals between what a patient says is their treatment goal versus what a provider thinks that treatment goal should be.

And this is, again, a unique research niche that plays very, very well to PCORI strengths.

For sleep disorders, our stakeholders have spoken loud and clear on the numerous non-pharmacologic interventions that warrant robust CER, whether in sequence or in combination treatment strategies and that we need to understand the full range of patient-centered outcomes that are measured for each of these treatment options, so that we can guide healthcare choices, knowing that there really

is no one size that fits all.

So here again, I'm going to point out that sleep health really intersects well with many of the other topic theme areas; such as IDD, such as mental health, cardiovascular health, as well as our national priority on achieving health equity.

PCORnet's capacity to support and accelerate sleep-focused CER will continue to be emphasized in our funding opportunities, and PCORI will continue to fund the development of vehicles and pathways for dissemination and implementation to get evidence more rapidly into practice and will continue to build the sleep community's capacity to meaningfully engage with us and sleep related sleep health-related CER.

So that's a very quick overview of our portfolio and sort of future directions based on again, strongly focused on stakeholder and research community input here. And at this point, we can forward to the next slide.

Again, I'm going to invite your thoughts on what you think are important not to miss directions

for the sleep health portfolio.

CHAIRMAN HOWERTON: Thank you Tracy. And before we open the floor for broad discussion, I would like to ask both Kimberly and James to share their thoughts. Perhaps Kimberly we can go with you first.

MS. RICHARDSON: Sure. Thank you, Tracy, for providing the overarching view. I think what I'm going to add is really will mirror what you said because I think intuitively, we all know we should get a good night's sleep, or anyone who's cared for a newborn, knows what sleep deprivation really feels like in a short-term.

But for those who are really dealing with this more as a chronic symptom, there's a lot more to look into in terms of the research. We know that our quality of sleep can be influenced by our diet, physical activity, environmental factors, and even genetics.

Some basic statistics that will sort of add to what Tracy was saying was 84 percent, this was out a 2019 poll of the U.S., 84 percent of people

don't get adequate sleep at least once a week. Twenty percent complain of insomnia. Sleep apnea is increasing as a direct result of rising rates of obesity. For older adults, 17 percent of men and nine percent of women over 50 have sleep apnea and don't really recognize it as a real problem.

Again, in terms of population school aged children are sleep deprived largely because of early start times for school.

So we're looking at 60 percent of middle school kids have sleep disturbances and 70 percent of high school students.

And then, we think about COVID in terms of how it has worsened sleep globally, right? The stress of the pandemic due to social isolation, decreased physical activity has resorted in disordered sleep, and we can see that those results appear greater for healthcare workers.

Of course, as we've all talked about it across the continuum, sleep disorders are directly associated with the onset and progression of cardiovascular disease, depression, cancer, and can

increase the risk of infectious diseases.

So one of the things I wanted us to look at, I'm glad that we're going to be focusing on insomnia and sleep apnea, but we also want to -- let's look at some research that is going to focus on those three areas. And more importantly, the relationship between sleep and diet, sleep and physical activity, and sleep and the health of the population across wider groups.

So I wanted us to focus on, older adults as well as those underserved populations. They're also areas where we could look at in terms of sleep and cognitive function in lower income Blacks. We can look at qualitative studies on the perception of sleep apnea.

I know personally for myself, it took me almost a decade to come to grips with the fact that I had it, and I was always looking for ways to get around it. And this second time around when my doctor told me about it, I said, "Oh, I don't want to spend overnight in the sleep study." They said, "Oh no, you can take it home and do it at home." We

found a lot of different ways over time in terms of technology to bring it closer to the patient.

I'd like to see us do a lot more with women from different ethnic minority groups and the stresses that it takes because there's this whole big cycle around sleep. It's not just sleep, it's sleep as it relates to pain, as it relates to fatigue, as it relates to stress of the day, as it relates to depression, and how we are dealing with difficult emotions throughout the day. And it would be interesting to see the intersections between those symptoms that are cyclical and relate to sleep.

And lastly, of course, for me I'm really interested in how we would be able to do longitudinal studies on allostatic load as it relates to sleep.

So those are my thoughts. Thank you.

CHAIRMAN HOWERTON: Thank you, Kimberly. James, may we ask for yours? Sure.

DR. SCHUSTER: Thank you. Those were great comments and I'll try to be concise and not

duplicate them.

One was, I was struck by the fact in Tracy's review that we've funded relatively few studies around sleep and we're not, I think, anomalous. There's not all that much sleep research that occurs in the context of research, and broadly, and that's -- from an economic perspective that's probably driven by the funding related.

So I'm really glad that we're looking at it.

One of the things that I did want to comment on, related to what Kimberly mentioned is that it is probably important as we think about this, to think about sleep disturbances that are secondary to another underlying issue, that's clear. You know, whether it's a behavioral or physical health issue, as opposed to what might be a primary sleep disturbance. And there's obviously going to be a huge gray zone. But it, I think those probably have potentially significant implications for how you think about it, obviously, and how you treat it.

And that, I think typically we've thought

about sleep disturbance as often secondary to something else, but often the other illnesses are actually secondary to the sleep disturbance. So I just think it's important to think about how we might want to approach that.

I wondered also, I don't think we touched on it there, but if there's also a role to think about prevention in the area of sleep disturbance. Particularly since it is a common problem, you know, at relatively young ages. Is that another area that we want to add to this?

And then the last one is, this is a really -- there's almost an innumerable set of questions that we could address. So it sounds like you're really trying to think critically about how we might want to pick out two or three or four, to really highlight for the researchers and I think would be, that's -- I think always useful, but probably especially so in a topic like this that's so heterogeneous.

CHAIRMAN HOWERTON: Thank you, James.

DR. SCHSUTER: You're welcome. And I

believe we are open to questions.

DE. DeVOE: I saw Chris and Connie.

MR. WHITE: Thank you. I really appreciate this. And similar to Kimberly, I struggle with sleep apnea myself, so I can speak firsthand about it.

But I do think there's a very unique opportunity because many of those medical device companies have now created digital companions to go along with these actual devices. So no longer do you see a world where you have a device and you have technology. I mean, they're essentially in sync.

And so, but there is an opportunity to sort of link much of that data that you're capturing with those devices, with much of the phenotypic data that we're capturing in many of the EHRs.

So I think that if we can better understand the -- to create longitudinality, I think that was mentioned earlier, is key. I also think being able to do that sort of subpopulation analysis to better understand disparities in the sort of diagnosis, the treatment plans, and what we think are the

effectiveness of many of these different types of therapies. Much of that is missing in the space. So you end up just doing just trial and error with many of these particular interventions. So I think that would be critical.

And then, I think there's an opportunity too to better define what PROs are relevant to patients as it pertains to this particular area, too.

So all in all, I think much of it was reflected in the looking at the opportunities slide. But I just wanted to reaffirm that I thought directionally it was the right thing to do.

CHAIRMAN HOWERTON: Thank you.

DR. HWANG: Thanks. Tracy, I appreciated that overview and great comments from folks already.

I also want to emphasize that I resonate with this being a priority topic area, especially with respect to its linkages to cardiometabolic health. As you mentioned, diabetes, obesity, cardiovascular health, I think that connection is important and really could be reflected across,

PCORI's portfolio work overall to kind of continue to elevate sleep as a factor.

I will say for myself, some of the experiences that we've had in working with evening shift workers, we actually have done some work with a trucking agency, and what's funny is when you sit in our care management rounds, the sleep optimization and challenges for that inevitably come up.

So it's funny in many cases before where I've sort of mentioned some of our, you know, the members that we work with, this is actually a very big factor, right? And I think many don't actually recognize that there's some education involved that sleep really does have this direct impact on your glucose levels the next day or the next following weeks as well as obesity, et cetera.

So, one thing I would point out, and I know folks may know this, I have sort of an interesting connection with the Pokémon Corporation.

[Laughter.]

DR. HWANG: We'll leave that aside, but the

but we keep up with the news there and what's interesting is that they're coming out with this product called Pokémon Sleep.

If you want to Google it, it’s coming out in the summer.

But it's fascinating. It sort of goes to this constant of gamification and their goal is to help individuals around the world get better sleep where you're almost playing, like where you have an app and a device that actually monitors sort of your movement on your pillow, right? And the better sleep that you get, the more sort of Pokémon that you capture, et cetera.

Now, obviously this is set for a specific community, so I'm just raising this, but I think there is work out there in terms of the industry and people that are studying some of this further or providing more context or insights in terms of gamification technology, digital health apps could really reach wide audiences.

I would love for us to explore that. So I wanted to share those thoughts.

CHAIRMAN HOWERTON: Thank you.

DR. WANG: In my former life, I actually wrote a paper on Pokémon gamification of physical fitness, so this is fun.

DR. HWANG: Pokémon Go, augmented reality. Absolutely.

CHAIRMAN HOWERTON: All right, thank you. Next?

DR. DeVOE: Alicia.

DR. FERNANDEZ: I just -- I really resonate with two issues. One is the screening for OSA and the other one is obviously the treatment for OSA.

It is so hard and I'm so glad to see that we have some studies already in the field helping patients with that and to see what can help.

But the screening is also as you know, a huge issue and it's like incredibly primitive, and I wonder whether there could be some comparative effectiveness there, particularly around things -- around not only what instruments are used, but how the workforce is structured. Like who's doing the screening and so on and so forth.

And I wonder whether that would be an area to call out in a larger TPFA on OSA?

And then, and then I was actually going to say, I didn't know about Pokémon Sleep, but I know that many times PCORI has been interested in emerging technologies. If there were emerging technologies that had something to do with improved treatment for OSA. Boy, that would be really wonderful for our patients. So thanks for that.

CHAIRMAN HOWERTON: Thank you.

DR. DeVOE: Ryan.

DR. BRADLEY: Yeah. This is really fantastic discussion and some thoughts came to mind while I was listening and, you know I have a bit of experience investigating mind/body interventions for insomnia. And with those studies, and some conversation was or some discussion was had on this already, but we've run into some significant methodological challenges of rigorously measuring sleep and sleep quality. And patients don't love sleep studies. People don't love sleep studies. They're not really practical to incorporate into

research. They're very expensive. People don't sleep well, anyway. It's very, very challenging.

And wearable devices, as you know, is just the wild, wild West in terms of what's claimed versus the reality of sleep assessment.

So that's an area where I guess I would advocate for more methodological development and standardization in any research that we fund, especially when we're looking pragmatically at real world outcomes and patient experience with sleep and assessment of sleep.

So that's request number one.

The second request is, there's a lot of interest in the public in taking natural products for sleep. And I would just really advise some careful consideration and caution in this area because I think in the absence of a detailed understanding of how those substances affect sleep architecture, it's very tempting to attempt to say we'll compare melatonin to a sleeping drug of one type or another or we'll look at Valerian or we'll look at Chamomile or a combination of herbal

products.

And I just want to be clear that a lot is known about how these natural products impact sleep and sleep architecture. And so, unless those interventions are matched with the physiology of the individual very carefully, the results will be neutral and it'll appear as though there's no signal for benefit. And so, should those funding opportunities be released or considered that the right reviewers are brought in to make those assessments? It's critically important to the potential signal.

The third point is another plug for the de-implementation of unsafe practices when it comes to prescribing behavior for insomnia, especially when it comes to older adults in the use of benzodiazepines and other potentially hypnotic drugs. We know that this is dangerous. And so, that's possibly another opportunity for some comparative effectiveness research to reduce that common practice.

And fourth point, this was actually kind of

a dinner table discussion last night, is opportunities to improve sleep quality in the hospital and issues related to you know, lack of integration in care team rounding. Waking patients up in recovery at two o'clock in the morning, four o'clock in the morning, panels of bright lights and buzzers and bells that patients have no control whether to turn off.

All of these things, I would submit it could be fascinating to look at recovery time, pain outcomes, other very important patient outcomes by cleaning up sleep hygiene in what are supposed to be our healing and recovery spaces. Thank you.

CHAIRMAN HOWERTON: Thank you. Connie, is your card still up or did it come up again?

Are there other questions from online or in the room?

Well, again, I would say we have gotten a very rich amount of feedback, although the answer to your last point is easy, Ryan. Don't go is the answer to sleep in the hospital.

[Laughter.]

CHAIRMAN HOWERTON: Just don't go there. That's the only solution for sleeping there.

Thank you all so very much. I believe if I'm not misinformed, that no one has joined us for public comment?

And if not, then we will move to Nakela for some closing remarks. You may have the microphone.

DR. COOK: Well, thank you to all of our Board members for a really exciting day, a lot of Board engagement on some really important topics.

We're excited to take in all the input and feedback that we've received and continue to work to move things forward with your guidance.

And I also want to thank all of the teams at PCORI for really an outstanding meeting, to supporting an outstanding meeting today, and the presentations really that teed up some robust discussion. I think they were really exciting and well done.

And just as I reflect on the day, you know, we talked about early on a lot of the funding opportunity activity going on at PCORI and some

highlights from that activity. We heard a lot of excitement around the Health Systems Implementation Initiative, and thinking about how we make connections across PCORI with the work that's going on at PCORnet and thinking about that distribution of coverage in terms of the health systems involved in PCORI activities.

And we look forward to bringing back some updates and further discussion to you on the Health Systems Implementation Initiative. I heard that interest.

I also heard in our discussions of the Methodology Committee nominations, a desire to talk further about the outreach strategy for our next round of solicitations and appointments for the Methodology Committee. So we look forward to doing that with all of you. And I want to take a moment, again, to congratulate all of the appointees to the Methodology Committee. We are looking forward to working with you and this is a really exciting time for us that PCORI.

We heard a lot of discussion around several

strategic issues, including the commitment plan, and appreciate your feedback in terms of the agreement with that overall front-loaded approach and the update on the model, and really a charge to us to think about how we may think about rapid approaches in a current year of commitments to handle what may be unobligated funds as we're moving into later parts of a fiscal year.

So we look forward to working with the FAC and coming back to you, further, on some discussions there.

And thank you for all the input and interest related to PCORnet, and the I think the valued recognition of the progress that's being made on the evaluation strategies and the strategies that were put forward to really advance the national priorities and we look forward to providing further updates on how that's going, and we'll be talking more about PCORnet in the coming board meetings.

And lastly, we couldn't have ended the day better than talking about the topic themes. I think there was a lot of engagement and pre-work, I could

tell from many of you, in terms of thinking about these topic themes.

I heard some clear takeaways there about thinking about the niche areas for PCORI and you know, if it may be about the opportunities we have because we really approach things in a pragmatic way to think about constellation of conditions that really appear in the clinic and how we may be uniquely positioned to think about emerging technologies across several of these areas, and the outcomes that are most important to patients and to stakeholders and thinking about that from a perspective of patient-centered value.

And we also heard, perhaps unique niche for PCORI to also think about the de-implementation aspects, and I think those were really great takeaways.

I also heard doubling down on the concepts of prevention on equity and disparities across these themes and thinking about the intersections amongst the themes. So we're really excited to bring back in the next Board meetings, more themes for our

topic themes for discussion, as well as a follow on in how we're incorporating what we heard today into some next steps.

So thanks again for all of your attention and engagement and for really a wonderful day.

[Applause.]

CHAIRMAN HOWERTON: Yes, I would like to on behalf of all of the Board, convey our thanks to you and the whole team who made this such a wonderful day. And for myself, personally, convey my thanks to all of you on the Board who give of your time. PCORI has greatly benefited for you being willing to give your time and talents to us.

Thanks to all who joined us today.

Today's meeting agenda slides, archived webinar, and approved minutes from the February 14th, 2023 meeting will be posted to PCORI's website within a week. As always, we welcome your feedback at info@PCORI.org, or through our website, www.PCORI.org. Thanks again for joining us.

[Whereupon, at 2:54 p.m. EST, the Board of Governors meeting was adjourned.]