# PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## BOARD OF GOVERNORS MEETING

Monday, May 24, 2021

Webinar

[Transcribed from the PCORI webinar.]

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Michael Herndon, DO
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Karin Rhodes, MD, Deignee of the AHRQ Director
James Schuster, MD, MBA
Ellen Sigal, PhD
Kathleen Troeger, MPH
Danny van Leeuwen, MPH, RN
Robert Zwolak, MD, PhD

AGENDA

P R O C E E D I N G S

[12:48 p.m. EST]

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

CHAIRPERSON GOERTZ: Thank you Nick.

Good morning. And welcome to the May 2021, meeting of the PCORI Board of Governors. I'm Christine Goertz, Chairperson. I want to welcome those of you who are joining us for today's Board meeting via teleconference and webinar. Thank you to everyone who's joined us virtually, online and by the phone.

We are very pleased to have you here. I want to remind you that conflict of interest disclosures of Board members are publicly available on PCORI's website and are required to be updated annually and if the information changes. If the Board will deliberate or take action on a matter that represents a conflict of interest for you, please recuse yourself or inform me if you have any questions. If you have questions about disclosures or recusals relating to you or others, contact your

staff representative.

All materials presented to the Board for consideration today will be available during the webinar. The meeting is being recorded and an archived webinar will be posted within a week.

Nick, would you please call roll?

MS. WILSON: Certainly. Kara Ayers.

DR. AYERS: Present.

MS. WILSON: Kate Berry.

MS. BERRY: I'm here.

MS. WILSON: Tanisha Carino. Tanisha, I believe you're on the line.

DR. CARINO: Present. Sorry.

MS. WILSON: Okay, great. Francis Collins or Mike Lauer, Designee of the NIH Director.

DR. COLLINS: I'm here.

MS. WILSON: Jennifer DeVoe.

DR. DeVOE: Present.

MS. WILSON: Alicia Fernandez.

[No response].

MS. WILSON: Christopher Friese.

DR. FRIESE: Present.

MS. WILSON: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. WILSON: Mike Herndon.

DR. HERNDON: Present.

MS. WILSON: Russell Howerton.

[No response.]

MS. WILSON: James Huffman.

[No response.]

MS. WILSON: Connie Hwang.

DR. HWANG: Present.

MS. WILSON: Sharon Levine.

DR. LEVINE: Present.

MS. WILSON: Michelle McMurry-Heath.

[No response.]

MS. WILSON: Barbara McNeil.

DR. McNEIL: Present.

MS. WILSON: David Meyers or Karin Rhodes, Designee of the AHRC Director.

DR. RHODES: Karin Rhodes is present.

MS. WILSON: Thank you. Eboni Price-Haywood.

DR. PRICE-HAYWOOD: Present.

MS. WILSON: James Schuster.

DR. SCHUSTER: Present.

MS. WILSON: Ellen Sigal.

DR. SIGAL: Yes.

MS. WILSON: Kathleen Troeger.

MS. TROEGER: Yes, I'm here.

MS. WILSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Present.

MS. WILSON: Janet Woodcock.

[No response.]

MS. WILSON: And Robert Zwolak.

DR. ZWOLAK: Here.

MS. WILSON: Dr. Goertz we have a quorum.

CHAIRPERSON GOERTZ: Great. Thank you so much. Can I have the next slide, please?

All right. As you can see, we have a very full agenda today. We are going to start out with continuing our strategic planning discussion related to our national priorities. And Sonja will be joining us for -- so that we're able to continue that as a facilitated discussion, we'll then have the Executive Director's Report followed by

consideration for acceptance the PCORI Methodology Report, as well as funding for a partnership with AHRQ to be followed by public comment before we wrap up and adjourn.

So why don't we get started, then? We're going to start with our Consent Agenda. Could I have the next slide? All right, next slide.

So we have two areas or two items on the Consent Agenda today. One is our minutes from the last meeting and the next is the proposed, revised, supplemental conflict of interest policy for PCORI staff. And I know you've already had time to take a look at this in your materials. So I'm not going to dwell on this slide.

Can I have that next slide, please?

So what I'd like to do is ask for a motion to approve the Consent Agenda. Again, that we'll approve the minutes for the April 13th, 2021 Board meeting, as well as the proposed revised supplement: a conflict-of-interest policy for PCORI staff.

DR. SCHUSTER: So moved.

DR. LEVINE: So moved.

CHAIRPERSON GOERTZ: All right. I'm sorry, who was it? I did not hear the first person.

DR. SCHUSTER: James.

CHAIRPERSON GOERTZ: Thank you, James. And can I get a second?

DR. LEVINE: Second, Sharon Levine.

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

[No response.]

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

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: All right, the motion passes. Thank you. All right. Next slide, please.

It's now my pleasure to once again introduce I'm Sonja Armbruster. Sonja, we're looking forward to continuing our discussions from yesterday's meeting and I will turn it over to you.

MS. ARMBRUSTER: Thank you, Christine. I am also looking forward to our conversations today.

As we continue our strategic conversations today, let us begin with a return to purpose.

This hour and 15 or 20 minutes that we have is an opportunity to engage with the Draft National Priorities for Health, and to gather Board members expertise and insights for further refinement. We do so in an effort to prepare the Board for a vote at the June 15th Board of Governors meeting, and that vote will be to consider for approval, the draft national priorities for posting for public comment.

And the next hour and 15 minutes, our goal is to review insights from yesterday's discussion, revisit one of the draft priorities, and have a fuller discussion about the overlapping interests, initial thinking about the opportunities to translate these ideas into an operational research agenda and to get a general sense of the gestalt of the whole conversation and ideas.

I'd like to begin our conversation with a

few themes from preliminary insights from yesterday's discussion. Several staff and I met yesterday after the meeting to prepare these notes, and we hope these observations are a starting point for continued conversations today. Throughout all of the draft priorities discussions, we heard the importance of incorporating health equity as a cross-cutting component, both relevant to all priorities and also as a distinct priority on its own to create opportunities, to explore comparative effectiveness research to improve health outcomes for individuals of all backgrounds and to strengthen supports for inclusive and diverse stakeholder engagement.

Another theme we heard throughout the discussions was the value of strategic partnerships as key avenues for progress. We heard a call for continued and new opportunities to engage multi-sectoral partners, traditional and non-traditional entities for engagement and patient-centered outcomes research.

We also heard that progress on the national

priorities will require getting local to move the needle. We heard this in many iterations, such as local community building for place-based or population-specific strategies, as well as taking the patient-centered outcomes research, work to local communities, meeting people where they are. Related to that notion the national priorities create opportunities for changing the culture of research, which will require extending work and engagement, bidirectional communication that promotes trust, and that trust building among all participants in the research work both individually and at systemic levels.

We also heard a call to be mindful of unintended consequences, which requires intentionality to capture and to learn from those outcomes and impacts. The Board connected to purpose for the work and these priorities, must continue to identify PCORI's unique role and contribution. That phrase "PCORI's unique role and contribution," surfaced many times throughout our discussions yesterday.

And finally, we heard acknowledgement that these draft national priorities are ambitious, aspirational, long-term goals. With all the forthcoming research agenda, we'll have more measurable strategies that PCORI will track to achieve the progress on those goals. In the spirit of national priorities as ambitious and aspirational goals, at this point in the strategic planning process we may tolerate ambiguity, even though that is sometimes uncomfortable because that ambiguity makes space for discovery through the research.

There appeared to be some consensus around four of the five draft priorities yesterday. And perhaps it would be helpful to briefly revisit one of those, perhaps it was because of the topic or perhaps it was because it was the end of the day, but the discussion around Advancing a Learning Health System requires a bit more input to help consolidate some of the Board's reflections about this topic and to provide additional direction for staff.

And to that end, I invite Nakela back to do

some level-setting about that topic and invite some further discussion. Nakela.

DR. COOK: Thanks Sonja for that nice recap of yesterday's discussions. Why don't we go ahead to the next slide?

Yesterday, we really had a dynamic discussion on advancing the learning health system and you revealed several insights. And today we wanted to try to take a little time, as Sonja mentioned, and build on those insights and try to consolidate some of the thinking to help her find the focus of it. We've heard from you that this area in terms of learning health systems is really relevant for PCORI's unique role and mission. And in some ways represents a sweet spot for us in the broader health ecosystem.

There was also a comment about some of the ways that this priority actually serves as almost like a capstone or even a culmination of the priorities we discussed before, and thus could be important to reflect on the unique contributions expected from this goal. We also heard about it

being important as a reflection of the mutually reinforcing nature of the priorities and the relevant interdependencies that are desired in these national priorities as we look at them all together.

And while there was much discussion about a learning healthcare system and a learning health system, there was a sentiment that solely focusing on the healthcare system could be limiting in our aspirational priorities that focus on outcomes related to health. And several of you mentioned the need for refinement of the boundaries within this priority and the PCORI-specific niche when broadening to the health system.

But there were some critical elements that emerged that could provide some of those boundaries and enhance our focus, including considering multifaceted interventions that may cross sectors that are inclusive of a clinical care setting, and also test aspects of interventions that may be more public health or social system-oriented with multimodal approaches. And this wouldn't necessarily ignore, and in fact it includes, the

aspects of place and other factors that we thought were critical in thinking about broadening to learning health systems.

And to that end, there was another area of focus that emerged around interventions that focus on the local aspect. As you heard, that comment really resonated across several priorities, but it came out here as well, to think about generating that practice-based or place-based evidence. And we also heard that one significant ways to focus and provide boundaries for this priority would be the concept of focusing on health outcomes for alignment with PCORI's remit and by narrowing what the focus on health outcomes we start to put some boundaries around what PCORI could do to advance this priority and goal.

So as we prepare for further refinement of this priority today, we'd really be interested in hearing what additional boundaries and areas of refinement would help to focus this priority for PCORI's unique mission, role, and opportunities. And just to remember that we have opportunities to

continue to engage on this priority as we reflect your input when we return in June and even after we hear public comment.

And so it's an important comment that Sonja made about there's a bit of ambiguity at this stage that can be refined with some time and further refinement of focus, but we're really interested in hearing some of your thoughts about additional boundaries or areas of refinement that could help us in focusing to PCORI's unique mission, role, and opportunities within the goal.

So Sonja I'll turn it back to you to help facilitate some of the discussion here.

MS. ARMBRUSTER: Thank you so much. And I would invite all to turn their cameras back on, if you so desire to engage in this conversation. And we can maybe hide the slide for a moment and I'd like to just focus on that conversation about what additional boundaries and areas of refinement would be helpful for focusing this priority and aligning it with PCORI's unique mission and role.

And to that end, I invite anyone who would

like to comment in the notes, if you would in the chat -- if you would indicate your interest in commenting on this. There was a robust discussion and it felt like we were hitting that time boundary a little hard yesterday. Who would like to be first to speak about revisiting any additional boundaries or any additional areas of refinement?

All right, Sharon, if you could kick us off, that would be great.

DR. LEVINE: Thanks, Sonja. And I just, my only comment is I think you did a beautiful job capturing the essence of our conversations yesterday. Both in terms of the themes that emerged throughout the discussion, as well as the perspectives on the final -- the role of the final priority, of the fifth priority. Not final. Both as a capstone, as well as in some ways a blank palette, a blank canvas on which we perhaps need to add some paint and some definition.

I think it did a great job.

MS. ARMBRUSTER: Thank you for that. And thank you for the team who was helping throughout

the day. You all offered a lot of good input and it's valuable to come back and revisit specific issues.

So are there additional -- thank you, Sharon. Are there additional ideas about this particular priority around a learning health system that you would like to revisit from our conversation yesterday or from your thoughts overnight, as you had opportunity to reflect about areas for refinement or after further reflection?

Do you concur with some of the ideas that were put forward yesterday? Danny?

MR. VAN LEEUWEN: Well, I think when we think about learning systems, learning organization, I think first we need to walk the talk and that some of the things that came up yesterday were examples of that. Like what can we learn from all the work that has occurred, all the studies that have happened, all the process challenges that we've had?

You know, we are no longer a startup. This is a mature organization and it's different being a mature organization than a startup. And I just

think we have -- we need to look to ourselves as we think about learning organizations.

MS. ARMBRUSTER: Thank you, Danny. I captured that yesterday and I note that I heard someone reflect on learning from our engagement portfolio.

So how can PCORI do you just, like you said, walk with the talk and learn from our own systemic role in the system. Kara?

DR. AYERS: Yeah. I really thought more about what Danny had shared yesterday about the need to streamline. And I think conversations like this when we think big can tend to be very additive, but also thinking about what we may need to -- what we've concluded work on. Not even looking at it as what do we need to stop or cut out, but I do think -- and we talked about that yesterday as well. What have we finished but we need to take an action step on. I think that stood out to me as I reflected.

MS. ARMBRUSTER: Thank you, Kara. Yes. I've been doing more about that. I like your phrasing there. What have we concluded? James.

DR. SCHUSTER: Thank you. I also think you did a great job of capturing the discussion. One of the as I'm thinking about people, potentially writing applications to a prompt like this, it strikes me that many individuals from, particularly kind of academic institutions, may have a variety of depth of experiences in terms of partnering with public health or social determinant type agencies.

And that one area that might be helpful for the staff or external readers to -- or thinkers, to help us with is, is to give them some examples of what those partnerships might look like, what kinds of themes they might want to partner on together. Maybe even point them to a couple of examples just as references to learn from. It might help jumpstart the work a bit.

MS. ARMBRUSTER: That's an exciting idea. And I'm curious about what examples come to mind. Are there you know, across -- with James' first few and then from others, are there specific examples of partnership that might prime the pump?

DR. SCHUSTER: So I'm just thinking off the

top of my head. There's not a long list at the tip of my tongue, which is probably a little bit of a screening result. So I think there, there certainly have been studies for example, where in studies of individuals with substance use and look at the impact of housing for homeless individuals with substance use, and they've noted for example, that just offering housing leads to a significant improvement in substance use, even aside from any treatment.

So that'd be an example. But I think those studies we're probably a little different in that, I think, they use grant funding, you know, or some other non-traditional or non-readily available funding source for the housing program. And I think what we probably were hoping folks do is that, you know, they partner with a HUD program or other existing strategies that could be replicated.

MS. ARMBRUSTER: Excellent. So I hear reflecting back about opportunities to engage with infrastructure. That's helpful. Infrastructure that's long lasting. Thank you.

All right. I see Tanisha and then Eboni, and then Mike, Tanisha go ahead.

DR. CARINO: I wanted to build on a couple of comments that have been made. When I think about the impact PCORI has made in the first 10 years. What resonates to me is a different level of engagement we've had with the patient community and an enormous amount of research that's been funded. And for me, when we think about that learning healthcare system and some of the comments that Danny has made also. In the next 10 years of our era as PCORI, I'd love to see us focus on getting that research actually implemented.

So I think that was a distinction of PCORI relative to other funding organizations, that it wasn't just considered a resource organization, that if we really stay with the mission of PCORI in driving more patient-centered outcomes, if the implementation of what we do that is to me of equal importance and if we really are serious about addressing health equity and some of these other issues, it's taking research that might've been

wholesale research and actually figuring out how to retail implement it in different kinds of communities and disseminate that information to other communities and stakeholders so that they can do the same.

MS. ARMBRUSTER: Thank you. Lots of overlap thinking about implementation. Thank you. Eboni.

DR. PRICE-HAYWOOD: So I've been quiet on this topic, to be honest with you, because I was overwhelmed with the text and was trying to understand what am I struggling with? And then, I realized this topic is a public health topic. So then I flipped my brain into a public health framework.

And the first thing that I was always taught is what is your conceptual model for whatever it is that you're talking about? Because if you don't have -- if you can't put it into a picture that simplifies concepts for the average person to just glance and look and see whatever relationships, interconnections that you're trying to convey. How

it connects to some other outside factor, internal factor, whatever the case may be.

I would like to request that for this specific one, that the staff work on developing that conceptual model. What were you trying to convey with the texts that perhaps we missed in reading and take it to a visual. If you can take it to a visual and then work backwards through the text, explain what you're trying to convey, or even some of the concepts that the Board has already shared.

Can we make a visual of all the priorities? This is the one, because it's so open to interpretation with various definitions, that if you don't define what you mean, everyone's going to be confused, including the researchers if they try to apply to a grant mechanism. So that was my observation I wanted to share.

MS. ARMBRUSTER: Thank you Eboni. I fully concur that images help, and if there are images that people have in mind, I encourage people to share in this conversation. Mike and then Christine.

DR. HERNDON: Well, just to echo the last two comments. I think they were perhaps thinking more eloquently than I. I have just a couple of additional comments.

I really struggled with wrapping my head around this fifth priority and just exactly what we meant by it. And it's one that's kind of articulated in kind of advancing a learning health system and what makes up and what drives the health system? Are we talking public health? Eboni, I appreciate comments there.

Are we talking medical societies? Are we taking clinical health networks? Are we, you know, what are we talking about when we are talking about a learning health system?

And then I just, I think, the comment that resonated kind of with me throughout yesterday's discussions with multiple comments is that we've long been talking about the need for integration of behavioral health into physical health. We really need to also start having conversations about integrating social determinants into physical

health. No longer can we just -- and I think we all know that, integration of social determinants is something that's going to challenge the healthcare system because -- and we heard over and over about the need for system delivery reform, how providers take care of patients and not just, you know, all of the spectrum of providers.

And I think this one is so confusing to me because the system, as we've heard from numerous experts, it is broken. And unless we fix that health system and start integrating, and not just be able to look at social determinants and all aspects of health. I think this -- you know, priorities is going to be a challenge. So I echo the previous comments and add some more confusing ones.

MS. ARMBRUSTER: Thank you, Mike. I think the complexity of the issue does drive the conversation and it creates the ambiguity, which also creates opportunity for innovation and solutions. Christine.

CHAIRPERSON GOERTZ: I would just want to echo Eboni's recommendation to develop a conceptual

model. I think having that framework can be really clarifying and regarding what we mean. And I'm also wondering how we can use; we have a health systems portfolio of research that we've funded over the past 10 years. And I think there are probably some lessons that can be learned, you know, not only about the CER that we've funded thus far, but what you know, what have we learned about implementation?

You know, at least some of those earlier studies, you know, presumably there would have been opportunities for implementation following the research findings. So I just think that there's an opportunity to look at our own portfolio to figure out. You know, what are some of the gaps and opportunities that may help inform that this framework and in addition to the discussion that we've had over the last couple of days.

MS. ARMBRUSTER: Thank you, Christine. We have maybe four or five more minutes that I wanted to devote to really unpacking and getting some specific guidance around additional boundaries and areas of refinement that you'd like to see around

learning health system to try to shape and soften the ambiguity and create specificity for public comment. And so, clarity about what we're asking for feedback about.

Are there are others who would like to weigh-in? Danny.

MR. VAN LEEUWEN: So I think this issue of partnerships and reducing redundancy, working together with other organizations is something. And I'll give you an example. So we are talking a lot about public health and that I think thinking about a partnership, for example, with the CDC that is -- that has an initiative that's also funded by the same fund, you know, the patient outcome research fund, the Med Morph public health data integrating that with PCORnet. So that we're taking advantage of our knowledge and our experience and a CDC initiative so that we can learn and not go it alone you know, with our own common data model.

MS. ARMBRUSTER: Thank you, Danny. I see a couple of other requests to speak in the chat. So Karin, did you want to share?

DR. RHODES: Yeah, I just want to share from the Agency for Healthcare Research and Quality that we look forward to partnering and aligning our vision and coordinating along the model and I put in the chat the Care and Learn model, which is something that was developed by a group of AHRQ representatives, but it incorporates the community and community-based research around social determinants and a way that I think AHQ doesn't really have the full bandwidth to do so.

So I would love to see PCORI as a patient-centered organization really embrace the community-based aspect of both research and implementation.

MS. ARMBRUSTER: Thank you. That helped guide the conversation. And I appreciate that feedback, specific feedback. Sharon, and then Robert, and then we may be wrapping this piece up.

So Sharon, go ahead.

DR. LEVINE: Yeah, I just want a second or third, I guess, Eboni's comment about the conceptual model and I add to it, I think. One of the things that will help both us and in the future in the

development of the research agenda and clarity for research is, is some definition of the terms we're using. As several people have said there is a level of ambiguity that I think we can reduce by making clear what, at least what we mean when we use the terms of equity, for example, and of health system as opposed to a healthcare system. Thanks.

MS. ARMBRUSTER: Thank you. And Robert.

DR. ZWOLAK: In terms of specificity, I've thought about it the last day and a half. And we haven't really talked that much about comparative effectiveness research and what is our primary tool. In terms of health care systems, I think of PCORnet as something that will add specificity. This is an amazing tool that we have, which you really haven't spoken very much about.

We've developed it. It has the IT power to really let us get to a more granular level. And we talked yesterday about going local and going big. If you have powerful analytics is another way to go local. And so, I think that we need to reflect back a little bit on our methods and the ability to apply

our methods in particular PCORnet to the healthcare system exploration.

MS. ARMBRUSTER: Thank you. I think before I transition, that was helpful and it feels like a transition point. I just wanted to do a last call about any other requests for refinement or suggestions or directions for staff around advancing a learning health system specifically?

[No response.]

MS. ARMBRUSTER: All right. Well, then I think we have an opportunity then to pivot to our discussion about all the gestalt of the full five priorities that we discussed yesterday. And if I could request that slide, just to share the questions for discussion. Can share that briefly. Here are three questions that we thought would be helpful as a springboard for our additional conversation.

So with our time remaining, we have an opportunity for each member to share about what resonates with you about these draft priorities and to offer ideas about what might be missing. The

questions are intended to be a springboard for conversation rather than prescriptive. So we don't necessarily have to answer each and every one. But I am interested in hoping that this primes the pump for conversation. I'm hoping we have time to hear from everyone as we think about what are some of those overlapping cross-cutting issues and priorities. And what opportunities might those create? What are the opportunities for these draft national priorities to be translated into a research agenda? That's the opportunity to come up with specific ideas that help guide the next phase and conversations could be helpful.

And then last, and I think most interesting, what's the next level of thinking needed to assure PCORI makes progress on all five draft national priorities?

So those are the questions we want to discuss and I hope that those are handy for you. And I think if it's okay, I think we can hide those questions and so we can all see each other and continue our conversation.

So I will continue to be the neutral call on and I will continue to look to the chat and/or your wave to speak about that. But we can begin with the idea of where do you see opportunities, new synergies, opportunities to have synergistic learning through research by having these overlapping broad priorities. So were there specific things that came to mind to you yesterday about opportunities we might be creating by having these broad priorities that have overlapping context.

And I will look to chat for who was ready to weigh-in on that.

I know at one point there was some concern that these are overlapping and another point there was a realization that "Yes, let's embrace that excitement."

So Christopher, thank you for kicking us off.

DR. FRIESE: Sure. good afternoon, everybody. And Sonja, thank you for wonderful facilitation and to my colleagues for their input,

and PCORI team for really giving us a wonderful place to start this work. Thank you all for your hard work.

I think a little bit of reflection even before this current conversation. I think I'm thinking about how PCORI can be different in 2.0 and what our unique assets and advantages are. And I think about what other funders are not able to do as well or they're not able to by statute, their mission is different, et cetera. And I heard a lot of excitement and energy about -- I think, about thinking about the settings of the opportunity for intervention being different than they currently are, which is historically acute care hospitals and big health systems.

And that's still very, very important work but PCORI might have an opportunity to really reach individuals before they're in the acute care system from a public health perspective, from a social and structural inequity perspective. And that would require a different kind of set of data and different kinds of partnerships and engagement, but

I think that might be a differentiator that some of the other funders who do health-related work can't do, and the social sector funders who really don't have the kind of budget to do what we're talking about.

So I'm excited about that. I'm a nervous about it because it's more difficult work, but that doesn't mean we shouldn't do it.

I think the other piece, and I really would argue or suggest, we have a deeper discussion with Karin and David from AHRQ to really understand the Venn diagram of implementation, to understand very clearly where AHRQ sees its opportunity with their dedicated funds and their other portfolio. And then where can we, as PCORI, be value add in addition to that? I think we've all agreed that more needs to be done, but exactly what that is for PCORI to be doing and have sort of clear understanding of that, I think would be extremely valuable to us as we craft the strategy. Thank you.

MS. ARMBRUSTER: Thank you for that succinct and clear suggestions for action. I

appreciate that and your reflections. Mike, and then Ellen.

DR. HERNDON: This came home to me yesterday about in the health equity conversation and I don't really mean to be the dead horse here, but we really need major disruption in the healthcare delivery system. I would say that, you know, we've had minor disruptions, but we've really not had a global understanding, you know, that providers simply have to start providing care in a different way in order -- and we have to reimburse in a different way if we're going to get providers to truly, truly take care of patients.

You know, you've heard me say, we've been paying providers to see patients. We've not been paying providers to take care of patients. And until we change the delivery system through some sort of major disruption, and I understand that there may be some disadvantages to create major disruption, being how we're funded and all. But until we get to system level changes in reimbursement, I'm just not sure that our priorities

are going to have the impact that they need to have. And I would like to see us focus on that delivery system redesign and payment, the value-based purchasing we recommended yesterday some reforms in payment methodologies for care.

MS. ARMBRUSTER: To that end, before we go on, do you think that one or more of these priorities speaks to delivery system redesign and reforms to payment mechanisms? And that could be a question to anyone.

DR. HERNDON: I don't know how you make a bridge -- we know that, I think, a couple of them that, you know, could impact -- when we talked about advancing the science advancing implement. You can't implement -- you can't get people at the patient care level to implement until you convince them that it's feasible for them to do so from a financial perspective and in a patient flow perspective.

So, but my opinion, maybe, a couple of them do, but I don't think we can achieve them without it was my main point.

MS. ARMBRUSTER: Thank you, Mike. And I hope that primes others to want to weigh-in on that comment. I'm going to call on Ellen and then Sharon, and then Kathleen. Ellen.

DR. SIGAL: So the goals are audacious and important and relevant, changing the system is important. I'd like us to focus on execution and which part of it we're going to take up on and deliverables and how we're going to focus. In a year from now, when we have this conversation, we can start to begin to achieve some of these goals because they're big and important and relevant, but we can't change the entire system. So rather than at 30,000 feet, I'd like to get us to 5,000 and maybe next year talk about things that we did do that are important.

MS. ARMBRUSTER: Okay. Thank you. And I think that that's a natural progression of strategic planning, to get to get us from this 30,000-foot level, to get continuously more granular to become clearer about where the action is in that research phase and the actual doing in the next phases.

Sharon and then Kathleen and then Tanisha.

DR. LEVINE: Yeah. And I think both Ellen's comments in terms of how well did these priorities lead to a clear, focused research agenda is critically important. And to Mike's comment, I mean, similarly, and so the issues Mike raises happen where -- I think that the question is which of the priorities would research proposals that address one or more aspects of the issues Mike raises fit under these broad priorities.

And I think to me, anyway, the answer is that the fifth or the fifth priority, the advancing system of health. Because in fact, what that and what Mike described as moved from a healthcare system that sees people to a system that cares for people is exactly one of the things that could be envisioned and translated into research questions that look at how well people are cared for with specific conditions or at specific stages of life, under different delivery models or payment models and to what extent are their lives improved and their health status improved, that can be

attributable either to the system in which they're being cared for or to the way and/or in the way that system is being compensated.

I mean, I think it is a critical issue that Mike raises. I'm not sure we can fix it, to be honest. I'm not sure where the will is in this country. If we think of the "disruptive" innovations in delivery systems that have emerged over the last several years. They, in fact, are more that they move more toward disaggregation, rather than integration and coordination of care. But certainly it's certainly more worth the effort.

MS. ARMBRUSTER: Thank you. I'm continuously curious about what would be a disruption that is something that can be tested through research? So I'm curious about that. I'm going to move to Eboni. Eboni wanted to weigh-in and then whomever after Eboni.

DR. PRICE-HAYWOOD: To answer your last question, plus go back to Mike's because they're related.

So I believe that health service delivery

design is fundamentally tied to equity to PCOR infrastructure discussion, as well as when we define the learning health system. All three of those are relevant. The question becomes what provokes behavior change and the delivery.

So we just had a comment about disruptors in the healthcare system. That's your most obvious; the Amazons and the CVSes, and whoever else is getting into this space with telemedicine, digital health technology, and other things that are more convenient. But on one level could create a digital divide that becomes an equity issue. But on the other hand, if we have concurrent infrastructure things outside of the health system, i.e. broadband or whatever else. That can be something that levels the playing field once we all have access to proper broadband in the rural areas or wherever else, everyone has a smartphone.

So that's a tangible example of a disruptor that falls into these different buckets that is currently an issue in terms of how do we get paid for that, whether or not we're going to continue to

get paid for it.

But the bottom line is how you incentivize behavior change in that setting has to do with the financial incentives. If we're moving towards a value-based system, which in theory should be helping get away from the volume-based type kind of work that's not really caring about the individual, but making the systems think about the person holistically in order to define how that care should be delivered and also recognizing that one size doesn't fit all. That's what value-based care involves if you're going to be a successful organization,.

PCORI is well-positioned to inform that. I think also building that relationship with AHRQ, as well as CMS or CMMI, whichever branch of it -- is incredibly important because quite frankly, CMS drives everybody else's behavior. So why not partner with them to discover these innovations and to help them understand, you know, what they're trying to achieve in their realm. But if they are the ones that everyone's responding to. So I don't

care how altruistic everyone wants to be, the bottom line is when the health plans tell you to report out information by race, you're going to report out the information by race. There's not going to be a question about it.

Move with the times, move at what's happening in the healthcare system, and the healthcare industry and get ahead of it to inform how that should look, I think is an incredibly important opportunity to consider.

MS. ARMBRUSTER: Thank you Eboni. And thinking about the role of convener. I've heard CMS, CMMI, AHRQ. I'm interested in other groups that maybe require new partnerships to support this kind of disruption or suggestions for change that you all are thinking about.

I saw Barbara was ready to weigh-in.

You need to unmute. I'm sorry.

DR. McNEIL: So maybe the staff has already done this, but there's a health group called Iora health. Who is a familiar with that? Alicia, I might've known.

So that's a group that's headed by a fellow named Rushika Fernandopulle. And he has said that he does exactly what we're saying should be done. That he takes disadvantaged, poor, multicolored, multi-comorbidity patients who live in terrible situations and pools them into a healthcare system where payment is less of an issue than the mechanism by which he cares for them. So I know he was very successful in his first activity of that in Atlantic City and then he moved to Utah or someplace where he was less successful. And then I believe he moved to Seattle or Portland. I don't think Jen is on the phone. But it might be nice to at least talk to them to see what kinds of activity he has done, which actually merged this finance situation with the greater complex patient.

In some sense, what we're talking about, or at least I think that what Eboni was saying, was say we have a really horrendously, complex set of patients. They lack on health insurance; they lack of housing. They have diabetes. They have hypertension. They're just a total medical mess.

But no doctor can afford to spend more than seven or 15 minutes with them. What would the system be like if CMS gave some extra payment or some extra reward to the Alicias or the world or the Jens of the world who actually take care of those patients in a way that fulfilled one or all of our aims.

I don't think we've actually talked about that in enough detail to know whether it's something that we should pursue. Just the thought. I mean, I think, what I would like us to do at this point is get very, very concrete. I don't think we need more lists about whom we should make relationships with. Let's just pick one or two and just do it.

MS. ARMBRUSTER: I love the pivot to the concrete, which is really, I think, aligned with the second question, which was what are the opportunities for the draft national priorities to be translated into an operational research agenda? So the next phase of the work will include some work groups around this. And the idea here is that we can perhaps jumpstart that work through some conversation now.

So what are some of those concrete ideas that relate to these five priorities that are exciting to you? Similar to what we just heard from Barbara. Who's ready? Research you'd like to see happening. Maybe it's cross-cutting and specifically tied to some of these priorities.

DR. McNEIL: What's wrong with the example I just gave? Just being totally honest.

MS. ARMBRUSTER: There's nothing wrong --

DR. McNEIL: Why can't we figure out how to do that? Nakela gets together with the new head of CMS or with Liz Fowler or somebody and says, let's figure out a creative way to make it more feasible for the primary care doctors of the world to take a more comprehensive -- to take a more comprehensive view of their patients and care of their patients so that they don't have to be rushed in and out.

I don't know Alicia, is that a horrendous idea?.

DR. FERNANDEZ: It's a great idea. I think that what we would want to do is use the fact that we're a research organization with a focus on

comparative effectiveness that can do intervention studies and can do observational studies and can build on prior research. And what I think that you're suggesting that is new or is to maybe do something like put out a large pragmatic -- there have been landmark studies, right? The Rand, whatever they call it, pay for the ER study.

There have been some very large, the moving to opportunity study. There have been some very large, very landmark studies that have been done in the United States. And I think that behind your question is saying, you know what? How do we partner with the key stakeholder in this case, CMS, CMMI, to create a large landmark study looking at different modes of care delivery for chronic disease in one or the populations in a comparative -- using research in comparative effectiveness for which we will actually maybe even use in PCORnet for which we will then actually do something that is big enough and important enough for people to take notice day.

DR. McNEIL: That's what I'm saying.

DR. FERNANDEZ: We do research, right? At

the end of the day we do research. And the question that you're saying to a little bit, what you're saying, I think -- embedded in what you're saying is, you know, that there've been lots of nibbles around the edges of this for 20, 30 years. Right? Do we have registries? We have case management. Do we have open access? Do we have teams? Do we have this? Do we have that?

Well, let's get the best idea. Set up a really, really robust comparative effectiveness type study with stakeholder engagement from the get-go, like we've done for lots of other diseases, and then do that. I think that's a fantastic idea Barbara. It's a landmark idea for a landmark study or a landmark set of studies.

And I also think that this is what a partnership with AHRQ and with other parts of the government might come into play just as in the same way that we've partnered with NIH to study falls or study other things.

MS. ARMBRUSTER: Thank you so much.

DR. McNEIL: This would cover several of

our goals. And it's very pragmatic. They're a zillion researchers around the country who could take the lead. Alicia, being one of them. We can just get together with a clinic partner.

DR. FERNANDEZ: It’s a conflict of interest.

DR. McNEIL: And just do it. I just don't understand why we think more about doing it. Why don't we just figure out whether it can be done and then just do it.

MS. ARMBRUSTER: Barbara, thank you. Jen does want to weigh in on your suggestion. Go ahead, Jen.

DR. DeVOE: Yeah, I agree with Barbara and Alicia. I think this is a perfect time given that PCORI joined AHRC and HRSA and a number of other sponsors of the Implementing High Quality Primary Care report that the National Academy has just released this month.

I think one next step could be to have members of that committee do a briefing with us as members of the committee, me being one, are going

around a number of the other sponsors. I believe we're talking to AHRQ and I just heard that there's going to be over a hundred people at that talk. We talked to CMMI; we've been to HRSA. There's several public webinars.

AHRQ has also been asked by Congress to produce a report of evidence showing what state actions have been effective at improving primary care. So that report, I believe comes out in the next couple of months. So there's going to be a huge bank of evidence showing what has been effective at the state level. And so, can we compare some of those evidence-based interventions in a comparative effectiveness research study?

So there's a lot happening in this space and a lot of evidence being produced. So perfect timing to begin to compare some different evidence-based interventions in large populations.

MS. ARMBRUSTER: Thank you Jen for that specificity and suggestions about specific action we can take to build on the ideas that Barbara and Alicia have put forward.

I would like to call on Ellen and then Connie. Ellen, go ahead.

DR. SIGAL: A few months ago, I was asked to present to the National Academy on Minorities in Clinical Trials. And I spoke about PCORI, but specifically talked about how trials, particularly for minority and underserved, who never really participated -- the level is very low, can change and PCORI can do it. There was an investigator actually out in New Mexico, who is actually doing an amazing job of genetic testing and has infrastructure in place with really populations that never get into clinical trials.

I can get the information, but she presented with me at the National Academy. But that would be tangible. That would be a benefit to patients and it would really start the work about getting minorities and, you know, real world evidence or people that real world people into these trials. So there -- that's almost shovel ready with a very minor investment could make a huge difference as a pilot.

MS. ARMBRUSTER: Thank you Ellen for a specific pilot -- like looking back and continuing to find the data and the opportunities that we can build from. Connie, you wanted to weigh-in.

DR. HWANG: Sure, thanks Sonja. And fantastic discussions yesterday and so many ideas swirling around. But I'm very appreciative about how ambitious I think our Board is being and PCORI overall in terms of laying out these strategic priorities. I'm all in on that. I know there's challenges of trying to stay focused and put putting right guard rails on, but directionally it feels right. So I just wanted to make a mention of that.

So a few themes that I think, you know, struck me and I certainly perk up anytime it's about distinctions about PCORI as being a really unique type of entity in terms of funding and engaging or convening on research. And I've been thinking a lot about that last mile, right? Where PCORI can be really helpful in bringing again, as noted yesterday, new entities and individuals. And so when I think about that, there's three priorities

that really jumped out at me. That health equity, the science of dissemination, implementation, and communication science, as well as bolstering up that health research infrastructure through, you know partnerships in communities.

So getting to a concept of like a concrete next step, I think some things we can consider and that becomes one of those goals about really extending our reach and engaging new groups that have valuable voices and perspectives. I do think PCORI would benefit by doing a real assessment of a lot of those targeted groups. You know, these community-based organizations or public health entities. I think we all have a lot of anecdotal experiences about that, but to put towards some real questions about it. Are you aware of what how one could partner with PCORI? Are you aware of where, you know, things may have actually really good alignment currently? And what is it that you need, you know, from an infrastructure perspective to more actively engaged?

I think that could be particularly

insightful. And then help to target some of that additional outreach.

One other step in that because PCORI already has a very significant network and organizations and entities that are very experienced in working with PCORI, we should leverage that and push one network out. Great, you can see you are very active in PCORI engagement awards and research awards, et cetera. Of course, some of those fantastic community partners that you've leveraged and could we create relationships even further to say, did you know that PCORI has all this work in the dissemination/implementation opportunities for et cetera?

But I think that could be a way to if we're trying to reach again, the last mile, get more local, get to those groups. I think leveraging those relationships would be helpful.

Two other quick thoughts. Throughout this and looking at the wording and the priorities, I do think that there is strong opportunity in weaving in more of the flexibilities PCORI has related to cost

analysis, cost assessment. I think it would be -- hearing through the conversations, you know, payment reform. Different ways of really trying to be disruptive.

I think that's going to be a focus. And I think in each one of the priorities, we could find a way to say, where is the role of that new flexibility and how do we push that forward? So food for thought there.

And the last thing, I know a lot of good conversation on that learning health system and everybody is loving the conceptual model. I am, too, that idea. I did want to tie it back to a suggestion I think Danny had made yesterday at the end was, "Hey, how about do that conceptual model on one of the congressionally mandated focused areas like maternal health." Build out that model, use that example, and create some momentum on that. So it sort of -- in some ways, ties sort of two priorities or -- two goals in one activity.

So I just wanted to share those ideas.

MS. ARMBRUSTER: Thank you, Connie. This is a great time in our discussion with the approximately 20 minutes that we have remaining for this to hear more of that, to hear more of your individual key takeaways that you have from this full breadth of conversation.

If it's helpful, one question that might guide your key takeaways is what's the next level thinking needed to ensure PCORI makes progress on these draft national priorities. And they had three specific suggestions from Connie there. And we've got a very specific suggestion from Barbara, Alicia, and you know, further development from Jen. And these are all building on conversations we've heard from each other.

So really we're at that point where we have final opportunities to shape and get your key takeaways from these ideas as we prepare to send them out for public comment.

James, please go ahead. And then Barbara.

DR. SCHUSTER: So just one comment is I know PCORI has done significant work in terms of

trying to engage a variety of stakeholders. You know, from my experience I've been especially engaged in the payer engagement group. But these other -- I wonder if something similar might be helpful for some of these other community-based type organizations that we're talking about, and if something like that already exists, that's great. But I didn't know if there was something similar or things like United Way or National Food Banks, I know that there there's a lot of outreach and engagement with kind of patient advocacy groups.

But I was wondering if you know, some groups focused on themes other than traditional medical care might be an opportunity.

MS. ARMBRUSTER: Thank you, James. And Barbara, I saw your hand.

DR. McNEIL: Maybe this has already been done, but before we send out these goals for public discussion. I'm wondering if under each one of them, we should ask "we," that's us to give some very specific examples that we think are feasible and that might generate more ideas from the people

whose opinions we're asking.

I really don't think we want people to be wordsmithing our general goals because that doesn't help us at all. And I don't think it is helps us for them to nitpick around this versus that. I think at this point, we need some very clear marching directions and that will happen via specific examples. We can start the ball rolling and that will help others do it as well.

MS. ARMBRUSTER: Thank you. And also now is a great time to continue some of these feasible, specific examples that you'd like to see included that align with those specific research priorities.

Are there others who would like to weigh-in on specific examples that you'd like to see included in those topic briefs or other ideas that you have about next level thinking for PCORI to make progress? Kathleen?

MS. TROEGER: Thank you. I would specifically like to see examples from PCORnet and the way that some of the research accelerator projects that have happened over the last year, pull

into the future so that we can consider those not just as pilot projects, but as true demonstration work as to how that network is, or is not, really capable of meeting the research questions and the needs, but understanding the new applications in the way that we've seen that network exercised over the last year and how to potentially extend it and extend its reach into centers that may not be, as we discussed yesterday, part of participative medical centers currently, but could expand to safety net hospitals or other with additional support from PCORI is just something I'd like us to think about.

MS. ARMBRUSTER: Thank you for that specificity. Thank you, Christine.

CHAIRPERSON GOERTZ: You know, obviously this is a question that we need to bring back to our stakeholder groups, you know, as we begin to get more and more concrete. But also I think this is an opportunity, you know, each of us represents a specific community on the Board. And I think that this is an opportunity for us to go back to our communities and to ask them, you know, these same

questions and to be able to bring that advice forward. And I think we've done a better job with engaging some communities then than others. And I think that this is an opportunity to really be thoughtful about how to make sure that we're getting that broad input that that we need.

We're talking about systems and, you know, clinicians like primary care, maybe, you know, thinking about how to do different things, but we're also talking about getting other public health and other, you know, other systems and other types of providers involved. And I think that, you know, if we're going to drive innovation, it's not only asking the normal suspects to do things differently, but also to think about how do we, you know, how can we cause disruption and, you know, positive disruption by including other players who have often been marginalized to including public health workers.

MS. ARMBRUSTER: Alicia. Thank you.

DR. FERNANDEZ: I think I'm building on what Christine is saying and I think we're thinking

around the same thing.

I still have a lot of questions about what should be in and what should be out. And I have a lot of questions about mechanisms. Okay.

So let's suppose we want to study how to take care, how to provide better care to homeless alcoholics with hypertension and cardiomyopathy, extremely common group, extraordinarily expensive to take care of. A comparative effectiveness on a drug, naltrexone versus the other drug is in. Clear cut. That's in a study on whether or not it's more effective to meet those folks to set up regular appointments every three months or to manage them via case management and tele-visits every, whatever. Is in. I think should be in classic comparative effectiveness, health services research. Right?

A study on whether or not it makes sense to give people housing and then try to manage them medically versus trying to manage them medically to the best of our abilities.

I don't think, I don't know that that study is feasible for PCORI. I would, I think that's a sort

of study that should be in. And when I think about that, I think, and let me give you an example. A study about does housing policies enacted on private/public partnerships in California versus Oklahoma, how does that rebound all the way down to alcoholics with hypertension and alcoholism is out, too distal.

So for that middle group that study, can PCORI play a role? And for this, I really have been challenged in my thinking -- you know, I've grown up on the NIH/AHRQ model. It's an RO1. You think about it. You right size it.

Recently with the pandemic, we've gotten things from the CDC, from HRSA, from Office of Minority Health, from a lot of people where they say the city is the applicant, but it has an evaluation group and it has this and it has the other, and we give you $4 million or we give you $15 million. And I've been involved in some of those.

And all of a sudden I can see us setting out a T-PFA that says the city provides a housing or not comes up with -- provides a housing. There is a

waiting list control, whatever, but PCORI, maybe alone or maybe with someone else partners to figure out the answer to this question. Do we give them housing first or do we try to stabilize them medically first.

And in fact, the answer I think is in, but the point is current according mechanisms, the types of studies that we typically do, don't do that, right? It could fit in under $15 million pragmatic study, but it's not the RO1 model. It's not -- it's what we're saying is that in order to do that, the city or someone else would have to come up with the housing.

So my point is, are we ready to do that? Are we ready to take those sorts of steps to create funding initiatives that require a level of partnerships specified or not? That would actually change our ability to create large scale experiments. And maybe there would be 10 municipalities throughout the city that want to investigate different models of housing for their alcoholics, and we would fund three of them and see

what model works best.

Do we want to be in that business? I think I would argue, yes. I'd be very curious to hear what Barbara and everyone else would argue. But I think right now and Nakela may say, it's obvious, of course, we want to do that, but I don't know that that's the case because it hasn't been the traditional way for PCORI to do things. And AHRQ, forgive me, hasn't had the money to do it on the scale that we're talking about in the way CDC or HRSA is now doing.

Is this helpful in terms of what's in and what's out?

MS. ARMBRUSTER: I think it's helpful. And it's interesting as it pushes disruption within the process for funding. So walking the walk as Danny was talking about, thinking about that. You called out Barbara, did you want to --

DR. FERNANDEZ: If she wants to.

MS. ARMBRUSTER: Barbara, this is an invitation.

DR. McNEIL: No, not yet. I have to think

about that.

MS. ARMBRUSTER: All right. Thank you. Karin, go ahead please.

DR. RHODES: I resonate with what Alicia's saying. I would really like PCORI to take some risks that I think governmental entities just can't do, things like studying safe consumption sites or housing first options. And I think it is really important to partner with states, which are each unique laboratories or cities that are willing to commit resources to study it because they're also the group that could go to sustainably.

So, great idea.

MS. ARMBRUSTER: Thank you. Okay, friends, we have eight minutes, or less, to weigh-in with your final comments, I feel like it's the end of the pledge drive and who wants to put us over the threshold.

So I appreciate your diligence and your challenging ideas so far and I look forward to hearing your final comments. So this may be a lightning round -- Danny, you were first to weigh-

in. Go ahead.

MR. VAN LEEUWEN: I'm worried, the more we talk about really large research projects. I worry about the only people that are going to be capable of doing that are the traditional entities of large academic medical centers that know how to do this big stuff. And that if we're going to push things down locally, the money needs to follow locally. And so, that we make sure that we balance, size and money and the who gets it. And so, I feel cautious.

MS. ARMBRUSTER: Barbara, and then Robert.

DR. McNEIL: So I take a different position Danny. I'm more, more interested in getting results that are good and that are exchangeable and transferable and whatever. And I actually don't care who does the study? I really do not care. I just want to have a well-done study, whether it's the President of the United States or some kid on the block, I just want a well-done study.

So I don't want us to just say, let's have the money fall down to where it's going to be implemented. Our goal is to get good results that

can be implemented successfully. Whoever does them.

DR. FERNANDEZ: [Inaudible] agrees with Harvard.

DR. McNEIL: Yeah, we'll go in together. Yeah, we just have to do it.

MS. ARMBRUSTER: Okay. We have folks in the queue, Robert and then Christopher.

DR. ZWOLAK: And I reiterate what Barbara said, we are a research Institute. We need to be doing research. We can't boil the ocean. We can't fix all of healthcare. I think our role is to investigate alternatives. And I don't think we should be disrupting the healthcare reimbursement system.

I think we can be testing various options in the healthcare reimbursement system, but that's an enormous, enormous task. And if we're going to do that, we need to find a discreet testable, studiable circumstance where we may be able to have a real positive result.

And when I look at PCORI, as much as I'm proud of PCORI, PCORI has turned into a very

traditional, relatively slow, research funder. And so we're going to have to go from zero to a hundred miles an hour if we're going to do something like this.

MS. ARMBRUSTER: Thank you. Christopher, and then Ellen and then Barbara.

DR. FRIESE: I appreciated everyone's comments and really resonate with where the discussion is landing at the moment. And I particularly want to thank Alicia for kind of walking us through the hypothetical, because it stimulated some thinking.

I think you've all heard me say this, we have such tremendous nimbleness in our legislation and in our authorization and we're not taking full advantage of it. And if we take full advantage of it, we can actually achieve what we're talking about. We can broker novel partnerships with government agencies, with health systems, with public health institutes, with patients directly, we have that authority. We have it, we have to take advantage of it.

So all I'll say at this point is what might help me, and because Alicia's discussion was so helpful to me, I wonder if we match our -- I think our five pillars our big, broad pillars. Can the strategic planning group help us with what would be a very high-risk, potentially high-reward question on each or issue we want to address in each of those to get our thinking moving forward? So we're doing a little bit of both. We're thinking, you know, what does the organization want to do for the next five years?

But to Ellen's point and to Barbara's point. Let's implement. Let's go.

So that might help accelerate the thinking a little bit. I know that's tricky. We've dealt with it SOC. It's a little bit difficult to get that specificity, but I think we want to get some big, bold questions out on the table that then we can work toward. And that might help us a little move this along a little bit. Thank you.

MS. ARMBRUSTER: Thank you Christopher, and I think it opens up the idea of both and not

either/or in terms of the high-risk, high-reward possibilities.

All right. And just a couple of minutes left. Ellen and then Barbara.

DR. SIGAL: So I resonate with what Chris and Bob said, we are not nimble and we have become very slow and bureaucratic. That was not the intent of PCORI in the legislation. But if we are going to do something or make changes we should execute, we should take risks and we should be focused, because otherwise we're going to be talking about this two years from now.

But I think the trend of what we want to do is there, how the execution works is beyond me, because I think this is a lot of -- we should take a few risks, take a few projects that we think are really important that are well thought about and go with them. Otherwise it's just a conversation. What is it? Innovation without execution is hallucination.

MS. ARMBRUSTER: Thank you. Ellen, Barbara.

DR. McNEIL: Well, I think Ellen said it

extremely well and I agree with that. And I think we haven't been nimble. I think we come up with an idea and then it just takes us a long, long time to get the RFA out. It takes us forever to get the grants reviewed. We ask the investigators to send back a second version. It just takes forever and somehow or other we have to be a learning healthcare system, as Danny said earlier, and just figure out how we do that. It may change how we do things, significantly. And I think we need to start that right away. And that would be up to the staff to look at how things have dragged on in the past and where we can make significant changes.

Nakela is the new executive director, so she can take that on as a charge. It would have been harder for the previous administration to do that.

MS. ARMBRUSTER: Thank you, you for that comment, and I don't see any additional comments in the queue.

So it's interesting, this conversation began with a charge to PCORI, ourselves as an

organization, to be a learning health system. And it closed with that as well. And I think there was a lot of rich challenge and discussion in the middle. Thank you for your careful thought and examination about these national priorities and what you think is the next level opportunities for PCORI to be a nimble and bold force in the innovation of the system.

So thank you for your thoughtful discussion. It's been an honor to be with you for that time I'm going to pass the baton back to the Nakela to talk about what the next steps are in the strategic planning process.

DR. COOK: Thanks so much Sonja, and I really do appreciate your excellent facilitation skills and working to bring forward all these great comments. And I really did appreciate what we've heard today in terms of thinking about the learning health system and the opportunities to focus and refine that concept. And I heard some important points around definitions, conceptual models and kind of imagery that can be helpful in grounding

that for all of us. So I think there are opportunities for us to continue to work on that.

I've also heard in some of the greater reflections some comments of things that I, as I mentioned yesterday, are very validating in terms of thinking about the relationships and partnerships with others that can be innovative in our collaborative efforts, particularly with CMMI and. I'm pleased that we started some of those conversations with the new director there and have heard about the Primary Care Report and glad that we've been a part of that and able to take some of those observations forward.

And I also heard the importance of thinking about PCORnet and how it's positioned and these priorities, as well as how we think about our full range of outcome that we can collect, including costs and really refining that in some of the cross-cutting areas in the priorities. And I guess I just wanted to end with a couple of reflections before we go to the Next Steps slide, which is that I think in the strategic planning opportunities here, we're not

confined by mechanisms in terms of thinking about what we're trying to do at PCORI and mechanisms are really the next step to get down to some of the operational planning that come from the strategic plan.

So I think it's good to hear the thoughts that put out there, some of the bold ideas, that's what we've been talking about. And as we start to think about those kind of examples that may fall in these national priorities and the high-risk high-reward opportunities. You know, we are going to continue some more engagement with key stakeholders around some of those opportunities as well. So we'll have opportunities to hear that, reflect some of what we were hearing from the Board, what we're hearing from stakeholders. And I think it's going to come together quite nicely.

So I just wanted to thank you for the comments today. I think they were quite insightful and will help us as we move to our next steps.

So let's go ahead and pull up the Next Steps slide. And what I wanted to mention in terms

of next step steps has that this slide just shows you in general anticipated guideline for the strategic planning efforts, and it's not comprehensive in the timeline, but it gives you a sense of the key overview of some of the activities and we recognize that it's not a precise schedule and we've had some shifts in the schedule already. But we do expect that as we've been talking about incorporating what we can hear, from what we've heard today, and the Strategic Planning Committee's comments into what we bring back for our June 15th meeting. And some refinements may still continue even during the public comment period, as we get comments in and you'll have opportunities, as we mentioned, to engage before the priorities are finalized.

The hope is, is that in September, the Board would consider the revised national priorities for adoption. So you can see it gives us that frame to be able to continue to work from the public comment input, the input that we'll have further from the Board in order to make sure that we've

reflected all of that before they are adopted.

You'll also note that on this slide, and parallel with the comment for the national priorities, we're continuing the process to gather input on the research agenda. And that, I think, also relates to some of the comments I heard earlier around trying to get down to what we can really do operationally within these priorities. And so, we'll have an opportunity to really delve into that further. Today's discussion started to kickstart some of that and we'll continue to do gather input on the research agenda.

And you'll also notice that the overall timeline is lengthened a bit from into 2022 for final drafting of all the elements of the strategic plan and that's due to some of the adjustments that we've had to garner some additional input, including our landscape review with the national academies that you've all heard about, but we anticipate this process is structured to allow us to adopt the key elements that will eventually flow into the strategic plan. And that allows us to continue

momentum and progress, as well as to operationalize what's been adopted, even while we're drafting some of the final elements of the plan.

So adopting the national priorities and research agenda as they're ready to move forward would allow for PCORI's work to really align with those elements of the strategic plan while the rest of that drafting is coming along so our momentum can continue while we're pulling together final products.

And that I think is where I'll turn it back to Christine. And again, thank you all. And thank Sonja for really robust discussions and excellent facilitation over yesterday and today around our strategic planning activities and the focus on national priorities.

CHAIRPERSON GOERTZ: So thank you, Nakela. And I also want to thank Sonja for just doing an excellent job over the last couple of days. We, you know, I feel like we have really advanced our thinking on our national priorities and you played a key role in that. So, thank you so much. And

thanks also to staff in preparing all of the background documents and to the Board for such a rich discussion, we really look forward to see the national priorities come back for a vote during our next meeting prior to posting for public comment.

So we have we are going to take a brief break now, about 13 minutes, we're going to reconvene at 2:30 Eastern time. So look forward to getting back to Nakela's executive report in just a few minutes.

[Recess.]

CHAIRPERSON GOERTZ: Nakela, are you back with us?

DR. COOK: I'm back Christine. ready when you are.

CHAIRPERSON GOERTZ: All right. Why don't we go ahead and get started. I'll turn it over to you then for your Executive Director's Report.

DR. COOK: Excellent. Thank you so much. So I look forward to updating the Board on our fiscal year '21 mid-year dashboard, as well as our opportunity to talk about a year in review. I've

now been at PCORI a year and marked that in April and wanted to talk a bit about what's happened in that year and what we've accomplished to-date. And then, I'll also give you a report on our diversity equity and inclusion initiative and follow up to some of our conversations from last year. Let's go ahead to our next slide.

So I wanted to begin with our FY '21 mid-year dashboard for review, and we can go to the next slide. This slide should look familiar to many of you it's represent several of the quantitative measures that lend themselves well to be encapsulated for reporting. And there are increased measures of impact on this slide, as you can see on the left from inputs to use, as you progress down the slide and inputting process metrics, which are at the top of the slide include things such as funds committed, our research project performance by quarter against our target. And these are represented as either coded green, yellow, or red to indicate if they're on track.

The second row has process and output

metrics, including our final research reports and posting of our results to PCORI's website as well as research results published in the literature.

And then finally, in terms of uptake and use metrics on the last row, you'll see uptake in the patient and public resources, uptake of results into a clinical decision support tool up to date, as well as other examples of uptake.

So at a glance, you can just see that we're meeting the targets in several areas as they're all green and I'll talk about why ones in gray in a moment. But we are on track as it relates to our funds committed, we're on track to meet the commitment plan for fiscal year 2021, and we'll be reviewing our next slate of awards in July as it relates to this plan. And if you look at our research project performance as measured by the percentage of projects that are on track, we're going to take a look at this in more detail in just a little bit in terms of what we're learning related to COVID-19 study delays as well. But our target is to have no less than 90 percent of our research

projects on track. And you can see that's the case here.

We also have a new metric that we've created in response to the Board's feedback during our end of year dashboard review last year and that's the final research reports posted to our website. And these reports are usually equivalent to the length and content of like three-to-five journal articles. And based on this data that target for our mid-year is to have about 49 final research reports posted. And by mid-year, we are within 10 percent of that target. And if you look at our cumulative final research reports that have been posted to PCORI.org, we have a total of 291 that have been posted thus far.

We're also on track with the posting of results to our website. And you may recall PCORI's authorizing law requires that we make research findings available no longer than 90 days after the conduct or receipt of the research findings. And this includes the time it takes to translate those findings into lay and scientific texts, and all

abstracts to-date have been posted within 90 days of completion of PCORI peer-reviewed. We also provide these abstracts and audio files as well as in Spanish language. And the average time to post our research results abstracts after acceptance of that final research report is about 85 days.

And if you also look on the right there, we have uptake into patient facing resources which we also have this as a new metric, a new target for the Board. We've developed this way to track citations and mentions of results from PCORI-funded studies and some of our public and patient facing resources, such as Wikipedia or health blogs, or WebMD, the things of that nature. And this is something that we've heard feedback from you about in our end-of-year report last year, that it would be of interest to the Board. And so, we'll be anticipating to expand this metric over time and I'll come back to this one, too, to ask your input about what may be valuable to track.

And on the last row as well, you see uptake into up-to-date and our provisional target based on

some historical data is to have about 14 results taken up in up-to-date by mid-year.
And then by mid-year, we had about 22 citations of CER results in up-to-date.

And there were some other examples of uptake, including uptake into other than uptake into up-to-date. So we're tracking things like uptake in the systematic reviews and guidelines, policy documents and other types of notable examples. And we'd like to see at least 90 examples of other uptake by mid-year, and we've identified a hundred different examples thus far related to these key documents.

So there's one metric that I mentioned that's in gray. And the reason it's in gray is because it's just not really applicable for our target. And this is results published in literature. And our target really is just to see positive trends in the uptake of our comparative clinical effectiveness research results and the provisional target that was based on historical data that was to have over 600 results cited by mid-year

and thus far, we have about 7,780 citations in the literature, which surpasses the provisional targets.

Let's go to our next slide.

So the dashboard report also includes examples of how we're meeting results on our goals and our strategic framework. And this first one relates to goal one increasing information and speeding implementation. And what we highlight here is the recent publication of the ADAPTABLR trial in the New England Journal of Medicine. This was the first randomized control trial conducted by using PCORnet.

And the study enrolled there 15,000 participants in a pragmatic protocol that found that for individuals with heart disease, there was no difference in efficacy or safety between aspirin at 81 milligrams or 325 milligrams. And there's still some ongoing analysis to understand some nuances related to dose switching and things of that nature in the trial.

But in addition to the interesting results, the study actually demonstrated that randomized

trials can leverage electronic health record data, direct participant methods, and participant reported outcomes to support greater efficiency in the trial.

So we thought this was a good example to bring your way. And we're noticing the climbing Altmetric score, which we'll talk about Altmetric scores in just a moment, but related to this very recent publication. Let's go to the next slide.

So this is another example related to Goal 1, and it highlights the systematic evidence review that was conducted via a memorandum of understanding with AHRQ and is the demonstration of that partnership and relationship with AHRQ in order to conduct these types of reviews. This review was evaluating the evidence of benefits and harms for pharmacologic and non-pharmacologic interventions for breathlessness in cancer and concluded that non-pharmacologic intervention safely improve breathlessness for adults with advanced cancer.

So let's go to the next slide, because we'll continue to talk about this evidence review as an example for Goal 2 speeding uptake and use of

information, because it's a really great example of the rapid and robust uptake in the guidelines.

The results from that systematic review were incorporated into the American Society of Clinical Oncology Practice guideline for the management of dyspnea in advanced practice within three months of the results publication. And the uptake into the guidelines occurred quickly because ASCO was continually involved in the planning as well as the identification of the topic for the systematic review with joint monthly calls between PCORI and AHRQ and ASCO and participated in the advisory committee. And so, as part of this contract that AHRQ has to do these evidence-based practice reviews, they were required to share the findings with the ASCO Guideline Writing Committee. Thus allowing us to make those connections as we've talked about for, in terms of the output from our research results into the appropriate committees for uptake.

Let's go to the next slide.

In this, I wanted to show you a highlight

related to Goal 3, influencing the culture of research. And during our strategic planning discussions, we've talked about influencing the culture of research. And this comes from a center at the VA. Also in the strategic planning discussions, we talked about learning from our engagement portfolio and this is an example of a center that utilized PCORI's engagement resources to build and manage the National Veteran Engagement Board. And they found that our readily accessible resources in terms of our best practices and guidances and things of that nature that we published on our website, were really helpful in thinking about how they would train their board and develop a board that was really focused on engagement.

So our engagement tool and resource repository was really the resource they used to create this engagement board at this Veteran center. Let's go to the next slide.

I did mention earlier on the review of the dashboard that I wanted to come back to you to talk

about for PCORI's metric for a research project performance, and particularly what we're seeing related to COVID-19 delays.

And so while research, project performance overall, what seen to be on track. We recognize that during the challenges of the pandemic, that we had to work really closely with the authorities to ensure that projects received the necessary modifications that were necessary -- that were needed to meet study aims. And since we first collected this type of data in July of 2020, about half as many of PCORI's research studies are experiencing severe pauses in study activities or are amid adaptations to their interventions.

The table below shows that about a third of PCORI active contracts though, have experienced some sort of COVID-related delay. And here you see the distribution of the type of disruption or delay as a percentage of those, the third, that had such delays. And of note, here there are fewer with major disruption, such as completely pausing an award or not being able to recruit. But what we're

seeing more commonly aren't delays in recruitment or reduction in the pace of activities. And so we're continuing to monitor this very closely and we'll update this information with our next dashboard report to the Board, or sooner, as circumstances shift.

But, all in all, we're starting to see that projects are still on track. And that those that have had COVID delays are not as severe as they were when we first started working with awardees in the pandemic. Let's go to our next slide.

So this one, I'd highlight some Altmetric scores and it shows attention to six PCORI comparative effectiveness research results publications as measured by an Altmetric score greater than 80. And these are the high score comparative effectiveness research publications from the first half of the year. And the score here indicates attention, whether it be a news article or on social media or in blogs, and of notice the first study that compared antibiotics with appendectomy for appendicitis is one of the -- is of the 10 --

I'm sorry -- is of the top 10 percentile for Altmetric scores for articles published in the New England Journal of Medicine, which is a pretty remarkable achievement and we thought worth sharing with the Board.

The second one that you see listed here is a study, that's funded as a COVID-19 enhancement project. And we thought this one was also quite interesting. It examined Metformin and the risk of mortality in patients hospitalized with COVID-19 in a retrospective observational analysis. But it was also seen as the top five percent for the journal it's published in, and exemplifies that rapid approach of the enhancement process, where we had studies that built on the existing projects to focus on COVID-19 related outcomes and studies were to have at least preliminary results within 12 months. And this one's even ahead of that 12-month period of time.

Also you see here, the systematic review on breathlessness, as well as a few other studies of note on back pain, weight management, and multiple

sclerosis. Let's go to the next slide.

I also mentioned when we were reviewing the dashboard slide that I wanted to spend a little time on this metric that was inspired by suggestions of Board members around uptake of CER results into public and patient resources. And we're really interested in any ideas of the kinds of things that you might want to see us track. Even if it doesn't really pan out, we can look into what we can do. And we're developing some methods for tracking citations and mentions of results for PCORI-funded studies and in these patients and public facing resources and are anticipating expanding over time.

So as you can see here on the left there are cumulatively over the prior year, at least 197 citations or mentions have been detected in patient are public facing resources. And we do see quarter-to-quarter variations in this data. And some of this may be related to the timing of PCORI's scheduled push to update Wikipedia, which is capturing some of this information.

And on the right, you see the types of

resources that we examine, including the blogs and articles, as well as educational materials and Wikipedia pages amongst others.

So, as we pause after talking about the dashboard, I'm interested in whether you may have suggestions about additional places that you think are important for PCORI to look for sources. Let's go to our next slide.

So I'd like to pause here to invite discussion about the dashboard. And we're just interested in whether our fiscal year 2021 dashboard and the associated background materials cover the topics that are most important for you to review, and to hear whether you have questions or comments about the performance of any of our dashboard indicators.

And I just want it to note, that we do envision as part of the overhaul of the evaluation framework that will happen alongside our strategic planning process, that we may need to identify some new goals and targets that correspond to our developing national priorities, as well as the

ultimate research agenda. And this is something that even the comments about how we might measure progress in our discussions yesterday were critical to here.

So I'll turn it back to Christine for any discussion on this point before we continue on with the rest of the Executive Director Report.

CHAIRPERSON GOERTZ: Thank you. Thank you, Nakela. Danny, did you have a comment or question?

MR. VAN LEEUWEN: I'm really excited to see this measure of the patients facing. I really appreciate seeing that. And I think we have an opportunity to consult with our ambassadors, with our advisory panels, with patient family advisor committees, to better understand where do people go when they're seeking evidence informed guidance and whether citations, you know -- how to, you know, like citations is a scientific concept and [inaudible] citations that people -- I think it's going to be difficult.

So I just think we could use more consultation, how to flesh this out and do a better

job of it. But I really appreciate we've started down this road.

CHAIRPERSON GOERTZ: Great. Thank you, Danny. Chris and then Barbara.

DR. FRIESE: Okay, thanks. Nakela, thank you for the presentation. In our prior reports from the ED, we had received a data point on time to peer-review, and I saw in our background material that that's no longer part of the dashboard, but one of the things I continually hear from the research community, is disappointment with that process. It's not -- and there are issues from both the PI needs to, you know, respond to queries and all that issue, but then there's also stuff on the internal review side.

So I'm okay with it not being reported on a routine basis in this report, but I think it's a really important metric and I really don't think we've really solved that problem yet.

So can you comment on that?

DR. COOK: Maybe just a couple of things. We wanted to make sure that we did get the metrics

in related to being on track for the Congressional reporting, and in terms of the time that we're at the 90-day report and so we have that included in the dashboard. We continue to work on making sure that we have a streamlined as process as possible with peer-review. And I think the last time we spoke about that, which probably was in December we mentioned that, yes, we recognize some issues in the back and forth on both ends of the equation in terms of that timeline.

But overall we have seen that that process is getting smoother. It's just taken us some time to get there and we will have that come back at the end-of-year. So mid-year, wasn't always like the perfect snapshot. We thought it actually takes a longer window of time to actually see some movement there. So we will bring it back at the end-of-year and compare it to last year's and hopefully you can see some of those improvements that we're also seeing.

CHAIRPERSON GOERTZ: great. Thank you. Barbara?

DR. McNEIL: This may actually be the same question that Chris asked, but whether it's part of the dashboard or whether we just get it as offsite, it doesn't really matter to me, but it would be really useful -- to every cycle actually to have data on the time from submission of an application to time for its funding. How many days does that take?

I don't think that's exactly what Chris was asking, but I think that would be very useful.

And there's subsets of that. The number of times an application that has been submitted, there was a request for a resubmission. And within that category, the percent of the resubmissions that are funded.

So it's a three-part question.

DR. COOK: I think the first part that I heard, Barbara, was around the time from submission of an application to funding. And that certainly is something that we have been talking about and tracking a bit because as we moved through our COVID-19 funding we were looking for some innovative

ways to compress that timeline. So, we definitely could give you some way to resurface that. And we'd like to look at that as well, at the end-of-year timeframe where we have a kind of larger number of the sample size in order to be able to report on, but we certainly can do that and provide you that kind of update.

And then I also heard a question that was related to resubmissions. And resubmissions may be a little bit harder for us because we do there, there is a time -- not cycle-to-cycle, but they may skip cycles. So it does take a little longer stretch to be able to give you some of that information. But if you have some cumulative information that we could probably pull in, you may remember that in some of our discussions around our expedited approach to developing PFAs while our strategic planning is underway, that we're really focused on providing those opportunities for resubmission in terms of the numbers of cycles that we post certain announcements for. So that is going to actually evolve very quickly with the next few

cycles, too, and we'll want to capture some of that information.

I think those were different than what Chris was asking about, which is the peer-review period at the end after the final -- draft research results are posted.

DR. McNEIL: So maybe I could just amplify on your comment about the time for resubmissions. At one of our last meetings, I think we talked about not asking investigators to do a complete resubmission and therefore miss a cycle or two, but rather to respond to some very specific questions that if answered yes or no would be an up or down. And I wonder how often that is happening.

DR. COOK: Yes, I understand. That's a little bit different than what I --

DR. McNEIL: It's a different question, it's different question. No, I was asking both questions but I didn't ask them clearly enough.

DR. COOK: Great. So we do have a programmatic review process, and that may be what you're describing, which is where we'll go out with

certain questions and if we can review those responses and then bring that to the Selection Committee and the Board for ultimate funding. And we definitely do track that as well. So we could summarize that information.

These are great points and it's how we've been updating our dashboard and the report that we've been bringing is by hearing the feedback you give at these meetings.

So those are definitely things we can think about incorporating because we do that --

DR. McNEIL: I have one more comment here. I think the dashboard is just fabulous for some of our stakeholders, but a lot of our stakeholders are researchers and what is on the dashboard, it's less important to them, frankly, than what the Altmetric score is because they can get that themselves.

It's much more important to them than what the cycle of the peer-review process is and the speed with which applications go through the process. So I would view that as critical as almost anything we publish.

DR. COOK: There's another place that I just want to mention quickly, I know that it's because it's a good point is that we've also been trying to bring more contextual information around the slate that we're bringing to the Board. And so with those slate-by-slate discussions, we've started to bring in some information like our number of letters of intent and then what was invited for application. And we can talk about even that, as you called it, the resubmission process that's not the full application resubmission, but more of that programmatic review in that context, because that does happen in the cycles. So that could provide another place for us to be able to talk about that.

CHAIRPERSON GOERTZ: Nakela? One of the things that we had talked about when we looked at funding COVID research was the opportunity to use the sort of the rapid cycle review in some of our other accelerated processes to look at ways to shorten the timeline between -- you know, sort of every phase of our award process. And I'm just wondering, and maybe not right now, but when we do

have that end of the year dashboard, if it would be possible to get a summary of what are some of the lessons learned and how has that already been or how could it potentially be incorporated into our review process and award process?

DR. COOK: Thanks for that Christine. I will mention a couple of things in my next piece of the Executive Director's report in terms of how we piloted a couple of processes, and we are taking a very evaluatory approach to these types of expedited processes. And so, we could definitely incorporate some more lessons learned that we've been thinking through as well in terms of what's been working and doesn't work with some of the expedited approaches.

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

DR. ZWOLAK: I'd like to go back like to compliment you and the staff on this evolving dashboard. I really do think it is a substantially improved and it gives us just sort of a nice 360 of the enterprise. So good work both on development of the dashboard and the results. Thank you.

DR. COOK: Thanks, Bob. I'm sure that the staff listening are happy to hear that.

CHAIRPERSON GOERTZ: Yeah. I want to agree with Bob. Very, very impressive. It is exciting to see, you know, how you're presenting the metrics, but also to see some of that, you know, look under the hood a little bit and see the impact that -- or at least the dissemination of our research findings.

James is saying great work and results.

All right. Any other comments or questions before Nakela moves on with her report?

[No response.]

CHAIRPERSON GOERTZ: All right, Nakela.

DR. COOK: Okay. Thank you for all those comments. Let's go forward to the next slide.

So I wanted to spend a little time talking about the year in review. And as I mentioned in that April, I marked my first year here at PCORI, and it's truly exceeded my expectations to be part of such a wonderful organization and work with all of you. And so I thought I'd spend a few minutes reviewing some of the memorable moments and

highlights and accomplishments of the organization over that year. Let's go to our next site.

So one of our more memorable moments was saying farewell to four of our Board members who had served since PCORI's establishment and we paid tribute to their remarkable tenures back in September. Let's go to our next slide.

We also welcomed seven new Board members who have already made noteworthy contributions, and we continue to look forward to our work together over the years to come. And next slide.

We also marked the year with PCORI's first virtual annual meeting and pivoted in record time to a virtual meeting, that more than doubled attendance in this type of setting.

And now we're turning to our ongoing work to plan for our next virtual meeting later this year. And next slide.

We were also pleased to have the GAO issue its third mandated review of PCORI in November of last year, with no criticisms and no recommendations for improvement. And really this is a testament to

the successes and achievement of the Board and the staff over PCORI's first decade. And I'm so pleased to be associated with this record of progress. Let's go to the next slide.

So over the past year, at PCORI we've been focusing our efforts on both what we do as well as how we work and what we do relates to fulfilling our mission and how we focus our attention on the activities of how we work, how it relates to collaboration, teamwork, diversity, equity, and inclusion as critical pillars and how we accelerate the fulfillment of that mission.

So let's go to the next slide.

With regard to fulfilling the mission, we've been engaged in organization-wide priority setting stemming from many of the discussions that have happened in the Board meetings, and we're working to nimbly and efficiently and effectively support our funding activities and alignment with the Board approved commitment plan. Let's go to our next slide.

So some of the details regarding fulfilling

the mission include two major areas of focus, one around strategic planning and one around funding approaches. And as it relates to strategic planning, we've been working with the Board and the Strategic Planning Committee on the development of the overarching plan, which has been the focus of many of our discussions earlier at the Board meeting.

And we've been trying to respond to the challenges and the external landscape. And we've had a lot of outreach and listening engagements and trying to enhance the reach of the stakeholders engaged. And we've also been really diligent in thinking about how we advanced trust for our patient and community engagement and research as part of this outreach and implementing and thinking about the implementation of the cost data provision in our legislation.

And with regard to funding approaches, we'll touch on a few things. We're building and implementing that COVID-19 response. And we were executing our PFA programming in alignment with the

commitment plan and implementing, as Christine alluded to some pilots for rapid funding approaches. And I'm also thinking about how that gets evaluated and is thought about in terms of the re-engineering of processes in the future. So let's go to our next slide.

As it relates to our strategic planning activities. You may recall this timeline. We began with engagement with PCORI advisory panels back in June of last year and today we're at the Board of Governors meeting considering draft national priorities. It's been a real milestone in this process.

And the Board has also worked with PCORI staff and identifying principals for the next phase for PCORnet, which have guided solicitations for the clinical research network and the coordinating center, which will returned to the Board for slate approvals in July and thereafter.

And we'll briefly discuss the commitment plan and the progress on the implementation of priorities from the reauthorizing legislation.

And next, as we think about strategic planning, we're also going to turn our attention to working with the Methodology Committee to consider the focus that the Methodology Committee has for PCORI's next phase, really bringing the wealth of their expertise from that committee to bear on for PCORI's future priorities. Let's go to the next slide.

Since we take a look at the priority research areas in our reauthorizing legislation, this is also an important part of our strategic activities and our strategic planning. And we began engaging stakeholders in 2019 on priorities for maternal morbidity and mortality and intellectual developmental disabilities. But with these long-term priorities, we anticipate that we can engage with existing stakeholders, new stakeholders, and diverse groups, as well as those with lived experience.

And this engagement is really driving the plans for a multi-year strategy, that has an approach that will entail a combination of short-

term and long-term efforts from funding opportunity announcements, to evidence, products, and plans for collecting data of importance that will be important to these analyses.

So our first efforts have been related to expediting a few funding announcements based on some of the early stakeholder input. And our first areas of focus were special areas of emphasis in the broad announcements for Cycle 3 2020. And we had set aside funding for those related to patient-centered maternal care, as well as improving care for individuals with intellectual and developmental disabilities, as they grow into adulthood. I'd really focused on that transition.

And earlier this year, the Board approved the development of two targeted PFAs, one focused on postpartum maternal outcomes, as well as mental health conditions in individuals with intellectual and developmental disabilities. Let's go to our next slide.

We've also made significant progress as it relates to our strategic planning efforts on the

provision in our reauthorizing legislation to consider the full range of outcomes data and PCORI-funded research. And this has been a very deliberate and stakeholder-engaged approach, and PCORI developed four key principles to guide the approach, responded to public comment, and then they were approved by the Board in March of this year.

And so we now move on to develop further guidance for applicants and work with the Methodology Committee on the development of the standards. Next slide.

As it relates to our funding approaches, a really key focus has been on our response to COVID-19. And at a prior Board meeting, the Board asked about PCORI's ongoing COVID-19 work and areas of focus. And our last update for the Board was the December Board meeting.

And it's a pleasure to show you a quick highlight and synopsis of some of the work to-date.

The COVID-19 response really has been a concerted focus during my first year at PCORI and this slide summarizes some of the efforts related to

research projects, including our enhancement program, which I've talked about briefly in the dashboard report. And I'll update you more on that momentarily. As well as target funding opportunities, both that included the fast-funding approaches that we'll talk about and one that's currently in review.

We also have had a continued focus on COVID-19 in special areas and our broad funding announcements, and a robust response in terms of letters of intent, including a focus on management and survivorship of post-acute COVID-19, as well as health system and healthcare delivery management of post-acute COVID-19. And strategies to improve COVID-19 for just disproportionately affected populations, as well as the impact of COVID-19 related social isolation and loneliness on health outcomes.

And while our first special areas of emphasis for in Cycle 1 2021, and we received almost 20 letters of intent out of the hundred that came in to that broad announcement. We're anticipating more

letters of intent for our second special area of emphasis announcement that was posted in Cycle 2 2021 in June. We also have experienced working with the investigator community and research community on adaptations to their awards.

And as I mentioned in our dashboard report while we've seen some COVID-19 related delays and have worked to make sure that we can conduct modifications to awards as needed, it's still early in the process of seeing some modifications and we still expect more. We have approved about 50 adaptation requests for research awards, and about less than half of those have required additional funding. And when funding was required, we are seeing approximately 300,000 in order to get them to be able to complete their study aims.

On the right side of the slide, you'll see some summaries related to some of the PCORnet activities as it relates to the COVID-19 response. I'll talk about the HERO program on the next slide. But many of you are familiar with the CDC partnership to fund surveillance work within the

PCORnet program and the queries of the COVID specific common data model that have been helpful for the surveillance activities. And there's been a recent focus on utilizing this information for Long COVID, including what you see in this common data model of over 8,000 adults and over 150,000 children.

The work with the FDA Accelerator has been a collaboration with the FDA, the Regan-Udall Foundation, the Friends of Cancer Research, and other partners to try to identify some core data elements and facilitate parallel analysis of real-world data to address COVID-19 evidence needs. And this work has helped to design and execute parallel analyses within the PCORnet data for use cases around Remdesivir in hospitalized COVID-19 patients, as well as understanding the natural history of coagulopathy in COVID-19 patients.

And then you'll see this act of six collaboration as part of the foundation for NIH active collaboration. And it's a randomized blinded and placebo-controlled Phase 3 platform trial that's

going to help test the efficacy of repurposed medications to treat COVID-19 in the outpatient setting. And PCORnet is leading ACTIV-6 serving as the clinical coordinating center, the data coordinating center and contributing about 40 Vanguard sites to this effort.

One of the interesting notes is that ACTIV-6 has a Stakeholder Engagement Committee which was really instigated by coordinates involvement in this protocol.

And then as we look at our vaccine work and the vaccine collaboration that's listed here, PCORI and leadership from several key NIH initiatives have been discussing a collaborative approach with the goal of leveraging their data infrastructures and assets to identify and investigate research topics that are related to individuals who become infected after full vaccination. What we can consider vaccine breakthrough.

And the natural starting point here has been the development of computable phenotypes, this kind of standardized algorithmic approach that can

be utilized in electronic health records to identify vaccine breakthroughs that would enable us to have a cohort for future research.

And our engagement program has been involved in several activities as well, including horizon scanning on a biweekly report basis in order to report on six different COVID-19 priority issues, including devices, prognostics, and risk factors, diagnostics, health systems, treatments, and vaccines. The engagement program has also had special cycle solicitations for engagement awards that focus on COVID-19 related issues and including one that's vaccine focused. And you are probably aware of the webinar series that we had early in the pandemic that's been archived on our website for future viewing.

And our dissemination and implementation program has also been very focused on COVID-19 enhancement work and you'll see a summary of that upcoming. Let's go to the next slide.

So back in March and July of last year, the PCORI Board of Governors approved this combined

total of about $160 million to focus on COVID-19 funding for projects and enhancements and these are those that have been awarded, but the others that are in progress, you've just heard some about, and we'll focus on some of the new ones in a moment.

So our targeted funding announcement that was focused in the three priority areas of adaptations to healthcare delivery, impact on vulnerable populations, and the healthcare workforce committed $30 million for nine awards in those three priority areas. And you may recall they focused on congregate and group homes, the impact of mitigation strategies on vulnerable populations, as well as mental health in underserved communities, nursing homes, tele-medicine and primary care remote monitoring, opioid use disorders ,and physical and mental health of frontline healthcare workers.

And our COVID-19 enhancement projects allowed for that adjustment in project aims to leverage existing research platforms to understand the implications in the pandemic. And these were the applications we reviewed on a rolling basis, and

we received about 250 proposals for this program and approved $34 million or 116 projects that were across the research dissemination and implementation and our engagement program.

And the enhancements really covered several different intervention strategies across a lot of different health conditions. And what we found is this program really allowed for that timely research focus in our broad array of conditions and emerging topics. And we'll be seeing the results of these research projects coming through in later summer and fall. As you may recall, I mentioned that we had anticipated some preliminary results within a 12-month period of time with these awards.

And the HERO program had both the registry and trial. And the registry, itself, has over 26,000 workers enrolled. And you may recall that HERO-Together is a Pfizer-funded study within that registry, as well, that is looking at long-term vaccine side effects.

And we've also had the trial that leveraged the registry, which was completed in February of 2021

and the publication should be coming. Let's go to right next slide.

So I did want to continue to focus on fast funding approaches. As we talked about our funding approaches and even building on the comment that Christine made earlier. And the COVID-19 imperative really allowed us to pilot some approaches that would advance our ability to nimbly and effectively respond to address priorities and provide us some lessons learned for perhaps even future opportunities to think about different ways of funding research at PCORI.

So in your second COVID-19 targeted PFA under that Board approved authority and funding commitments for new research leverages the learnings from the first expedited PFA. And I mentioned we had a real strengthening and evaluation protocol that helped inform some of the elements of that expedited approach that worked well and some elements that we'd want to change or think about differently.

This second PFA also was really issued at a

spirit of innovation. And we think this is something the Board has been looking for us to learn from these various pilots during the pandemic. And the goal was really to solicit and award COVID-19 research projects on a timeline consistent with the public health and research needs and we implement this within PCORI's existing mechanisms, but approached it in a fast-funding model that moved from planning to contract negotiation in about 12-weeks period of time, which is less than a third of our typical PFA implementation timeline.

And the process focuses on a narrow research question, has a very streamlined application submission, and utilizes a reverse site visit for application consultation and merit review, and the streamlined approach for selection committee review and executive director approval.

And so for this approach, we're focusing on increasing vaccine confidence amongst workers in long-term care facilities, as well as thinking about the booster shots that may be necessary and how we build confidence for that next phase. And we have,

in this case, are currently under review of these applications and anticipate that we would have outcomes to follow along this timeline and lessons learned that may be important, longer term. Let's go to our next slide.

A substantial component of fulfilling our mission and guiding our funding approaches has been our three-year commitment plan. And you may recall back in December, the Board approved a three-year commitment plan for PCORI after reviewing several models and scenarios for the future. And that plan is really driving our programmatic activities. And as you saw on the dashboard, we're on track for the fiscal year 2021 plan. This was a huge milestone for us to start to really guide our funding approaches for the future. Next slide.

Another major effort over the past year related to our funding approach has been the establishment of our expedited and enhanced process for developing targeted PFAs while our strategic planning is underway. And we began consideration of this approach back in January of this year in a

Board meeting. And the Board approved the first of three topics under this approach for development for targeted PFAs for Cycle 2 2021 in March. These were the ones that focused on postpartum maternal outcomes, as well as mental health conditions in individuals with intellectual and developmental disabilities.

And in April, the Board approved a set of potential topics for development for future cycles. And we're working through those tentative schedules in order to bring those specific PFAs back to the Board for approval ahead of release. And in June, the Board will consider for approval and development of targeted PFAs for Cycle 3 2021. Three of them that have been recommended by the other. Let’s go to the next slide.

So I'm going to pivot a little bit from what we do in terms of the fulfilling our mission in the strategic plan and funding approaches, to how we work and thinking about teamwork and collaboration and emphasizing that teamwork and collaboration with colleagues across PCORI that allow us to lend and

share our expertise to maximize our outcomes. And we're implementing support for this approach and working with the leadership learning labs across the organization that we'll be launching. Let's go to the next slide.

So teamwork and collaboration are manifested in our focus on culture, on our focus on workforce in our workplace, as well as our organization transformation activities to position PCORI for its next decade of service.

As it relates to culture, we're creating a unified cultural vision and optimizing our work in a virtual environment. We've also developed a cohesive and collaborative leadership team as well as many cross-functional and cross-departmental staff teams that are accelerating that work that you're seeing.

As it relates to workforce and workplace, we're building and implementing our staffing plan for what we're terming as PCORI Next, in terms of this next phase for PCORI. And aligned with that securing our sustainable space plan and implementing

our COVID-19 response in a way that keeps our staff's safety at the center. And as it relates to our organizational transformation, we've been working on an organizational assessment and future state model to help us think through the important implementation of recruiting and onboarding efforts for new staff at PCORI that need to help us in terms of optimizing our approaches to achieving our commitment plan and our fulfillment of our mission. Let's go to the next slide.

So we're really fortunate that we have a remarkable health emergency preparedness planning team that's been continuing to work with us to keep us operational, even in this remote environment. And our staff continues to function very well remotely with a remarkably accelerated workload in response to our COVID-19 efforts. And we've also laid out our COVID-19 reopening plan, and this plan keeps the safety and wellbeing of PCORI's workforce front and center. It's also a flexible approach that considers different needs and circumstances of the PCORI workforce and the COVID-19 environment in

the local area. And we've put forward a very deliberate and gradual and multi-phase approach to the return to PCORI's work site that considers multiple factors including access to the availability of vaccines, as well as public transportation, schools for children, and other types of scenarios that are specific to our workforce.

But we anticipate that we have this opportunity to think through this gradual phased approach that will bring us back into the offices and in a very safe way. Let's go to our next slide.

And I mentioned PCORI Next does one of our opportunities to really think about our organizational transformation in a way that invests in our operational cultural and professional excellence, and ultimately helps us to strengthen and optimize the delivery of our mission focused on patient-centered outcomes, research that enable better informed healthcare decisions. And this PCORI Next vision serves as a cultural vision, unified cultural vision for all of us at PCORI, but

also helps to emphasize the importance of how we work together toward the fulfillment of that mission, and sets up for us some of the high priority recruitments that were necessary for the organization. Let's go to the next slide.

So we have to ongoing high priority recruit. That's one is the Deputy Executive Director for Patient-Centered Research Programs. And this position is really serving to reflect internally that integration across our engagement, research, dissemination, and implementation activities that we expect external to the organization and we also think we can serve to integrate effectively internal to the organization.

We also anticipate that in recruiting for this position, this will be a strategic leader and will bring management oversight for our programmatic opportunities within PCORI. And we're excited that this person can help us in terms of building that vision for the next phase of PCORI.

We're also recruiting for a Chief Information Officer, another key position at PCORI,

to align with the future state model vision, where we have information and technology, including data governance activities and transformation technology processes, and information and technology systems management that integrates all of the information and technology efforts across PCORI and more broadly. And brings that strategic planning and oversight experience to the organization with existing and extensive knowledge and experience in managing this type of information that we deal with on a regular basis at PCORI. Next slide.

I also wanted to mention one last point that transitions into the next part of my Executive Director report, which is the importance of how we work related to diversity, equity, and inclusion. And when we talk about diversity, equity, and inclusion at PCORI, we want to work with each other in a manner that creates an inclusive workplace culture, and one that values and derives strengths from the diverse backgrounds, perspectives, talents, and experiences of PCORI employees, and really promotes all staff feeling included, connected, and

engaged in bringing all of their skill sets to fulfill the mission.

And we've developed and are working to execute our PCORI-wide DEI initiative with internal and external components, that I'll tell you about in a little bit more in our DE&I report. So let's go to our next slide.

Okay. I wanted to go ahead and transition to giving you a report on our Diversity, Equity, and Inclusion Initiative, and would love to hear thoughts and inputs and have opportunity for discussions. We'll pause thereafter.

I'm pleased to let you know about the update on these efforts. And the last time we discussed our ongoing efforts related to diversity, equity, and inclusion, it was in the September meeting of the Board last year, and we placeholdered some time for further discussions with the Board in spring of this year. And so, today I wanted to share a little bit of background with you, provide you an update on how we've been approaching our strategy, and the opportunities that we see for

PCORI on the horizon. Let's go to the next slide.

As we think about the motivation for focusing on diversity, equity, and inclusion. These two seminal reports came to mind for me. The first, from more than 30 years ago, which described the pervasiveness of health disparities in the United States and began to really identify some key drivers. The Heckler report was published in 1985 and detailed the wide range of health and healthcare areas where significant disparities existing for Blacks and other populations of color and their root causes.

And then 2003, the Institute of Medicine report entitled "Unequal Treatment," provided an authoritative definition for healthcare disparities, grounded really in differences in quality of care. And notably, actually, discredited justification's related to different clinical needs, preferences, and appropriateness of interventions as mediators and in some ways by doing so the report validated and raised the prominence of discrimination as well as system level factors that were at play in the

extensive racial and ethnic disparities it documented. Let's go to the next slide.

And I don't have to tell all of you over 30 years later, as the COVID-19 pandemic continues, we are grappling with the same issues. The pandemic has simply exacerbated some longstanding health disparities by race and ethnicity, and undeniably reveals the disproportionate burden of underlying conditions that affect health and their drivers. And these drivers include things such as socioeconomic status, access to care, racism, discrimination and bias, and occupation and housing related exposures. Next slide.

And today we mark a solemn year since the murder of George Floyd. And last year we released a statement entitled, "Together Toward Change," which highlighted PCORI's critical role to play in identifying solutions to a second crisis that this country faces related to the legacy and really ongoing racism and continuing inequality of access and opportunity. And in the statement, we reiterated our commitment to stand united with

others and efforts to implement such solutions. Let's go to the next slide.

This collective call to action is really underscored by a recognition of the increasing diversity in America, as we've seen over the last decade. Yet, really a disproportionate representation of diverse racial and ethnic groups in science medicine and the healthcare workforce. And as a research community attempts to heed the call to find actionable solutions to eliminate health disparities that continue to affect racial and ethnic populations, which represent more than a third of the nation's population.

It's really our imperative to improve health outcomes for all by reflecting and representing the diversity of the nation in everything we do, and certainly we recognize that research is no exception. Yet, the disproportionate representation is one of our more pressing challenges. And the graph on the right demonstrates three distinct categories rather than the change over time in the diversity of the nation that you

see on the left. And the reports on this right side of the slide, demonstrate low representation of diverse racial and ethnic groups in STEM faculty, in medical school faculty, and an academic leadership positions.

And for example, if you look at the last bar on the right Blacks comprise about five percent of President, Provost, Chancellor, Dean, Department Head, and Chair positions in academia yet are 12 percent of the nation's population. And you may note that these percentages don't add up to 100 percent, given not all categories are shown. Let's go to the next slide.

We also recognize that PCORI as an organization, a funder, and a partner is not immune to the challenges that faced the larger research ecosystem. And data there demonstrate, challenges for organizations related to disproportionate representation in STEM activities, proportionately, fewer Black, Indigenous, and people of color in higher ranks of academia, as well as gender and racial bias influences that are related to faculty

perceptions of post-doctoral candidates have been reported.

And concerns related to the cultural taxation of representing a community or group when representation is limited. Data also reveal challenges relevant to a funder with evidence of disparities in research funding, and data that is revealed less favorable scores for topics of relevance to communities and population health and reviews settings, as well as the potential for bias in research and funding processes. And the data also show that challenges are relevant to our partner role as well with disproportionate representation in clinical trials, as well as the lack of trust and trustworthiness in many communities we really aim to engage.

So let's go to the next slide.

This is really motivated PCORI's commitment to diversity, equity, and inclusion is critical to achievement of our mission. And internally we are committed to cultivating a diverse workplace and a culture that values equity and derives strength from

these diverse backgrounds, perspectives, talents, and experiences of our staff. And we want all of our staff to feel included, connected, and engaged.

And externally for our stakeholders in our community, we're committed to being equitable in engaging diverse stakeholders, promoting diverse and inclusive convenings, as well as promoting a diverse pool of applicants, awardees, and participation in our research.

So I want to talk further about diversity, equity and inclusion and take each of them in turn. Let's go to the next slide.

There's several relevant dimensions of diversity as we pursue this work and imperative to achieving our mission. As I mentioned before, is reflecting and representing the diversity of the nation in everything we do, but we face challenges with this imperative at every phase of our search from processes to participation. And those difficulties include reaching populations historically excluded in research, engaging diverse stakeholder groups and communities and expanding our

reach, building a diverse applicant reviewer and awardee pool, as well as successfully, including in recruiting diverse study participants, and bringing the focus to the research topics that are relevant to underserved communities and historically excluded communities, and building trust in those communities.

Let's go to the next slide.

Related to equity. We've talked a lot about equity and equality recently and the differences between them being so important as we try to drive toward equity. And equality ensures that every individual or group of people is given the same resources or opportunities. While when we think about equity, we're really talking about and acknowledging the different circumstances and needs, and providing the required resources and opportunities to promote equal outcomes.

Next slide.

And if we think further about what we mean by inclusion, the CDC defines inclusion as a set of behaviors that's going to encourage everyone to feel

valued for their unique qualities and to experience a sense of belonging. But traditionally funders and researchers have set targets for inclusion in studies, and we recognize that there are challenges that occur following theoretical targets to actual recruitment and enrollment rates, especially amongst historically excluded committee. Next slide.

We've been motivated to articulate three main goals of our DE&I strategy or our Diversity, Equity, and Inclusion strategy as learn, expand, and engage. And they correlate to PCORI as an organization, a funder, and a partner. So as we consider learning in this space, we're really referring to fostering a learning and action-oriented culture. That's focused on workforce-wide learning opportunities, assessing an action planning of all internal and external processes and knowledge acquisition and sharing, as well as enhancing workforce diversity.

We also want to expand our efforts to doing research differently, and we want to relate it to engage, to think about how we capacity build and

build the applicant and participant diversity and enhance and deepen our strategic partnerships.

Christine, I just want to check in.

CHAIRPERSON GOERTZ: I think we're getting near the end of our time here for the Executive Report.

DR. COOK: Okay. Thank you. I'll just maybe go through two other quick slides. I wanted to just show the next slide around three pillars of our strategy that are related to PCORI as an organization, PCORI as a funder, and PCORI as a partner. And we can go to our next slide.

As we think about PCORI as an organization, there are three domains, the strategy that focused on practices, culture, and workforce, and what you'll see here within our practices is that we're focused on building a data collection framework that will help us with our assessment and evaluation activities, as well as thinking about how we incorporate issues of DE&I principles into our procurement processes and the implementation of our strategic plan.

As it relates to culture. You've heard us talk about the importance of articulating our commitments, and we'd like to further that with our diversity, equity, and inclusion values statement. And you're seeing today the development of our strategic framework with some work streams that are accompanying that. And we also recognize related to work force the importance of the training and learning opportunities, as well as the resources and tools to bring best practices to our work. Let's go to the next slide.

As a funder, it certainly relates to our portfolio or practices and evaluation, and we've had a lot of discussion around the importance of a health equity research portfolio as we think about our national priorities and leveraging our engagement awards, which is something that we're thinking about in terms of how we can specifically reach certain populations as we work to eliminate health disparities. Let's go to the next slide.

And as a partner, we're certainly committed to collective action, relationship building, and

research participation, and recognize the opportunities to provide and collect relevant insights through a variety of thought leadership forums that we participate in, as well as expand our synergistic collaborations with other organizations, funders, and agencies, and expand our connections to populations through enhanced outreach strategies, including some of the historically minority serving institutions and organizations.

And you see, lastly here, the focus on our research participation. You go to the last slide. So I really just wanted to look forward to any comments you may have on our framework for diversity, equity, and inclusion, as essential to integrate and integral, really, to deliver on our mission. And with that, I'll go ahead and wrap up and turn it over to Christine for any questions.

We can go to the last line.

CHAIRPERSON GOERTZ: Thank you Nakela for that really in-depth presentation -- you know, just your entire Executive Director's report was really, it was really exciting to see, you know, this level

of detail about all the things that you and the staff have been working on over the last year. And I just want to congratulate you on an incredibly successful first year. In some ways I can't believe it's been a year already, and sometimes on the other hand, I can't really believe that you haven't been here for a lot longer given all that you've accomplished.

So I just want to thank you and staff for all the incredible work.

I know we're running a little bit behind time, but I did want to give the Board just a minute or two for any comments or questions before we move on to the Methodology report.

[No response.]

CHAIRPERSON GOERTZ: All right. Well, I think people will have an opportunity to, you know, ask questions as we continue to cover your work in these important areas, Nakela, so thank you.

DR. COOK: Thank you.

CHAIRPERSON GOERTZ: All right. I'm going to turn the agenda over to Steve then.

DR. GOODMAN: Okay, great. Thank you. So this should be very brief, although the appendix that was of the entire Methodology report, wasn't so brief. I hope for those of you, who've never seen the methodology report that that was interesting and illuminating if you had a chance to even scan it, because it involves a prodigious amount of work that's been put into the effort to promote the top-notch methodology of PCORI since its inception and much of that work was done shortly after PCORI was founded. So we can move on to the next slide.

So what we're asking for today is almost proforma. Let me just set the stage. In 2019, the Board actually already accepted the version of the Methodology report at that time.

And it also approved the standards that we had added since in the preceding year, one for qualitative methods, another for mixed methods research, and another for individual patient-level data meta-analysis, IPDMA. And so the Board approved the standards and it approved the report.

What it had not approved, which is in front

of the Board today, is the incorporation of those standards into the report, which involves not just the standards, which have not changed, but the standards, plus a lot of explanatory text to help both be a sort of text and elaborate on the meeting motivation and intent of these standards, which are pretty short. In addition, there were some public comments on the original standards, which we responded to and we responded to not by changing the standards, but by changing the explanatory text, which is part of the Methodology report.

The final thing that was added was a recommendation to use, and this is specifically for randomized clinical trials, we didn't want to reinvent the wheel and have a, yet different, template for protocol elements. So we suggested that applicants could use either the SPIRIT guidelines, which are the product of a large international group of researchers about common on common protocol elements, or the NIH template which actually overlaps about 90 percent with the SPIRIT guidelines. We thought it was actually quite

important to be using as many common standards as we could. And again, not invent something else that would probably overlap with these about 95 percent and not be materially different.

So we said people can use them. It's not a directive that they must use them. And that's added.

So that's basically what we've changed. The other updates are just the MC membership and a few minor changes stemming from the language in the reauthorization.

So we'll be asking for a formal vote on these. Again, I'm hopeful that all of you were able to at least scan things in the Methodology report. If you were able to spend any time on it, you will see the complete text of all those new standards and the ancillary elaborating language, as well as the details on how we responded to public comments in the explanatory text.

So we can either go straight to a vote or take any comments, questions, or suggestions for us going forward for a minute or two it's up to you.

CHAIRPERSON GOERTZ: Well, thank you, Steven. I just want to, on behalf of the Board, I want to thank the entire Methodology Committee for the tremendous amount of work that has, you know, over all of these years, but in providing these updates and with such thoughtful responses to public comments, et cetera. So thank you so much.

DR. GOODMAN: Thank you. And we have to share a lot of credit with PCORI staff over the years, who've been top notch and who have spearheaded a lot of the writing and certainly responses to public comments.

CHAIRPERSON GOERTZ: Great. Thank you. All right. are there any questions for Steve or comments before we go to the vote?

And I also want to thank you by the way for providing the entire Methodology report, it is just a terrific resource to have.

DR. GOODMAN: Yeah, we hope it's helpful to PCORI.

CHAIRPERSON GOERTZ: All right. Danny.

MR. VAN LEEUWEN: Yes. Thank you. This

was amazing. And I confess I didn't read all of it. But I did a little more than skim. I actually got stuck almost at the beginning with identifying gaps in evidence.

And I think that I would be interested in the future to learn more about looking for gaps in evidence not in the scientific literature, because the questions people ask about safe and healthy living are really different than what people research.

And so, if we're just looking at the scientific, you know, what's in the systematic review of scientific literature, we're missing like a whole constellation of people's concerns, but thank you very much. This is amazing. And I will in small doses read more.

DR. GOODMAN: Thank you.

CHAIRPERSON GOERTZ: Any other comments or questions before we go to the vote?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm going to ask for a motion then to accept the updated PCORI

Methodology report.

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: Thank you Barbara, can I get a second?

MR. VAN LEEUWEN: Second, Danny.

CHAIRPERSON GOERTZ: Thank you Danny.

All right. Is there any further discussion? Ellen. Did you want to make a comment before we vote?

DR. SIGAL: [Indicates no.]

CHAIRPERSON GOERTZ: All right. We're going to do this as a voice vote then.

So all those in favor please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No opposition.]

CHAIRPERSON GOERTZ: Abstentions?

[No abstentions.]

CHAIRPERSON GOERTZ: All right, again. Thank you. Thank you, Steve, Robin, and the entire Methodology Committee.

DR. GOODMAN: Thank you.

CHAIRPERSON GOERTZ: All right. Now we're going to turn the agenda back over to Nakela to discuss sustaining our partnership with AHRC for systematic reviews.

DR. COOK: Thanks, Christine. I'm pleased to talk with you about our partnership with AHRQ for systematic reviews. And PCORI has a mandate, not only to conduct primary research, which you have been talking about quite a bit, but also to conduct systematic reviews and other types of reviews. And the original authorizing document states that "Related to research, the Institute shall carry out the research agenda using methods, including systematic reviews and assessments of existing and future research and evidence, as well as primary research, such as randomized clinical trials and observational studies."

So I state that just to give you that breadth of what's really included in PCORI's remit. And one of the ways that PCORI has responded to this mandate is through the partnership with AHRQ to conduct systematic reviews. So let's go to the next

slide.

I just want to give you a little bit about the history of this long-standing partnership with AHRQ. We implemented this partnership through a memorandum of understanding to conduct the systematic reviews through the AHRQ's funded evidence-based practice center program and the history of this work really dates back to earlier days of PCORI with the first MOU, with AHRQ to fund systematic review updates that included topics around drug therapy for rheumatoid arthritis, non-surgical treatments for urinary incontinence, and psychological and pharmacologic treatments for adults with post-traumatic stress disorder, as well as stroke prevention in atrial fibrillation patients.

And then more recently, just about a year and a half or two years ago, PCORI piloted some nominations from professional societies for systematic reviews to inform clinical practice guidelines and similar types of activities.

And those activities included topics around

breathlessness for patients with advanced cancer, one of the studies or that I highlighted one of the reviews I highlighted when I talked about the dashboard, as well as another topic around cervical ripening in the outpatient setting, and the management of infantile epilepsy, as well as the radiation therapy for brain metastasis systematic review.

And these reviews have resulted in and supported things such as PCORI evidence updates, as well as targeted research, PCORI funding announcements. And you may recognize some of these from some of the targeted PFAs that we've discussed with the Board in the past, as well as implementation PFAs. They've also informed and resulted in AHRQ dissemination and implementation initiatives. And we've talked about that relationship with AHRQ and that dissemination space. As well as some of the clinical specialty society practice guidelines, as we talked about with the breathlessness in the advanced cancer review. We can go to the next slide.

So this partnership for systematic reviews is envisioned to continue over the next years of PCORI.

And we see an increasing need for systematic reviews that are flowing from the work with stakeholders on our research agenda activities, our topic development activities, as well as our communication dissemination and implementation efforts. And we have periodic MOUs with AHRQ for several reviews at a time. Typically are helpful for us in terms of trying to move the momentum forward on these reviews. The MOUs tend to be typically in about the 1.5 to $2.5 million range, and we're requesting approval for funding these MOUs up to about $6 million per year for the next five years.

And in the works, we have systematic reviews that are proposed to cover three topics that we think are really important for maternal morbidity and mortality, as well as intellectual and developmental disabilities priority. We also recognize that in the future there will be increased

capacity to do these reviews and to be able to support these reviews. And we'll be able to continue to discuss the topics for these reviews, with the strategy committees, particularly the EDIC and the SOC that have engaged on these in the past.

So doing them individually would require us bringing small amounts to the Board for approval, as opposed to clustering them like this and asking for an advanced approval would help to really streamline the process. And we wanted to bring forward a motion to ask the Board for consideration of approving up to $6 million per fiscal year, not to exceed a total of $30 million for five fiscal years to support the AHRQ's partnership with PCORI to fund the conduct of systematic reviews. So let's go to the next slide.

And I believe at this point, I'll turn it back to you, Christine, to see if there are any questions or discussion.

CHAIRPERSON GOERTZ: Great. Thank you so much Nakela.

Before we begin a discussion while Karin

Rhodes, the AHRQ Director Designee is recused from the deliberative discussion and vote on the funding for this partnership, she is available to answer any questions the Board members might have about the initiative and the collaboration. If any other Board member believes they should recuse themselves from this deliberative discussion and vote, please feel free to do so.

Any questions for either Nakela or Karin?

[No response.]

CHAIRPERSON GOERTZ: I want to say I'm incredibly excited about this continued collaboration. We're very pleased with the work that you've done in the past, and look forward to continue to work with you.

DR. McNEIL: I have a question, Christine. I don't think you can see my hand.

CHAIRPERSON GOERTZ: I cannot go ahead, Barbara.

DR. McNEIL: So just one question, just to Nakela. I wasn't quite sure -- did your previous slide, maybe you could go back to it if you could,

indicate that $6 million was going to be spent on those two systematic reviews, one for mortality and morbidity, and one for intellectual disability -- in developmental disabilities, that is $3 million each? Or are there other reviews embedded in this work?

DR. COOK: There are other reviews embedded in the work. I just highlight those because I thought they were really important as to --

DR. McNEIL: Oh, no. They're critical. So what are the others? Do we know Karin?

DR. RHODES: So I know that there are at least four reviews that are in the contracting process. And I can't name each one of them, but --

DR. McNEIL: That's okay. What I was trying to get a handle on is how much does it system systematic review cost?

DR. COOK: Oh yes. So Barbara, I can mention a couple of things that could help you. The other reviews, you know, the topics still are in development in terms of what those topics would be that would be part of that full MOU, but on average my sense is that they can cost somewhere between

$500 and $750,000 to complete.

DR. McNEIL: Okay. That's what I wanted to know. Thank you.

CHAIRPERSON GOERTZ: Great. Any other comments or questions?

[No response.]

CHAIRPERSON GOERTZ: All right. Hearing none then I'm going to ask for a motion to approve funding of up to $6 million per fiscal year, not to exceed $30 million over five fiscal years. So the Agency for Healthcare Research and Quality for PCORI's partnership with AHRQ to fund the conduct of systematic reviews, subject to finalization of the memorandums of understanding between PCORI and AHRQ.

DR. McNEIL: So moved

CHAIRPERSON GOERTZ: I heard Barbara. Thank you. And can I get a second?

MS. TROEGER: Kathleen will second. Troeger.

CHAIRPERSON GOERTZ: Thank you Kathleen.

All right. Any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. Can we get a roll call vote then?

MS. WILSON: Certainly. Kara Ayers.

DR. AYERS: Approve.

MS. WILSON: Kate Berry.

MS. BERRY: Approve.

MS. WILSON: Tanisha Carino.

[No response.]

MS. WILSON: Mike Lauer.

[No response.]

MS. WILSON: Jennifer DeVoe.

DR. DeVOE: Approve.

MS. WILSON: Alicia Fernandez.

DR. FERNANDEZ: Approve.

MS. WILSON: Christopher Friese.

DR. FRIESE: Approve.

MS. WILSON: Christine Goertz.

CHAIRPERSON GOERTZ: Approve.

MS. WILSON: Mike Herndon.

DR. HERNDON: Approve.

MS. WILSON: Russell Howerton.

[No response.]

MS. WILSON: James Huffman.

[No response.]

MS. WILSON: Connie Hwang.

[No response.]

MS. WILSON: Sharon Levine.

DR. LEVINE: Approve.

MS. WILSON: Michelle McMurry-Heath.

[No response.]

MS. WILSON: Barbara McNeil.

DR. McNEIL: Approve.

MS. WILSON: Karin Rhodes is recused.

Eboni Price-Haywood.

DR. PRICE-HAYWOOD: Approve.

MS. WILSON: James Schuster.

DR. SCHUSTER: Approve.

MS. WILSON: Ellen Sigal.

DR. SIGAL: Approve.

MS. WILSON: Kathleen Troeger.

MS. TROEGER: Approve.

MS. WILSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Approve.

MS. WILSON: Janet Woodcock.

[No response.]

MS. WILSON: And Robert Zwolak.

[No response.]

MS. WILSON: Dr. Goertz, the motion passes.

CHAIRPERSON GOERTZ: Thank you very much, Nick.

All right. So as no one has registered or joined for public comment, we will not be initiating our public comment period. And we'll -- so I'm going to turn it back to Nakela for some closing remarks.

DR. COOK: Thank you Christine.

And I offered some comments following the strategic planning discussion. So maybe I'll just comment briefly that I really appreciate the engagement of all of the Board on our strategic planning discussions. And I am just so thrilled that it worked out well to have our facilitated activities yesterday and today.

I also wanted to acknowledge all the staff work that went into preparing for this meeting and these discussions and under some rapid timelines and

competing priorities and thank them all for the efforts that led us to be to where we are today. As it relates to our dashboard, I just wanted to thank those that commented about the potential for us really enhancing the public and patient facing metric that we discussed that's new for the dashboard, some of the other areas of interest related to understanding the peer-review metrics, as well as the metrics around application submission, the timeline for funding, and resubmission processes.

And so, we appreciate you providing those inputs. We're going to start to think about how we incorporate them in our end-of year-report, as well as with our cycle reviews with the Board when we bring slates to the Board for funding decisions.

And then lastly, I am pleased that we were able to talk today about some things and follow-up from the year that I've been at PCORI as well as the Diversity, Equity, and Inclusion Initiative. And I look forward to engaging with the Board further on several of those work streams that we're working

toward.

So thank you. And thanks to all the staff and team for that orchestrated the work of the Board meeting logistically, et cetera, it's worked out so well in that virtual environment. We still got quite a bit done. And so, I appreciate all their efforts to make that happen. I'll turn it back to you, Christine.

CHAIRPERSON GOERTZ: Thank you, Nakela. I just want to echo your thanks to -- well, thanks to you and to the staff for incredible work and the many phases of preparation for this meeting and to the Board for being so fully engaged over two long days via video conference, which is not easy. And to Sonja, for doing an excellent job as our facilitator as we discussed our national priorities.

I wanted to let the Board members know that we will be engaging in a planning session starting at 4:30 Eastern time. So I look forward to seeing you again there. And I'm going to close by thanking everyone who joined us today via webinar and teleconference.

A reminder that all of the materials presented to the Board today will soon be available on our website. Today's webinar was recorded and the archive, the webinar will be posted within a week.

We always welcome your feedback at info@PCORI.org or through our website at www.PCORI.org. Thanks again for joining us. Have a good evening.

[Whereupon, at 3:57 p.m. EST, the Board of Governors meeting was adjourned.]