PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday,
March 16, 2021

Webinar

[Transcribed from PCORI webinar.]

B&B REPORTERS
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APPEARANCES:

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Christopher Friese, PhD, RN, AOCN, FAAN
Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
James Huffman
Connie Hwang, MD, PhD
Mike Lauer, MD, Designee of the NIH Director
Sharon Levine, MD [Vice Chairperson]
Michelle McMurry-Heath, MD, PhD
Barbara J. McNeil, MD, PhD
David Meyers, MD, FAAFP
Eboni Price-Haywood, MD. MPH, FACP
James Schuster, MD, MBA
Ellen Sigal, PhD
Kathleen Troeger, MPH
Danny van Leeuwen, MPH, RN
Robert Zwolak, MD, PhD
AGENDA

Welcome, Call to Order, and Roll Call

Christine Goertz, DC, PhD,
Board Chairperson 6

Consider for Approval:
Minutes of the February 9, 2021 Board Meeting 10

Consider for Approval:
Research and Dissemination & Implementation
Award Slates 11

Nakela Cook, MD, MPH, Executive Director 11

Mike Herndon, DO, Chair, Engagement,
Dissemination, & Implementation Committee 36

Barbara McNeil, MD, PhD, Chair, Selection Committee 22

Slate of Awards from the Cycle 2 2020 Second-line Pharmacological Agents in Type 2 Diabetes PFA

Kim Bailey, MS, Interim Associate Director,
Clinical Effectiveness and Decision Science (CEDS) 23

Slate of Awards from the Conducting Rare Disease Research Using PCORnet PFA

Penny Mohr, MA, Senior Advisor, Emerging Technology and Delivery System Innovation Research Initiatives 29

Slate of Awards Deferred from the Cycle 1 2020 Broad PFAs

Steve Clauser, PhD, MPA, Program Director,
Healthcare Delivery and Disparities Research (HDDR) 33
AGENDA [continued]  Page

Consider for Approval:
Research and Dissemination & Implementation Award Slates [continued]

Slates of Awards from Cycle 2 2020 Dissemination and Implementation PFAs:

- Limited Competition Dissemination and Implementation PFA
- Dissemination and Implementation Shared Decision Making PFA

Joanna Siegel, ScD, Program Director, Engagement, Dissemination and Implementation (D&I)  

Consider for Approval:
Research Topics for Targeted PFAs for Cycle 2 2021

Nakela L. Cook, MD, MPH  
Alicia Fernandez, MD, Science Oversight Committee (SOC) Chair

Targeted PFA for Cycle 2 2021: Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities

Els Houtsmuller, PhD, Associate Director, HDDR

Targeted PFA for Cycle 2 2021: Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Development Disabilities (IDD)

Holly Ramsawh, PhD, Senior Program Officer, CEDS

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AGENDA [continued]

Consider for Approval: Research Topics for Targeted PFAs for Cycle 2 2021 [continued]

Targeted PFA for Cycle 2 2021: Nonsurgical Interventions for Women with Urinary Incontinence

   Nora McGhee, PhD, Senior Program Officer, CEDS

Discussion: Topics for Development for Future Cycles

   Nakela L. Cook, MD. MPH

Consider for Approval: PCORIs Principles for the Consideration of the Full Range of Outcomes Data

   Nakela L. Cook, MD, MPH

   Andrew Hu, MPP, Director, Public Policy and Government Relations

   Joanna Siegel, ScD, Program Director, D&I

Wrap up and Adjournment

   Christine Goertz, DC, PhD,
   Board Chairperson
OPERATOR: Dr. Goertz, the floor is yours.

CHAIRPERSON GOERTZ: Thank you so much.

Good afternoon and welcome to the March 16, 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 those who have joined us virtually online and on the phone, we're very pleased to have you here.

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

All materials presented to the Board for
consideration today will be available during the webinar and then after the webinar will be posted on our website at www.PCORI.org. The webinar is being recorded, and the archive will be posted within a week or so.

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

Nick, would you please call roll.


DR. AYERS: Present.

MS. WILSON: Kate Berry.

MS. BERRY: I’m here.

MS. WILSON: Tanisha Carino.

DR. CARINO: Present.

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

DR. LAUER: Here, Mike Lauer.

MS. WILSON: Jennifer DeVoe.

DR. DeVOE: Present.

MS. WILSON: Alicia Fernandez.

DR. FERNANDEZ: Present.
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.
DR. HOWERTON:  Present.

MS. WILSON:  James Huffman.
MR. HUFFMAN:  Present.

MS. WILSON:  Connie Hwang.
DR. HWANG:  Present.

MS. WILSON:  Sharon Levine.
[No response.]

MS. WILSON:  Michelle McMurry-Heath.
[No response.]

MS. WILSON:  Barbara McNeil.
DR. McNEIL:  Here.

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

DR. MEYERS:  David Meyers is here.

MS. WILSON:  Thank you. Eboni Price-
Haywood

DR. PRICE-HAYWOOD: Present.

MS. WILSON: James Schuster.

DR. SCHUSTER: Present.

MS. WILSON: Ellen Sigal.

DR. SIGAL: Here.

MS. WILSON: Kathleen Troeger.

MS. TROEGER: Yes, 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: All right, thank you so much. All right. Can I have the next slide please?

So our agenda today is we'll consider our minutes for approval and then we have a number of other approvals. We will be looking at our research and dissemination implementation award slates,
research topics for targeted PFAs for Cycle 2 2021. And then, finally principles for the consideration of the full range of outcomes data in PCORI-funded research. So this is a very ambitious agenda so we've asked the staff to make really condensed presentations and we'll be moving through as quickly as we can to make sure that we're able to have some time for Board discussion, but also so that we're able to get through the agenda today. So I thank you for your patience and consideration as we move relatively quickly through the agenda today.

All right. Can I have the next slide?

So, our first order of business has to approve the minutes of the February 9, 2021 Board of Governors meeting. Can I have a motion to approve?

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: Okay. Barbara. Thank you. Can I have a second?

DR. AYERS: Second. This is Kara.

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

[No response.]
CHAIRPERSON GOERTZ: All those in favor, please signify by saying aye.
[Ayes.]
CHAIRPERSON GOERTZ: Opposed?
[None.]
CHAIRPERSON GOERTZ: Abstentions?
[None.]
CHAIRPERSON GOERTZ: All right, thank you.
I am now going to I'm asked Nakela to provide an overview of our award slates, Nakela.
DR. COOK: Thank you so much. You may recall that at our December Board meeting we discussed approaches to monitor our progress against what's laid out on in the Board-approved commitment plan, and also provide the Board with some context for the slates under consideration for approval within each cycle. And so, I wanted to begin today, our review of our slates that we are putting forward for consideration for approval with some overarching contextual remarks and I wanted to ask that we all recall that the slates have been -- that are going to be presented today have gone through the multi-
step process of merit review, staff review, and the relevant selection committee. And at the Board level today, the focus is really for consideration of approval of the slates and to ensure that they are aligned, that the slates are aligned with the overall goals of the priorities of the PCORI funding announcement, which are aligned, as well to PCORI priorities as well as budgetary oversight.

So let's go ahead to our next slide.

So the today, the Board will consider the following five award slates for approval. Three of them come from Research solicitations and two from Dissemination and Implementation solicitations, they total $48.5 million, all together, and from a timing perspective, it may be helpful for you to know that all of these were the very first cycles after reauthorization and all were unfolding as well during the COVID-19 pandemic. None of them come in at over the set-aside budget that we had for each PCORI funding announcement, there's no additional request for funding at this time.

Let's go to the next slide.
So this slide demonstrates how the funding cycles for the targeted PFA award slates that you'll be considering today fit into the larger context of data related to Letters of Intent, applications, and funding rates compared to historical average. And what you can see here is that we've had a pretty robust response to these announcements that you're considering, with more Letters of Intent submitted as compared to our historical average. And we also had a higher proportion of Letters of Intent that were invited to actually submit for the diabetes studies. While we had a lower proportion for the rare diseases studies and a high proportion of those that had accepted Letters of Intent, actually did submit applications to PCORI.

And with the Board approval today, these slates represent funding rates that are at or above our historical average.

And since these were fairly typical PFAs, with better than average performance in some rounds, and as you can see for the targeted PFA on the right side of the slide for Cycle 3 on Suicide Prevention,
which is really timely given what we are seeing right now with this pandemic, we’ll be coming back to the Board in July. And we'll again, we'll see that we have a robust response in applications that have come in to PCORI and they're making their way through the process. So you'll see those as slates in the July meeting.

Let's go to our next slide.

So this slide is to demonstrate how the Cycle 1 2020 broad PFA slate fits into the larger context of data related to Letters of Intent and application and funding rates, and it's really to help us kind of gauge whether or not a given cycle is a typical cycle or departure. And this slide should be familiar to you because we looked at the Cycle 1 2021 broad slate in our prior Board meeting. And what we have in confer consideration for the Board today are two applications which were deferred due to COVID-19, and during the early days of the pandemic, we didn't have a Cycle 2 issue, and so you'll see these as for inclusion in the Cycle 1 2020 slate.
And you may recall that because of the pandemic, there were a high number of deferrals in the timing of the launch of this PFA. And what we see with the approval of the deferrals from Cycle 1 2020, there are a few things that are notable. It turns out that actually even though there were a lot of things that were unusual about this cycle, given the deferrals and the pandemic that ultimately it performs similar to a typical cycle. And when you look at the return of Letters of Intent and applications funded, and you see the funding rate overall was about 15 percent inclusive of the deferrals similar to what we've seen in our historical average.

For the deferrals we had actually 35 applications that requested a deferral and were granted a deferral, but only 19 of those submitted at the next opportunity. And so, together those that submitted plus the deferral submissions yield an overall submission rate of 75 percent, which is very similar to historical average. And on the right side of the slide you see the next broad
slate, which is anticipated to come through for Cycle 3 2020 since the broads again we're not offered in Cycle 2. And you can see that it looks very similar in terms of yield.

Let's go the next slide.

So this slide is to provide some context for the cycles in terms of the commitment plan in 2021. And here you can see that the research line, the planned commitment for 2021 is $290 million, and the proposed total award for the slates with the additional studies that we will discuss today is $84 million, with approximately $260 million available for awards from the Cycle 3 2020.

So upcoming for Cycle 3 2020 are several slates, including a Cycle 3 2020 broad slate with two special areas of emphasis included. There's also a Cycle 3 2020 phased large award slate for comparative effectiveness research or the PLACER announcement, remember these are those large stage clinical trial awards.

And we also anticipate having the PFA slate coming from Cycle 3 2020 on the brief interventions.
for youth.

So this is really a robust group of slates that will be coming to the Board, later in July for review. We're also working on a COVID-19 targeted PFA that's been developed in a fast-track way under our previously approved plans, and that'll likely launch off-cycle, so it's also included here as a future announcement.

So given what we see that we've currently made progress against with a commitment plan and what we have teed up for Cycle 2 of 2020, at this time we're not proposing changes to the commitment plan for 2021, and we don't anticipate requesting additional funding for the remaining cycles, unless we have a better than anticipated batch of applications from the slates, for these Cycle 3 announcements that will be coming to you in July.

Let's go to our next slide.

So I'm going to transition and talk about the Dissemination and Implementation slates, and you'll see a similar pattern for the context for the slates. And this slate demonstrates how the Cycle 2
limited competition Dissemination and Implementation slate fits into a larger context and compares it against historical average. And it's important to note that for this cycle, and the subsequent cycles on this slide, they were also affected by the pandemic given the timelines and it may have affected our number of Letters of Intents and our applications that came in.

But with the approval of the slate for Cycle 2 2020, you're going to see a few things here. We see that we have a greater success of the conversion of the Letters of Intent that were invited to applications that were submitted, and we see a higher funding rate.

As we move out into the future cycles that will come before the Board in the summer and beyond. In addition to COVID-19, application numbers may be affected by the throughput in the research-funding pipeline. So you may recall that this is a limited competition announcement, and it's limited to findings from research funding that are primed for Dissemination and Implementation awards, and so,
this comes in waves depending on historical funding patterns, and we're still working to understand how COVID-19 will affect that wave of funded awards that may actually move into Dissemination and Implementation Limited Competition awards.

And you'll also note here that this slate includes one smaller word that was approved under the authority of the Chief Engagement and Dissemination Officer who delegated the authority for smaller budget size.

Let's go to our next slide.

And this slide is actually -- this slide tries to demonstrate how the Cycle 2 2020 implementation awards related to shared decision making, fit into the larger context and how it compares to historical average. And so, this table is really also designed to kind of give you a sense of if things are typical or a departure and it's important to note the same things that I talked about on the prior slide apply here. That the number of Letters of Intent and applications were likely affected by the pandemic, and given the
And with the approval of the slate for this PFA you'll see a few things. While there was only one award, it was a really strong application and is being proposed for funding. It does also raise an important topic for us related to our strategic planning. It brings to the fore the question about PCORI’s role and the continued opportunity. And this is a really important space, and we may be at a point that we've cleared some of our backlog in terms of pending demand and pent-up demand for this space and now we're maybe entering a more steady state, but these are the sorts of things that we can look forward to discussing through our strategic planning activities at a future time.

Let's go to the next slide.

This is the last slide to provide some context and this slide is really focused on thinking about the dissemination and implementation slates in terms of our commitment plan for 2021. And again here you can see that the D&I align, had a plan commitment for 2021 of about $28 million, and the
proposed total award for the slate with the additional study that's being discussed today is $6 million. And that leaves approximately $22 million available for awards for Cycle 3 2020. And upcoming are several slates including a Cycle 3 2020 limited competition D&I PFA, as well as the Cycle 1 2021 limited competition PFA

But based on submissions to the remaining cycles that are supposed to be funded in fiscal year 2021, that you saw on the prior slides, we anticipate that the funding plan for D&I awards this year would be sufficient and at this time we're not proposing changes to the commitment plan, we don't think we'll anticipate requesting any additional funding, but in fact we do anticipate that with the trends of the applications coming in, we may be below our funding commitment allocation in this phase.

So that's the context I wanted to provide for the slates that you're going to be seeing today in considering for approval. And I'll turn it back over to Dr. Goertz for any discussion and to
introduce the Selection Committee chair.

CHAIRPERSON GOERTZ: Great, thank you so much, Nakela, I really appreciate it.

Does, does the Board have any questions or comments on this overview? I think it's really helpful to have this broad overview, and so we can put that in context as we're as we're moving forward with consideration of the slates that we'll be looking at today.

DR. COOK: Great.

CHAIRPERSON GOERTZ: Thank you. All right, I'm not seeing anything in the chat or anyone turning on their camera, so in that case I think we'll move along. So what I'd like to do is I'd like to, to turn this over to Barbara McNeil, who will introduce the three research awards slates.

DR. McNEIL: So thank Chris, the Selection Committee for PCORI met on February 3rd and recommended three slates of awards for approval by this board. These slates come from the broad PFAs as well as the targeted PFAs in focus on Type 2 Diabetes and rare disease research, and the staff
will present the results of our deliberations now, so we can move on.

Kim.

MS. BAILEY: Thank you. Slide please.
I'm pleased to be presenting for the Board's review and approval a slate of four awards from this targeted funding announcement. The goal of this announcement is to find high quality observational studies that compare the effectiveness of older versus newer second-line pharmacological agents in Type 2 Diabetes in a patient population at moderate cardiovascular risk, with a focus on cardiovascular outcomes. Drug classes of interest specified in the planning announcement, are the newer SGLT2 inhibitors and GLP-1 receptor agonist, and the older sulfonylureas and DPP-4 inhibitors.

As a quick reminder this funding announcement was the result of more than four years of work and stakeholder engagement, during which PCORI explored the possibility of funding a randomized trial in this space. A number of factors limiting the feasibility of a randomized trial
resulted in our issuance of this funding call for studies using robust observational designs. While not a substitute for randomized trials, the evidence generated by studies funded through this initiative may help to inform clinical decision making and the design of future trials, the availability of up to $20 million in total funds was posted with direct cost limited at $4 million per study and maximum project periods of three years.

Next slide please.

The total award amount of the four studies on the proposed slate is $18.4 million. The four studies proposed for funding are highly complementary to one another, both in terms of the methods used and sources of data proposed for analysis, and each is directly responsive to the priority research question, outlined in the funding announcement. Together they form a robust slate of studies that employ diverse approaches to answering this key question of interest.

I am happy to answer any questions, but we'll turn things back over now to Dr. Goertz to
facilitate discussion and the vote.

CHAIRPERSON GOERTZ: Thank you so much, Kim. I really appreciate it. Are there any questions or comments for Kim before we move forward with the vote?

MR. VAN LEEUWEN: No questions for me.

CHAIRPERSON GOERTZ: Great, thank you.

DR. McNEIL: I move approval.

CHAIRPERSON GOERTZ: All right, thank you.

In that case what I'm going to do is I'm actually going to ask for a motion to approve the Cycle 2 2020 observational analysis,

UNIDENTIFIED BOARD MEMBER: Motion to approve.

CHAIRPERSON GOERTZ: All right.

DR. ZwOLAK: Zwolak, second.

CHAIRPERSON GOERTZ: Okay, thank you. Is there -- so now we're going to do something a little bit differently. Normally we've done a voice, or a roll call vote for this. Instead we're going to be doing a voice vote I do want to announce that Michelle McMurry-Heath has joined the Board meeting
so that everyone that was engaged in the original
roll call at the beginning and in addition to
Michelle is on the call for this voice vote.

So, all those in favor please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

DR. McNEIL: I abstain I'm in conflict.

MS. HENNESSEY: Christine, I think you were
going to note the Board members who did not intend
to participate --

CHAIRPERSON GOERTZ: Yeah. Okay, I'm
sorry. For the Board members that did not attend
for this are Janet Woodcock, I believe -- and then
Kathleen also?

MS. HENNESSEY: Yes, I believe, who did not
intend to participate in the vote due to conflict of
interest.

CHAIRPERSON GOERTZ: Okay, yes.

DR. McNEIL: No, did I Mary. I believe I'm
in conflict with numbers three and four, is that not
true?

CHAIRPERSON GOERTZ: Sorry. I believe that myself, Barbara, and then Sharon Levine who is not in present is recused from this. Does that match your notes, Mary?

MS. HENNESSEY: Yeah, it does Christine. Thanks so much. And so I think in terms of a motion, let's just make sure someone moves that who doesn't have a conflict, I believe Barbara --

DR. FERNANDEZ: So moved, Fernandez.

CHAIRPERSON GOERTZ: Okay, great. Thank you Alicia. Can we just start over here?

[Laughter.]

CHAIRPERSON GOERTZ: So we're doing voice votes. We have three people in conflict, myself, Barbara, and Sharon, who is not present and so I would like to ask for a motion to approve the recommended slate of awards for the Cycle 2 2020 observational analysis of second-line pharmacological agents in Type 2 Diabetes.

DR. FERNANDEZ: So moved, Alicia.

CHAIRPERSON GOERTZ: Thank you, Alicia.
Can I have a second?

DR. ZWOLAK: Zwolak, second.

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

[No response.]

CHAIRPERSON GOERTZ: All right, I'm now going to call for a voice vote.

All those in favor?

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[No additional.]

CHAIRPERSON GOERTZ: Okay, I think we think we did it. Thank you. It takes a little bit of getting used to this new to this new process.

All right, I believe that Penny Mohr, are you up next?

MS. MOHR: I am.

DR. McMURRY-HEATH: Can you guys hear me?

Sorry, Christine, can you guys hear me? This is Michelle. I voted on the minutes as well. I’m not
sure if it got recorded.

CHAIRPERSON GOERTZ: Okay thanks Michelle.

I appreciate it.

MS. MOHR: Great, thank you very much Dr. Goertz I'm very pleased to be presenting four applications for Board approval today on the rare disease funding announcement. If you could go to the next slide please.

So this funding announcement had two objectives. The first was to answer one or more important questions about the care of patients with rare disease through observational cohort studies, utilizing PCORnet resources. The second was to enhance the capabilities for the conduct of multi-site rare disease research by creating or strengthening partnerships, methods, tools, and data linkages for rare disease research.

This funding announcement set aside $25 million, and allowed for studies with total direct costs of up to $3.5 million, and a maximum duration of three years. It was designed to encourage more large-scale studies that are national in scope.
across PCORnet. This is fitting with the Board's recently passed strategic prioritizing principles for PCORnet.

Also, while PCORI has a mandate to have a rare disease advisory panel, and this underscores the importance of our authorizing legislation places on rare disease research, our Rare Disease Advisory Panel has urged us to use PCORnet for better use for these purposes, given the scale of PCORnet.

The funding announcement was designed with a recognition of the difficulty of conducting rare disease research, and allowed for either comparative effectiveness research or descriptive studies that can form the basis for the comparative effectiveness research question. That is describing treatments or care management studies being used and outcomes, importantly, we're hoping that the work done under this funding announcement will lay the groundwork for future randomized controlled trials or robust observational studies in rare disease.

Next slide please.

The slate includes four studies that span a
variety of rare diseases and conditions, focusing both on pediatric conditions and those affecting adults, and also spanning the critical period for the transition between pediatric to adult care, which often suffers due to gaps in care.

So I'm going to hand this off now to Dr. Goertz for further questions or a vote.

CHAIRPERSON GOERTZ: Thank you so much Penny. Before we begin any discussions the following Board members have notified us of their intention to recuse themselves from the deliberative discussion vote on the slate of awards from the conducting rare disease research using PCORnet PFA: Kara Ayres, Michael Lauer, Alicia Fernandez, myself and Eboni Price-Haywood.

If there are other Board members who believe they should recuse themselves from the deliberative discussion vote, then please feel free to do so. All right, I'll now open it up for discussion, please remember to identify yourself before making a comment.

Any comments or questions for Penny?
MR. VAN LEEUWEN: No question.

CHAIRPERSON GOERTZ: Great, thank you.

All right, in that case, I'm going to ask for a motion to approve the slate of awards for the Cycle 2 2020 conducting rare disease research using PCORNet PFA.

Can I have a motion?

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: Thank you, Barbara.

DR. SIGAL: Ellen, second.

CHAIRPERSON GOERTZ: Thank you Ellen.

All right. Is there any further discussion?

[No response.]

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

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: All right, the motion
pass. Thank you.

I'm now going to ask Steve Clauser to present our next slate for us.

Steve, you're on mute -- Steve, still on mute. We can't hear you.

DR. CLAUSER: Okay --

CHAIRPERSON GOERTZ: There you are. Good, thank you.

DR. CLAUSER: The organizer got me.

Today I'm presenting the for the Board's consideration for approval the addition of two projects to the slate of awards for the Cycle 1 2020 broad PFAs recommended by the Selection Committee.

Next slide.

These additions to the previously Board-approved slate from Cycle 1 2020 broad PFA result from the fact that applicants could differ applications from Cycle 1 during the COVID-19 pandemic, and they bring the total slate to 10 awards. Next slide.

On this slide you can see the additions to the slate under consideration today in red. The
first slate addition comes from the Addressing Disparities PCORI funding announcement, and it's entitled Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program, and the second comes from the Methods PCORI funding announcement, and it's entitled Development of Methods to Improve Identification of Patients with Rare or Complex Diseases. We are requesting an additional $5.3 million for the slate of awards.

I would be happy to answer questions and now turn it back to Dr. Goertz to facilitate any discussion and address the motion.

CHAIRPERSON GOERTZ: Thank you so much, Steve. Before we begin a discussion the following Board members have notified us of their intent to recuse themselves from the deliberative discussion vote on the additions to the slate of awards from the Cycle 1 2020 broad PFAS, and those are Mike Lauer, Christopher Friese, and David Meyers. If there are any other Board members that feel that they should recuse themselves from this discussion and vote, please do so.
Now, I’ll open it up for discussion and any questions or comments for Steve.

[No response.]

CHAIRPERSON GOERTZ: All right, in that case I'm going to ask for a motion to approve funding for the addition of the recommended projects to this slate of awards for the Cycle 1 2020 broad PFAs.

DR. DeVOE: So moved, DeVoe.

CHAIRPERSON GOERTZ: Thank you, Jen.

DR. HERNDON: Second, Michael Herndon.

CHAIRPERSON GOERTZ: Was that Mike?

DR. HERNDON: Yes.

CHAIRPERSON GOERTZ: Thank you. Okay, any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, we're once again going to have a voice vote. So, all those in favor?

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]
CHAIRPERSON GOERTZ: Abstentions?
[None.]

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

Now I'm going to ask Mike Herndon, then to start our discussion on our two D&I awards slates. Are you here, Mike?

DR. HERNDON: Yes, I'm sorry. Yeah, I'm excited. I think we have a good slate the EDIC committee has discussed these in detail. I think that it is a very interesting and I think very worthy of our vote in consideration for approval so I'll turn it over now to Joanna.

DR. SIEGEL: Thanks Mike.

The first proposed slate that I'd like to present to you is for the D&I limited competition PFA. As Nakela mentioned a bit earlier this funding initiative provides the opportunity for PCORI awardee teams who've completed a PCORI-funded study to take the next steps in promoting uptake of the evidence in the context of related work into practice and lay the groundwork for broader, future
uptake.  

Next slide.  

This slate includes three projects, proposing to implement findings from studies funded through PCORI’s CDR; communication and dissemination research and addressing disparities research priority areas, with the total funds requested for these proposed projects at $3.8 million.  

Next slide.  

The second slate that I'd like to present is for our implementation of effective shared decision-making approaches in practice settings funding initiative. This PFA is designed to promote the uptake of shared decision-making in healthcare settings in line with PCORI’s goal of supporting patients in making informed, evidence-based decisions about their care with their clinicians.  

Next slide please.  

The proposed project will use a learning collaborative approach to support the uptake of tested conversation aids to support women with early-stage breast cancer in making treatment
decisions, the total funds requested for the proposed project is $2.1 million. And now I will turn it back to you Dr. Goertz for any questions or discussion.

CHAIRPERSON GOERTZ: Thank you, Joanna. Are there any -- before we begin any discussions, the following Board members have notified us of their intention to recuse themselves from the deliberative discussion vote on the slate of awards from the Cycle 2 2020 limited competition D&I PFA and shared decision-making PFA. And those are Jennifer DeVoe and Alicia Fernandez; if any other board members believe that they should recuse themselves from this deliberative discussion vote, please feel free to do so.

All right, I'm now going to open it up for discussion, just a reminder to identify yourself, Danny, I see you. Oh yes, I'm sorry -- what?

MS. HENNESSEY: This is Mary. I'm sorry. I had on my notes that also Ellen Sigal had been identified, do you have that?

CHAIRPERSON GOERTZ: I do not have that.
DR. SIGAL: That was a mistake, it was a disclosure that was old and I reversed. That was two years old. So no, I don't have a conflict.

MS. HENNESSEY: Thanks for clarifying Ellen. Sorry to interrupt.

CHAIRPERSON GOERTZ: That's okay, Mary. Thanks for checking. Okay, Danny I see you on camera so I'm going to assume you have a question or comment so please proceed.

MR. VAN LEEUWEN: I do. I just want to be sure that we're paying attention to dissemination and implementation to regular people outside of academic and specialty channels and implementation in life flow of regular people.

I think the slate is fine; I don't have any questions about the slate. I just want to make sure that we're paying attention to regular people.

CHAIRPERSON GOERTZ: Thank you, thank you for that Danny.

Joanna, do you have any comments on that?

DR. SIEGEL: Sure. I know we don't have time for a really full response on to your point
there Danny but, I do want to point out just -- that
even just with this particular slate, one of these
projects is taking basically information on
effective contraceptives to adolescent girls with a
reach of more than 16,000. You know, bringing very
relevant, very timely information to people at the
point of decisions, which is where we like to be.

So, I'm very happy to present more examples
about at a later time, but I know we're quite
pressed for time today.

CHAIRPERSON GOERTZ: Thank you.

MR. VAN LEEUWEN: Thank you.

CHAIRPERSON GOERTZ: Any other additional
comments or questions?

DR. HOWERTON: No thank you.

CHAIRPERSON GOERTZ: All right, thank you.

In that case I'm going to ask for a motion
to approve the slate of awards from the Cycle 2 2020
limited competition D&I PFA as well as the shared
decision-making PFA.

DR. HOWERTON: Howerton, motion.

CHAIRPERSON GOERTZ: Thank you. Thank you,
Russ. Can I get a second?

DR. McNEIL: Barbara seconds.

MS. TROEGER: Second.

CHAIRPERSON GOERTZ: I'm sorry I have to do that again I couldn't tell who it was.

MS. TROEGER: Troeger, seconds.

CHAIRPERSON GOERTZ: Okay, thank you.

Thank you Kathleen.

All right. Any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor?

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: All right, the motion passes and I just want to congratulate all of our awardees today. We really are very grateful for the huge amount of time and effort that you put into preparing your applications and we look very forward to working with you as you progress on your research.
and to seeing the results when you're done. So, again, congratulations.

All right, I'm now going to turn the turn the agenda over to Nakela so that she could provide us with an overview of our targeted PFAs.

DR. COOK: Thank you. And again, congratulations to all of the awardees.

We're going to shift gears now and talk about developing targeting targeted PFA is in the short-term while strategic planning is underway.

Let's go to our next slide.

So this discussion really picks up from our discussion at our last meeting, when the Board discussed our expedited and enhanced approach to developing targeted PFAs. And you may remember that, under that expedited and enhanced process that we were working on some perspective planning for our upcoming cycles. And so today, the Board will consider three targeted PFAs that were recommended by our Science Oversight Committee for Cycle 2 of 2021, and the three topics for Cycle 2 were really thought to be important and feasible in the
timeframe to maintain pace against meeting our commitment plan, and the Board also may recall that we will need about three PFAs for the next several cycles to meet our commitment plan goals. So next month we will be coming back to the Board to consider a set of topics that we would like to continue for development for future cycles, and simultaneously as we talked about before, we'll also be developing that fast tracked targeted PFA for COVID-19.

Let's go to our next slide.

So all three of the topics that you're going to see today under consideration are part of that expedited and enhanced process that we discussed at our last Board meeting and they leverage our prior and ongoing work, and have a high likelihood to converge with our national priorities and research agenda and help to fill that gap until we have that research agenda in place. They meet several criteria that you see here, including having high burden conditions and issues, or being responsive to mandates or express interest from
stakeholders and the Board in terms of scenarios. They also relate to emerging themes from some of our strategic planning discussions. And even though these PFAs are expedited, the development of the PFAs included literature review with a focus on systematic reviews, which we'll hear a little bit about, as well as clinical guidelines. And the development also focused on outreach to relevant patient groups and stakeholders and a review of PCORI's funded portfolio as well as consultation with other funders, including the NIH, AHRQ, and other relevant entities.

We can go ahead to our next slide.

So what you're going to see in terms of the main differences in the targeted PFAs that are stemming from this expedited and enhanced approach include several things. Number one, that these PFAs are designed to be more open for the research and stakeholder community to develop and propose relevant studies that are within the PCORI-identified focus area. And so, you're going to note that study parameters are highly specified when
appropriate for a topic, including, for example, populations or interventions or outcomes. And these PFAs are open to a wider range of study duration and funding level to allow for a range of study designs as well as study sizes.

And in an effort to try to increase the likelihood of accomplishing the objective of the PFA, we're going to propose to offer more than one cycle as warranted and allow for deferrals and submissions as needed as well.

We can go ahead to our next slide.

So just wanted to give you a brief summary of the topics that you're considering today for approval for Cycle 2 2021. So you'll be hearing about two topics that were developed within priority research areas that are in our reauthorizing legislation: maternal morbidity and mortality as well as intellectual and developmental disabilities. And you may recall, these are 10-year priorities, and so we're really just getting started.

It's important to note that there's a multi-year planning effort that's underway for both
of these topics, and we anticipate that there'll be many future topics and opportunities in these areas as well. And previously, just to jog your memory, PCORI posted special areas of emphasis in our broad PFA back in 2020 with set aside funding, and we had a robust response from the community for that. And those applications are now currently under review. And we anticipate that the areas of focus around maternal care coordination and health care transitions for individuals with intellectual and developmental disabilities will be important areas that you'll see in the slates coming forward in future board meetings.

But today the PFAs that we're going to present in these two areas of our Congressional mandates are going to focus on the postpartum space for maternal morbidity and mortality, and for individuals with developmental and intellectual disabilities, also with mental health conditions. The PFA will focus on interventions in that space.

The third topic that is up for consideration for approval today is related to
urinary incontinence in women. And this is focused on an issue that PCORI’s been working on for a while, it just stalled during the period leading up to reauthorization, and so we're really excited to pick it back up because it's still highly relevant. And this works stems from systematic evidence review that PCORI funded with the intention of trying to identify clinical comparative effective research gaps. And so, that you'll also see that coming forward.

So here you see the list of the three topics that we'll be talking about and the funding profiles, and for a total of up to $130 million for this upcoming cycle.

So if time allows, I think, Dr. Goertz I'll turn it back to you for some discussion and then we could turn it over to Dr. Fernandez for the presentation of the actual PFAs.

CHAIRPERSON GOERTZ: Thank you. Thank you Dr. Cook, I appreciate it. So does anyone have any questions or comments about this, our proposed targeted PFA strategy?
DR. SCHUSTER: It's clear I think. This is James.

CHAIRPERSON GOERTZ: Thank you James.

All right, Mike. Did you have a question?

DR. HERNDON: Just a question of clarity.

When we talk non-surgical interventions for women that urinary incontinence that would include the non-surgical intervention -- the surgical intervention would be like the sacral stimulators right? I mean -- can you kind of give me an idea of what we're trying to get at for surgical versus non-surgical? And what all is in that surgical bucket?

DR. COOK: I think I'm actually going to allow a little bit of deferral of the question if that's okay with you, because Nora McGhee is actually going to present that topic and talk about the interventions that we're interested in. And so, if you still have questions after that I'd be happy to come back but I think your question will be answered in that frame.

DR. HERNDON: That's fine. I wasn't quite sure when to ask it.
DR. COOK: No problem.

DR. HERNDON: As a payer-policymaker, I'd be supremely interested in kind of the steps leading up to those sacral stimulators that are quite expensive and oftentimes ineffective. Thank you.

DR. COOK: Certainly.

CHAIRPERSON GOERTZ: Thanks Mike.

Great. Any other sort of big picture questions then for Nakela before we move on?

DR. HOWERTON: No, thank you.

DR. McMURRY-HEATH: Christine?

CHAIRPERSON GOERTZ: Michelle.

DR. McMURRY-HEATH: So my understanding is this is really supposed to be for quickly emerging issues that we're trying to make sure we also fund. Am I understanding that premise correctly?

DR. COOK: One of the things that we are going to talk about, just briefly, after we go through these three PFAs is the concept around setting up some topics that we will be talking about for the next four or five cycles. And what we're trying to do there is think about things that are...
high priority and feasible but also leave the space, if there are emerging, high priority topics that we need to bring into play. And I think that's what you may be asking about Michelle, is the latter point and if there are high priority topics that the Board feels we need to think about how we select them into our programming. Then we certainly want to hear about that.

DR. McMURRY-HEATH: Okay.

DR. COOK: Thank you.

CHAIRPERSON GOERTZ: Any other questions?

[No response.]

CHAIRPERSON GOERTZ: All right, in that case, Nakela, did you have anything else that you wanted to add before we turn it over to Alicia?

DR. COOK: I think we can go ahead. Thank you.

CHAIRPERSON GOERTZ: Thank you. Alicia.

DR. FERNANDEZ: Thank you Christine. So, the Science Oversight, we want -- we're moving now toward consideration for approval of improving postpartum maternal outcomes of populations
experiencing disparity and comparative effectiveness of interventions targeting mental health conditions in individuals with IBD, and the non-surgical interventions for women with urinary incontinence. And I am pleased to tell you that the Science Oversight Committee met on February 26th, and we recommended that all three of these be approved, be turned over to the Board for approval. And we are pleased to present these to you today and I will turn it over to Dr. Elisabeth Houtsmuller to describe the first PFA.

DR. HOUTSMULLER: And thank you, Alicia. This proposal for a targeted funding announcement is part of our ongoing work in maternal mortality, which as you know is one of the two new research priorities that were included in our reauthorizing language. There's been a lot of attention in the press and on social media, on the United States ranking lowest among high income countries in parameters for maternal health, and especially the significant disparities in maternal mortality and morbidity outcomes.
Now maternal mortality occurs not just during the pregnancy, but in fact 40 percent of maternal mortality in the United States occurs during the first six weeks following delivery. This is a time period that has until fairly recently been overlooked in terms of care. And so, for this targeted funding announcement we have focused on improving postpartum maternal outcomes for populations that experience disparities in those outcomes.

Next slide please.

In the targeted funding announcement we would ask for comparative effectiveness on multicomponent interventions to improve early detection and timely care for complications during the first six weeks postpartum and for their risk factors of those complications. We’re focusing on the populations that experienced the worst disparities.

Next slide, please.

And so, the populations that experienced the worst disparities include Black, American
Indian, Alaskan Native, and Hispanic women, women that live in rural areas, and women of lower socio-economic status.

We're interested in comparisons of multicomponent interventions that really increase both awareness and detection of both the risk factors and the complications. Outcomes should include health-related measures as well as patient experience of care, and importantly patient engagement in care, as well as follow up until one year.

The total we request for this announcement is up to $50 million in total costs, we're planning to fund four-to-six studies over two-to-three cycles with a maximum project duration of five years.

Next slide please.

I will now turn this over to Dr. Goertz for a vote, but I am happy to answer any questions as well.

CHAIRPERSON GOERTZ: Thank you Els, I really appreciate it. I'm going to open it up for discussion, just a reminder to identify yourself if
you're making a comment and not on video.

[No response.]

CHAIRPERSON GOERTZ: Right, not hearing any questions or comments; I'd like to ask for a motion to approve the targeted PFA for Cycle 2 2021, improving postpartum maternal outcomes for populations experiencing disparities. Can I have a motion for approval, please?

DR. SCHUSTER: This is James. I make a motion.

CHAIRPERSON GOERTZ: Thank you James.

DR. FRIESE: This is Christopher, second.

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

[No response.]

CHAIRPERSON GOERTZ: Just a note that no Board members have left or joined, so we still have a quorum for our voice votes.

So I'm going to ask for all those in favor, to please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?
[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: All right, the motion passes, then now I turn the meeting over to Dr. Holly Ramsawh, to present us with our next PFA.

DR. RAMSAWH: Thank you. Good afternoon everyone.

I'm here to present an overview of the first targeted PCORI funding announcement proposal for a new intellectual and developmental disabilities research priority.

Next slide please.

For this funding announcement, we've been able to leverage feedback from stakeholder groups, and they've called out a variety of issues relevant to mental health in individuals with IDD. Although those with IDD are at increased risk of mental health conditions, there are broad, wide-ranging evidence gaps in this area, stressing the need for future studies of both pharmacologic and non-pharmacologic interventions that target co-occurring...
mental health conditions. And so, the research question that you see here, addresses these broad evidence gaps.

Next slide please.

And here you can see the specifications for this request. And as you can see we're keeping the parameters, fairly broad to allow for a wide variety of submissions. A funding allocation of up to $40 million is requested to fund what we're estimating to be 10-to-12 studies over two-to-three funding cycles. Each would be three years in duration.

Next slide please.

And that concludes my presentation, I'll hand it back to Dr. Goertz for any questions and discussion.

CHAIRPERSON GOERTZ: Thank you so much Holly. Danny, did you have a comment or question?

MR. VAN LEEUWEN: Yes. I'm just seeing -- this does not include comparative effectiveness of health systems related to evidence-based approaches to addressing mental health conditions, is that purposeful?
DR. RAMSAWH: Sure, I can address that question. So we didn't specify that here, but we would be allowing for proposals that address sort of healthcare systems questions. So that wasn't intentional. That was we were just trying to be as broad as possible in this initial description.

MR. VAN LEEUWEN: Thank you.

CHAIRPERSON GOERTZ: All right. Thank you.

Any other comments or questions?

DR. HOWERTON: No, thanks.

CHAIRPERSON GOERTZ: All right, in that case, I am going to ask for a motion to approve the targeted PFA for Cycle 2 2021, comparative effectiveness of interventions targeting mental health conditions and individuals with IDD with funding up to $40 million in total costs.

DR. HOWERTON: Howerton, approved.

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: Thank you. Thank you, Russ and Barbara, are you willing to be a second?

DR. McNEIL: Sure.

CHAIRPERSON GOERTZ: Thank you. Any
further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, well once more, we’ll do a voice vote. So all those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]

CHAIRPERSON GOERTZ: All right, the motion passes. Thank you. Now I'd like to introduce Dr. Nora McGhee, to present on our final targeted PFA.

Hi Nora.

DR. McGHEE: Hi, good afternoon.

So extensive stakeholder interest and evidence gaps led PCORI to undertake an update to our 2012 Agency for Healthcare Research and Quality Systematic Review on Non-Surgical Treatments for Urinary Incontinence, or UI, in women.

The update funded through our research partnership with AHRQ was completed in 2018. The
updated review found good evidence for the efficacy of many non-surgical interventions for UI. However, important evidence gaps remain, particularly related to direct comparisons of the options. Building on this and other prior work and in recognition of the high prevalence and burden of UI to U.S. women, we bring forward this request for your approval to develop this targeted PFA.

Next slide please.

We propose that the PFA focus broadly on the comparative effectiveness of non-surgical options for women with UI.

Next slide please.

I’ll run through the basic requirements we're proposing. Participants can have either of the three main types of UI: stress, urge, or mixed UI. Applicants can propose to compare two or more of the non-surgical treatment options; alternative systems approaches will also be welcomed.

Investigators should include at a minimum, both functional outcomes and adverse events.

We're requesting a total of $40 million be
allocated to this PFA, which could fund up to eight studies. We anticipate posting this announcement for two cycles, but this will depend on the number and type of applications received. We will allow studies of up to five years in duration. As always, study duration should be appropriate for the design as justified in the application.

And now I will turn it back over to our Board chairperson for any questions, and to call for the vote. Thank you.

CHAIRPERSON GOERTZ: Thank you so much, Nora.

Can we start out with -- I know Mike, if you want to ask your question again.

DR. HERNDON: Yeah. So, can you just explain what your understanding is when we talk about surgical interventions? Obviously there's urethra slings and all sorts of, you know, periurethral-type procedures.

Would we intend or expect to get some potential, you know, applications that would include sacral nerve stimulators?
DR. McGHEE: Sure. So I can address that.

So the first items you mentioned, those are clearly surgical treatments, but the implementation of the nerve stimulators, we would consider those non-surgical, and they were considered in the updated systematic review as such. So those would be allowed.

DR. HERNDON: As non-surgical?

DR. McGHEE: As non-surgical. Correct.

DR. HERNDON: Okay. Thank you.

DR. McMURRY-HEATH: Sorry this is Michelle. Was there a reason that you guys settled on only non-surgical?

DR. McGHEE: The bulk of the prior work that PCORI has done was in that area, so we felt that was appropriate area to start with, we might want to address the surgical treatment in a later announcement once we do further background work in that area.

The existing systematic review by AHRQ was on non-surgical treatments, so that's what was updated a few years ago, and there were clear gaps
that were found. So we wanted to issue the
announcement and start research in that area first.

   DR. McMURRY-HEATH: Okay, just note that

the surgical interventions have really progressed
since 2012. So it's a different kind of landscape
in terms of treatment choice.

   DR. McGHEE: Yeah, so that may point to us

needing to do some background work in that area to
look and see where the gaps are, it sounds like
maybe new areas to explore there. Thanks.

   CHAIRPERSON GOERTZ: Thank you. Any other

comments or questions at this point for Nora?

   DR. HWANG: Christine, I have a question.

This is Connie.

   Thanks. Hi. Nora, in the Board materials,

there's a lot of mention of collaboration with AHRQ
on this, and I think there's mention of a concurrent
funding announcement by AHRQ. So I just wanted to
get a sense when it notes here that there will be
coordination between PCORI and AHRQ. If you could
give a little more detail or insight on that I think
that'd be helpful.
DR. McGHEE: Okay, sure. When we mentioned that previously, it was really to indicate there's been a lot of prior collaboration with AHRQ in this area, and there is the announcement out from them right now for dissemination and implementation work in this area.

And really it was just the intent that as we develop this PFA to ensure that our announcement clarifies the research areas that we'd like there to be focused in, and how those are distinct from the AHRQ announcement. That's really what we were referring to.

DR. HWANG: Great, thank you that's helpful. It seems like it's going to be important not to, you know, have unnecessary overlap, and try to be as synergistic as possible. So I appreciate it.

DR. McGHEE: Yeah, certainly. Yeah, we view them as complimentary and we want to just make sure that's clear in our messaging.

CHAIRPERSON GOERTZ: Thank you. Any other comments or questions?
CHAIRPERSON GOERTZ: All right, well thank you very much, Nora.

DR. McGHEE: Sure. Thank you.

CHAIRPERSON GOERTZ: All right. I am going to then ask for a motion to approve the targeted PFA on non-surgical interventions for women with urinary incontinence with funding up to $40 million in direct costs.

DR. HERNDON: Motion to approve.

CHAIRPERSON GOERTZ: Is that Mike?

DR. HERNDON: Yes.

CHAIRPERSON GOERTZ: Okay, thank you. And can I get a second?

DR. McNEIL: I second, Barbara.

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

[No response.]

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

All those in favor, please say aye.

[Ayes.]
CHAIRPERSON GOERTZ: Opposed?
[None.]
CHAIRPERSON GOERTZ: Abstentions?
[None.]
CHAIRPERSON GOERTZ: All right, the motion passes. Thank you.

DR. MEYERS: Dr. Goertz, this is David Meyers. I was just hoping you would let Karin Rhodes take my place, as I need to leave for a bit.

CHAIRPERSON GOERTZ: Absolutely. Thanks for letting us know and welcome Karin.

DR. RHODES: Thank you.

DR. MEYERS: Thank you all.

CHAIRPERSON GOERTZ: All right. I just want to also thank the staff and the SOC, I recognize the tremendous amount of work that has gone into putting together these PFAs and I'm, you know, very excited to see them turned into applications that we can look forward to finding, so thanks. Thanks to everyone for your hard work on this.

Now I’d like to turn the agenda over to

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Nakela, to talk about candidate topics for PFA development.

DR. COOK: Thank you Christine. So, next Board meeting, we're going to be talking about a set of candidate topics for targeted PFA development for our future cycles that will take us through 2022. And so, I just wanted to kind of tee that up for our future discussions,

Let's go to the next slide.

So under this expedited and enhanced process that we're undertaking to identify areas for targeted PFA development while our strategic planning is underway, we anticipate bringing to the Board at our next meeting a set of topics for PFA development for future cycles. And we know that in bringing the full set to you early on, that they're going to be at the idea stage. And so, we're going to come back to the Board with each targeted PFA with a recommendation from the SOC for consideration of approval, after they've gone through further development.

And the set you'll be looking at would be

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in addition to things such as targeted areas for COVID-19 or maternal morbidity and mortality or intellectual and developmental disabilities topics. So we have work going on and those kind of three high priority spaces, alongside the development of a larger set of topics.

We also anticipate that these topics will be really developed for that full range of options of different types of PCORI funding announcements, and that we want to make sure that we're still responsive even though we'd be thinking about a set in a prospective way. We want to be responsive to development.

For example, if there's a development with in a topic area that's proposed that we would still be able to incorporate it in the time that that topic is ready for solicitation announcement. We also want to still be responsive to emerging topics that may arise, and I believe this is what Michelle McMurry-Heath was raising.

We also want to make sure that we're thinking about the learnings from each of our PFAs,
as we're going through a process, it's a little bit different in terms of developing PFAs.

And I think all of these things were raised at a prior board meeting in terms of allowing some of that nimbleness and responsiveness to the emerging needs.

Let's go to our next slide.

So some of the things that we see as potential advantages and additional benefits of the Board approving a set of topics for development for PFAs for several cycles, versus looking at them one at a time. Instead it's going to allow for some longer-range perspective planning, both by PCORI as well as by the research and stakeholder community with advanced notice the community could even generate a greater number of applications in response to our PCORI funding announcements and more fully develop applications. And within the PCORI, we have an opportunity with lead time to really enhance what's needed for merit review. It also could facilitate more rapid development by focusing our concentration area and our focus at PCORI on a
fewer topics over a certain period of time.

The approval of the set will still allow for us to accommodate those emerging and critical, time critical areas into any of the cycles that is warranted. And we really do look forward to further discussion with you in April, when we bring that full set to the Board for consideration.

So this is just to kind of whet your appetite for what's to come and follow up from what you're seeing now for our Cycle 2 2021 topics and what we're thinking about for that set that will take us through 2021 and into 2022 while our strategic planning efforts are underway.

So I'll turn it back to you Dr. Goertz in case there's any questions or discussion that people would like for me to chime in on before we move to our final agenda item.

CHAIRPERSON GOERTZ: Thank you so much.

Any comments?

DR. SIGAL: Christine -- this is Ellen.

I'm sorry I'm not on video.

So I think this is really important but,
you know, with the urgency that we're seeing, and
the opportunities in COVID. I just hope that we can
be a little bit more explicit about where we can fit
in and what we can do in outreach to, whether it's
the NIH, FDA, or other -- CDC, to see where our role
could be in there where we can enhance some of the
work that is going on. We have PCORnet, and we
certainly have a distribution of sites all over the
country, and it would be interesting for us to bring
back some very specific proposals.

Because, you know, we are not understanding
post-COVID. There are huge opportunities in vaccine
hesitancy, in diagnostics and, you know, all sorts
of things.

Yeah, and I know we are working a little
bit on coagulopathy and some other things but I
would hope that we could come back with some
specific proposals that we could act on that would
be enhancing the value of what others are doing or
complimentary.

DR. COOK: And I was just going add,
Christine, we certainly can come back and have a
more robust descriptor of all things that are going on and things that are being planned related to COVID-19.

CHAIRPERSON GOERTZ: Thank you. I think that would be helpful to have an overview of everything that we're doing in that space.

DR. McMURRY-HEATH: So Nakela to that --

DR. SIGAL: Or can do. There are things that we may need -- there may be new opportunities now.

DR. COOK: Absolutely.

CHAIRPERSON GOERTZ: Thank you.

I've got Michelle and then Alicia

DR. McMURRY-HEATH: So to that point, you know, all of the PFAs that we just approved are very sound and they make a lot of sense, but I just kind of wonder if the scale of our response to what is staring us in the face has really been broad enough and I know there are a lot of different efforts going, but there's some key questions that have to be answered in a very tight turnaround like, how the vaccine is behaving in the populations that are
getting it and how the variants are interacting.

There are just so many huge health questions up here that I just wonder if we couldn't be using the vast resources that PCORI has at their disposal, to really shine a new light on those in a very proactive way.

Alicia, I'll turn it over to you.

DR. FERNANDEZ: Thank you, it's really good to hear people's thoughts on this.

I think one of the challenges for the staff and ultimately for the Board will be figuring out PCORI's contribution in this space. The NIH has several extraordinarily large, well-funded RFAs out on long COVID, for example. And both NIH and CDC are also working very hard in the vaccine uptake space. [Inaudible] just to say that I think that we, PCORI, shouldn't be doing a great deal of work in here, but just think, I just think -- I just think it'll be important for us to think through where -- where the PCORI niche is, in terms of -- so that we can deploy our resources in an additive -- in an additive way.
And I for one really appreciate hearing what different Board members are thinking about. I think it's -- it's really important. Thank you.

DR. SIGAL: Yeah, Alicia, I’ll add one more thing and then I promise I will be quiet. The COVID accelerator, which is where we're aggregating information on drugs, diagnostics, treatments, and now vaccines; is a place that we can play well with it because you're right, there's a lot going on and there's a lot of money allocated to the NIH, CDC, and FDA, but there are spots were our database in our population could be very helpful so we should try to work with them and see where the gaps are, that could be very important.

DR. FERNANDEZ: I couldn't agree with you more. For example, PCORnet could be used in COVID research in a very fundamental way that could be very different, both in terms of diseases, and also in terms of getting estimates on a local prevalence and also in terms of the vaccine, and at the same time, the PCORI is really special focused on patient-centeredness.
I think that is truly important here. So, I think, our long-standing focus on impact on caregivers and families, and so on is very, very important.

So I think we have a lot to do, and I'm very happy to hear this, to hear how aligned we all are in trying to support the staff to do this, this really difficult work in a very rapidly moving funding environment.

CHAIRPERSON GOERTZ: Great. Thank you, Alicia. Kathleen.

MS. TROEGER: Yeah, just a quick comment and I want to underscore Ellen's interest, and at Alicia’s support for the utilization of PCORnet. It’s similar to look for ways, for synergies and ongoing opportunities within the networks to support both mission, a little bit broader outside of COVID. And then certainly, direct to COVID, and perhaps continue the work that accelerator project has done. It really does utilize PCORnet as part of the mechanism of machinery to conduct research.

CHAIRPERSON GOERTZ: Good comment. Thank
Chris Friese, I believe you had a question or comment.

DR. FRIESE: Sure, I don't want to take a lot of time. I think we're all sort of, I'm hearing a lot of consensus here and I think the sweet spot is to find how we can be helpful and additive. And to that point, I guess I don't understand. Do we have senior program staff or a program official who is sort of heading up the COVID-related portfolio? And if so, is that person sort of regularly corresponding the appropriate other agencies? Or how are we, I guess, structuring that response? Because I agree with Michelle. I mean I think we have to really kind of, you know, and I said this at the SOC last week, I think we need to be very bold but we also need to be in a lane that's helpful.

DR. COOK: Yes. Maybe -- it may be helpful for me just to comment on a couple of things which is -- one is that we have been having pretty robust discussions with NIH, CDC, and FDA on a regular basis and have several collaborative efforts that
are underway. And so we will -- that's why I was saying it'd be great for us, I think, to come back and give you a sense of the breadth of some of those activities. And internally we have organized, what we've been calling our COVID Connect Team. It's basically a team that's co-led by some of our leadership from PCORnet as well as from our Research and Engagement teams, related to COVID-19.

And so, we've started to focus on the efforts that we're trying to move forward across all the spaces that PCORI covers, and I believe we were going to make sure that you also have -- just available to you, our fact sheet around several of the things that we have going on in the space related to COVID-19. Many of them have been presented at different times at a Board meeting and so I feel like bringing it all together in a more of a comprehensive presentation and discussion could be quite beneficial for the Board based off of what I'm hearing here.

And some things, you know, are still ahead of primetime for announcement but we definitely
think that when those are ready that they would be
great to bring to the Board as well.

DR. McMURRY-HEATH: Just one last
suggestion, given the prominence of this issue and
the health disparities that it's really
highlighting, Perhaps it could have a standing item
on COVID at our Board meetings, so we could have a
sense of the progress and where we all can plug in
and help, because I have researchers who reach out
to me trying to get a sense of the comparative
effectiveness of various vaccines or therapies or
what happens on secondary infections and I know a
lot of these things aren't being covered by either
FDA or NIH.

DR. COOK: Okay.

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

[No response.]

CHAIRPERSON GOERTZ: All right, this was a
good discussion. There were definitely some things,
Nakela, to take back and think about a little bit
and bring back to the Board I think.
DR. COOK: We'd be happy to. Thank you.
Thanks for all the input.

CHAIRPERSON GOERTZ: Thanks. All right, I think we're going to go into our final agenda item then. So, Nakela if you could continue on.

DR. COOK: Certainly, and so we're pleased to transition to talk about approving the principles for the consideration of the full range of outcomes data in PCORI-funded research, and we can go to our next slide. I'm sorry we can go back.

So the principles that we're bringing forward for consideration of approval today have been discussed with the Board and Board committees on an iterative basis, and so now we're at that stage of considering them for Board approval. And we first reviewed the principles with the Board when they were draft back in September of last year ahead of posting them for public comment, and we've engaged in substantial efforts to seek stakeholder and public input.

And following this input at the February board meeting, the Board reviewed high level themes
from the input that we've received in its December meeting and then more detailed synthesis of the input, some of which was really relevant to reflect on the principles and some that we thought was really relevant for upcoming implementation plans. And so the proposed principles reflect a lot of careful consideration of the stakeholder and public input as well as the comments of committees and the Board and are now presented for a Board motion to approve.

At this point the Board's focus is really on the proposed principles, which capture the key substantive issues that PCORI applicants and stakeholders would need to be addressed to move forward. And if we have potential edits to the principles and issues that require change to the principles because they're so substantive in nature, we're going to need to make sure we capture that exact language in an amended motion, so I just wanted to alert the Board to that.

And we also wanted to remind the Board that while we're discussing principles today, the
principles do lead to the formulation of guidance for applicants as well as other products as part of our implementation plan. And those products are where we're going to be able to reflect a deeper level of specificity, guided by some of our next steps in our processes including our ongoing engagement with the Methodology Committee and our Stakeholder Advisory Committee.

Comments that you may have related to the details that may be helpful for those implementation plans, we're going to note those today and will inform our implementation planning, but we'll also some have additional insights that we think will emanate from our implementation activities themselves, and we'll look forward to continually revising our approaches.

So I'm going to ask that Dr. Andrew Hu, our Director of Public Policy and Government Relations presents the principles for consideration for your approval. Andrew, do you want to go ahead?

MR. HU: Yep. Very good. Thanks Dr. Cook and good afternoon everybody. So for this session,
as Dr. Cook mentioned, we will be presenting for approval, the principles for the full range of outcomes data and PCORI-funded research.

Next slide.

As a reminder, here is an overview of the PCORI’s implementation proposal and the three pillars of activity. Pillar one is where most of the activity has taken place, and is nearly complete. This includes the development and finalizing of the principles that describes how the PCORI interprets the law. The inclusion of initial set of guidance and FAQs as part of Cycle 1 2021, and the potential development of additional guidance as needed for future funding cycles.

Pillar two is focused on updating methods and standards, as we are staying coordinated with the Methodology Committee on this effort.

And pillar three, will be a more public policy-focused activity, looking at opportunities where PCORI can advance and support discussions related to a patient-centered approach to addressing healthcare value and rising healthcare costs.
As part of our transparent and deliberative approach, we have laid out a robust plan to collect public input on the principles. This included a 60-day public comment period, two PCORI-hosted webinars, and numerous discussions and meetings with individual stakeholders that informed the initial development of an input on the principles. We also sought input from PCORI’s advisory panels, the Methodology Committee, as well as from the Board during presentations in December and February.

We shared this slide with the Board at last month's meeting so we won't go through it in too much detail again. But it shows the overarching themes and potential considerations we received from our analysis of the public comments. And as Dr. Cook mentioned, you know, the important thing to note here is that through the broad input that we received, the implications for PCORI fall under two categories: considerations that inform the revision of the principles and considerations for additional
activities or additional implementation activities and goals.

So the next few slides will showcase what we heard from the comments, and how we revise the principles, and what we may consider for additional implementation activities.

Next slide.

Principle one focuses on identifying outcomes important to patients and caregivers. From the comments we heard support for maintaining principle one is central to PCORI’s work, and that the PCORI should ensure patient and caregiver engagement in our research studies and that we prioritize cost burden and economic impact measures that are important to them. And also to consider ways to monitor unintended consequences from the use of this data,

Based off the input, the principles further emphasize the importance of patient-centeredness in our funded research, we note that the importance of engagement when identifying outcomes, and we clarified that when we referenced the full range of
outcomes when we're talking about relevant health outcomes, patient reported outcomes, in addition to the burden economic impact outcomes.

Next slide.

Principle two focuses on identifying outcomes important to stakeholders. Here, we heard the need to facilitate continuous engagement of a diverse set of stakeholders and provide opportunities for them to engage at individual project levels. Based on the input, we did not need to make significant changes to the principle itself, but we did clarify certain examples of outcomes that may be important to patients, caregivers, and stakeholders that were identified from the public comments.

Next slide.

Principle three focuses on the collection of data as appropriate and relevant. Commenters across the board agreed that the collection of burden and economic data is important, but also that it should not be a requirement across all PCORI studies. We also heard that it'd be helpful for
PCORI to identify outcomes we may want prioritized research, noting that any of those outcomes should be appropriate and relevant, and that PCORI factor in social risk factors when considering costs and economic impacts. So in the principles we clarify that PCORI encourages the collection of this data, but will not require it.

We also provided some examples of where the collection of data is appropriate and relevant and further emphasized the importance of engagement, when identifying outcomes. And we specifically highlight social risk factors and social determinants of health as an area of particular interests for PCORI when considering costs and economic impacts.

Next slide.

Principle four focuses on the conduct of certain types of economic analysis, similar to the request for additional clarity on what are appropriate and relevant outcomes. We also heard the need for clarity on the types of analyses for PCORI will support. And even with broad support for
the collection of burden and economic impact data, the commenters still noted strong support for the prohibitions from PCORI authorizing law that prevented PCORI from developing and employing a dollars-per-quality adjusted life year threshold, and maintaining PCORI’s policy for not funding cost effectiveness analysis.

So in the principles we clarify that certain analysis will be allowable, either in the course of a PCORI-funded research study, or independent of one if appropriate. But note that the limitations from our authorizing a law that prohibited PCORI from developing or employing a dollars-per-quality adjusted life year threshold or from conducting cost-effectiveness analysis still remain. But we do clarify that those limitations stop at PCORI-funded research, and that researchers can seek additional funding outside of the PCORI, if they choose to conduct further analysis.

Next slide.

Beyond the principles, we are considering additional implementation activities that were
identified from the public comments. These include undertaking additional steps to further ensure patient-centeredness across PCORI’s work, including and looking for opportunities to advance and support discussions related to a patient-centered approach to rising healthcare costs and value, to support ongoing patient and stakeholder engagement. We will also build on our existing engagement work, and perhaps consider additional convenings to directly connect stakeholders with researchers to help identify appropriate and relevant outcomes.

And to further support future applicants and our investigators, PCORI may develop additional guidance as needed, and will work with the Methodology Committee to develop and update the methodology standards related to the collection of cost burden and economic impact data.

Next slide.

So to bring us back full circle. Here again, are the four principles for the consideration of the full range of outcomes in PCORI-funded research, then address the goals of identifying
outcomes important to patients and caregivers,
identify outcomes important to stakeholders,
providing criteria for the collection of this data,
and considering the conduct of certain types of
economic analyses.

Next slide.

So with that I'll turn it back to Dr. Goertz to facilitate any discussion and are happy to answer any questions. Thank you.

CHAIRPERSON GOERTZ: Thank you so much, Andrew and, and I want to thank you for the tremendous amount of work that's gone into putting these principles together and also thank you for the many times you -- the way that you've kept the Board informed, you know, throughout this this process. I think that's been incredibly helpful as we consider the motion before us today, to have seen this evolve over time, you know, based on the information that you've presented to the Board as you worked through, to get us to this particular point.

So does anyone have any questions or comments for either Andrew or Nakela? Mike.
DR. HERNDON: Yeah. So Andrew through all of the conversations and meetings and all. What, what do we really feel like will be the research community uptake for this, you know, elaborate allowance that kind of gives this broader range of outcomes, including the burdens and the economic impact?

Now, I don't know if I asked it very eloquently but if you got it, can you answer it? If you didn't get it, I can clarify.

MR. HU: Yeah and I want to let Penny and Joanna, and Bill, the rest of the team who really worked with me on this effort jump in as well.

But, you know, I think the comments that we got, you know that this is a huge addition and --

DR. HERNDON: Right.

MR. HU: -- for PCORI here, which is really helpful for the community. I think we're already hearing from a lot of investigators who want to do this work and we're getting questions on, you know, what's allowable and what's not. So those are the things that we are already trying to consider in the...
And I think for the most part of the comments that we got from the stakeholder committees is really positivity and willingness and interest in how we're going to work on methods, standards, and guidance.

And as the Nakela mentioned, and as we're already trying to think about, how can we move toward that phase? That really stem from the principles themselves. And I think that's where most of the interest is aligned, especially around identifying what are some of the patient-centered costs, you know the indirect costs that aren't traditionally measured or not as frequently captured in research or in practice. Those are some areas where we heard, saw support for PCORI to kind of jump in and play a leadership role.

DR. HERNDON: And I know at the EDIC, to follow up if you don't mind. We had some discussion about potentially doing a kind of toolkit for researchers who want to include this type of work, can you just kind of give the Board a bit of an idea
of what we're thinking there and when that might be implemented?

MR. HU: Yeah, and if Kristin Carman is on the line, our Director for Public and Patient Engagement, she can definitely chime in too, but one of the things that we considered based on the comments we heard was, you know, we really -- the stakeholders, both from the patient, caregiver, and stakeholder communities all wanted to be engaged in this work, both at the system level and institution level, but also at the project level.

So one of the things that we've already done in our work, I know Kristin has done a lot of work leading this effort is building together these toolkits to support researchers, and to engage with the community. So I think this is an area where we can do more of that, I know a little work has already been underway on some of these proposals.

I'm not sure Kristin is here but we can definitely provide more input in background on that information.

DR. HERNDON: I was kind of asking just as
a way to kind of make sure that the Board understood that, you know that was, and I'm not sure what all committees have heard the presentation, we heard it, EDIC, a couple of weeks ago so I just wanted to clarify that, I do think that's important. And I do think that it will be helpful to the research community, as we go forward with this addition. Thanks.

CHAIRPERSON GOERTZ: Thanks, Mike. All right. Sharon welcome. Good to see you. You’re on mute.

DR. LEVONE: Sorry. I'm sorry to miss the first part of the Board meeting.

Andrew, could you go to the previous slide, can you go back to the previous slide?

Yeah. This is offered -- sorry about the lateness of my observation but in principle three as a friendly amendment, whether we could expand potential burdens and economic impacts of treatment options and interventions that must be appropriate and relevant to the clinical aims of the study. And I add that only because some of the interventions

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that we study are not just clinical interventions, they are environmental and system interventions, and so just expanding the language to signal that we’re not limiting this to drug versus drug research.

MR. HU: Thanks Sharon. That’s definitely helpful. That's definitely not the intent to limit it to just drug versus drug -- we are trying to take a holistic view of this, and I may have to defer a little bit. Nakela, I see you jumped on because I know we, if we have to make tweaks to the language itself; it takes a little bit more effort.

DR. COOK: Yeah, one of the things I was just going to ask for may be a bit of clarification, is it treatment options and interventions or just intervention Sharon that you --?

DR. LEVONE: And.

DR. COOK: And. One of the things we're trying to also think about is making sure if we want to make an amendment to the principle that we're capturing the exact language so we wouldn’t have to amend the motion. So I wanted to make sure I was understanding.
And that to me is kind of as -- it was intended but maybe me is a substantive comment if it's not signaling that and so maybe one of the things we'd have to consider for an amendment to the motion.

DR. LEVINE: Sorry to gum up the works.

DR. COOK: No, we're capturing it.

CHAIRPERSON GOERTZ: Good. So, one option that we have is to -- for that to be a friendly amendment at the time that we make the motion.

All right. Bob.

DR. ZWOLAK: Yes, thank you Andrew. That's a very nice presentation and these are excellent principles but they are principles and I want to not only emphasize what Mike said about the toolkit, but the details of the toolkit and examples of what works and what's out of bounds. Examples of offerings of the Methodology Committee are really important.

And finally, this is so new and so important; I would hope that it would be a recurring an agenda item for updates at the Board level.
because this really is groundbreaking. And I think that we all want to understand this as it rolls out. So congratulations and please come back to us frequently with updates and any new information.

MR. HU: Yeah, thank you and I definitely heard the comments and we are happy to provide ongoing updates to inform the Board as you continue with the implementation activities, including the development of guidance and working with the Methodology Committee and updates on the progress there.

DR. LEVINE: Thank you.

CHAIRPERSON GOERTZ: Eboni.

DR. PRICE-HAYWOOD: Just to follow up on the inquiry about Methodology Committee. My question is, you know, Board members have expressed concerns about the research method background of staff and things that we need to do to become more rigorous in the representation of that, and especially as it relates to cost measures and economic analysis. I guess my -- I don’t know if this is a premature question, but was wondering, is
part of the strategy, not only to engage those stakeholders who may use certain types of information but in building your toolkit and working with the Methodology Committee, are we looking to bring in experts in certain areas representing those perspectives who have done research in a certain area?

And I'm asking that question because I worry from the researcher’s perspective about seeing a list of things that you could measure, but not necessarily using them in the way we are or analyzing them in a way that really is meaningful say to a healthcare system or provider or whomever. I don’t know if that question makes sense but it's more about the methodology.

MR. HU: Thank you. It does and, you know, one of the things that we heard and we're obviously working on and centering on is, you know, how can we, PCORI, support the Methodology Committee and host some of these convenings or bring together additional meetings as necessary.

One thing that that we do know will take
place for any of the work that the Methodology Committee does update it does update its standards, and we'll go through a public comment period as well, before coming back to the Board. So it's a concern that we are trying to address and thinking about as well.

And one thing that I -- PCORI is working on establishing a Resource Center, as well, to help support PCORI’s work, and as well as support the needs of the Methodology Committee, and address some of these issues.

CHAIRPERSON GOERTZ: That's great. Any other comments or questions? Kate.

MS. BERRY: Yeah. Just a quick one and Andrew, thank you so much and I know that you guys have done so much work to engage stakeholders on this process. You know, given the questions and the comments, so far I just wonder if there is something in-between the principles and how do we operationalize that that we need to flesh out further and I know that you're trying to get approval today on these, but I hate to say it but
they're, you know there's devil in the detail right. And this is so complex.

So, you know, just a question there.

MR. HU: No thanks, Kate for the question. And you're right, these aren't meant to be principles and they will inform the development of guidance and further work so there's a step down from here.

CHAIRPERSON GOERTZ: Andrew, what will that process look like? You know, sort of what are next steps after this.

MR. HU: Yeah, so we've already kind of worked in and again, I'll ask Joanna and others to chime in here as well, but we've already kind of developed at least an initial set of guidance and FAQs that were included in Cycle 1 2021’s PFA. As we learn more and as you can see the work that's coming in to the LOIs and this process, we can develop further and additional guidance as needed to kind of address some further clarity, questions, provide a little more detail as we learn more about what are the types of things that our applicants are
looking for or asking.

We're working with our science team, the merit reviewers to kind of flag this so they're prepared to answer and look at applications appropriately. But these are some of the things that we're still working on right now, as we move forward to the next phase of this, which is the development of additional guidance. And obviously working with the Methodology Committee to update any methods and standards on that on that front as well.

CHAIRPERSON GOERTZ: Thank you. That's helpful. Any other comments or questions? Mike?

DR. HERNDON: Christine, before we make a motion or an amended motion, I just want to go back to Sharon's input and make sure that I was kind of understanding.

I understand, I think what Sharon was getting at there may be a difference between treatment options and interventions in her mind but I think in Nakela’s -- if I understood Nakela correctly, that treatment options would include both interventions, and there may not be a need for the
amendment or they may be. I'm just -- before we get
to the voting phase I just want to make sure that
the Board is clear on whether we really want to make
that amendment or consider it complete as is.

CHAIRPERSON GOERTZ: I'm wondering if
maybe, you know, Sharon if this would meet the
spirit of what you're trying to do and is to replace
the word “treatment” with ‘health options.” Because
I think what Sharon is trying to say is that she's
certainly better at speaking for herself.

DR. LEVINE: I don't want to hold up a vote
on this, voting on the principles is important so
that the rest of the work can proceed and I think as
we move on to the next phase of this, we can -- in
government, they say, you know, bad legislation can
be sometimes fixed by good regulation.

And so, as we as we go to the next step in
terms of providing guidance to researchers, we can
make clear that it's more than just clinical
treatments, that this encompasses the full range of
interventions that PCORI has studied and will
continue to study.
CHAIRPERSON GOERTZ: So are you comfortable with leaving the language as is for now, in that case?

DR. LEVINE: Yes, I am.

CHAIRPERSON GOERTZ: All right. Great.

Any other comments or questions?

[No response.]

CHAIRPERSON GOERTZ: Okay, before we take our --

DR. McNEIL: I'm sorry, Chris --

CHAIRPERSON GOERTZ: Barbara.

DR. McNEIL: I'm sorry. I just caught on to the difference that Sharon, I think, was trying to make with that change. I hadn't gotten it at first.

Sharon, I think you may be saying is that not only are we talking about the options that patients have when they undergo a treatment, but that we are also studying the kinds of changes in the settings, the interventions in the settings, under which those treatment options can take place.

DR. LEVINE: That's exactly right.
DR. McNEIL: So the treatment options alone -- I'm sorry I didn't quite catch it the beginning. Treatment options alone does not capture, I think what we're getting at. We're trying to look at the totality of experiences that a patient has, and those include both the actual intervention, the medical or surgical intervention that the patient has, as well as the setting in which it is accomplished. And for example we've talked about medical decision-making, informed medical decision-making. That is one of the things that we've studied in the past.

And that is not a treatment option, it's a setting or it's something else, in which the treatment changes are embedded.

So I think Sharon is onto something, but I'm not sure that we have the wording quite right and if we don't, I think, if that's where she's going, treatment option alone doesn't capture her sentiment.

Do I have that right Sharon?

DR. LEVINE: Yeah. You got to what I was
trying to -- the point I was trying to make better than I did Barbara. And I guess I am okay though with making clear in supporting documents what we intend here. And this isn't limited to the actual therapy, but both the setting community versus hospital versus home, kind of thing. There are multiple interventions that we study and the collection of data on the burdens and economic impacts of any of the interventions we study must be appropriate to the aims of the study, I guess.

DR. McNEIL: Sharon, I think a principle is a principle and it doesn't get refined by further subdivisions. I mean, that should be an overarching concept, if I'm understanding what a principle is. So, and I don't think the analogy of government and regulations quite fits here, because treatment options is very, very specific. It’s Drug A versus Drug B or a urethral sling or a drug.

What you're saying is, is it an in-home physical therapy or is outpatient physical therapy, or was an ambulatory blood pressure monitoring or was in-office monitoring, or something like that.
So I really think they're different and I don't think that they should be further explicated by a little footnote in the next document.

So it could be the impacts of treatment options in their settings?

MR. HU: So, if I may jump in real quick. I know the language of the principles is obviously what's on the slide right now, in the Principles Document itself there is obviously more context to each of the other principles and for this one, pulling directly from the language, and I hope this, I think it kind of addresses the issue that is being discussed.

But the language is, “PCORI encourages investigators to capture appropriate and relevant cost burdens and economic impacts associated with the impact of an intervention for two or more alternative approaches that are studied within the context of CER.” So I think the intent of the principle itself does try to be holistic, in the sense of what we're capturing in this discussion and in the course of what PCORI studies.
DR. LEVINE: That language that you read is exactly what I was trying to get to.

DR. SIEGEL: Yeah, I think that the issue is it didn't quite make it into the language of the principle itself. It's very much in the Principles Document.

MR. HU: Yes.

DR. SIEGEL: I'll defer to you Sharon on whether you think the language of the principle itself really should be tweaked or whether we can rely on the larger document.

DR. McNEIL: This is Barbara; I think it should be tweaked.

DR. RHODES: This is Karin Rhodes; I agree that it should be tweaked slightly. And what about economic impacts of intervention options?

DR. McNEIL: Oh, that's better thing.

CHAIRPERSON GOERTZ: Yeah, I was thinking that same thing.

DR. LEVINE: Yeah, intervention options must be appropriate and relevant to the aims of the study.
DR. McNEIL: That would work.

CHAIRPERSON GOERTZ: So Andrew and Nakela, do you have any concerns about making that change?

DR. COOK: That was where I was going when I first heard Sharon's comment, was wondering if interventions would be more considered all inclusive if treatment options wasn't signaling that.

CHAIRPERSON GOERTZ: Is there anyone that feels uncomfortable with making that change? Mike?

DR. HERNDON: I was just going to say, when I think of intervention, I agree with you Nakela and I'm especially thinking about social determinants, you know, when we talk about interventions with community health workers and peer navigation and that sort of thing, and I think interventions gets added, and I think when we get to the motion phase, just interject that in place of treatment and I'd be good with that.

CHAIRPERSON GOERTZ: Is there anyone who does not feel comfortable with that because if, then, I think we can amend the motion. So in fact, to that language so that, you know, so that we don't
have to do anything further at the time that we make
the motion.

    Any concerns about moving forward in a
direction? Andrew, are you okay with that?

    MR. HU: Yep. I think we're okay.

    CHAIRPERSON GOERTZ: Okay. All right.

Then what I'd like to do is go ahead and move
towards a motion and a voice vote. Just before we
do that for record keeping purposes, I wanted to
note that James Schuster had to leave the call and
is not in attendance, and obviously Sharon Levine is
now in attendance. So --

    DR. SCHUSTER: This this is James. I'm
back.

    CHAIRPERSON GOERTZ: Okay, great. Great,
James. Okay, James is back Sharon is back, we still
have a quorum, so I think we're in good shape. And
so --

    MS. WILSON: One more. Michelle McMurry-
Heath had to leave the call, I just wanted to put
that in there.

    CHAIRPERSON GOERTZ: Okay, thank you. All
right. So what I'd like to ask then is for a motion

to approve PCORI’s principles for the consideration

of the full range of outcomes data in PCORI-funded

research, including the amended language to replace

treatment options with intervention options in

principle three. So that’s the motion that I’m

looking for.

DR. HOWERTON: This is Howerton, so moved.

CHAIRPERSON GOERTZ: Howerton. Okay, thank

you. Can I get a second please?

DR. HERNDON: Mike, second.

CHAIRPERSON GOERTZ: Okay, Mike. Thank

you. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right, in that

case I'm going to ask for a voice vote. All those

in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[None.]

CHAIRPERSON GOERTZ: Abstentions?

[None.]
CHAIRPERSON GOERTZ: All right, the motion passes. Thank you everyone. Thank you Andrew. Great, great work we really appreciate you and for you and your entire team.

Nakela, I am going to -- I'm going to turn the meeting back to you then for any closing remarks that you might have.

DR. COOK: Thank you. And thanks for a great meeting today. It's actually the first meeting that we've had, where we've had to go through so many slates all together and provide that type of context for the slates to facilitate the Board's deliberation. So I hope you found that helpful in terms of getting some overviews that allowed you to really see how things are aligning with our commitment plan.

I also thought it was just a rich group of slates that you looked at from targeted PFAs, the additions to the broads and the D&I solicitations, and we also had some really rich discussions around the three PCORI funding announcements for the next cycle, for Cycle 2 2021. And we're seeing momentum...
around those two priorities, from our reauthorizing legislation and also saw some momentum around an area of urinary incontinence that we've been working in, and heard the comments about the importance of thinking about surgical approaches in addition to non-surgical approaches and approaches when we're thinking about urinary incontinence in the future.

I also appreciate the great discussion about the niche for PCORI related to priorities for COVID-19 and we look forward to coming back to talk more fully and comprehensively about some of the activity going on in that space and I mentioned some of our ongoing work with other federal agencies and hopefully we'll be at that point where we can discuss some of that more publicly at our next meeting where we can tee that up for discussion.

Also, I just wanted to mention that in addition to some of the work that you've seen related to COVID-19 with the enhancements in the new awards and the solicitations we had with our engagement and dissemination and implementation activities for COVID-19. We also are working on

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another targeted funding announcement under our previously approved authorities that would be fast tracked and we're looking forward to talk with you further on that.

And we also had special areas of emphasis in our broad announcement in Cycle 1 2021 related to COVID-19. So we will be looking at slates from those solicitations at future board meetings.

And I heard the importance of some recurring updates at the Board level related to our COVID-19 activities.

And then lastly, related to cost principles, again, I want to commend our hard-working team that has really engaged, I think all of you and the stakeholder community very extensively and in a remarkable way to bring the principles that you saw today to consideration for your approval and glad that we're moving forward on those and really look forward to this next steps. So working with the Methodology Committee, the new economic resource center that we'll be pulling together to support our activities and the awardees, and bring in some of
the expertise around the space, as well as thinking
about that guidance that will stem from the
principles and we’re continuing to refine that for
our applicants.

And so, a very great meeting and I’m
looking forward to our next one and I'll turn it
back over to you, Christine to wrap this up.

CHAIRPERSON GOERTZ: Thank you, thank you
so much Nakela. I want to close by once again
congratulating our new awardees and for thanking
those who joined us today via webinar and
teleconference. A reminder that all materials
presented to the Board today will soon be available
on our website. Today's webinar was recorded and
the archive will be posted within a week or so. We
always welcome your feedback at info@PCORI.org, or
through our website at www.PCORI.org.

Thanks again for joining us. Have a great
afternoon.

[Whereupon, at 2:58 p.m. EST, the Board of
Governors meeting was adjourned.]