PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday, May 24, 2021

Webinar

[Transcribed from the PCORI webinar.]
APPEARANCES:

BOARD OF GOVERNORS

Kara Ayers, PhD  
Kate Berry  
Tanisha Carino, PhD  
Jennifer DeVoe, MD, MPhil, MCR, DPhil, FAAFP  
Alicia Fernandez, MD  
Christopher Friese, PhD, RN, AOCN, FAAN  
Christine Goertz, DC, PhD [Chairperson]  
Michael Herndon, DO  
Russell Howerton, MD  
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  
Eboni Price-Haywood, MD, MPH, FACP  
Karin Rhodes, MD, Designee of the AHRQ Director  
James Schuster, MD, MBA  
Ellen Sigal, PhD  
Kathleen Troeger, MPH  
Danny van Leeuwen, MPH, RN  
Robert Zwolak, MD, PhD
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Connie Hwang, MD, PhD, Board Member
Eboni Price-Haywood, MD, Board Member
Board Discussion

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Nakela L. Cook, MD, MPH, Executive Director
Christine Goertz, DC, PhD, Chairperson
PROCEEDINGS

[11:34 a.m. EST]

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

CHAIRPERSON GOERTZ: Thank you so much, Nick. Good morning. And welcome to the May 24th, 2021, meeting of the PCORI Board of Governors. I'm Christine Goertz chairperson. I want to welcome those of you who are joining us for today's Board meeting via teleconference and webinar. Thank you to everyone who's joined us virtually online and by the phone.

We are very pleased to have you here for the first of two days of meetings. I want to remind everyone that conflict of interest disclosures of Board members are publicly available on PCORI's website and are required to be updated annually and if the information changes. If the Board will deliberate or take action on a matter that represents a conflict of interest for you, please recuse yourself or inform me if you have any questions.
If you have questions about disclosures or recusals relating to you or others, contact your staff representative. All materials presented to the Board for consideration today will be available during the webinar. The meeting is being recorded and an archived webinar will be posted within a week.

Nick, would you please call roll?


DR. AYERS: Present.

MS. WILSON: Kate Berry.

MS. BERRY: Present.

MS. WILSON: Tanisha Carino.

DR. CARINO: Present.

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

[No response.]

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.

[No response.]

MS. WILSON: Connie Hwang.

DR. HWANG: Present.

MS. WILSON: Sharon Levine.

DR. LEVINE: Present.

MS. WILSON: Michelle McMurry-Heath.

DR. McMURRAY-HEATH: Present.

MS. WILSON: Barbara McNeil.

DR. McNEIL: Present.

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

DR. RHODES: Karin Rhodes is present.

DR. PRICE-HAYWOOD: Present.

MS. WILSON: James Schuster.

DR. SCHUSTER: Present.

MS. WILSON: Ellen Sigal.

DR. SIGAL: Present.

MS. WILSON: Kathleen Troeger.

MS. TROEGER: Present.

MS. WILSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Present.

MS. WILSON: Janet Woodcock.

[No response.]

MS. WILSON: And Robert Zwolak.

DR. ZWOLAK: Here.

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

CHAIRPERSON GOERTZ: Great. Thank you.

All right, can I have the agenda slide please?

We have a very exciting meeting ahead of us today, I think. We are going to start with a discussion on our strategic planning initiative, both an overview and structure, and then we're going to start a really important discussion on our draft national priorities including the five that that we
have already mentioned in a real broad sense previously.

And I want to thank Board members for agreeing to be panelists to help lead a more in-depth discussion on each of our priority areas today. And then we will wrap up and adjourn around 4:30.

So now I'm going to turn it over to Sharon and Nakela to introduce today's discussion.

DR. LEVINE: Thanks, Christine. Can we have the next slide, please?

Just as -- first of all, I want to thank the members of the Strategic Planning Committee who have contributed a substantial amount of time to thinking about reviewing and contributing to the materials that we're going to review today. It's been a substantial commitment on everyone's part to get the work where it is today.

And just as a reminder, today's discussion is an opportunity for the Board to engage with the draft national priorities and for us to gather additional insights from Board members in terms of...
the work that will go on between now and our June
15th Board meeting to further refine these
priorities and to bring them forward to the Board on
June 15th for approval for posting for public
comment. Once -- and we will, that will happen in
our June 15th Board meeting and subsequent to that
we will open the priorities for public comment and
then using public comment, continue to refine the
priorities for a final vote in the fall on our
national priorities.

And I'm going to turn it over to Nakela
now.

DR. COOK: Thank you, Sharon. And I'll
just mention a bit about the structure of today's
meeting. And then we'll also give you a little bit
of overview ahead of our facilitated discussions.

So today we're actually going to review the
input to-date very briefly, and then we're going to
have a structured dialogue for each of our national
draft national priorities. And we look forward to
hearing all of your input through those discussions
and dialogue. Let's go to the next slide.
Just as a quick reminder, this is the slide that you've seen before that demonstrates the scope of the strategic planning activities. And you may recall that our activities encompass multiple things, and that will inform PCORI’s next phase. But today we're really focused on the national priorities, which will serve as a foundational element for our future strategy. Let's go to our next slide.

And this slide serves as a reminder of our revised strategic framework. And in this framework, you see that our strategic imperatives frame what we accomplished in the midterm and subsequently our long-term goals as well, which are our national priorities for health, with a focus on our desired impact related to achieving better healthcare, better informed health decisions, and improved health outcomes.

And this revised framework that we examined in prior Board meetings involves our national priorities from priorities for research to priorities for health that are the long-term goals.
that are accomplished through our research and our research agenda, and that stem from these priorities, along with our other strategic imperatives. Plus, the national priorities are no longer really categories for research rather they are goals to accomplish through our research, as well as our other strategies. Next slide.

You may recall that since summer of last year, through the spring of this year, that we've received input on the national priorities from multiple stakeholder groups. In addition to holding discussions at our Board of Governors meetings and other several activities to help identify priorities. And as Sharon mentioned, the Strategic Planning Committee and the Board really worked together to refine the input and consider what this input could mean for PCORI's mission and vision.

And so, the journey has really led us here where we're talking about the draft priorities and what will follow our discussions around our research agenda as well as continued engagement related to other activities of our strategic plan. Let's go to
So last month we reviewed the resulting themes from the public input gathered to-date, and there were five themes identified that are listed here: health equity; emerging innovations; communication, dissemination and implementation; infrastructure and workforce; and the learning health system.

And what we really heard from the input to-date around health equity is that addressing disparities is more important than ever and that systemic inequities are really pervasive. We also heard related to emerging innovations about the application of new technologies and system interventions as important for the future of health and the need to address evidence gaps and time sensitive decision-making that's focused on patient-centered outcomes related to communication, dissemination and implementation. We heard about the importance of both the research and practice of communication, dissemination and implementation, and the importance of getting the right information to
the right people at the right time to make informed decisions.

Related to infrastructure and workforce, we heard about building human data and systems capacity for patient-centered outcomes research. And related to the learning health system, we heard about the imperative to better reflect the patient perspective and support health systems that enable coordinated care, easy navigation and utilization for patients.

So the strategic planning committee considered all of this input and the themes and how to transition them as long-term goals for PCORI to pursue related to patient-centered outcomes research. Let's go to our next slide.

So the resulting draft national priorities were really developed based on the strategic planning committee's input and PCORI staff expertise and considered the research environment and how PCORI can utilize its mission to improve health outcomes. And the draft national priorities are intentionally action-oriented in how they're framed to try to move the needle toward improving health outcomes.
outcomes. And each will be relevant and grounded in patient-centered comparative clinical effectiveness research that PCORI funds.

And you're also going to notice, as we talk about these today, reinforcing concepts that are interweaving elements between each of them and that's actually intentional and a good thing. They were designed to be mutually reinforcing and with some relevant interdependencies.

So with that overview, I'm going to turn it back over to Christine who's going to introduce Sonja Armbruster who will facilitate today's discussions.

CHAIRPERSON GOERTZ: Thank you so much. Nakela and Sharon, as we mentioned at our last at our last board meeting, we have engaged a facilitator for today's discussion.

Sonja Armbruster will support the meeting allowing for both Sharon and I to participate in the discussion rather than leading the discussion. And we're excited to have her facilitation expertise and look forward to the dialogues.
Sonja is a health sciences educator and teaches full-time in the Department of Public Health Sciences at Wichita State University. Her public health career includes 10 years of service in various roles at Sedgwick County Health Department. Last serving as Division Director for Community Health Planning and Performance Improvement. As a public health consultant, Sonja provides training and technical assistance to state, local, tribal, and territorial health departments, as well as facilitation support for variety of health-related organizations.

Sonja I'll turn it over to you now.

Welcome.

MS. ARMBRUSTER: Thank you so much, Christine. I'm honored to be with all of you today as we work toward achieving our shared purpose, creating an opportunity for all members of the PCORI Board of Governors to engage with the draft national priorities for health and for all of us to hear from the Board members’ expertise and insights for further refinement.
Over the last few months, staff from PICORI and the Board leadership have been working to design a process for this conversation today and tomorrow, we've worked to create conditions for a robust sharing of ideas, and we will need input from all members to fulfill our purpose today. You'll be hearing prepared remarks from 19 people today. If members of the public would like to learn more about the speakers, you can read their bios on the PCORI website. We will not be devoting time to introductions today for staff or for Board of Governors members.

If you could advance to the next slide, please.

As you can see from this slide for each of the five priorities, we will hear a brief presentation, some opening comments about the topic from a PCORI staff member who provides staff support for the Strategic Planning Committee and then select members of the Board of Governors will provide a reaction to a prepared set of questions. And after they share those reactions, we will have
an opportunity for the full board to discuss the
topic.

Today, the full Board will discuss all five
draft national priorities, and we will have an
additional opportunity for discussion tomorrow.
Today we've scheduled about 45 minutes to discuss
each priority and we have a short break scheduled
after each of those discussions.

During the full Board discussions, I invite
all Board of Governors members to turn on their
cameras when possible to encourage and support a
robust sharing of ideas. Board members can gesture
or use the chat function to indicate their readiness
and their interest in being called upon to share
reactions and insights.

If we could turn to the guiding questions.

Our guiding questions today are thinking
about what excites and concerns you about this
particular national priority and what are the
opportunities that it brings to the work? What
opportunities does this create for PCORI’s mission
and mandate? And then looking to the specifics, how
does this -- what does progress look like and how does this help us think about the research agenda?

It is our hope that a discussion of specific examples of progress and ideas related to the research agenda can provide a springboard for the next phase in strategic planning.

So without further ado, let's begin. Our first topic is Achieving Health Equity. Michelle Orza, PCORI’s Chief of Staff will provide a brief overview.

Michelle?

DR. ORZA: Thank you, Sonja and hello everyone.

The health equity theme emerged clearly and with a sense of urgency from our earliest engagements with stakeholders, and it continues to be top of mind and top priority across all stakeholders in our ongoing interactions. As brought into stark relief by the pandemic persistently poor health outcomes, disproportionately affecting people with low income, people with disabilities and people of color, as
well as entrenched and negative influences on health in some communities that compound over generations drive concerns about health equity.

Can you go to that next slide, please?

This theme leads to our first proposed national priority, achieving health equity and PCORI’s goal for this priority is to advance health equity in the U.S. Next slide please.

Although health equity has been an explicit goal of the public health community for over a decade and a focus of many health and healthcare entities, including PCORI, much more progress is needed. In shaping this priority, the input we've received to-date includes urging PCORI to fortify its existing addressing disparities priority; calling for us to expand existing mechanisms and create new ones to advance health equity; and advising that to achieve health equity we need to widen our focus beyond healthcare to include the public health ecosystem and the broader social determinants of health.

I turn it back to you Sonja so we may have

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Our exploration and discussion with reactions from a panel of two members of the Board of Governors. We will hear from Kara Ayers and Alicia Fernandez. Thank you both for taking time to give special attention to this draft national priority, achieving health equity. You’ve been asked to consider those two initial questions and to reflect for about three to five minutes, about what excites and concerns you about PCORI achieving health equity, and what opportunities it creates to help us meet our mission and mandate.

And so, Kara let's begin with you.

DR. AYERS: Sure. I can start with the first question.

So I think the first thing that stands out to me is that the evolution from health equity from recognizing its existence to now our newer title is to achieving health equity is an ambitious goal and that both excites me and concerns me.
So I see the goal of achievement as so far away that I don't want this title to be merely performative for us. At the same time, I think that there's certain motivation in the title and encouragement. And so, I really feel mixed about whether you know, whether this title is the most accurate representation of what we hope to achieve. It does excite me that we're prepared to make such an important impact in this area. One of our challenges is the systemic oppression is built into so many, if not every part of our healthcare systems and there remains resistance to make the depth and breadth of changes that are needed.

So it will be an interesting challenge for us and one that does concern me as someone who's very bought into achieving this goal. It'll be an interesting challenge for us to still do the things like building visibility of PCORI and fostering those relationships with partners and calling out and calling in people to address inequities because somewhat distinct from some of our other areas of focus is this level of resistance and defensiveness.
when these shortcomings are pointed out where healthcare inequities exist.

Things that excite me and what I'm looking forward to is that I do see the opportunities for more organic inclusion of different stakeholder groups across, I think that it is an opportunity to build trust in recognizing what many people have always seen as part of their healthcare experience, but will now be recognized at a more systemic level. I think it's an opportunity to think big and look towards transformation rather than just, you know, short term repairs. And I think that we'd also while thinking big, we also have to think about practical solutions also that our stakeholders can resonate with and apply on the ground as well.

So that's my response to the first prompt. Do we want to take it one at a time? Is that right? Or should we continue? I’m sorry, I can’t hear you.

MS. ARMBRUSTER: You can continue with what you think about the opportunities this provides for PCORI’s mission.

DR. AYERS: Sure. Yeah. I think that when
I look at our mission and the opportunities related to this priority, it's almost like speaking the quiet part out loud, and that again, for many people from marginalized groups, this is part of every part of the mission that we work towards in PCORI but it's not identified. So it's the unspoken or the unseen section.

So I think that this lends us the opportunity to bring that to the surface and to have these discussions. And some of them will be difficult, but I'm excited about the opportunity of having a more full picture of what we're looking at when we talk about things like helping patients make different decisions about their healthcare, these factors related to healthcare equity and inequities that people experience weigh in and as, you know, without identifying them and putting them front and center, we're kind of not counting that weight. And so I think that's exciting.

And I also spend some time thinking about what progress would look like and for me, I think this will be challenging, but exciting to be able to
measure this progress. I think that we would need
and want to see change at multiple levels that we
would want bi-directional feedback to flow to and
from different stakeholders. And again, this will
take some trust building within these different
groups, in-between these different groups. And I
think we'll need some more meaningful metrics on
dissemination.

I very much want to see more than just how
many people we’ll reach, but I want to see how the
information that reaches people factored into
decision-making. So it's almost this intersection
of communication measures, but also patient
outcomes, satisfaction experience, you know, even I
see places for social determinants of health, which
you know, are definitely a hot topic, but often
don't include all the areas of oppression that
people experience across these.

So I think we have a lot of opportunity
with this priority and I'm excited about it, but
also, you know, keep what I'm tentatively cautious
about in mind as well. Thank you.
MS. ARMBRUSTER: Thank you very much, Kara. And I would encourage all Board members as we look toward the fuller conversation in a few minutes, I was particularly struck with your discussion point about not being performative and what it might look like if it weren't performative. So I would be interested in hearing more discussion later specifically about that, and I'm going to come back to the trust building concept as well.

But thank you, Kara for already getting us started with some initial groundwork to think about. Alicia your thoughts about what opportunities this creates and what excites and concerns you.

DR. FERNANDEZ: Thank you, Sonja. I want to start out by saying how much on target and how much I agree with Kara’s comments. They really I think that we were very aligned and that you were extraordinarily concise in being able to highlight so many of joint concerns.

Let me start by saying that I think that this is a great start, that PCORI’s sort of renewed emphasis and more ambitious framing is an
extraordinary it's a great start and it is very exciting. And I want to talk particularly, I think, to the members of the Board who may have had less experience thinking about health equity, and just give a very brief framing.

If one thinks about health equity in two very big categories, the social determinants of health, which really determine big, broad patterns of illness. And then within that, and then the health care system, which really determines more about how people live with their disease and how they get better or not.

I think one of the things that's very exciting right now and that PCORI recognized in its brief is that there is a lot -- that the health -- at the intersection of the healthcare system and the social determinants of health, it is a sort of a new terrain that we can really explore. And chief among those are questions such as how our resources that are currently directed through the healthcare system; how can those be used to mitigate disparities caused by the social determinants of
So I think we're going to see a very exciting decade of research. Let's call it five years of research in this, and that it will take place in the social determinants of health. PCORI has the ability to do this research and into sort of two big groupings. One is on the individual level. We will see a lot about how the social determinants of health are integrated into the electronic medical record and into the -- and that will help us understand disparities and how they can be mitigated in a much more targeted way.

Let me give you an example of that. One of my favorite studies conducted by Mike Pignone, a long-time friend now at Dell, was a study published in JAMA that showed some years ago -- that showed the impact of a low literacy intervention on a group of people with uncontrolled diabetes in North Carolina.

And what that study showed is that for people who it turned out had low literacy, no surprise, a low literacy intervention was wonderful.
And they ended up with glycemic control. Whereas, with the people in that group who had other factors that were impeding their ability to achieve glycemic control did not end up with glycemic control.

So one way of thinking about this is that there's going to be a whole body of research that tries to get more narrowly and more proximately of how the social disparities of health works and will lead to healthcare mechanisms that can mitigate those disparities. Another big advance that we will see are – that where PCORI will play a role, has to do with population level research. Where PCORI can lead. And I think that there were hints of this in the brief where PCORI can lead on evaluating policies.

For example, some policy, some evaluations have now shown that taxation of sugar-sweetened beverages works quite well to decrease consumption among high consumers.

Those are the sorts of policies that PCORI may or may not choose to fund and comparative policies that I think will be very interesting.
Leaving aside the social determinants of health, moving toward healthcare disparities, we are poised in the next five years to make huge advances. These have to do with how can the healthcare system become more nuanced? How can it bring more or different or better resources to bear on disparities?

And this is where the use of new technology, use of tele-health, and so on will be very important. And this fits into PCORI’s comparative effectiveness learned emphasis on disease control. I also think that we will see incorporation of new roles and an expansion of all roles among workers in the healthcare system. And I'm very excited that PCORI specifically has called out partnerships with other sectors: community-based organizations, schools, businesses, and so on as areas for exploration for research.

So what concerns me? As I say, I am mainly very excited by this, but there are concerns and those, I would think, fall into two categories. One is there are plenty of areas where more research is not needed. And this resonates with what Kara is
saying. We do not need more research to show that poverty is a risk factor for poor health for many people. Instead, what we need to think about is a different form of dissemination and whether or not, how can PCORI as a research voice within the broader healthcare policy community interact with others and be more flexible and more powerful in disseminating its research.

Let me give you an example. PCORI early on did great work on navigators. Navigators are extraordinarily effective in mitigating the social disparities of health on many people. PCORI has produced a family of research in this area. Okay. That's good. Where are we with that? How has that been taken up and not by different healthcare systems?

What are the different -- what would be the next step in evaluating policies that seek to incorporate navigators versus the status quo? What are the roles, how is a stakeholder organization now committed -- a research organization, now committed to achieving health equity? How can it, how can it
partner with other organizations within the healthcare ecosystem to assess what policies are worthwhile and what policies are not?

And now that we understand, that we have more breadth around understanding costs from many perspectives, including societal perspective. What can that tell us about policies that should be enacted to say, to bring this form of healthcare innovation to scale?

So I will stop there and say again, that I do think that this was a really exciting first step, really congratulate the staff that worked on this. And I find this mainly a source of joy, but at the same time, I think we need to do a lot more. I think that we will need to continue to be innovative in our thinking to say, how can we actually make a difference in achieving our aim of better health for all?

MS. ARMBRUSTER: Thank you very much, Alicia. Many notes written down here, I'm specifically interested in the idea of what do we need to not do to make progress on this. I think
that is an insightful lens for as we turn toward thinking about what progress looks like. Are there any further comments that either of you would like to make around what progress looks like?

And I would like to invite Kara to think, to share more about, you mentioned progress looks like includes trust-building. And I'm curious about as we think about measures and the research agenda, how we incorporate that trust building, and maybe thinking about who is it that we need to be building that trust with?

DR. AYERS: Thank you. I don't think there's any of our stakeholder groups that we don't need to be building the trust with. I think that they're, you know, one of the examples that stands out in my mind is, you know, we know we all know the difference between equality and equity, but a lot of our systems are built in a very rigid way in terms of you know, equal appointment times. And for many patients with disabilities, just an extended appointment time would allow for the accommodation that needs for a transfer or whatever may happen.
But on the provider side, that's not just an extended appointment time. That's a whole, you know, restructuring and there's so many. So that's one example of we would need, you know, on the stakeholder group of patients, we need to listen to how frustrating it is to feel like that you don't have enough time to have, you know, your basic needs met. On the providers side, we need to hear how these systems could be more flexible to meet their needs as well. And I mean, that's a really, really basic example, but I don't think there's any groups that we don't need to build trust.

Also, as we get to talk about issues like systemic racism and systemic ableism, some of these things conflict with, you know, there's the idea that the system is broken and then there's the idea that the system was actually built this way. And this way is problematic for marginalized groups. And so, I mean, our very basis of a lot of medical training is framed around some pretty ableist ideas. And so, we first have to build trust before we can have those open discussions about where we are now.
And also as Alicia mentioned, framing policy around those and having stakeholder groups. When I think about things like non-invasive prenatal testing, having different stakeholder groups from the communities and what this technology means to them, you know, all that requires trust to have a meaningful discussion about it.

MS. ARMBRUSTER: Excellent. Thank you. Your specific example about rigid systems, I think dovetails very nicely with Alicia's comment about nuanced. We need a nuanced healthcare system that meets patient needs. So thank you for that specific example. Alicia, was there more you wanted to say about what progress looks like and what we might be thinking about as it relates to the research agenda?

DR. FERNANDEZ: I think one metric of progress will look like uptake of interventions known to reduce disparities. And that, that would be, I really loved what Kara said that we need new metrics. And I think that is one that we would both, that we would both agree with and I think that that's very important.
MS. ARMBRUSTER: Excellent. Well, thank you both for your thoughtful reflections and for teeing up the conversation for the rest of the Board. Now we have about 20, 25 minutes to hear from as many Board members as possible, your additional reflections on this draft national priority. There is wisdom in this room and your perspectives are valued.

During these conversations, I invite all Board members to turn on your cameras. Thank you. If you desire to speak, you can wave or you can indicate in the chat that you are ready to be called upon. As a neutral convener, my job is to create conditions where as many can weigh-in as possible. So please share, please be succinct and I'll raise my hand to signal if we're running short of time or I see additional people in the queue who would like an opportunity to speak.

And with that, I invite you all to consider, let's start with that initial question. What excites you and what are your concerns about PCORI adopting achieving health equity as a national
priority?

    Eboni, would you unmute and join the conversation?

    DR. PRICE-HAYWOOD: Yes. Thank you. First I want to start by saying that Alicia and Kara are spot on. They hit all the high points and I'm sitting here thinking, how can I add to what they said?

    So I think I want to emphasize a couple of points that were made and maybe expand on them. One very important thing that Alicia said was folks who do this work, think of it in two rooms. There's the social determinants of health and then there's the health system in terms of mitigating in making things worse. That distinction is incredibly important because of, from the health systems perspective, we are the recipient of a lot of things that have historically been in place. And we're put in a position to basically mitigate or make it worse, but you're not really changing those things that are upstream, that you're constantly dealing with.
And so, that research that is upstream of the health system is incredibly important to tease through that. And that means valuing health policy related research, and not necessarily looking for a research that's always within the clinical area because it was incredibly frustrating downstream of that to try to deal with the problem. The other piece that's important is the concern that was brought up about not focusing on highlighting disparities, because it has been studied for decades.

And again, from the health system community perspective, don't highlight a problem if we don't have a solution. So can we focus the research agenda on finding what those solutions are so that we can employ them in whatever setting? That may be the public health sector. It may be the healthcare system. It may be, you know, within government. Those best practices that these groups can then pick up, these different stakeholder groups can pick up to employ in their setting.

The uptake is going to be very low if
there's a very limited repertoire of types of interventions. What setting does this intervention apply to? Does it apply to my setting? How can I best incorporate that into my organization?

The other piece in terms of the -- and I'll stop running my mouth, the other piece in terms of the health system, is this resistance that Kara brought up within your organization. The work that needs to be done is not all about clinical interventions. I would argue that 80 to 90 percent of it has to do with people. And what do you need to do to reduce the barriers first to hearing the message, understanding increasing awareness and responsiveness to it, and understanding that this work is actually designed to help you do your job better.

How do you frame this in such a way that people will be receptive to talking about disparities, talking about equity, and being open to maybe the way we do things is actually worsening the disparities, but we were all taught that it's all ingrained into how we do what we do. What can we do
to shift that mindset?

So I would argue in the healthcare system, it needs to be people-focused research, not necessarily clinical interventions, diagnosis, treatment, and that sort of stuff. That's important, but you will have biases in clinical decision-making if you don't deal with the people part of the problem, I'll stop there.

MS. ARMBRUSTER: Thank you, Eboni. I'm really hearing your focus on the people, all of the people in the system, including the providers and implementing solutions that are setting-specific and really focusing our research on that work. Thank you Eboni.

And I see three in the queue, so we'll hear from Michelle and then Michael, and then Christopher. Michelle, you are up.

DR. McMURRAY-HEATH: Hello. Thank you so much. And I just wanted to thank Alicia and Kara for their comments and Eboni's comments as well. I just think you really captured all the nuances of this priority, which I think we all agree is very,
very important.

Just two things I'd like to highlight and draw out. One, and this gets to Eboni's point that you just raised. I think we have to not be shy about tackling racism in the delivery of healthcare, either individually initiated racism or systemic racism in the healthcare system. And two, I think there's a real opportunity to advance the science around the intergenerational aspects of race and disparities.

I think that is an area that's just beginning to grow and PICORI could do so much in both of those areas to give more credence and acceptance of those two schools of thought. I'll leave it there.

MS. ARMBRUSTER: Thank you, Michelle. I am curious and interested in more discussion, so I will go to Michael with your initial insights and reflections.

DR. LAUER: Great. Thank you. This is a great discussion. I'm excited about this priority. My question for thought is how you make sure that
what you're doing fits within the rubric of clinical comparative effectiveness research. I totally agree with Alicia. We've had plenty of studies that show that poverty is bad for health, but the question is what interventions work and how do we do it as comparative effective this work? Thank you.

MS. ARMBRUSTER: So for point of clarification, are you saying that if the efforts are to frame it back to CER that perhaps we are able to better keep this within the bounds of the priorities that are within PCORI’s scope?

DR. LAUER: Yes. Thank you. Yes, exactly.

MS. ARMBRUSTER: Thank you, Michael.

Christopher, you're up next.

DR. FRIESE: Sure. Hello everybody. Great to see you all. Thanks for the great discussion. I'll just briefly underscore Dr. Price-Haywood's comment. I think setting really matters for a lot of this. So I just want to underscore that. I had more to say, but she did it far better than I would.

The piece that might be a new addition to the conversation I wrote down here is, you know,
PCORI can do things that other funders and other agencies can't do in this space. And so I always look for those opportunities where we can be a differentiator, where we can move the conversation, generate evidence in a way that other institutions and other groups can't. And I think one example of that, we might have others, is on our engagements space, where we've been very strong, to really take full the full opportunity of our engagement resources to-date.

I think historically though, and this isn't an issue for PCORI it's an issue for the entire ecosystem, is much of that has been focused properly on engaging groups, engaging professional organizations, patient advocacy groups, and others. And just as I've heard this conversation, I think to myself, who are we missing when we engage with specific groups and agencies? Who's not at the table that we need to have at the table? And that might be a more difficult and challenging piece. But I think that's a challenge that PCORI is up to doing because they've already built such great
strength in engagement.

So I'd like a lens on that to making sure that we are truly inclusive, that we're thinking about not just groups of folks that needs to be at the table, but folks with very important perspectives that may historically not be at the table because they don't have the resources and the time to be a member of a group and spend time with that group.

So I'd like us to think a little bit about that as well. Thank you very much.

MS. ARMBRUSTER: Thank you, Chris. And are there specific groups that you had in mind or just broadly?

DR. FRIESE: So it's on mind because I'm working on a project where we're engaging with some patient advocacy groups. And I actually look at the demographics of the attendees of the group and they don't truly -- so this is a group for a particular disease state. They are a wonderful group. They're giving us great insights.

But the demographics of that group do not
match the demographics of the diagnosis and this is a clinical model. I apologize for that, but these are not the folks that I see in clinic, even at Michigan, they are another group there. They have time, they have resources, they can transport themselves to a meeting.

So I think we just want to think about, is there a novel way to engage folks who may not be able to historically be at the table in a different way? Does that help a little bit?

MS. ARMBRUSTER: Absolutely. That last piece, like novel ways to reach people where they are really made a difference in my understanding of your comments. So thank you so much.

I understand Danny is next in the queue. And then anyone else who's interested, please add your name to the list. Danny.

MR. VAN LEEUWEN: Thank you. So I feel -- I’m not going to repeat all the wonderful things everybody has said. But I am really aware of the inherent conflict between the exclusion that's needed for scientific rigor and reasonable budget,
and the inclusion needed to reduce disparities and study the broadest possible range of populations and situations.

And so, my nightmare is actually that there needs to be huge studies costing tens of millions of dollars, taking 10 years needing the most senior researchers to manage them, and then leaving out the small communities of study. So I'm wondering if with input from the Methodology Committee that we perhaps could think about weighing positively in our scrutiny studies that end up with -- this is not the right words, but camera-ready methodology that can be easily applied to other settings and that we fund a series so that they can just be instead of giant they're small, but they cover many different populations in different settings, in different circumstances.

And I think, again, I think, you know, our power is in our charisma and reputation and gobs of money and scoring the way we score the applications that we review. So I think we need to think about all of those as we're talking about how we
influence. Thank you.

MS. ARMBRUSTER: Thank you, Danny. I appreciate your comments in others leveraging the strengths of PCORI in this specific work. I'm excited to see several are ready to weigh-in. So we'll hear from Ellen and then Tanisha and then Kathleen and Sharon. Ellen.

DR. SIGAL: Okay. Can you hear me now? I'm sorry.

MS. ARMBRUSTER: Yes, go ahead.

DR. SIGAL: First of all, I think this is incredibly important and I'm happy we're doing it. There's no doubt that this is needed.

The issue is how are we value-added and how are we going to add and to really do something specific with an outcome. I mean, we could spend our entire budget on this issue and still not solve the problem. So how do we figure out ways where we are unique and partner with others and figure out what would really move the ball and what are pilots that really are special to our special sauce?

So that's really the complicating factor.
There's no one that can or will disagree with the urgent priority. The issue is what can we do that's measurable that will make a difference even as a pilot?

But again, I support the work. It's an issue of figuring out where we can truly add something.

MS. ARMBRUSTER: I think that's an important distinction. And I think that it relates to what does progress look like and what is the specific role that can be played? So thank you Ellen.

Tanisha did you have a question you wanted to help shape the conversation?

DR. CARINO: I did, and I appreciate the comments that have been made today. And one of the, you know, for me, what I'm hearing is this full acknowledgement by the Board for the priority of health equity. But how do we differentiate the contributions that PCORI can make relative to this question that every institution is trying to address and to the point that Ellen's making, I think so
much of this, and you'll hear me say this when we talk about the [inaudible] healthcare system. It takes a lot of local community building to understand what are the institutional biases that have been created by institutions that may have an impact in changing clinical health outcomes.

And so, you know, Michael, your comment really resonated with me. Like if we stay within the lane of clinical comparative effectiveness research, I hear that as, okay, we need to focus on the clinical outcomes that biases can have, but the interventions that we study as PCORI may be things that are not within the walls of the traditional healthcare system, because ultimately those are the things that we all acknowledged have a huge impact in terms of the outcomes that are being achieved by populations and individuals. So I’ll stop there.

MS. ARMBRUSTER: Thank you, Tanisha. All of that, thinking about the role of social determinants of health and the intersection with clinical outcomes and how we weave and thread that needle as it specifically relates to PCORI's
funding. Kathleen?

MS. TROEGER: I would to hear a little more discussion on a point that Alicia raised, and then Eboni, I think I heard it in your comments and they aren't necessarily exclusive each other. So I'd be interested in how the two of you think this could work.

So Alicia, your comment was around you don't need any more studies on things like poverty it is a risk factor for, you know, lack of preventive care or access or just overall poor health. And then the paraphrase Eboni. It's important not to bring problems forward that we don't have solutions for. So let me just kind of stop there to make sure that I haven't mischaracterized comments from either of the two of you, particularly Eboni.

Did I understand that correctly? That you're, we're in an interesting spot to not just sort of throw stuff out there that we can't propose a solution for, because there's a bunch of stuff we don't have solutions for that I think we may need
more research around in order to better impact
issues related to equity, that I don't begin to know
kind of how we solve. So if there's just a little
bit of give and take there, I'd be interested in the
two of you talking through that a little bit.
Because it just doesn't seem -- you know, so that's
what I'd be interested in hearing.

DR. PRICE-HAYWOOD: So part of my statement
about don't bring a problem without a solution.
Yes. You do have to have research that's
descriptive of the problem. I think we're at -- to
Alicia's point, where we have quite a bit of
information that we've not done anything with. So
those who are hearing about the disparities and then
are in a position where they're supposed to be doing
something about it within their realm, the
receptivity to disparities research and work around
health equity, fizzles, because people are
overloaded with a problem, but even if a solution
does not exist, they have not received guidance on
how to work towards that solution.

So you have to be careful about, you know,
there's a public health significance to displaying the problem, because if you don't measure it, we won't know about it and you won't be able to discover innovations to move towards those solutions.

But understand that disparities measures are just a measure of how close or far you are from equity. And equity, thinking of equity means that you have to be thinking about strategies to remove those barriers that cause a problem in the first place. So your framework needs to think about both ends of it. And not just to describe a problem without giving me some forward view of what I need to address, even if I don't know the answer yet.

MS. ARMBRUSTER: That's really -- that's very helpful in terms of clarifying your remark. Alicia, your thoughts?

DR. FERNANDEZ: Yeah. I'd like to comment if it's okay.

MS. ARMBRUSTER: Yes.

DR. FERNANDEZ: I think what you're raising is similar to what Tanisha is raising, it's similar
to what Ellen is raising, and it's similar to what Mike Lauer is raising. And I have I'd like to respond to that. Okay.

And that is sort of like where's PCORI in this? Like how's it going to work? Okay. So I'm going to be super concrete because I really feel like we all need to understand this and then we can agree or disagree or tweak, but at least we all need to understand.

PCORI just funded a very important study on what the right dose of aspirin is for people with heart disease or actually with heart disease. [inaudible]. That was really important. And PCORI should continue to do those forms of study. Now that we know that people can take either dose, we still have to get them to take their meds. We still have to get people to take aspirin. Not a cost problem. It is a complex issue on why people take or don't take aspirin, right?

That is a classic health services research question. We could say, is it better to have to stick with your 15 minutes, Q-four months visit...
where the doctor goes through and say, by the way, you should take your aspirin versus telehealth visits that are super short and done with a health educator and which one will result in fewer heart attacks?

Or should we be more innovative? Do we give people cat robots that say to “Meow, it's time to take your aspirin.” versus funding versus community-based organizer who go through the neighborhoods and say, “Time to take your aspirin.”

What's my point? These are traditional health services questions. They are no different than other traditional health services questions. These are not NIH's traditional bailiwick, they are however AHRQ’s traditional bailiwick. None of them include overthrowing the systems that are in place. They are all about everything is in place. Nothing changes. This is great. Many of us believe nothing should change.

But we still have a problem that people need to take their aspirin. It is the traditional health services question. How do we get people to
take their aspirin?

Mike, I want you to be really crystal clear on what I'm saying so that you can disagree or agree or whatever, but I see this as classic comparative effectiveness health services research and does not interfere, you know, people can have the same terrible jobs, same wonderful jobs, everything stays the same. How do we get people to take their aspirin? It's not revolutionary. It is classic 30-year-old health services research.

What becomes a little bit more revolutionary is if we end up concluding, you know what, instead of one every 15-minute appointment, it really helps if we do a one hour appointment once a year, followed by with a physician followed by six telehealth appointments with a health educator. Why is that revolutionary? Because there's so much entrenched in the way we do this.

And that's why Eboni was saying there is resistance, expect resistance, expect people to resist. I need my 15-minute appointment says a primary care doctor.
So those things are revolutionary. Within the healthcare system, no one is talking about anything else. No one is talking about applying millions of dollars to ameliorating poverty. That's not what any of us, not what Kara said, not what I said. And for that matter, not Eboni said. I hope this is really, I hope this is helpful. I want to be super clear. I'll shut up now.

MS. ARMBRUSTER: I appreciate the clarification and I think it hearkens back to the conversations we were having last month about doing different things. And I saw that Sharon wanted to comment and also Karin. So Sharon.

DR. LEVINE: Great. Thanks. Can you hear me?

MS. ARMBRUSTER: Yes.

DR. LEVINE: Okay, great. Just a couple of comments. I was struck by Nakela’s opening comment that in many ways, each of these priorities is not discrete. In fact, they are overlapping and interdependent and it's helpful to separate them for purpose of the discussion, but to understand, as we
think about how it will then influence our work, PCORI’s work as a funder, as a convener they come together.

And a couple of a couple of things. I think it'll be important that in that light, when you think about how do we apply an equity lens to all research we consider funding or to any convening we bring, we create or are partner with on. So the equity lens can apply throughout our funding activities, through our convening activities. And in particular, around our thinking about the dissemination -- health communication, dissemination, and implementation. So to me, it's a thread that runs through everything and I really appreciate the conversation about focusing on funding research that focuses on solutions rather than further massage and clarification and problem definition.

The other thing is, I think it'll be important as we communicate what the priorities are. To have very clear definition about what PCORI, what the terms mean as PCORI uses them, because there
are, you know, a hundred different definitions of

equity is a lot of confusing use of equity,
equality, equitable. And so being very clear about
what PCORI means as we use these terms in each of
the priorities, in any of the priorities, I think
it's going to be important.

And again, and several people have said
this, there's important work to be done around
metrics and the ability to measure progress toward
what is clearly a very aspirational goal.

And that's it. Thanks.

MS. ARMBRUSTER: Thank you, Sharon. All
right. Our last three comments in this timeframe
are going to be from Karin and then Mike, and then
James.

So as we wrap up in our last seven or eight
minutes in this topic area. Karin.

[No response.]

MS. ARMBRUSTER: Did we lose Karin?

DR. McMURRAY-HEATH: I think she might've
turned her camera off instead of her mic on turn.

Karin, we can't see you.
MS. ARMBRUSTER: I’ll come right back to Karin then, and let's go to Mike.

DR. HERNDON: Great discussion. Thanks. Especially to Alicia and Kara getting us started off. I couldn't agree more with a lot of the comments.

My comment, I don't know how we can do effective health equity research without running a collision course with a delivery system, you know, design flaws. Payment reform. Doing healthcare right for the underserved and the non-served is going to run a collision course with the way we do medicine, with the way societies practice medicine, the way we're taught to practice medicine.

So as we embark on this journey, which is much, much needed, we're going to have to recognize that the resistance is not just resistance, you know of equality. It's going to be resistance that is monetary and it's going -- it's going to butt the system. And I think the best description that is as we embark on this, we need to anticipate somewhat of a collision up against the system. Thanks.
MS. ARMBRUSTER: Thank you, Mike. I see your hand, Barbara. I'm going to come back to Karin and then James, and then we're going to see if we can get all the comments. And Karin.

DR. RHODES: Was I on mute the whole time?

Oh no! Sorry, I just want to say on behalf of AHRQ that we are thrilled to continue to partner and we highly applaud this advancing health equity and are looking forward to doing that through complimentary dissemination/implementation work, and as well as evidence synthesis, identifying the gaps in both research and also policy gaps that need to be addressed that are inhibiting health equity.

And, of course, helping provide the metrics to measure the impact of our mutual work in terms of advancing health equity. Thank you. And I apologize for not unmuting.

MS. ARMBRUSTER: Thank you so much. And thank you for the focus on policy. I'm excited to hear that. All right, James, and then Steve, and then Barbara. James.

DR. SCHUSTER: Yeah. So these were all
great comments. I wanted to just kind of go maybe a
half-step beyond Mike's comments, which is that
there are certainly interventions that can occur
within the medical system to address health equity
issues. But many of the challenges require
collaboration with entities outside the health
system; whether it be around, you know,
transportation or housing or other issues that
impair access to care.

And I don't know exactly how to frame this
within a research context. It requires
significantly more thought, but I think a study -- a
focus in terms of evaluating strategies to engage
partners in the community and effective ways to do
that would be a really helpful way -- it will be
important because we'll have potential, but maybe
somewhat limited opportunities to address some of
the equity issues we feel so strongly about without
that. Thanks.

MS. ARMBRUSTER: Thank you, James. Steve.
Steve we see you.

DR. GOODMAN: There we go.
DR. McNEIL: He's having trouble with his mic.

DR. GOODMAN: There we go. Can you hear me?

MS. ARMBRUSTER: Yes.

DR. GOODMAN: Sorry. So actually my comment, I'll try to make it very quick, falls on Mike's and Alicia's but I want to make sure we don't lose Danny's comment there. And it indeed does touch a little bit on Methodology Committee issues around exploring heterogeneity and it can do that in two ways.

One is you can take a single intervention and make sure, and this was sort of what Danny was saying, it's employed purposely in different settings with profoundly different racial-socioeconomic context to see if explore - if you can see differences there. But another way to do it is to, is to redefine what intervention means. And here, I think a lot about the checklists that were promoted, where it was thought, it's thought by many that the checklist for avoiding, you know,
infections around surgery where the instrument, but the actual instrument was the tailored, personalized development of a different checklist in every context. And it was that discussion between nurses and caregivers and doctors that was actually the intervention. It was not the checklist itself.

So here, and this falls on Mike's point, you can imagine where the intervention is not just do we give aspirin or not, you know, you can have a multi-site study where each group tries to tailor the health services dimension to that -- optimize it to that context, and the test of the hypothesis is, does the customization in this population make a difference? And then you have like six or eight or 10 parallel studies where the intervention is not just the aspirin, but something that's customized through community engagement and other, maybe structured ways, that where that structured way is what's common, but the actual intervention is different.

MS. ARMBRUSTER: Thank you, Steve. All right, Barbara, it's our last comment. We're right
at the time boundary.

DR. McNEIL: A quick comment and it relates to several that have already been made.

I think Mike is one who first started off on the discussion that we would have to have a delivery system change to make a lot of our interventions work. And I’m wondering if this isn’t the time for us to think about some kind of pilot relationship with CMMI and perhaps talk to Liz Fowler to see about whether or not we could have a joint RFA, at least for one of our projects that involved an experimental design that CMMI would approve and the grant that we would approve to see if we could link our experimental approach that Alicia was talking about with an actual payment design that would make it more feasible and more generalizable than what we could ever do with that.

MS. ARMBRUSTER: Thank you. Thank you for the creativity from everyone and for the expertise and the ideas and pushing the system to be -- to continue to think differently.

We are at a time boundary and I am just
even more delighted than I thought I was going to be with the way the conversation might happen today. Thank you so much for all that you've shared so far, it's going to be an exciting day, at least from my perspective. So thank you.

You're encouraged to keep thinking about this. We will come back to these ideas tomorrow and with that, I pass to you, Christine.

CHAIRPERSON GOERTZ: Thank you so much, Sonja, and to all of you for just a really robust discussion. It was so many great, great ideas. And you know, this is starting to take shape even more clearly in my mind that than it was after reading the materials that that were presented. So thank you.

So we are going to take a short break now, and then we will return at 1:00 p.m. Eastern time. So we'll see you back in just a few minutes.

[Recess.]

CHAIRPERSON GOERTZ: All right. Nick, do we have a quorum? Are we able to get?

DR. FERNANDEZ: Christine, I just wanted to
say that I really appreciated the discussion and hearing from so many of the Board voices. I hope I didn't overstep my time and really want to say that I think this sort of focused discussion where people can bring out their questions and concerns and ideas is really helpful.

CHAIRPERSON GOERTZ: No. I think so, too. I think in a lot of ways this can, you know, can be a model for -- you know, it's difficult, especially when we're having our meetings virtually to generate that kind of discussion and I just really want to thank Sonja for being so helpful in structuring this meeting. I truly do think that there are things from this that we'll be able to adopt for our future virtual meetings.

All right. Are we -- do we have a quorum? Are we able to move forward again?

MS. WILSON: It looks like 19 Board members are on the line, so that's a quorum.

CHAIRPERSON GOERTZ: Okay, great. Well, welcome back. Just a reminder to mute your microphone when you're not speaking and I'll turn it
back over to Sonja then.

MS. ARMBRUSTER: Thank you, Christine and thank you everyone. I appreciate the way you are all making connections among the comments of your colleagues and I invite you to continue to direct questions to each other and to seek additional clarification from each other. And I know it's a bit artificial for me to call people out in the queue, but it’s the virtual world of -- this is our version of nonverbal nods. Right? So we'll do our best in our virtual conversations and if they look like what you just, what I just observed I'm excited about the remaining four conversations.

So our second national draft priority for your consideration is Increasing Evidence for Existing Interventions and Emerging Innovations in Health. And our introductory comments today will be provided by the Nakela Cook of PCORI's Executive Director.

Nakela.

DR. COOK: And also just to echo, thank you all for an engaging discussion and looking forward
to talking about this next priority. Let's go to the next slide.

So the goal this priority is to strengthen and expand our ongoing comparative clinical effectiveness research initiatives related to innovations on the horizon as well as existing interventions, where there are evidence gaps that PCORI can utilize its evidence generation, dissemination, and implementation efforts toward improving care delivery, outcomes, and health equity. So this goal covers a range of innovations from clinical care interventions or interventions such as diagnostics or therapeutics, procedures or even things like precision medicine, all the way to systems changes and innovations in healthcare delivery, and at the intersections of public health and social determinants of health.

And you may recall that we've heard from stakeholders about the importance of focus on the application of new technologies and systems interventions for the future of health and healthcare, as well as the need to address evidence
gaps and support time-sensitive decision-making needs, where there are evidence vacuums and inform new delivery innovations that are focused on patient-centered outcomes.

So advancing this priority will really require us to monitor the research terrain, evaluate existing and emerging innovations, and study the intended as well as the unintended consequences of interventions and innovations on the horizon. It also will require us to expand the scope of the stakeholders that are engaged in PCORI's work. And I think this is related to a comment we heard in the prior discussions, as well as reemphasize the inclusion of underserved historically excluded and disadvantaged populations in our comparative clinical effectiveness research efforts. And support CR evidence gaps in diverse populations, geographic areas or settings that will help foster equitable uptake.

Let's go to the next slide.

So in sum, this draft priority really aims to evolve our existing assessment of prevention,
diagnosis, and treatment options priority. Keeping a focus on the comparative studies, but strengthens and expands existing imperatives to increase evidence for emerging innovations. And it has special considerations on our strategies for specific populations for intended equity outcomes. And this is really a good example of how health equity is a cross-cutting priority that’s embedded in everything that PCORI would pursue.

So with that Sonja, I'll turn it back to you for the panel discussion.

MS. ARMBRUSTER: Thank you so much. And thank you for that overview of this priority area. We will begin our Board discussion with a three-person reactor panel. The panelists for this national priority are Kathleen Troeger, Barbara McNeil, and James Schuster. Thank you to Kathleen, Barbara, and James for giving special attention to increasing evidence for existing interventions and emerging innovations in health.

We will structure this in two parts. First, we will hear from each of them about what
excites and concerns you about this area. And as well as opportunities this creates for PCORI. And then we will hear from a different order. We'll hear from Kathleen then Barbara, then James about -- the different order will be Barbara and then James, and then Kathleen, about the opportunities for metrics and thinking about what progress looks like. So let's begin with thinking about what excites and concerns you about this national priority and the opportunities it brings to the work and the opportunities for PCORI. And if we could first hear from Kathleen.

MS. TROEGER: Thank you very much, Sonja. So we've already heard so much this morning about the interdependencies and the synergies among the priorities, and as I listened to the presentation earlier and thought through the content that's still in front of us, I really think it will be fascinating for us to watch and see how these conversations build throughout the afternoon. So I'm looking forward to that just more globally.

And Alicia, I agree with you. This is an
interesting format for us to be working in and then I found it really productive. Specific to the topic of evidence and evidence intervention, evidence innovation, and innovation. What excites me is the rapid acceleration of real-world evidence and applications to address the urgency of needs created by the pandemic among areas that we've heard mentioned already this morning. Design from Danny, policy-related issues and working with groups like CMMI or FDA or CMS. Interventions, the ability to assess what works and what doesn't driven from an acute need, but one that I think carries forward as the work that PCORI needs to do addressing really national level research priorities.

Use of AI, certainly it's sort of a buzz right now, but artificial intelligence and EMRs to identify the populations that will benefit the most are things that excite me about the opportunity of the innovation and the ways that evidence can in some ways be accelerated. But the ability to use this information to reach broader populations of
more representative data sets and address the questions and the interventions, are really what I find the most exciting.

So how do we do really truly research differently? Which dovetails, I think, immediately into the concern and the concern is that as we emerge from the immediacy of the issues that have surfaced in the last year, not just the pandemic, but more issues around disparity and access and equity, which I think have come to the surface again in a way that I haven't seen them discussed in a while. I'm concerned that the policies that were rapidly put in place for the pandemic to expand access and identify at-risk and at-need populations as well as those that benefit will slow down or regress. And I think we've seen some of that already.

Similarly, the technologies that we can use to identify things that work can also be used or the concern is that AI and EMR can be used to restrict.

Kara spoke a little bit about building trust among communities. And I feel that for
technology and the innovation to be accepted, that trust will be a really important piece of all of that. So that's sort of my thoughts on one and two Sonja, I don't know if we bridge into opportunities.

MS. ARMBRUSTER: That was great. Thank you, Kathleen. Your opportunities and your concerns and what's exciting to you was spot on. We'll come back to, to progress. So thank you.

MS. TROEGER: Yeah, so I think just quickly there then. Because -- so it was exciting and concerns for opportunities. I think the innovation here, particularly with comparative effectiveness research is the opportunity to address the challenges as they relate to access, equity, and costs in a way to rapidly reach populations of needs, low resource and they extend to places like pediatric oncology, rare disease populations, where these things can really be pooled. Where we can look at social determinants of health and things that are now more easily pooled.

We've come up with ways to aggregate this data and think about more than just ZIP+4 and create
evidence that's relevant to payers, patients, providers, and payers. So really across the different spectrum to set that up.

So that for me is really the opportunity.

MS. ARMBRUSTER: Thank you. Thank you very much, Kathleen and now let's hear from Barbara. I believe you are muted Barbara.

DR. McNEIL: Okay, how's that?

MS. ARMBRUSTER: Thank you so much.

DR. McNEIL: So I think it's quite clear why this is exciting, so I'm actually not going to say another word. It is absolutely self-evident.

But I did want to say several words on the topic that on -- what I saw in one of the sides, which was, oh, maybe it was what you just said, Sonja, the increasing -- the need for the ability to get increasing evidence for existing or emerging interventions. And I'd like to say -- ask -- put that in the perspective of three points that we haven't addressed so far and I actually don't see it anywhere in the agenda.

This is an extremely important issue, and
unless we tackle this front -- head on, we're going
to get nowhere and here are the three problems.
First is what do the plans or the physicians or
other healthcare delivery systems actually need in
terms of this increasing evidence? So they really
care? And that sounds like a pretty simple-minded
question, but it actually isn't.

The second one is who will do what, in
terms of getting these new pieces of data and what
kinds of incentives do they need to actually embark
on studies to get the new data, particularly for
existing technologies? Nobody gets credit for
studying existing technologies. And these are
generally done in academic institutions and people
who do that do not get promoted for studying
mammograms 10 years ago to follow-on Kathleen's
specialty.

And the third question is whatever we do
here, if we're talking about the emerging
interventions, who pays for these? I know we said
that PCORI can start doing that, but we can't pay
for everything. So unless we decide who cares about
what we do, who wants to do it, and how we pay for it, we can blue sky from now until the cows come home.

So I think these are very, very fundamental issues that we have to address before we even think about designing studies in this area. That's it.

MS. ARMBRUSTER: Thank you for those succinct and insightful questions. And I hope that everyone was jotting those down so we can have a fuller discussion with the full Board about those specific questions. Thank you, Barbara.

James, your initial reflections on concerns and excites about exploring innovation.

DR. SCHUSTER: Well, thank you. I'm definitely excited about it because this theme really is a large part of the PCORI's mission. Right? It's to evaluate what's out there. And I think it's, you know, in the slide, it talks about looking at medications, at devices, at healthcare system interventions, and at digital or technological approaches. And I really think those last two were potentially worthy of the primary
focus in this area, partly because there are a number of other routes for people to try to evaluate medications and devices, including, you know, even the FDA reviews them. Right? And decides if they're at least have some value or not.

But there's been so much work and energy put over the last five-to-10 years and continuing to grow, around health system intervene innovations, you know, starting with things like Jeff Brenner's hot-spotting and other, you know, innumerable now -- other strategies that people have developed to work with particularly high-need populations. And there's also -- there is an amazing amount of money flowing into technological approaches to support health. Much of which is received very little formal evaluation. I mean, most of the funding is through private equity, and so there's a lot of it's funded, I think, based on its marketability, as much as it's actual value to the individual patients.

So I think those two areas in particular are really fertile areas for us to us to focus on.

I certainly support Barbara's comment and I
had noted that as well, that there are also many traditional medical approaches, like annual screening and other things that we consider kind of usual practice of medicine that have a relatively variable degree of evidence-based associated with them. So I think that's the, the other area where our investment could have really significant return.

I think, you know, in terms of areas that we want to look at, I agree that we also want to think about the value of the interventions to the patients. So as you know, particularly in traditional studies we look at whether or not an intervention is effective according to whatever the measurement that's chosen is. But we don't often enough combine that with a sense of whether or not these interventions are appropriate to patients. So I think putting a really, I know we always have a patient-focus our study design, but I think particularly reinforcing it with this one, particularly around evaluating the new interventions would really be key.

And I think I'm going to stop there. I
have some few other comments about the metrics, but it sounds like that's our second part. So I'll hold those. Thank you.

MS. ARMBRUSTER: Thank you, James. I'm taking copious notes from all three. Thank you very much. I'm thinking about evaluation of marketability versus efficacy and the opportunities for PCORI and thank you.

Let's now turn our attention to thinking about what does progress look like and how do we get there as we might think about a springboard toward that research agenda. So let's -- we're going to shake up the order here. Let's hear from Barbara and then James, and then Kathleen, about your initial ideas about what progress might look like.

Barbara.

Unmute please.

DR. McNEIL: That's a tough one because I think we actually have to be a little more specific about what it is we're trying to measure. I don't think there's a generic answer about what progress will look like. I'm trying to think of how I could
even begin to answer that without sounding incredibly stupid.

So I suppose one possible outcome would be for new existing interventions, progress might be measured by noting that patients of all demographic age, and geographical areas, had equal access to that. That might be one metric. So that would apply to many different types of interventions that were new.

And the same thing would actually apply to existing ones. That would probably be the most important outcome measure, but then actually it's at one of the subsequent questions, which is what are some of the emerging innovations in health. So I personally would recommend deferring the question with what progress would look like until we have a better understanding of what it is we're looking at. I think this is a premature question from my perspective, but others may disagree. Obviously, can disagree.

MS. ARMBRUSTER: Thank you for that thought provoking -- I love it when people question the
question. I think there's value in that and I'm thinking about your questions initially and how we might be healing about measuring those. Thank you.

James, what are your initial reflections on what progress looks like?

DR. SCHUSTER: Well, I'll go a little further out on the ice, I could fall through, but anyway -- so I think though Barbara's theme is right, which is hard to be very specific until we know what the questions are we're looking at. But just kind of generically broadly, one of the themes that I think will be important to look at is kind of patient function at the end of the intervention as the outcome in terms of trying to get a sense of whether or not, you know, we're making these systemic changes matter.

So in addition to looking at any clinical metrics that we would typically, or others would typically look at, I think actually looking beyond that, and we've traditionally done that looked at a number of self-reported metrics, but I think those are especially important in this area.
The second is particularly when we're looking at the health system design changes or the technologies. I think to look carefully at the resources utilized as part of the effort and I think Kathleen alluded to this in her first answer, but to look at the resources used and also what the resources potentially saved are, what are the efficiencies?

Because these are, you know, all -- particularly the health system interventions, the interventions generally looking at themes like equity that we talked about initially. You know, at least from the health perspective, those at least primarily are going to be funded out of existing funding streams. And so that means, you know, either we're going to not find something else or the intervention is going to create some efficiencies and could be self-sustaining over time in that way. So I think it's important to evaluate that.

And then the last thing I wanted to say, which is maybe touch on a theme that I mentioned, we were talking about the first question, which is the
first panel -- which is, you know, particularly when
we're looking at health system issues we should, I
think encourage investigators to look at systems
beyond the health system, per se, as they look at
partners. So we should actually, you know,
encourage them to look at community partners,
whether it be agencies that supply, you know, have
community partners -- folks who have other types of
health navigators, agencies that work on social
determinants of health and so on. I think it would
be invaluable to include some of those folks in the
study.

It certainly increases the complexity and
to Barbara’s point, it makes the measurement piece
ever more difficult. On the other hand, certainly
the federal programs, especially CMS, you know, a
variety of CMS programs both in Medicare and
especially Medicaid are now -- have that as an
increasing focus of what they're using the funding
for.

So I think we have a really excellent
opportunity to help inform that discussion and help
lead to, you know, how those resources get directed most effectively.

MS. ARMBRUSTER: Thank you, James. And now we'll turn to Kathleen for the first and last word from our initial panel, thinking about innovation and what progress might look like.

MS. TROEGE: So I'll go way out on a limb and talk a little bit about, Barbara, what I think it looks like and then a little bit of science fiction as to what the future and progress would look like to me.

I do think over the course of the last 14 or 18 months, and even prior to the pandemic, we've seen just tremendous growth in applications from learning health systems and other examples through things like PCORnet on how to operationalize some of the services and innovations, like telemedicine. I'll just use that as an example, we've heard it come up a bunch, that changed the way patients and technology interact, the emergence of digital health to monitor all sorts of things and do informed clinical trial findings, I think are right on the
edge of where we are.

So that to me is we've had a glimpse of what it can look like and where we're going and how these things can address issues about who participates in the clinical trial, the whole dispersed clinical trial model and changes in some of the ways and types of evidence that FDA will look at and CMS will look at and that the community will begin to accept pre-pubs, prior to peer review, good or bad. Now, the way that a lot of people have gained early information, just as -- is it changed. So it's progress which moves forward and allows us to debate whether it's kind of good or bad.

Policies, as well. Methodologies for, as I mentioned, clinical trial design, FDA payment structures, telemedicine. I think that to me is a path toward progress.

The future for emerging technologies. I think there's a lot about diffusion of technology and whether it's a new technology or a new intervention or one as Alicia was mentioning with aspirin. How do we reach back with things that work
and get them to patients and communities that need them the most? That's where, I think, some of, again, the AI, the PCORnets, the learning health systems, things that we'll hear more about in the afternoon, dissemination and implementation will come together to really more broadly use the intervention and innovation piece to bring it forward and address the challenges.

And I think this is how a close. On, you know, related to access and equity, who's been in a randomized clinical trial versus people that never got into those kinds of trials that need to reach. I think about the lines that we've seen in ways that the vaccine, even for COVID has been disseminated entirely differently than anything we've done in the last 30 or 40 years. And yet it isn't necessarily meeting, yet, the needs of the communities potentially have been the most impacted by COVID.

So they're not there, but the last time I saw lotteries to get people to take, you know, a vaccination or a medicine, and not a lottery for, you know, the ticket lottery, right? Not a sort of
get your assigned space.

So I think there are all sorts of things here that we're right on the edge of that technology enables and the way to get that there and then make it -- to figure out a way to measure it. Because I agree with you there. We're not there yet. And then to bring that meaning back to sort signal from noise are things that we're really right on the horizon, right over the next hill.

MS. ARMBRUSTER: Thank you. And it looks like Barbara wants to respond to that.

DR. McNEIL: I just wanted to make one little addition to Kathleen's comment when she mentioned both the FDA and CMS, and I think it would be useful if -- I don't -- I think it's out of our power and Janet's not on the call, I don't think, but it would be useful if there was some mechanism by which -- when the FDA approved something, not an accelerated approval for example, but a plain old approval, that there was automatic payment by Medicare and Medicaid. Instead of having to go through MedPAC, for example, to get payment.
So that would increase the availability of new interventions or technologies to a much broader group of people who would not have to worry about payment.

That turns out to be a very big problem. And I don't think it's anything that we're going to solve, but it is something that we could bring up with a dialogue with Janet, when she's at a meeting to say, how could we ever do this?

MS. ARMBRUSTER: Thank you. Thank you all for your thoughtful reflections and for providing a groundwork for the conversation for the full Board.

We now have 15 or 20 minutes to hear from as many more Board members as possible for some additional reflections and insights about increasing evidence for existing interventions and emerging innovations and health.

And I invite you all back on camera and I look for your notes in the queue about your interest in readiness to speak on this topic.

We'll start with what excites and concerns you about this national priority and/or
clarifications you'd like to see as we think about existing interventions and emerging innovations in health.

        Thank you, Karin. Please go ahead.

        DR. RHODES: I really appreciate the comments that have been brought up and I wanted to add that as we look at technology-enabled innovations and new system changes that we follow through and look at the cost impact on patients and cost sharing and financial toxicity related to innovations, as well as the equity and access to those innovations, like tele-health.

        And I also want to add that we should also consider unintended consequences of new innovations and put that front and center as we evaluate their impact. Thank you.

        MS. ARMBRUSTER: Thank you. Just as a pacing, we're going to hear from Sharon, Connie, and Danny next. Sharon.

        DR. LEVINE: Thanks Sonja. So I think it might be helpful for us to define what we mean by emerging innovations. And assuming that we're
talking about things that have -- that have been approved for general use as opposed to something that's in a Phase 3 clinical trial still. But certainly in terms of non-drug or device stuff, it will be useful to have a definition of emerging innovations that would communicate clearly what we intend by this.

And taking us back to our core business of comparative clinical effectiveness research, part of the importance of comparing "innovative," either interventions or products with existing approaches, is to determine whether in fact there is additional benefit because most of the things that are approved, are approved compared to either placebo or to standard therapy. And so there is some value in comparing innovative stuff to existing to determine if in fact there is additional benefit that accrues either a health or an economic benefit that accrues to individuals from the innovation.

And it's, to me, it raises the question about the issue you raised Barbara, because if coverage is automatic, when something passes
through; for example, FDA approval and the approval is based on a comparator of a placebo, for example, without it ever requiring coverage, it creates some opportunity -- to me anyway -- of forcing the hand of the providers in terms of using it in the absence of evidence of additional benefits. I think there's some caution to think through there what coverage means in that circumstance.

Anyway, that's it.

MS. ARMBRUSTER: Thank you, Sharon.

Connie, then Danny, then Christine, then David. So Connie.

DR. HWANG: Thanks so much. I appreciate the conversation. I was also pretty excited about this priority. I appreciate, as noted Barbara's problem facing questions about who wants to see evidence, do physicians and plans actually want it? And it's funny because that actually very much resonated with me and brought back memories of a lot of the conversations that we had on the payer forum meetings, you know, before I was on the Board here. And there is so much desire and focus to think about
these emerging innovations and tech, particularly those that when they come out, they tend to be pretty high cost. Right? And there is the, as James noted this lack of evidence out there to figure out, you know, is it worth it? Is it generating good value? You know, not only on the outcome side compared to other modalities.

So I do think actually in this priority area as Karin and, I think, Sharon both noted, there could be some more explicit mention about cost impacts. I think, at least in the wording when I glanced back through and just though conversation, this is where I think weaving that new mandate and you know, being able to be freer to consider that, will really -- I think push forward some of those insights and would make it very valuable. I know certainly from the community health plan perspective, but they, and also sort of physician groups.

I also think and sort of picking up where James and Kathleen's comments left off. When you think about the different interventions, I think
system level interventions, digital tech, I'd give a
double thumbs up on that, based on all the
conversations I've been having with again, health
plan and clinical leaders across the country. I
also think given that if we do continue to push
forward towards more value and risk sharing
arrangements through ACOs, physician groups, you
know, with health plans, I just think the level of
interest in terms of, you know, a set of -- you
know, modes of operation and also within science in
terms of some kind of costs impact are going to be
pretty valuable, especially when you think about how
this would be applied to patients and ideally, you
know, make health care more affordable in the long
run.

MS. ARMBRUSTER: Thank you, Connie. Danny.

MR. VAN LEEUWEN: So I was sort of pulling
on the thread of innovation to processes in the
system related to social disparities in health. And
in our conversation, in the strategy group, in one
version of what we looked at, we were, there was the
words, disruptive innovation. And my comment on
that was watch what you wish for.

And that innovation is risky. It's really risky. And frankly, I'm a change agent, but I'm a coward and I'm not a revolutionary. I'm no good at it. And so, my style is more meeting people in organizations where they are, and trying to be careful that I don't have more than a 15-minute advantage, because if I'm too far ahead, I have to go back and get them because I lose my effectiveness, if not my voice and my job.

So I think that one of the things that we could be thinking about as we're thinking about innovation and process in equity is how is it that we design things so we encourage people applying to take one more step forward, one more step of inclusion, one more step of partnership. A small risk. And I think, I don't know.

For me, I know how to do that better. Again, I am not a revolutionary. I'm no good at it. That's somebody else's job. So anyway, that's the thought.

MS. ARMBRUSTER: Thank you, Danny. I look
forward to hearing more about risk tolerance and
disruption. David, Christine, and then Mike.

DR. MEYERS: Thanks Sonja. And thanks so
much, everybody for a great discussion. I wanted to
take up the thread of measurement. I think there
are two different levels that we have to look at
measurement, and the panel really focused on the
individual study. And clearly, we can't say how
individual studies should measure, but I think
PCORI, and as the Board, we have to think. If we
adopt a goal, how will we, as PCORI, know we've met
our goal. That's the measurement I want to think
about.

So for this one, I'll put out there as a
possibility that this is about our different
stakeholders, patients, clinicians, systems,
policymakers, payers, we could think about the
priorities there. Do they have the information they
need when making healthcare decisions? And if PCORI
is successful in this field of giving better
evidence about when either old or new innovations
are useful and for whom, which is what PCORI is, you
know, I think is its deepest root: who, when, why, how, all those things. That if we tried to measure that collectively, do people feel -- do the system -- do the patients feel that they had the information they needed?

We would be able to say we were successful under this mission and under this goal.

MS. ARMBRUSTER: Thank you, David.

Christine.

CHAIRPERSON GOERTZ: You know, David largely spoke to the issue that I wanted to bring up regarding, you know, how do we define success in this incredibly tricky area? You know, not at the individual study level, but at the level of, you know, PCORI's mission. And, you know, and I'm probably jumping too far into the weeds here, but I also wonder how do we choose, you know, how do we set the bar for the technologies that we're willing to evaluate?

I mean, our practice has been that we study -- we conduct comparative effectiveness research on therapies that have already demonstrated efficacy.
and yet, you know, but these innovative technologies by their very definition are probably not going to meet that bar. And so, which is the reason why I think it's incredibly important to focus on what the end game looks like too to us, because I think it would be pretty easy to go down a rabbit hole here.

MS. ARMBRUSTER: Thank you, Christine. I think it seems that it connects back with clearly defining what counts as an emerging innovation and how that's being defined to discern what gets in.

Thank you. Mike.

DR. HERNDON: David and Christine both kind of hit on what I was considering and thinking about kinds of risk, but let me first kind of address what Barbara brought up as far as the FDA approval equals automatic approval by Medicare and Medicaid. And as a Medicaid Chief Medical Officer, there are a lot of things to consider not the least of which is budget considerations for at the FDA approval of things. And of course, you know, if you participate the rebate program, if it's a medication, then all state Medicaid agencies have to pay, have to cover that
drug.

Of course there's the national rebate program and all that, but as far as non-medical things there's a lot to consider including budget and policy and that sort of thing. So anyway, I just had to throw that out there for Medicaid to work.

I did want, I think, and again, kind of as non-researcher. I think one of the things we'd have to consider with this, you know, discussion is when is enough, enough? You know, when does something no longer emerging and established and, you know, it seems to me like there was a ton of research on telemedicine and at some point we all knew telemedicine's effect. We all knew there was a lot of research on shared decision support, you know, in shared decision-making.

And at what point does PCORI say as a priority that, you know, that's enough of that and it's no longer emerging? And then it becomes more of an issue not of investing in the research, but investing in the dissemination/implementation. So
to me, I think, that that's kind of the question that I have about this priority -- is, you know, when do you say that nationally and you know, when you consider all the research that's going on in NIH, AHRQ, PCORI, et cetera, when is it enough and no longer do we need to invest in it, but we need to switch to the dissemination/implementation?

MS. ARMBRUSTER: Thank you, Mike. Thank you all for the insightful comments that you've raised. We have a last chance to weigh-in on your thoughts about the opportunities related to this national priority. Are there additional thoughts?

Robert, please go ahead.

DR. ZWOLAK: All right. Thank you. This has been a great discussion. My comment also goes to this suggestion that FDA approval results in immediate and sort of automatic coverage, and at least in the Medicare program for devices, which I'm familiar with, that's not the case. And I think there is an excellent opportunity for PCORI to get involved in this space.

Kathleen, I think, pointed out that new
treatments and new devices are very expensive, which is absolutely true. And for devices at least, is a pretty strong tailwind for implementation of the device and newer procedures, because there is potential financial gain for the vendors. I think that there really is an enormous opportunity for PCORI to partner with the CMS coverage and assessment group at CMMI. I just think there's huge opportunity for us to do this and I don't think in our past, or at least to-date, we've taken much opportunity to do so.

So I think there's lots of space there. I think if we get into that space that we can do our core mission, which is comparative effectiveness research and we'll have great benefits based on the results. Thank you.

MS. ARMBRUSTER: Thank you, Robert. Alicia and then Kathleen, and then we've got to call time. So Alicia.

DR. FERNANDEZ: I'm very pleased with so many of the comments that have been made in such an incredible breadth of what's being considered.
I want to add a note of questioning or caution, but I have thought hard about how PCORI can work on innovation, in new meds or new technologies. And I just really don't see it. I don't see that. I don't understand how we can get around the time restrictions of doing research. That by the time you innovate something, by the time you research something, it's not innovative. And I think that's -- I guess I would love to hear more about whether or not people have sort of found a way around what seems to me to be an inevitable problem in doing this. And part of the reason why PCORI has been unable to work effectively in this area.

MS. ARMBRUSTER: Thank you Alicia. And just a brief closing thought, Kathleen.

MS. TROEGER: Yes. So one, I think, there is -- just to address this automatic approval with payment type thing. There are breakthrough designations and other mechanisms, dual approval track available right now through the agency to sort of get to approval with both. But one of the points that I think may have been set aside is a real
concern that I have that innovations like technology.

So I think of things like PCORnet or other learning health systems as innovations in and of themselves, right? That then help us evaluate interventions, whether they are new or old, but that those interventions often -- and in technology, something as simple as a mammogram, which Barbara raised earlier, often don't get into the communities that need them the most. And so to me, there are innovations in addressing equity and access issues and clinical trial participation that the technology helps us bridge.

And I'll end with that because this is one of those things that I could go on about all afternoon. This is the part that lights me up about how do we change it? How do we go faster? I think that's what we've seen in the past year.

So I would challenge anybody that says we can't overcome things to do them well and work quickly, to take a look at PCORnet's contributions to evidence accelerator, and then think about how we
amplify that and the work that's been done for COVID into areas like pediatric oncology and Chris Forrester's work, federated data sets, patients having agency over their own data -- which I know that Danny and Eboni and I have talked about before. So that these are just things that are happening in the background and I think they do happen faster and methodology needs to help us think through how we get the right measures and metrics around it to change things again; like disperse trial design, when you couldn't get participants into a clinical setting to do the evaluation. How did we make it happen? And how do we improve on that to broaden patient participation and get the cost measures in there as well? So I think we can do it. I think we've been doing it. We just need to do it more and better.

MS. ARMBRUSTER: Thank you, Kathleen, for those summary thoughts. And thank you all, again, for your robust creative ideas about how to push this idea and shape this idea as a national priority.
for PCORI. We are at a time boundary and I will remind you that we'll have additional time to think about this tomorrow, so please keep those thoughts percolating. And with that, I’ll pass it back to Christine.

CHAIRPERSON GOERTZ: Thank you, Sonja. And everyone else for, again, another just very robust and important discussion. We're going to take about a five-minute break. We're a little bit behind, so it really is just five minutes. We'll just stand up, run around your house for a minute or two and come back and we'll go ahead and get started.

[Recess.]

CHAIRPERSON GOERTZ: All right, Sonja, are you ready?

MS. ARMBRUSTER: Yes, ma'am.

CHAIRPERSON GOERTZ: Okay. I see we've got Jen and then -- and I know Danny's is here, so I think we're ready to get started.

MS. ARMBRUSTER: All right. Thank you, Christine. Our next draft national priority for your consideration is Building the Bridge from
Research to Improved Health by Advancing the Science and Dissemination, Implementation, and Health Communication. The introductory comments today will be provided by Jean Slutsky, PCORI’s Senior Advisor to the Executive Director.

Jean.

MS. SLUTSKY: Thank you. Good afternoon. And good morning to everyone -- if we could go to the next slide please. It seems fitting that we're talking about this potential priority at this point in our discussion, given how often it's come up in our previous discussions today.

I just want to preface this by reminding everyone that in PCORI’s pre-authorization in December of 2019, there was enhanced language about the responsibility for dissemination/implementation of PCORI research findings and the measurement of how well we've done. And this goal of this priority really is to assure that the findings that we generate through the research we fund ultimately are used to improve healthcare, better informed healthcare decisions, and achieving approved health
outcomes.

And this actually would build upon not only the mechanisms that we have now, to do dissemination and implementation research, by building evidence-based on how best to do it and how to reach those audiences that need it most. And if we could go to the next slide.

Okay. So just to amplify some of these points. Really the priority aims is to revise and expand our current priority area on communication and dissemination research. As well as not only advancing the science in this area, but the practice of dissemination, implementation and health communication, particularly around patient-centered outcomes research or comparative clinical effectiveness research. And then charting the progress that we've made toward improving evidence-based decision-making at all levels of decision-making.

So Sonja, I'm going to turn it back to you for what I hope is a really robust discussion.

MS. ARMBRUSTER: Thank you Jean for that
background and for providing us some context for considering what we mean by Building the Bridge from Research to Improved Health by Advancing the Science of Dissemination, Implementation, and Health Communication.

And now we have the good fortune of hearing from three panelists on a reactor panel, three Board members. We're going to hear from Jennifer DeVoe, Christine Goertz, and Danny van Leeuwen. We're going to hear from you each in to two parts. First, I'd like to hear from you both about what excites and concerns you and what you see as the opportunities for PCORI. And then, we'll come back and talk about opportunities for success and what we think progress looks like.

So we'll begin with Jen.

DR. DeVOE: Sure. Good morning. Good afternoon. Depending upon where you are in the world. Thanks for this opportunity.

I think there's a lot of threads that are going to continue to arise from the previous conversation. I’m so excited that we're talking
about this topic now and I do also want to channel Gail, one of our former Board members who I believe brought this topic up at every single Board meeting. And I am as excited about dissemination and implementation research and practice as Gail is. So thanks to Gail for championing this issue over the years.

The other person that I want to briefly thank for my career essentially in implementation science and all the work that I've been doing is Steve Wolf. Who's a family physician, who in one of the very first issues of the Annals of Family Medicine back in, I believe 2004, he wrote a really impactful article that spoke to me, and that was really looking at health disparities and saying, you know, if we worked to develop methods and the science of effectiveness for implementing all existing evidence equitably, we would save more lives than if we developed new interventions.

And this really spoke to me in that we have a lot of evidence-based interventions in our wheelhouse, many, many, many across the healthcare
system, as well as throughout society. And we're just not figuring out the best ways to implement those interventions completely and equitably across all people in all populations. And this is, I think, as a primary care physician, this is what drew me to health services research as well as implementation science, perhaps even before that term was widely known.

So this is a topic near and dear to my heart. I think comparing the effectiveness of implementation strategies to implement evidence in all populations equitably is important. And the exciting thing for PCORI is this is a sweet spot for us. I think the practice of disseminating and implementing information is really important. And the science of comparing those implementation strategies also critically important and something that PCORI can do incredibly well with our focus on comparative effectiveness research.

So that's where there's excitement, I think, concerns and those were alluded to earlier, but I'll mention them again. I think if we get out
ahead of our skis and we have new innovations and interventions that we prove to be evidence-based and we get out to implement those to the privileged populations that are already advantaged and have significantly longer life expectancy, better health outcomes, we potentially can exacerbate disparities. So the health equity strategy and this strategy go hand-in-hand in really focusing on what are the implementation strategies needed to implement evidence-based interventions, whether they be existing ones or new ones, and knowing that one size doesn't fit all. That there are certain populations and people that are going to need very, very different strategies.

So speaking to Alicia's point before that, we need to figure out how to get everybody on aspirin who needs to be on aspirin. There's likely going to be very different implementation strategies needed in different populations. Another example, right now, we know we have a very effective COVID vaccine, but there are certainly implementation strategies different in different populations from a
million-dollar lottery to ensuring that those vaccines are available in every primary care office across the country, so that patients can have conversations with trusted care teams to understand the risks and benefits of getting those vaccines. 

So lots of opportunity. It's very exciting here. Some of the concerns that have been raised earlier also, I think play out here as well.

MS. ARMBRUSTER: Thank you Jen.

DR. DeVOE: I will turn it over to whoever's next.

MS. ARMBRUSTER: Thank you so much.

Christine, what were your initial reflections about these priorities, opportunities, and concerns.

CHAIRPERSON GOERTZ: Yeah, absolutely. So it's hard to follow Jen because you know, like her, this is something that's so close to my heart and Jen, I think you did a really great job of outlining the opportunities and the way that, you know, especially the opportunity that PCORI has to make a difference in terms of both science and actual
You know, a big part of my job is actually trying to implement evidence into clinical practice in a large health system. And often, I'm grateful for the research that I have that has helped show me some ways to do that. But the truth is that that research does not address every barrier and let's just talk about payment policy. You know, until payment policy is aligned with value-based care and best practices, I think it will continue to be a struggle. And, I don't know how research addresses that, but I think that that's something that we need to think about or, you know, where are the areas that we can make a difference and to really be focused on the very real barriers that exists in this process.

But I think that when I think about the way that this particular national priority can serve PCORI’s mission -- I mean, it's already been mentioned that this is actually a part of our legislative mandate, which makes it -- our role very
I think it's up to us to decide what that role continues to evolve to be. And I would like to see us build on the important work that Jean and others have led and in this area to work with the Methodology Committee. Because this is, you know, a relatively nascent area of research inquiry. I think there's opportunities to continue to work with our Methodology Committee to make sure that we are staying on top of best practices.

I think we need to be developing a strategy for how we prioritize our D&I research efforts, given the fact that the need is so broad and we cannot address it all. We're going to have some hard work to do in prioritizing what it is that we need to do.

And then I just want to emphasize the need, I think we have a unique opportunity to bring together the kind of multidisciplinary teams that it really takes to do this research. And you know, it's not always your normal, you know, scientists but also, you know, working with, you know,
marketing experts and payers and we talked earlier about technology, but there's a lot of technology that can actually advance dissemination and implementation as well through EHR and other methods.

So I think that we truly do have a rich opportunity here to make a difference.

MS. ARMBRUSTER: Thank you, Christine for helping us think more about how this aligns with the mandate and opportunities to partner with new partners and so many other ideas. We get to turn now to Danny and hear about your initial reactions to what excites and concerns you about this and the opportunities for PCORI.

MR. VAN LEEUWEN: Well, I'm really delighted to be the third person who is so passionate about this topic because I am in good company.

So just as a little background. So, you know, my biases, which I have considerable in this area, is that I served for a couple of years as co-chair of the Communication and Dissemination
Advisory Panel. And during that term, I listened and I really learned about the challenges of the science of communicating about uncertainty, which is all research. And about communicating complex health and life challenges. And so, when you start thinking about the disparate communities around us, well, there's a lot of complexity.

As a podcaster, I've listened and learned about the challenges of communicating and dissemination outside of the expert bubble. And finally, now as a patient caregiver activist involved in a Person-First Safe Living in a Pandemic Initiative, we've really seen a gap, really -- no, a chasm between the questions people are asking about safe living and the evidence informed guidance that's available to help guide them.

So I think I want to say that this paper about this priority is really well done and I want to thank the staff. It is rich and exceeded my expectations, definitely. The thing that I was excited the most about was their emphasis about getting the right information to the right people at
the right time, in the right manner. And I always pay attention to the non-clinicians in the non-clinician settings, because I know that decisions and implementation often happens first outside of the clinical settings and then people come back to the clinical settings with information.

So whether it's about something rare, like sickle cell disease or whether it's about taking aspirins. There are people doing it and they're implementing.

I also think it's really important when we talk about health communications. It's not like there's science and research and then there's communication. Communication is like really more about listening and the science of listening is really a second cousin that, you know, now PCORI does an amazing job of listening to its stakeholders.

As far as I'm concerned, it's a model. You do not see this kind of listening and distillation of what they hear, as good as I hear at these strategy meetings and the board meetings, it is
really hard to do. But we need to bottle that somehow and fund the science of listening. And listening happens at the beginning of the process, not after the research is done. So this business, I was saying that we've learned about, you know, the gap between the questions people have and the evidence informed guidance they can find. Well, people are asking questions. Well, who's listening to the questions that people are asking?

So, and one last thing I'll get off my soap boxes, is that I want us to remember that the ultimate goal here is changing change in life. Not change in practice. Change in practice does not mean that anything changed anywhere else.

So back to what I was saying about how people change, and then they go back and they tell their doctor, “I changed.” And sometimes it's a good change. Sometimes it's not a good change. But the goal is about change in life, not change in practice. Done. Thank you.

MS. ARMBRUSTER: Thank you, Danny.

Thinking about listening and how we support
continued listening and stakeholder engagement and I appreciate all your comments there.

We're going to go in order from Danny then Jen, then Christine, to think about what progress looks like. So just briefly in a couple of minutes, thinking about that more specific piece, what does progress look like? Or how do you see us needing to begin to shape the research agenda as it relates to dissemination and communication of the emerging research? So Danny.

MR. VAN LEEUWEN: Well, I mean, I have to go back to the listening stuff, you know, what are the questions we're asking? I mean, I think we've talked about it in the other priorities and we're going to talk about it more, but that partnership with stakeholders, and even though I'm representing patients and caregivers, I don't mean just them. I mean, all stakeholders. I think that our -- I'll see success when we're as good at helping our researchers learn to listen as good as we are good at listening to them.

Oh, man that was twisted, but you get the
MS. ARMBRUSTER: Thank you. And Jen, what are your thoughts about what progress looks like and how this priority area might influence the research agenda?

DR. DeVoe: Sure. I liked your point Danny, about change in life. And I think it relates to one of the things I was thinking about as far as new measures of dissemination and implementation in going beyond some of the traditional ones.

We like to look at the impact factor of a journal that a paper was published in, how many clicks we got on a website, and that gives us at least a sense that people are looking at the material. Maybe reading it, maybe digesting it, but getting to metrics to know that it's actually being implemented in a meaningful way, such that someone's health has improved and their life has changed hopefully in a positive way, but maybe not always. And just really working again with our Methodology Committee with our broad range of stakeholders and diverse groups.
So think about how do we meaningfully measure our reach in the dissemination of findings that are going to change people's health and lives in a positive way. So that is a big aspiration. I know. But I think that we can do it at PCORI and there are some exciting opportunities to move in that direction.

And then I think the other thought I had just building on equitable implementation and thinking about if we're successful at implementing equitably across a population, I think it also brings up new opportunities for observational studies in different ways, such that we can be sure that we've gotten interventions to the population and then we can start looking at methods related to observational studies and natural experiments and be more sure that our data is valid and that we have everyone participating in whatever particular data set that we have compiled. So those are just two exciting opportunities for future. Thanks.

MS. ARMBRUSTER: Thank you, Jen. And Christine, progress?
CHAIRPERSON GOERTZ: Yeah, so to me, progress is, you know, similar to what Jen and Danny have already said. It's, defining what success means in a measurable manner, you know, all the way down to the patient level. So at every single level of the intervention

I think it also is looking at the depth and breadth of a national D&I research portfolio. Not only what research is PCORI able to do, but are we able to influence other funders to really ratchet up the way that they prioritize D&I? And I think to continue to look at it from a broader perspective than the, you know, what was the impact factor of the journal and how many clicks did you get on that?

I really liked Barbara's idea to partner with, you know, agencies such as CMMI to really bring together experimental approaches to payment design. And I think that that has not only is it incredibly important for health equity, but it could also be used for more general D&I efforts.

And then just finally, I think, you know, I would like to see us find ways to contribute towards
training the next generation of D&I scientists and other stakeholders.

MS. ARMBRUSTER: Okay. Thank you so much. Thank you all three for giving this a closer look. Thank you, Christine, Danny, and Jen for giving us all a little grist for the mill, some groundwork for the conversation. We want to invite all of the rest of the Board back and we have about 20, 25 minutes to think about Building the Bridge from Research to Improved Health by Advancing the Science of Dissemination, Implementation, and Health Communication.

And since this is so closely aligned with the mandate, I suspect we'll have robust conversations. So I look forward to seeing your queue in the chat or you can wave on the screen and we'll begin for all about what excites and concerns you about this national priority.

There we go. Welcome back everyone. So Sharon, please kick us off.

DR. LEVINE: Thanks. And I want to add my name to the list of people for whom this is a high
priority and one of my personal passions. And I also want to tag onto Danny's comment, complimenting the staff for the incredibly well-done brief. It really helped to focus my thinking around how I could make comments that were helpful and additive to what's already been said.

One of the things I think we've all experienced in the last year was a dramatic display in how the absence of trust interferes with effective health communication and effective implementation of established, and potentially very important, health interventions. And I think there's real opportunity for us as a funder and as a convener to work with not just CMMI, but with the CDC and with local public health agencies around, which have been seriously under-funded and under-invested in for decades. And I think we're caught flat-footed and not blaming in any way, but caught flat-footed in terms of the critical role they should have been prepared to play in the face of the pandemic.

And I think there's so much we can learn
from this in terms of the need for collaboration and place-based collaborative research involving communities, public health departments, and healthcare systems in communities around understanding what are trustworthy behaviors in relationship to community members, building the basis of trust, and then research around the most effective ways to communicate health information and to execute in partnership with community important health interventions.

And to me, PCORI has a powerful role to play here in terms of bringing these not, not necessarily natural allies together and using both our convening and funding functions to make this very important research a reality.

MS. ARMBRUSTER: Thank you, Sharon. We have several in the queue. We're going to hear from Eboni and then David, and then I'm looking for additional people who want to share their passion for thinking about what are the opportunities, what excites you about this priority, and what are your concerns? So Eboni.
DR. PRICE-HAYWOOD: So I want to
[inaudible] the comments that everyone's made thus far. And so I'm trying to think about how to say something different. And so, I think I want to focus on the implementation science piece and also from the perspective of, again, health systems.

I think a primary example where we struggle to get more concrete is think about behavioral health integration in primary care. Something that has been well-documented through randomized control trials over 20 years, and yet, and now there's for value-based payment from CMS with regards to the Medicare patient population. But then when you look at the uptake of this well, you know, designed intervention with very important, you know, driven by patient reported outcomes, we struggled to figure out how to implement that in real practice.

And even within a given organization, you may have differences in terms of how that is implemented, be it telemedicine versus in-person versus whatever, what's the composition of your team? These are very practical questions that at
1 the base of it have concerns about how something
2 that I think Barbara said earlier is: Who cares,
3 what resources do I have, and how's it going to get
4 paid for? And how can I do it in the most efficient
5 manner for the context in which we are working, the
6 community that we serve? Which may look very
7 different than in the South versus the East Coast or
8 the West Coast or somewhere else.
9
10 And so having implementation science,
11 promoting implementation science is something that I
12 think a lot of healthcare systems and even other
13 environments would appreciate because it's something
14 tangible that they can see the immediate --
15 potential immediate benefit for. It's also a great
16 way to engage stakeholders in the actual questions
17 from the various perspective. And so for example,
18 the behavioral health integration, you have the
19 health plan, the health system, the patient, or a
20 number of different views that may shape how the
21 program is designed within a given context.
22
23 And so I applaud the focus on increasing
24 implementation science. And I can tell you, there
are a lot of folks who are in C-suites, who would appreciate more of this work as well.

MS. ARMBRUSTER: Thank you, Eboni. David.

DR. MEYERS: Thank you. And yes, adding that this is an passioned part, but I guess they all are for all of us. So that's a good thing.

I think one of my roles here is to ask the group to think about how PCORI partners with its legal partners at HHS and specifically AHRQ to move the agenda forward. And this area really gets into the place where we are most overlapping. AHRQ is required by law to invest the PCOR trust fund funds that we receive in training researchers, the next generation of CR researches and also implementation science researchers.

So we have money to do the training. We also, like you, spend and invest in getting the evidence that PCORI and NIH and others have shown works into practice.

What's really exciting to me about this piece, where the way this is phrased, it's research about the science of implementation. That's a part
where we don't overlap.

So how we elevate that part to show it's PCORI's, and then think about that second part of getting that evidence used. And as Christine said, training researchers within health systems, we have a great partnership that PCORI and AHRQ are already doing. And so, how do we think forward about making this -- building that partnership so that AHRQ is a partner in the implementation not the implementation research, but the practice implementation as well as the training.

I think there are real opportunities to align ourselves there. Thank you.

MS. ARMBRUSTER: Thank you, David. Listening to you, I want to draw an illustration of the flow of that work together and that makes up -- that helped illustrate in a significant way for me. So thank you.

Mike, thoughts about what this might look like, what excites and concerns you about this priority?

Oh, I'm sorry, Mike, you need to unmute.
DR. HERNDON: I think back to my 20 years in clinical practice and thinking what made me change, you know, what made me adapt something new and truthfully and just listening to all these comments, which it is incredibly important priority, but just reading something from a research journal, rarely, I think, creates a lot of change. You know what created change in my practice was when my peers and the people in my clinic, you know, started adopting change. And I was in a network of providers and when my network started producing you know, evidence and saying, hey, this is the new norm, if you will.

So I think as people who are so much smarter than I am about implementation science, I think, it’s just so critical that PCORI develop the partnerships with the medical associations, with the specialty societies as we go forward and not just put stuff out there for others to come and get. But that we put the information collaboratively with the associations and the societies and the health systems so that the dissemination becomes real and
not just something to be read and hopefully grasped and adopted.

And my last comment is, it seems to me that so far all three of these topics come back in some way or another to just kind of practice redesign and order some sort of change in how we do medicine and how we got to start having that national discussion.

MS. ARMBRUSTER: Thank you, Mike. We are at an opportunity to continue discussion about this and there are no named people in the queue. So here's your opportunity to weigh-in? I've heard a lot about how do we implement the science of change and change norms and we've talked a little bit about what excites you about that opportunity and how it relates to PCORI and do you have thoughts about what that might look like in the research agenda or what progress looks like? How do we know when we're doing this well?

MR. VAN LEEUWEN: You know, the measurement needs to be worth the work. And one of the challenges with this is that most of the measurement that I can think of related to this is just too much
work. And so, I'm wondering if to me it would be
really interesting if people came to us with ideas
about how to spread the word in whatever world it is
they're living in.

So receiving unsolicited advice or examples
which would be like really easy to measure, you
know, you just set up a place for people to dump
whatever it is they're thinking about. You know,
it's not taken a bunch of scientists going all over
the place, spending a lot of money, but I don't
know. I mean, I think that -- and then, and then
the goal would justice be to see that increase?

You know? The first month it's one, the
next one it's 20. I don't know. But you know, it's
like, without, like, I don't know. I'm just trying
to think simply.

MS. ARMBRUSTER: Thank you. I've heard
several mentioned that we need to go to additional
disciplines that thinking about implementation
science and health communication may involve
researchers that are not the normal group for PCORI.
And are there some new opportunities? Are there
some people whose voices might be most impacted by
this work that need an opportunity to weigh in on
the process as we think about the research agenda?

[No response.]

MS. ARMBRUSTER: All right. This is your
last chance. We are not running up against time, so
our last chance to comment on this. Ellen.

DR. SIGAL: I just want to add that we're
not that easy to go to. We have a very, I would

call it rigid, but we have a process in place that
is very directed. And if we want to change or try
new models or do different things, we have to make

it more accessible to people to visit focus with us
on what they want to do or how we can change or
different areas of partnerships or collaboration.

You know, who do they come into? Do they
come to the Board? You know, who do they speak to?

How does this work? If we're serious about it, we
have our infrastructure, we have our group, but we
have a relatively -- how should we say it? Way of
working that isn't necessarily easy to change
quickly or to incorporate new ideas in.
So if we're going to do that, we should think about that and what the process would be.

MS. ARMBRUSTER: Thank you, Ellen. I think this has been a running theme that I've heard and something we might want to revisit. We have two additional comments in the queue. First let's hear from Chris.

DR. FRIESE: Sure, good afternoon colleagues. My apologies, I had to miss the first part of this session I was teaching. And I apologize if my comment has been shared, but I'm just picking up a little bit on Sonja's sort of a macro assessment of the conversation.

As we think about, I'm going to use the word implementation science for a moment, but then I'm going to pull back from that a little bit and say, I think one of the challenges, at least in the cancer realm where there's been a lot of work in implementation science and a real embrace -- implementation science has been embraced by funders of cancer research is as a relatively rigid definition of that discipline that I don't think
serves us well. And I think it just speaks to the point of having diverse disciplinary perspectives, people who can really be partnering with our research community with our key stakeholders. With the requisite expertise that is not defined by what somebody puts on their business card or something like that.

So I want us to just think, you know, we do research differently, right? That's part of our tagline. And so, just making sure that we have an — just as we were talking earlier about an inclusive approach, I think the same is true here. There might be some scientists and some expertise that can really help us in this space, that if we stick with that classic definition, some classic definitions of disciplinary boundaries I think we might be missing some opportunity.

I hope that makes sense. And I apologize if that was duplicative to what someone else said prior.

MS. ARMBRUSTER: Thank you, Chris. You got a lot of head nods on that. So I would say that was
an affirmation.

Let's hear from Sharon and then Christine.

DR. LEVINE: So two comments. The first is just to remind the Board about the opportunity with the Alda Institute, I think it's at Long Island University. The Institute on communicating science and health information to the public. There's a lot of expertise there and I think some opportunity to understand what their experience has been in terms of training scientists and people in both basic and health science fields around communication.

And in a similar vein, if we were to do a systematic review of successful and unsuccessful implementation efforts of health system -- of health interventions, it would be interesting to be certain that we captured the learnings from the failures. Most of the time when an effort is made to implement something and it is less than successful, people have a good sense of why it didn't work. And you know, the ability to capture the learnings from failures, too, in some ways, inform practice-based evidence around how to improve the practice of
implementation might be a useful exercise for us.

MS. ARMBRUSTER: Thank you, Sharon.

Christine.

CHAIRPERSON GOERTZ: I agree with Sharon that the ability to learn from failures is critically important. The issue is that they don't end up in the literature as often as the successes do. And so, it's somewhat challenging, I think, to identify them. But I agree that I think it's worth the effort to try to do so.

And then the other comment I wanted to make is just to affirm the incredible opportunity that we have through our partnership with AHRQ to work in this space. It means, I think, we have an intellectual partner as well as a partner to help us to fund this kind of research and the next generation of investigators.

MS. ARMBRUSTER: Excellent. Thank you so much. All right. Last call for commentary about Building the Bridge from Research to Improved Health by Advancing the Science of Dissemination, Implementation, and Health Communication.
Yes, Jen, please.

DR. DeVOE: I was just going to build on that comment you made Christine and others about just strategic partnerships in this area. I've heard CMMI mentioned. I think AHRQ is another one.

A lot of folks in the more traditional implementation science realm that you described; Chris are realizing that they need laboratories. And those laboratories are the real world and their health systems and their tech companies, and they're all kinds of people that are doing innovation on a daily basis. And also moving the needle on methodology so that you can do hybrid effectiveness and implementation studies to really push the science and accelerate the pace at which you get answers, whether they're positive or negative, whether it works, whether it doesn't work.

So I think this is another area where I don't know if there's opportunities to partner with AHRQ's ACTION 4 network or some of the other networks, maybe PCORnet, other places where we can really think about innovation laboratories to do
implementation science, and payers, health systems, other federal agencies, et cetera, would be opportunities to do so.

So just thinking about the laboratories that we want to support and partner more closely with in this space.

MS. ARMBRUSTER: Thank you. Steve.

DR. GOODMAN: Yeah, I just wanted to sort of connect this to the very first discussion in the health equity space. You know, the way this is framed, assumes that if we have perfect information flow, better health will follow. But, of course, we know very well that making people, and this is again, linking to the aspirin example and the other things we talked about. Even if people know all the science, even if the physicians and healthcare deliverers are giving the proper information, people often don't behave in the ways that will result in improved health.

So this is captured, and I do think the previous comment was also good, by implementation scientists, but also by behavioral scientists, and
the kinds of interventions that induce behavior change are very, very different in different communities. So this goes back to the point one. So what was missing from the text here, although is in some of the comments is behavior. Not just not the behavior of the patient or the participant, not just the behavior of the providers. And that requires a completely different model for thinking about what induces health promoting behaviors in many, many contexts where the physical infrastructure, the economic infrastructure, and many other support systems don't support or promote optimal, you know, following even perfect advice. And if you gave people a quiz, they might score a hundred percent on the quiz. So it looks like we've disseminated. It looks like we've communicated, and yet people don't do the right thing. And I actually include some people on camera right now. So that is, I often don't take very, very good advice, but the issues for me are very different than other populations. So I want to make sure you have health
behavior and the heterogeneity of different cultures and different populations in mind here.

MS. ARMBRUSTER: Thank you, Steven for bringing us back to purpose and back to some of the other issue topic briefs that we've discussed and for reminding us of the complexity of health communication involving health behavior change.

Thank you all for a robust discussion of this national priority draft. We are at a time boundary. We will have additional time to discuss this tomorrow and you have made it through three of five. So we are over the midpoint and I hope that that sends you to break in an energizing way with that, I pass back to Christine.

CHAIRPERSON GOERTZ: Thank you, Sonja and all for another rich discussion.

We are going to take about a nine-minute break. So please come back at 2:50 Eastern time and we will finish up with our last two national priority discussions.

[Recess.]

CHAIRPERSON GOERTZ: All right, so we have
Connie and Eboni. Why don’t go ahead and get started then?

MS. ARMBRUSTER: All right. Well, thank you, Christine and welcome back everyone, as you know we are working our way through the five draft priorities. And as we turn to our fourth of five, we are looking at Enhancing Infrastructure to Accelerate Patient-Centered Outcomes Research and our introductory comments will be provided by Laura Lyman Rodriguez, PCORI’s Interim Program Support Officer and Senior Advisor to the Executive Director. Laura.

MS. LYMAN RODRIGUEZ: Thank you, Sonja. And thank you all for having such a wonderful conversation this afternoon and as we go into this final session of the discussions for the draft priorities today, as is evident from the title of this draft priority. We’re going to focus here on support for and support for advancement of the infrastructure that undergirds the ecosystem to enable and empower health research, in particularly, patient-centered outcomes research within health
research to go forward.

As we've discussed this morning and we're all very familiar with the health research enterprise is incredibly complex. And it also overlaps greatly with the healthcare infrastructure, which it sits next to or within or in many different relationships with, but here the focus for PCORI is really on the elements of the health research infrastructure itself. And in particular, the people, the information -- both in terms of data generated and captured; as well as the knowledge that emerges from those data, and the policies and processes that must come together for there to be true connectivity across the ecosystem for optimal performance and the generation of benefit through timely and responsive research.

I also just want to note here, too, as we have been developing this draft priority, thinking about the unique opportunity for leadership for PCORI here -- oh sorry, thank you for moving this slide -- to think about this because of the breadth of our relationships and remit with regard to
stakeholders that interact with activities across
the different parts of the ecosystem for different
aspects that must come together for Health Research
to go forward.

And also, again, reflecting on conversation
from today and conversation over the years of just
the acknowledgement of when this ecosystem and the
different components of the ecosystem are not well-
aligned or they're not able to work together
efficiently, can really lead to some missed
opportunities to make a difference in important
areas, as well as undermine the overall success of
realizing improved health outcomes.

So if we move to the next slide now and
review as we have with the other draft priorities
and some of the inputs that we've received in the
conversations with stakeholders, the discussions
with this group, as well as within the Strategic
Planning Committee. Here, again, really focusing
within this draft priority on enhancing the
connectedness of the different components that I've
already mentioned within this health research
infrastructure and the ecosystem within which it must exist.

And again, reflecting our conversation this morning and some of the discussion that was noted by Board members about how important different definitions are for the terminology that we use to know what we're actually talking about to say a little bit more about those three components. So starting with the people, of course, we heard earlier about how important that people are to have the people really working together and the right groups included within that.

So here PCORI, within this draft priority, is thinking very broadly and thinking about the patients and the providers, of course, but communities and other stakeholders that come together and the research workforce as well that comes together to affect the research and conduct the research. And again our definition of workforce in this case is broader than just providers or researchers, but all of the different groups and disciplines and partners that must come together,
again, to accomplish the work of the research, in a way that enables it to be very patient-centric in its design and its implementation.

From an information perspective, again, just to talk a little bit more about that and focus in each of these areas that it's not just about who they are and the draft priority doesn't just focus on the connectedness, but also about pushing forward and driving improvements and enhancements in each of these components. So with the information, it's not just talking about the data that are generated or that are captured, but making sure our methods and our systems for capturing that data ensure that it is accessible, that it's interoperable, and that it's secure so that the system itself and the way that the data are used can be trustworthy.

And again, we've heard a lot about trust already within the context of the other priorities.

And then finally, thinking about the policies and processes. We all know within these systems, how important it is and how important it is for them to be connected, but really thinking here
about what are the opportunities to pursue, how to truly make them not just connected but to create connectivity across them so that there is real momentum and so that this focus on the patient-centered nature of the work can really come through and how research is designed, how it is prioritized, and again, how it is implemented to truly be inclusive and evidence-based in what is going forward.

So with that I will stop and I will turn it over to our discussants, and really look forward to the conversation with everyone.

MS. ARMBRUSTER: Thank you Laura for that foundation and for giving the greater context to this title, Enhancing Infrastructure to Accelerate Patient-Centered Outcomes Research. We now get to hear from two of our Board of Governors members in a reactor panel, we have Connie Hwang and Eboni Price-Hayward.

And thank you both for giving special attention to this area. Would you please each both share a few minutes about what excites and concerns
you about this national priority, and the
opportunities you see it bringing to the work for
PCORI. And let's begin with Connie.

DR. HWANG: Great. Thanks so much. And I
appreciated that nice summary about this priority.

So when I was reviewing this, you know, I
understood the purposes of this brief to be focusing
on a fairly broad term; the health research
infrastructure encompassing people, information,
processes, and policies. Where frankly, PCORI is
really well-situated, you know, as a convener and a
funder.

So what excited me the most, especially if
this is executed successfully is that we can really
bring forth new opportunities for a variety of new
individuals and entities to engage in patient-
centered outcomes research. And, you know, with
that, maybe what I can try and do is just give you
some of my top little thinking on each of those
three sections.

Now, so let's talk about the people section
and I was really happy to see here the great
interweaving of a focus on health equity and
advancing diversity, equity, and inclusion
principles in that. And it's really thinking a lot,
I think, when you read through the career
trajectories of health research workforce. So
mentoring, networking funding, there was a good
example in there about the partnership with AHRQ,
which I think was mentioned in our previous
discussion. So all great ideas.

I think the part that jumped out to me or
where I was most intrigued, is this concept
investing in communities and community organizations
with a lived knowledge of health and social
environment. Especially since they're uniquely
situated to really inform a lot of the healthcare
research. You know, especially also related to
delivery.

So it really brings to mind for me in a lot
of the daily work that I do, but so many healthcare
entities partner with these community-based
organizations. So think local, regional economic,
you know, prosperity groups. You name it. Groups
that are faith-based, et cetera focused on care, coordination, and services. But what's funny is you hear about all these fantastic examples of pilot work, you know, that involve community health workers.

There's a collection of data points, et cetera, but it brings to mind, to me, what's really stopping more groups like these be it patient groups, community health, community-based organizations, or even, you know, community health plans that I work very closely with. But really deriving source funding from an organization like PCORI. So I think this is a question for us to potentially spend some more time pursuing.

So with that, in terms of what I reacted to in terms of the information section, I agree fully with, you know, building out a more robust infrastructure focused on real world data and are interoperable, readily accessible. I think that's everybody's dream. Right? And where PCORnet could be a leading example.

Again, what stood out to me and where I
think we can do some better emphasis is really on this data linkages aspect. And it seems like we probably have, globally, some opportunities there.

So when I was previously on the PCORnet Working Group several months back, I found really interesting that claims data fees, you know, for potential joint analysis out of the nine clinical research networks. There were really only just two payers, so it was Anthem and Humana. And this was just one of the things that stood out and I thought, you know, access to the data infrastructure here could potentially deepen and, you know, and when you think about a lot of the commercial activities out there, when you're speaking with healthcare entities, you know, particularly community-based health plans, anything that they're doing to support a population health initiative, or working with a vendor, being able to utilize those two data sources: claims and EHR data, is in many ways table-stakes. Right?

So I think here, could there be an opportunity to deepen particularly like you know,
with a very, a major data source, like from CMS. We get, you know, some of that claims data you know, in a way that that could be integrated. Food for thought.

And the last thing I want to comment on is on policies and processes. And here PCORI offers an opportunity to enhance sort of organizational processes and programs to make, you know, itself more available to all stakeholders. And so you know, when I was preparing this, I kind of hesitated whether I was going to share this example or not, because it's really like an N of 1. So everybody's got to take it with a grain of salt.

But truly last week I was on a call with a former head of a nonprofit organization, that's focused on advocacy in clinical area. And this individual, when they were discussing their grant-based portfolio and fully unprompted by me actually said, “You know, even though PCORI reached out to engage, found that the administrative requirements potentially too burdensome for our small staff.”

So I thought fascinating. Again, take it
with a grain of salt. It was N of 1, it was totally random, but I thought, wow, what a fascinating signal kind of out there.

And so, I think this opens up ways to think about how we can engage new individuals, entities, who really don't think of themselves as traditional academic researchers. And I already recognize that PCORI is exploring some new funding mechanisms, which I think is really exciting. But I do think having this called out in this priority could really be a very promising channel.

With that, I'll pause and hand it over to Eboni.

DR. PRICE-HAYWOOD: Thank you. [Laughing.] Well, you stole my thunder and a lot of my points, but that's okay because I'm going to pivot and come up with a different angle on the spot. I want to feed off of some of the things that you said. So in several different ways on the people part, the workforce, you had mentioned working with these other community groups, right?

So in my notes, I said to myself, working
outside of your traditional academic institutions and what can we do to build the infrastructure, to support those communities who have knowledge, who can come up with solutions, but to this last point that you made, they may not have the resources or the knowledge to adapt to the way things are currently under PCORI’s structure for funding.

And then the question is, what skills do we need to build in those community groups in order to participate in PCOR? And then if that's the case, have we actually defined what the core competencies are for the conduct of this research?

So if I'm going to engage different groups, academic/non-academic, researcher versus public health versus some other sector. And the idea is for them to come together and collaborate across disciplines in a given study. Are they coming to this collaboration with the requisite knowledge — base knowledge, I would say besides their own personal expertise? So how do we define that in order to know how to develop that workforce inside and outside of an academic center, health system,
and other settings? I think that's incredibly important.

I think we also have to be mindful that in how we incentivize participation or diversifying the workforce, that we have to be careful to not disincentivize the potential for research in those non-academic settings. So yes, we have the, the relationship with AHRQ. I wonder, are there other agencies that we should connect with in different sectors, kind of in the same relationship, but recognizing the different contexts or, you know, the perspective of those stakeholders in those different agencies is something to consider.

In terms of real-world data and PCORnet, again, I was also on the work group. And also as you will most of, you know, a former site PI. So the perspective or the lens through which I am speaking is in that formal role and also as a health system who struggled to participate, who sees value, but then, you know, there are some gaps that need to be filled.

So the very first conversation we had today
was around equity. One of the concerns that we have to be careful about when you're using data for secondary analysis is, is the sample representative? And when you say representative, of who? Because if we're going to use this data for some larger purpose and it is connected to equity, and we want it to be connected to equity, you have to be careful to make sure what we're using allows us to do that.

You know, our methodology focuses on heterogeneity of treatment effect. Well, you can't do that analysis if you don't trust the data. If you don't feel that it's representative of however you define that. So that's something to be noted.

The issue of data linkage is again important. And I agree with the Medicare claims data. There are other types of data that are out there that would be helpful to integrate if we could figure out how. And I'm not always sure that some of the different data sets that we've talked about including state registries or patient -- like data from wearable devices, how do you integrate that in this kind of a network? By the way, the network is
limited to those participating institutions, right?
So it's not the whole country.

And so with that in mind, have to think
about are we missing social determines of health?
Is there a way for us to do something to integrate
that into that network? We know that the health
systems that are contributing the data are not all
collecting it the same way. So you're going to have
issues of data quality there. So we do need to
think forward about that.

That may be an opportunity for us to
develop patient registries, where people,
institutions who are participating may have a
separate initiative around getting patients who are
in those networks to participate in registries,
where you can prospectively collect whatever
information we need to link to EMR data that
otherwise is not systematically collected.

The other piece is the disseminating best
practices around research informatics, right?
Outside of those academic institutions. And if
we're going to build up this network, I would say,
think about it sort of like what the new generation CTSAs. Where if you participate in these CTSAs, there's an expectation that you contribute knowledge around technology and some other veins. Can we develop that? That's incredibly important for reaching back to the health systems who are contributing so that they can shore up what they contribute so that your data is an accurate valid data set. And I think we went through some concerns or questions about variability across the different systems.

The last piece in terms of inclusivity, I think ties into the other two, but I want to comment specifically on a statement around funding, the science, and engagement and the need for evidence-based models for patient and community-driven research. That provoked in my mind, you know, we've had these engagement awards. What have we learned from past funded studies? What works for whom under which circumstances? And have we ever compared engagement methods?

Right? You can start there with what we
have. But we also have to think about how to develop sustainable research infrastructures outside of academic institutions. And so really thinking about those other sectors, the health systems, payers, industry, public health, social service agencies, whoever the case may be -- some community organization.

How are you going to strengthen them to be able to sustain the work, if we just said that the source of truth and source of solutions comes from those groups. You know, so all of this people, data, policies and procedures around accessing the infrastructure, all of that is incredibly important. But there are tons of opportunities that we can explore in order to do those, I think, in the best way.

MS. ARMBRUSTER: Thank you both for those thoughtful reflections on infrastructure and what we can do to support infrastructure for patient-centered outcomes. We're going to shift our attention from what's exciting about this to what you think success or progress might look like and
how might we influence that national research agenda as a starting point. And I want to go in reverse order on this. So Eboni, you get to speak first, no thunder stealing.

So I'm curious about, I mean, you even just your first -- one of your questions that you asked about what engagement methods work. I'm excited about thinking about those kinds of metrics. So what, what were you thinking about progress and what success might look like?

DR. PRICE-HAYWOOD: Honestly, I hadn't thought about performance metrics. I actually thought about what would be the next steps to answer some of the questions I just had.

MS. ARMBRUSTER: Yes.

DR. PRICE-HAYWOOD: So starting backwards with engagement strategies. And, you know, I asked myself, do we know the secret sauce? What's the formula? How do I replicate this in other places? Well, first maybe go back and look at the information that we have from prior awardees. And we may need to generate an evidence-based report
from that past studies and to figure out where's the knowledge gap, because we can't inform future research or anything else that we do if we don't pause and look back first. And so to me, generating something like that, if it doesn't already exist is incredibly important, but I think out of that work, you can develop as an agency, a toolkit or some sort of guide for different forms of engagement targeting specific stakeholders.

Doing so may then generate those research questions that we need to do some sort of comparative effectiveness around engagement strategies, and you know, all that goes into that. So that was one initial thought.

The other thing is, you know, for PCORnet, I'll probably go back the same thing I said before, which is around setting the standards for how we're going to define representativeness of a data set. And that's important because if you're going to use that, how are we going to have external generalizability of studies if the baseline data is not representative?
The other thing in terms of informatics that we have to be mindful of is a systematic introduction of bias into analytics because of your baseline dataset. So I wouldn’t think about anything else until you first set a standard of what you mean by representative. And then you can get into data linkages and all the rest of that stuff.

And then finally, as far as the workforce is concerned, If we’re going to develop things like the equivalent of a career development or a training award. And again, not thinking about that academic traditional pathway. Can you establish stakeholder tracks in this training? Right? Whatever the, you know, there are some core competencies that we’re going to teach you, but from this perspective of this stakeholder, this is an asset or skill that you bring to the mix and we’re going to, you know, have some sort of development around that.

Now where that training sits, I don’t have all the answers to that. But I just want us to be mindful of the end product of workforce development, is that we are looking at different types of people.
and we are developing these tracks in PCOR for different types of stakeholders and doing things in such a way that we're optimizing their contribution to the research, as well as leaving them with a larger capacity of skills in this particular area. So some of those barriers that Connie had mentioned before, part of the process would be to not only just change our policies about how we do things, but give people the extra skills sets to diversify the resources that they could tap into because you've increased their knowledge-based skills and everything else that goes along with doing any type of research.

MS. ARMBRUSTER: Thank you Eboni. So many new directions to think about what progress looks like. And I appreciate your, your considerable thought about that.

Connie, it's your turn.

DR. HWANG: Yeah, well, it's always great following Eboni because I would say, “Yeah, that too.” Right?

So I did very much like Eboni, what you
mentioned about taking stock in many ways of our
engagement awards so far to really say, "Hey, what
kind of interesting, you know, knowledge have we
generated best practices this way and where it leads
us better to understand what kind of potential gaps
we would want to set our sights on. I think that
makes great sense.

And very much resonated with that whole
workforce development and really trying to approach
it from a non-traditional academic perspective but
through development throughout with these different
stakeholders, and how would that sort of look. I
think a fantastic suggestions and questions.

You know, again, what I'm most excited
about for this, and when we think about just overall
progress is, you know, what kinds of new entities,
new individuals can we engage with at PCORI? Right?
And so, maybe some of the metrics that I'm sure will
require lots of brain cycles on, but just, you know,
understanding like what new organizations have we
brought into fold? Which geographies do they
represent? What kind of patient population, you

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know, are the areas there.

And then ultimately it’s a harder one to answer, but what kind of new questions are we surfacing? Right? And that really represent some unique perspective that, you know, really needs some visibility and really has an opportunity to improve health.

I would be really fascinated by ways to track and think about that.

And ultimately the end, I mean, through all of this and if we sort of step much further back. What outcomes are we interested in, in engaging all these other diverse stakeholders in groups, is really has the health of your community improved? Right? Can we link in many ways, some of this work to actual shifts in outcomes and I think, again, worthy of some time and thought.

One other thing that was in this prompt, it was -- or earlier on, you know, what are you excited about? What are you concerned about? So lots to be excited about and I would caveat, I wouldn't say I was concerned, but it would be one of these things
that if PCORI is truly to pursue this and execute on it. There really has to be a willingness for this to be really bidirectional and willing to change.

So this is not so much about PCORI has a great idea, I'm going to go out to these small groups and tell them why it's such a great idea. And this is how you can engage. Really, I think to take this on I think it would be best positioned for PCORI were willing to be extremely flexible with a lot of the new potential stakeholders groups coming in.

So that's more of a, just a mental note, right? In terms of ways to go about this. Again, lots to be excited about, but I think important to also recognize that in order for this to be successful, probably a lot of change may need to happen.

MS. ARMBRUSTER: Thank you Connie for that challenge. And a reminder, this was discussing what our concerns were was a piece that the Strategic Planning Committee really wanted the full Board to have an opportunity to discuss. And thinking about
if we're going to bring in new partners, how do we create bidirectional conversations, I think is a cross-cutting theme that I'm hearing across several of these priorities.

Thank you both for your thoughtful analysis. I want to bring back the rest of the Board. We have about 20 minutes, 15 to 20 minutes to continue to discuss this national priority related to Enhancing Infrastructure to Accelerate Patient-Centered Outcomes Research. And I want to invite everyone back and again, invite you to use the chat and/or wave, and we will get a queue of speakers going, but we have much to discuss.

I'm interested in what excites and concerns you. I'm interested in where else you're seeing cross-cutting themes and launch points for research. So after listening to the, to the prepared thoughts what are some initial reflections from the Board? Who'd like to go first?

All right, Alicia. Thank you.

DR. FERNANDEZ: I'll just make a simple comment, which is that to really underscore what
Eboni said about representative, I am not excited about investing in infrastructure that is not representative and does not allow us to align with the work. I think it leads to bad science, which is as Eboni pointed out. And for me, that is -- that's really going to be a lot of what is shaping my views on all of this moving forward.

With that said, I do think that if we are able to make PCORnet and other investments more representative to continue to fill, just as has been said that there's a lot of exciting work that could be done. So it's sort of like if we can get past that hurdle, I think it's extraordinarily valuable.

MS. ARMBRUSTER: Thank you, Alicia. I'm looking in that chat for requests to speak and also on camera, you can just unmute and wave. Yes, David.

DR. MEYERS: So really exciting again, I thought the panelists had brilliant comments. I want to encourage PCORI -- this time, I don't have to speak as much from AHRQ, who're in the workforce, at least the academic workforce. We're a good
partner for you, but needs the plan as it moves forward really needs, and so this is my concern, specificity about NIH is spending a lot of investments, CDC is spending a lot of investment, and HHS through the PCOR trust fund gets a small investment every year with almost the exact words of this description.

And so, we've got to be very, very clear in what's our lane, even more so than in the others. How are we going to invest in moving forward the infrastructure for research? I think the panelists did a really great job of focusing on the areas that HHS would be less likely to focus on, the non-traditional partners and how to bring them into it.

But we're in jeopardy of investing in PCORnet, when NIH is building a very similar kind of EHR distributed network, where CDC is revamping the public health workforce with close to $900 million. We want to really be able to show clearly what's our space and then set our measurement in that and show how we're not competing.

MS. ARMBRUSTER: Thank you, David. I hear
it clarity about the PCORI's lane as it relates to other partners in this work.

Danny, James, and Chris. Danny.

MR. VAN LEEUWEN: So I'm curious about what -- wait a minute, my brain just froze. Hang on.

What is unreal-world data? That I'm just curious about calling something real-world data now in my world. I would say that EMR and claims data would be called unreal-world data. But it's included here under real-world data. So I wonder what isn't included.

Now in a similar thread, I think one of the things that we can do, especially with PCORnet is be thinking about what I might call real world data and including that in our basic set of data, like all the work that's happening right now with MedMorph incorporating the public health data set that there's lots of people working on that. And I'll bet they'd love an opportunity to bridge into the PCORnet common dataset.

MS. ARMBRUSTER: Thank you. Before we move on, is there someone who could answer Danny's
question about what we mean when we say real-world data?

MR. VAN LEEUWEN: No, there's no, there's a good definition of real-world data. I don't know what unreal-world data is. Like, what isn't? It seems like it's everything.

MS. ARMBRUSTER: I think it's a useful distinction.

MR. VAN LEEUWEN: Yeah. So I'd like to know what's not included, like what's unreal-world.

DR. MEYERS: So Danny, this is David. I'm not sure this is an answer, but I think it may be that when we do clinical trials where everything is standardized and people are getting incredible supports, and then you find the data that, you know, what happened to their blood pressure or what happened to their quality of life and then say, therefore, this thing is effective.

It was done in an unreal-world environment, as opposed to how does that medication, how does that intervention affect people or help people thrive in a real-world situation?
So it's removing, it's trying to understand what happens when you don't have the incredible infrastructure that research sometimes brings. I think one of our great successes recently is the COVID vaccines and everybody knew how effective the COVID vaccine was in its trial. And we were all really, really anxious to see what would happen when it wasn't in the trial. And the good news is it looks like it has similar efficacy and effect and therefore effectiveness.

Does that help and do others agree? Is that what we're talking about?

MS. ARMBRUSTER: Thank you. That was -- lots of head nods there. So we're going to accept that as the distinction and we really appreciate you taking that moment.

I see a question in the chat and I'm going to come back to that, but I want to give the opportunity for those who want it to reflect first. So I'm going to move to James and then Christopher.

DR. SCHUSTER: Thank you. And I had to switch devices. I missed a little bit of the
discussion. So if somebody said this, please
forgive me.

But I wanted to come back to the comment
Connie made about her conversation with the small
not-for-profit and the fact that they felt that
participating in standardized research was beyond
the capacity of the organization. And I have to say
that that's even true for relatively large
organizations that have not -- are not affiliated
with or tied in with a traditional academic setting.

There are many health payers, there are
many large not-for-profit systems that really see
participation in research as something they're not
familiar with and probably anxiety provoking or of
little interest for other reasons.

So I think, I think this is a great
priority, but I think one of the strategies for us,
and this is not really a research strategy, but more
of a process strategy for us to think about is, are
there things that we can do to provide some kind of
joint infrastructure that we might maintain in some
way or otherwise provide some support or engagement
strategies for these organizations who aren't going
to participate in research. At least that's been
our experience up until now. Thanks.

   MS. ARMBRUSTER: Thank you. Christopher.

   DR. FRIESE: Sure. Thanks. Thank you all.

   I'll try to be brief.

   I think the Board is pretty aware of my
prior viewpoints on PCORnet past, present and
future. I won't reiterate those here. Just to the
current discussion as we do strategic planning, I
want to underscore Dr. Price-Haywood and Dr.
Fernandez's really important point on inclusion and
representativeness because if we're not meeting
that, I have even more concern.

   But I want to think about it from the input
perspective, but also from the output perspective.
And I think one of the concerns I've had about
PCORnet is the accessibility of that asset that is
publicly funded, it is funded through us, and making
sure that that asset is as accessible as possible
that aligns with our strategic objective. I think
in some ways it is used by a certain group of folks
disproportionately and not either accessible or available or realized as an asset to other groups that would benefit from it.

So I think that needs to be part of the planning as we think about who is part of the network, is also who is using the network, and is the use of the network equitable and reasonable, and are we answering the right kinds of questions?

And it goes a little bit to what Dr. Meyers was saying. You know, what's our lane in this new environment? And I see Dr. Fernandez's point about that, too. I mean, we want to be really clear, particularly in this more-crowded space than it was five or six years ago.

What are we adding? And are we meeting the needs? Are we able to use the asset appropriately?

Thanks.

MS. ARMBRUSTER: Thank you. And that tees up a question that was raised related to a comment that David had made about NIH, having something similar to PCORnet, and maybe someone could elaborate on that? And perhaps Michael has the
answer to that. Can you speak to that?

DR. LAUER: Yeah, I'm sorry. You know, I was hitting, I thought I had answered it in the chat box, but I see, I only sent this to the organizers and not to everybody else. But the bottom line is there is a specific project that we presented to our ACD on May the 6th. This is a special allocation that has been given to us by Congress to use to develop AI or machine learning methodologies.

And so, what we're going to be doing is -- we're going to, it's $50 million, and we're going to be using this for figuring out ways to apply AIML to electronic health record data. and it could be used to conduct research on health disparities, mitigate biases, evaluate various factors on health, ways to measure health disparities and inequities. In any case, this has very little to do with what PCORnet does.

So as mentioned earlier, PCORnet has made it possible to do a trial like ADAPTABLE, just absolutely amazing, you know, 15,000 patient, practical trial. The kind of trial that we usually
think of as something that can't be done in the United States, but can only be done elsewhere. And that's because of the infrastructure that established the common data elements and so forth. So anyway, what's being done here is very different. Yes. So you're absolutely right. That it can be done with PCORnet and yeah. We sure hope so. And there is another project called N3C, which is a COVID data project and PCORnet is actually part of that. PCORnet is a critical component.

MS. ARMBRUSTER: These questions and ideas are critical to the strategic planning process, which this identifying and better understanding these national priorities is core to and our purpose for today was to solicit the insights and wisdom of the Board, and this conversation is really rich. So thank you for those insights and expertise that you're all bringing.

We have just a few more moments with this particular issue related to Enhancing Infrastructure to Accelerate Patient-Centered Outcomes Research.
Are there additional comments anyone would like to make?

MR. VAN LEEUWEN: I have another question. Are study participants considered workforce?

MS. ARMBRUSTER: Several nods to the no.

DR. CARINO: I would think, I would say that they should be because you want them to be continuous participants in research. Wouldn’t we want to cultivate, we used to call it a citizenship in research. So why wouldn’t we treat them like any other stakeholder?

We don’t have to answer that now.

MS. ARMBRUSTER: I think this is an interesting idea that is related to the cross-cutting theme that I'm hearing around work in this national priority and in all of those that you've mentioned involves working with new and different partners, which also may involve working with different disciplines and different kinds of workforce.

So the continued conversation about how we engage new and different partners as part of the
infrastructure of this work looks like an apt area for exploration.

DR. AYERS: I would also add -- this is Kara, that considering them -- I mean, I don't know if we need to consider them as workforce, but just trying to dismantle that idea of us and them in recognizing that we're all patients, and I'm not so much thinking of our individual status as patients. Although, you know, we are at some point, but just that all of us traverse both of those worlds. And so, trying to yeah -- bring down that us and them is helpful.

DR. CARINO: Yeah.

MS. ARMBRUSTER: Thank you. Thank you, Kara. And Steve has a comment.

DR. GOODMAN: Yes, I was -- I had to be gone for about 15 minutes, so I apologize if this was already made, but you know, we've been talking about the difficulties of maintaining health. But, of course, the best way to do that is through prevention.

Most huge advances in health are through
public health measures, not through the therapeutic sick care system. So I just wonder if anybody's talked about these partners being public health systems who worked so hard, and yet is seemingly completely divorced from the healthcare system. And we've seen that -- this loom incredibly large in the COVID response where we get these robust and dramatic responses from healthcare systems where the public health systems are grotesquely underfunded and understaffed.

And they're looking at many of the very same factors that we have been talking about today and operating in settings where they're trying to maintain health and not just take care of those who are already sick.

Has that been already broached? No.

So I think we should think of in terms of our partners. We might want to extend to our public health partners who often work in care settings and they left for public health because they felt that they weren't making enough impact on health. And they're very, very embedded in communities. Exactly
what we have talked about wanting to be, and they are embedded in ways that can dramatically extend our impact.

So, and they need our help. So we'd have to think creatively how to do that. Most research funders don't partner with them because they can barely do research because they're so understaffed. But again, COVID offers a really interesting model and perhaps we could extend that to other conditions.

MS. ARMBRUSTER: Thank you. I think that reinforces a comment that was made during another priority session and also some comments from Dr. Hwang. So yes, absolutely, public health engagement I hear as being an important opportunity as we think about infrastructure.

Okay. So many more conversations that are valuable if we had more time, but we are back at a time boundary, please keep thinking about this so we can have a conversation tomorrow about those intersections of all of these national priorities and your final takeaways.
So we have one more priority to go. Christine, I pass it back to you.

CHAIRPERSON GOERTZ: Thank you Sonja. Once again, a very rich discussion. We have a five-minute break. So please come back at 3:40 Eastern time for our last discussion of the day.

[Recess.]

CHAIRPERSON GOERTZ: All right, Sonja, I'm going to turn it back over to you then for our last discussion of the day on national priorities.

MS. ARMBRUSTER: Excellent. Well, welcome back everyone. I'm so pleased you are; this is the last of five. Let's just enjoy and appreciate. There's been so much work done and hold fast to purpose as we continue our conversation now.

We are going to end our day with a robust discussion of Advancing a Learning Health System and to help us begin with some background, Steven Clauser, who is the Program Director of the Healthcare Delivery and Disparities Research Program at PCORI will provide some background information.

DR. CLAUSER: Okay. Thank you so much,
Sonja.

Okay. This is the last one for the day. And what we're going to discuss is the priority Advancing a Learning Healthcare System. Now this direct national priority really reflects feedback from stakeholders that, you know, high performance, healthcare systems both today and in the future are going to be those that use data and evidence to continually evaluate their organization, environment, and customers to continually improve their performance on behalf of the individuals and communities they serve.

And from a patient-centered perspective, this really means striving to build systems of care that are designed and a little more weighted towards the needs and preferences of individuals and communities rather than weighted more towards the needs and preferences of health systems. So new approaches to engagement in evidence generation will be required to address the barriers and some of the practical challenges in organizing, delivering clinical care to advance this goal. Next slide.
Now this threat priority really extends the existing improving healthcare systems priority to support generating evidence that hopefully results in less fragmented care oriented around outcomes, preferred by individuals, including their care experiences. Areas of potential exploration can include promoting cross-sector partnerships among public health, community-based, and other systems of care to advance knowledge about how to address population health from a more whole-person framework. And this is throughout the care continuum.

To improve our understanding of approaches to information sharing and exchange, to reduce the gap between knowledge generation and improved outcomes by decreasing barriers to care and advancing health equity for all Americans. And research to compare policies, care delivery practices, and payment models to improve patient-centered outcomes, including the patient experience.

And finally, initiatives create a culture of integrating research into practice through new
methods and strategies for conducting research and
feeding this information into successful health
system implementation.

That's all I've got Sonja. So I'll return
it back to you for discussion.

MS. ARMBRUSTER: Thank you, Steve, for
giving us that foundation and to help us further
consider advancing a learning health system.

We will now hear from PCORI Board members
Tanisha Carino and is Sharon Levine with us?

DR. LEVINE: Yes, I am.

MS. ARMBRUSTER: All right. I can't see
you, so great -- thank you. All right.

So welcome back. thank you both for taking
the time to provide some background and additional
thoughts about this today. We're going to begin
with Tanisha and you know, the questions; what
excites you and concerns you about PCORI's role and
our opportunities to advance change in this area?

DR. CARINO: Thanks Sonja. And I’ve been
intentionally pretty quiet throughout the previous
discussions because I actually view this session and
this priority almost as a capstone to all of the things that we've talked about as a Board today.

So I loved in the pre-read that we've acknowledged that for the last couple of decades, we've been talking about a learning healthcare system, much work has been done by the National Academy of Medicine to prepare for this session. I went back to look at where are the frameworks at this moment for what constitutes a learning healthcare system and what are the factors for success?

So I found a very interesting paper that tried to synthesize what the body of literature was around learning healthcare systems that was published in 2019. And what I really liked about it is, they divided it into three sections: frameworks around what the outcomes of a learning healthcare system are, what the processes are and what the pillars are a foundation for a learning healthcare system.

So I'll start there. You know, when I think about a learning healthcare system, it's a
system because there are actors within the system that share goals and I think the goal that's been stated today in terms of the learning health care system that I loved in the pre-read was the idea of not retrofitting the system to the individual. But in addition to individual goals, we have to consider population, community-based goals, the provider experience, and we have to consider what's of value and acknowledge that healthcare costs are part of that equation. Particularly here in the U.S., where we're constantly having to balance the public health needs with affordability for how we're going to achieve that.

The second area around processes we've talked about today, whether it's knowledge management, whether it's change management, implementation science, data management, and the role of infrastructure. But one of the things that I'll say is all three of these processes for me, are really important to get right in the local level. What the COVID-19 experience for me has resonated is that we can have scientific research, but at the end
of the day, there's a difference between vaccines and vaccinations. And in order to fully achieve the promise of any new innovation, you have to get very local. And to get really local, it means that we have to think about creating capabilities in a way that are both enduring and sustainable and flexible because not every community is the same.

And I always think about like the idea of the diversity of communities, especially when Eboni talks to us about the experience of PCORnet. So with that, I will say that there are on the foundations of what creates a learning health care system, whether it's legal frameworks, whether it's scientific knowledge, policy, all of these factors to me are areas that PCORI has a really distinguishing role in what we've already invested in how to drive those forward.

So there's a couple of things that stand out to me. We've talked about the role of PCORnet. I also was on the PCORnet Working Group and what excited me about that was the array of different kinds of communities that had come together to
design PCORnet. But also the opportunity that still existed to actually align what we're learning in clinical research, clinical practice in those same exact geographic sites.

So how do we break down those walls between leaders of research and leaders of practice? And that's a lot of how do we think about stakeholder engagement? And when you think about a learning healthcare system, it goes beyond the walls of research, and in fact, it goes beyond the walls of the healthcare system itself.

So for me, like the opportunities are continuing to build on data needs, how we think about stakeholder engagement, how we think about capabilities building. But the real heart of it and I think this has been said multiple times is who and what is the role of culture change of creating champions that are long-term champions? You know, I've done work on vaccine hesitancy. And what you find is that people who are -- the way to change and address vaccine hesitancy tends to be with cultivating the same champions that they turn to for
information about diabetes, information on prenatal screening. In communities these tend to be the same voices of trust that the other members of the community listened to.

So that's what I would emphasize this idea of enduring sustainable investments and that really does raise questions. I think Ellen raised it earlier about how do we maintain flexibility? How do we create a process and an approach for PCORI that is accessible?

How do we make big bets? Possibly big bets in fewer places so that we actually can get deeper and see what it is that works, and then be an agent for disseminating information through a lot of different kinds of partnerships, whether they're with an AHRQ who's already created learning healthcare systems network, or through HRSA that's already got the FQHCs, or through CMMI that would provide the same kind -- some kinds of policy flexibilities in terms of implementation.

So I'll pause there and let Sharon go next.

MS. ARMBRUSTER: Thank you very much.
Exciting ideas and what an incredible ability to recap and listen to your colleagues throughout the day. So thank you, Tanisha. Sharon, thank you for taking your time to share your initial thoughts about our opportunities and what excites and concerns you about this priority.

DR. LEVINE: So let's start off by saying that like Tanisha, to me, this priority is -- Tanisha, you called it a capstone. For me, it's where all of the others come together and we can't achieve a learning health system without accomplishments and progress at each of the core elements that are part of the other priorities.

And I think actually I took somewhat of a contrarian view. The title of the priority I took literally, which is a advancing or I wouldn't say achieving a learning health system, not a learning healthcare system and I think those things are different. And I think where we need to start with this first opportunity would be to create a definition of a learning health system that is bigger than, and broader than, and more expansive
than a learning healthcare system.

I think Danny said earlier something about learning happens in many places where it's challenging to capture the learnings and I thought Steve's comments about public health, community health sectors that have a huge impact on health, but are not part of the healthcare system. So when we think of a learning health system, to me, it's creating a mindset and an environment where we look beyond the health care system and create opportunities for access to and contribution to this work from non-traditional partners. And I think that theme has been replicated throughout the conversation today.

Initially, I was kind of intrigued by the National Academy of Medicine definition as a starting point. And yet, there's a lot that's missing from that definition in terms of stakeholders, in terms of other influences, in terms of what are the things that contribute to health. And so, I think that first opportunity it excites me. Actually, it’s creating a meaningful definition
would be resonant around what a learning health
system is.

And in some ways, what excites me about
this is also what I think scares me about this
priority. If it is, in fact, the place where the
other priorities come together, if it is the
capstone of the other work, then for it to have a
legitimate place as the fifth priority there needs
to be a unique contribution that we can make in this
arena that leads to a meaningful research agenda and
meaningful value contributed by the research in this
arena towards a system of health. And I think
that's going to be a bit of a challenge to figure
out because it will require some creative thinking
about. So what is unique about this notion of a
health system and PCORI's ability, unique ability,
as a funder and as a convener to contribute to the
work in understanding what it will take and in
enabling us to make progress toward that goal.

Talk about a goal that is aspirational,
this is one.

And the other opportunity or the other
challenge for us is to figure out if we're talking about a learning health system that is something that encompasses all of the places and venues and things that people do that lead to health or are we talking about learning health systems?

So advancing learning health systems that is place-based interventions, that fund and organize multi-sector collaborations. Around improving health in communities. Are we looking at multiple or do we see this as somehow leading to a national collaborative? Where in, you know, eventually in the long-term we actually can speak to, we have a national learning health system. I could talk about aspirational, that certainly is far off in the distance.

And again, like in many of the other -- in many of the other, perhaps all of the other priorities, how do we measure progress towards a learning health system? I think one way would be to measure PCORI's capacity to fund research that is non-traditional in terms of stimulating and incentivizing collaborations that look at health in
a broader perspective, and that produce results that I think as Barbara said before, that people care about, that communities care about producing information that is of value to people who are invested in improving the health within their own communities. That’s certainly one measure. And I think I will stop there.

MS. ARMBRUSTER: Thank you, Sharon. So much there, she addressed a couple of ideas about progress. Tanisha, did you have some ideas about what progress might look like?

DR. CARINO: Yeah, I want to build on what Sharon’s saying. I think a lot of, and again like this may not be in PCORI’s sweet spot, but I do think that with partnership, we can get a total picture that could support enabling these types of systems at the community level to really evolve and mature and flourish.

But I would say that most funders want to fund research or they want to fund a study. I mean, and that's really key to who we are, but we're also an organization who is distinctive in stakeholder
engagement and capabilities building. And maybe that's, you know, back to some of the comments that have been made, what is distinguishing of PCORI? Because there's a lot of research being funded in local communities and academic centers, right? Look at the city of Boston, how much research is getting funded? Tons of research. But what people don't -- fail to realize is if you're going to do culture change, like the stakeholder engagement and the repeated communication and bringing people together, that's a lot of work that takes a lot of time and is very much something that most funders don't acknowledge actually takes support.

So, you know, I know Ellen's on the phone today and, you know, forensic cancer research is such a great example of like bringing people together and that being such a critical part of what success looks like for the community-based outcomes that we want. And so, I would really encourage us to think about the engagement awards being a critical part of how to support and enable the kind
of convening and the kind of work that needs to be done to get to that learning healthcare system.

MS. ARMBRUSTER: Okay. Thank you Tanisha and thank you, Sharon, both, for providing this foundation and some grist for the mill for discussion among the full Board. And I invite everyone back for your last time to have a conversation about this specific priority, Advancing a Learning Health System.

You're welcome to turn on your cameras and you're welcome to indicate your interest in speaking next in the queue as we begin thinking about what are concerns and opportunities related to this a national priority, what's exciting to you, and what you see as progress. Personally, I’m taking away some ideas thinking about, you know, all politics is local and all advanced research is also local thinking about this work with communities, and at the same time, having a healthcare system -- having a learning health system is that one or many systems. You know, these are all rich discussion questions that have been challenges from Tanisha and
Sharon for the full group.

So with that, I want to turn to your initial comments. You can indicate your interest in the chat or you can wave and I'll call on you as we get started thinking about what excites and concerns you about advancing a learning health system.

Thank you, Christine.

CHAIRPERSON GOERTZ: I actually think we need to spend a little bit of time talking about trying to answer Sharon's questions about, you know, how do we define, you know, a learning health system? Is this a learning health system or a learning health healthcare system, and you know, what does, what does that mean for how we, you know, what the scope of the work that we're describing here?

MS. ARMBRUSTER: That makes good sense to me. And it sounds like that is work that needs to happen as part of the defining and setting the research agenda, more continuing to define what a learning health system is.

Tanisha, you were talking about an article
that you referenced from the beginning. Is that something you want to share about?

DR. CARINO: Yeah, I'm happy to circulate it, post the Board meeting. But one of the things I think most people think about -- what we've seen in the discussion on learning a healthcare system is tailor it in the way that it's been defined. And James, correct me if I'm wrong. Is tailoring the system to the needs of the individual.

And it's more on the health care delivery side is how I read it. But one of the -- you know, I would challenge us to think about sort of PCORI's role in actually creating and engaging people in research as being part of that. You know, the idea that we go, you know, particularly in the world of -- for us in rare disease, you know, they're trying to find physicians, it takes seven years to get diagnosed. Like there may not be a treatment and they want, you know, patients want to be part of the research process at that point. And those two worlds should come together more efficiently in something like a learning healthcare system. So how
does that happen?

So I would push us beyond thinking about learning healthcare system as just a part of delivery, but really part of building sort of our muscle as a country around research.

Which is why for me like PCORnet is such a great chassis for building on the success to-date for how do we begin to change culture, begin to achieve some of these broader health system goals. And it may be a ten-year plan, not a two-year plan, but when I look at where there's been investment by PCORI, that feels to me like the best foundation to achieve the goals as stated.

MS. ARMBRUSTER: Thank you to Tanisha. I'm looking for gestures for who wants to weigh-in. Danny? Go ahead.

MR. VAN LEEUWEN: Well, Nakela, this is blowing my mind and I know I'm not supposed to think about operations, but I think that it, I just can't imagine what you and your staff are going to do with this. And I think that as leaders, we need to think about what PCORI is going to stop doing. Because
we cannot just all this stuff we're talking about, layering it on. I mean, I don't know Nakela -- it just seems like, I'm glad I don't have your job. I mean, we need to, I mean, some of this, maybe it's tomorrow, we need to think about if we're going to shift stuff has to come off the table. Because we just can't layer it on.

MS. ARMBRUSTER: Thank you. The process of strategic planning is about thinking about what we are going to continue doing, what we are going to stop doing, and also how we're reframing the work that we're doing.

Nakela. It looked like you wanted to weigh-in there.

DR. COOK: I did it. And I just wanted to emphasize one of the things that's been really helpful during some of these dialogues too, was in terms of thinking about the areas that PCORI should focus within these priorities. And I think that also is quite helpful in terms of how we think about the implementation of these priorities. And so, I just wanted to encourage -- to hear more of that
dialogue and the thoughts on your mind.

    MS. ARMBRUSTER: I also think there's some interesting dialogue opportunity to consider the tension between a learning healthcare system and a learning health system. I've heard that distinction a couple of different times, and I'm wondering if others would like to weigh-in on that thinking.

       James and then Sharon.

    DR. SCHUSTER: I think it's a great point. And, you know, in several of the questions that we talked about today, we've talked about the need to include community partners including those that we think about as probably working more within social systems rather than health systems and I don't have any magic framework for that, but I think the same theme is relevant for this question as well.

       And maybe one of the things that would make sense for us to spend some time on or for the staff to even help us think about would be, you know, is there a methodology that we could use for identifying what partners beyond traditional health systems, you know, beyond providers and payers,
makes sense to include or what are some guidelines that we would use to think about that? Because we've established it, I think, as an important goal, but it's I think the emphasis that we're putting on it is somewhat of a change, is somewhat higher than maybe we have historically.

MS. ARMBRUSTER: Thank you. Who was next?

DR. LEVINE: Me, Sharon.

MS. ARMBRUSTER: Yes. Sharon and then Robert. Thank you.

DR. LEVINE: Yeah. So just to take us back to the decision we made as a Board to frame this entire exercise, this go around as national priorities for health rather than national priorities for health care, which was the original formulation of 10 years ago. Which is why, for me anyway, thinking about advancing a learning health system is -- creates the opportunity to think more broadly than learning healthcare system.

Because I think as Tanisha said, there is a lot of work. There's been a lot of work and a lot written about healthcare systems. And if we look at
the material that we were provided within the brief, the definition, the NAM and AHRQ definitions and the qualities of the learning healthcare system, which are articulated there.

They very much are internal to the healthcare system other than the only exception to that is making sure patients are partners in this work. And if the goal really is health and not just improving healthcare, then broadening -- to me anyway, broadening the definition or broaden the category to a learning health system. And then using the research agenda as a way of testing the feasibility and validity of interventions that, in fact, are multi-sectorial and potentially engaging non-traditional partners in answering questions that are very important -- of importance to patients and consumers.

So I guess I'm advocating for a learning health system. Not very subtly, but advocating for a learning health system.

A part of which obviously are learning healthcare systems and they both depend upon care
being open to capturing the learnings, both
traditional learnings. What the literature calls
practice-based evidence, as well as non-traditional
learnings that exists in sites and sectors outside
of the healthcare system.

MS. ARMBRUSTER: Thank you, Sharon.
Robert, what were some of your reflections?

DR. ZWOLAK: So, thank you. This has been
a fascinating discussion and I think this is sort of
the capstone of the conversation, but to me, the
issue is we sort of have to ask if Americans really
want to be healthy. I mean, some of the political
things that have gone on, I mean, do we want to be a
healthy? Do we care whether we're healthy or not?

And if that's the case, maybe we need to
have whole section on psychology. And how do you
decide if people want to be healthy? Because if
they want to be healthy, then they should buy into
learning healthcare. So, that makes me really think
about this whole picture.

But I also want to say that I agree with
Danny. We've heard so many fantastic, wonderful

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ideas today. So operationalization of this, how much of our budget do we spend on these really exciting ideas that some of them have fabulous potential return on investment, but some of them are kind of long shots in terms of what we would do. I think that we have a challenging road in front of us to try to figure out how we're going to parse on budget among these various fabulous ideas. Thank you.

MS. ARMBRUSTER: Thank you, Robert. Who else would like to weigh-in on advancing a learning health system?

DR. GOODMAN: I find it very daunting. Eighty percent of it, I think I'm just going to say what I said before. It seems to be public health; the language of the brief goes back and forth between patients healthcare systems. It's very confusing. It really is very confusing. There's no boundaries to the remit. So I do think that that was brought up by Sharon right at the top.

And we have to establish boundaries because otherwise we become responsible for, you know,
transportation systems and infrastructure. And you know, where supermarkets are. I mean, these are all part of a health system -- health maintenance system that we probably cannot extend. We could partner with some of these organizations, but they themselves are very, very, very stretched. They don't even have the bandwidth partner sometimes. You need to fund a person within the organization.

We saw this with COVID. We tried to partner with multiple health departments and they literally did not have a person who could spend, you know, half an hour a day because they were, they were devoting their time to yet more urgent priorities. And so, we have to talk about to achieve some of these investment in infrastructure and people within these other organizations, we can't just talk about partnering with the organizations. We have to invest in those organizations, which are very underfunded.

The scope is so broad, I don't even, it's hard to know even where to begin to talk about it. And again, I think there's a too facile moving
between healthcare and health. And I see it within, almost within sentences here. I don't think of learning health system as involving patients. I think of it as involving mainly healthy people who are trying to keep healthy. A learning healthcare system absolutely involves patients and involve systems who are gathering information continuously and trying to make them better.

Just because the healthcare system touches healthy people sometimes in their interactions, it doesn't mean that we are the dominant or even the minority force. So I think this needs both boundaries and clarity that even know where to begin, even though everything that's said is noble.

MS. ARMBRUSTER: Thank you, Steve, for challenging process and urging us on a little more. We have about 10 minutes to continue our conversation. And in the queue we have Jennifer and Ellen. So Jen, you're first up.

You need to unmute, I'm sorry. No?

Well, that's unusual. Well, we'll look for her to be able to unmute and/or I can -- let's start
with that effort, but first let's hear from Ellen while she works on that.

DR. SIGAL: I agree with Steve. I think this is noble, all important. It requires focused boundaries and deliverables [inaudible] pieces the elephant and tackle pieces of it. But we have to figure out where we can deliver and what the most important impact would be because it's daunting. Any of us who lived through COVID know that and anyone that works in the healthcare system understands that. So I think we have to be judicious and focused on which part of it we can make a difference on.

MS. ARMBRUSTER: Thank you. Jen, can we test your audio one more time?

DR. DeVOE: How about now? Is it working now?

Oh, okay. I guess unplugging the microphone and plugging it back in, a high-tech solution.

Yeah, I mean, I'm definitely going back and forth between the boil the ocean, and then a comment.
that was made earlier on several previous occasions
in that clinical outcomes, so we're talking about
clinical comparative effectiveness research. Many
of those outcomes are influenced by many
interventions outside the healthcare system. And
so, if graduating from high school has a bigger
impact on health than me prescribing Drug A versus
Drug B, then if we're not including some of those
other factors, I don't think that we're going to get
to the answer that's going to move the needle on
health outcomes and especially achieve equity for a
lot of populations.

So I get it that like Drug A versus Drug B,
and then comparing all these other things as a
difficult study to undertake. But if we just focus
what the healthcare system is doing, I think we're
missing some of the biggest interventions that have
the biggest impact on improving health, and really
not understanding how to incorporate those into our
study designs, into the list of interventions that
we're allowed to compare, the outcomes that we seek.
It's going to be a very narrow lens and we'll
continue to look through a narrower and narrower lens.

And the impact is going to be far less than if we are more broad and look at all the impacts on health and all the impacts on clinical outcomes, because a clinical intervention doesn't always make the biggest impact on a clinical outcome.

MS. ARMBRUSTER: Thank you, Jen. Next in the queue, we have Kathleen.

MS. TROEGER: All right. I'm going to try bringing everything online here and see what happens.

So quickly to just tag on to what Jennifer said and with respect to everybody's thoughts on this as a really big and be, in some cases, lacking methodology. One of the opportunities I see for learning health or more importantly, AI, is to use some of the AI applications to search for solutions that work.

So where you start with the outcome in mind and look backwards at interventions and patterns that may be naturally occurring and aren't
specified. So who does best post-MI or pre-term birth and working retrospectively using some of the natural language processing to look for what the algorithms of tear may have been that predicted those outcomes to set future questions or hypothesis to answer.

So just kind of a thought about where I agree. There's a lot of swag and difficulty measuring some of this stuff, but there's an opportunity not to study Drug A versus Drug B, but to look instead at what drove potential improvements that may not be initially apparent if we just asked the people doing it.

So just a comment there. And it is big and it does boil the ocean.

MS. ARMBRUSTER: Yes. And thank you, Kathleen, for a specific example of what we might be thinking about on the research agenda in moving forward. Ellen, were you ready with a comment?

DR. SIGAL: I already made my comment.

MS. ARMBRUSTER: Okay, I just wanted to make sure. Alicia, thank you.
DR. FERNANDEZ: There are a lot of exciting comments made here, and I do think that this will require a little bit more definition in terms of what's in and what's out. And in order to be in, what does something have to have? And I also feel that a lot of this is really cutting edge.

Like for example, with AI, one of the things that I love what Kathleen said, and at the same time, I recognize that there isn't any algorithm that's not going to come up with the fact that certain groups of people consistently do worse. And that it encodes reality rather than luminates reality or it can't get to the sorts of things that we need and this is a good, important research question.

I'm not sure whether PCORI needs to be in this space. To me, we're still very early in all of this and it needs to be done through NIH and AHRQ and other places, but I may be wrong around that. But I think -- what I'm trying to say here? I think that there is so much we can do around learning healthcare systems. And that is our sweet spot.
That's where we need to go. It overlaps with every other one of the priorities that we laid out today.

And the things that are outside of the healthcare system should be considered to the extent that they, that the main outcome of interest -- this is how I would organize it. But the main outcome of interest is a healthcare -- it is a health outcome. In other words the outcome needs to be a health one in order for that to be of sufficient interest, I think for PCORI.

But, I think, what perhaps what we're all seeing is that this brief important as it is, is still in an earlier stage of development, even though from a certain perspective, it's the one that is the most -- it's the most in our sweet spot. To the extent that we can really help healthcare system learn, that would be something that a contribution that PCORI can make. Other people cannot make it quite as well. And I think would be fantastic.

Sorry. I rambled.

MS. ARMBRUSTER: No, I appreciate your depth of thought about that. And, you know, really
kind of recapping and I think restating some of the
both excitements and concerns that people have
raised in this discussion thus far.

We have about four more minutes. Are there
last comments anyone wants to make about your
thoughts as we start our last full discussion about
this topic before the full Board vote in June? And
there will also be an opportunity to bring this back
to the table tomorrow when we recap and consider the
cross-cutting themes.

Kathleen, a quick comment? Go ahead.

MS. TROEGEGER: It was just a -- if you
could've seen me Alicia, I was nodding my head. I
completely agree. And I think this gets back to
things other people have said as well, which is that
we can't measure outcomes in people that don't have
encounters. So if you are not even in the
healthcare system, the healthcare system can't learn
about you. And so, the challenge then becomes how
to, you know, find the digital twin or an
application that does work and that's just where I
see there are possibilities there and ways to
identify strategy.

But I couldn't agree more with what you said about the sort of encoding the systematic gaps that exist for some of these things if we don't approach it carefully.

MS. ARMBRUSTER: Thank you. And Sharon.

DR. LEVINE: Yeah, so I would agree that the only outcomes PCORI, is and should be interested in are health outcomes. No question about that. And that partners, collaborators, research partners should all be focused on health outcomes. I'm not sure I agree with Kathleen that the only universe is people who have an encounter with the healthcare system. I have to think about that a little more.

But I also want to say that I think to be fair that this brief needs more work, needs some work. And some of it is work that I think we, as a Board, need to give direction to staff in terms of what our intention is. And I think, I hope, this conversation today has helped in terms of illuminating and elucidating people's perspectives on the issue.
And my final comment is, for us to have a priority on advancing a learning health system, we need to be clear that there is a research agenda that flows from this that is different than potentially, that has something unique to offer in terms of the research agenda and health outcomes from the other priorities, because if it is completely subsumed by the other priorities and what we end up with is an introductory session statement about how all these priorities are leading us to a better world. We have a learning health system or learning health systems.

MS. ARMBRUSTER: So we're really close to a time boundary. We have time for just a brief comment. Danny, it looked like you wanted to speak. So last brief comment.

MR. VAN LEEUWEN: I'm wondering how much our focus can be guided by our priorities of maternal health and IDD. That those be the playgrounds, the sandboxes, whatever, that we apply some of this to so that we're dealing with those priorities as well.
MS. ARMBRUSTER: Thank you for offering some specificity for us to frame and consider this national priority.

All right. You all have given a lot of grist for the mail. I suspect we'll return to this conversation a bit tomorrow. Thank you for your insights and guidance for further shaping this priority. And as you know, we've had a team taking notes during the discussions today. Tomorrow, we will review a few of the themes from today's discussion and look for overlapping interests and priorities.

It's been my honor to be with you all. And with that, I pass to Nakela.

DR. COOK: Thanks so much Sonja. And thank you to all of the Board members for such a rich discussion. It's been so good to hear from all of you as we discussed, I think, one of the more important activities on our agenda for the year, really, and I'm excited that for the most part, it seems that the five priorities seem to resonate and you've added some focus to the priorities and helped
us identify some potential challenges and provided a lot of insights, even for considering an evaluation framework that will need to be updated as we move through our strategic planning efforts.

I also just wanted to comment that I appreciated so many of your comments around focusing on PCORI’s unique opportunities within each of the priorities and expanding the opportunity for partnerships and collaborations outside of our traditional walls, and was really pleased to hear comments about relationships with other federal agencies like AHRQ or FDA or CMS, and even CMMI as we’ve been having a lot of recent discussions with all of them related to synergies around dissemination and implementation, even coverage and data linkages, and with CMMI, on ways we can innovate together.

So it was really helpful to hear your thoughts there and helpful to hear your comments about incorporating our provision around the full range of health outcomes data, including costs and burdens into some of this work. And I heard some
rich comments too, around trust and bidirectional communications is central to many of the traffic priorities we discussed.

It was really validating to hear your comments about optimizing contributions to research outside of academia and understanding what we've learned over time with our engagement portfolio and tomorrow just as a teaser, you'll also hear an example of how we've provided tools and resources on engagement best practices that have been learned through the evaluation of our engagement portfolio. And so, we're excited to continue to evolve this over time. It seems it would be of resonance to you.

I just wanted to wrap up before turning it over to Christine with one additional slide, do you mind going to the next slide?

Perhaps it's not today. I'll do that tomorrow after our facilitated discussions and wrap up on the timeline with you. I just wanted to remind you that we expect that we'll be able to present our net draft national priorities to the
Board at the June 15th meeting.

And the goal, there was for a vote to release them for public comment. But I want to emphasize the point that following public comment, that we'll be engaged again and the Board will engage with revisions on the priorities in response to the public comment period before the priorities are finalized. So as you take a rest tonight and come back tomorrow and think about that facilitated discussion we have tomorrow to bring everything together, we're hopeful that we'll have the input that will be helpful for us to move these toward the June meeting where you'll be considering them for release for public comment.

So with that, I think I'll turn it back over to Christine to close us out for the day.

Thank you.

CHAIRPERSON GOERTZ: Thank you Nakela. And I’m going to start by thanking Sonja for doing just such an excellent job in facilitating our discussions today. We really appreciate your work and look forward to our continued discussions.
tomorrow when we come back together again.

I want to close by thanking those who joined us today via webinar and teleconference. We hope you're also able to join us for tomorrow's meeting. A reminder that all materials presented to the Board today will soon be available on our website and that today's webinar was recorded and that the archive will be posted within a week.

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

[Whereupon, at 4:29 p.m. EST, the Board of Governors meeting was adjourned.]