PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday, May 24, 2021

Webinar

[Transcribed from the PCORI webinar.]

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541

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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1 P R O C E E D I N G S

2 [11:34 a.m. EST]

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

4 yours.

5 CHAIRPERSON GOERTZ: Thank you so much,

6 Nick. Good morning. And welcome to the May 24th,

7 2021, meeting of the PCORI Board of Governors. I'm

8 Christine Goertz chairperson. I want to welcome

9 those of you who are joining us for today's Board

10 meeting via teleconference and webinar. Thank you

11 to everyone who's joined us virtually online and by

12 the phone.

13 We are very pleased to have you here for

14 the first of two days of meetings. I want to remind

15 everyone that conflict of interest disclosures of

16 Board members are publicly available on PCORI's

17 website and are required to be updated annually and

18 if the information changes. If the Board will

19 deliberate or take action on a matter that

20 represents a conflict of interest for you, please

21 recuse yourself or inform me if you have any

22 questions.

1 If you have questions about disclosures or
2 recusals relating to you or others, contact your
3 staff representative. All materials presented to
4 the Board for consideration today will be available
5 during the webinar. The meeting is being recorded
6 and an archived webinar will be posted within a
7 week.
8 Nick, would you please call roll?
9 MS. WILSON: Certainly. Kara Ayers.
10 DR. AYERS: Present.
11 MS. WILSON: Kate Berry.
12 MS. BERRY: Present.
13 MS. WILSON: Tanisha Carino.
14 DR. CARINO: Present.
15 MS. WILSON: Francis Collins or Mike Lauer,
16 Designee of the NIH Director.
17 [No response.]
18 MS. WILSON: Jennifer DeVoe.
19 DR. DeVOE: Present.
20 MS. WILSON: Alicia Fernandez.
21 DR. FERNANDEZ: Present.
22 MS. WILSON: Christopher Friese.

1 DR. FRIESE: Present.
2 MS. WILSON: Christine Goertz.
3 CHAIRPERSON GOERTZ: Present.
4 MS. WILSON: Mike Herndon.
5 DR. HERNDON: Present.
6 MS. WILSON: Russell Howerton.
7 DR. HOWERTON: Present.
8 MS. WILSON: James Huffman.
9 [No response.]
10 MS. WILSON: Connie Hwang.
11 DR. HWANG: Present.
12 MS. WILSON: Sharon Levine.
13 DR. LEVINE: Present.
14 MS. WILSON: Michelle McMurry-Heath.
15 DR. McMURRAY-HEATH: Present.
16 MS. WILSON: Barbara McNeil.
17 DR. McNEIL: Present.
18 MS. WILSON: David Meyers or Karin Rhodes,
19 Designee of the AHRC Director.
20 DR. RHODES: Karin Rhodes is present.
21 MS. WILSON: Thank you. Eboni Price-
22 Haywood.

1 DR. PRICE-HAYWOOD: Present.
2 MS. WILSON: James Schuster.
3 DR. SCHUSTER: Present.
4 MS. WILSON: Ellen Sigal.
5 DR. SIGAL: Present.
6 MS. WILSON: Kathleen Troeger.
7 MS. TROEGER: Present.
8 MS. WILSON: Daniel van Leeuwen.
9 MR. VAN LEEUWEN: Present.
10 MS. WILSON: Janet Woodcock.
11 [No response.]
12 MS. WILSON: And Robert Zwolak.
13 DR. ZWOLAK: Here.
14 MS. WILSON: Dr. Goertz we have a quorum.
15 CHAIRPERSON GOERTZ: Great. Thank you.
16 All right, can I have the agenda slide please?
17 We have a very exciting meeting ahead of us
18 today, I think. We are going to start with a
19 discussion on our strategic planning initiative,
20 both an overview and structure, and then we're going
21 to start a really important discussion on our draft
22 national priorities including the five that that we

1 have already mentioned in a real broad sense
2 previously.
3 And I want to thank Board members for
4 agreeing to be panelists to help lead a more in-
5 depth discussion on each of our priority areas
6 today. And then we will wrap up and adjourn around
7 4:30.
8 So now I'm going to turn it over to Sharon
9 and Nakela to introduce today's discussion.
10 DR. LEVINE: Thanks, Christine. Can we
11 have the next slide, please?
12 Just as -- first of all, I want to thank
13 the members of the Strategic Planning Committee who
14 have contributed a substantial amount of time to
15 thinking about reviewing and contributing to the
16 materials that we're going to review today. It's
17 been a substantial commitment on everyone's part to
18 get the work where it is today.
19 And just as a reminder, today's discussion
20 is an opportunity for the Board to engage with the
21 draft national priorities and for us to gather
22 additional insights from Board members in terms of

1 the work that will go on between now and our June
2 15th Board meeting to further refine these
3 priorities and to bring them forward to the Board on
4 June 15th for approval for posting for public
5 comment. Once -- and we will, that will happen in
6 our June 15th Board meeting and subsequent to that
7 we will open the priorities for public comment and
8 then using public comment, continue to refine the
9 priorities for a final vote in the fall on our
10 national priorities.
11 And I'm going to turn it over to Nakela
12 now.
13 DR. COOK: Thank you, Sharon. And I'll
14 just mention a bit about the structure of today's
15 meeting. And then we'll also give you a little bit
16 of overview ahead of our facilitated discussions.
17 So today we're actually going to review the
18 input to-date very briefly, and then we're going to
19 have a structured dialogue for each of our national
20 draft national priorities. And we look forward to
21 hearing all of your input through those discussions
22 and dialogue. Let's go to the next slide.

1 Just as a quick reminder, this is the slide
2 that you've seen before that demonstrates the scope
3 of the strategic planning activities. And you may
4 recall that our activities encompass multiple
5 things, and that will inform PCORI's next phase.
6 But today we're really focused on the national
7 priorities, which will serve as a foundational
8 element for our future strategy. Let's go to our
9 next slide.
10 And this slide serves as a reminder of our
11 revised strategic framework. And in this framework,
12 you see that our strategic imperatives frame what we
13 accomplished in the midterm and subsequently our
14 long-term goals as well, which are our national
15 priorities for health, with a focus on our desired
16 impact related to achieving better healthcare,
17 better informed health decisions, and improved
18 health outcomes.
19 And this revised framework that we examined
20 in prior Board meetings involves our national
21 priorities from priorities for research to
22 priorities for health that are the long-term goals

1 that are accomplished through our research and our
2 research agenda, and that stem from these
3 priorities, along with our other strategic
4 imperatives. Plus, the national priorities are no
5 longer really categories for research rather they
6 are goals to accomplish through our research, as
7 well as our other strategies. Next slide.
8 You may recall that since summer of last
9 year, through the spring of this year, that we've
10 received input on the national priorities from
11 multiple stakeholder groups. In addition to holding
12 discussions at our Board of Governors meetings and
13 other several activities to help identify
14 priorities. And as Sharon mentioned, the Strategic
15 Planning Committee and the Board really worked
16 together to refine the input and consider what this
17 input could mean for PCORI's mission and vision.
18 And so, the journey has really led us here
19 where we're talking about the draft priorities and
20 what will follow our discussions around our research
21 agenda as well as continued engagement related to
22 other activities of our strategic plan. Let's go to

1 the next slide.
2 So last month we reviewed the resulting
3 themes from the public input gathered to-date, and
4 there were five themes identified that are listed
5 here: health equity; emerging innovations;
6 communication, dissemination and implementation;
7 infrastructure and workforce; and the learning
8 health system.
9 And what we really heard from the input to-
10 date around health equity is that addressing
11 disparities is more important than ever and that
12 systemic inequities are really pervasive. We also
13 heard related to emerging innovations about the
14 application of new technologies and system
15 interventions as important for the future of health
16 and the need to address evidence gaps and time
17 sensitive decision-making that's focused on patient-
18 centered outcomes related to communication,
19 dissemination and implementation. We heard about
20 the importance of both the research and practice of
21 communication, dissemination and implementation, and
22 the importance of getting the right information to

1 the right people at the right time to make informed
2 decisions.
3 Related to infrastructure and workforce, we
4 heard about building human data and systems capacity
5 for patient-centered outcomes research. And related
6 to the learning health system, we heard about the
7 imperative to better reflect the patient perspective
8 and support health systems that enable coordinated
9 care, easy navigation and utilization for patients.
10 So the strategic planning committee
11 considered all of this input and the themes and how
12 to transition them as long-term goals for PCORI to
13 pursue related to patient-centered outcomes
14 research. Let's go to our next slide.
15 So the resulting draft national priorities
16 were really developed based on the strategic
17 planning committee's input and PCORI staff expertise
18 and considered the research environment and how
19 PCORI can utilize its mission to improve health
20 outcomes. And the draft national priorities are
21 intentionally action-oriented in how they're framed
22 to try to move the needle toward improving health

1 outcomes. And each will be relevant and grounded in
2 patient-centered comparative clinical effectiveness
3 research that PCORI funds.
4 And you're also going to notice, as we talk
5 about these today, reinforcing concepts that are
6 interweaving elements between each of them and
7 that's actually intentional and a good thing.
8 They were designed to be mutually reinforcing and
9 with some relevant interdependencies.
10 So with that overview, I'm going to turn it
11 back over to Christine who's going to introduce
12 Sonja Armbruster who will facilitate today's
13 discussions.
14 CHAIRPERSON GOERTZ: Thank you so much.
15 Nakela and Sharon, as we mentioned at our last at
16 our last board meeting, we have engaged a
17 facilitator for today's discussion.
18 Sonja Armbruster will support the meeting
19 allowing for both Sharon and I to participate in the
20 discussion rather than leading the discussion. And
21 we're excited to have her facilitation expertise and
22 look forward to the dialogues.

1 Sonja is a health sciences educator and
2 teaches full-time in the Department of Public Health
3 Sciences at Wichita State University. Her public
4 health career includes 10 years of service in
5 various roles at Sedgwick County Health Department.
6 Last serving as Division Director for Community
7 Health Planning and Performance Improvement. As a
8 public health consultant, Sonja provides training
9 and technical assistance to state, local, tribal,
10 and territorial health departments, as well as
11 facilitation support for variety of health-related
12 organizations.
13 Sonja I'll turn it over to you now.
14 Welcome.
15 MS. ARMBRUSTER: Thank you so much,
16 Christine. I'm honored to be with all of you today
17 as we work toward achieving our shared purpose,
18 creating an opportunity for all members of the PCORI
19 Board of Governors to engage with the draft national
20 priorities for health and for all of us to hear from
21 the Board members' expertise and insights for
22 further refinement.

1 Over the last few months, staff from PICORI
2 and the Board leadership have been working to design
3 a process for this conversation today and tomorrow,
4 we've worked to create conditions for a robust
5 sharing of ideas, and we will need input from all
6 members to fulfill our purpose today. You'll be
7 hearing prepared remarks from 19 people today. If
8 members of the public would like to learn more about
9 the speakers, you can read their bios on the PCORI
10 website. We will not be devoting time to
11 introductions today for staff or for Board of
12 Governors members.
13 If you could advance to the next slide,
14 please.
15 As you can see from this slide for each of
16 the five priorities, we will hear a brief
17 presentation, some opening comments about the topic
18 from a PCORI staff member who provides staff support
19 for the Strategic Planning Committee and then select
20 members of the Board of Governors will provide a
21 reaction to a prepared set of questions.
22 And after they share those reactions, we will have

1 an opportunity for the full board to discuss the
2 topic.
3 Today, the full Board will discuss all five
4 draft national priorities, and we will have an
5 additional opportunity for discussion tomorrow.
6 Today we've scheduled about 45 minutes to discuss
7 each priority and we have a short break scheduled
8 after each of those discussions.
9 During the full Board discussions, I invite
10 all Board of Governors members to turn on their
11 cameras when possible to encourage and support a
12 robust sharing of ideas. Board members can gesture
13 or use the chat function to indicate their readiness
14 and their interest in being called upon to share
15 reactions and insights.
16 If we could turn to the guiding questions.
17 Our guiding questions today are thinking
18 about what excites and concerns you about this
19 particular national priority and what are the
20 opportunities that it brings to the work? What
21 opportunities does this create for PCORI's mission
22 and mandate? And then looking to the specifics, how

1 does this -- what does progress look like and how
2 does this help us think about the research agenda?
3 It is our hope that a discussion of
4 specific examples of progress and ideas related to
5 the research agenda can provide a springboard for
6 the next phase in strategic planning.
7 So without further ado, let's begin. Our
8 first topic is Achieving Health Equity. Michelle
9 Orza, PCORI’s Chief of Staff will provide a brief
10 overview.
11 Michelle?
12 DR. ORZA: Thank you, Sonja and hello
13 everyone.
14 The health equity theme emerged clearly and
15 with a sense of urgency from our earliest
16 engagements with stakeholders, and it continues to
17 be top of mind and top priority across all
18 stakeholders in our ongoing interactions. As
19 brought into stark relief by the pandemic
20 persistently poor health outcomes,
21 disproportionately affecting people with low income,
22 people with disabilities and people of color, as

1 well as entrenched and negative influences on health
2 in some communities that compound over generations
3 drive concerns about health equity.
4 Can you go to that next slide, please?
5 This theme leads to our first proposed
6 national priority, achieving health equity and
7 PCORI's goal for this priority is to advance health
8 equity in the U.S. Next slide please.
9 Although health equity has been an explicit
10 goal of the public health community for over a
11 decade and a focus of many health and healthcare
12 entities, including PCORI, much more progress is
13 needed. In shaping this priority, the input we've
14 received to-date includes urging PCORI to fortify
15 its existing addressing disparities priority;
16 calling for us to expand existing mechanisms and
17 create new ones to advance health equity; and
18 advising that to achieve health equity we need to
19 widen our focus beyond healthcare to include the
20 public health ecosystem and the broader social
21 determinants of health.
22 I turn it back to you Sonja so we may have

1 our panelists launch the Board’s discussion.
2 MS. ARMBRUSTER: Excellent. Thank you,
3 Michelle.
4 Our exploration and discussion with
5 reactions from a panel of two members of the Board
6 of Governors. We will hear from Kara Ayers and
7 Alicia Fernandez. Thank you both for taking time to
8 give special attention to this draft national
9 priority, achieving health equity. You’ve been
10 asked to consider those two initial questions and to
11 reflect for about three to five minutes, about what
12 excites and concerns you about PCORI achieving
13 health equity, and what opportunities it creates to
14 help us meet our mission and mandate.
15 And so, Kara let's begin with you.
16 DR. AYERS: Sure. I can start with the
17 first question.
18 So I think the first thing that stands out
19 to me is that the evolution from health equity from
20 recognizing its existence to now our newer title is
21 to achieving health equity is an ambitious goal and
22 that both excites me and concerns me.

1 So I see the goal of achievement as so far away that
2 I don't want this title to be merely performative
3 for us. At the same time, I think that there's
4 certain motivation in the title and encouragement.
5 And so, I really feel mixed about whether
6 you know, whether this title is the most accurate
7 representation of what we hope to achieve. It does
8 excite me that we're prepared to make such an
9 important impact in this area. One of our
10 challenges is the systemic oppression is built into
11 so many, if not every part of our healthcare systems
12 and there remains resistance to make the depth and
13 breadth of changes that are needed.
14 So it will be an interesting challenge for
15 us and one that does concern me as someone who's
16 very bought into achieving this goal. It'll be an
17 interesting challenge for us to still do the things
18 like building visibility of PCORI and fostering
19 those relationships with partners and calling out
20 and calling in people to address inequities because
21 somewhat distinct from some of our other areas of
22 focus is this level of resistance and defensiveness

1 when these shortcomings are pointed out where
2 healthcare inequities exist.
3 Things that excite me and what I'm looking
4 forward to is that I do see the opportunities for
5 more organic inclusion of different stakeholder
6 groups across, I think that it is an opportunity to
7 build trust in recognizing what many people have
8 always seen as part of their healthcare experience,
9 but will now be recognized at a more systemic level.
10 I think it's an opportunity to think big and look
11 towards transformation rather than just, you know,
12 short term repairs. And I think that we'd also
13 while thinking big, we also have to think about
14 practical solutions also that our stakeholders can
15 resonate with and apply on the ground as well.
16 So that's my response to the first prompt.
17 Do we want to take it one at a time? Is that right?
18 Or should we continue? I’m sorry, I can’t hear you.
19 MS. ARMBRUSTER: You can continue with what
20 you think about the opportunities this provides for
21 PCORI’s mission.
22 DR. AYERS: Sure. Yeah. I think that when

1 I look at our mission and the opportunities related
2 to this priority, it's almost like speaking the
3 quiet part out loud, and that again, for many people
4 from marginalized groups, this is part of every part
5 of the mission that we work towards in PCORI but
6 it's not identified. So it's the unspoken or the
7 unseen section.
8 So I think that this lends us the
9 opportunity to bring that to the surface and to have
10 these discussions. And some of them will be
11 difficult, but I'm excited about the opportunity of
12 having a more full picture of what we're looking at
13 when we talk about things like helping patients make
14 different decisions about their healthcare, these
15 factors related to healthcare equity and inequities
16 that people experience weigh in and as, you know,
17 without identifying them and putting them front and
18 center, we're kind of not counting that weight. And
19 so I think that's exciting.
20 And I also spend some time thinking about
21 what progress would look like and for me, I think
22 this will be challenging, but exciting to be able to

1 measure this progress. I think that we would need
2 and want to see change at multiple levels that we
3 would want bi-directional feedback to flow to and
4 from different stakeholders. And again, this will
5 take some trust building within these different
6 groups, in-between these different groups. And I
7 think we'll need some more meaningful metrics on
8 dissemination.
9 I very much want to see more than just how
10 many people we'll reach, but I want to see how the
11 information that reaches people factored into
12 decision-making. So it's almost this intersection
13 of communication measures, but also patient
14 outcomes, satisfaction experience, you know, even I
15 see places for social determinants of health, which
16 you know, are definitely a hot topic, but often
17 don't include all the areas of oppression that
18 people experience across these.
19 So I think we have a lot of opportunity
20 with this priority and I'm excited about it, but
21 also, you know, keep what I'm tentatively cautious
22 about in mind as well. Thank you.

1 MS. ARMBRUSTER: Thank you very much, Kara.
2 And I would encourage all Board members as we look
3 toward the fuller conversation in a few minutes, I
4 was particularly struck with your discussion point
5 about not being performative and what it might look
6 like if it weren't performative. So I would be
7 interested in hearing more discussion later
8 specifically about that, and I'm going to come back
9 to the trust building concept as well.
10 But thank you, Kara for already getting us
11 started with some initial groundwork to think about.
12 Alicia your thoughts about what opportunities this
13 creates and what excites and concerns you.
14 DR. FERNANDEZ: Thank you, Sonja. I want
15 to start out by saying how much on target and how
16 much I agree with Kara’s comments. They really I
17 think that we were very aligned and that you were
18 extraordinarily concise in being able to highlight
19 so many of joint concerns.
20 Let me start by saying that I think that
21 this is a great start, that PCORI’s sort of renewed
22 emphasis and more ambitious framing is an

1 extraordinary it's a great start and it is very
2 exciting. And I want to talk particularly, I think,
3 to the members of the Board who may have had less
4 experience thinking about health equity, and just
5 give a very brief framing.
6 If one thinks about health equity in two
7 very big categories, the social determinants of
8 health, which really determine big, broad patterns
9 of illness. And then within that, and then the
10 health care system, which really determines more
11 about how people live with their disease and how
12 they get better or not.
13 I think one of the things that's very
14 exciting right now and that PCORI recognized in its
15 brief is that there is a lot -- that the health --
16 at the intersection of the healthcare system and the
17 social determinants of health, it is a sort of a new
18 terrain that we can really explore. And chief among
19 those are questions such as how our resources that
20 are currently directed through the healthcare
21 system; how can those be used to mitigate
22 disparities caused by the social determinants of

1 health?
2 So I think we're going to see a very
3 exciting decade of research. Let's call it five
4 years of research in this, and that it will take
5 place in the social determinants of health.
6 PCORI has the ability to do this research and into
7 sort of two big groupings. One is on the individual
8 level. We will see a lot about how the social
9 determinants of health are integrated into the
10 electronic medical record and into the -- and that
11 will help us understand disparities and how they can
12 be mitigated in a much more targeted way.
13 Let me give you an example of that. One of
14 my favorite studies conducted by Mike Pignone, a
15 long-time friend now at Dell, was a study published
16 in JAMA that showed some years ago -- that showed
17 the impact of a low literacy intervention on a group
18 of people with uncontrolled diabetes in North
19 Carolina.
20 And what that study showed is that for
21 people who it turned out had low literacy, no
22 surprise, a low literacy intervention was wonderful.

1 And they ended up with glycemic control. Whereas,
2 with the people in that group who had other factors
3 that were impeding their ability to achieve glycemic
4 control did not end up with glycemic control.
5 So one way of thinking about this is that
6 there's going to be a whole body of research that
7 tries to get more narrowly and more proximately of
8 how the social disparities of health works and will
9 lead to healthcare mechanisms that can mitigate
10 those disparities. Another big advance that we will
11 see are - that where PCORI will play a role, has to
12 do with population level research. Where PCORI can
13 lead. And I think that there were hints of this in
14 the brief where PCORI can lead on evaluating
15 policies.
16 For example, some policy, some evaluations
17 have now shown that taxation of sugar-sweetened
18 beverages works quite well to decrease consumption
19 among high consumers.
20 Those are the sorts of policies that PCORI
21 may or may not choose to fund and comparative
22 policies that I think will be very interesting.

1 Leaving aside the social determinants of health,
2 moving toward healthcare disparities, we are poised
3 in the next five years to make huge advances. These
4 have to do with how can the healthcare system become
5 more nuanced? How can it bring more or different or
6 better resources to bear on disparities?
7 And this is where the use of new
8 technology, use of tele-health, and so on will be
9 very important. And this fits into PCORI's
10 comparative effectiveness learned emphasis on
11 disease control. I also think that we will see
12 incorporation of new roles and an expansion of all
13 roles among workers in the healthcare system.
14 And I'm very excited that PCORI specifically has
15 called out partnerships with other sectors:
16 community-based organizations, schools, businesses,
17 and so on as areas for exploration for research.
18 So what concerns me? As I say, I am mainly
19 very excited by this, but there are concerns and
20 those, I would think, fall into two categories.
21 One is there are plenty of areas where more research
22 is not needed. And this resonates with what Kara is

1 saying. We do not need more research to show that
2 poverty is a risk factor for poor health for many
3 people. Instead, what we need to think about is a
4 different form of dissemination and whether or not,
5 how can PCORI as a research voice within the broader
6 healthcare policy community interact with others and
7 be more flexible and more powerful in disseminating
8 its research.
9 Let me give you an example. PCORI early on
10 did great work on navigators. Navigators are
11 extraordinarily effective in mitigating the social
12 disparities of health on many people. PCORI has
13 produced a family of research in this area. Okay.
14 That's good. Where are we with that? How has that
15 been taken up and not by different healthcare
16 systems?
17 What are the different -- what would be the
18 next step in evaluating policies that seek to
19 incorporate navigators versus the status quo? What
20 are the roles, how is a stakeholder organization now
21 committed -- a research organization, now committed
22 to achieving health equity? How can it, how can it

1 partner with other organizations within the
2 healthcare ecosystem to assess what policies are
3 worthwhile and what policies are not?
4 And now that we understand, that we have
5 more breadth around understanding costs from many
6 perspectives, including societal perspective. What
7 can that tell us about policies that should be
8 enacted to say, to bring this form of healthcare
9 innovation to scale?
10 So I will stop there and say again, that I
11 do think that this was a really exciting first step,
12 really congratulate the staff that worked on this.
13 And I find this mainly a source of joy, but at the
14 same time, I think we need to do a lot more. I
15 think that we will need to continue to be innovative
16 in our thinking to say, how can we actually make a
17 difference in achieving our aim of better health for
18 all?
19 MS. ARMBRUSTER: Thank you very much,
20 Alicia. Many notes written down here, I'm
21 specifically interested in the idea of what do we
22 need to not do to make progress on this. I think

1 that is an insightful lens for as we turn toward
2 thinking about what progress looks like. Are there
3 any further comments that either of you would like
4 to make around what progress looks like?
5 And I would like to invite Kara to think,
6 to share more about, you mentioned progress looks
7 like includes trust-building. And I'm curious about
8 as we think about measures and the research agenda,
9 how we incorporate that trust building, and maybe
10 thinking about who is it that we need to be building
11 that trust with?
12 DR. AYERS: Thank you. I don't think
13 there's any of our stakeholder groups that we don't
14 need to be building the trust with. I think that
15 they're, you know, one of the examples that stands
16 out in my mind is, you know, we know we all know the
17 difference between equality and equity, but a lot of
18 our systems are built in a very rigid way in terms
19 of you know, equal appointment times. And for many
20 patients with disabilities, just an extended
21 appointment time would allow for the accommodation
22 that needs for a transfer or whatever may happen.

1 But on the provider side, that's not just
2 an extended appointment time. That's a whole, you
3 know, restructuring and there's so many. So that's
4 one example of we would need, you know, on the
5 stakeholder group of patients, we need to listen to
6 how frustrating it is to feel like that you don't
7 have enough time to have, you know, your basic needs
8 met. On the providers side, we need to hear how
9 these systems could be more flexible to meet their
10 needs as well. And I mean, that's a really, really
11 basic example, but I don't think there's any groups
12 that we don't need to build trust.
13 Also, as we get to talk about issues like
14 systemic racism and systemic ableism, some of these
15 things conflict with, you know, there's the idea
16 that the system is broken and then there's the idea
17 that the system was actually built this way. And
18 this way is problematic for marginalized groups.
19 And so, I mean, our very basis of a lot of medical
20 training is framed around some pretty ableist ideas.
21 And so, we first have to build trust before we can
22 have those open discussions about where we are now.

1 And also as Alicia mentioned, framing
2 policy around those and having stakeholder groups.
3 When I think about things like non-invasive prenatal
4 testing, having different stakeholder groups from
5 the communities and what this technology means to
6 them, you know, all that requires trust to have a
7 meaningful discussion about it.
8 MS. ARMBRUSTER: Excellent. Thank you.
9 Your specific example about rigid systems, I think
10 dovetails very nicely with Alicia's comment about
11 nuanced. We need a nuanced healthcare system that
12 meets patient needs. So thank you for that specific
13 example. Alicia, was there more you wanted to say
14 about what progress looks like and what we might be
15 thinking about as it relates to the research agenda?
16 DR. FERNANDEZ: I think one metric of
17 progress will look like uptake of interventions
18 known to reduce disparities. And that, that would
19 be, I really loved what Kara said that we need new
20 metrics. And I think that is one that we would
21 both, that we would both agree with and I think that
22 that that's very important.

1 MS. ARMBRUSTER: Excellent. Well, thank
2 you both for your thoughtful reflections and for
3 teeing up the conversation for the rest of the
4 Board. Now we have about 20, 25 minutes to hear
5 from as many Board members as possible, your
6 additional reflections on this draft national
7 priority. There is wisdom in this room and your
8 perspectives are valued.
9 During these conversations, I invite all
10 Board members to turn on your cameras. Thank you.
11 If you desire to speak, you can wave or you can
12 indicate in the chat that you are ready to be called
13 upon. As a neutral convener, my job is to create
14 conditions where as many can weigh-in as possible.
15 So please share, please be succinct and I'll raise
16 my hand to signal if we're running short of time or
17 I see additional people in the queue who would like
18 an opportunity to speak.
19 And with that, I invite you all to
20 consider, let's start with that initial question.
21 What excites you and what are your concerns about
22 PCORI adopting achieving health equity as a national

1 priority?
2 Eboni, would you unmute and join the
3 conversation?
4 DR. PRICE-HAYWOOD: Yes. Thank you. First
5 I want to start by saying that Alicia and Kara are
6 spot on. They hit all the high points and I'm
7 sitting here thinking, how can I add to what they
8 said?
9 So I think I want to emphasize a couple of
10 points that were made and maybe expand on them.
11 One very important thing that Alicia said was folks
12 who do this work, think of it in two rooms. There's
13 the social determinants of health and then there's
14 the health system in terms of mitigating in making
15 things worse. That distinction is incredibly
16 important because of, from the health systems
17 perspective, we are the recipient of a lot of things
18 that have historically been in place. And we're put
19 in a position to basically mitigate or make it
20 worse, but you're not really changing those things
21 that are upstream, that you're constantly dealing
22 with.

1 And so, that research that is upstream of
2 the health system is incredibly important to tease
3 through that. And that means valuing health policy
4 related research, and not necessarily looking for a
5 research that's always within the clinical area
6 because it was incredibly frustrating downstream of
7 that to try to deal with the problem. The other
8 piece that's important is the concern that was
9 brought up about not focusing on highlighting
10 disparities, because it has been studied for
11 decades.
12 And again, from the health system community
13 perspective, don't highlight a problem if we don't
14 have a solution. So can we focus the research
15 agenda on finding what those solutions are so that
16 we can employ them in whatever setting? That may be
17 the public health sector. It may be the healthcare
18 system. It may be, you know, within government.
19 Those best practices that these groups can then pick
20 up, these different stakeholder groups can pick up
21 to employ in their setting.
22 The uptake is going to be very low if

1 there's a very limited repertoire of types of
2 interventions. What setting does this intervention
3 apply to? Does it apply to my setting? How can I
4 best incorporate that into my organization?
5 The other piece in terms of the -- and I'll
6 stop running my mouth, the other piece in terms of
7 the health system, is this resistance that Kara
8 brought up within your organization. The work that
9 needs to be done is not all about clinical
10 interventions. I would argue that 80 to 90 percent
11 of it has to do with people. And what do you need
12 to do to reduce the barriers first to hearing the
13 message, understanding increasing awareness and
14 responsiveness to it, and understanding that this
15 work is actually designed to help you do your job
16 better.
17 How do you frame this in such a way that
18 people will be receptive to talking about
19 disparities, talking about equity, and being open to
20 maybe the way we do things is actually worsening the
21 disparities, but we were all taught that it's all
22 ingrained into how we do what we do. What can we do

1 to shift that mindset?
2 So I would argue in the healthcare system,
3 it needs to be people-focused research, not
4 necessarily clinical interventions, diagnosis,
5 treatment, and that sort of stuff. That's
6 important, but you will have biases in clinical
7 decision-making if you don't deal with the people
8 part of the problem, I'll stop there.
9 MS. ARMBRUSTER: Thank you, Eboni. I'm
10 really hearing your focus on the people, all of the
11 people in the system, including the providers and
12 implementing solutions that are setting-specific and
13 really focusing our research on that work. Thank
14 you Eboni.
15 And I see three in the queue, so we'll hear
16 from Michelle and then Michael, and then
17 Christopher. Michelle, you are up.
18 DR. McMURRAY-HEATH: Hello. Thank you so
19 much. And I just wanted to thank Alicia and Kara
20 for their comments and Eboni's comments as well. I
21 just think you really captured all the nuances of
22 this priority, which I think we all agree is very,

1 very important.
2 Just two things I'd like to highlight and
3 draw out. One, and this gets to Eboni's point that
4 you just raised. I think we have to not be shy
5 about tackling racism in the delivery of healthcare.
6 either individually initiated racism or systemic
7 racism in the healthcare system. And two, I think
8 there's a real opportunity to advance the science
9 around the intergenerational aspects of race and
10 disparities.
11 I think that is an area that's just
12 beginning to grow and PICORI could do so much in
13 both of those areas to give more credence and
14 acceptance of those two schools of thought. I'll
15 leave it there.
16 MS. ARMBRUSTER: Thank you, Michelle. I am
17 curious and interested in more discussion, so I will
18 go to Michael with your initial insights and
19 reflections.
20 DR. LAUER: Great. Thank you. This is a
21 great discussion. I'm excited about this priority.
22 My question for thought is how you make sure that

1 what you're doing fits within the rubric of clinical
2 comparative effectiveness research. I totally agree
3 with Alicia. We've had plenty of studies that show
4 that poverty is bad for health, but the question is
5 what interventions work and how do we do it as
6 comparative effective this work? Thank you.
7 MS. ARMBRUSTER: So for point of
8 clarification, are you saying that if the efforts
9 are to frame it back to CER that perhaps we are able
10 to better keep this within the bounds of the
11 priorities that are within PCORI's scope?
12 DR. LAUER: Yes. Thank you. Yes, exactly.
13 MS. ARMBRUSTER: Thank you, Michael.
14 Christopher, you're up next.
15 DR. FRIESE: Sure. Hello everybody. Great
16 to see you all. Thanks for the great discussion.
17 I'll just briefly underscore Dr. Price-Haywood's
18 comment. I think setting really matters for a lot
19 of this. So I just want to underscore that. I had
20 more to say, but she did it far better than I would.
21 The piece that might be a new addition to
22 the conversation I wrote down here is, you know,

1 PCORI can do things that other funders and other
2 agencies can't do in this space. And so I always
3 look for those opportunities where we can be a
4 differentiator, where we can move the conversation,
5 generate evidence in a way that other institutions
6 and other groups can't. And I think one example of
7 that, we might have others, is on our engagements
8 space, where we've been very strong, to really take
9 full the full opportunity of our engagement
10 resources to-date.
11 I think historically though, and this isn't
12 an issue for PCORI it's an issue for the entire
13 ecosystem, is much of that has been focused properly
14 on engaging groups, engaging professional
15 organizations, patient advocacy groups, and others.
16 And just as I've heard this conversation, I think to
17 myself, who are we missing when we engage with
18 specific groups and agencies? Who's not at the
19 table that we need to have at the table? And that
20 might be a more difficult and challenging piece.
21 But I think that's a challenge that PCORI is up to
22 doing because they've already built such great

1 strength in engagement.
2 So I'd like a lens on that to making sure
3 that we are truly inclusive, that we're thinking
4 about not just groups of folks that needs to be at
5 the table, but folks with very important
6 perspectives that may historically not be at the
7 table because they don't have the resources and the
8 time to be a member of a group and spend time with
9 that group.
10 So I'd like us to think a little bit about
11 that as well. Thank you very much.
12 MS. ARMBRUSTER: Thank you, Chris. And are
13 there specific groups that you had in mind or just
14 broadly?
15 DR. FRIESE: So it's on mind because I'm
16 working on a project where we're engaging with some
17 patient advocacy groups. And I actually look at the
18 demographics of the attendees of the group and they
19 don't truly -- so this is a group for a particular
20 disease state. They are a wonderful group. They're
21 giving us great insights.
22 But the demographics of that group do not

1 match the demographics of the diagnosis and this is
2 a clinical model. I apologize for that, but these
3 are not the folks that I see in clinic, even at
4 Michigan, they are another group there. They have
5 time, they have resources, they can transport
6 themselves to a meeting.
7 So I think we just want to think about, is
8 there a novel way to engage folks who may not be
9 able to historically be at the table in a different
10 way? Does that help a little bit?
11 MS. ARMBRUSTER: Absolutely. That last
12 piece, like novel ways to reach people where they
13 are really made a difference in my understanding of
14 your comments. So thank you so much.
15 I understand Danny is next in the queue.
16 And then anyone else who's interested, please add
17 your name to the list. Danny.
18 MR. VAN LEEUWEN: Thank you. So I feel --
19 I'm not going to repeat all the wonderful things
20 everybody has said. But I am really aware of the
21 inherent conflict between the exclusion that's
22 needed for scientific rigor and reasonable budget,

1 and the inclusion needed to reduce disparities and
2 study the broadest possible range of populations and
3 situations.
4 And so, my nightmare is actually that there
5 needs to be huge studies costing tens of millions of
6 dollars, taking 10 years needing the most senior
7 researchers to manage them, and then leaving out the
8 small communities of study. So I'm wondering if
9 with input from the Methodology Committee that we
10 perhaps could think about weighing positively in our
11 scrutiny studies that end up with -- this is not the
12 right words, but camera-ready methodology that can
13 be easily applied to other settings and that we fund
14 a series so that they can just be instead of giant
15 they're small, but they cover many different
16 populations in different settings, in different
17 circumstances.
18 And I think, again, I think, you know, our
19 power is in our charisma and reputation and gobs of
20 money and scoring the way we score the applications
21 that we review. So I think we need to think about
22 all of those as we're talking about how we

1 influence. Thank you.
2 MS. ARMBRUSTER: Thank you, Danny. I
3 appreciate your comments in others leveraging the
4 strengths of PCORI in this specific work. I'm
5 excited to see several are ready to weigh-in. So
6 we'll hear from Ellen and then Tanisha and then
7 Kathleen and Sharon. Ellen.
8 DR. SIGAL: Okay. Can you hear me now?
9 I'm sorry.
10 MS. ARMBRUSTER: Yes, go ahead.
11 DR. SIGAL: First of all, I think this is
12 incredibly important and I'm happy we're doing it.
13 There's no doubt that this is needed.
14 The issue is how are we value-added and how
15 are we going to add and to really do something
16 specific with an outcome. I mean, we could spend
17 our entire budget on this issue and still not solve
18 the problem. So how do we figure out ways where we
19 are unique and partner with others and figure out
20 what would really move the ball and what are pilots
21 that really are special to our special sauce?
22 So that's really the complicating factor.

1 There's no one that can or will disagree with the
2 urgent priority. The issue is what can we do that's
3 measurable that will make a difference even as a
4 pilot?
5 But again, I support the work. It's an
6 issue of figuring out where we can truly add
7 something.
8 MS. ARMBRUSTER: I think that's an
9 important distinction. And I think that it relates
10 to what does progress look like and what is the
11 specific role that can be played? So thank you
12 Ellen.
13 Tanisha did you have a question you wanted
14 to help shape the conversation?
15 DR. CARINO: I did, and I appreciate the
16 comments that have been made today. And one of the,
17 you know, for me, what I'm hearing is this full
18 acknowledgement by the Board for the priority of
19 health equity. But how do we differentiate the
20 contributions that PCORI can make relative to this
21 question that every institution is trying to address
22 and to the point that Ellen's making, I think so

1 much of this, and you'll hear me say this when we
2 talk about the [inaudible] healthcare system. It
3 takes a lot of local community building to
4 understand what are the institutional biases that
5 have been created by institutions that may have an
6 impact in changing clinical health outcomes.
7 And so, you know, Michael, your comment
8 really resonated with me. Like if we stay within
9 the lane of clinical comparative effectiveness
10 research, I hear that as, okay, we need to focus on
11 the clinical outcomes that biases can have, but the
12 interventions that we study as PCORI may be things
13 that are not within the walls of the traditional
14 healthcare system, because ultimately those are the
15 things that we all acknowledged have a huge impact
16 in terms of the outcomes that are being achieved by
17 populations and individuals. So I'll stop there.
18 MS. ARMBRUSTER: Thank you, Tanisha. All
19 of that, thinking about the role of social
20 determinants of health and the intersection with
21 clinical outcomes and how we weave and thread that
22 needle as it specifically relates to PCORI's

1 funding. Kathleen?
2 MS. TROEGER: I would to hear a little more
3 discussion on a point that Alicia raised, and then
4 Eboni, I think I heard it in your comments and they
5 aren't necessarily exclusive each other. So I'd be
6 interested in how the two of you think this could
7 work.
8 So Alicia, your comment was around you
9 don't need any more studies on things like poverty
10 it is a risk factor for, you know, lack of
11 preventive care or access or just overall poor
12 health. And then the paraphrase Eboni. It's
13 important not to bring problems forward that we
14 don't have solutions for. So let me just kind of
15 stop there to make sure that I haven't
16 mischaracterized comments from either of the two of
17 you, particularly Eboni.
18 Did I understand that correctly? That
19 you're, we're in an interesting spot to not just
20 sort of throw stuff out there that we can't propose
21 a solution for, because there's a bunch of stuff we
22 don't have solutions for that I think we may need

1 more research around in order to better impact
2 issues related to equity, that I don't begin to know
3 kind of how we solve. So if there's just a little
4 bit of give and take there, I'd be interested in the
5 two of you talking through that a little bit.
6 Because it just doesn't seem -- you know, so that's
7 what I'd be interested in hearing.
8 DR. PRICE-HAYWOOD: So part of my statement
9 about don't bring a problem without a solution.
10 Yes. You do have to have research that's
11 descriptive of the problem. I think we're at -- to
12 Alicia's point, where we have quite a bit of
13 information that we've not done anything with. So
14 those who are hearing about the disparities and then
15 are in a position where they're supposed to be doing
16 something about it within their realm, the
17 receptivity to disparities research and work around
18 health equity, fizzles, because people are
19 overloaded with a problem, but even if a solution
20 does not exist, they have not received guidance on
21 how to work towards that solution.
22 So you have to be careful about, you know,

1 there's a public health significance to displaying
2 the problem, because if you don't measure it, we
3 won't know about it and you won't be able to
4 discover innovations to move towards those
5 solutions.
6 But understand that disparities measures
7 are it's just a measure of how close or far you are
8 from equity. And equity, thinking of equity means
9 that you have to be thinking about strategies to
10 remove those barriers that cause a problem in the
11 first place. So your framework needs to think about
12 both ends of it. And not just to describe a problem
13 without giving me some forward view of what I need
14 to address, even if I don't know the answer yet.
15 MS. ARMBRUSTER: That's really -- that's
16 very helpful in terms of clarifying your remark.
17 Alicia, your thoughts?
18 DR. FERNANDEZ: Yeah. I'd like to comment
19 if it's okay.
20 MS. ARMBRUSTER: Yes.
21 DR. FERNANDEZ: I think what you're raising
22 is similar to what Tanisha is raising, it's similar

1 to what Ellen is raising, and it's similar to what
2 Mike Lauer is raising. And I have I'd like to
3 respond to that. Okay.
4 And that is sort of like where's PCORI in
5 this? Like how's it going to work? Okay. So I'm
6 going to be super concrete because I really feel
7 like we all need to understand this and then we can
8 agree or disagree or tweak, but at least we all need
9 to understand.
10 PCORI just funded a very important study on
11 what the right dose of aspirin is for people with
12 heart disease or actually with heart disease
13 [inaudible]. That was really important. And PCORI
14 should continue to do those forms of study. Now
15 that we know that people can take either dose, we
16 still have to get them to take their meds. We still
17 have to get people to take aspirin. Not a cost
18 problem. It is a complex issue on why people take
19 or don't take aspirin, right?
20 That is a classic health services research
21 question. We could say, is it better to have to
22 stick with your 15 minutes, Q-four months visit

1 where the doctor goes through and say, by the way,
2 you should take your aspirin versus telehealth
3 visits that are super short and done with a health
4 educator and which one will result in fewer heart
5 attacks?
6 Or should we be more innovative? Do we
7 give people cat robots that say to "Meow, it's time
8 to take your aspirin." versus funding versus
9 community-based organizer who go through the
10 neighborhoods and say, "Time to take your aspirin."
11 What's my point? These are traditional
12 health services questions. They are no different
13 than other traditional health services questions.
14 These are not NIH's traditional bailiwick, they are
15 however AHRQ's traditional bailiwick. None of them
16 include overthrowing the systems that are in place.
17 They are all about everything is in place. Nothing
18 changes. This is great. Many of us believe nothing
19 should change.
20 But we still have a problem that people
21 need to take their aspirin. It is the traditional
22 health services question. How do we get people to

1 take their aspirin?
2 Mike, I want you to be really crystal clear
3 on what I'm saying so that you can disagree or agree
4 or whatever, but I see this as classic comparative
5 effectiveness health services research and does not
6 interfere, you know, people can have the same
7 terrible jobs, same wonderful jobs, everything stays
8 the same. How do we get people to take their
9 aspirin? It's not revolutionary. It is classic 30-
10 year-old health services research.
11 What becomes a little bit more
12 revolutionary is if we end up concluding, you know
13 what, instead of one every 15-minute appointment, it
14 really helps if we do a one hour appointment once a
15 year, followed by with a physician followed by six
16 telehealth appointments with a health educator.
17 Why is that revolutionary? Because there's so much
18 entrenched in the way we do this.
19 And that's why Eboni was saying there is
20 resistance, expect resistance, expect people to
21 resist. I need my 15-minute appointment says a
22 primary care doctor.

1 So those things are revolutionary. Within
2 the healthcare system, no one is talking about
3 anything else. No one is talking about applying
4 millions of dollars to ameliorating poverty. That's
5 not what any of us, not what Kara said, not what I
6 said. And for that matter, not Eboni said. I hope
7 this is really, I hope this is helpful. I want to
8 be super clear. I'll shut up now.
9 MS. ARMBRUSTER: I appreciate the
10 clarification and I think it hearkens back to the
11 conversations we were having last month about doing
12 different things. And I saw that Sharon wanted to
13 comment and also Karin. So Sharon.
14 DR. LEVINE: Great. Thanks. Can you hear
15 me?
16 MS. ARMBRUSTER: Yes.
17 DR. LEVINE: Okay, great. Just a couple of
18 comments. I was struck by Nakela's opening comment
19 that in many ways, each of these priorities is not
20 discrete. In fact, they are overlapping and
21 interdependent and it's helpful to separate them for
22 purpose of the discussion, but to understand, as we

1 think about how it will then influence our work,
2 PCORI's work as a funder, as a convener they come
3 together.
4 And a couple of a couple of things. I
5 think it'll be important that in that light, when
6 you think about how do we apply an equity lens to
7 all research we consider funding or to any convening
8 we bring, we create or are partner with on. So the
9 equity lens can apply throughout our funding
10 activities, through our convening activities. And
11 in particular, around our thinking about the
12 dissemination -- health communication,
13 dissemination, and implementation. So to me, it's a
14 thread that runs through everything and I really
15 appreciate the conversation about focusing on
16 funding research that focuses on solutions rather
17 than further massage and clarification and problem
18 definition.
19 The other thing is, I think it'll be
20 important as we communicate what the priorities are.
21 To have very clear definition about what PCORI, what
22 the terms mean as PCORI uses them, because there

1 are, you know, a hundred different definitions of
2 equity is a lot of confusing use of equity,
3 equality, equitable. And so being very clear about
4 what PCORI means as we use these terms in each of
5 the priorities, in any of the priorities, I think
6 it's going to be important.
7 And again, and several people have said
8 this, there's important work to be done around
9 metrics and the ability to measure progress toward
10 what is clearly a very aspirational goal.
11 And that’s it. Thanks.
12 MS. ARMBRUSTER: Thank you, Sharon. All
13 right. Our last three comments in this timeframe
14 are going to be from Karin and then Mike, and then
15 James.
16 So as we wrap up in our last seven or eight
17 minutes in this topic area. Karin.
18 [No response.]
19 MS. ARMBRUSTER: Did we lose Karin?
20 DR. McMURRAY-HEATH: I think she might've
21 turned her camera off instead of her mic on turn.
22 Karin, we can't see you.

1 MS. ARMBRUSTER: I’ll come right back to
2 Karin then, and let's go to Mike.
3 DR. HERNDON: Great discussion. Thanks.
4 Especially to Alicia and Kara getting us started
5 off. I couldn't agree more with a lot of the
6 comments.
7 My comment, I don't know how we can do
8 effective health equity research without running a
9 collision course with a delivery system, you know,
10 design flaws. Payment reform. Doing healthcare
11 right for the underserved and the non-served is
12 going to run a collision course with the way we do
13 medicine, with the way societies practice medicine,
14 the way we're taught to practice medicine.
15 So as we embark on this journey, which is
16 much, much needed, we're going to have to recognize
17 that the resistance is not just resistance, you know
18 of equality. It's going to be resistance that is
19 monetary and it's going -- it's going to butt the
20 system. And I think the best description that is as
21 we embark on this, we need to anticipate somewhat of
22 a collision up against the system. Thanks.

1 MS. ARMBRUSTER: Thank you, Mike. I see
2 your hand, Barbara. I'm going to come back to Karin
3 and then James, and then we're going to see if we
4 can get all the comments. And Karin.
5 DR. RHODES: Was I on mute the whole time?
6 Oh no! Sorry, I just want to say on behalf of AHRQ
7 that we are thrilled to continue to partner and we
8 highly applaud this advancing health equity and are
9 looking forward to doing that through complimentary
10 dissemination/implementation work, and as well as
11 evidence synthesis, identifying the gaps in both
12 research and also policy gaps that need to be
13 addressed that are inhibiting health equity.
14 And, of course, helping provide the metrics
15 to measure the impact of our mutual work in terms of
16 advancing health equity. Thank you. And I
17 apologize for not unmuting.
18 MS. ARMBRUSTER: Thank you so much. And
19 thank you for the focus on policy. I'm excited to
20 hear that. All right, James, and then Steve, and
21 then Barbara. James.
22 DR. SCHUSTER: Yeah. So these were all

1 great comments. I wanted to just kind of go maybe a
2 half-step beyond Mike's comments, which is that
3 there are certainly interventions that can occur
4 within the medical system to address health equity
5 issues. But many of the challenges require
6 collaboration with entities outside the health
7 system; whether it be around, you know,
8 transportation or housing or other issues that
9 impair access to care.
10 And I don't know exactly how to frame this
11 within a research context. It requires
12 significantly more thought, but I think a study -- a
13 focus in terms of evaluating strategies to engage
14 partners in the community and effective ways to do
15 that would be a really helpful way -- it will be
16 important because we'll have potential, but maybe
17 somewhat limited opportunities to address some of
18 the equity issues we feel so strongly about without
19 that. Thanks.
20 MS. ARMBRUSTER: Thank you, James. Steve.
21 Steve we see you.
22 DR. GOODMAN: There we go.

1 DR. McNEIL: He’s having trouble with his
2 mic.
3 DR. GOODMAN: There we go. Can you hear
4 me?
5 MS. ARMBRUSTER: Yes.
6 DR. GOODMAN: Sorry. So actually my
7 comment, I’ll try to make it very quick, falls on
8 Mike's and Alicia's but I want to make sure we don't
9 lose Danny's comment there. And it indeed does
10 touch a little bit on Methodology Committee issues
11 around exploring heterogeneity and it can do that in
12 two ways.
13 One is you can take a single intervention
14 and make sure, and this was sort of what Danny was
15 saying, it's employed purposely in different
16 settings with profoundly different racial-
17 socioeconomic context to see if explore - if you can
18 see differences there. But another way to do it is
19 to, is to redefine what intervention means. And
20 here, I think a lot about the checklists that were
21 promoted, where it was thought, it's thought by many
22 that the checklist for avoiding, you know,

1 infections around surgery where the instrument, but
2 the actual instrument was the tailored, personalized
3 development of a different checklist in every
4 context. And it was that discussion between nurses
5 and caregivers and doctors that was actually the
6 intervention. It was not the checklist itself.
7 So here, and this falls on Mike's point,
8 you can imagine where the intervention is not just
9 do we give aspirin or not, you know, you can have a
10 multi-site study where each group tries to tailor
11 the health services dimension to that -- optimize it
12 to that context, and the test of the hypothesis is,
13 does the customization in this population make a
14 difference? And then you have like six or eight or
15 10 parallel studies where the intervention is not
16 just the aspirin, but something that's customized
17 through community engagement and other, maybe
18 structured ways, that where that structured way is
19 what's common, but the actual intervention is
20 different.
21 MS. ARMBRUSTER: Thank you, Steve. All
22 right, Barbara, it's our last comment. We're right

1 at the time boundary.
2 DR. McNEIL: A quick comment and it relates
3 to several that have already been made.
4 I think Mike is one who first started off
5 on the discussion that we would have to have a
6 delivery system change to make a lot of our
7 interventions work. And I'm wondering if this isn't
8 the time for us to think about some kind of pilot
9 relationship with CMMI and perhaps talk to Liz
10 Fowler to see about whether or not we could have a
11 joint RFA, at least for one of our projects that
12 involved an experimental design that CMMI would
13 approve and the grant that we would approve to see
14 if we could link our experimental approach that
15 Alicia was talking about with an actual payment
16 design that would make it more feasible and more
17 generalizable than what we could ever do with that.
18 MS. ARMBRUSTER: Thank you. Thank you for
19 the creativity from everyone and for the expertise
20 and the ideas and pushing the system to be -- to
21 continue to think differently.
22 We are at a time boundary and I am just

1 even more delighted than I thought I was going to be
2 with the way the conversation might happen today.
3 Thank you so much for all that you've shared so far,
4 it's going to be an exciting day, at least from my
5 perspective. So thank you.
6 You're encouraged to keep thinking about
7 this. We will come back to these ideas tomorrow and
8 with that, I pass to you, Christine.
9 CHAIRPERSON GOERTZ: Thank you so much,
10 Sonja, and to all of you for just a really robust
11 discussion. It was so many great, great ideas. And
12 you know, this is starting to take shape even more
13 clearly in my mind that than it was after reading
14 the materials that that were presented. So thank
15 you.
16 So we are going to take a short break now,
17 and then we will return at 1:00 p.m. Eastern time.
18 So we'll see you back in just a few minutes.
19 [Recess.]
20 CHAIRPERSON GOERTZ: All right. Nick, do
21 we have a quorum? Are we able to get?
22 DR. FERNANDEZ: Christine, I just wanted to

1 say that I really appreciated the discussion and
2 hearing from so many of the Board voices. I hope I
3 didn't overstep my time and really want to say that
4 that I think this sort of focused discussion where
5 people can bring out their questions and concerns
6 and ideas is really helpful.
7 CHAIRPERSON GOERTZ: No. I think so, too.
8 I think in a lot of ways this can, you know, can be
9 a model for -- you know, it's difficult, especially
10 when we're having our meetings virtually to generate
11 that kind of discussion and I just really want to
12 thank Sonja for being so helpful in structuring this
13 meeting. I truly do think that there are things
14 from this that we'll be able to adopt for our future
15 virtual meetings.
16 All right. Are we -- do we have a quorum?
17 Are we able to move forward again?
18 MS. WILSON: It looks like 19 Board members
19 are on the line, so that's a quorum.
20 CHAIRPERSON GOERTZ: Okay, great. Well,
21 welcome back. Just a reminder to mute your
22 microphone when you're not speaking and I'll turn it

1 back over to Sonja then.
2 MS. ARMBRUSTER: Thank you, Christine and
3 thank you everyone. I appreciate the way you are
4 all making connections among the comments of your
5 colleagues and I invite you to continue to direct
6 questions to each other and to seek additional
7 clarification from each other. And I know it's a
8 bit artificial for me to call people out in the
9 queue, but it’s the virtual world of -- this is our
10 version of nonverbal nods. Right? So we'll do our
11 best in our virtual conversations and if they look
12 like what you just, what I just observed I'm excited
13 about the remaining four conversations.
14 So our second national draft priority for
15 your consideration is Increasing Evidence for
16 Existing Interventions and Emerging Innovations in
17 Health. And our introductory comments today will be
18 provided by the Nakela Cook of PCORI's Executive
19 Director.
20 Nakela.
21 DR. COOK: And also just to echo, thank you
22 all for an engaging discussion and looking forward

1 to talking about this next priority. Let's go to
2 the next slide.
3 So the goal this priority is to strengthen
4 and expand our ongoing comparative clinical
5 effectiveness research initiatives related to
6 innovations on the horizon as well as existing
7 interventions, where there are evidence gaps that
8 PCORI can utilize its evidence generation,
9 dissemination, and implementation efforts toward
10 improving care delivery, outcomes, and health
11 equity. So this goal covers a range of innovations
12 from clinical care interventions or interventions
13 such as diagnostics or therapeutics, procedures or
14 even things like precision medicine, all the way to
15 systems changes and innovations in healthcare
16 delivery, and at the intersections of public health
17 and social determinants of health.
18 And you may recall that we've heard from
19 stakeholders about the importance of focus on the
20 application of new technologies and systems
21 interventions for the future of health and
22 healthcare, as well as the need to address evidence

1 gaps and support time-sensitive decision-making
2 needs, where there are evidence vacuums and inform
3 new delivery innovations that are focused on
4 patient-centered outcomes.
5 So advancing this priority will really
6 require us to monitor the research terrain, evaluate
7 existing and emerging innovations, and study the
8 intended as well as the unintended consequences of
9 interventions and innovations on the horizon. It
10 also will require us to expand the scope of the
11 stakeholders that are engaged in PCORI's work. And
12 I think this is related to a comment we heard in the
13 prior discussions, as well as reemphasize the
14 inclusion of underserved historically excluded and
15 disadvantaged populations in our comparative
16 clinical effectiveness research efforts. And
17 support CR evidence gaps in diverse populations,
18 geographic areas or settings that will help foster
19 equitable uptake.
20 Let's go to the next slide.
21 So in sum, this draft priority really aims
22 to evolve our existing assessment of prevention,

1 diagnosis, and treatment options priority. Keeping
2 a focus on the comparative studies, but strengthens
3 and expands existing imperatives to increase
4 evidence for emerging innovations. And it has
5 special considerations on our strategies for
6 specific populations for intended equity outcomes.
7 And this is really a good example of how health
8 equity is a cross-cutting priority that's embedded
9 in everything that PCORI would pursue.
10 So with that Sonja, I'll turn it back to
11 you for the panel discussion.
12 MS. ARMBRUSTER: Thank you so much. And
13 thank you for that overview of this priority area.
14 We will begin our Board discussion with a three-
15 person reactor panel. The panelists for this
16 national priority are Kathleen Troeger, Barbara
17 McNeil, and James Schuster. Thank you to Kathleen,
18 Barbara, and James for giving special attention to
19 increasing evidence for existing interventions and
20 emerging innovations in health.
21 We will structure this in two parts.
22 First, we will hear from each of them about what

1 excites and concerns you about this area. And as
2 well as opportunities this creates for PCORI. And
3 then we will hear from a different order. We'll
4 hear from Kathleen then Barbara, then James about --
5 the different order will be Barbara and then James,
6 and then Kathleen, about the opportunities for
7 metrics and thinking about what progress looks like.
8 So let's begin with thinking about what
9 excites and concerns you about this national
10 priority and the opportunities it brings to the work
11 and the opportunities for PCORI. And if we could
12 first hear from Kathleen.
13 MS. TROEGER: Thank you very much, Sonja.
14 So we've already heard so much this morning about
15 the interdependencies and the synergies among the
16 priorities, and as I listened to the presentation
17 earlier and thought through the content that's still
18 in front of us, I really think it will be
19 fascinating for us to watch and see how these
20 conversations build throughout the afternoon. So
21 I'm looking forward to that just more globally.
22 And Alicia, I agree with you. This is an

1 interesting format for us to be working in and then
2 I found it really productive.
3 Specific to the topic of evidence and
4 evidence intervention, evidence innovation, and
5 innovation. What excites me is the rapid
6 acceleration of real-world evidence and applications
7 to address the urgency of needs created by the
8 pandemic among areas that we've heard mentioned
9 already this morning. Design from Danny, policy-
10 related issues and working with groups like CMMI or
11 FDA or CMS. Interventions, the ability to assess
12 what works and what doesn't driven from an acute
13 need, but one that I think carries forward as the
14 work that PCORI needs to do addressing really
15 national level research priorities.
16 Use of AI, certainly it's sort of a buzz
17 right now, but artificial intelligence and EMRs to
18 identify the populations that will benefit the most
19 are things that excite me about the opportunity of
20 the innovation and the ways that evidence can in
21 some ways be accelerated. But the ability to use
22 this information to reach broader populations of

1 more representative data sets and address the
2 questions and the interventions, are really what I
3 find the most exciting.
4 So how do we do really truly research
5 differently? Which dovetails, I think, immediately
6 into the concern and the concern is that as we
7 emerge from the immediacy of the issues that have
8 surfaced in the last year, not just the pandemic,
9 but more issues around disparity and access and
10 equity, which I think have come to the surface again
11 in a way that I haven't seen them discussed in a
12 while. I'm concerned that the policies that were
13 rapidly put in place for the pandemic to expand
14 access and identify at-risk and at-need populations
15 as well as those that benefit will slow down or
16 regress. And I think we've seen some of that
17 already.
18 Similarly, the technologies that we can use
19 to identify things that work can also be used or the
20 concern is that AI and EMR can be used to restrict.
21 Kara spoke a little bit about building
22 trust among communities. And I feel that for

1 technology and the innovation to be accepted, that
2 trust will be a really important piece of all of
3 that. So that's sort of my thoughts on one and two
4 Sonja, I don't know if we bridge into opportunities.
5 MS. ARMBRUSTER: That was great. Thank
6 you, Kathleen. Your opportunities and your concerns
7 and what's exciting to you was spot on. We'll come
8 back to, to progress. So thank you.
9 MS. TROEGER: Yeah, so I think just quickly
10 there then. Because -- so it was exciting and
11 concerns for opportunities. I think the innovation
12 here, particularly with comparative effectiveness
13 research is the opportunity to address the
14 challenges as they relate to access, equity, and
15 costs in a way to rapidly reach populations of
16 needs, low resource and they extend to places like
17 pediatric oncology, rare disease populations, where
18 these things can really be pooled. Where we can
19 look at social determinants of health and things
20 that are now more easily pooled.
21 We've come up with ways to aggregate this
22 data and think about more than just ZIP+4 and create

1 evidence that's relevant to payers, patients,
2 providers, and payers. So really across the
3 different spectrum to set that up.
4 So that for me is really the opportunity.
5 MS. ARMBRUSTER: Thank you. Thank you very
6 much, Kathleen and now let's hear from Barbara. I
7 believe you are muted Barbara.
8 DR. McNEIL: Okay, how's that?
9 MS. ARMBRUSTER: Thank you so much.
10 DR. McNEIL: So I think it's quite clear
11 why this is exciting, so I'm actually not going to
12 say another word. It is absolutely self-evident.
13 But I did want to say several words on the
14 topic that on -- what I saw in one of the sides,
15 which was, oh, maybe it was what you just said,
16 Sonja, the increasing -- the need for the ability to
17 get increasing evidence for existing or emerging
18 interventions. And I'd like to say -- ask -- put
19 that in the perspective of three points that we
20 haven't addressed so far and I actually don't see it
21 anywhere in the agenda.
22 This is an extremely important issue, and

1 unless we tackle this front -- head on, we're going
2 to get nowhere and here are the three problems.
3 First is what do the plans or the physicians or
4 other healthcare delivery systems actually need in
5 terms of this increasing evidence? So they really
6 care? And that sounds like a pretty simple-minded
7 question, but it actually isn't.
8 The second one is who will do what, in
9 terms of getting these new pieces of data and what
10 kinds of incentives do they need to actually embark
11 on studies to get the new data, particularly for
12 existing technologies? Nobody gets credit for
13 studying existing technologies. And these are
14 generally done in academic institutions and people
15 who do that do not get promoted for studying
16 mammograms 10 years ago to follow-on Kathleen's
17 specialty.
18 And the third question is whatever we do
19 here, if we're talking about the emerging
20 interventions, who pays for these? I know we said
21 that PCORI can start doing that, but we can't pay
22 for everything. So unless we decide who cares about

1 what we do, who wants to do it, and how we pay for
2 it, we can blue sky from now until the cows come
3 home.
4 So I think these are very, very fundamental
5 issues that we have to address before we even think
6 about designing studies in this area. That's it.
7 MS. ARMBRUSTER: Thank you for those
8 succinct and insightful questions. And I hope that
9 everyone was jotting those down so we can have a
10 fuller discussion with the full Board about those
11 specific questions. Thank you, Barbara.
12 James, your initial reflections on
13 concerns and excites about exploring innovation.
14 DR. SCHUSTER: Well, thank you. I'm
15 definitely excited about it because this theme
16 really is a large part of the PCORI's mission.
17 Right? It's to evaluate what's out there. And I
18 think it's, you know, in the slide, it talks about
19 looking at medications, at devices, at healthcare
20 system interventions, and at digital or
21 technological approaches. And I really think those
22 last two were potentially worthy of the primary

1 focus in this area, partly because there are a
2 number of other routes for people to try to evaluate
3 medications and devices, including, you know, even
4 the FDA reviews them. Right? And decides if
5 they're at least have some value or not.
6 But there's been so much work and energy
7 put over the last five-to-10 years and continuing to
8 grow, around health system intervene innovations,
9 you know, starting with things like Jeff Brenner's
10 hot-spotting and other, you know, innumerable now --
11 other strategies that people have developed to work
12 with particularly high-need populations. And
13 there's also -- there is an amazing amount of money
14 flowing into technological approaches to support
15 health. Much of which is received very little
16 formal evaluation. I mean, most of the funding is
17 through private equity, and so there's a lot of it’s
18 funded, I think, based on its marketability, as much
19 as it's actual value to the individual patients.
20 So I think those two areas in particular
21 are really fertile areas for us to us to focus on.
22 I certainly support Barbara's comment and I

1 had noted that as well, that there are also many
2 traditional medical approaches, like annual
3 screening and other things that we consider kind of
4 usual practice of medicine that have a relatively
5 variable degree of evidence-based associated with
6 them. So I think that's the, the other area where
7 our investment could have really significant return.
8 I think, you know, in terms of areas that
9 we want to look at, I agree that we also want to
10 think about the value of the interventions to the
11 patients. So as you know, particularly in
12 traditional studies we look at whether or not an
13 intervention is effective according to whatever the
14 measurement that's chosen is. But we don't often
15 enough combine that with a sense of whether or not
16 these interventions are appropriate to patients. So
17 I think putting a really, I know we always have a
18 patient-focus our study design, but I think
19 particularly reinforcing it with this one,
20 particularly around evaluating the new interventions
21 would really be key.
22 And I think I'm going to stop there. I

1 have some few other comments about the metrics, but
2 it sounds like that's our second part. So I'll hold
3 those. Thank you.
4 MS. ARMBRUSTER: Thank you, James. I'm
5 taking copious notes from all three. Thank you very
6 much. I'm thinking about evaluation of
7 marketability versus efficacy and the opportunities
8 for PCORI and thank you.
9 Let's now turn our attention to thinking
10 about what does progress look like and how do we get
11 there as we might think about a springboard toward
12 that research agenda. So let's -- we're going to
13 shake up the order here. Let's hear from Barbara
14 and then James, and then Kathleen, about your
15 initial ideas about what progress might look like.
16 Barbara.
17 Unmute please.
18 DR. McNEIL: That's a tough one because I
19 think we actually have to be a little more specific
20 about what it is we're trying to measure. I don't
21 think there's a generic answer about what progress
22 will look like. I'm trying to think of how I could

1 even begin to answer that without sounding
2 incredibly stupid.
3 So I suppose one possible outcome would be
4 for new existing interventions, progress might be
5 measured by noting that patients of all demographic
6 age, and geographical areas, had equal access to
7 that. That might be one metric. So that would
8 apply to many different types of interventions that
9 were new.
10 And the same thing would actually apply to
11 existing ones. That would probably be the most
12 important outcome measure, but then actually it's at
13 one of the subsequent questions, which is what are
14 some of the emerging innovations in health. So I
15 personally would recommend deferring the question
16 with what progress would look like until we have a
17 better understanding of what it is we're looking at.
18 I think this is a premature question from my
19 perspective, but others may disagree. Obviously,
20 can disagree.
21 MS. ARMBRUSTER: Thank you for that thought
22 provoking -- I love it when people question the

1 question. I think there's value in that and I'm
2 thinking about your questions initially and how we
3 might be healing about measuring those. Thank you.
4 James, what are your initial reflections on
5 what progress looks like?
6 DR. SCHUSTER: Well, I'll go a little
7 further out on the ice, I could fall through, but
8 anyway -- so I think though Barbara's theme is
9 right, which is hard to be very specific until we
10 know what the questions are we're looking at. But
11 just kind of generically broadly, one of the themes
12 that I think will be important to look at is kind of
13 patient function at the end of the intervention as
14 the outcome in terms of trying to get a sense of
15 whether or not, you know, we're making these
16 systemic changes matter.
17 So in addition to looking at any clinical
18 metrics that we would typically, or others would
19 typically look at, I think actually looking beyond
20 that, and we've traditionally done that looked at a
21 number of self-reported metrics, but I think those
22 are especially important in this area.

1 The second is particularly when we're
2 looking at the health system design changes or the
3 technologies. I think to look carefully at the
4 resources utilized as part of the effort and I think
5 Kathleen alluded to this in her first answer, but to
6 look at the resources used and also what the
7 resources potentially saved are, what are the
8 efficiencies?
9 Because these are, you know, all --
10 particularly the health system interventions, the
11 interventions generally looking at themes like
12 equity that we talked about initially. You know, at
13 least from the health perspective, those at least
14 primarily are going to be funded out of existing
15 funding streams. And so that means, you know,
16 either we're going to not find something else or the
17 intervention is going to create some efficiencies
18 and could be self-sustaining over time in that way.
19 So I think it's important to evaluate that.
20 And then the last thing I wanted to say,
21 which is maybe touch on a theme that I mentioned, we
22 were talking about the first question, which is the

1 first panel -- which is, you know, particularly when
2 we're looking at health system issues we should, I
3 think encourage investigators to look at systems
4 beyond the health system, per se, as they look at
5 partners. So we should actually, you know,
6 encourage them to look at community partners,
7 whether it be agencies that supply, you know, have
8 community partners -- folks who have other types of
9 health navigators, agencies that work on social
10 determinants of health and so on. I think it would
11 be invaluable to include some of those folks in the
12 study.
13 It certainly increases the complexity and
14 to Barbara's point, it makes the measurement piece
15 ever more difficult. On the other hand, certainly
16 the federal programs, especially CMS, you know, a
17 variety of CMS programs both in Medicare and
18 especially Medicaid are now -- have that as an
19 increasing focus of what they're using the funding
20 for.
21 So I think we have a really excellent
22 opportunity to help inform that discussion and help

1 lead to, you know, how those resources get directed
2 most effectively.
3 MS. ARMBRUSTER: Thank you, James. And now
4 we'll turn to Kathleen for the first and last word
5 from our initial panel, thinking about innovation
6 and what progress might look like.
7 MS. TROEGER: So I'll go way out on a limb
8 and talk a little bit about, Barbara, what I think
9 it looks like and then a little bit of science
10 fiction as to what the future and progress would
11 look like to me.
12 I do think over the course of the last 14
13 or 18 months, and even prior to the pandemic, we've
14 seen just tremendous growth in applications from
15 learning health systems and other examples through
16 things like PCORnet on how to operationalize some of
17 the services and innovations, like telemedicine.
18 I'll just use that as an example, we’ve heard it
19 come up a bunch, that changed the way patients and
20 technology interact, the emergence of digital health
21 to monitor all sorts of things and do informed
22 clinical trial findings, I think are right on the

1 edge of where we are.
2 So that to me is we've had a glimpse of
3 what it can look like and where we're going and how
4 these things can address issues about who
5 participates in the clinical trial, the whole
6 dispersed clinical trial model and changes in some
7 of the ways and types of evidence that FDA will look
8 at and CMS will look at and that the community will
9 begin to accept pre-pubs, prior to peer review, good
10 or bad. Now, the way that a lot of people have
11 gained early information, just as -- is it changed.
12 So it's progress which moves forward and allows us
13 to debate whether it's kind of good or bad.
14 Policies, as well. Methodologies for, as I
15 mentioned, clinical trial design, FDA payment
16 structures, telemedicine. I think that to me is a
17 path toward progress.
18 The future for emerging technologies. I
19 think there's a lot about diffusion of technology
20 and whether it's a new technology or a new
21 intervention or one as Alicia was mentioning with
22 aspirin. How do we reach back with things that work

1 and get them to patients and communities that need
2 them the most? That's where, I think, some of,
3 again, the AI, the PCORnets, the learning health
4 systems, things that we'll hear more about in the
5 afternoon, dissemination and implementation will
6 come together to really more broadly use the
7 intervention and innovation piece to bring it
8 forward and address the challenges.
9 And I think this is how a close. On, you
10 know, related to access and equity, who's been in a
11 randomized clinical trial versus people that never
12 got into those kinds of trials that need to reach.
13 I think about the lines that we've seen in ways that
14 the vaccine, even for COVID has been disseminated
15 entirely differently than anything we've done in the
16 last 30 or 40 years. And yet it isn't necessarily
17 meeting, yet, the needs of the communities
18 potentially have been the most impacted by COVID.
19 So they're not there, but the last time I
20 saw lotteries to get people to take, you know, a
21 vaccination or a medicine, and not a lottery for,
22 you know, the ticket lottery, right? Not a sort of

1 get your assigned space.
2 So I think there are all sorts of things
3 here that we're right on the edge of that technology
4 enables and the way to get that there and then make
5 it -- to figure out a way to measure it. Because I
6 agree with you there. We're not there yet. And
7 then to bring that meaning back to sort signal from
8 noise are things that we're really right on the
9 horizon, right over the next hill.
10 MS. ARMBRUSTER: Thank you. And it looks
11 like Barbara wants to respond to that.
12 DR. McNEIL: I just wanted to make one
13 little addition to Kathleen's comment when she
14 mentioned both the FDA and CMS, and I think it would
15 be useful if -- I don't -- I think it's out of our
16 power and Janet's not on the call, I don't think,
17 but it would be useful if there was some mechanism
18 by which -- when the FDA approved something, not an
19 accelerated approval for example, but a plain old
20 approval, that there was automatic payment by
21 Medicare and Medicaid. Instead of having to go
22 through MedPAC, for example, to get payment.

1 So that would increase the availability of
2 new interventions or technologies to a much broader
3 group of people who would not have to worry about
4 payment.
5 That turns out to be a very big problem.
6 And I don't think it's anything that we're going to
7 solve, but it is something that we could bring up
8 with a dialogue with Janet, when she's at a meeting
9 to say, how could we ever do this?
10 MS. ARMBRUSTER: Thank you. Thank you all
11 for your thoughtful reflections and for providing a
12 groundwork for the conversation for the full Board.
13 We now have 15 or 20 minutes to hear from
14 as many more Board members as possible for some
15 additional reflections and insights about increasing
16 evidence for existing interventions and emerging
17 innovations and health.
18 And I invite you all back on camera and I
19 look for your notes in the queue about your interest
20 in readiness to speak on this topic.
21 We'll start with what excites and concerns
22 you about this national priority and/or

1 clarifications you'd like to see as we think about
2 existing interventions and emerging innovations in
3 health.
4 Thank you, Karin. Please go ahead.
5 DR. RHODES: I really appreciate the
6 comments that have been brought up and I wanted to
7 add that as we look at technology-enabled
8 innovations and new system changes that we follow
9 through and look at the cost impact on patients and
10 cost sharing and financial toxicity related to
11 innovations, as well as the equity and access to
12 those innovations, like tele-health.
13 And I also want to add that we should also
14 consider unintended consequences of new innovations
15 and put that front and center as we evaluate their
16 impact. Thank you.
17 MS. ARMBRUSTER: Thank you. Just as a
18 pacing, we're going to hear from Sharon, Connie, and
19 Danny next. Sharon.
20 DR. LEVINE: Thanks Sonja. So I think it
21 might be helpful for us to define what we mean by
22 emerging innovations. And assuming that we're

1 talking about things that have -- that have been
2 approved for general use as opposed to something
3 that's in a Phase 3 clinical trial still. But
4 certainly in terms of non-drug or device stuff, it
5 will be useful to have a definition of emerging
6 innovations that would communicate clearly what we
7 intend by this.
8 And taking us back to our core business of
9 comparative clinical effectiveness research, part of
10 the importance of comparing "innovative," either
11 interventions or products with existing approaches,
12 is to determine whether in fact there is additional
13 benefit because most of the things that are
14 approved, are approved compared to either placebo or
15 to standard therapy. And so there is some value in
16 comparing innovative stuff to existing to determine
17 if in fact there is additional benefit that accrues
18 either a health or an economic benefit that accrues
19 to individuals from the innovation.
20 And it's, to me, it raises the question
21 about the issue you raised Barbara, because if
22 coverage is automatic, when something passes

1 through; for example, FDA approval and the approval
2 is based on a comparator of a placebo, for example,
3 without it ever requiring coverage, it creates some
4 opportunity -- to me anyway -- of forcing the hand
5 of the providers in terms of using it in the absence
6 of evidence of additional benefits. I think there's
7 some caution to think through there what coverage
8 means in that circumstance.
9 Anyway, that's it.
10 MS. ARMBRUSTER: Thank you, Sharon.
11 Connie, then Danny, then Christine, then David. So
12 Connie.
13 DR. HWANG: Thanks so much. I appreciate
14 the conversation. I was also pretty excited about
15 this priority. I appreciate, as noted Barbara's
16 problem facing questions about who wants to see
17 evidence, do physicians and plans actually want it?
18 And it's funny because that actually very much
19 resonated with me and brought back memories of a lot
20 of the conversations that we had on the payer forum
21 meetings, you know, before I was on the Board here.
22 And there is so much desire and focus to think about

1 these emerging innovations and tech, particularly
2 those that when they come out, they tend to be
3 pretty high cost. Right? And there is the, as
4 James noted this lack of evidence out there to
5 figure out, you know, is it worth it? Is it
6 generating good value? You know, not only on the
7 outcome side compared to other modalities.
8 So I do think actually in this priority
9 area as Karin and, I think, Sharon both noted, there
10 could be some more explicit mention about cost
11 impacts. I think, at least in the wording when I
12 glanced back through and just though conversation,
13 this is where I think weaving that new mandate and
14 you know, being able to be freer to consider that,
15 will really -- I think push forward some of those
16 insights and would make it very valuable. I know
17 certainly from the community health plan
18 perspective, but they, and also sort of physician
19 groups.
20 I also think and sort of picking up where
21 James and Kathleen's comments left off. When you
22 think about the different interventions, I think

1 system level interventions, digital tech, I'd give a
2 double thumbs up on that, based on all the
3 conversations I've been having with again, health
4 plan and clinical leaders across the country. I
5 also think given that if we do continue to push
6 forward towards more value and risk sharing
7 arrangements through ACOs, physician groups, you
8 know, with health plans, I just think the level of
9 interest in terms of, you know, a set of -- you
10 know, modes of operation and also within science in
11 terms of some kind of costs impact are going to be
12 pretty valuable, especially when you think about how
13 this would be applied to patients and ideally, you
14 know, make health care more affordable in the long
15 run.
16 MS. ARMBRUSTER: Thank you, Connie. Danny.
17 MR. VAN LEEUWEN: So I was sort of pulling
18 on the thread of innovation to processes in the
19 system related to social disparities in health. And
20 in our conversation, in the strategy group, in one
21 version of what we looked at, we were, there was the
22 words, disruptive innovation. And my comment on

1 that was watch what you wish for.
2 And that innovation is risky. It's really
3 risky. And frankly, I'm a change agent, but I'm a
4 coward and I'm not a revolutionary. I'm no good at
5 it. And so, my style is more meeting people in
6 organizations where they are, and trying to be
7 careful that I don't have more than a 15-minute
8 advantage, because if I'm too far ahead, I have to
9 go back and get them because I lose my
10 effectiveness, if not my voice and my job.
11 So I think that one of the things that we
12 could be thinking about as we're thinking about
13 innovation and process in equity is how is it that
14 we design things so we encourage people applying to
15 take one more step forward, one more step of
16 inclusion, one more step of partnership. A small
17 risk. And I think, I don't know.
18 For me, I know how to do that better.
19 Again, I am not a revolutionary. I'm no good at it.
20 That's somebody else's job. So anyway, that's the
21 thought.
22 MS. ARMBRUSTER: Thank you, Danny. I look

1 forward to hearing more about risk tolerance and
2 disruption. David, Christine, and then Mike.
3 DR. MEYERS: Thanks Sonja. And thanks so
4 much, everybody for a great discussion. I wanted to
5 take up the thread of measurement. I think there
6 are two different levels that we have to look at
7 measurement, and the panel really focused on the
8 individual study. And clearly, we can't say how
9 individual studies should measure, but I think
10 PCORI, and as the Board, we have to think. If we
11 adopt a goal, how will we, as PCORI, know we've met
12 our goal. That's the measurement I want to think
13 about.
14 So for this one, I'll put out there as a
15 possibility that this is about our different
16 stakeholders, patients, clinicians, systems,
17 policymakers, payers, we could think about the
18 priorities there. Do they have the information they
19 need when making healthcare decisions? And if PCORI
20 is successful in this field of giving better
21 evidence about when either old or new innovations
22 are useful and for whom, which is what PCORI is, you

1 know, I think is its deepest root: who, when, why,
2 how, all those things. That if we tried to measure
3 that collectively, do people feel -- do the system
4 -- do the patients feel that they had the
5 information they needed?
6 We would be able to say we were successful
7 under this mission and under this goal.
8 MS. ARMBRUSTER: Thank you, David.
9 Christine.
10 CHAIRPERSON GOERTZ: You know, David
11 largely spoke to the issue that I wanted to bring up
12 regarding, you know, how do we define success in
13 this incredibly tricky area? You know, not at the
14 individual study level, but at the level of, you
15 know, PCORI's mission. And, you know, and I'm
16 probably jumping too far into the weeds here, but I
17 also wonder how do we choose, you know, how do we
18 set the bar for the technologies that we're willing
19 to evaluate?
20 I mean, our practice has been that we study
21 -- we conduct comparative effectiveness research on
22 therapies that have already demonstrated efficacy

1 and yet, you know, but these innovative technologies
2 by their very definition are probably not going to
3 meet that bar. And so, which is the reason why I
4 think it's incredibly important to focus on what the
5 end game looks like too to us, because I think it
6 would be pretty easy to go down a rabbit hole here.
7 MS. ARMBRUSTER: Thank you, Christine. I
8 think it seems that it connects back with clearly
9 defining what counts as an emerging innovation and
10 how that's being defined to discern what gets in.
11 Thank you. Mike.
12 DR. HERNDON: David and Christine both kind
13 of hit on what I was considering and thinking about
14 kinds of risk, but let me first kind of address what
15 Barbara brought up as far as the FDA approval equals
16 automatic approval by Medicare and Medicaid. And as
17 a Medicaid Chief Medical Officer, there are a lot of
18 things to consider not the least of which is budget
19 considerations for at the FDA approval of things.
20 And of course, you know, if you participate the
21 rebate program, if it's a medication, then all state
22 Medicaid agencies have to pay, have to cover that

1 drug.
2 Of course there's the national rebate
3 program and all that, but as far as non-medical
4 things there's a lot to consider including budget
5 and policy and that sort of thing. So anyway, I
6 just had to throw that out there for Medicaid to
7 work.
8 I did want, I think, and again, kind of as
9 non-researcher. I think one of the things we'd have
10 to consider with this, you know, discussion is when
11 is enough, enough? You know, when does something no
12 longer emerging and established and, you know, it
13 seems to me like there was a ton of research on
14 telemedicine and at some point we all knew
15 telemedicine's effect. We all knew there was a lot
16 of research on shared decision support, you know, in
17 shared decision-making.
18 And at what point does PCORI say as a
19 priority that, you know, that's enough of that and
20 it's no longer emerging? And then it becomes more
21 of an issue not of investing in the research, but
22 investing in the dissemination/implementation. So

1 to me, I think, that that's kind of the question
2 that I have about this priority -- is, you know,
3 when do you say that nationally and you know, when
4 you consider all the research that's going on in
5 NIH, AHRQ, PCORI, et cetera, when is it enough and
6 no longer do we need to invest in it, but we need to
7 switch to the dissemination/implementation?
8 MS. ARMBRUSTER: Thank you, Mike. Thank
9 you all for the insightful comments that you've
10 raised. We have a last chance to weigh-in on your
11 thoughts about the opportunities related to this
12 national priority. Are there additional thoughts?
13 Robert, please go ahead.
14 DR. ZWOLAK: All right. Thank you. This
15 has been a great discussion. My comment also goes
16 to this suggestion that FDA approval results in
17 immediate and sort of automatic coverage, and at
18 least in the Medicare program for devices, which I'm
19 familiar with, that's not the case. And I think
20 there is an excellent opportunity for PCORI to get
21 involved in this space.
22 Kathleen, I think, pointed out that new

1 treatments and new devices are very expensive, which
2 is absolutely true. And for devices at least, is a
3 pretty strong tailwind for implementation of the
4 device and newer procedures, because there is
5 potential financial gain for the vendors. I think
6 that there really is an enormous opportunity for
7 PCORI to partner with the CMS coverage and
8 assessment group at CMMI. I just think there's huge
9 opportunity for us to do this and I don't think in
10 our past, or at least to-date, we've taken much
11 opportunity to do so.
12 So I think there's lots of space there. I
13 think if we get into that space that we can do our
14 core mission, which is comparative effectiveness
15 research and we'll have great benefits based on the
16 results. Thank you.
17 MS. ARMBRUSTER: Thank you, Robert. Alicia
18 and then Kathleen, and then we've got to call time.
19 So Alicia.
20 DR. FERNANDEZ: I'm very pleased with so
21 many of the comments that have been made in such an
22 incredible breadth of what's being considered.

1 I want to add a note of questioning or
2 caution, but I have thought hard about how PCORI can
3 work on innovation, in new meds or new technologies.
4 And I just really don't see it. I don't see that.
5 I don't understand how we can get around the time
6 restrictions of doing research. That by the time
7 you innovate something, by the time you research
8 something, it's not innovative. And I think that's
9 -- I guess I would love to hear more about whether
10 or not people have sort of found a way around what
11 seems to me to be an inevitable problem in doing
12 this. And part of the reason why PCORI has been
13 unable to work effectively in this area.
14 MS. ARMBRUSTER: Thank you Alicia. And
15 just a brief closing thought, Kathleen.
16 MS. TROEGER: Yes. So one, I think, there
17 is -- just to address this automatic approval with
18 payment type thing. There are breakthrough
19 designations and other mechanisms, dual approval
20 track available right now through the agency to sort
21 of get to approval with both. But one of the points
22 that I think may have been set aside is a real

1 concern that I have that innovations like
2 technology.
3 So I think of things like PCORnet or other
4 learning health systems as innovations in and of
5 themselves, right? That then help us evaluate
6 interventions, whether they are new or old, but that
7 those interventions often -- and in technology,
8 something as simple as a mammogram, which Barbara
9 raised earlier, often don't get into the communities
10 that need them the most. And so to me, there are
11 innovations in addressing equity and access issues
12 and clinical trial participation that the technology
13 helps us bridge.
14 And I'll end with that because this is one
15 of those things that I could go on about all
16 afternoon. This is the part that lights me up about
17 how do we change it? How do we go faster? I think
18 that's what we've seen in the past year.
19 So I would challenge anybody that says we
20 can't overcome things to do them well and work
21 quickly, to take a look at PCORnet's contributions
22 to evidence accelerator, and then think about how we

1 amplify that and the work that's been done for COVID
2 into areas like pediatric oncology and Chris
3 Forrester's work, federated data sets, patients
4 having agency over their own data -- which I know
5 that Danny and Eboni and I have talked about before.
6 So that these are just things that are
7 happening in the background and I think they do
8 happen faster and methodology needs to help us think
9 through how we get the right measures and metrics
10 around it to change things again; like disperse
11 trial design, when you couldn't get participants
12 into a clinical setting to do the evaluation. How
13 did we make it happen? And how do we improve on
14 that to broaden patient participation and get the
15 cost measures in there as well?
16 So I think we can do it. I think we've
17 been doing it. We just need to do it more and
18 better.
19 MS. ARMBRUSTER: Thank you, Kathleen, for
20 those summary thoughts. And thank you all, again,
21 for your robust creative ideas about how to push
22 this idea and shape this idea as a national priority

1 for PCORI. We are at a time boundary and I will
2 remind you that we'll have additional time to think
3 about this tomorrow, so please keep those thoughts
4 percolating. And with that, I'll pass it back to
5 Christine.
6 CHAIRPERSON GOERTZ: Thank you, Sonja. And
7 everyone else for, again, another just very robust
8 and important discussion. We're going to take about
9 a five-minute break. We're a little bit behind, so
10 it really is just five minutes. We'll just stand
11 up, run around your house for a minute or two and
12 come back and we'll go ahead and get started.
13 [Recess.]
14 CHAIRPERSON GOERTZ: All right, Sonja, are
15 you ready?
16 MS. ARMBRUSTER: Yes, ma'am.
17 CHAIRPERSON GOERTZ: Okay. I see we've got
18 Jen and then -- and I know Danny's is here, so I
19 think we're ready to get started.
20 MS. ARMBRUSTER: All right. Thank you,
21 Christine. Our next draft national priority for
22 your consideration is Building the Bridge from

1 Research to Improved Health by Advancing the Science
2 and Dissemination, Implementation, and Health
3 Communication. The introductory comments today will
4 be provided by Jean Slutsky, PCORI's Senior Advisor
5 to the Executive Director.
6 Jean.
7 MS. SLUTSKY: Thank you. Good afternoon.
8 And good morning to everyone -- if we could go to
9 the next slide please. It seems fitting that we're
10 talking about this potential priority at this point
11 in our discussion, given how often it's come up in
12 our previous discussions today.
13 I just want to preface this by reminding
14 everyone that in PCORI's pre-authorization in
15 December of 2019, there was enhanced language about
16 the responsibility for dissemination/implementation
17 of PCORI research findings and the measurement of
18 how well we've done. And this goal of this priority
19 really is to assure that the findings that we
20 generate through the research we fund ultimately are
21 used to improve healthcare, better informed
22 healthcare decisions, and achieving approved health

1 outcomes.
2 And this actually would build upon not only
3 the mechanisms that we have now, to do dissemination
4 and implementation research, by building evidence-
5 based on how best to do it and how to reach those
6 audiences that need it most. And if we could go to
7 the next slide.
8 Okay. So just to amplify some of these
9 points. Really the priority aims is to revise and
10 expand our current priority area on communication
11 and dissemination research. As well as not only
12 advancing the science in this area, but the practice
13 of dissemination, implementation and health
14 communication, particularly around patient-centered
15 outcomes research or comparative clinical
16 effectiveness research. And then charting the
17 progress that we've made toward improving evidence-
18 based decision-making at all levels of decision-
19 making.
20 So Sonja, I'm going to turn it back to you
21 for what I hope is a really robust discussion.
22 MS. ARMBRUSTER: Thank you Jean for that

1 background and for providing us some context for
2 considering what we mean by Building the Bridge from
3 Research to Improved Health by Advancing the Science
4 of Dissemination, Implementation, and Health
5 Communication.
6 And now we have the good fortune of hearing
7 from three panelists on a reactor panel, three Board
8 members. We're going to hear from Jennifer DeVoe,
9 Christine Goertz, and Danny van Leeuwen. We're
10 going to hear from you each in to two parts. First,
11 I'd like to hear from you both about what excites
12 and concerns you and what you see as the
13 opportunities for PCORI. And then, we'll come back
14 and talk about opportunities for success and what we
15 think progress looks like.
16 So we'll begin with Jen.
17 DR. DeVOE: Sure. Good morning. Good
18 afternoon. Depending upon where you are in the
19 world. Thanks for this opportunity.
20 I think there's a lot of threads that are
21 going to continue to arise from the previous
22 conversation. I'm so excited that we're talking

1 about this topic now and I do also want to channel
2 Gail, one of our former Board members who I believe
3 brought this topic up at every single Board meeting.
4 And I am as excited about dissemination and
5 implementation research and practice as Gail is. So
6 thanks to Gail for championing this issue over the
7 years.
8 The other person that I want to briefly
9 thank for my career essentially in implementation
10 science and all the work that I've been doing is
11 Steve Wolf. Who's a family physician, who in one of
12 the very first issues of the Annals of Family
13 Medicine back in, I believe 2004, he wrote a really
14 Impactful article that spoke to me, and that was
15 really looking at health disparities and saying, you
16 know, if we worked to develop methods and the
17 science of effectiveness for implementing all
18 existing evidence equitably, we would save more
19 lives than if we developed new interventions.
20 And this really spoke to me in that we have
21 a lot of evidence-based interventions in our
22 wheelhouse, many, many, many across the healthcare

1 system, as well as throughout society. And we're
2 just not figuring out the best ways to implement
3 those interventions completely and equitably across
4 all people in all populations. And this is, I
5 think, as a primary care physician, this is what
6 drew me to health services research as well as
7 implementation science, perhaps even before that
8 term was widely known.
9 So this is a topic near and dear to my
10 heart. I think comparing the effectiveness of
11 implementation strategies to implement evidence in
12 all populations equitably is important. And the
13 exciting thing for PCORI is this is a sweet spot for
14 us. I think the practice of disseminating and
15 implementing information is really important. And
16 the science of comparing those implementation
17 strategies also critically important and something
18 that PCORI can do incredibly well with our focus on
19 comparative effectiveness research.
20 So that's where there's excitement, I
21 think, concerns and those were alluded to earlier,
22 but I'll mention them again. I think if we get out

1 ahead of our skis and we have new innovations and
2 interventions that we prove to be evidence-based and
3 we get out to implement those to the privileged
4 populations that are already advantaged and have
5 significantly longer life expectancy, better health
6 outcomes, we potentially can exacerbate disparities.
7 So the health equity strategy and this strategy go
8 hand-in-hand in really focusing on what are the
9 implementation strategies needed to implement
10 evidence-based interventions, whether they be
11 existing ones or new ones, and knowing that one size
12 doesn't fit all. That there are certain populations
13 and people that are going to need very, very
14 different strategies.
15 So speaking to Alicia's point before that,
16 we need to figure out how to get everybody on
17 aspirin who needs to be on aspirin. There's likely
18 going to be very different implementation strategies
19 needed in different populations. Another example,
20 right now, we know we have a very effective COVID
21 vaccine, but there are certainly implementation
22 strategies different in different populations from a

1 million-dollar lottery to ensuring that those
2 vaccines are available in every primary care office
3 across the country, so that patients can have
4 conversations with trusted care teams to understand
5 the risks and benefits of getting those vaccines.
6 So lots of opportunity. It's very exciting
7 here. Some of the concerns that have been raised
8 earlier also, I think play out here as well.
9 MS. ARMBRUSTER: Thank you Jen.
10 DR. DeVOE: I will turn it over to
11 whoever's next.
12 MS. ARMBRUSTER: Thank you so much.
13 Christine, what were your initial
14 reflections about these priorities, opportunities,
15 and concerns.
16 CHAIRPERSON GOERTZ: Yeah, absolutely. So
17 it's hard to follow Jen because you know, like her,
18 this is something that's so close to my heart and
19 Jen, I think you did a really great job of outlining
20 the opportunities and the way that, you know,
21 especially the opportunity that PCORI has to make a
22 difference in terms of both science and actual

1 implementation of implementation in in our research
2 findings.
3 You know, a big part of my job is actually
4 trying to implement evidence into clinical practice
5 in a large health system. And often, I'm grateful
6 for the research that I have that has helped show me
7 some ways to do that. But the truth is that that
8 research does not address every barrier and let's
9 just talk about payment policy. You know, until
10 payment policy is aligned with value-based care and
11 best practices, I think it will continue to be a
12 struggle. And, I don't know how research addresses
13 that, but I think that that's something that we need
14 to think about or, you know, where are the areas
15 that we can make a difference and to really be
16 focused on the very real barriers that exists in
17 this process.
18 But I think that when I think about the way
19 that this particular national priority can serve
20 PCORI's mission -- I mean, it's already been
21 mentioned that this is actually a part of our
22 legislative mandate, which makes it -- our role very

1 clear or the fact that we have a role, very clear.
2 I think it's up to us to decide what that role
3 continues to evolve to be. And I would like to see
4 us build on the important work that Jean and others
5 have led and in this area to work with the
6 Methodology Committee. Because this is, you know, a
7 relatively nascent area of research inquiry. I
8 think there's opportunities to continue to work with
9 our Methodology Committee to make sure that we are
10 staying on top of best practices.
11 I think we need to be developing a strategy
12 for how we prioritize our D&I research efforts,
13 given the fact that the need is so broad and we
14 cannot address it all. We're going to have some
15 hard work to do in prioritizing what it is that we
16 need to do.
17 And then I just want to emphasize the need,
18 I think we have a unique opportunity to bring
19 together the kind of multidisciplinary teams that it
20 really takes to do this research. And you know,
21 it's not always your normal, you know, scientists
22 but also, you know, working with, you know,

1 marketing experts and payers and we talked earlier
2 about technology, but there's a lot of technology
3 that can actually advance dissemination and
4 implementation as well through EHR and other
5 methods.
6 So I think that we truly do have a rich
7 opportunity here to make a difference.
8 MS. ARMBRUSTER: Thank you, Christine for
9 helping us think more about how this aligns with the
10 mandate and opportunities to partner with new
11 partners and so many other ideas. We get to turn
12 now to Danny and hear about your initial reactions
13 to what excites and concerns you about this and the
14 opportunities for PCORI.
15 MR. VAN LEEUWEN: Well, I'm really
16 delighted to be the third person who is so
17 passionate about this topic because I am in good
18 company.
19 So just as a little background. So, you
20 know, my biases, which I have considerable in this
21 area, is that I served for a couple of years as co-
22 chair of the Communication and Dissemination

1 Advisory Panel. And during that term, I listened
2 and I really learned about the challenges of the
3 science of communicating about uncertainty, which is
4 all research. And about communicating complex
5 health and life challenges. And so, when you start
6 thinking about the disparate communities around us,
7 well, there's a lot of complexity.
8 As a podcaster, I've listened and learned
9 about the challenges of communicating and
10 dissemination outside of the expert bubble. And
11 finally, now as a patient caregiver activist
12 involved in a Person-First Safe Living in a Pandemic
13 Initiative, we've really seen a gap, really -- no, a
14 chasm between the questions people are asking about
15 safe living and the evidence informed guidance
16 that's available to help guide them.
17 So I think I want to say that this paper
18 about this priority is really well done and I want
19 to thank the staff. It is rich and exceeded my
20 expectations, definitely. The thing that I was
21 excited the most about was their emphasis about
22 getting the right information to the right people at

1 the right time, in the right manner. And I always
2 pay attention to the non-clinicians in the non-
3 clinician settings, because I know that decisions
4 and implementation often happens first outside of
5 the clinical settings and then people come back to
6 the clinical settings with information.
7 So whether it's about something rare, like
8 sickle cell disease or whether it's about taking
9 aspirins. There are people doing it and they're
10 implementing.
11 I also think it's really important when we
12 talk about health communications. It's not like
13 there’s science and research and then there's
14 communication. Communication is like really more
15 about listening and the science of listening is
16 really a second cousin that, you know, now PCORI
17 does an amazing job of listening to its
18 stakeholders.
19 As far as I'm concerned, it's a model. You
20 do not see this kind of listening and distillation
21 of what they hear, as good as I hear at these
22 strategy meetings and the board meetings, it is

1 really hard to do. But we need to bottle that
2 somehow and fund the science of listening. And
3 listening happens at the beginning of the process,
4 not after the research is done. So this business, I
5 was saying that we've learned about, you know, the
6 gap between the questions people have and the
7 evidence informed guidance they can find. Well,
8 people are asking questions. Well, who's listening
9 to the questions that people are asking?
10 So, and one last thing I'll get off m soap
11 boxes, is that I want us to remember that the
12 ultimate goal here is changing change in life. Not
13 change in practice. Change in practice does not
14 mean that anything changed anywhere else.
15 So back to what I was saying about how
16 people change, and then they go back and they tell
17 their doctor, "I changed." And sometimes it's a
18 good change. Sometimes it's not a good change. But
19 the goal is about change in life, not change in
20 practice. Done. Thank you.
21 MS. ARMBRUSTER: Thank you, Danny.
22 Thinking about listening and how we support

1 continued listening and stakeholder engagement and I
2 appreciate all your comments there.
3 We're going to go in order from Danny then
4 Jen, then Christine, to think about what progress
5 looks like. So just briefly in a couple of minutes,
6 thinking about that more specific piece, what does
7 progress look like? Or how do you see us needing to
8 begin to shape the research agenda as it relates to
9 dissemination and communication of the emerging
10 research? So Danny.
11 MR. VAN LEEUWEN: Well, I mean, I have to
12 go back to the listening stuff, you know, what are
13 the questions we're asking? I mean, I think we've
14 talked about it in the other priorities and we're
15 going to talk about it more, but that partnership
16 with stakeholders, and even though I'm representing
17 patients and caregivers, I don't mean just them. I
18 mean, all stakeholders. I think that our -- I'll
19 see success when we're as good at helping our
20 researchers learn to listen as good as we are good
21 at listening to them.
22 Oh, man that was twisted, but you get the

1 point.
2 MS. ARMBRUSTER: Thank you. And Jen, what
3 are your thoughts about what progress looks like and
4 how this priority area might influence the research
5 agenda?
6 DR. DeVOE: Sure. I liked your point
7 Danny, about change in life. And I think it relates
8 to one of the things I was thinking about as far as
9 new measures of dissemination and implementation in
10 going beyond some of the traditional ones.
11 We like to look at the impact factor of a
12 journal that a paper was published in, how many
13 clicks we got on a website, and that gives us at
14 least a sense that people are looking at the
15 material. Maybe reading it, maybe digesting it, but
16 getting to metrics to know that it's actually being
17 implemented in a meaningful way, such that someone's
18 health has improved and their life has changed
19 hopefully in a positive way, but maybe not always.
20 And just really working again with our Methodology
21 Committee with our broad range of stakeholders and
22 diverse groups.

1 So think about how do we meaningfully
2 measure our reach in the dissemination of findings
3 that are going to change people's health and lives
4 in a positive way. So that is a big aspiration. I
5 know. But I think that we can do it at PCORI and
6 there are some exciting opportunities to move in
7 that direction.
8 And then I think the other thought I had
9 just building on equitable implementation and
10 thinking about if we're successful at implementing
11 equitably across a population, I think it also
12 brings up new opportunities for observational
13 studies in different ways, such that we can be sure
14 that we've gotten interventions to the population
15 and then we can start looking at methods related to
16 observational studies and natural experiments and be
17 more sure that our data is valid and that we have
18 everyone participating in whatever particular data
19 set that we have compiled. So those are just two
20 exciting opportunities for future. Thanks.
21 MS. ARMBRUSTER: Thank you, Jen. And
22 Christine, progress?

1 CHAIRPERSON GOERTZ: Yeah, so to me,
2 progress is, you know, similar to what Jen and Danny
3 have already said. It's, defining what success
4 means in a measurable manner, you know, all the way
5 down to the patient level. So at every single level
6 of the intervention
7 I think it also is looking at the depth and
8 breadth of a national D&I research portfolio. Not
9 only what research is PCORI able to do, but are we
10 able to influence other funders to really ratchet up
11 the way that they prioritize D&I? And I think to
12 continue to look at it from a broader perspective
13 than the, you know, what was the impact factor of
14 the journal and how many clicks did you get on that?
15 I really liked Barbara's idea to partner
16 with, you know, agencies such as CMMI to really
17 bring together experimental approaches to payment
18 design. And I think that that has not only is it
19 incredibly important for health equity, but it could
20 also be used for more general D&I efforts.
21 And then just finally, I think, you know, I
22 would like to see us find ways to contribute towards

1 training the next generation of D&I scientists and
2 other stakeholders.
3 MS. ARMBRUSTER: Okay. Thank you so much.
4 Thank you all three for giving this a closer look.
5 Thank you, Christine, Danny, and Jen for giving us
6 all a little grist for the mill, some groundwork for
7 the conversation. We want to invite all of the rest
8 of the Board back and we have about 20, 25 minutes
9 to think about Building the Bridge from Research to
10 Improved Health by Advancing the Science of
11 Dissemination, Implementation, and Health
12 Communication.
13 And since this is so closely aligned with
14 the mandate, I suspect we'll have robust
15 conversations. So I look forward to seeing your
16 queue in the chat or you can wave on the screen and
17 we'll begin for all about what excites and concerns
18 you about this national priority.
19 There we go. Welcome back everyone. So
20 Sharon, please kick us off.
21 DR. LEVINE: Thanks. And I want to add my
22 name to the list of people for whom this is a high

1 priority and one of my personal passions. And I
2 also want to tag onto Danny's comment, complimenting
3 the staff for the incredibly well-done brief. It
4 really helped to focus my thinking around how I
5 could make comments that were helpful and additive
6 to what's already been said.
7 One of the things I think we've all
8 experienced in the last year was a dramatic display
9 in how the absence of trust interferes with
10 effective health communication and effective
11 implementation of established, and potentially very
12 important, health interventions. And I think
13 there's real opportunity for us as a funder and as a
14 convener to work with not just CMMI, but with the
15 CDC and with local public health agencies around,
16 which have been seriously under-funded and under-
17 invested in for decades. And I think we're caught
18 flat-footed and not blaming in any way, but caught
19 flat-footed in terms of the critical role they
20 should have been prepared to play in the face of the
21 pandemic.
22 And I think there's so much we can learn

1 from this in terms of the need for collaboration and
2 place-based collaborative research involving
3 communities, public health departments, and
4 healthcare systems in communities around
5 understanding what are trustworthy behaviors in
6 relationship to community members, building the
7 basis of trust, and then research around the most
8 effective ways to communicate health information and
9 to execute in partnership with community important
10 health interventions.
11 And to me, PCORI has a powerful role to
12 play here in terms of bringing these not, not
13 necessarily natural allies together and using both
14 our convening and funding functions to make this
15 very important research a reality.
16 MS. ARMBRUSTER: Thank you, Sharon. We
17 have several in the queue. We're going to hear from
18 Eboni and then David, and then I'm looking for
19 additional people who want to share their passion
20 for thinking about what are the opportunities, what
21 excites you about this priority, and what are your
22 concerns? So Eboni.

1 DR. PRICE-HAYWOOD: So I want to
2 [inaudible] the comments that everyone's made thus
3 far. And so I'm trying to think about how to say
4 something different. And so, I think I want to
5 focus on the implementation science piece and also
6 from the perspective of, again, health systems.
7 I think a primary example where we struggle
8 to get more concrete is think about behavioral
9 health integration in primary care. Something that
10 has been well-documented through randomized control
11 trials over 20 years, and yet, and now there's for
12 value-based payment from CMS with regards to the
13 Medicare patient population. But then when you look
14 at the uptake of this well, you know, designed
15 intervention with very important, you know, driven
16 by patient reported outcomes, we struggled to figure
17 out how to implement that in real practice.
18 And even within a given organization, you
19 may have differences in terms of how that is
20 implemented, be it telemedicine versus in-person
21 versus whatever, what's the composition of your
22 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 And so having implementation science,
10 promoting implementation science is something that I
11 think a lot of healthcare systems and even other
12 environments would appreciate because it's something
13 tangible that they can see the immediate --
14 potential immediate benefit for. It's also a great
15 way to engage stakeholders in the actual questions
16 from the various perspective. And so for example,
17 the behavioral health integration, you have the
18 health plan, the health system, the patient, or a
19 number of different views that may shape how the
20 program is designed within a given context.
21 And so I applaud the focus on increasing
22 implementation science. And I can tell you, there

1 are a lot of folks who are in C-suites, who would
2 appreciate more of this work as well.
3 MS. ARMBRUSTER: Thank you, Eboni. David.
4 DR. MEYERS: Thank you. And yes, adding
5 that this is an passioned part, but I guess they all
6 are for all of us. So that's a good thing.
7 I think one of my roles here is to ask the
8 group to think about how PCORI partners with its
9 legal partners at HHS and specifically AHRQ to move
10 the agenda forward. And this area really gets into
11 the place where we are most overlapping. AHRQ is
12 required by law to invest the PCOR trust fund funds
13 that we receive in training researchers, the next
14 generation of CR researches and also implementation
15 science researchers.
16 So we have money to do the training. We
17 also, like you, spend and invest in getting the
18 evidence that PCORI and NIH and others have shown
19 works into practice.
20 What's really exciting to me about this
21 piece, where the way this is phrased, it's research
22 about the science of implementation. That's a part

1 where we don't overlap.
2 So how we elevate that part to show it's
3 PCORI’s, and then think about that second part of
4 getting that evidence used. And as Christine said,
5 training researchers within health systems, we have
6 a great partnership that PCORI and AHRQ are already
7 doing. And so, how do we think forward about making
8 this -- building that partnership so that AHRQ is a
9 partner in the implementation not the implementation
10 research, but the practice implementation as well as
11 the training.
12 I think there are real opportunities to
13 align ourselves there. Thank you.
14 MS. ARMBRUSTER: Thank you, David.
15 Listening to you, I want to draw an illustration of
16 the flow of that work together and that makes up --
17 that helped illustrate in a significant way for me.
18 So thank you.
19 Mike, thoughts about what this might look
20 like, what excites and concerns you about this
21 priority?
22 Oh, I'm sorry, Mike, you need to unmute.

1 DR. HERNDON: I think back to my 20 years
2 in clinical practice and thinking what made me
3 change, you know, what made me adapt something new
4 and truthfully and just listening to all these
5 comments, which it is incredibly important priority,
6 but just reading something from a research journal,
7 rarely, I think, creates a lot of change. You know
8 what created change in my practice was when my peers
9 and the people in my clinic, you know, started
10 adopting change. And I was in a network of
11 providers and when my network started producing you
12 know, evidence and saying, hey, this is the new
13 norm, if you will.
14 So I think as people who are so much
15 smarter than I am about implementation science, I
16 think, it's just so critical that PCORI develop the
17 partnerships with the medical associations, with the
18 specialty societies as we go forward and not just
19 put stuff out there for others to come and get. But
20 that we put the information collaboratively with the
21 associations and the societies and the health
22 systems so that the dissemination becomes real and

1 not just something to be read and hopefully grasped
2 and adopted.
3 And my last comment is, it seems to me that
4 so far all three of these topics come back in some
5 way or another to just kind of practice redesign and
6 order some sort of change in how we do medicine and
7 how we got to start having that national discussion.
8 MS. ARMBRUSTER: Thank you, Mike. We are
9 at an opportunity to continue discussion about this
10 and there are no named people in the queue. So
11 here's your opportunity to weigh-in? I've heard a
12 lot about how do we implement the science of change
13 and change norms and we've talked a little bit about
14 what excites you about that opportunity and how it
15 relates to PCORI and do you have thoughts about what
16 that might look like in the research agenda or what
17 progress looks like? How do we know when we're
18 doing this well?
19 MR. VAN LEEUWEN: You know, the measurement
20 needs to be worth the work. And one of the
21 challenges with this is that most of the measurement
22 that I can think of related to this is just too much

1 work. And so, I'm wondering if to me it would be
2 really interesting if people came to us with ideas
3 about how to spread the word in whatever world it is
4 they're living in.
5 So receiving unsolicited advice or examples
6 which would be like really easy to measure, you
7 know, you just set up a place for people to dump
8 whatever it is they're thinking about. You know,
9 it's not taken a bunch of scientists going all over
10 the place, spending a lot of money, but I don't
11 know. I mean, I think that -- and then, and then
12 the goal would justice be to see that increase?
13 You know? The first month it's one, the
14 next one it's 20. I don't know. But you know, it's
15 like, without, like, I don't know. I'm just trying
16 to think simply.
17 MS. ARMBRUSTER: Thank you. I've heard
18 several mentioned that we need to go to additional
19 disciplines that thinking about implementation
20 science and health communication may involve
21 researchers that are not the normal group for PCORI.
22 And are there some new opportunities? Are there

1 some people whose voices might be most impacted by
2 this work that need an opportunity to weigh in on
3 the process as we think about the research agenda?
4 [No response.]
5 MS. ARMBRUSTER: All right. This is your
6 last chance. We are not running up against time, so
7 our last chance to comment on this. Ellen.
8 DR. SIGAL: I just want to add that we're
9 not that easy to go to. We have a very, I would
10 call it rigid, but we have a process in place that
11 is very directed. And if we want to change or try
12 new models or do different things, we have to make
13 it more accessible to people to visit focus with us
14 on what they want to do or how we can change or
15 different areas of partnerships or collaboration.
16 You know, who do they come into? Do they
17 come to the Board? You know, who do they speak to?
18 How does this work? If we're serious about it, we
19 have our infrastructure, we have our group, but we
20 have a relatively -- how should we say it? Way of
21 working that isn't necessarily easy to change
22 quickly or to incorporate new ideas in.

1 So if we're going to do that, we should
2 think about that and what the process would be.
3 MS. ARMBRUSTER: Thank you, Ellen. I think
4 this has been a running theme that I've heard and
5 something we might want to revisit. We have two
6 additional comments in the queue. First let's hear
7 from Chris.
8 DR. FRIESE: Sure, good afternoon
9 colleagues. My apologies, I had to miss the first
10 part of this session I was teaching. And I
11 apologize if my comment has been shared, but I'm
12 just picking up a little bit on Sonja's sort of a
13 macro assessment of the conversation.
14 As we think about, I'm going to use the
15 word implementation science for a moment, but then
16 I'm going to pull back from that a little bit and
17 say, I think one of the challenges, at least in the
18 cancer realm where there's been a lot of work in
19 implementation science and a real embrace --
20 implementation science has been embraced by funders
21 of cancer research is as a relatively rigid
22 definition of that discipline that I don't think

1 serves us well. And I think it just speaks to the
2 point of having diverse disciplinary perspectives,
3 people who can really be partnering with our
4 research community with our key stakeholders. With
5 the requisite expertise that is not defined by what
6 somebody puts on their business card or something
7 like that.
8 So I want us to just think, you know, we do
9 research differently, right? That's part of our
10 tagline. And so, just making sure that we have an -
11 - just as we were talking earlier about an inclusive
12 approach, I think the same is true here. There
13 might be some scientists and some expertise that can
14 really help us in this space, that if we stick with
15 that classic definition, some classic definitions of
16 disciplinary boundaries I think we might be missing
17 some opportunity.
18 I hope that makes sense. And I apologize
19 if that was duplicative to what someone else said
20 prior.
21 MS. ARMBRUSTER: Thank you, Chris. You got
22 a lot of head nods on that. So I would say that was

1 an affirmation.
2 Let's hear from Sharon and then Christine.
3 DR. LEVINE: So two comments. The first is
4 just to remind the Board about the opportunity with
5 the Alda Institute, I think it's at Long Island
6 University. The Institute on communicating science
7 and health information to the public. There's a lot
8 of expertise there and I think some opportunity to
9 understand what their experience has been in terms
10 of training scientists and people in both basic and
11 health science fields around communication.
12 And in a similar vein, if we were to do a
13 systematic review of successful and unsuccessful
14 implementation efforts of health system -- of health
15 interventions, it would be interesting to be certain
16 that we captured the learnings from the failures.
17 Most of the time when an effort is made to implement
18 something and it is less than successful, people
19 have a good sense of why it didn't work. And you
20 know, the ability to capture the learnings from
21 failures, too, in some ways, inform practice-based
22 evidence around how to improve the practice of

1 implementation might be a useful exercise for us.
2 MS. ARMBRUSTER: Thank you, Sharon.
3 Christine.
4 CHAIRPERSON GOERTZ: I agree with Sharon
5 that the ability to learn from failures is
6 critically important. The issue is that they don't
7 end up in the literature as often as the successes
8 do. And so, it's somewhat challenging, I think, to
9 identify them. But I agree that I think it's worth
10 the effort to try to do so.
11 And then the other comment I wanted to make
12 is just to affirm the incredible opportunity that we
13 have through our partnership with AHRQ to work in
14 this space. It means, I think, we have an
15 intellectual partner as well as a partner to help us
16 to fund this kind of research and the next
17 generation of investigators.
18 MS. ARMBRUSTER: Excellent. Thank you so
19 much. All right. Last call for commentary about
20 Building the Bridge from Research to Improved Health
21 by Advancing the Science of Dissemination,
22 Implementation, and Health Communication.

1 Yes, Jen, please.
2 DR. DeVOE: I was just going to build on
3 that comment you made Christine and others about
4 just strategic partnerships in this area. I've
5 heard CMMI mentioned. I think AHRQ is another one.
6 A lot of folks in the more traditional
7 implementation science realm that you described;
8 Chris are realizing that they need laboratories.
9 And those laboratories are the real world and their
10 health systems and their tech companies, and they're
11 all kinds of people that are doing innovation on a
12 daily basis. And also moving the needle on
13 methodology so that you can do hybrid effectiveness
14 and implementation studies to really push the
15 science and accelerate the pace at which you get
16 answers, whether they're positive or negative,
17 whether it works, whether it doesn't work.
18 So I think this is another area where I
19 don't know if there's opportunities to partner with
20 AHRQ’s ACTION 4 network or some of the other
21 networks, maybe PCORnet, other places where we can
22 really think about innovation laboratories to do

1 implementation science, and payers, health systems,
2 other federal agencies, et cetera, would be
3 opportunities to do so.
4 So just thinking about the laboratories
5 that we want to support and partner more closely
6 with in this space.
7 MS. ARMBRUSTER: Thank you. Steve.
8 DR. GOODMAN: Yeah, I just wanted to sort
9 of connect this to the very first discussion in the
10 health equity space. You know, the way this is
11 framed, assumes that if we have perfect information
12 flow, better health will follow. But, of course, we
13 know very well that making people, and this is
14 again, linking to the aspirin example and the other
15 things we talked about. Even if people know all the
16 science, even if the physicians and healthcare
17 deliverers are giving the proper information, people
18 often don't behave in the ways that will result in
19 improved health.
20 So this is captured, and I do think the
21 previous comment was also good, by implementation
22 scientists, but also by behavioral scientists, and

1 the kinds of interventions that induce behavior
2 change are very, very different in different
3 communities. So this goes back to the point one.
4 So what was missing from the text here,
5 although is in some of the comments is behavior.
6 Not just not the behavior of the patient or the
7 participant, not just the behavior of the providers.
8 And that requires a completely different model for
9 thinking about what induces health promoting
10 behaviors in many, many contexts where the physical
11 infrastructure, the economic infrastructure, and
12 many other support systems don't support or promote
13 optimal, you know, following even perfect advice.
14 And if you gave people a quiz, they might
15 score a hundred percent on the quiz. So it looks
16 like we've disseminated. It looks like we've
17 communicated, and yet people don't do the right
18 thing. And I actually include some people on camera
19 right now. So that is, I often don't take very,
20 very good advice, but the issues for me are very
21 different than other populations.
22 So I want to make sure you have health

1 behavior and the heterogeneity of different cultures
2 and different populations in mind here.
3 MS. ARMBRUSTER: Thank you, Steven for
4 bringing us back to purpose and back to some of the
5 other issue topic briefs that we've discussed and
6 for reminding us of the complexity of health
7 communication involving health behavior change.
8 Thank you all for a robust discussion of
9 this national priority draft. We are at a time
10 boundary. We will have additional time to discuss
11 this tomorrow and you have made it through three of
12 five. So we are over the midpoint and I hope that
13 that sends you to break in an energizing way with
14 that, I pass back to Christine.
15 CHAIRPERSON GOERTZ: Thank you, Sonja and
16 all for another rich discussion.
17 We are going to take about a nine-minute
18 break. So please come back at 2:50 Eastern time and
19 we will finish up with our last two national
20 priority discussions.
21 [Recess.]
22 CHAIRPERSON GOERTZ: All right, so we have

1 Connie and Eboni. Why don't go ahead and get
2 started then?
3 MS. ARMBRUSTER: All right. Well, thank
4 you, Christine and welcome back everyone, as you
5 know we are working our way through the five draft
6 priorities. And as we turn to our fourth of five,
7 we are looking at Enhancing Infrastructure to
8 Accelerate Patient-Centered Outcomes Research and
9 our introductory comments will be provided by Laura
10 Lyman Rodriguez, PCORI's Interim Program Support
11 Officer and Senior Advisor to the Executive
12 Director. Laura.
13 MS. LYMAN RODRIGUEZ: Thank you, Sonja.
14 And thank you all for having such a wonderful
15 conversation this afternoon and as we go into this
16 final session of the discussions for the draft
17 priorities today, as is evident from the title of
18 this draft priority. We're going to focus here on
19 support for and support for advancement of the
20 infrastructure that undergirds the ecosystem to
21 enable and empower health research, in particularly,
22 patient-centered outcomes research within health

1 research to go forward.
2 As we've discussed this morning and we're
3 all very familiar with the health research
4 enterprise is incredibly complex. And it also
5 overlaps greatly with the healthcare infrastructure,
6 which it sits next to or within or in many different
7 relationships with, but here the focus for PCORI is
8 really on the elements of the health research
9 infrastructure itself. And in particular, the
10 people, the information -- both in terms of data
11 generated and captured; as well as the knowledge
12 that emerges from those data, and the policies and
13 processes that must come together for there to be
14 true connectivity across the ecosystem for optimal
15 performance and the generation of benefit through
16 timely and responsive research.
17 I also just want to note here, too, as we
18 have been developing this draft priority, thinking
19 about the unique opportunity for leadership for
20 PCORI here -- oh sorry, thank you for moving this
21 slide -- to think about this because of the breadth
22 of our relationships and remit with regard to

1 stakeholders that interact with activities across
2 the different parts of the ecosystem for different
3 aspects that must come together for Health Research
4 to go forward.
5 And also, again, reflecting on conversation
6 from today and conversation over the years of just
7 the acknowledgement of when this ecosystem and the
8 different components of the ecosystem are not well-
9 aligned or they're not able to work together
10 efficiently, can really lead to some missed
11 opportunities to make a difference in important
12 areas, as well as undermine the overall success of
13 realizing improved health outcomes.
14 So if we move to the next slide now and
15 review as we have with the other draft priorities
16 and some of the inputs that we've received in the
17 conversations with stakeholders, the discussions
18 with this group, as well as within the Strategic
19 Planning Committee. Here, again, really focusing
20 within this draft priority on enhancing the
21 connectedness of the different components that I've
22 already mentioned within this health research

1 infrastructure and the ecosystem within which it
2 must exist.
3 And again, reflecting our conversation this
4 morning and some of the discussion that was noted by
5 Board members about how important different
6 definitions are for the terminology that we use to
7 know what we're actually talking about to say a
8 little bit more about those three components. So
9 starting with the people, of course, we heard
10 earlier about how important that people are to have
11 the people really working together and the right
12 groups included within that.
13 So here PCORI, within this draft priority,
14 is thinking very broadly and thinking about the
15 patients and the providers, of course, but
16 communities and other stakeholders that come
17 together and the research workforce as well that
18 comes together to affect the research and conduct
19 the research. And again our definition of workforce
20 in this case is broader than just providers or
21 researchers, but all of the different groups and
22 disciplines and partners that must come together,

1 again, to accomplish the work of the research, in a
2 way that enables it to be very patient-centric in
3 its design and its implementation.
4 From an information perspective, again,
5 just to talk a little bit more about that and focus
6 in each of these areas that it's not just about who
7 they are and the draft priority doesn't just focus
8 on the connectedness, but also about pushing forward
9 and driving improvements and enhancements in each of
10 these components. So with the information, it's not
11 just talking about the data that are generated or
12 that are captured, but making sure our methods and
13 our systems for capturing that data ensure that it
14 is accessible, that it's interoperable, and that
15 it's secure so that the system itself and the way
16 that the data are used can be trustworthy.
17 And again, we've heard a lot about trust
18 already within the context of the other priorities.
19 And then finally, thinking about the
20 policies and processes. We all know within these
21 systems, how important it is and how important it is
22 for them to be connected, but really thinking here

1 about what are the opportunities to pursue, how to
2 truly make them not just connected but to create
3 connectivity across them so that there is real
4 momentum and so that this focus on the patient-
5 centered nature of the work can really come through
6 and how research is designed, how it is prioritized,
7 and again, how it is implemented to truly be
8 inclusive and evidence-based in what is going
9 forward.
10 So with that I will stop and I will turn it
11 over to our discussants, and really look forward to
12 the conversation with everyone.
13 MS. ARMBRUSTER: Thank you Laura for that
14 foundation and for giving the greater context to
15 this title, Enhancing Infrastructure to Accelerate
16 Patient-Centered Outcomes Research. We now get to
17 hear from two of our Board of Governors members in a
18 reactor panel, we have Connie Hwang and Eboni Price-
19 Hayward.
20 And thank you both for giving special
21 attention to this area. Would you please each both
22 share a few minutes about what excites and concerns

1 you about this national priority, and the
2 opportunities you see it bringing to the work for
3 PCORI. And let's begin with Connie.
4 DR. HWANG: Great. Thanks so much. And I
5 appreciated that nice summary about this priority.
6 So when I was reviewing this, you know, I
7 understood the purposes of this brief to be focusing
8 on a fairly broad term; the health research
9 infrastructure encompassing people, information,
10 processes, and policies. Where frankly, PCORI is
11 really well-situated, you know, as a convener and a
12 funder.
13 So what excited me the most, especially if
14 this is executed successfully is that we can really
15 bring forth new opportunities for a variety of new
16 individuals and entities to engage in patient-
17 centered outcomes research. And, you know, with
18 that, maybe what I can try and do is just give you
19 some of my top little thinking on each of those
20 three sections.
21 Now, so let's talk about the people section
22 and I was really happy to see here the great

1 interweaving of a focus on health equity and
2 advancing diversity, equity, and inclusion
3 principles in that. And it's really thinking a lot,
4 I think, when you read through the career
5 trajectories of health research workforce. So
6 mentoring, networking funding, there was a good
7 example in there about the partnership with AHRQ,
8 which I think was mentioned in our previous
9 discussion. So all great ideas.
10 I think the part that jumped out to me or
11 where I was most intrigued, is this concept
12 investing in communities and community organizations
13 with a lived knowledge of health and social
14 environment. Especially since they're uniquely
15 situated to really inform a lot of the healthcare
16 research. You know, especially also related to
17 delivery.
18 So it really brings to mind for me in a lot
19 of the daily work that I do, but so many healthcare
20 entities partner with these community-based
21 organizations. So think local, regional economic,
22 you know, prosperity groups. You name it. Groups

1 that are faith-based, et cetera focused on care,
2 coordination, and services. But what's funny is you
3 hear about all these fantastic examples of pilot
4 work, you know, that involve community health
5 workers.
6 There's a collection of data points, et
7 cetera, but it brings to mind, to me, what's really
8 stopping more groups like these be it patient
9 groups, community health, community-based
10 organizations, or even, you know, community health
11 plans that I work very closely with. But really
12 deriving source funding from an organization like
13 PCORI. So I think this is a question for us to
14 potentially spend some more time pursuing.
15 So with that, in terms of what I reacted to
16 in terms of the information section, I agree fully
17 with, you know, building out a more robust
18 infrastructure focused on real world data and are
19 interoperable, readily accessible. I think that's
20 everybody's dream. Right? And where PCORnet could
21 be a leading example.
22 Again, what stood out to me and where I

1 think we can do some better emphasis is really on
2 this data linkages aspect. And it seems like we
3 probably have, globally, some opportunities there.
4 So when I was previously on the PCORnet
5 Working Group several months back, I found really
6 interesting that claims data fees, you know, for
7 potential joint analysis out of the nine clinical
8 research networks. There were really only just two
9 payers, so it was Anthem and Humana. And this was
10 just one of the things that stood out and I thought,
11 you know, access to the data infrastructure here
12 could potentially deepen and, you know, and when you
13 think about a lot of the commercial activities out
14 there, when you're speaking with healthcare
15 entities, you know, particularly community-based
16 health plans, anything that they're doing to support
17 a population health initiative, or working with a
18 vendor, being able to utilize those two data
19 sources: claims and EHR data, is in many ways table-
20 stakes. Right?
21 So I think here, could there be an
22 opportunity to deepen particularly like you know,

1 with a very, a major data source, like from CMS. We
2 get, you know, some of that claims data you know, in
3 a way that that could be integrated. Food for
4 thought.
5 And the last thing I want to comment on is
6 on policies and processes. And here PCORI offers
7 an opportunity to enhance sort of organizational
8 processes and programs to make, you know, itself
9 more available to all stakeholders. And so you
10 know, when I was preparing this, I kind of hesitated
11 whether I was going to share this example or not,
12 because it's really like an N of 1. So everybody's
13 got to take it with a grain of salt.
14 But truly last week I was on a call with a
15 former head of a nonprofit organization, that's
16 focused on advocacy in clinical area. And this
17 individual, when they were discussing their grant-
18 based portfolio and fully unprompted by me actually
19 said, "You know, even though PCORI reached out to
20 engage, found that the administrative requirements
21 potentially too burdensome for our small staff."
22 So I thought fascinating. Again, take it

1 with a grain of salt. It was N of 1, it was totally
2 random, but I thought, wow, what a fascinating
3 signal kind of out there.
4 And so, I think this opens up ways to think
5 about how we can engage new individuals, entities,
6 who really don't think of themselves as traditional
7 academic researchers. And I already recognize that
8 PCORI is exploring some new funding mechanisms,
9 which I think is really exciting. But I do think
10 having this called out in this priority could really
11 be a very promising channel.
12 With that, I'll pause and hand it over to
13 Eboni.
14 DR. PRICE-HAYWOOD: Thank you. [Laughing.]
15 Well, you stole my thunder and a lot of my points,
16 but that's okay because I'm going to pivot and come
17 up with a different angle on the spot. I want to
18 feed off of some of the things that you said. So in
19 several different ways on the people part, the
20 workforce, you had mentioned working with these
21 other community groups, right?
22 So in my notes, I said to myself, working

1 outside of your traditional academic institutions
2 and what can we do to build the infrastructure, to
3 support those communities who have knowledge, who
4 can come up with solutions, but to this last point
5 that you made, they may not have the resources or
6 the knowledge to adapt to the way things are
7 currently under PCORI’s structure for funding.
8 And then the question is, what skills do we
9 need to build in those community groups in order to
10 participate in PCOR? And then if that's the case,
11 have we actually defined what the core competencies
12 are for the conduct of this research?
13 So if I'm going to engage different groups,
14 academic/non-academic, researcher versus public
15 health versus some other sector. And the idea is
16 for them to come together and collaborate across
17 disciplines in a given study. Are they coming to
18 this collaboration with the requisite knowledge --
19 base knowledge, I would say besides their own
20 personal expertise? So how do we define that in
21 order to know how to develop that workforce inside
22 and outside of an academic center, health system,

1 and other settings? I think that's incredibly
2 important.
3 I think we also have to be mindful that in
4 how we incentivize participation or diversifying the
5 workforce, that we have to be careful to not
6 disincentivize the potential for research in those
7 non-academic settings. So yes, we have the, the
8 relationship with AHRQ. I wonder, are there other
9 agencies that we should connect with in different
10 sectors, kind of in the same relationship, but
11 recognizing the different contexts or, you know, the
12 perspective of those stakeholders in those different
13 agencies is something to consider.
14 In terms of real-world data and PCORnet,
15 again, I was also on the work group. And also as
16 you will most of, you know, a former site PI. So
17 the perspective or the lens through which I am
18 speaking is in that formal role and also as a health
19 system who struggled to participate, who sees value,
20 but then, you know, there are some gaps that need to
21 be filled.
22 So the very first conversation we had today

1 was around equity. One of the concerns that we have
2 to be careful about when you're using data for
3 secondary analysis is, is the sample representative?
4 And when you say representative, of who? Because if
5 we're going to use this data for some larger purpose
6 and it is connected to equity, and we want it to be
7 connected to equity, you have to be careful to make
8 sure what we're using allows us to do that.
9 You know, our methodology focuses on
10 heterogeneity of treatment effect. Well, you can't
11 do that analysis if you don't trust the data. If
12 you don't feel that it's representative of however
13 you define that. So that's something to be noted.
14 The issue of data linkage is again
15 important. And I agree with the Medicare claims
16 data. There are other types of data that are out
17 there that would be helpful to integrate if we could
18 figure out how. And I'm not always sure that some
19 of the different data sets that we've talked about
20 including state registries or patient -- like data
21 from wearable devices, how do you integrate that in
22 this kind of a network? By the way, the network is

1 limited to those participating institutions, right?
2 So it's not the whole country.
3 And so with that in mind, have to think
4 about are we missing social determines of health?
5 Is there a way for us to do something to integrate
6 that into that network? We know that the health
7 systems that are contributing the data are not all
8 collecting it the same way. So you're going to have
9 issues of data quality there. So we do need to
10 think forward about that.
11 That may be an opportunity for us to
12 develop patient registries, where people,
13 institutions who are participating may have a
14 separate initiative around getting patients who are
15 in those networks to participate in registries,
16 where you can prospectively collect whatever
17 information we need to link to EMR data that
18 otherwise is not systematically collected.
19 The other piece is the disseminating best
20 practices around research informatics, right?
21 Outside of those academic institutions. And if
22 we're going to build up this network, I would say,

1 think about it sort of like what the new generation
2 CTSAs. Where if you participate in these CTSAs,
3 there's an expectation that you contribute knowledge
4 around technology and some other veins. Can we
5 develop that? That's incredibly important for
6 reaching back to the health systems who are
7 contributing so that they can shore up what they
8 contribute so that your data is an accurate valid
9 data set. And I think we went through some concerns
10 or questions about variability across the different
11 systems.
12 The last piece in terms of inclusivity, I
13 think ties into the other two, but I want to comment
14 specifically on a statement around funding, the
15 science, and engagement and the need for evidence-
16 based models for patient and community-driven
17 research. That provoked in my mind, you know, we've
18 had these engagement awards. What have we learned
19 from past funded studies? What works for whom under
20 which circumstances? And have we ever compared
21 engagement methods?
22 Right? You can start there with what we

1 have. But we also have to think about how to
2 develop sustainable research infrastructures outside
3 of academic institutions. And so really thinking
4 about those other sectors, the health systems,
5 payers, industry, public health, social service
6 agencies, whoever the case may be -- some community
7 organization.
8 How are you going to strengthen them to be
9 able to sustain the work, if we just said that the
10 source of truth and source of solutions comes from
11 those groups. You know, so all of this people,
12 data, policies and procedures around accessing the
13 infrastructure, all of that is incredibly important.
14 But there are tons of opportunities that we can
15 explore in order to do those, I think, in the best
16 way.
17 MS. ARMBRUSTER: Thank you both for those
18 thoughtful reflections on infrastructure and what we
19 can do to support infrastructure for patient-
20 centered outcomes. We're going to shift our
21 attention from what's exciting about this to what
22 you think success or progress might look like and

1 how might we influence that national research agenda
2 as a starting point. And I want to go in reverse
3 order on this. So Eboni, you get to speak first, no
4 thunder stealing.
5 So I'm curious about, I mean, you even just
6 your first -- one of your questions that you asked
7 about what engagement methods work. I'm excited
8 about thinking about those kinds of metrics. So
9 what, what were you thinking about progress and what
10 success might look like?
11 DR. PRICE-HAYWOOD: Honestly, I hadn't
12 thought about performance metrics. I actually
13 thought about what would be the next steps to answer
14 some of the questions I just had.
15 MS. ARMBRUSTER: Yes.
16 DR. PRICE-HAYWOOD: So starting backwards
17 with engagement strategies. And, you know, I asked
18 myself, do we know the secret sauce? What's the
19 formula? How do I replicate this in other places?
20 Well, first maybe go back and look at the
21 information that we have from prior awardees. And
22 we may need to generate an evidence-based report

1 from that past studies and to figure out where's the
2 knowledge gap, because we can't inform future
3 research or anything else that we do if we don't
4 pause and look back first. And so to me, generating
5 something like that, if it doesn't already exist is
6 incredibly important, but I think out of that work,
7 you can develop as an agency, a toolkit or some sort
8 of guide for different forms of engagement targeting
9 specific stakeholders.
10 Doing so may then generate those research
11 questions that we need to do some sort of
12 comparative effectiveness around engagement
13 strategies, and you know, all that goes into that.
14 So that was one initial thought.
15 The other thing is, you know, for PCORnet,
16 I'll probably go back the same thing I said before,
17 which is around setting the standards for how we're
18 going to define representativeness of a data set.
19 And that's important because if you're going to use
20 that, how are we going to have external
21 generalizability of studies if the baseline data is
22 not representative?

1 The other thing in terms of informatics
2 that we have to be mindful of is a systematic
3 introduction of bias into analytics because of your
4 baseline dataset. So I wouldn't think about
5 anything else until you first set a standard of what
6 you mean by representative. And then you can get
7 into data linkages and all the rest of that stuff.
8 And then finally, as far as the workforce
9 is concerned, If we're going to develop things like
10 the equivalent of a career development or a training
11 award. And again, not thinking about that academic
12 traditional pathway. Can you establish stakeholder
13 tracks in this training? Right? Whatever the, you
14 know, there are some core competencies that we're
15 going to teach you, but from this perspective of
16 this stakeholder, this is an asset or skill that you
17 bring to the mix and we're going to, you know, have
18 some sort of development around that.
19 Now where that training sits, I don't have
20 all the answers to that. But I just want us to be
21 mindful of the end product of workforce development,
22 is that we are looking at different types of people

1 and we are developing these tracks in PCOR for
2 different types of stakeholders and doing things in
3 such a way that we're optimizing their contribution
4 to the research, as well as leaving them with a
5 larger capacity of skills in this particular area.
6 So some of those barriers that Connie had
7 mentioned before, part of the process would be to
8 not only just change our policies about how we do
9 things, but give people the extra skills sets to
10 diversify the resources that they could tap into
11 because you've increased their knowledge-based
12 skills and everything else that goes along with
13 doing any type of research.
14 MS. ARMBRUSTER: Thank you Eboni. So many
15 new directions to think about what progress looks
16 like. And I appreciate your, your considerable
17 thought about that.
18 Connie, it's your turn.
19 DR. HWANG: Yeah, well, it's always great
20 following Eboni because I would say, "Yeah, that
21 too." Right?
22 So I did very much like Eboni, what you

1 mentioned about taking stock in many ways of our
2 engagement awards so far to really say, "Hey, what
3 kind of interesting, you know, knowledge have we
4 generated best practices this way and where it leads
5 us better to understand what kind of potential gaps
6 we would want to set our sights on. I think that
7 makes great sense.
8 And very much resonated with that whole
9 workforce development and really trying to approach
10 it from a non-traditional academic perspective but
11 through development throughout with these different
12 stakeholders, and how would that sort of look. I
13 think a fantastic suggestions and questions.
14 You know, again, what I'm most excited
15 about for this, and when we think about just overall
16 progress is, you know, what kinds of new entities,
17 new individuals can we engage with at PCORI? Right?
18 And so, maybe some of the metrics that I'm sure will
19 require lots of brain cycles on, but just, you know,
20 understanding like what new organizations have we
21 brought into fold? Which geographies do they
22 represent? What kind of patient population, you

1 know, are the areas there.
2 And then ultimately it’s a harder one to
3 answer, but what kind of new questions are we
4 surfacing? Right? And that really represent some
5 unique perspective that, you know, really needs some
6 visibility and really has an opportunity to improve
7 health.
8 I would be really fascinated by ways to
9 track and think about that.
10 And ultimately the end, I mean, through all
11 of this and if we sort of step much further back.
12 What outcomes are we interested in, in engaging all
13 these other diverse stakeholders in groups, is
14 really has the health of your community improved?
15 Right? Can we link in many ways, some of this work
16 to actual shifts in outcomes and I think , again,
17 worthy of some time and thought.
18 One other thing that was in this prompt, it
19 was -- or earlier on, you know, what are you excited
20 about? What are you concerned about? So lots to be
21 excited about and I would caveat, I wouldn't say I
22 was concerned, but it would be one of these things

1 that if PCORI is truly to pursue this and execute on
2 it. There really has to be a willingness for this
3 to be really bidirectional and willing to change.
4 So this is not so much about PCORI has a
5 great idea, I'm going to go out to these small
6 groups and tell them why it's such a great idea.
7 And this is how you can engage. Really, I think to
8 take this on I think it would be best positioned for
9 PCORI were willing to be extremely flexible with a
10 lot of the new potential stakeholders groups coming
11 in.
12 So that's more of a, just a mental note,
13 right? In terms of ways to go about this. Again,
14 lots to be excited about, but I think important to
15 also recognize that in order for this to be
16 successful, probably a lot of change may need to
17 happen.
18 MS. ARMBRUSTER: Thank you Connie for that
19 challenge. And a reminder, this was discussing what
20 our concerns were was a piece that the Strategic
21 Planning Committee really wanted the full Board to
22 have an opportunity to discuss. And thinking about

1 if we're going to bring in new partners, how do we
2 create bidirectional conversations, I think is a
3 cross-cutting theme that I'm hearing across several
4 of these priorities.
5 Thank you both for your thoughtful
6 analysis. I want to bring back the rest of the
7 Board. We have about 20 minutes, 15 to 20 minutes
8 to continue to discuss this national priority
9 related to Enhancing Infrastructure to Accelerate
10 Patient-Centered Outcomes Research. And I want to
11 invite everyone back and again, invite you to use
12 the chat and/or wave, and we will get a queue of
13 speakers going, but we have much to discuss.
14 I'm interested in what excites and concerns
15 you. I'm interested in where else you’re seeing
16 cross-cutting themes and launch points for research.
17 So after listening to the, to the prepared
18 thoughts what are some initial reflections from the
19 Board? Who'd like to go first?
20 All right, Alicia. Thank you.
21 DR. FERNANDEZ: I'll just make a simple
22 comment, which is that to really underscore what

1 Eboni said about representative, I am not excited
2 about investing in infrastructure that is not
3 representative and does not allow us to align with
4 the work. I think it leads to bad science, which is
5 as Eboni pointed out. And for me, that is -- that's
6 really going to be a lot of what is shaping my views
7 on all of this moving forward.
8 With that said, I do think that if we are
9 able to make PCORnet and other investments more
10 representative to continue to fill, just as has been
11 said that there's a lot of exciting work that could
12 be done. So it's sort of like if we can get past
13 that hurdle, I think it's extraordinarily valuable.
14 MS. ARMBRUSTER: Thank you, Alicia. I'm
15 looking in that chat for requests to speak and also
16 on camera, you can just unmute and wave. Yes,
17 David.
18 DR. MEYERS: So really exciting again, I
19 thought the panelists had brilliant comments. I
20 want to encourage PCORI -- this time, I don't have
21 to speak as much from AHRQ, who're in the workforce,
22 at least the academic workforce. We're a good

1 partner for you, but needs the plan as it moves
2 forward really needs, and so this is my concern,
3 specificity about NIH is spending a lot of
4 investments, CDC is spending a lot of investment,
5 and HHS through the PCOR trust fund gets a small
6 investment every year with almost the exact words of
7 this description.
8 And so, we've got to be very, very clear
9 in what's our lane, even more so than in the others.
10 How are we going to invest in moving forward the
11 infrastructure for research? I think the panelists
12 did a really great job of focusing on the areas that
13 HHS would be less likely to focus on, the non-
14 traditional partners and how to bring them into it.
15 But we're in jeopardy of investing in
16 PCORnet, when NIH is building a very similar kind of
17 EHR distributed network, where CDC is revamping the
18 public health workforce with close to $900 million.
19 We want to really be able to show clearly what's our
20 space and then set our measurement in that and show
21 how we're not competing.
22 MS. ARMBRUSTER: Thank you, David. I hear

1 it clarity about the PCORI's lane as it relates to
2 other partners in this work.
3 Danny, James, and Chris. Danny.
4 MR. VAN LEEUWEN: So I'm curious about what
5 -- wait a minute, my brain just froze. Hang on.
6 What is unreal-world data? That I'm just
7 curious about calling something real-world data now
8 in my world. I would say that EMR and claims data
9 would be called unreal-world data. But it's
10 included here under real-world data. So I wonder
11 what isn't included.
12 Now in a similar thread, I think one of the
13 things that we can do, especially with PCORnet is be
14 thinking about what I might call real world data and
15 including that in our basic set of data, like all
16 the work that's happening right now with MedMorph
17 incorporating the public health data set that
18 there's lots of people working on that. And I'll
19 bet they'd love an opportunity to bridge into the
20 PCORnet common dataset.
21 MS. ARMBRUSTER: Thank you. Before we move
22 on, is there someone who could answer Danny's

1 question about what we mean when we say real-world
2 data?
3 MR. VAN LEEUWEN: No, there's no, there's a
4 good definition of real-world data. I don't know
5 what unreal-world data is. Like, what isn't? It
6 seems like it's everything.
7 MS. ARMBRUSTER: I think it’s a useful
8 distinction.
9 MR. VAN LEEUWEN: Yeah. So I'd like to
10 know what's not included, like what's unreal-world.
11 DR. MEYERS: So Danny, this is David. I'm
12 not sure this is an answer, but I think it may be
13 that when we do clinical trials where everything is
14 standardized and people are getting incredible
15 supports, and then you find the data that, you know,
16 what happened to their blood pressure or what
17 happened to their quality of life and then say,
18 therefore, this thing is effective.
19 It was done in an unreal-world environment,
20 as opposed to how does that medication, how does
21 that intervention affect people or help people
22 thrive in a real-world situation?

1 So it's removing, it's trying to understand
2 what happens when you don't have the incredible
3 infrastructure that research sometimes brings. I
4 think one of our great successes recently is the
5 COVID vaccines and everybody knew how effective the
6 COVID vaccine was in its trial. And we were all
7 really, really anxious to see what would happen when
8 it wasn't in the trial. And the good news is it
9 looks like it has similar efficacy and effect and
10 therefore effectiveness.
11 Does that help and do others agree? Is
12 that what we're talking about?
13 MS. ARMBRUSTER: Thank you. That was --
14 lots of head nods there. So we're going to accept
15 that as the distinction and we really appreciate you
16 taking that moment.
17 I see a question in the chat and I'm going
18 to come back to that, but I want to give the
19 opportunity for those who want it to reflect first.
20 So I'm going to move to James and then Christopher.
21 DR. SCHUSTER: Thank you. And I had to
22 switch devices. I missed a little bit of the

1 discussion. So if somebody said this, please
2 forgive me.
3 But I wanted to come back to the comment
4 Connie made about her conversation with the small
5 not-for-profit and the fact that they felt that
6 participating in standardized research was beyond
7 the capacity of the organization. And I have to say
8 that that's even true for relatively large
9 organizations that have not -- are not affiliated
10 with or tied in with a traditional academic setting.
11 There are many health payers, there are
12 many large not-for-profit systems that really see
13 participation in research as something they're not
14 familiar with and probably anxiety provoking or of
15 little interest for other reasons.
16 So I think, I think this is a great
17 priority, but I think one of the strategies for us,
18 and this is not really a research strategy, but more
19 of a process strategy for us to think about is, are
20 there things that we can do to provide some kind of
21 joint infrastructure that we might maintain in some
22 way or otherwise provide some support or engagement

1 strategies for these organizations who aren't going
2 to participate in research. At least that's been
3 our experience up until now. Thanks.
4 MS. ARMBRUSTER: Thank you. Christopher.
5 DR. FRIESE: Sure. Thanks. Thank you all.
6 I'll try to be brief.
7 I think the Board is pretty aware of my
8 prior viewpoints on PCORnet past, present and
9 future. I won't reiterate those here. Just to the
10 current discussion as we do strategic planning, I
11 want to underscore Dr. Price-Haywood and Dr.
12 Fernandez’s really important point on inclusion and
13 representativeness because if we're not meeting
14 that, I have even more concern.
15 But I want to think about it from the input
16 perspective, but also from the output perspective.
17 And I think one of the concerns I've had about
18 PCORnet is the accessibility of that asset that is
19 publicly funded, it is funded through us, and making
20 sure that that asset is as accessible as possible
21 that aligns with our strategic objective. I think
22 in some ways it is used by a certain group of folks

1 disproportionately and not either accessible or
2 available or realized as an asset to other groups
3 that would benefit from it.
4 So I think that needs to be part of the
5 planning as we think about who is part of the
6 network, is also who is using the network, and is
7 the use of the network equitable and reasonable, and
8 are we answering the right kinds of questions?
9 And it goes a little bit to what Dr. Meyers
10 was saying. You know, what's our lane in this new
11 environment? And I see Dr. Fernandez's point about
12 that, too. I mean, we want to be really clear,
13 particularly in this more-crowded space than it was
14 five or six years ago.
15 What are we adding? And are we meeting the
16 needs? Are we able to use the asset appropriately?
17 Thanks.
18 MS. ARMBRUSTER: Thank you. And that tees
19 up a question that was raised related to a comment
20 that David had made about NIH, having something
21 similar to PCORnet, and maybe someone could
22 elaborate on that? And perhaps Michael has the

1 answer to that. Can you speak to that?
2 DR. LAUER: Yeah, I'm sorry. You know, I
3 was hitting, I thought I had answered it in the chat
4 box, but I see, I only sent this to the organizers
5 and not to everybody else. But the bottom line is
6 there is a specific project that we presented to our
7 ACD on May the 6th. This is a special allocation
8 that has been given to us by Congress to use to
9 develop AI or machine learning methodologies.
10 And so, what we're going to be doing is --
11 we're going to, it's $50 million, and we're going to
12 be using this for figuring out ways to apply AIML to
13 electronic health record data. and it could be used
14 to conduct research on health disparities, mitigate
15 biases, evaluate various factors on health, ways to
16 measure health disparities and inequities. In any
17 case, this has very little to do with what PCORnet
18 does.
19 So as mentioned earlier, PCORnet has made
20 it possible to do a trial like ADAPTABLE, just
21 absolutely amazing, you know, 15,000 patient,
22 practical trial. The kind of trial that we usually

1 think of as something that can't be done in the
2 United States, but can only be done elsewhere. And
3 that's because of the infrastructure that
4 established the common data elements and so forth.
5 So anyway, what's being done here is very different.
6 Yes. So you're absolutely right. That it
7 can be done with PCORnet and yeah. We sure hope so.
8 And there is another project called N3C,
9 which is a COVID data project and PCORnet is
10 actually part of that. PCORnet is a critical
11 component.
12 MS. ARMBRUSTER: These questions and ideas
13 are critical to the strategic planning process,
14 which this identifying and better understanding
15 these national priorities is core to and our purpose
16 for today was to solicit the insights and wisdom of
17 the Board, and this conversation is really rich. So
18 thank you for those insights and expertise that
19 you're all bringing.
20 We have just a few more moments with this
21 particular issue related to Enhancing Infrastructure
22 to Accelerate Patient-Centered Outcomes Research.

1 Are there additional comments anyone would like to
2 make?
3 MR. VAN LEEUWEN: I have another question.
4 Are study participants considered workforce?
5 MS. ARMBRUSTER: Several nods to the no.
6 DR. CARINO: I would think, I would say
7 that they should be because you want them to be
8 continuous participants in research. Wouldn’t we
9 want to cultivate, we used to call it a citizenship
10 in research. So why wouldn't we treat them like any
11 other stakeholder?
12 We don't have to answer that now.
13 MS. ARMBRUSTER: I think this is an
14 interesting idea that is related to the cross-
15 cutting theme that I'm hearing around work in this
16 national priority and in all of those that you've
17 mentioned involves working with new and different
18 partners, which also may involve working with
19 different disciplines and different kinds of
20 workforce.
21 So the continued conversation about how we
22 engage new and different partners as part of the

1 infrastructure of this work looks like an apt area
2 for exploration.
3 DR. AYERS: I would also add -- this is
4 Kara, that considering them -- I mean, I don't know
5 if we need to consider them as workforce, but just
6 trying to dismantle that idea of us and them in
7 recognizing that we're all patients, and I'm not so
8 much thinking of our individual status as patients.
9 Although, you know, we are at some point, but just
10 that all of us traverse both of those worlds. And
11 so, trying to yeah -- bring down that us and them is
12 helpful.
13 DR. CARINO: Yeah.
14 MS. ARMBRUSTER: Thank you. Thank you,
15 Kara. And Steve has a comment.
16 DR. GOODMAN: Yes, I was -- I had to be
17 gone for about 15 minutes, so I apologize if this
18 was already made, but you know, we've been talking
19 about the difficulties of maintaining health. But,
20 of course, the best way to do that is through
21 prevention.
22 Most huge advances in health are through

1 public health measures, not through the therapeutic
2 sick care system. So I just wonder if anybody's
3 talked about these partners being public health
4 systems who worked so hard, and yet is seemingly
5 completely divorced from the healthcare system. And
6 we've seen that -- this loom incredibly large in the
7 COVID response where we get these robust and
8 dramatic responses from healthcare systems where the
9 public health systems are grotesquely underfunded
10 and understaffed.
11 And they're looking at many of the very
12 same factors that we have been talking about today
13 and operating in settings where they're trying to
14 maintain health and not just take care of those who
15 are already sick.
16 Has that been already broached? No.
17 So I think we should think of in terms of
18 our partners. We might want to extend to our public
19 health partners who often work in care settings and
20 they left for public health because they felt that
21 they weren't making enough impact on health. And
22 they're very, very embedded in communities. Exactly

1 what we have talked about wanting to be, and they
2 are embedded in ways that can dramatically extend
3 our impact.
4 So, and they need our help. So we'd have
5 to think creatively how to do that. Most research
6 funders don't partner with them because they can
7 barely do research because they’re so understaffed.
8 But again, COVID offers a really interesting model
9 and perhaps we could extend that to other
10 conditions.
11 MS. ARMBRUSTER: Thank you. I think that
12 reinforces a comment that was made during another
13 priority session and also some comments from Dr.
14 Hwang. So yes, absolutely, public health engagement
15 I hear as being an important opportunity as we think
16 about infrastructure.
17 Okay. So many more conversations that are
18 valuable if we had more time, but we are back at a
19 time boundary, please keep thinking about this so we
20 can have a conversation tomorrow about those
21 intersections of all of these national priorities
22 and your final takeaways.

1 So we have one more priority to go.
2 Christine, I pass it back to you.
3 CHAIRPERSON GOERTZ: Thank you Sonja. Once
4 again, a very rich discussion. We have a five-
5 minute break. So please come back at 3:40 Eastern
6 time for our last discussion of the day.
7 [Recess.]
8 CHAIRPERSON GOERTZ: All right, Sonja, I'm
9 going to turn it back over to you then for our last
10 discussion of the day on national priorities.
11 MS. ARMBRUSTER: Excellent. Well, welcome
12 back everyone. I'm so pleased you are; this is the
13 last of five. Let's just enjoy and appreciate.
14 There's been so much work done and hold fast to
15 purpose as we continue our conversation now.
16 We are going to end our day with a robust
17 discussion of Advancing a Learning Health System and
18 to help us begin with some background, Steven
19 Clauser, who is the Program Director of the
20 Healthcare Delivery and Disparities Research Program
21 at PCORI will provide some background information.
22 DR. CLAUSER: Okay. Thank you so much,

1 Sonja.
2 Okay. This is the last one for the day.
3 And what we're going to discuss is the priority
4 Advancing a Learning Healthcare System. Now this
5 direct national priority really reflects feedback
6 from stakeholders that, you know, high performance,
7 healthcare systems both today and in the future are
8 going to be those that use data and evidence to
9 continually evaluate their organization,
10 environment, and customers to continually improve
11 their performance on behalf of the individuals and
12 communities they serve.
13 And from a patient-centered perspective,
14 this really means striving to build systems of care
15 that are designed and a little more weighted towards
16 the needs and preferences of individuals and
17 communities rather than weighted more towards the
18 needs and preferences of health systems. So new
19 approaches to engagement in evidence generation will
20 be required to address the barriers and some of the
21 practical challenges in organizing, delivering
22 clinical care to advance this goal. Next slide.

1 Now this threat priority really extends the
2 existing improving healthcare systems priority to
3 support generating evidence that hopefully results
4 in less fragmented care oriented around outcomes,
5 preferred by individuals, including their care
6 experiences. Areas of potential exploration can
7 include promoting cross-sector partnerships among
8 public health, community-based, and other systems of
9 care to advance knowledge about how to address
10 population health from a more whole-person
11 framework. And this is throughout the care
12 continuum.
13 To improve our understanding of approaches
14 to information sharing and exchange, to reduce the
15 gap between knowledge generation and improved
16 outcomes by decreasing barriers to care and
17 advancing health equity for all Americans. And
18 research to compare policies, care delivery
19 practices, and payment models to improve patient-
20 centered outcomes, including the patient experience.
21 And finally, initiatives create a culture
22 of integrating research into practice through new

1 methods and strategies for conducting research and
2 feeding this information into successful health
3 system implementation.
4 That's all I've got Sonja. So I'll return
5 it back to you for discussion.
6 MS. ARMBRUSTER: Thank you, Steve, for
7 giving us that foundation and to help us further
8 consider advancing a learning health system.
9 We will now hear from PCORI Board members
10 Tanisha Carino and is Sharon Levine with us?
11 DR. LEVINE: Yes, I am.
12 MS. ARMBRUSTER: All right. I can't see
13 you, so great -- thank you. All right.
14 So welcome back. thank you both for taking
15 the time to provide some background and additional
16 thoughts about this today. We're going to begin
17 with Tanisha and you know, the questions; what
18 excites you and concerns you about PCORI's role and
19 our opportunities to advance change in this area?
20 DR. CARINO: Thanks Sonja. And I’ve been
21 intentionally pretty quiet throughout the previous
22 discussions because I actually view this session and

1 this priority almost as a capstone to all of the
2 things that we've talked about as a Board today.
3 So I loved in the pre-read that we've
4 acknowledged that for the last couple of decades,
5 we've been talking about a learning healthcare
6 system, much work has been done by the National
7 Academy of Medicine to prepare for this session. I
8 went back to look at where are the frameworks at
9 this moment for what constitutes a learning
10 healthcare system and what are the factors for
11 success?
12 So I found a very interesting paper that
13 tried to synthesize what the body of literature was
14 around learning healthcare systems that was
15 published in 2019. And what I really liked about it
16 is, they divided it into three sections: frameworks
17 around what the outcomes of a learning healthcare
18 system are, what the processes are and what the
19 pillars are a foundation for a learning healthcare
20 system.
21 So I'll start there. You know, when I
22 think about a learning healthcare system, it's a

1 system because there are actors within the system
2 that share goals and I think the goal that's been
3 stated today in terms of the learning health care
4 system that I loved in the pre-read was the idea of
5 not retrofitting the system to the individual. But
6 in addition to individual goals, we have to consider
7 population, community-based goals, the provider
8 experience, and we have to consider what's of value
9 and acknowledge that healthcare costs are part of
10 that equation. Particularly here in the U.S., where
11 we're constantly having to balance the public health
12 needs with affordability for how we're going to
13 achieve that.
14 The second area around processes we've
15 talked about today, whether it's knowledge
16 management, whether it's change management,
17 implementation science, data management, and the
18 role of infrastructure. But one of the things that
19 I'll say is all three of these processes for me, are
20 really important to get right in the local level.
21 What the COVID-19 experience for me has resonated is
22 that we can have scientific research, but at the end

1 of the day, there's a difference between vaccines
2 and vaccinations. And in order to fully achieve the
3 promise of any new innovation, you have to get very
4 local. And to get really local, it means that we
5 have to think about creating capabilities in a way
6 that are both enduring and sustainable and flexible
7 because not every community is the same.
8 And I always think about like the idea of
9 the diversity of communities, especially when Eboni
10 talks to us about the experience of PCORnet. So
11 with that, I will say that there are on the
12 foundations of what creates a learning health care
13 system, whether it's legal frameworks, whether it's
14 scientific knowledge, policy, all of these factors
15 to me are areas that PCORI has a really
16 distinguishing role in what we've already invested
17 in how to drive those forward.
18 So there's a couple of things that stand
19 out to me. We've talked about the role of PCORnet.
20 I also was on the PCORnet Working Group and what
21 excited me about that was the array of different
22 kinds of communities that had come together to

1 design PCORnet. But also the opportunity that still
2 existed to actually align what we're learning in
3 clinical research, clinical practice in those same
4 exact geographic sites.
5 So how do we break down those walls between
6 leaders of research and leaders of practice? And
7 that's a lot of how do we think about stakeholder
8 engagement? And when you think about a learning
9 healthcare system, it goes beyond the walls of
10 research, and in fact, it goes beyond the walls of
11 the healthcare system itself.
12 So for me, like the opportunities are
13 continuing to build on data needs, how we think
14 about stakeholder engagement, how we think about
15 capabilities building. But the real heart of it and
16 I think this has been said multiple times is who and
17 what is the role of culture change of creating
18 champions that are long-term champions? You know,
19 I've done work on vaccine hesitancy. And what you
20 find is that people who are -- the way to change and
21 address vaccine hesitancy tends to be with
22 cultivating the same champions that they turn to for

1 information about diabetes, information on prenatal
2 screening. In communities these tend to be the same
3 voices of trust that the other members of the
4 community listened to.
5 So that's what I would emphasize this idea
6 of enduring sustainable investments and that really
7 does raise questions. I think Ellen raised it
8 earlier about how do we maintain flexibility? How
9 do we create a process and an approach for PCORI
10 that is accessible?
11 How do we make big bets? Possibly big bets
12 in fewer places so that we actually can get deeper
13 and see what it is that works, and then be an agent
14 for disseminating information through a lot of
15 different kinds of partnerships, whether they're
16 with an AHRQ who's already created learning
17 healthcare systems network, or through HRSA that's
18 already got the FQHCs, or through CMMI that would
19 provide the same kind -- some kinds of policy
20 flexibilities in terms of implementation.
21 So I'll pause there and let Sharon go next.
22 MS. ARMBRUSTER: Thank you very much.

1 Exciting ideas and what an incredible ability to
2 recap and listen to your colleagues throughout the
3 day. So thank you, Tanisha. Sharon, thank you for
4 taking your time to share your initial thoughts
5 about our opportunities and what excites and
6 concerns you about this priority.
7 DR. LEVINE: So let's start off by saying
8 that like Tanisha, to me, this priority is --
9 Tanisha, you called it a capstone. For me, it's
10 where all of the others come together and we can't
11 achieve a learning health system without
12 accomplishments and progress at each of the core
13 elements that are part of the other priorities.
14 And I think actually I took somewhat of a
15 contrarian view. The title of the priority I took
16 literally, which is a advancing or I wouldn't say
17 achieving a learning health system, not a learning
18 healthcare system and I think those things are
19 different. And I think where we need to start with
20 this first opportunity would be to create a
21 definition of a learning health system that is
22 bigger than, and broader than, and more expansive

1 than a learning healthcare system.
2 I think Danny said earlier something about
3 learning happens in many places where it's
4 challenging to capture the learnings and I thought
5 Steve's comments about public health, community
6 health sectors that have a huge impact on health,
7 but are not part of the healthcare system. So when
8 we think of a learning health system, to me, it's
9 creating a mindset and an environment where we look
10 beyond the health care system and create
11 opportunities for access to and contribution to this
12 work from non-traditional partners. And I think
13 that theme has been replicated throughout the
14 conversation today.
15 Initially, I was kind of intrigued by the
16 National Academy of Medicine definition as a
17 starting point. And yet, there's a lot that's
18 missing from that definition in terms of
19 stakeholders, in terms of other influences, in terms
20 of what are the things that contribute to health.
21 And so, I think that first opportunity it excites
22 me. Actually, it’s creating a meaningful definition

1 would be resonant around what a learning health
2 system is.
3 And in some ways, what excites me about
4 this is also what I think scares me about this
5 priority. If it is, in fact, the place where the
6 other priorities come together, if it is the
7 capstone of the other work, then for it to have a
8 legitimate place as the fifth priority there needs
9 to be a unique contribution that we can make in this
10 arena that leads to a meaningful research agenda and
11 meaningful value contributed by the research in this
12 arena towards a system of health. And I think
13 that's going to be a bit of a challenge to figure
14 out because it will require some creative thinking
15 about. So what is unique about this notion of a
16 health system and PCORI's ability, unique ability,
17 as a funder and as a convener to contribute to the
18 work in understanding what it will take and in
19 enabling us to make progress toward that goal.
20 Talk about a goal that is aspirational,
21 this is one.
22 And the other opportunity or the other

1 challenge for us is to figure out if we're talking
2 about a learning health system that is something
3 that encompasses all of the places and venues and
4 things that people do that lead to health or are we
5 talking about learning health systems?
6 So advancing learning health systems that
7 is place-based interventions, that fund and organize
8 multi-sector collaborations. Around improving
9 health in communities. Are we looking at multiple
10 or do we see this as somehow leading to a national
11 collaborative? Where in, you know, eventually in
12 the long-term we actually can speak to, we have a
13 national learning health system. I could talk about
14 aspirational, that certainly is far off in the
15 distance.
16 And again, like in many of the other -- in
17 many of the other, perhaps all of the other
18 priorities, how do we measure progress towards a
19 learning health system? I think one way would be to
20 measure PCORI's capacity to fund research that is
21 non-traditional in terms of stimulating and
22 incentivizing collaborations that look at health in

1 a broader perspective, and that produce results that
2 I think as Barbara said before, that people care
3 about, that communities care about producing
4 information that is of value to people who are
5 invested in improving the health within their own
6 communities. That's certainly one measure.
7 And I think I will stop there.
8 MS. ARMBRUSTER: Thank you, Sharon. So
9 much there, she addressed a couple of ideas about
10 progress. Tanisha, did you have some ideas about
11 what progress might look like?
12 DR. CARINO: Yeah, I want to build on what
13 Sharon's saying. I think a lot of, and again like
14 this may not be in PCORI's sweet spot, but I do
15 think that with partnership, we can get a total
16 picture that could support enabling these types of
17 systems at the community level to really evolve and
18 mature and flourish.
19 But I would say that most funders want to
20 fund research or they want to fund a study. I mean,
21 and that's really key to who we are, but we're also
22 an organization who is distinctive in stakeholder

1 engagement and capabilities building. And maybe
2 that's, you know, back to some of the comments that
3 have been made, what is distinguishing of PCORI?
4 Because there's a lot of research being
5 funded in local communities and academic centers,
6 right? Look at the city of Boston, how much
7 research is getting funded? Tons of research. But
8 what people don't -- fail to realize is if you're
9 going to do culture change, like the stakeholder
10 engagement and the repeated communication and
11 bringing people together, that's a lot of work that
12 takes a lot of time and is very much something that
13 most funders don't acknowledge actually takes
14 support.
15 So, you know, I know Ellen's on the phone
16 today and, you know, forensic cancer research is
17 such a great example of like bringing people
18 together and that being such a critical part of what
19 success looks like for the community-based outcomes
20 that we want. And so, I would really encourage us
21 to think about the engagement awards being a
22 critical part of how to support and enable the kind

1 of convening and the kind of work that needs to be
2 done to get to that learning healthcare system.
3 MS. ARMBRUSTER: Okay. Thank you Tanisha
4 and thank you, Sharon, both, for providing this
5 foundation and some grist for the mill for
6 discussion among the full Board. And I invite
7 everyone back for your last time to have a
8 conversation about this specific priority, Advancing
9 a Learning Health System.
10 You're welcome to turn on your cameras and
11 you're welcome to indicate your interest in speaking
12 next in the queue as we begin thinking about what
13 are concerns and opportunities related to this a
14 national priority, what's exciting to you, and what
15 you see as progress. Personally, I'm taking away
16 some ideas thinking about, you know, all politics is
17 local and all advanced research is also local
18 thinking about this work with communities, and at
19 the same time, having a healthcare system -- having
20 a learning health system is that one or many
21 systems. You know, these are all rich discussion
22 questions that have been challenges from Tanisha and

1 Sharon for the full group.
2 So with that, I want to turn to your
3 initial comments. You can indicate your interest in
4 the chat or you can wave and I'll call on you as we
5 get started thinking about what excites and concerns
6 you about advancing a learning health system.
7 Thank you, Christine.
8 CHAIRPERSON GOERTZ: I actually think we
9 need to spend a little bit of time talking about
10 trying to answer Sharon's questions about, you know,
11 how do we define, you know, a learning health
12 system? Is this a learning health system or a
13 learning health healthcare system, and you know,
14 what does, what does that mean for how we, you know,
15 what the scope of the work that we're describing
16 here?
17 MS. ARMBRUSTER: That makes good sense to
18 me. And it sounds like that is work that needs to
19 happen as part of the defining and setting the
20 research agenda, more continuing to define what a
21 learning health system is.
22 Tanisha, you were talking about an article

1 that you referenced from the beginning. Is that
2 something you want to share about?
3 DR. CARINO: Yeah, I'm happy to circulate
4 it, post the Board meeting. But one of the things I
5 think most people think about -- what we've seen in
6 the discussion on learning a healthcare system is
7 tailor it in the way that it's been defined. And
8 James, correct me if I'm wrong. Is tailoring the
9 system to the needs of the individual.
10 And it's more on the health care delivery
11 side is how I read it. But one of the -- you know,
12 I would challenge us to think about sort of PCORI’s
13 role in actually creating and engaging people in
14 research as being part of that. You know, the idea
15 that we go, you know, particularly in the world of -
16 - for us in rare disease, you know, they're trying
17 to find physicians, it takes seven years to get
18 diagnosed. Like there may not be a treatment and
19 they want, you know, patients want to be part of the
20 research process at that point. And those two
21 worlds should come together more efficiently in
22 something like a learning healthcare system. So how

1 does that happen?
2 So I would push us beyond thinking about
3 learning healthcare system as just a part of
4 delivery, but really part of building sort of our
5 muscle as a country around research.
6 Which is why for me like PCORnet is such a
7 great chassis for building on the success to-date
8 for how do we begin to change culture, begin to
9 achieve some of these broader health system goals.
10 And it may be a ten-year plan, not a two-year plan,
11 but when I look at where there's been investment by
12 PCORI, that feels to me like the best foundation to
13 achieve the goals as stated.
14 MS. ARMBRUSTER: Thank you to Tanisha. I'm
15 looking for gestures for who wants to weigh-in.
16 Danny? Go ahead.
17 MR. VAN LEEUWEN: Well, Nakela, this is
18 blowing my mind and I know I'm not supposed to think
19 about operations, but I think that it, I just can't
20 imagine what you and your staff are going to do with
21 this. And I think that as leaders, we need to think
22 about what P PCORI is going to stop doing. Because

1 we cannot just all this stuff we're talking about,
2 layering it on. I mean, I don't know Nakela -- it
3 just seems like, I'm glad I don't have your job.
4 I mean, we need to, I mean, some of this,
5 maybe it's tomorrow, we need to think about if we're
6 going to shift stuff has to come off the table.
7 Because we just can't layer it on.
8 MS. ARMBRUSTER: Thank you. The process of
9 strategic planning is about thinking about what we
10 are going to continue doing, what we are going to
11 stop doing, and also how we're reframing the work
12 that we're doing.
13 Nakela. It looked like you wanted to
14 weigh-in there.
15 DR. COOK: I did it. And I just wanted to
16 emphasize one of the things that's been really
17 helpful during some of these dialogues too, was in
18 terms of thinking about the areas that PCORI should
19 focus within these priorities. And I think that
20 also is quite helpful in terms of how we think about
21 the implementation of these priorities. And so, I
22 just wanted to encourage -- to hear more of that

1 dialogue and the thoughts on your mind.
2 MS. ARMBRUSTER: I also think there's some
3 interesting dialogue opportunity to consider the
4 tension between a learning healthcare system and a
5 learning health system. I've heard that distinction
6 a couple of different times, and I'm wondering if
7 others would like to weigh-in on that thinking.
8 James and then Sharon.
9 DR. SCHUSTER: I think it's a great point.
10 And, you know, in several of the questions that we
11 talked about today, we've talked about the need to
12 include community partners including those that we
13 think about as probably working more within social
14 systems rather than health systems and I don't have
15 any magic framework for that, but I think the same
16 theme is relevant for this question as well.
17 And maybe one of the things that would make
18 sense for us to spend some time on or for the staff
19 to even help us think about would be, you know, is
20 there a methodology that we could use for
21 identifying what partners beyond traditional health
22 systems, you know, beyond providers and payers,

1 makes sense to include or what are some guidelines
2 that we would use to think about that? Because
3 we've established it, I think, as an important goal,
4 but it's I think the emphasis that we're putting on
5 it is somewhat of a change, is somewhat higher than
6 maybe we have historically.
7 MS. ARMBRUSTER: Thank you. Who was next?
8 DR. LEVINE: Me, Sharon.
9 MS. ARMBRUSTER: Yes. Sharon and then
10 Robert. Thank you.
11 DR. LEVINE: Yeah. So just to take us back
12 to the decision we made as a Board to frame this
13 entire exercise, this go around as national
14 priorities for health rather than national
15 priorities for health care, which was the original
16 formulation of 10 years ago. Which is why, for me
17 anyway, thinking about advancing a learning health
18 system is -- creates the opportunity to think more
19 broadly than learning healthcare system.
20 Because I think as Tanisha said, there is a
21 lot of work. There's been a lot of work and a lot
22 written about healthcare systems. And if we look at

1 the material that we were provided within the brief,
2 the definition, the NAM and AHRQ definitions and the
3 qualities of the learning healthcare system, which
4 are articulated there.
5 They very much are internal to the
6 healthcare system other than the only exception to
7 that is making sure patients are partners in this
8 work. And if the goal really is health and not just
9 improving healthcare, then broadening -- to me
10 anyway, broadening the definition or broaden the
11 category to a learning health system. And then
12 using the research agenda as a way of testing the
13 feasibility and validity of interventions that, in
14 fact, are multi-sectorial and potentially engaging
15 non-traditional partners in answering questions that
16 are very important -- of importance to patients and
17 consumers.
18 So I guess I'm advocating for a learning
19 health system. Not very subtly, but advocating for
20 a learning health system.
21 A part of which obviously are learning
22 healthcare systems and they both depend upon care

1 being open to capturing the learnings, both
2 traditional learnings. What the literature calls
3 practice-based evidence, as well as non-traditional
4 learnings that exists in sites and sectors outside
5 of the healthcare system.
6 MS. ARMBRUSTER: Thank you, Sharon.
7 Robert, what were some of your reflections?
8 DR. ZWOLAK: So, thank you. This has been
9 a fascinating discussion and I think this is sort of
10 the capstone of the conversation, but to me, the
11 issue is we sort of have to ask if Americans really
12 want to be healthy. I mean, some of the political
13 things that have gone on, I mean, do we want to be a
14 healthy? Do we care whether we're healthy or not?
15 And if that's the case, maybe we need to
16 have whole section on psychology. And how do you
17 decide if people want to be healthy? Because if
18 they want to be healthy, then they should buy into
19 learning healthcare. So, that makes me really think
20 about this whole picture.
21 But I also want to say that I agree with
22 Danny. We've heard so many fantastic, wonderful

1 ideas today. So operationalization of this, how
2 much of our budget do we spend on these really
3 exciting ideas that some of them have fabulous
4 potential return on investment, but some of them are
5 kind of long shots in terms of what we would do. I
6 think that we have a challenging road in front of us
7 to try to figure out how we're going to parse on
8 budget among these various fabulous ideas. Thank
9 you.
10 MS. ARMBRUSTER: Thank you, Robert. Who
11 else would like to weigh-in on advancing a learning
12 health system?
13 DR. GOODMAN: I find it very daunting.
14 Eighty percent of it, I think I'm just going to say
15 what I said before. It seems to be public health;
16 the language of the brief goes back and forth
17 between patients healthcare systems. It's very
18 confusing. It really is very confusing. There's no
19 boundaries to the remit. So I do think that that
20 was brought up by Sharon right at the top.
21 And we have to establish boundaries because
22 otherwise we become responsible for, you know,

1 transportation systems and infrastructure. And you
2 know, where supermarkets are. I mean, these are all
3 part of a health system -- health maintenance system
4 that we probably cannot extend. We could partner
5 with some of these organizations, but they
6 themselves are very, very, very stretched. They
7 don't even have the bandwidth partner sometimes.
8 You need to fund a person within the organization.
9 We saw this with COVID. We tried to
10 partner with multiple health departments and they
11 literally did not have a person who could spend, you
12 know, half an hour a day because they were, they
13 were devoting their time to yet more urgent
14 priorities. And so, we have to talk about to
15 achieve some of these investment in infrastructure
16 and people within these other organizations, we
17 can't just talk about partnering with the
18 organizations. We have to invest in those
19 organizations, which are very underfunded.
20 The scope is so broad, I don't even, it's
21 hard to know even where to begin to talk about it.
22 And again, I think there's a too facile moving

1 between healthcare and health. And I see it within,
2 almost within sentences here. I don't think of
3 learning health system as involving patients. I
4 think of it as involving mainly healthy people who
5 are trying to keep healthy. A learning healthcare
6 system absolutely involves patients and involve
7 systems who are gathering information continuously
8 and trying to make them better.
9 Just because the healthcare system touches
10 healthy people sometimes in their interactions, it
11 doesn't mean that we are the dominant or even the
12 minority force. So I think this needs both
13 boundaries and clarity that even know where to
14 begin, even though everything that's said is noble.
15 MS. ARMBRUSTER: Thank you, Steve, for
16 challenging process and urging us on a little more.
17 We have about 10 minutes to continue our
18 conversation. And in the queue we have Jennifer and
19 Ellen. So Jen, you're first up.
20 You need to unmute, I'm sorry. No?
21 Well, that's unusual. Well, we'll look for
22 her to be able to unmute and/or I can -- let's start

1 with that effort, but first let's hear from Ellen
2 while she works on that.
3 DR. SIGAL: I agree with Steve. I think
4 this is noble, all important. It requires focused
5 boundaries and deliverables [inaudible] pieces the
6 elephant and tackle pieces of it. But we have to
7 figure out where we can deliver and what the most
8 important impact would be because it's daunting.
9 Any of us who lived through COVID know that and
10 anyone that works in the healthcare system
11 understands that. So I think we have to be
12 judicious and focused on which part of it we can
13 make a difference on.
14 MS. ARMBRUSTER: Thank you. Jen, can we
15 test your audio one more time?
16 DR. DeVOE: How about now? Is it working
17 now?
18 Oh, okay. I guess unplugging the
19 microphone and plugging it back in, a high-tech
20 solution.
21 Yeah, I mean, I'm definitely going back and
22 forth between the boil the ocean, and then a comment

1 that was made earlier on several previous occasions
2 in that clinical outcomes, so we're talking about
3 clinical comparative effectiveness research. Many
4 of those outcomes are influenced by many
5 interventions outside the healthcare system. And
6 so, if graduating from high school has a bigger
7 impact on health than me prescribing Drug A versus
8 Drug B, then if we're not including some of those
9 other factors, I don't think that we're going to get
10 to the answer that's going to move the needle on
11 health outcomes and especially achieve equity for a
12 lot of populations.
13 So I get it that like Drug A versus Drug B,
14 and then comparing all these other things as a
15 difficult study to undertake. But if we just focus
16 what the healthcare system is doing, I think we're
17 missing some of the biggest interventions that have
18 the biggest impact on improving health, and really
19 not understanding how to incorporate those into our
20 study designs, into the list of interventions that
21 we're allowed to compare, the outcomes that we seek.
22 It's going to be a very narrow lens and we'll

1 continue to look through a narrower and narrower
2 lens.
3 And the impact is going to be far less than
4 if we are more broad and look at all the impacts on
5 health and all the impacts on clinical outcomes,
6 because a clinical intervention doesn't always make
7 the biggest impact on a clinical outcome.
8 MS. ARMBRUSTER: Thank you, Jen. Next in
9 the queue, we have Kathleen.
10 MS. TROEGER: All right. I'm going to try
11 bringing everything online here and see what
12 happens.
13 So quickly to just tag on to what Jennifer
14 said and with respect to everybody's thoughts on
15 this as a really big and be, in some cases, lacking
16 methodology. One of the opportunities I see for
17 learning health or more importantly, AI, is to use
18 some of the AI applications to search for solutions
19 that work.
20 So where you start with the outcome in mind
21 and look backwards at interventions and patterns
22 that may be naturally occurring and aren't

1 specified. So who does best post-MI or pre-term
2 birth and working retrospectively using some of the
3 natural language processing to look for what the
4 algorithms of tear may have been that predicted
5 those outcomes to set future questions or hypothesis
6 to answer.
7 So just kind of a thought about where I
8 agree. There's a lot of swag and difficulty
9 measuring some of this stuff, but there's an
10 opportunity not to study Drug A versus Drug B, but
11 to look instead at what drove potential improvements
12 that may not be initially apparent if we just asked
13 the people doing it.
14 So just a comment there. And it is big and
15 it does boil the ocean.
16 MS. ARMBRUSTER: Yes. And thank you,
17 Kathleen, for a specific example of what we might be
18 thinking about on the research agenda in moving
19 forward. Ellen, were you ready with a comment?
20 DR. SIGAL: I already made my comment.
21 MS. ARMBRUSTER: Okay, I just wanted to
22 make sure. Alicia, thank you.

1 DR. FERNANDEZ: There are a lot of exciting
2 comments made here, and I do think that this will
3 require a little bit more definition in terms of
4 what's in and what's out. And in order to be in,
5 what does something have to have? And I also feel
6 that a lot of this is really cutting edge.
7 Like for example, with AI, one of the
8 things that I love what Kathleen said, and at the
9 same time, I recognize that there isn't any
10 algorithm that's not going to come up with the fact
11 that certain groups of people consistently do worse.
12 And that it encodes reality rather than luminates
13 reality or it can't get to the sorts of things that
14 we need and this is a good, important research
15 question.
16 I'm not sure whether PCORI needs to be in
17 this space. To me, we're still very early in all of
18 this and it needs to be done through NIH and AHRQ
19 and other places, but I may be wrong around that.
20 But I think -- what I'm trying to say here? I think
21 that there is so much we can do around learning
22 healthcare systems. And that is our sweet spot.

1 That's where we need to go. It overlaps with every
2 other one of the priorities that we laid out today.
3 And the things that are outside of the
4 healthcare system should be considered to the extent
5 that they, that the main outcome of interest -- this
6 is how I would organize it. But the main outcome of
7 interest is a healthcare -- it is a health outcome.
8 In other words the outcome needs to be a health one
9 in order for that to be of sufficient interest, I
10 think for PCORI.
11 But, I think, what perhaps what we're all
12 seeing is that this brief important as it is, is
13 still in an earlier stage of development, even
14 though from a certain perspective, it's the one that
15 is the most -- it's the most in our sweet spot. To
16 the extent that we can really help healthcare system
17 learn, that would be something that a contribution
18 that PCORI can make. Other people cannot make it
19 quite as well. And I think would be fantastic.
20 Sorry. I rambled.
21 MS. ARMBRUSTER: No, I appreciate your
22 depth of thought about that. And, you know, really

1 kind of recapping and I think restating some of the
2 both excitements and concerns that people have
3 raised in this discussion thus far.
4 We have about four more minutes. Are there
5 last comments anyone wants to make about your
6 thoughts as we start our last full discussion about
7 this topic before the full Board vote in June? And
8 there will also be an opportunity to bring this back
9 to the table tomorrow when we recap and consider the
10 cross-cutting themes.
11 Kathleen, a quick comment? Go ahead.
12 MS. TROEGER: It was just a -- if you
13 could've seen me Alicia, I was nodding my head. I
14 completely agree. And I think this gets back to
15 things other people have said as well, which is that
16 we can't measure outcomes in people that don't have
17 encounters. So if you are not even in the
18 healthcare system, the healthcare system can't learn
19 about you. And so, the challenge then becomes how
20 to, you know, find the digital twin or an
21 application that does work and that's just where I
22 see there are possibilities there and ways to

1 identify strategy.
2 But I couldn't agree more with what you
3 said about the sort of encoding the systematic gaps
4 that exist for some of these things if we don't
5 approach it carefully.
6 MS. ARMBRUSTER: Thank you. And Sharon.
7 DR. LEVINE: Yeah, so I would agree that
8 the only outcomes PCORI, is and should be interested
9 in are health outcomes. No question about that.
10 And that partners, collaborators, research partners
11 should all be focused on health outcomes. I'm not
12 sure I agree with Kathleen that the only universe is
13 people who have an encounter with the healthcare
14 system. I have to think about that a little more.
15 But I also want to say that I think to be
16 fair that this brief needs more work, needs some
17 work. And some of it is work that I think we, as a
18 Board, need to give direction to staff in terms of
19 what our intention is. And I think, I hope, this
20 conversation today has helped in terms of
21 illuminating and elucidating people's perspectives
22 on the issue.

1 And my final comment is, for us to have a
2 priority on advancing a learning health system, we
3 need to be clear that there is a research agenda
4 that flows from this that is different than
5 potentially, that has something unique to offer in
6 terms of the research agenda and health outcomes
7 from the other priorities, because if it is
8 completely subsumed by the other priorities and what
9 we end up with is an introductory session statement
10 about how all these priorities are leading us to a
11 better world. We have a learning health system or
12 learning health systems.
13 MS. ARMBRUSTER: So we're really close to a
14 time boundary. We have time for just a brief
15 comment. Danny, it looked like you wanted to speak.
16 So last brief comment.
17 MR. VAN LEEUWEN: I'm wondering how much
18 our focus can be guided by our priorities of
19 maternal health and IDD. That those be the
20 playgrounds, the sandboxes, whatever, that we apply
21 some of this to so that we're dealing with those
22 priorities as well.

1 MS. ARMBRUSTER: Thank you for offering
2 some specificity for us to frame and consider this
3 national priority.
4 All right. You all have given a lot of
5 grist for the mail. I suspect we'll return to this
6 conversation a bit tomorrow. Thank you for your
7 insights and guidance for further shaping this
8 priority. And as you know, we've had a team taking
9 notes during the discussions today. Tomorrow, we
10 will review a few of the themes from today's
11 discussion and look for overlapping interests and
12 priorities.
13 It's been my honor to be with you all. And
14 with that, I pass to Nakela.
15 DR. COOK: Thanks so much Sonja. And thank
16 you to all of the Board members for such a rich
17 discussion. It's been so good to hear from all of
18 you as we discussed, I think, one of the more
19 important activities on our agenda for the year,
20 really, and I'm excited that for the most part, it
21 seems that the five priorities seem to resonate and
22 you've added some focus to the priorities and helped

1 us identify some potential challenges and provided a
2 lot of insights, even for considering an evaluation
3 framework that will need to be updated as we move
4 through our strategic planning efforts.
5 I also just wanted to comment that I
6 appreciated so many of your comments around focusing
7 on PCORI's unique opportunities within each of the
8 priorities and expanding the opportunity for
9 partnerships and collaborations outside of our
10 traditional walls, and was really pleased to hear
11 comments about relationships with other federal
12 agencies like AHRQ or FDA or CMS, and even CMMI as
13 we've been having a lot of recent discussions with
14 all of them related to synergies around
15 dissemination and implementation, even coverage and
16 data linkages, and with CMMI, on ways we can
17 innovate together.
18 So it was really helpful to hear your
19 thoughts there and helpful to hear your comments
20 about incorporating our provision around the full
21 range of health outcomes data, including costs and
22 burdens into some of this work. And I heard some

1 rich comments too, around trust and bidirectional
2 communications is central to many of the traffic
3 priorities we discussed.
4 It was really validating to hear your
5 comments about optimizing contributions to research
6 outside of academia and understanding what we've
7 learned over time with our engagement portfolio and
8 tomorrow just as a teaser, you'll also hear an
9 example of how we've provided tools and resources on
10 engagement best practices that have been learned
11 through the evaluation of our engagement portfolio.
12 And so, we're excited to continue to evolve this
13 over time. It seems it would be of resonance to
14 you.
15 I just wanted to wrap up before turning it
16 over to Christine with one additional slide, do you
17 mind going to the next slide?
18 Perhaps it's not today. I'll do that
19 tomorrow after our facilitated discussions and wrap
20 up on the timeline with you. I just wanted to
21 remind you that we expect that we'll be able to
22 present our net draft national priorities to the

1 Board at the June 15th meeting.
2 And the goal, there was for a vote to
3 release them for public comment. But I want to
4 emphasize the point that following public comment,
5 that we'll be engaged again and the Board will
6 engage with revisions on the priorities in response
7 to the public comment period before the priorities
8 are finalized. So as you take a rest tonight and
9 come back tomorrow and think about that facilitated
10 discussion we have tomorrow to bring everything
11 together, we're hopeful that we'll have the input
12 that will be helpful for us to move these toward the
13 June meeting where you'll be considering them for
14 release for public comment.
15 So with that, I think I'll turn it back
16 over to Christine to close us out for the day.
17 Thank you.
18 CHAIRPERSON GOERTZ: Thank you Nakela. And
19 I’m going to start by thanking Sonja for doing just
20 such an excellent job in facilitating our
21 discussions today. We really appreciate your work
22 and look forward to our continued discussions

1 tomorrow when we come back together again.
2 I want to close by thanking those who
3 joined us today via webinar and teleconference. We
4 hope you're also able to join us for tomorrow's
5 meeting. A reminder that all materials presented to
6 the Board today will soon be available on our
7 website and that today's webinar was recorded and
8 that the archive will be posted within a week.
9 We always welcome your feedback at
10 info@PCORI.org or through our website at
11 www.PCORI.org. Thanks again for joining us. Have a
12 good evening.
13 [Whereupon, at 4:29 p.m. EST, the Board of
14 Governors meeting was adjourned.]
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