PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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Washington, DC 20037

[Transcribed from PCORI teleconference.]

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AGENDA

AGENDA [continued]

P R O C E E D I N G S

[9:05 a.m.]

OPERATOR: Dr. Norquist, the floor is yours.

CHAIRMAN NORQUIST: Thanks. Good morning and welcome to the May 13th meeting of the PCORI Board of Governors. I'm Gray Norquist, Chair of the Board. I want to welcome those of you who are joining us for today's Board meeting, which is being held in person in Washington, D.C. and via teleconference and Webinar. We're very pleased to have you here.

As a reminder, instructions for logging in or calling in today are available on our website, PCORI.org/events. All board members are present with the following exceptions; Trent Haywood and Michelle McMurry-Heath and Kara Ayers is on her way, so she will be here soon.

I want to remind everyone that disclosures of conflicts of interest of members of the Board of Governors are publicly available on our website and are required to be updated annually. Members of the

Board of Governors are also reminded to update your conflict of interest disclosures if the information has changed. You can do this by contacting your staff representative. If the Board will deliberate or take action in a matter that presents a conflict of interest for you, please inform me so we can discuss how to address the issue at the time.

If you have questions about conflicts of interests or recusals relating to you or others, please contact your staff representative.

All materials presented to the Board for consideration today will be available during the Webinar and then after will be posted on our website. The webinar is being recorded and the archive will be posted within a week or so. We have a scheduled public comment period today from 12:30 to 1:00 p.m. Eastern daylight time.

If you are interested in registering to provide public comment, please visit our event page for instructions. Alternatively, you can always email us and Info@PCORI.org or provide input through our website.

Finally, a reminder. We are live Tweeting today's activities on Twitter and you can join the conversation with @PCORI. So Joe, did you want to add anything at this point?

DR. SELBY: No. No Gray, thanks.

CHAIRMAN NORQUIST: Okay, so the first item up is the consent agenda. Do I have to move it forward?

So on the consent agenda are the minutes of our April 16th Board meeting and an amended Governance Committee Charter that includes provisions relating to the Governance Committee Vice Chair selection and voting by written consent on audit matters. So are there any additional comments or corrections to the minutes and if anybody wishes to take any items off the consent agenda, let me know.

I don't see anybody doing that. Okay.

So let's see, I think at this, yeah, I think it's, I'm just reading my notes here about what else Mary wanted me to --

DR. SELBY: Is there anything else Mary?

CHAIRMAN NORQUIST: No, we're okay on this. You had something that the governance committee, I didn't think there was anything else.

UNIDENTIFIED SPEAKER: No. Just need to clean up items [off microphone].

CHAIRMAN NORQUIST: Thank you. Yeah, that, that was the point I wanted to just clarify.

So Larry, where are you going to make a motion?

MR. BECKER: Yeah, I'll make a motion to move these consent agenda items.

CHAIRMAN NORQUIST: Okay. And Chris, second. Okay. Thanks.

All right, I think we can do this by voice vote, is that correct? Yeah. Okay. All in favor?

[Ayes.]

CHAIRMAN NORQUIST: You can raise your hand, actually, we don't have to do it --

[Hands raised.]

CHAIRMAN NORQUIST: Anybody opposed? And anybody abstaining?

Okay, great. So Joe, you want to move it

on? There we go. So now Joe Selby, who's our Executive Director will give his report and review of the Dashboard.

DR. SELBY: Yep. Thanks Gray. Good morning everyone. I was reading through the note that we sent out that I wrote that accompanied the materials last weekend and I made a fateful statement that we almost always have lovely weather here at this time of the year.

[Laughter.]

DR. SELBY: So my apologies for jinxing it.

So we're going to start with the return to our strategic planning process, which has been really ongoing, you know, in a kind of continuous way for about a year and a half now, but particularly back to the planning session that we held in March of this year, we began thinking about PCORI 2.0, as we call it, the long for PCORI post-reauthorization.

And we identified several topics that we would continue discussing at board meetings, at public board meetings throughout 2019. We're in

this, I call it a lull, while we -- I mean we continue funding research and we continue managing research, dissemination, implementation and all, but there's a sense of waiting for the decision to be made. And in that, it's a good time to think about where we've gone, what we've produced, and how we can make it even better.

So one of the areas that we want to discuss, and this is always a factor, is how we continue to revitalize, enhance, enlarge, improves the quality of our topic generation process starting with stakeholders, and make it more transparent. So one of the topics for today's meeting is, in fact, an aspect of this topic generation and how we will continue to grow at into PCORI 2.0. So that's a series of presentations that we'll kick off today. And today we will start with are a relatively large telehealth portfolio and you'll have a presentation from one of PCORI's scientists on that.

Also another big area in the strategic planning process is the area of disseminating and implementing findings. The Board has been seemingly

clear that dissemination and implementation activities are important to them and to PCORI. And so, that discussion we'll kick off today with the presentation from Jean and from a guest.

So you have seen a slide quite a bit like this before. So starting with the green topics in the center and moving to the right, we receive ideas for topics that we can prioritize and fund research in from a variety of sources, which I'll get to in a minute. But we then, PCORI staff working closely with the SOC, in particular, triage these initial ideas. This may generate the need for topic briefs or evidence maps or systematic reviews.

As the topics develop and get prioritized and refined, they eventually make their way to funding or commitments for funding in a variety of ways. It may be a targeted funding announcement as you know, it may be placed on the list for the pragmatic clinical studies or it may be listed as an area of special interest in our broad funding announcements.

So we have a lot of ways of telling the

world about the topics that we're interested in, and the topics for which funding exists.

So now back to the right -- to the left. There are three broad sources of topics. One is by conducting landscapes across the spectrum of clinical care of high priority topics, topics that are changing; topics for which there's a lot of variability and particularly topics, almost all topics, that create a huge burden either for society by virtue of their numbers or for individual patients by virtue of high degree of suffering, and maybe an absence of available treatments. So that would be the case with rare diseases.

So we have commissioned a new landscape. The National Academy of Medicine back in 2009 published the 100 CER priority areas and you could almost think of this as an update of that. We will within a two to three months a landscape report for the Board and the SOC particularly to consider.

The second source of topics is an analysis of our current portfolio and to look at what we've funded, what we've published and what appears to be

remaining gaps. So in many instances we will have funded a good amount of research, but there will be obvious remaining gaps. And that's the report that you'll hear today on telehealth. And in an ongoing way, I'll show you in a minute, that the next four or five of those.

And the third is ongoing input from stakeholders and applicants. And we have many ways including forums and one-on-one meetings with organizations, patient, clinician, payer, purchaser meetings that generate topics that way and we're working on that and you'll hear reports from time-to-time on steps we're taking to improve and make that flow more systematic, as well.

So this is just a preview today, telehealth, Penny Mohr will be presenting on telehealth and this will be a regular series in the coming months. We have already in preparation presentations on our portfolio and opioids, on our portfolio in multiple sclerosis, on mental health and cancer. In just a second I'll ask you if you've got suggestions for other portfolios that

you're aware of, you're aware of the funding and if you'd like us to put together a report on that.

So that is it except for a discussion of the agenda that’s coming up. So this would be a good place to stop and see if there are questions about the topic generation process or other topics that you'd like to hear us put together, other than these five here.

Bob.

DR. ZWOLAK: Joe, I apologize that I missed the retreat but if you look at this list of telehealth, opioids, MS, mental health, and cancer, and you think about what's different on this list four of them are diseases or disorders and one of them is a means to deliver care. So how exactly does that one get on the list?

DR. SELBY: Because there is -- as you'll hear today, there really are a large number of projects and actually, you know, I could name a few others like shared decision making or community health workers that are more in that genre. It's interesting. You're right, it's interesting that we

wound up with four conditions and one systems approach. But again, you know, that's kind of our character is that we have a lot of work focused on diseases, but we do also have quite a lot of work on systematic approaches that go across diseases.

Alicia.

DR. FERNANDEZ: It was a great list and I think it'll be really great to take a deep dive and to think about dissemination along these lines. I would add community health workers to this list.

DR. SELBY: Yes.

DR. FERNANDEZ: Everywhere one goes, one gets asked about it. There has not been, to my knowledge, a good synthesis of that literature and PCORI has done a lot of work in here, so I would consider adding that.

DR. SELBY: Excellent. Thanks.

Larry.

MR. BECKER: How about the evidence synthesis map that we saw about a year ago and kind of how that has developed and how that's been used and you know, is it making in roads? Is it hitting

a, you know, a chord with people out there?

DR. SELBY: Okay. My hunch is that Jean might be able to update us on that later this afternoon.

Chris, were you pointing to someone? Ellen. Oh, Ellen, I'm sorry.

DR. SIGAL: Sorry I've been playing with the WIFI and unsuccessfully.

So I'm a big believer in all of this telehealth. But one of the areas, recently, probably every week I have someone come to my office with metrics on telehealth and on specific apps on cancer, specifically, making claims that I find are not -- how should we say it? Aspirational rather than real.

So how do we validate these tools, because the end points in what they're measuring are soft and there've been a lot of publications, and again, the only area that I can really talk specifically about is cancer, but even in symptom management some people are suggesting there are, you know, survival benefits to it and lots and lots and lots of, you

know, adherence. So how do we kind of see what is really -- what we can replicate and what's real other than aspirational claims?

DR. SELBY: Yeah. Well, again, I think that's a great question for Penny. She's going to speak directly to the apps, which is more mHealth, which is part of telehealth. And I know she has some comments directly related to cancer in that area, but you're totally right. That evidence map that Larry mentioned -- was an evidence map. One of them was an evidence map of mHealth and it revealed that there are a lot of very small, low-quality studies and not much in the way of sizable or definitive studies. So excellent point.

Jen.

DR. DeVOE: I'm just echoing what folks have said about healthcare delivery and where we're looking at individual diseases. I wonder about something that's more related to population health or a comprehensive look at health equity.

I know we have quite a robust health disparities portfolio, and so thinking about where

are we closing gaps here and where are gaps widening and whether it's delivery of care or specific diseases. Can we get one focused on our population as a whole and more comprehensively on people?

DR. SELBY: Thanks. Yeah, we'll think about it. We definitely will -- we can put one together on disparities and giving it this population health flavor is an interesting angle. Thanks. Any others?

Okay. Not seeing any other tent cards, we can move along.

Here is just a preview again of the agenda today.

The next thing on it is the Quarter 2 2019 dashboard followed by the first of the research portfolio explorations. I'm going to give some opening -- brief opening comments and then hand it off to Penny Mohr and she will give you the focused presentation on telehealth. Then after a break at 11:15, we'll resume at 11:30, and there will be a proposal coming from the Research Transformation Committee to approve a commitment of up to $2

million for a linkage method within the PCORnet. So we'll explain that more then.

And then the presentation from Jean and from the guest speaker on a dissemination and implementation, including a focus on a particular sizable implementation process that comes from PCORI-funded publication. So that's it.

We'll have a public comment period and we will be done with the open meeting at one o'clock.

So again, another quarter has passed and here is our dashboard for Quarter 2 of 2019, a familiar format by now all of you. But there's -- you can train your eyes first on the two yellow bars as opposed to the green bars or gray bars. And the yellow bars, the first one is the funds committed. This one is -- often falls a little short this time you'll see that it just fell short by the skin of its teeth, just barely, and that is entirely due to a post, a delay in a commitment within PCORnet for the coordinating center.

It turned out that the coordinating center had some remaining funds from the last cycle, and

so, it was able to extend that funding and covered this quarter and perhaps next quarter.

Meanwhile, with some change in leadership at PCRF, it was a very good time to go more deliberately on this, a negotiation of a new proposal for the coordinating center. So this actually turned out to be a good thing and it's, as I said, if you can imagine if the $15 to $16 million that was set aside for that were added, we would be well above that green line.

And I'll just speak to the second one that's yellow at this point, the speed of PCORI peer review, this has always been high, higher than the target six months. That target six months may be on the low -- just an almost unrealistic target given the nature of peer review and the time it takes to go back and forth.

But the good news buried in this is that -- or apparent, really is the continued decline in the median times for the meeting time is less than seven months now. So it's the median is just over one -- is just under a month longer than the target for

everyone. So continued progress and we're going to have an in-depth report on that very shortly as part of this presentation.

So in going back to the top row and just moving quickly across under operational expenses, we are -- we met our target and so we're a little underspent. Being a little underspent in this particular year is not a bad thing, but basically we are spending almost as we projected.

In terms of project performance 91 percent of projects appear to be on target. That's just a tiny blip up, but it did manage to cross the target line. So we're back in a good territory and that bar is no longer yellow. So that was good.

And moving to the second row on the left.

In terms of results published in the peer literature, we don't have a target here, but more is better obviously. And you'll see that we had a good number of 22 CER publications and about close to 80 publications total in Quarter 2. And that number sometimes rises a bit after this presentation because some papers just don't quite make it to Pub

Med or we just don't quite find them by the time of this report, but 22 is a good number of CER publications.

The Altmetric score jumps around a lot from a quarter-to-quarter, but you see we just fell just under the target this time, we were well-above the target last time. And the target is that we would like to have at least 10 percent of our publications in the top 10 percent of Altmetric scores controlling for the time period and the actual publication -- the journal in which it's published.

So we compare our papers to other papers in the same journal at the same time and 9 percent of ours we're in the top 10 percent.

And then to the far right, here, the results viewed on PCORI.org. We've set a target, we'd like to have at least 80 views per project per quarter, and I think we were at 77 or 78 this time, 78. Just a little bit under that target, but this means, the number of projects that are posted on there, the results, keep going up quarter-by-quarter. So even as the number of projects goes up

we're still having nearly 80 visits to the website per project, per quarter. So that's a pretty impressive number of contacts.

Your background materials in the Board book actually do give some information on the time spent. And really the time spent is often when I click, I spend 30 seconds, but this is well into the minutes on average spent on these sites.

Next, on the bottom is how we disseminate our findings. And there are many ways as you know, but one of them is to get results from our published studies into widely used clinical decision support tools like UpToDate, which is an online set of guidelines that physicians and other clinicians usually carry with them on their iPhone. And we've had 27 of our publications added to at least one UpToDate recommendation and we had five more, I believe that's a five, in Quarter 2. And again, your materials will mention exactly what they were.

In addition, moving to the right one. Others examples of uptick. We also had -- it looks like about 10 or 11 additions, mentions, citations

of PCORI publications in systematic reviews, clinical practice guidelines, or other policy documents.

So again, this is an important and an effective way of getting PCORI findings out to broader audiences, both research audiences with the systematic reviews, but then clinicians in terms of guidelines and policy documents. PCORnet chugs along and PCORnet had six new studies added in the most recent quarter. And it has, I think something like 140, actually I'll be talking to you about the PCORnet in just a minute as well. And Front Door requests are up a bit in the last quarter, too, just reflecting ongoing interest from a variety of sources in what the PCORnet can produce.

So any questions about the overall dashboard before I move on to --

CHAIRMAN NORQUIST: Barbara.

DR. SELBY: Barbara.

DR. McNEIL: I thought this was great. Joe, when I was reading it a thought hit me and maybe we've discussed this before and I just zoned

out, but have we ever thought of having something on the dashboard given that we're very anxious to move our studies and our data along, have something on the dashboard that was time for first review of the submitted application and then time to start of an application once it has been approved.

The latter would take into account all of the problems that we sometimes get with universities or hospitals and their contracting offices. So basically it will be two parts. The first would be our review and that's under our control. And the second one would be a mixture, part of us and part of the recipient in terms of getting the study actually started.

DR. SELBY: That's an excellent suggestion. We have discussed this at times in the past and I think it's a good time to bring it back. Maybe we'll start by just reporting to the Board at a Board meeting on it and seeing if this is something that we want to add to the dashboard.

Yes.

DR. McNEIL: It relates to the Front Door.

What kinds of requests have come in to the Front Door of PCORnet and what has actually happened to them?

DR. SELBY: I'm going to show you some details on that in just a minute.

Any others?

Okay. If there are no others this is just as we always do. We like to show you a few examples, one, at least, that meets with each goal.

So in the goal of increasing information for health decision making, this is a very well received update of a systematic review. AHRQ and PCORI collaborate on this. We fund -- through AHRQ we fund an evidence-based practice center to do this work. And this one was on the nonsurgical treatments for urinary incontinence published in the *Annals*. And you'll see that this is a really quite a high Altmetrics score. It says top 10 percent there, but I, gosh, I'm surprised it's not even higher than that. Usually a score over a hundred is in the top five.

And it essentially concluded that it

compared the effectiveness of a wide range of treatments including pharmacologic and nonpharmacologic interventions, 84 trials were included. And what was found the conclusion, one of them was that behavioral therapy alone or in combination with other interventions is generally more effective than the pharmacologic therapies alone in treating both stress and urgency incontinence.

So you see the quote there from the senior author, “A reasonable approach is to start with behavioral modifications. If that's unsuccessful, then move on to medications or procedures. But it's a quality-of-life issue, not a life-threatening problem -- go through all the options and let the patient decide.”

This is a subsequent paper from the same authors in the *Journal of General Internal Medicine* just this month and it addressed the adverse effects. And it certainly found that behavioral therapies and neuromodulation have low-risk of adverse effects, whereas the many of the medications

do have their expected side effects; like dry mouth, fatigue, GI complaints. The botulism toxin injection is associated with urinary tract infections and voiding dysfunction.

So they concluded that the choice of which treatment option is best for a particular woman with urinary incontinence will vary depending on her symptoms, the severity of those symptoms for history of prior treatments, treatment goals, preferences and values.

So I'm moving on to goal two, which is to speed the uptake and use of information. This is really -- I've been waiting for this for some time, but we finally gotten word that the three studies by Keren about the equivalence or superiority of oral antibiotics compared to intravenous antibiotics delivered by a PICC line in children going home from the hospital after a serious infection.

This has now been built into Infectious Diseases Society of America Clinical Practice Guideline and they said there's mounting evidence that oral therapy can be substituted for parenteral

therapy without compromising cure rates, safety is enhanced by avoiding parental therapy related complications, where that has been the traditional preferred treatment. So very good news that this has made it into the Clinical Practice Guidelines.

And we do have some evidence already that the use of parenteral therapy post-discharge is a declining rather quickly following the publication of these papers.

And a third, our third goal is to influence the way research is done and the way it's done elsewhere. These are two publications; Dr. Evelyn Whitlock was provided the leadership for these, but you'll see that one of them involved both PCORI staff, as well as, PCORI Board members -- the first one. And this was a study self-assessing how PCORI follows a set of recommendations for efficient clinical research that were published in the *Lancet* in 2012 through 2014. I think these recommendations actually were around at the time PCORI got started and you can see the echo of a number of them in our Methodology Committee report and standards.

But this basically showed that we are doing well in about nine of the -- there are 17 areas, 15 applied to PCORI, the kind of research we do. We were doing well in nine of them. And six of them had recommendations for improvements that we could put into place.

So a nice example of how a research organization holds itself up to scrutiny. And it actually was patterned after a similar publication from the National Institute of Health Research in the UK, which funds research much like ours in which had self-assessed its practices.

The second paper was in *JAMA Network Open* and it compared nine, the nine largest noncommercial funders of research in the U.S. and six of the nine met three key criteria of having publically available policies on clinical trial registration, on posting of summary results, and on individual patient data sharing. PCORI looked very good there. But another nice example of not only talking about how we would do research, but bringing in the idea of influencing the way others do it.

Okay. So there's a focus in the dashboard this time on peer review, our peer review process, and on PCORnet.

So in the peer review process, and we've gone through this before, there is an initial receipt of a draft final research report. It goes through a period of pre-review wherein the editor and PCORI staff review for completeness and for following the format. And sometimes there's some back and forth. We'll get into this in just a minute. Just to get the report ready to send out for peer review.

Then there is a peer review process and this is managed externally and very well. And the peer reviewers provide their comments and the associate editor synthesizes the comments and sends them back to PCORI. And then there is a back and forth. That's the third part, back and forth between PCORI and the author and principle investigator.

So this is a very nice picture. It reminds me of a snake wherein the big bolus has passed

through. And so, you see now very different than it was a few quarters ago, 182 out of 285 projects are completely through the review process with results posted on PCORI's website. Thirty-one more have been completed and approved and they are in the process of having the reports drafted for the lay and the research audience. And we know that this, by statute, needs to take less than 90 days and we've never had one that didn't make it to posting within less than -- within 90 days or less. So 31 more will be added, now within well-under 90 days to the 182. Forty-eight are in peer review, nine out of 48 are through peer review and the final edits processes underway. Nine are currently in peer review and 15 are in the either the pre-review or the investigators are still putting them together.

So you'll see that the numbers are starting to go down. We have gone through a bolus where we funded a lot of small studies in the earliest years, as more of our commitments have gone to larger studies, longer studies there are fewer each quarter coming to completion.

This just shows where the target is the green line. It's less than six months. We'd like to have the complete, the peer review process completed. You'll see that that doesn't happen all that often, although there are 39, it looks like that in which it did. But you see that there's a long tail, most of them cluster just above six months, but there is a long tail and these are those that just take multiple iterations.

This shows that the number that used two or more revisions during pre-review that is the bluish, the light blue has really shrunk. So there's very few times when we have to go back and forth more than once with applicants before we send it off for peer review. And the number in dark -- review -- where we can send them directly, they're good enough to send directly to peer review is up now these last four quarters. And this is really due to a lot of work in our communications, a lot of work by our staff communicating with changing the format of the application so that we get what we need off the bat.

This is a nice story of us being responsive

to the initial submissions of some not-so-ready final reports.

This is another part of the story. This is what we called the Cohort View, where the red line shows that if you just take each quarter's projects and see how long they take to get completed, you'll see a steady decline from back in 2016 and now we are down at 7.1 months on average for the most recent cohort, most recent cohort that's made it through the last couple -- that time hasn't elapsed yet. So we hope that they will continue to be brief like the last couple of quarters.

This is just a reminder. I've already said this, that we always get the final approved reports posted in abstract form, both lay and clinician, in less than 90 days.

And now -- this is very exciting, an increasing number of the reports have been posted in abstract form for long enough that we can now post in final form the entire searchable report. And so, there are something like -- it looks like there are -- thank you -- 60 reports for reports posted and by

the end of this year we anticipate we'll have 152 final reports posted. It takes less than the 12 months.

We allow up to 12 months, but we on average get them posted in 10 months and there's a new search function on the website so that you can find these reports more easily and coming soon will be measures of attention to these final reports.

This is a very nice publication that Hal Sox who leads this effort, Marina Broitman who works closely with Hal, published as a viewpoint in *JAMA* on our process. So I would really commend it to you. It's -- not many funding organizations go through this process and we do it in a, I think, very outstanding way that actually benefits researchers in getting their papers ready for publication.

This just shows that the gold line is a benchmark that is from two publications shown there of how long it takes following the primary completion date of a study to get published results. And you'll see that at 30 months after the primary

date we are, PCORI is, and this is published in the scientific literature, we're at about 56 percent, whereas the benchmark is 40. So we are doing a better job in getting PCORI publications out the door within 30 months than the benchmark.

If you add in, if you count posting the report on our website as publications, you see that we get to 100 percent by 30 months. That is the final reports are posted within 30 months in 100 percent of ours compared to the 40 percent. So we are doing a better job, I think you'd say, in getting PCORI-funded CER results to the attention of the public, both in scientific presentations, scientific journal articles, but also on our website.

Any questions, Barbara?

DR. McNEIL: That's very interesting Joe.

I've been trying to think about this and maybe it's just a reflection of the kinds of studies that I've done. Frequently a study gets done, we have all the results and boom, we send the manuscript off of publication to *JAMA* or the *New*

England Journal or what ever, and it gets published pretty fast. It's accepted for publication pretty fast. So have you ever been in a situation where an investigator finishes the study, sent out a manuscript, has it accepted for publication, and you still haven't finished your review?

DR. SELBY: Yes, oftentimes.

DR. McNEIL: So why would you bother continuing review when it's already been accepted by a publication?

DR. SELBY: I think mainly because the final report is broader and more comprehensive than any publication. Publication typically doesn't present the entire -- it doesn't respond to all the aims that were in a study and the final report does.

DR. McNEIL: Can I just follow up on that a little bit? So if the final report is on the website, there is some journals -- and Hal would know this better, there was some journals that will not publish an article if the information is already publicly available.

DR. SELBY: Yes.

DR. McNEIL: So how does that work?

DR. SELBY: So we've worked through that with multiple journals and I'm going to just ask Hal if he would mind speaking to it, my impression is that has not been a problem, but Hal is in a better position to speak.

DR. SOX: Well, we want our PIs to publish in journals and so we don't -- we ask them for permission basically to post the final research report on our website after, you know, basically we follow their lead, with the exception that if it goes 12 months and they haven't published their results, then unless it's under review, we're pretty much obligated to do so.

DR. McNEIL: That makes sense. Thanks.

DR. SELBY: Okay, if there are no other questions, we'll move on to the update on PCORnet.

So to speak in two areas. One is data improvements and one is new projects and prospects for new research.

So this is just -- I asked them to get me a recent update on their entire membership that they

could track. So this is from the perspective of the nine clinical research networks and you'll see that there are -- so this is 43 DataMarts from the nine clinical CRNs, and it's for the period from mid-2017 through mid-2018. About 31 million persons had at least one entry into the electronic health record of these sites. Then very nice distribution by race, ethnicity -- and race and ethnicity is shown there. And pretty complete data on that, as well.

This is one of the nice things about an electronic health record. The female-to-male ratio is not surprising in that this is a database built on people who use services and women use more at many points in life than men.

So now this is the perspective. I'll also say that this is somewhat fewer than I've shown you in the past because PCORnet is somewhat trimmed. There are now nine clinical research networks in PCORnet, and this is what they generated in one year.

This is from the perspective of the health plans. And two health plans are part of PCORnet and

they together cover the lives of 24 million persons. Now there is a lot of overlap. We don't know quite how much yet and that's what a proposal later on today is about, between what's in those electronic health records and these two health plans. So some of those people have these two types of insurance.

And again you'll see here that the balance, male-to-female, is somewhat better and somewhat more closer to 50/50, and they have a lot of missing data just to say that health plans do not tend to have race and ethnicity data. So that's just another reason that makes linkage important and a lot of people with any of these conditions, I'm not going to go into this much. That's the health plans are -- the first one was the CRNs and the second one is the health plans.

It's kind of interesting to see that sometimes the health plans generate more people than the electronic health records and that could bear some exploration. So, for example, anxiety in the CRNs there were 2.6 million. And in the health plans who have less people over all, there were 3.5

million. So I think that says that the health plan becomes aware of these diagnoses of anxiety more often than they show up in the electronic health record.

This is just the Coordinating Committee and all of the CRNs continue to work at standardizing their data. And this is for lab tests. It just shows you that they have now standardize the data across the nine CRNs for 206 lab tests, 206 lab tests begins to get into some pretty esoteric lab tests. So even when you had, you know, a much smaller number, you had the bulk, the vast bulk of all the lab tests, but they continue characterizing the less frequent ones and that just makes them more able to do particular types of research.

This is an example of two tests that have been widely available since 2016. That is Serum Creatinine and the Hemoglobin A1c because those are two the most studied the lab results and diabetes particularly is a commonly studied disease in these kinds of data.

Another one, the Serum White Blood Cell

count has just gotten up above 90 percent, and the estimated glomerular filtration rate, the purple line is now -- I'm sorry, the blue line is not quite at 90 percent yet, but great progress in capturing that one, which is very valuable for renal failure and cardiovascular disease research.

And this is an example from prescriptions. Now these are not prescriptions filled. These are prescriptions entered into the electronic health record. And the question here was for a biosimilar, how often can you distinguish whether it was the actual branded drug or the biosimilar and we've improved -- and that would be very important if, for example, you wanted to do a comparative effectiveness research study on a biosimilar, you'd have to be able to distinguish who got which. Not all EHRs are good at doing that. But you'll see that we have improved from 50 to about 76 percent of the instances where a patient got the drug. You could distinguish whether it was the biosimilar or the original branded agent.

And this is latency. One of the reasons

that the data only goes through mid-2018 in what I showed you overall in table one. But they the sites and the DataMarts continue working on shortening that time and is now down to just about three months from the time that data are entered into the electronic health record until they're reliably into the common data model and available.

This just shows that in the last quarter we had six new studies in PCORnet and they were all externally-funded studies. So the green, or the externally-funded, the orange are co-funded and those were mostly the PaCR awards from about a year ago, and in the blue are PCORI-funded.

This is Front Door activity. And the Front Door mostly happens through the coordinating center. And you'll see that there were 29, 22 queries of the Front Door in the most recent quarter. They come from funding agencies. They come from -- and organizations, companies. They also come from individuals who may be thinking about submitting an application. So a lot of them are just early queries, but this shows the proportion, that it

hasn't changed dramatically over time. Industry maybe has gotten a little bit larger in terms of the proportion. I should say that these pies kind of hide the fact that the numbers are increasing year on year. But the blue is PCORI and the green is federal inquiries from federal funders. And then the red is not specified, not indicated. And those may be preliminary queries from -- particularly from individual investigators.

Now I'm going to show you updates on three clinical trials that have been conducted or are being conducted in PCORI and I say clinical trials, but one of them, the second one is not a clinical trial. This is a clinical trial an NHLBI-funded clinical trial of using increased -- a double dose of flu vaccine in persons with congestive heart failure to see if that confers added protection.

There are four participating organizations. A network in Canada, a non-VA U.S. network, a VA U.S. network, and PCORnet. And the point here is that PCORI uses -- PCORnet uses electronic identification methods and cross-network

collaboration to enroll patients. PCORnet has had the fewest sites, 25 sites in the third year were PCORnet sites, but delivered the most patients per site and in year three was tied for the highest enrollment rate. So probably because of its streamlined electronic methods PCORnet is somewhat more efficient than the other collaborators in this multi-institutional study. There's going to be one more year of enrollment this fall. And my understanding is that trial will be concluded at that point.

This is the large cohort study of patients with congestive heart failure, with systolic heart failure, some of whom are given a branded agent, a new agent for treating heart failure and others who get the more traditional therapies for heart failure. And it's a study, a cohort study of 400 patients with chronic heart failure and it's entirely focused on patient reported outcomes of physical limitations, symptoms, self efficacy, social interference, and quality of life.

Again, the electronic recruitment

techniques were used, that a lot was learned from ADAPTABLE in launching this study. And this study actually completed enrollment ahead of schedule, 400 chronic heart failure patients. And the final study query for this will be done in late summer of 2019.

And this is ADAPTABLE and I'm very happy to tell you that ADAPTABLE is now at about 14,300 enrolled patients out of a target population of 15,000. So they are preparing for a massive celebration in June.

Just to remind you, the patients are enrolled electronically, most of them, a few in the clinic, but about 90 percent are enrolled electronically using email and the Portal. Follow-up as either by telephone or via the Portal for patient reported outcomes, medication use, and health outcomes. And follow-up is enhanced then by linkage to CMS and to commercial payers. So a lot of linkage goes on in this study.

And so, I think the results are due out either toward the end of 2020 or early 2021.

And this is a study that's not funded.

This was an application that really put a lot of pressure on PCORnet to work together. Seven, all-eligible PCORnet networks. That is seven. One is a pediatrics network and that's not eligible and the other is an FQHC network that did not have enough elderly patients for this study of the effectiveness of using lipid lowering agents in persons, I think it's persons over 75, if I'm not mistaken.

So this would be a very large study. The submission is in, this is funded by multiple institutes at the NIH, and the review takes place this month. So we will know soon how they did.

So just back to the end of the presentation to ask if there are any other questions about any aspects of this report in the dashboard.

CHAIRMAN NORQUIST: Chris.

DR. SELBY: Okay, Chris.

DR. FRIESE: Thanks Joe. This is really nice, a lot of great stuff here. One question I had -- it was sort of triggered from the PCORnet conversation, but going back a little bit, is the very nice uptake of the Pediatric Antibiotic Study.

And so, we now see that IDSA has adopted that. I'm wondering if we can go a little farther to say or examine whether health plans have now integrated that into their coverage decisions for those kids, so that we have actual policy change from the research. That's question one. Then I'll ask question two.

DR. SELBY: It's an excellent question. And, you know, we do stay in touch with the principal investigator from that study and we've talked about actually conceivably through PCORnet monitoring the trends over time and the actual performance. I'm not sure. I wouldn't know whether this was a good one to actually institute a coverage policy on or not. I don't know -- I mean, given that it's so clinical and if clinicians, it may be the kind of thing we're clinicians seeing this evidence spontaneously convert and you don't need to do it and you don't need to then make it difficult when there is the rare patient where for whatever reason you really do feel you should use IV line. So we'll see. We'll put that into the mix of

questions we asked the investigator.

Your second question?

DR. FRIESE: Yeah. And I just think --

DR. NORQUIST: Wait, a minute [off microphone].

DR. SELBY: Oh yes.

DR. LEVINE: Yes, a pediatrician reaction to your question. I think, it's an important question as to the degree of uptake into clinical practice of the guidelines. I second Joe's comment that this would be a very problematic issue or problematic way of approaching coverage decisions because there's too much clinical nuance with little kids and it would be very difficult to try and implement this as a coverage policy.

DR. FRIESE: I guess the broader point is downstream uptake, after the guideline is probably the better way to ask that question.

The second point I wanted to make was about the peer review data that you showed and the fact that we haven't been able to really hit that six month target. And what I didn't see in the

presentation, maybe we can dive a little deeper at some point is, I saw a variety of potential areas where that process is delayed both from the investigator providing information in the review process. Do we have a really good sense of where the lag in the time occurs within that whole process? That might be an area for QI work or other efforts?

DR. SELBY: We have looked at it. I'm not recalling exactly, my recollection is that, you know, it falls somewhat more on the investigator.

In other words, sending things around in the investigator's office than here, but we can get back to you on that.

Sharon did you still -- should we -- I'm sorry, Alicia.

DR. FERNANDEZ: So great presentation Joe and so wonderful to see PCORnet bearing fruit on the interventional studies. And that's really, I think, where we're actually seeing a ton of movement and I think we should feel very good about that. And important research questions like the flu one.

I want to come back to the slide on the observational stuff, slide number 33, and ask us or you if -- and we may need to just come back to this.

DR. SELBY: This one?

DR. FERNANDEZ: No, 33 on my slide deck.

DR. SELBY: Thirty-three.

DR. FERNANDEZ: That one. Sorry. Oops. Did I do that?

DR. SELBY: No, no. Yeah, you did it.

DR. FERNANDEZ: But the next one, because these are CRNs, and CRNs are by definition selective population groups. But the next slide has the data on the health plans. It's unusual for breast cancer to be concentrated in the pediatric group and to have 40 percent in men, and it would be unusual for asthma to be concentrated among adults and be 99 percent among women.

So there is -- I think what I'm trying to say is that these sorts of results indicate that we still have a ton of work to do, so that they can be so that PCORnet can be used and I'm not even going to touch the race stuff, because you know it's

federally mandated.

But it just shows that we have a lot of work to do to be able to get results that are somewhat useful for observational studies, which of course is of such importance, both in terms of all of the things that we want to do. So for all the things that we want to do that are public health related.

DR. SELBY: Thankfully.

DR. FERNANDEZ: So all I'm saying is I love where we are with PCORnet. Love it, love the interventional stuff. We should all feel really happy with that and continue to support that. But we do need to do a little bit more to support the quality of the data. And I'm wondering where are, where we are with that.

DR. SELBY: Okay. Who's next? Janet and Barbara.

DR. NORQUIST: Let me -- at some point -- [off microphone].

DR. FERNANDEZ: Where are we with the in terms of -- or does that come later in the meeting?

DR. SELBY: I think I just owe you a report back on this.

DR. NORQUIST: Okay.

DR. SELBY: Yeah.

DR. FERNANDEZ: That's fantastic.

DR. NORQUIST: Okay. So a little bit more detail. Actually Barbara and then Ellen.

DR. McNEIL: So I just had one quick question. I'd be interested to know Joe and what happens in PCORnet to the Front Door inquiries from a couple of years ago. Did they actually lead to data? Do they actually lead to grant submissions from somebody to someplace because somebody must have those data?

DR. SELBY: That's a good question. I can tell you that. I think most of them, without a doubt, most of them have not led to projects. Most of them are queries, you know, they're preliminary -- they're inquiries about whether PCORnet could be a good place to do this, for example. So I think that will probably always be the case.

DR. McNEIL: So, but just following up on

that, some of those came I thought from fiscal year ‘16 or ‘17.

DR. SELBY: Yes.

DR. McNEIL: So it would be, I would think it would be unusual to have six or eight Front Door inquiries say three or four years ago, and then to find out that PCORnet was not an appropriate vehicle for doing those studies. Is that what you're saying?

DR. SELBY: No, not necessarily. I mean, it could be that the query either suggested that it wasn't a problem, you know, that there wasn't enough use that the suspected exposure just wasn't happening. You know, for example, PCSK9s, one might want to know if PCSK9 could be studied in PCORnet. The answer is no because it's not -- it has not really taken off in terms of use.

Okay. Who's next?

DR. SIGAL: Joe, I had a question on the lab tests and something on biosimilars and I’m happy that you were doing some concordance on them because it's an area of great concern and differentiation.

Can you explain exactly what you're doing? What -- how -- what's the sample size is and how you're making sure they are coordinate? And I have follow up on that.

DR. SELBY: No, I can't personally. This was something from the PCORnet dashboard that they use to tell us about EHR prescriptions, which is a suspect area. Prescriptions from an electronic health record are -- have not been widely studied yet. And so, I can't -- I know that there was an inquiry about this, so probably had to do with "could you do a study?"

DR. SIGAL: Yeah. But this huge variability and it would be nice to understand. The other thing is you mentioned biosimilars on the EHR. Were you talking about biosimilars or generics or just prescriptions?

DR. SELBY: No, this was a specific biosimilar.

DR. SIGAL: Yeah, it would be interesting, one of these days to do some comparison testing on that, but that's another whole issue.

DR. NORQUIST: Okay, Bob.

DR. ZWOLAK: Thank you Joe. Overall, this was a most reassuring report and it's wonderful to see things working out so well. I have a question and a comment. That the questions on slide 35 regarding the completeness of the lab tests and we seem to be stuck in the mid-90s for several of these tests and since there are only 47 DataMarts, that means two or three of them are noncompliant.

Is there ever any hope of capturing those last few or are there barriers that we should know about?

And the brief comment back to Alicia, is on page 33, I believe the columns -- I believe the columns of breast cancer and asthma are just flipped.

DR. FERNANDEZ: I agree. I was just, I was just letting Joe now. It’s as if they were flipped and it’s actually okay.

DR. SELBY: Would you like to elaborate on that? Like five more minutes of you know, explaining that. Thanks. That's helpful. And I

think you're speaking now to Alicia's question about the quality of the data. This is something that when PCORnet talks about governance, one of the issues it's got to talk about is what are we showing to each other and what do we do about sites that over quarters, over a year or more, just don't get it together. And you know, I think that's ongoing discussions between PCORnet and PCRF and PCORI right now.

DR. NORQUIST: Okay. Janet.

DR. WOODCOCK: I want to follow up on Chris's comment. I think it's really important to follow this research all the way to practice and see how from what extent it's implemented. So the antibiotics, you could use something like claims data to figure out the degree of conformant over time and you wouldn't need to necessarily look at the insurance companies.

They could go through Reagan-Udall IMEDS program or something like that and not use the sentinel data to see whether there's any shift in practice. We do that after on a box warning or

something to see if people start conforming. I think for all PCORI studies it's really important, not just if they're published or whatever, but to see what impact and be able to demonstrate what impact they've had. And I think doable in many settings.

DR. SELBY: Thanks Janet.

Okay, good. So thank you all. We're going to go now to the report on our portfolio analysis, unless there's any other suggestions for changes to the dashboard or new information on the dashboard?

DR. NORQUIST: And I think if there are others that come up, certainly email them to Joe or let him know it doesn't happen today. It doesn't have to be the final say on it.

DR. SELBY: Okay. I'm going to try and be very brief and, and turn to Penny for the specific discussion of the telehealth portfolio. But this is just a very brief overview of our portfolio in general. It may occasion you to think about what else you'd like to know. We can take -- we're going to do the in-depth look at telehealth and then we're

going to ask you again about other topic portfolios, we've already gotten two or three of those.

And so a brief reminder, this is the number of broad, pragmatic, and targeted PFAs. We've issued a number of studies that we've funded and the amounts of money that we've distributed. A little less than half is in the broad, a little more than half is in the larger studies, the pragmatics and targeteds. And by the number of studies and by the amounts funded, this just shows you the topics. High burden conditions predominate, you know, that's true in both the broads and the targeteds.

This is populations of interest, just to show you that an awful lot of our investment in our projects do focus on one or more priority populations such as racial and ethnic minorities or low-income and it makes a lot of sense since that's where poor outcomes tend to cluster.

Over a half of PCORI studies are led by a principal investigator with a medical degree. So that -- this is in contrast to NIH, which funds a lot. The majority of its research does go to PhD

researchers. Not surprisingly, since we are purely clinical research and real world clinical research, that the majority of our investigators are clinicians and internists followed by surgeons, pediatricians, Hem/Onc and psychiatry are the most frequently funded PIs.

This always surprises me a little bit that fully 76 percent of our studies are randomized trials. I think I would have guessed it would have been closer to 50-50, but it's a combination of what people submit and what the reviews sections like and then a very, very small amount of quasi-experimental research.

And just to show that out of I think 452 studies, 365 have health status and well-being as well as the outcomes. And also that we measure clinical outcomes in just about as many as we measure any patient reported outcome. But we do have, and are known for, having a lot of patient reported outcomes in our studies.

This is an interesting slide that simply shows arrays common clinical conditions by their

national per capita expenditures and stroke is at the top and autism it looks like it's at the bottom, but it's a function of both prevalence in costs per patient. And we have funded more than 260 studies in these areas. I think there are 19 here. Yeah.

And the only thing that jumps out at me here is that it seems a little bit surprising that there's only one osteoporosis study. And I knew I would get a reaction from Sharon there. And really only two in autism is also surprising.

So just, you know, there's sometimes other explanations but it's worth keeping an eye on this.

Yes. Janet.

DR. WOODCOCK: What about substance abuse? Is it across --

DR. SELBY: I guess that it's not, it wasn't counted as a condition in the same way. I mean --

DR. WOODCOCK: Because it underlies, it cuts across so many.

DR. SELBY: Yeah. I noticed that obesity is not on here either. And so, this must be a very

narrow definition of the word clinical.

MR. BECKER: Joe, these are the ones we funded. Is there a companion list of the numbers of submitted?

DR. SELBY: No. You know, our data systems are just beginning to catch up. We have great data now I can say on the numbers of -- on all of our funded studies, we are just now getting the application data cleaned up so that we can do, there's any number of interesting questions there. Is it because they didn't get submitted or is it because they got submitted, didn't get funded? So we will have that in the not too distant future.

In fact, this slide just speaks to the -- it says, in fact, just that we're going to have growing information on applications.

Sharon.

DR. LEVINE: Yeah. The other question, I had was maternal mortality.

DR. SELBY: Maternal mortality. As I was looking at this list yesterday or the earlier -- last week, I think -- I can't remember what it was,

but I noticed one, too. So it's a funny list in terms of costs, you'd think that maternal -- I mean that may not -- I mean that may not rise to the level of one of the top 19 in terms of costs.

DR. LEVINE: Well pregnancy certainly is.

DR. SELBY: Yeah. Yeah.

UNIDENTIFIED SPEAKER: Could we get a copy of the study that generated --

DR. SELBY: That generated that --

UNIDENTIFIED SPEAKER: That was used to generate the list?

DR. SELBY: I'm sure we can.

UNIDENTIFIED SPEAKER: That would be helpful.

DR. SELBY: Yeah. Okay. So I am going to just turn this over now to Penny Mohr and here comes Penny.

Penny seems to have her arms around any number of portfolios. She is also known as one of the three project officers or scientists at PCORI who knows a ton about opioids, but telehealth is Penny's and she's got a very interesting

presentation that I think a lot of you will be -- have comments on. And this is, as I said, the first of these types of presentations and we have a good time for it.

MR. MOHR: Okay. We're ready to go?

UNIDENTIFIED SPEAKER: Yeah, go ahead Penny, thank you.

MR. MOHR: Fantastic. I'm really glad to be the inaugural presenter today for a little slice look at our portfolio. I think telehealth is a really good area to start in because you'll see we have a very healthy investment in this particular area. So I'm going to give you a little bit of background about the environment in which a lot of these studies are taking place.

As you know, there's just been a rapid change in health delivery and telehealth is part of that story.

And then I want to get into a bit more detail about our telehealth portfolio, highlighting a couple of the studies. And I also want to talk a little bit about some of the initiatives that we

have ongoing, which I think are pretty exciting initiatives to try to better understand this portfolio and put it into context. And then I'll end with some potential remaining gaps, because I think this was something that several SOC members had specifically asked us to look at.

So right when I began, I want to make sure that we are all on the same page, because when I say telehealth a lot of my colleagues may think of something very differently than I think of. There's a lot of definitions. In fact, there was an article published not too long ago that showed that there are 104 different definitions for telehealth.

So when we first started out looking at our portfolio, we had to circumscribe what was in and what was out. And the approach that we took was to use a fairly broad definition of telehealth. So we require that if information is exchanged from one site to another. So specifically, we are not looking at the use of web portals within a clinician's office. We also require that it be electronic communication. So voice only

interactions are excluded. Again, this is just the way we're circling this portfolio.

We also thought it would be very important to define a couple of other areas which are commonly thought of when you think about telehealth, specifically telemedicine, which I think a lot of people is more the traditional way they think of telehealth. This is really the two-way, real-time interactive communication with the provider and their patient to evaluate, diagnose, or treat a condition.

To this definition we've also added asynchronous communication, which specifically is like in teledermatology where you take your images and you upload them to the web and your dermatologist looks at them at a later date and communicates at a later date. It's not real-time.

We also thought it was important to talk about mHealth, because again, this is an area that a lot of times people think of as part of telehealth.

Now for mHealth we had a very broad definition. It's just the use of mobile or wireless

devices to improve health outcomes or health care services. And one thing that's a little bit different about this definition from the broader definition of telehealth, is that we actually allow for you unidirectional communication in the mHealth. So for example, a lot of text messaging that goes to support behavioral change. That's something that we have included when we circumscribed this portfolio.

So I did ask myself, why are we attracting so many studies in this particular area? And I, from my perspective, I think there are three major reasons why we have so many -- funded so much work in this area. And two of them are reflected on the slide here in green.

The first is that I think a lot of the research gaps that we have seen in the area of telehealth reflect a lot of PCORI's mission. And I'll get back to that in a little bit. The second is I think that telehealth affords patient-centered care. Specifically, it can provide delivery of care when and where it's needed for a patient in the comfort of their home.

And also there's personalization of the interface. So there's a potential to address the issues related to low health literacy or issues related to cultural preferences. You can potentially tailor the interface and address some of the barriers to care.

With respect to -- going back to some of these research gaps, we see there's a lot of literature in this area, but there is still a lot of poor quality literature. There's a need for more robust comparative studies, specifically head-to-head comparisons of functionality and integration. And also, a lot of the research that's out there has focused on acceptability to patients. I think this was raised by somebody earlier. You know, it's pretty soft outcomes or outcomes looking at a feasibility of the technology and not really focused on those outcomes that are important to the patients.

The other thing is that a lot of telehealth studies have tended to be concentrated in the technologically literate population. So these tend

to be the whiter population, the younger population, the population who was very facile at the use of technology. And there's a need for understanding how it can be used to potentially reduce barriers to care for more diverse populations and in also more diverse settings.

And finally, a lot of the systematic reviews that we looked at have said that there is disconnect between the technologies that are being studied and what is actually acceptable to the patients or acceptable to the clinicians. And so, what you find is there's a lack of integration into the workflow. Patients stopped using it. And so there's a need to engage patients and clinicians and other end-users early on in the development of the technology. And this has been stated quite frequently. And this is engagement. This is what PCORI is all about.

The other reason why I think that telehealth has also -- we have so many studies in this area, is just the environment. The delivery system is changing rapidly and there's a lot of

uptake of telehealth. And one of -- the parity laws is one example of this. So parity laws, basically states require commercial insurers to pay for telehealth the same as they would for an in-person visit. The definitions vary by state-by-state, but here shows what it was like in 2000. And when we look at 2018, we actually see a pretty dramatic change where there's only 10 states now, as of last year, where two parity laws were not in place or were not under current content consideration.

So parity laws did result in a major increase in the use of telehealth within commercial insurance among other things. And you can see here the growth in the use of outpatient telehealth service based on a look at a commercial health database in the line in blue between 2010 and 2015 over this five year period versus those in non-parity states in the orange line. And there was basically a four-fold increase in outpatient telehealth services over this five year period.

Now we, this is just commercial insurance. We also see major growth occurring in public

insurance, and of course, within the VA. I have to say though, although we see these dramatic changes in growth, this over a very small space, a modest space. And so, we still have a lot of people who are not using telehealth. It hasn't had that great of a penetration yet.

The other thing that is really changing of the uptake of telehealth is trends in coverage. And specifically last year Medicare really made some major changes in what they will pay for now for telehealth. Under the Medicare Advantage plans, it allows a more flexibility in coverage for telehealth and also within their physician fee schedule they've created something called a Brief Virtual Visit, which really wasn't reimbursed before and expands the coverage for addiction treatment. Just among a few things to mention.

State Medicaid programs have also been expanding coverage. And recently some states have moved towards eliminating what we call originating site restrictions, which basically require that patients be in a clinic to connect with a distant

provider and now they can receive services in the home in those states and get reimbursed for that.

Now I want to dive into our portfolio. There's a lot here and I apologize if I -- you know, I'm going to go through this fairly quickly, but as I said before, we have invested a lot in this area, over $350 million supporting over 80 projects. And back to the definitions that I said earlier on, the bulk of what we've invested in is in mHealth.

It should be noted though that a lot of the studies that we have invested in actually use multiple modalities. So for example, it could be using telemedicine but have developed an app that supports the patient in-between visits.

So looking at when we are expecting research results, right now we are -- about half of our studies have ended their research period, which means they've completed the research. That doesn't mean that we have the full final research report. And there are actually 14 studies at this point that we have the full final research report that's published on our website or that the final seminal

results have been published in the peer reviewed literature. So we're just starting to learn about what are the findings from this portfolio.

What I can say is it's mixed at this point. So we have a handful of studies that show very positive findings. So for example, we have a study in teledermatology that was done looking at the use of collaborative care, linking primary care physicians with dermatologists and the patients in their home. And what that study found was improved, both clinical outcomes, improved quality of life, and markedly improved access to care. So this is a fairly important study for dermatology.

By contrast, we have another study that was looking specifically at the use of telehealth in peripheral artery disease. And in that particular study they used a wearable device and provided consultation for home, walking exercises. And what they found in that study was telehealth was not as effective. And in fact, we actually found an increase in pain among that population that was using the telehealth.

Then there's a handful of studies that are what we call mixed, as well, with the findings. So we have some studies, for example, in HIV where they were providing access to an iPod that would provide information for helping patients manage their disease and provide better education about their disease and hopefully improve adherence to medication. And in that particular study we found the medication did not improve, but patients were much more involved and engaged in their care.

Back to the slide that Joe presented earlier in terms of by study design, we see that over 96 percent, well 96 percent of our studies in telehealth are randomized controlled studies, which is higher than the portfolio overall.

And most of our studies are moderate in size, but a very important aspect of this portfolio is that there are a significant number that are large. So we have over a third of our portfolio that have been enrolled that are enrolling over a thousand patients, which is pretty significant given that a lot of the literature has been focused on

single site studies and also that there's been that a lot of people have said it's very important to understand how this can be rolled out and be more generalizable across different settings, across different states with different reimbursement barriers and the challenges there, as well as the different population in the heterogeneity of uptake and also a impact in different populations.

This is one example of a very large study that we funded recently. This is a response to our targeted funding announcement in palliative care and this study is being conducted in over 1,200 patients and enrolling over 900 caregivers in 20 institutions across 17 states. It's being led by Jennifer Temel and specifically it's comparing the effectiveness of early integration of palliative care delivered by telemedicine versus in-person visits. This basically is addressing a shortage of palliative care providers as well as a shortage of space for providing palliative care and allows access to palliative care services in remote areas.

Oh, I did want to say one more thing about

this study. One of the important things, again, because it's very large, is that it is allowing now to be able to look at differences both in terms of the technological expertise of the people that are being enrolled, the health literacy. Also looking specifically at differences in terms of access to caregivers. So this is going to be a very important study.

Looking at the portfolio by the number of -- by types of conditions that are being addressed, the main point that I wanted to say here is that it's very diverse. It spans a lot of different diseases and conditions. Now we do have a concentration in those areas where telehealth is commonly used, specifically looking at telemental health and also in the use of mHealth for managing diabetes or congestive heart failure.

But an interesting thing about this portfolio and when we looked at the systematic reviews that some of the specific disease areas that have been called out as major gaps in evidence for the use of this technology; cancer, rare diseases,

and also reproductive and perinatal health. We have some studies in those areas. And one way to look at telehealth portfolio is by its purpose. And I think the main point here is really to say that, again, consistent with the fact that we've funded a lot of studies in the area of mHealth is that a lot of the focus of our studies is on promoting self-efficacy and knowledge. And a smaller number of our studies are looking at improving access to primary and specialty care, which is more traditional thinking of how -- what telehealth is used for and a much smaller number in remote monitoring.

Another thing that I think is very unique about our portfolio, which I think also is reflective of our portfolio overall, not just the telehealth portfolio is a large number of our studies in this area, almost half target the underserved population. So we have some really interesting studies that are looking at management of chronic kidney disease in the Zuni Indian population, linking patients in very remote rural areas in Alaska to audiologists for hearing

screening and exams among the Alaska Native population. And also we have studies that are looking specifically at cultural tailoring for the African Americans in underserved populations in the South for self-management of diabetes and that specifically is comparing the use of mHealth application of text messaging, culturally-tailored text messaging to the use of community health coaching.

A lot of people ask what kind of modalities are covered. And again, this reflects that a lot of our studies are focusing on mobile phones or tablets, but again, a lot of our studies really do incorporate multiple modalities. So although web portals is the major focus, those are web portals that can be accessed through a variety of different devices.

Yes.

DR. SIGAL: Just a clarification. You just brought it up. So when you're talking telehealth you're talking about telephone, right?

MS. MOHR: So telephone voice-only

interactions have not been circumscribed within this portfolio in what I'm talking about now. We do have studies in that area, but they're not, well, included in our telehealth portfolio.

DR. SIGAL: Okay. So more mobile, because I was trying to figure out, you can never get anyone anymore.

MS. MOHR: Yeah. You know, this is through apps and mobile phones. Yes.

DR. SIGAL: Okay. But then you get into the caregiver and the ability for people that are not so good at these devices --

MS. MOHR: Exactly. Yes, exactly. That's right.

DR. SIGAL: Okay, great. Thank you. Sorry.

MS. MOHR: Yeah, no problem.

Regarding the outcomes that are being studied, as I mentioned, one of them. Yes. Sorry, there's another question.

DR. LEWIS-HALL: Yeah, I just had one quick one. I guess Ellen spirited it. Are any of these

facilitated caregivers? And by that I mean, there may be like the Arvind Eye Care Center in India where, you know, young women out in remote villages are using the technology themselves to facilitate others. Or is this all the individual that is affected is facilitated?

MS. MOHR: It varies a lot and what I can say very preliminarily, but what we are seeing is that the importance of potentially having a person there to work with the person that is interacting with the technology is very important. So for example, we have a study that's using what we call mHealth specialists that are there or peer navigators are often a very important component of this.

So a lot of our studies are focusing, just as our portfolio in general, on those outcomes that are really important for patient's health status and well-being, representing 90 percent of our studies.

I did want to focus on another study and this study I selected specifically because in addition to it being completed and finding some very

good findings, this study has been awarded a dissemination and implementation award. So this particular study was looking at the use of telemedicine for delivery of care for people with Parkinson's disease in their home. It was a randomized controlled trial with 200 patients and it spanned a lot of the United States. It found that telehealth was feasible. There are high levels of satisfaction and there were no differences in quality of life. The study has now been awarded a dissemination and implementation award. And basically what this award is doing is it's allowing the study to expand the reach to rural areas.

Yes. Sorry.

DR. McNEIL: [Off microphone] -- a little bit more about what the telehealth vehicle was.

MS. MOHR: Yes, it was actually, I'm sorry, I'm just trying to go through this really quickly, but it was telemedicine. So it was a link through, I think it was Blue Jeans that they were using on a web portal in the patient's home to connect with a neurologist.

DR. McNEIL: I'm sorry.

MS. MOHR: So it’s a consult.

UNIDENTIFIED SPEAKER: [Off microphone.]

MS. MOHR: Oh, it's consultation with a doctor, right. Yeah.

And so now what they're hoping to do with this study is to reach a broader array of population with racial ethnic minorities, low-income, and the elderly, and also to expand the intervention to include multidisciplinary care to address some comorbid conditions such as anxiety, depression, and dementia. And the interesting thing about this study is it's actually being implemented statewide in the state of New York, where care is being provided free of charge through a nonprofit Parkinson's disease foundation. And they're also looking to build national capacity by training neurologists throughout the United States and Allied healthcare workers in telehealth, and also in Comorbid disease management. Yes, Janet.

DR. WOODCOCK: Thanks. Are these looking at physician satisfaction as well? Because again,

this implementation all the way into practice, it's going to be important to see how well this works for the doctor as well as for the caregiver and patient in my opinion.

MS. MOHR: Absolutely and I'm going to get to that just shortly, but I do want to say that some do and some don't. Yeah.

And so, it's also worthy to note that within PCORnet we have some of our partners -- the partners that we've funded in the Patient Powered Research Network using telehealth, specifically using mHealth component to incorporate data from mHealth apps and wearable devices into the data network and capturing patient generated data for research.

Now, let me get to a couple areas that we have some very interesting initiatives on. Somebody mentioned our evidence maps that we've funded. We did this particular slide I want to emphasize is not a slide that -- I hope that you can digest, there's a lot here, but I do want to say that these evidence maps that we've funded are interactive. And there's

a link here on the slide and you can go in to our website and find out more about this.

But what is an evidence map? Basically it's a rapid, systematic review looking at other systematic reviews and it's some summarizes the information visually so you can help understand where are the gaps in evidence, where there's a concentration of evidence, where we have stronger confidence in the findings, and was very helpful for us to understand specifically what our portfolio was doing in terms of addressing some of these gaps and where we might potentially need to go in the future.

And some of the key findings that we came away from, from this particular evidence gap is, as I mentioned before, there's a lot of research in this area. They looked at over 500 systematic reviews that were published over seven years just in mHealth for self-management of chronic disease. They narrowed it down to just under 100 that we're assessing the strength of evidence.

And then, when we overlaid our studyies over this evidence map, we actually found that our

studies are addressing some really important gaps, specifically vulnerable populations, which I mentioned before. We have some studies in the pediatric populations that have been understudied and also the measuring of patient outcomes, which I mentioned before.

The other thing we did was last May we hosted a meeting with stakeholders and specifically to look at what do they need to know from our studies before the studies are published so that potentially that we can improve uptake and implementation. And this gets back to the point, I think, Janet, that you made specifically that there's been a lot of concerns about in long-term adherence with technology. And we need to know a lot more, not just about patient satisfaction but also provider satisfaction in the experience that contributes to adoption and the lack of interest or sustained use and discontinuation.

Also you know, we fund comparative effectiveness research studies, but it's not just whether it works and whether it works better as

well. But what we really also need to report out is the contextual factors that make it work. What are the type of support personnel that are needed in order to make it work? What training is needed and those types of requirements.

So we have been reporting this back to our investigators. We also have established some -- just recently some investigator communities focusing on very different slices within our portfolio where we have a large number of studies looking specifically at addressing vulnerable populations and we also -- looking at mHealth for self-management of chronic disease and challenges of implementing multisite telemedicine trials.

Now the reason why we've done this, is we want to get investigators together to discuss some of the common challenges, what are some of the insights from conducting these studies and potentially leading to a publication that highlights our portfolio in these areas as well as highlights some of the lessons that they've learned as a community.

The other thing that we've done is we have actually funded several engagement awards in this area and this is just one where we have funded the National Academy for State Health Policy and they are looking at ways to better share the information to potentially understand what is needed in order to implement actionable telehealth research. And this is ongoing.

So I'm sorry, this has been really a whirlwind. There's a lot here in the portfolio, a lot that I didn't get to and I don't want to be too didactic, but people did ask specifically for these gaps. And this just shows some of the gaps that we've found in recent systematic reviews that we have not addressed that well with this portfolio. Specifically head-to-head trials of mobile apps, maternal and child care.

While we do have one study, there's more that can be done on looking at management of serious pediatric conditions, specifically child adolescent suicide and some of the other things that apps have great potential for that we don't have a lot of

studies.

That being said, this does not say that this is the most important area for us to be investing in the future. We need to talk with stakeholders and weigh these gaps with the importance of other areas that we could potentially invest in.

And with that I will turn -- well, I do want to thank all of my colleagues. I have -- there's a lot of people that I've been working with and just a great staff that I work with at PCORI for this. So thank you.

And onto the questions and I don't know what order, but --

DR. GOERTZ: I think we're starting with Sharon then, Gail, then Kara.

DR. LEVINE: Just do you know if the Parkinson's work is connected to ParkinsonNet, the international -- because they tapped into the International ParkinsonNet mobile telehealth community?

MS. MOHR: You know, I would be surprised

if not, but I don't know the exact answer to that. I can find out.

MS. HUNT: Yeah, I'm sort of following up on Janet's question do we -- we've learned, you said, from a number of these projects that perhaps they were not looking at the providers satisfaction with the technology, focusing really more on the patients.

So because we've learned this is an issue, when we look at doing future projects, can we build in to the RFP that that's something that needs to be looked at for the future? That they need to look at that. And actually, I think that's going to be true of many of PCORIs, if not all of PCORI's future projects that we build in this issue of provider satisfaction with whatever the outcome is?

MS. MOHR: Yeah, I think that's a very important point. And what I can say is after our stakeholder meeting that we had in May, all the projects that we funded in this particular area during the sort of negotiation period, contract negotiations, this is a message that we convey to

people. And so, it is part of some of the negotiations that we have with our projects saying, you know, this is what we hear from stakeholders. How are you building this into your project?

DR. GOERTZ: Kara.

DR. AYERS: Yes, so we know that some people don't use these technologies because they may not be tech savvy, but we also know that some people may not use them because they're not accessible. So I was wondering, is there any reporting out or is it something that's discussed in the investigator group about accessibility?

And just another reason why I'm thinking of this is, you know, if they are successful and they do move to practice, you know, then they would be required to be accessible. So, and I'm thinking of like screen readers and for patients who are deaf and other modalities of accessibility.

MS. MOHR: Yeah. So you're thinking more about more -- yeah, that I don't know about, but I think that's a really important point and something to be thinking about.

DR. GOERTZ: Barbara then Larry.

DR. McNEIL: Okay, that was a terrific presentation. So with regard to cancer and the lack of enough data in that portion, are you thinking about studying more in virtual visits?

MS. MOHR: Yeah, that's really the area that we don't have anything in. We have more in symptom management.

DR. GOERTZ: Larry.

MR. BECKER: This is amazing. I mean, there's so much richness to this. I wonder if we have thought about pulling it all together into a series of toolkits, CME-kinds of things, seminars for various audiences to help communities, insurers, physicians, all the different stakeholders, prepare them educate them so that these things can be most effectively utilized.

MS. MOHR: Yeah. So I think there's a two-prong strategy that we have going on here. Like I said, the engagement has made three awards in this area with some of that intent. And I can also say that for example, one of the webinars that we have

with the investigators is focusing on challenges of implementing multi-site telemedicine studies. Really then you get into scope of practice, issues related to regulatory changes across the state. We have some studies that are spanning, like I said, 20 different states and they're running into all sorts of barriers and coming up with really interesting solutions.

So hopefully developing a blueprint is what we're hoping with these investigators. And we had our discussion just last week and people are pretty excited about that idea.

DR. GOERTZ: Thank you. Frieda.

DR. LEWIS-HALL: So I had two questions. One is Kara -- you reminded me of this, does trust come up as a deterrent and any of these sub-populations in terms of the use of telemedicine across the board?

MS. MOHR: Yeah. And so, the other Webinar that we're focusing on is what we call Addressing Disparities and we do see differences across populations. Specifically, that teledermatology

study that I talked about had a large Hispanic population. They were enrolling. A lot -- not an insignificant amount of people were undocumented and were really concerned about privacy issues much more so than we see normal concerns. So yeah.

DR. LEWIS-HALL: And then the second question was is any of the work specifically in adherence and is any of that work, in particular in the monitoring, using any of the interim medication and other monitoring technology?

MS. MOHR: Yes. We have some of those studies that are ongoing. The one that I was thinking about specifically was this HIV, looking at HIV medications, but we have some other examples in other diseases where they're looking at adherence -- not only in medications but also in terms of like nutrition and other types of adherence to behavioral change.

DR. GOERTZ: Great. Thank you. Gail, did you still have your -- okay, are there any other questions or comments? Joe?

DR. SELBY: So Penny, I know you know you

sit closer to this than most of us. And I just wonder, and I've asked you this before, how's it going to roll out in this kind of applies to topic after topic, really. How do we know when there's enough? How do we know when we've studied a particular area sufficiently that we should sort of wait, let things happen. I just -- 84 studies is a lot of studies.

So I'm just wondering whether we should fund another 84 in the next four or five years or whether -- and what should they be?

MS. MOHR: Yeah. So Joe, I'm going to tell you what I've already told you by email, and I'm going to say this publicly here, but I do feel that telehealth is a mechanism of delivery. It's a tool. And so, it's a little bit different. Like if we, it's almost like thinking of surgery, you know, there's a lot of -- so many different variants of it. It's hard to kind of put it into this big bucket.

So, for example, if we know that we've funded a study in telemental health and we've shown

that it's very effective in telemental health, does that mean that we shouldn't fund a study that's looking at medication-assisted treatment among patients with, you know, substance use disorders, which it's a very different population, very different in terms of motivating. So I think that it really, it really depends upon the context, it depends upon the technology, it depends upon the population, and that's the way that I look at it anyway.

DR. McNEIL: I think that is a fantastic question, Joe. And I love -- I feel like you did such a wonderful presentation and it really has allowed us to get a much better handle on the portfolio. I think it's a great model for portfolio discussions as we move forward. And I think that is a question that we need to be asking every time we look at the portfolio. I don't know the answer and I think that you're right. I do think it'll push us not to be duplicative and it'll push, perhaps I hope, the field also to not be duplicative.

But doing this portfolio-type review allows

us to ask those questions and it's a huge step forward for PCORI. So thank you very much for your outstanding presentation. Thank you.

DR. GOERTZ: Thank you. Anything else, Joe?

Thank you Penny for that excellent presentation, I think we all really appreciate that information.

We are in the somewhat unusual situation being quite a bit ahead of schedule, so I've actually have asked Kathleen if she wants to move forward with the next item on the agenda prior to our break. And so, I'd like to introduce both Kathleen and Maryan Zirkle, who will be doing a presentation on funds to support implementation of the PCORnet common data linkage method, which is going to be considered for approval.

And this -- we have the following Board members who have notified us of their intention to recuse themselves from the deliberative discussion and to vote on the funding for this project. Those are our Jennifer DeVoe, myself, Freda Lewis-Hall,

and Barbara McNeil. So if any other Board members believe they should recuse themselves from this discussion vote, please feel free to do so.

No, you can stay. Just please don't participate in a conversation or vote.

And I will be doing the same, other than to lead it. Kathleen.

MS. TROEGER: Certainly, thanks Christine. And I was going to make sure you check with Maryan also, but I see her up at the front so I think we're ready to go.

As Christine mentioned, the next agenda item is the voting item, which we'll review a proposal for common data linkage within PCORnet. Joe referred to this earlier, I think we've seen a lot of information about the progress within PCORnet and as some of the discussion has pointed out the importance of then moving toward linkage and being able to get really better clarity with the data.

I want to thank Maryan Zirkle for her work on this initiative which continues PCORI's commitment to optimize linkage and that is really

the ability to connect information between patient records within an EHR and their insurance claims.

We can go to the first slide. This has been a long-term -- click, click? Well, when we get to the next slide, you'll see that this has been a long-term initiative and focus of PCORI to really fund to this work through PCORnet. The effort has been followed closely over the last few years by the RTC. This proposal that you're about to hear from Maryan has been reviewed and approved by the RTC. It was approved for funding in the April 2019 meeting for up to $2 million budgeting committed from the existing $20 million. I'm sorry, budgeting committed from the existing $10 million committed 2019 funds.

I'm going to turn the presentation over and Maryan and thank her for her efforts to lead both the informatics and present the details of the project.

DR. ZIRKLE: Thank you, Kathleen. So as Kathleen mentioned we provided a brief description here. Basically high level dates of sort of how the

thinking has evolved over time in PCORnet around linkage. So starting about three years ago, we did focus more on obtaining complete data in PCORnet. That meant linking several different sources of data, together at the patient or individual level, which require a lot of attention to security and privacy as you know, and it's called privacy preserving record linkage. So you'll hear that or PPRL a lot throughout this presentation and just in general when you're talking about linkage.

During that time, around 2016, one of the major focuses that PCORI invested money in was the linkage between claims and EHR data. So we funded some health plans to work directly with our clinical research networks, as you know, the majority of those health systems bringing in electronic medical record data for them to link the data and test, I think, and work through the barriers and challenges related to linking for particular projects and at the time we called those demonstration projects. After about two years of working in the weeds and trying to better understand the challenges and the

barriers to this linkage, the PCORnet community came together and realized that there needs to be a more efficient way to link in a privacy preserving method, rather than taking these governance and technical issues as a one-off each time they had a project.

And just so you know, sort of what we're referring to, one of the demonstration projects, for instance, it took about a year, the governance is much more time consuming than the linkage itself, but to figure out how they would even link, how they even get to that point and then roughly a little more than half a million dollars to essentially affect this linkage. A lot of that was in kind funds.

So in October of 2018 the PCORI approved fiscal year 2019 commitment plan for the research infrastructure department, which you all know, oversees the development and sustainment of PCORnet allowed for $10 million for infrastructure support for integration and linkage of additional sources as Kathleen mentioned. And then, also for general

expansion of the network.

At the same time the PCORnet community set out to identify what they were calling a common linkage method instead of saying PPRL over and over again. The partners would use each time they did linkage or conducted research in PCORnet so that they wouldn't have to run through this governance issue each time. So certainly lessening the cost and diminishing the time spent to have to do this.

So at the end of last year and then into early this year, they went through a robust search and review process to find a vendor and approach to support this common linkage method. And then, as Kathleen mentioned last month, PCORI RTC who oversees the development and sustainment of PCORnet recommended to the Board to approve up to $2 million in funds to support these efforts.

So now I'm trying to keep this out of the technical components and more high level. I wanted to let you all know who's actually playing a role in implementing this method. And then what they'll do in particular.

So you'll see we have three entities, networks or sites, that's the clinical research networks. You'll hear me say CRNs and the health plan research networks, we call them HPRNs. We have the selected vendor, as I mentioned. The contract is pending so we can't mention the name. And then the coordinating center, and it's basically the data core obviously, so that would be Duke Clinical Research Institute and Harvard Pilgrim Healthcare Institute.

So for the networks and sites, basically they're going to be spending a lot of time over the next two years expanding or amending their existing infrastructures. Certainly we don't want to reinvent the wheel. We've already invested a lot of money in their current infrastructure.

So what they'll do is build out the common data model a little bit more to include tables to support the data needed to do linkage. They will amend their IRB approvals to allow for the transfer of this data. They will actually have to create -- get a new IRB approval rather, to do sort of what

we're calling proof of concept, which is an initial overlap analysis and then a table one or demographics table.

So as Joe just showed you earlier on the dashboard, we'll recreate that table after linking to make sure that we do duplicate the participants or patients covered in PCORnet.

And then lastly, they'll have to amend their data sharing end use agreements again to cover the transfer of the data necessary to complete the linkage.

The vendor and with the software will essentially install that software remotely at the network sites and the coordinating center behind their firewall to ensure the security and privacy of the data. And then, also participate in ongoing technical support or training for the software.

And lastly, the coordinating center, they have the biggest lift here of all the entities. They have to amend some of the querying architecture and develop some new queries to help support the use of more advanced or complex clearing for the linkage

in the future for future studies and I think that you can imagine there's new data, so the queries that they've already created that are reusable, they have to sort of build out a little bit more to hit on that data and be able to execute the query.

So I thought, you know, in and of itself that seems reasonable, but I thought it would be helpful to sort of walk you through what this really means in action. So for instance, I mentioned the overlap analysis, which will be the first piece of this proof of concept. If you keep in mind that everything in green are the CRNs or the HPRNs. Everything in blue is the vendor coming into play here, the software rather. And then the coordinating center in purple.

And if you move with me from left to right, in green, you'll see the CRNs and the HPRNs. They'll transform their data into the common data model behind the secure firewall just as they always do, but now there will be the software embedded that allows for the privacy preserving record linkage to take place and sends encrypted data. A coordinating

center will also have the software in place that allows them to do the same things, same thing essentially and then match the secure data or encrypted data on there.

And so, for instance, for overlap analysis, the coordinating center in the purple, will release a query to the CRNs and HPRNs in green. They will return back encrypted data. And if you look at the lower right hand corner, this will be the output essentially that comes through to the coordinating center so that they can look at the overlap.

The first column, HASH_ID is just a technical term for the encrypted data. Essentially that means that that's a participant in our network in a CRN. The second column shows you if you have a one there that they are also in another CRN and the third column shows you that they are also in an HPRN.

Now again, you'll see the second row shows you that there's a participant that is in two CRNs and an HPRN. Then we have to go through sort of the advanced analytics to de-duplicate and identify and

connect the data and things of that nature. But I thought this would be helpful to sort of let you know how these parts are all working together.

And the last slide here again is just highlighting where these funds would come from. The approved 2019 fiscal year commitment plan as Kathleen noted and I said earlier on included the use of $10 million for linkage as well as expansion of the network. And as I had mentioned briefly, and I think most folks know, this will significantly increase the capacity to readily link data in PCORnet as opposed to dealing with the one-off the time, the costs that incur from that process.

And then lastly, this was recommended by the RTC and we are here requesting approval for up to $2 million in funds to support this linkage method in PCORnet moving forward.

DR. GOERTZ: Thank you very much, Maryan.

Are there any, are there any questions or comments? Okay, Chris.

DR. FRIESE: Sorry. And this is probably just my ignorance in terms of the need for two

coordinating centers, could you just explain why -- it's probably very easy but --

DR. ZIRKLE: Oh no, definitely. The Duke Clinical Research basically deals with the data related to building out the common data model and Harvard Pilgrim is our analytics query fulfillment and tool development group. So they use the -- they create tools to use the data, but Duke actually works at expanding the tables and housing the data in a standardized way.

DR. GOERTZ: Thank you. Bob.

DR. ZWOLAK: This was a very nice presentation and an important project. My question has to do with the ability of the vendor to make a product, which perfectly well preserves privacy of the records. And yet on the other end of the screen would be able to identify duplicates with confidence and eliminate duplication. That would almost seem, if you're perfect on the way out, that it would be nearly impossible to identify the duplicates.

DR. ZIRKLE: So I think nothing in linkage is perfect. I'll say that. And I didn't get into

the review process, but there was a lot time spent as you could see with about four or five months, we had around seven applications come in for folks that were out there that basically spend all their time honing these types of efforts. And there was a lot of detail and time put in to making sure that the security and privacy was at its highest. And you can imagine we have more than 100 systems, health systems in PCORnet and reason why the anticipated period of time to implement this as about two years is because there's an extensive security review that will happen on the front end here with this group to make sure that that's taken into account.

I would say once we work through that, as I mentioned, the overlap analysis is the initial piece of that and then duplication as certainly a little bit more advanced and enhanced. And the approach at this point in time is not totally figured out. That will probably take place in the six to eight months. And so, we'll be coming back to folks to explain how that's going to work and what they'll do. But right now I wouldn't be able to tell you in detail what

they're going to be able to do and I could get you additional information if you'd like in the future as well.

DR. GOERTZ: Alicia,

DR. FERNANDEZ: Just so that we do our due diligence our due role, what are the assurances around the vendor keeping the data versus not keeping the data?

DR. ZIRKLE: Oh, so again, that would be something that I'd probably have to get you in more detail because the technical components would probably escape me. But at this point in time, there is actually no keeping of the data. So it's, there's use of identifiers turned into, I mentioned the HASH_ID, so an encrypted sort of identifier and it's basically the software because it's behind the firewall, that data doesn't go anywhere that it ever went before. It does exactly what it would typically do. And so, there is no movement to the vendor of that data. They actually just help support software that encrypts it.

DR. GOERTZ: Thank you. Larry.

MR. BECKER: So I thought I heard you say, and correct me if I'm wrong, that we don't exactly know how this is going to work yet. And so, I mean there's the possibility this is not going to work because this is an idea and this will turn out to be vaporware. Not that it's not worth going after, but the expectation it, you know, I ran HR technology for years and so how confident are you in this vendor?

DR. ZIRKLE: Yes. So I will restate that it's not that we don't know it will work. That there is high confidence in this vendor and this method that they've used in the past has been used by several of the actual network partners in the past as well as others, it’s been around for a really long time.

The piece of it that is still yet unknown is the approach to de-duplication. So the overlap analysis as I mentioned is, it’s pretty straight forward. But then once we get into a project, it's the idea of making sure that the network partners become familiar with that de-duplication stuff and

the data stays sort of attached in it's encrypted format for use in the future.

So we have high confidence that the method will work. Sorry, I misspoke there. Thank you.

DR. GOERTZ: Great. Thank you. Any other questions or comments?

All right, I'm going to ask for a motion to approve. Kathleen.

MS. TROEGER: [Off microphone.]

DR. GOERTZ: Okay. Thank you. Can I ask each person to identify themselves just to make sure that we get a before making the motion.

So Kathleen.

MS. TROEGER: Kathleen Troeger, motion to approve.

DR. GOERTZ: Thank you. Can I get a second?

DR. WOODCOCK: Janet Woodcock, I second.

DR. GOERTZ: Thank you very much. And is there any further discussion or -- all right.

I'm going to call the question then and ask for those in favor. Please raise your hand.

[Hands raised.]

DR. GOERTZ: Okay. Opposed? Abstentions? Do we have any Board members on the phone?

Okay. Thank you. The motion carries.

We are now going to take a break for about 20 minutes. We will resume at 11:30. Thank you.

[Recess.]

DR. GOERTZ: All right, let's go ahead and get started.

I'm going to introduce Jean, but she really needs no introduction and ask her to start our presentation on dissemination and implementation. Give us an update.

MS. SLUTSKY: Thanks very much. It's a pleasure to be here today and hopefully it stopped raining, but maybe that's the advantage of not having any windows down here is we don't know. Right?

So I'm delighted to give you an introduction to this dissemination implementation project, which I hope you'll find really interesting. It's in process now, but just a little

background about PCORI's dissemination and implementation activities. You all have seen this slide which talks about making sure that our research findings actually get into the hands of people who are making decisions about either their own health or providing health care for others.

PCORI's dissemination implementation program is charged with heightening awareness of the results of our funded research and with advancing those efforts to put these findings into practice to improve healthcare delivery and health outcomes. And this encompasses a lot of activity including the transparent reporting and public release of findings that is derived of our peer review of our final research report. And also is charged with increasing awareness of these findings among the right people, so the people that the research has the greatest impact on and promoting systems for doctors, patients, and others to use evidence to help with real life decisions and to improve care.

This is a relatively new program as you know, under the oversight of the EDIC Strategic

Committee chaired by Sharon Levine and co-chaired by Larry Becker. We've completed 10 funding cycles and made 25 awards. So far the total PCORI investment has been $29 million and the project budgets range from $500,000 to $2.2 million. And so far we have implementation sites in 32 states.

This slide I particularly like because as you can see, our dissemination implementation awards by priority areas for the original PCORI-funded research is almost evenly divided amongst our research among national priority areas. And so, even the Methods portfolio is well-represented. And so, this slide is really illustrative that this is, I guess, we could call it an equal opportunity dissemination and implementation program.

So just to remind you the PCORI dissemination implementation program funding initiative now has three different initiatives. The first to be implemented with limited competition of the implementation of PCORI-funded research results. And this provides our PCORI investigator teams the opportunity to propose next steps to put their

findings into practice. These are limited to up to about a million dollars in direct cost per project.

The second initiative that was implemented last year is implementation of effective shared decision making and approaches in practice settings. And this promotes the implementation and systematic update of shared decision making in private settings and these are up to $1.5 million in total cost per project. And the most recent award announcement is implementation of findings from PCORI's major research investments.

And this is, was approved by the Board last year and it's intended to provide a broad applicant pool the opportunity to propose strategies to put evidence from specific high priority PCORI initiatives into practice in the context of related evidence. And these are larger awards up to $2.5 million in total cost per project.

So what you're going to hear about today from Dr. Cuddeback is about a project that was funded actually through our Methods portfolio called Improving Diabetes Prevention Based on Predictive

Benefits of Treatment. The principal investigator is David Kent from Tufts Medical Center. This PCORI study analyzed individual patient data from 32 studies including the 2002 Diabetes Prevention Program study to see how treatments affect different groups of people. And as you can see, it was published, the main results were published in *The BMJ*.

The study found that the risk of developing diabetes very dramatically across patients and low-risk patients showed little benefit from intense lifestyle modification or taking metformin. High-risk patients showed significant benefit from these interventions.

And so, the D&I project or dissemination implementation project, which is in progress now is incorporating the prediction model into the clinical workflow in the electronic health record so it can be used in shared decision making. They're partnering with the American Medical Group Association to implement the EHR tool at 50 clinic sites at Mercy in St. Louis and Premier Medical

Associates in Pittsburgh.

So right now I'd like to introduce John Cuddeback who is a project partner and he's the Chief Medical Informatics Officer at the American Medical Group Association. So maybe you'll be a little less stuttery than me.

DR. CUDDEBACK: Well, we mostly just say AMGA, so that and there's probably a reason for that.

MS. SLUTSKY: Yes.

DR. CUDDEBACK: I really, really appreciate the opportunity to be here and to work with our partners at Tufts on this project. It obviously is very much a team effort. So Tufts Medical Center, David Kent as the principal investigator, Jason Nelson, a statistician who's been developing these predictive models from the data from the Diabetes Prevention Program, the original study, and then applying that to EHR data. Jean mentioned our two provider partners who are AMGA members; Premier Medical Associates in Pittsburgh and Mercy in St. Louis. Each of those groups has a patient advisory

group for this project and we've learned a lot from them, which I will talk about as we go through. But Frank Colangelo, Carolyn Koenig and Todd Stewart have been wonderful partners. And then our little group within AMGA, our research and analytics group, Elizabeth Ciemins, Jill Powelson and Rich Stempniewicz.

So this is the team, a little bit about American Medical Group Association. We're a 501(c)(6), a not-for-profit trade association. So that means that we have organizations, not individuals as our members and we are able to lobby. Our advocacy is to move the healthcare system from volume to value. And the idea is to align payment incentives with managing population health. And our advocacy group was a big part of the ACO provisions that are in the Affordable Care Act. And so, we've been at this for quite a while.

And then what we do on our program side, some of which is done through 501(c)(3) foundation is to help our members redesign their delivery systems to manage population health. So we're

mostly a catalyst and the members mostly learn from each other, but we act as a convener and a catalyst for that process. And, of course, it's a closed loop because as you have value-based payment, then you have a business model that supports transitioning to managing population health.

So it's really important that both sides of that work in concert.

We also have the luxury of working with members. Everybody that we work with actually chose to join a multispecialty medical group. So that gives us people to work with who are systems thinkers and quality improvement comes naturally to them. So it's a really great group to work with. And I have just a small sample of some AMGA members on here. Apologies for leaving off WakeMed and Emory, I should have put them on too.

We have about 440 members total; 175,000 FTE physicians across all of our members. And you can see there are a large number of large integrated systems, about 40 academic centers. And then, we have some smaller groups like Premier, which is

about a hundred physicians and then Mercy, which is 3,200 providers. So they range in size quite a bit, but the one thing that they have in common is the process of managing patient care and the interest in population health.

A little bit about translation. Some people think translation is a fairly simple linear process. And, in fact, one of the sponsors for a program that we have done on adult immunization came to us and said, well, we've done some analysis on this and we would like you through your members to see if you could implement this process. Identify the patients, intervene, treat, and then document and report and then you're done. Right?

Well, it doesn't actually work that way as you know.

And so, here's what we actually came up with in our pilot program with seven of our members. But we all learned a great deal. Our sponsor learned a great deal and actually sponsored two more larger implementations of this learning collaborative. So we've now administered about 4

million vaccines to adults as a result of this collaborative. We're also working on obesity now and it's a similarly complex process and, in fact, just figuring out how you build a care model for obesity is really an issue. And the mixed methods opportunities for research, understanding not just what the numbers are showing, but then doing interviews to actually understand why the numbers are showing what they're showing. So those are the opportunities that we have at AMGA.

Let me give you a quick overview of the story. As Jean mentioned, this started with the Diabetes Prevention Program that was published in 2002. It was about 3,000 adults with pre-diabetes, which was at that time defined as impaired glucose tolerance, but very similar to what to the population that we would call pre-diabetes today. And the incidence of diabetes at three years for the overall population was 29 percent. Now taking metformin reduced that a little bit to 22 percent, and this intensive lifestyle program was more effective, reduced it to 14 percent. But you'll see

we can be a bit more precise in targeting those interventions.

And that comes from a population risk stratification model that was developed as part of the PCORI method study that David Kent and his colleagues did at Tufts with one, this being one of the 32 clinical trials. What has been done as part of the dissemination and implementation study is to adapt that for use in clinical practice.

So first, would this kind of information be useful? That was a question we needed to answer. And then how would you present the information that it would be useful to both patients and clinicians in shared decision making? And then it turns out you have to redevelop the model using the data that are realistically available in the EHR. So in order to get personalized estimates at the point of care, then that has to be built into the EHR, which can be done in some EHRs is using some clinical decision support logic that is available but is a pretty heavy lift for an EHR team that has this long queue of requests for improvements in the system.

So what we're hoping to do as part of this project, and we begun, we've done begun the process already is to create the model as a cloud hosted smart app that can be subscribed to by any major EHR that supports the standards of a FHIR, Fast Healthcare Interoperability Resources, and the smart apps that use those data.

So it is important that there were these other things going on to enable this at the same time. So the National Diabetes Prevention Program, the CDC has been working for about 10 years on that, Ann Albright has actually been an advisor to us at AMGA. The growth in value-based payment gives us a business model that allows this to make sense to our members and allows them to be able to afford investments in prevention. And, of course, the work now that the Office of the National Coordinator and CMS are doing on to encourage EHR standards and the adoption of standards by all of the major EHR vendors to enable this cloud hosted predictive model to work is, is also crucial here.

So in 2016, our foundation began a national

diabetes campaign called “Together 2 Goal” and we are looking to improve care for a million people with Type 2 diabetes by 2021. And the results after year two demonstrate that our members, when they get together and work in concert, can really have a big impact. More than three-quarters of a million patients have had improved care, about two-thirds net improvement in control on the bundle measure that we're using, which is glycemic control, blood pressure control, lipid management, and medical attention to nephropathy. And another third have been identified as having Type 2 diabetes, a new diagnosis identified through screening.

So this is a really important part of the campaign because one in four people who have Type 2 diabetes don't even know they have it. And among Asian Americans and Hispanic Americans, it's almost twice that rate. So it's really important to do screening.

We also should note that there are more than 300,000 patients who are already in control on the bundle measure and had been maintained in

control. So just to give our members credit for the work they're doing. There's 11 planks, classified in terms of empowering patients, improving care delivery, and leveraging information technology. But let's talk about one which is conducting practice-based screening.

And at the beginning of the campaign, we surveyed our members who are participating and said, "Well, which planks do you plan to adopt? Are there any you don't plan to adopt?" And 31 percent said they wouldn't focus on screening. Even though we've seen it's pretty important. The reason is they're already overwhelmed with the number of people who have Type 2 diabetes, let alone pre-diabetes.

So pre-diabetes, elevated blood sugar, but not high enough to indicate diabetes. Now, today that's usually designated either fasting plasma glucose or Hemoglobin A1c. As I mentioned, an oral glucose tolerance test is the way it was done for the DPP study, but the populations generally overlap. There are a few differences, but they generally are pretty close.

And then, the elevated risk of progression, which we mentioned over three years from the DPP study, is that 29 percent, 28.9, that was found for the placebo arm of the DPP study. So that's 84.1 million Americans, more than one out of three. And so, just to give you a sense of what this means in terms of screening, okay, so that's going a little faster than it's supposed to go.

So this is 5 million patients. Sometimes when you drag slides in it automatically checks the go ahead without waiting.

But at any rate -- so 5 million patients, I'll try to keep it under control here.

Seventy percent are actually eligible for screening. And then of those, you can see that about 45 percent get screened in any given year. About 60 percent of those have no evidence of diabetes or pre-diabetes.

But the screening result in the diabetes range you get for about groups for about 6 percent of the population. And then 36 percent, you get a pre-diabetes. And what that means is that there are

600,000 people out of this 5.1 million population on whom we have data through a partnership with Optum, who are missed with pre-diabetes because they weren't screened and another 100,000 with a result in the diabetes range who are missed. So it's a very important part of caring for a population.

What can you learn from the Diabetes Prevention Program? Well, as Jean said, you can from taking metformin and intensive lifestyle, you can reduce the risk substantially. But what we learned from the Methods project on heterogeneity of treatment effect is that you can find variables in the data at the beginning of the study. So what we knew about the patients as they were going into the study that will allow you to stratify their risk of developing diabetes. So the overall risk is 29 percent. The high risk quartile is a 45 percent risk down to the lower risk quartile of 7 percent.

So the absolute risk reduction seen in the DPP study stratified into quartiles for both intensive lifestyle and metformin, is this graph that is actually from the PCORI website from that

initial method study.

So you can see the average benefit for the lifestyle intervention is 14 percent. You can get double that intervention that benefit in a quarter of the patients. The average benefit for metformin is about half that. You can get triple the benefit, triple the average.

So most of the benefit from metformin is really just in a quarter of the patients with pre-diabetes. And as you can see, there's a sort of a stair step as you go down for lifestyle. Everybody benefits to some extent, but some particularly.

So the question of will a predictive model be useful? Patient focus groups, there was a lot of skepticism that people would be able to interpret and assimilate these probabilistic estimates. But what we learned is that most of the patients who had a screening result in the pre-diabetes range had family members with Type 2 diabetes and virtually all of them could quote the ages at which three or four family members were diagnosed with diabetes. So we could do a lot better than that. They were

already dealing with numbers, but we could give them something that was personalized to their own physiology.

The provider focus groups, while the providers they want to support and encourage their patients, especially for this lifestyle program, which is kind of hard to stick to, but they feel overwhelmed and they need to prioritize. And just a quick a review of the lifestyle program at 16 weekly meetings with a trained lifestyle coach, supervised physical activity sessions. It can be it can be personalized for ethnic diversity and all of that has been worked out by the CDC. The goal is a 7 percent weight loss. And the program is actually even paid for by Medicare now.

But the real problem is sticking to it and the support that it takes to be able to do that. And with the patient's permission our members are arranging with the YMCA, when they refer a patient to let the YMCA let them know how the patients are doing so that the group can reach out and actually encourage them because that's what it takes to make

it work.

Now, what people are mostly doing now is taking A1c or fasting glucose and using a single variable, but a multivariable model is a much better predictor because as you can see in the lowest risk quartile, 15 percent of the patients have A1cs that are in the high end of the pre-diabetes range and then vice versa. So that's the advantage of the of the model is it's a lot better than any individual parameter.

These are the data elements that were from the DPP study that that turned out to be predictive in the model, in the original model. And as you can see, there's a hemoglobin A1c, fasting glucose, triglycerides. But then there's also a lot about a sort of body shape, height, waist circumference, and waist-to-hip ratio. But as David Kent says, we need models that can be used by doctors, not tailors. So he really likes the fact that we were able to redevelop the model for use in the EHR.

And we did this using a dataset with about 50 million patients, longitudinal data that's

available at Optum Labs. And only three of the variables are actually the same. All of these other variables are things that are typically available in the EHR, but sometimes they aren't. So we do have to actually make sure that the model is robust against missing data. And there are imputed values that you can put in if it turns out that that's not, that you don't have a data element that you need.

So here's an example of a couple of patients and you can see over on the left, we have a 38-year-old female who has an A1c in the low end of the pre-diabetes range over on the right, a male who's just a bit older, but is actually a former smoker and his A1c is in the high rate, high-end of the range.

And actually about the patient on the left, we don't really actually have a smoking status. So that's one of the places where we have to use the imputed value. But you can see the person that you think might be low-risk is actually high-risk and vice versa.

So here's how the results are for

hypothetical patients are presented in the EHR at Premier Medical Associates. So you've got a low-risk patient. A predicted risk of progressing to diabetes is 5.5 percent. And then you can lower that with metformin or the lifestyle intervention, but you can see that that 58 percent relative risk reduction is on such a low initial risk, baseline risk that the number needed to treat is 31.5. So it's really you know, that's not very efficient to treat that patient.

On the other hand, you've got another patient who's risk of progressing to diabetes over three years is more than half, more than one out of two, and same relative risk reduction but in this case, the number needed to treat is four. So it's a great example of how you can actually, and these are the numbers that the -- and the way they're displayed, we're going to try to make them a little more graphical, a little easier to assimilate.

But this is what's been used at Premier pretty successfully because over nine months they saw 670 patients with no history of diabetes and a

result in the pre-diabetes range, 670 patients who were classified as high-risk before having the estimates, 11 of those were on Metformin. Now 134 were started on metformin. None had been referred to a diabetes prevention program. Now almost 300 have been referred.

So it's a real impact and it's exactly stratified the way you would want it to be because the high-risk patients, 65 percent of those, some action was taken; moderate risk, 18 percent, low-risk, 4 percent. And as a result of the screening that they were willing to do because they could deal with the results in a risk stratified way, 87 patients were identified as having diabetes through the screening that they were doing.

So it's always good when you're trying to do something like this to start with something where there's a big potential for cost savings and fortunately, pre-diabetes and prevention of progression to diabetes is a great place to work because the Intermountain Insurance Plan has published their finding that they save $3,500 per

person per year that development of diabetes is either averted or delayed.

And just to underscore that, they say, well, if we can do it for five years, we save $17,500. So they are really very, very clear about that estimate.

The CMS Office of the Actuary is a little more conservative, but they're estimating even net of the program $2,650 over 15 months for Medicare beneficiaries. And that was part of the logic and part of the research that allowed Medicare to cover the diabetes lifestyle program. Its cost is in the range of $600, but you can imagine that if you're a provider organization taking risks, you may not even need to try to get paid for this.

It makes sense to make this kind of an investment, if you can make the investment where it's going to actually do the most good.

So the personalized estimates at the point of care, Premier Medical Associates has an Allscripts EHR. They had a calculator that had an add-in that they already were using and so it was

fairly easy to implement this model.

Mercy on the other hand is running a very large Epic implementation and they have done a preliminary build using the native clinical decision support logic. But it requires manual data entry. And there've been a few intrepid physicians who are actually using it even though it does, but of course, they're using it preferentially when they think they need either to convince the patient or sort of to confirm their hunch. So it would be nice if we could do this all the time for every patient.

So the alternative -- and this is what Todd Stewart at Mercy suggested to us as we could, we could build this, but then we'd have to test it, we'd have to maintain it, and why don't you use these new standards that the EHR vendors are all now supporting. And it's early in the standards, they are just emerging. But the idea of having a cloud hosted version of the models where we only have to implement it one place using these open inter-operability standards is what we're working on now.

And I won't take you through the details of

all of those standards and how that's working, but that is the benefit I think that we have in doing this work at exactly this point in time, because we can scale this up. We'll start with Mercy East, which is about 45 clinics and then we'll go up to all of Mercy and then hopefully to lots more AMGA members and other provider organizations nationwide.

So that's the story. Starting with the Diabetes Prevention Program, heterogeneity of treatment effect methods project, all the way to personalized risk estimates at the point of care; and a way of thinking about this, I think, is that this is using the longitudinal data we already have in our EHRs to create precision medicine without having to wait for genomics.

Thank you.

[Applause.]

DR. GOERTZ: Great. Our work is done. Great. Thank you so much. Sharon first, and then Barbara.

DR. LEVINE: Couple of questions. One, this is a snapshot in time screening. So for the

low-risk, moderate-risk is there periodic rescreening to see if they've moved and the second part of the question was, you start someone on metformin. What's the projection about how long they stay on metformin?

DR. CUDDEBACK: Well, I think, Dr. Selby, you're an endocrinologist by background as I understand.

DR. SELBY: No family doctor. I studied all those years.

DR. CUDDEBACK: Diabetes interest. Okay. All right. So I won't -- I started out in clinical pathology so I won't pretend to, but to two points. One is the ADA standards for screening are, and it's people under age 45 with overweight or obese and a risk factor, and they need to be screened. If the screening is negative, then they need to be rescreened every three years.

If the screening comes in the pre-diabetes range, it needs, they need to be rescreened every year. And everybody over 45 should be screened at least once every three years, is the recommendation.

And then the metformin question, I will --

DR. SELBY: I'll just say, I think that's a bold use of metformin. It's kind of on the aggressive end, but it's really worth studying and Sharon, your question is right on the money. Will they stay on it?

Brilliant presentation. Really, I loved it.

DR. GOERTZ: Janet, was your comment on that particular point? Okay.

DR. WOODCOCK: Yeah, so I would say basically that currently Type 2 diabetes is a progressive disease. And so, this showed that it was delayed, but not it requires more follow-up to see if it was actually prevented.

And actually, the threshold for whether you have diabetes or not is artificial. It's just established. And so, maybe some of these people alter their lifestyle enough that they would never, they could go off metformin, but many of them will progress, and actually the natural history is that you just add more drugs on top of metformin.

So that's how a Type 2 diabetes is treated in today's world. So hopefully, you know, getting some of these people hooked on lifestyle changes will alter the trajectory. But if not, if they're in a state of progression than they would have had to be started on metformin any way.

DR. CUDDEBACK: Right.

DR. WOODCOCK: Because they'd gone over the artificial threshold that had been established and then eventually they might have to take other drugs.

DR. LEVINE: And the reason I asked the question is, with this screening and the assignment of a risk category, you wonder if there's, you know, some clarion call that might make the notion of lifestyle changes a little more pressing so that we see a flattening of the curve of progression and the need for lifetime, you know, lifelong metformin potentially not happen.

DR. GOERTZ: Okay, great. Thank you. Barbara.

DR. McNEIL: A quick question and maybe this isn't the time to ask, but I was intrigued by

your platform in the sky. What exactly would that do?

DR. CUDDEBACK: So the, the idea is that the EHR exposes certain data elements as they -- the term that uses FHIR resources, Fast Healthcare Interoperability Resources. And so, basically exposes those in a secure way that a cloud calculator that's deployed in the cloud, can go and request the patient's data for the patient you have identified and say, I have this patient in front of me now. We call the calculator and then it performs the calculation and returns the results.

DR. McNEIL: I'm just naïve. Is that better than having every institution make its own calculator as an app to Epic or --

DR. CUDDEBACK: Well, there are certain calculators that the vendors are incorporating, like for example, the ASCVD calculator that that's used in the Hypertension Guidelines today. But you know, a perfect example of where we're actually working with a team at Johns Hopkins who's extending that calculator, but it's already implemented in its

current form in a whole bunch of EHRs nationwide.

Wouldn't it be nice if we only had one place we had to change the way that calculator works and everybody could get the benefit?

Now we're not going to change it by surprise, of course, we don't want to surprise people, but the point is there's a lot of testing and validation that is necessary, particularly when you're going and actually retrieving the data from the patient's record and making sure -- one interesting thing about this, is very often fasting glucose values are not reflected as fasting in the EHRs. So you have to look at all the glucose values that were obtained in an ambulatory setting and then try to figure out well which one was drawn on the same day as the lipid panel?

So that kind of logic is the sort of thing that you can put in this calculator in the sky. That would be pretty difficult for everybody to implement, test, and maintain in their own EHRs.

DR. GOERTZ: Thank you. Russ.

DR. HOWERTON: Well, I will give a

disclaimer and I really want to express an opinion more than ask a question as the health system representative, I should say that Wake Forest is deeply involved with the AMGA and several of our physicians are senior leaders at the AMGA. So you can interpret this comment as you wish, but I would say that the kind of work Dr. Cuddeback described there is about as good as sweet spot is PCORI could ever find.

Out in the delivery system a body like the AMGA, because it is composed of members who actually have to run a business, understand the challenges, that thing from linear to that slide he showed, they deeply understand and know how to impact at the face of care. That they've won the affinity of healthcare deliverers, individual physicians or groups. They understand the economics of needing to triage resource investment.

In many ways it doesn't make sense to not invest in these lower risks. Why wouldn't we do that? But out in the real world, it's nearly impossible when you run a business.

I'm willing to wager that most people interacting with the AMGA will have no earthly idea that PCORI ever contributed anything to the underpinnings of this process. And really we should be happy about that. They don't ever need to know, but well. I shouldn't say we should be happy, but it's an example of how we can truly change society if we put linchpins like that way upstream and partner with entities like this, we will in fact influence millions of people over time.

Dr. Cuddeback, thank you very much.

DR. CUDDEBACK: Thank you.

DR. GOERTZ: Thank you. Chris.

MR. FRIESE: Well, Russ you just stole all my thunder.

[Laughter.]

MR. FRIESE: I want to underscore exactly what you said and applaud you and this group.

Actually, the comment I was going to make is building upon that, but I want us to be aspirational for the next opportunity for PCORI and the partnership. And so, maybe Jean and John, maybe

you could just think aloud with us for just 30 seconds. Where could we -- we've learned so much from this work, where could we go next that would have similar or even greater potential?

MS. SLUTSKY: So that's a great question. And something that we've thinking about with the EDIC over the past year, including supplementing, you know, activities that have shown to be fruitful and are ready for a much broader spread.

So rest assured that this is an active discussion where we're trying to leverage organizations like AMGA and others. And we hope to bring you examples of that, just like you're seeing portfolio examinations of our research investments, but so that you can see them in our implementation projects. And that's -- this is just one example of the beginning of a project. This is a relatively new one. But you can already see the potential for a much larger activity.

DR. GOERTZ: Alicia, would you like to make a quick point on that particular topic?

DR. FERNANDEZ: I do.

DR. GOERTZ: Okay, Alicia and then Bob.

DR. FERNANDEZ: [Off microphone] -- agreeing so much with Russ and Chris and just thinking that this work is so fantastic. I think that there is a potential for doing, for PCORI to think carefully about whether there are other areas in which we can do this. So the example that comes to mind is not a PCORI study, but SPRINT for example, where there are a lot of people where as you know, additional antihypertensive, efforts benefited the population as a group.

Now within any trial, obviously some benefit more than others. There's work going on in SPRINT. Is that an area that PCORI could help translate into a tool that is useful like that, that is the sort of type of thing that it's not only PCORI studies, but the type of work that we as a board and the staff need to be in dialogue with because it is very important taking research into practice.

Similarly for this particular project, there is a crying need in pediatrics with a high

risk for diabetes. And also as you know, among more ethnically diverse patient populations and perhaps you had access to in your original data, I think some of the parameters would change and I hope that we at PCORI continue to support you and the different groups that you work with in order to make this even more useful and extend it to other groups.

DR. GOERTZ: Thank you Alicia. Bob.

DR. ZWOLAK: Thanks. I'd also like to extend my appreciation and congratulations on that.

The question I had was on your slide 131, where you display two different systems and two different EHR, and the takeaway I had was at one seemed to work well and the other had not worked quite so well and I was wondering if you would expound on that and also explain if there's any opportunity -- if I am correct, that one didn't seem to be working so well. If there's any opportunity for an intervention at the PCORI or other level?

DR. CUDDEBACK: Well, actually this is a good story, I think of evolving standards that are being adopted industry-wide by EHR vendors. And I

think the work of the office of the National Coordinator and CMS putting a little purchasing power behind that actually it has been very helpful.

At Mercy they would have -- they sort of evaluated how much work it would be. They run the fifth largest Epic installation in the world. So it's a big deal. It's not as big as Kaiser, not as big as Cleveland Clinic, but it's pretty big.

And so, they would have to -- they analyzed how much work they would have to do and they needed a software license for a particular component in order to be able to implement a model like this, particularly a model that did the kind of logic that finds the fasting glucose by looking for when something was drawn with the lipid panel. And in order to do that they said, you know, the amount of effort there, what we ought to do is switch our strategy to this new industry standard that is evolving. And Epic is supporting the standard. Cerner is supporting the standard, actually Allscripts. It doesn't happen to be necessary for Premier Medical Associates since they have another

solution.

But at any rate, all of the major vendors are supporting these standards. So that's the real opportunity here, I think, for us to build something that anybody can subscribe to. And I know that it's not quite that simple and there will be work to do as it gets implemented because the way each data element is expressed. And of course, you know this from PCORnet there's a lot of work to do to actually make things that uniform, but it's still much -- once it's done, it's done for the organization and then the maintenance happens in the cloud version.

So that's the benefit. It's not that Epic was unable or unwilling to do it, or Mercy was unable or unwilling. They just said, you know, this is a better long-term strategy and it's much more scalable.

DR. GOERTZ: Thanks. Joe.

DR. SELBY: I'll defer to Board members, but, okay. Well, John, one more time, I think the reason people, one of the reasons we're resonating so strongly to this is because it has such a

patient-centered bent to it. In other words, it gets more out of data and tries to understand who will really benefit and with some treatments, those people who are at low-risk for low likelihood of benefiting also stand a great chance of being harmed by the treatment. So sometimes it's more risky than taking metformin or changing your lifestyle in a positive way.

I just, Sharon's question and Janet's earlier question and comment, just make me want to ask, how are you going to be able to follow these people to really monitor their likelihood of staying on metformin converting to diabetes? And do you have a comparison group so that will actually, my hunch is that this will turn out to be a really effective, efficient intervention but how likely are you to be able to really show that?

DR. CUDDEBACK: We would love to talk to you about that and some of the methodologists who can help us with study design, whether we -- at this point where we're just doing a demonstration to show that it works and it's useful and people are able to

and to use the information in making decisions. But then I think the question of whether we should try to randomize people to this predictive model or not.

And we do have the ability, one of the nice things about the relationship we have with Optum is for our members who are using an Optum population health tool, we have access to their longitudinal EHR data. So these are in essence, instrumented practices for us, and so, we can actually follow the patients relatively easily. So that part is pretty straightforward. The question, of course, is the study design and the methodology and what would be the right way to determine the utility of this.

We have patient surveys that are currently out at Premier. Obviously it'll take a little longer for Mercy because of the way we're implementing it. But at least we'll know more from the patient perspective in the next three months.

DR. GOERTZ: Janet.

DR. WOODCOK: Yeah, my comment follows up on some other Board members'. I as I said before, my personal opinion is that PCORI ought to pick up

the research that is positive, that is done, move it to the next level and have an overt plan to do this and here it isn't even done yet as you said, as Joe just said.

So then there'd be able to be a plan to implement and practice and evaluate the impact and publish that, as well, so that there is a sort of train of moving pieces and you can actually show. That would require, I think, thinking through more broadly how do you actually set all this up? Okay. So you have done all this work over the five years or whatever and you've gotten all this research, which of it is actually implementable in practice in theory.

But actually to do it as you said, is another giant step to take. You have to do the implementation work on the ground and then try to implement it and then evaluate it. What effect has it actually had? And I do think all the research that PCORI does, should be on that track and that will require, I think more planning and some very overt goal-oriented activities.

MS. SLUTSKY: So if I could just briefly speak to that. You're absolutely right. And so, all of our dissemination and implementation activities have common data elements that need to be captured throughout the project, including fidelity to the original intervention and study results so we can make those criteria available to the Board. We've shared them with the EDIC, we absolutely agree that we should -- we need to capture that information across our implementation project.

DR. WOODCOCK: No, I guess what I'm saying, Jean, is we've got to think of the research that's been done. The exploratory research is a giant funnel. Okay. Then sometimes you find things that are actually startlingly effective or whatever or appear or they might be, then it ought to get into this next stage which is the stage of can it actually be implemented widespread and not a group of true believers. Okay? But in the healthcare system and private practice and this and that and the other thing.

We ought to evaluate that to see if it

actually works is what -- and that ought to be the objective in my mind, overall, is that this research is evaluated and if it isn't ripe or it isn't effective enough, then discard it and the other pieces really put resources against making them happen.

DR. GOERTZ: Joe wanted to comment and then Russ.

DR. SELBY: Speaking directly to Janet's point, sometimes we tend to think about you do the CER and then you do the dissemination because you know it's the right thing to do. But in many cases, and particularly here where this didn't exactly come straight out of a trial that came out of a reanalysis of a trial. It's kind of one step removed, the DPP was anything but a pragmatic trial. And so, sometimes as we're doing dissemination, there's a critical need to actually make that a CER study in the real world as well, much more pragmatic than the original.

I just wanted to say one other thing, which is that Evelyn Whitlock, when she was here, launched

a program called PASS where we engaged people from Tufts in looking at a number of other studies. We've shown this to you before, but there's nothing like an example like John's to just bring out the meaning of this.

There's a great paper in *The BMJ* about how this should be done, you know, and in nearly every trial it should be done and in many times a population approach would dictate that you use those trial results in a high-risk subgroup and that you really have a different conclusion and a strategy for the low-risk people.

MS. SLUTSKY: I just want to also add that this didn't go straight from the original Methods study to this dissemination implementation study. There was an interim step with a stakeholder-researcher meeting that looked at the modeling and the prediction. So it was -- this is -- we're just showing you one part of the process.

DR. GOERTZ: Great. Thanks Russ.

DR. HOWERTON: Just following up on Alicia's comments about SPRINT and highlighting the

need for convener organizations like the AMGA.

We at Wake Forest, we're proud to be the host of SPRINT and have lead PIs there and almost everyone is aware of the intellectual work in SPRINT and the whole Wake Forest family. And you might think that the disseminated primary care fleet at Wake Forest was acting in accordance to SPRINT. But for those of you not familiar with the delivery system, nothing could be further from the truth. And without the kind of work with an intermediary like this, I think we're somewhere in that 17 year cycle of transmission. And this is exactly the kind of work that leads to change at the face of care of the delivery system.

DR. GOERTZ: Thank you. And David.

DR. MEYERS: Thank you. And I'm sorry I wasn't here to introduce myself. I'm David Meyers and I serve as the representative from the Agency for Healthcare Research and Quality. And we're grappling with some of the same issues. And so, I applaud the presentation and the work that PCORI is doing in D&I and this needs to continue, but I was

somewhere with Joe and Janet, that building into PCORI's system, how to bring this back into the research pathway as well, and that's not necessarily this project's original goal.

This was the SPREAD project and it should be allowed to go, but to be able to partner with AGMA or one of their partners to bring it back to a different level of research that would let us know what we're learning here. Not just about dissemination but about the science behind this and I actually, I'm a little concerned that the original premise that using the three-year progression that we discovered that the people at highest risk are the most likely to benefit in a short period of time, is actually not the most important patient-centered question.

What if those middle risk people, if given this now, actually have the greatest long-term chance of avoiding going on to diabetes and we'd miss them if we run down this track without ever looking at the other research questions that this important work will generate.

DR. GOERTZ: Janet, did you have -- okay, Russ.

DR. HOWERTON: Well, I appreciate that perspective, but in the real world and also as a proxy, the people who are members of the AMGA have a follow-up method in that they are almost all in risk-based contracts for which there's financial reward if they impact this cost of care.

I'd be surprised if they'd randomize many people if they had any thought that it actually would impact the cost of care and if you comment on the brokenness of the healthcare system in America, transmission of value across decades is not financially incented in this model. We are rewarded for the claims cost in that year and we're going to be challenged if it's a $600 intervention that's got an 8 to 10 year pay off because we don't know if that patient will be attributed to us in that future time.

So that question may need to be studied, but I'm not sure that's going to be as easy to study in the cohort that is the AMGA where we're

struggling to make a value-based risk model business case, which we believe is good for society as is.

DR. GOERTZ: Thank and thanks to both Jean and John for such an excellent presentation. As you can tell, you've definitely caught the interest of the Board and we're excited about where this will lead next. So thank you very much.

DR. CUDDEBACK: Thank you.

DR. NORQUIST: Okay, so now we would have the public comment period, but as no one is present or waiting on the line, we will not be initiating our public comment period. We always welcome your feedback at Info@PCORI.org or through our website, PCORI.org.

So before we get ready to adjourn, Joe, I'll turn it back to you to see if you have any comments.

DR. SELBY: No. It was a good morning and thanks again to John and also to Penny for their -- and Maryan, for the presentations and we'll have the Strategy Committee meeting tomorrow.

DR. NORQUIST: So any further comments and

then I'll close us out.

Let me close by thanking those who joined us today. A reminder, all material was presented to the Board today will soon be available on our website. Today's Webinar was recorded and the archive will be posted within a week or so. We always welcome your feedback at Info@PCORI.org or through our website. Thanks again and have a good day.

[Whereupon, at 12:28 p.m., the Board of Governors meeting was adjourned.]