PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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Alicia Fernandez, MD
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Leah Hole-Marshall, JD
Russell Howerton, MD
Gopal Khanna, MBA
Harlan Krumholz, MD, SM [via telephone]
Richard E. Kuntz, MD, MSc [via telephone]
Sharon Levine, MD
Freda Lewis-Hall, MD
Barbara McNeil, MD. PhD [via telephone]
Grayson Norquist, MD, MSPH [Chairperson]
Robert Zwolak, MD, PhD

AGENDA

AGENDA [Continued]

P R O C E E D I N G S

[10:18 a.m.]

CHAIRMAN NORQUIST: Thanks. Good morning and welcome to the October 30th meeting of the PCORI Board of Governors, I'm Gray Norquist, chair of the board. Welcome to those of you who are also joining us for today's board meeting by teleconference.

We're pleased to have you here as a reminder, instructions for logging in or calling in today are available on our website at PCORI.org/events. All board members are present in person with the following exceptions: Gail Hunt and Ellen Sigal and Kathleen Troeger are not able to join us. Allen Douma, Harlan Krumholz, Rick Kuntz and Barbara McNeil are expected to join us by phone today.

DR. McNEIL: I am on the phone.

CHAIRMAN NORQUIST: That’s fine Barbara. I want to remind everyone that disclosures of conflicts of interest of members of the Board of Governors are publicly available on PCORI’s website

and are required to be updated annually. Members of the board 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 deliberates or takes action on a matter that presents a conflict of interest for you please let me know so we can discuss how to address the issue. If you have questions about conflict of interest disclosures 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 the webinar will be posted on our website at PCORI.org. The webinar is being recorded and archive will be posted probably by next week.

We have a scheduled public comment period today from 5:00 to 5:30 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

at info@PCORI.org or provide input through our website. Finally a reminder, we're like Tweeting today's activities on Twitter and you can join the conversation with us @PCORI

So before I introduce the first agenda item, there just a couple of comments. One is this is our first in-person board meeting without one of our board members; Bob Jesse, who we did bring up a phone conversation, we lost Bob this past summer and of course, we'll greatly miss Bob his wise advice at our board meetings. So I just wanted to remember Bob again. And also, I want to -- on a positive note, a good note basically, I want to welcome Gopal Khanna for his very first in-person meeting with us. He's the director at AHRQ.

Our first agenda item are the minutes, so I need to ask if there any edits or comments on the minutes from our September 26th telecon.

[No comments.]

BOARD MEMBER: So moved.

CHAIRMAN NORQUIST: Thank you, a second?

DR. HOWERTON: Second.

CHAIRMAN NORQUIST: All right Russell.

I think we can do this by voice vote, yes. Okay all those in favor?

[Ayes.]

CHAIRMAN NORQUIST: Thank you anybody opposed?

[None.]

CHAIRMAN NORQUIST: And anybody abstaining?

[None.]

CHAIRMAN NORQUIST: And let me just double-check for Mary's benefit, who's on the phone?

DR. DOUMA: Allen.

DR. McNEIL: Barbara is on the phone.

CHAIRMAN NORQUIST: Barbara?

DR. McNEIL: Yep.

CHAIRMAN NORQUIST: Okay. Allen are you on?

DR. DOUMA: I am.

CHAIRMAN NORQUIST: Okay, good. Allen Douma and Harlan Krumholz?

[No response.]

CHAIRMAN NORQUIST: Okay and I don't know

whether Rick Kuntz -- we have two on.

The next item, of course, is Joe's update and the director's report. So Joe Selby.

DR. SELBY: Okay, good morning everyone and let me wish you a happy seventh birthday, welcome Gopal as well. It is just a little over seven years since you were all named and a little less than seven years since you met for the first time in November of 2010. And today is going to be in some ways a catching up, a looking back, looking to where we are at seven years.

The agenda includes after the Quarter 3 Dashboard Review and my report a report from the Methodology Committee and an opportunity to approve for the release for public comments of some new methodology standards, so we'll hear from I'm not sure how we'll do that, whether Robin will call in for that but we will hear that report.

At Noon we'll take a break in the afternoon we'll start off with an address as we do from stakeholders and an address from Doctor Congressman Phillip Gingrey, who was a member of Congress from

Georgia for about 13 years and cofounder of the Docs Caucus in the House and he's going to talk to us about his observation on PCORI at this point. We have another -- one more project, I think it is a project from the targeted announcement for opioid use in chronic pain. That took a little longer to get approved by the Selection Committee, but now is up for your consideration. And then reports from each strategy committee with a long time for discussion after the three reports on where we are at seven years.

So unless there any questions, I'll start out and is really an interesting time at PCORI, we're looking back at our accomplishments at the arrival of a lot of publication; which I'll speak to in just a minute. It's nice to have results on hand as we go forward, but I want to speak first just about how the PCORI portfolio itself has evolved and continues to evolve. So as you know we started with broad announcements which were on the relative scale smaller awards, very numerous, and on any topic that applicants could convince us had patient engagement,

patient-centeredness, and could change practice. A little bit later towards the end of 2013, we introduced the concept of larger, very focused awards that we called targeted awards. These were questions that stakeholders put to us and we had developed into specific topics and assessed that there was a need for comparative effectiveness research in these areas.

And a couple years later we introduced the pragmatic awards, which were in some ways a hybrid. They could be stakeholder initiated topics, they could also be topics from a list of questions that have been brought to us by stakeholders and they were large. They were more the size of the targeted awards and they had to have intense engagement and had to have a high potential for both changing practice and dissemination.

So if you look at the numbers you can see that as of today's date we have now invested more in the larger awards combining the targeted and the pragmatic awards. We have invested more overall than we have in the broads, just a little bit more.

I can tell you that the next two years as planned will continue to exaggerate that difference and the board and much of the public has told us that we should be focused more on larger, more definitive studies on targeted areas that stakeholders say are important; so that's an evolution that has come as we've gotten our stakeholder engagement in place and all of our infrastructure for identifying topics, refining them, soliciting them, reviewing them, and funding them.

But the real point of this slide is to say that we are embarking on some new areas now very fitting for the time we are in our evolution -- the first -- and Jean Slutsky deserves a lot of credit for this and the Engagement and Dissemination group we are beginning to award funding to dissemination on things that are related to research projects that we funded; the results are in, the final reports are in and approved, and now investigators can apply for funds to disseminate and/or implement the findings from this research.

I know that we have about ten of these

funded now, we'll hear more about this this afternoon in the report from the EDIC Committee.

We'll also hear about the new shared decision-making application that the board approved over the summer and this is an opportunity for anyone to apply to develop a project that involves shared decision-making, to apply and disseminate, implement the findings from our projects. A lot of our projects particularly because they consider multiple outcomes and they take into account patient preferences, the solution for disseminating those findings involves a shared decision-making process, so not everything is as cut-and-dried; that it's simply leads to a change in guidelines.

Somethings do, but many other things enrich the evidence when put together with evidence from other studies, we can help to present this in ways that patients and clinicians can use at the point of decision-making so that's dissemination-implementation, a new way forward. The money there looks smaller but we'll hear more this afternoon about how much we intend to invest and the numbers

of projects we'll have by certain dates.

And the last, all credit here goes to Evelyn Whitlock, our chief science officer, we have initiated under Evelyn's guidance over the last year-and-a-half a program of evidence synthesis which is very useful both at the beginning when we're trying to assess which projects really need more CER research. And also at the end when we're trying to get our new findings in with other available evidence. Evidence synthesis individual patient data meta-analysis starts by pooling data from clinical trials and then tries to make much more gain much more insight into particularly the person-centric information in those trials than the original publications from them.

So I'm by looking at subgroups, by looking for treatment heterogeneity, by understanding how we personalized information from files for individual patients with different clinical characteristics and preferences. And lastly, predictive analytics which I'm very excited about Evelyn and science have posted an announcement for a predictive analytics

center and this is going even a step farther, I think, in which we use data from trials; large observational studies, to get very personalized into predicting in a multivariate way not in a just a are you male or female, but in a multivariate way: What your actual risk is and probably even more importantly how are you are -- how you personally are likely to respond to a particular treatment so you'll hear more about this this afternoon from Evelyn in the report from the SOC.

Also I want to say that as our literature, as the published products of PCORI research increase, our website has kept up. I tip my hat to Phil and the communication staff, Marla Bolotsky for work on keeping our website in a state-of-the-art state. I particularly draw your attention to the PCORI awardees peer-reviewed publications. There are 700-plus peer-reviewed publications, many of them are publications about the protocols for studies, others are publications -- numerous publications about how engagement worked in their studies. Some of them are review papers preparing

for the study, but there now or nearly 50 final results CER results from publications.

You can now go to the PCORI website, look under research and results and look at PCORI in the literature and you can either view the entire list of our publications, all 700 of them and those blue -- that blue column in the middle are links to the PubMed abstracts but you can also search this list on very nicely with a set of filters and keywords. So you can search -- I did it the other day for all the publications on diabetes and all the publications on depression, you can find absolutely everything we've published. I commend that to you.

Similarly, we have upgraded our capacity to search our portfolio so you can go to explore our portfolio and enter keywords and/or use filters and search the 500 and some projects that we've funded. Here's just an example of some of the available filters.

This is the filter on conditions.

So again, I encourage you -- I use this all the time as I'm getting ready to give talks to, you

know, maybe a particular specialty group or a patient advocacy group just to find out, quickly summarize what we've done.

I've got to say a word about the annual meeting, we are most excited about this meeting, our third annual meeting. It's called delivering results in recognition of the fact that we have results in informing choices, this is going to be a meeting where patients and their caregivers, clinicians, and researchers, policymakers, industries sit down in the same room at the same time to hear reports on research. Not all published but research that's coming and the fascinating thing is how we deliver this information in ways that serve all the stakeholders in the room and how they talk about it together. There are four plenaries. All linked to this title of -- to this theme of what patients need and how we communicate it.

I will just -- let's see we have the special sessions over there on the right, include for example, one on addressing the opioid crisis, one on multiple sclerosis research, there's a third

one I know that Sharon is leading. It has to do with efficiency in healthcare and I think -- if I'm not mistaken you're leading one on shared decision-making. So very exciting breakout sessions. The plenaries -- it doesn't say it here it -- I'll just mention that among the four plenaries and keynote sessions; I should say one is by Alan Alda who in his career has included a very strong investment of his time and energy on the topic of communicating science to the public, whether this started when he was an Army surgeon on MASH or whether he started it when he was the emcee of the Scientific American Frontiers for PBS.

He's gotten very good. He has a center at Stony Brook University in New York and so one of the four plenaries is by him on how we communicate science to the public.

So that's it in terms of comments and unless there are questions on this point, I will go ahead to the dashboard review.

So the first thing I want to say about this dashboard review is that it's a little later than

usual, this reports on progress through June 30th and it's now October 30th. So we will have a four month gap and that's because despite having two meetings in September, we had to spend all that time reviewing and approving funding so we did not have a chance to present this dashboard to you until now so keep in mind as I present it that another quarter is actually finished and sometimes I'll slip in a little information, I won't be able to resist.

For example, in the upper left-hand corner on the Funds Committed to Research, even though it looks like we're almost on target and we were at the end of the third quarter. We committed a very large amount of funding in Quarter 4 of fiscal year 2017, so that we are just very slightly under our budgeted amounts in terms of commitments.

Project Performance in the middle -- on top, continues and this includes a good deal about recruitment.

I'm going to be talking to you more about recruitment later in this presentation, but I include a lot about recruitment and continues

project performance to have above 90 percent of all of our projects in either the green or the yellow zone; so there's four zones, and yellow indicates some concerned by the project officers but we believe that it can be gotten back on track. Most of this 93 or 94 percent is in fact in green.

The same story with the budget, we were on just slightly under at the end of the third quarter we remain slightly under but the gap was much smaller than it has been in previous years and the bar at the top of that is in green because it was less than a 10 percent gap.

Down to the middle row, the draft final research reports are coming in in large numbers and this is just through Quarter 3, but you will see that more than 90 percent of the awardees are getting their draft final research reports in to PCORI on time. And the one section of this dashboard that's yellow is PCORI peer review. We had set as a target that we would have these peer review draft out and have these draft down reports peer reviewed within four months of receipt. And we

have fallen flat in that area and it's in part, I think, because we are just still learning to do it.

I'm going to say more about this and Evelyn is going to say more about it this afternoon. So we are learning to speed up different components of it, but also I think we're going to conclude and suggest to you that four months was probably over-ambitious and you just don't get peer review done with all the back and forth between reviewers and the awardees in a four month window. We did have two draft down reports approved as of the end of Quarter 3 and I'll show you some numbers for where we are now in just a bit, but on the median time -- the median, not mean, the median time it took was 8.6, so there are some that are substantially higher than 8.6 months.

The public report of research findings refers to our policy where we say that within 90 days of approving the final report we will have it posted in a lay-friendly and a researcher friendly abstract on our website. We only had one that had gotten to that point, 90 days, and it was on target and we think that this is not going to be a barrier

it seems that our translation center is able to get these done in 90 days.

Results in the published literature keeps going up and the most recent quarter will undoubtedly be augmented with a little bit more time because it takes some time to find the publications.

The number of CER studies keeps going, and so you can see that by the end of the third quarter we had about -- we had exactly 30 CER results and publications. Altmetrics, I think in part because of the types of topics we cover, a lot of our projects are in the top five percent and in fact you see that 11 of our 30 CER results are in the top five percent of all altmetrics scores. And in terms of PCORnet, now that we have added another two externally funded projects. Two are extremely funded, one by NIH and one by AHRQ, and then there are six -- I think maybe five at this time, five co-funded projects at this time and those are co-funded by CDC and the FDA.

And I'm going to turn to three narrative examples just to show how we are increasing

information, speeding uptake and influencing research. First I guess I want to mention something further about the peer-review process. We've divided the peer-review process into five stages. The first stage is we take a look at what came in in the draft final report and we make pre-review edits before we send it out to the editors. And what we found is that sometimes these actually have to go back to the applicant, the awardee that is, for some editing before we even feel good about sending it out to the reviewer. So that's stage one and stage two is we send it out to the peer-reviewers and they're doing their review. Stage three is we're going back and forth with applicants about the comments of the reviewers and this usually involves getting at least one revised final report from the applicant and then completing the peer-review and developing those summaries.

Now in the green below, I say now as of today 20 studies -- I'm not talking about the end of Quarter 3 anymore, I'm taking about today, 20 studies have completed PCORI peer-review, but over

the weekend two more got approved. Hal just slipped me the number this morning, Hal Sox, so it's 22 studies have now completed peer-review. I think we can say that within 90 days we will have at least 22, actually there are five I think posted now and we will have -- no that's not true, there will be 22 posted within 90 days of now, because the final stage is getting the results posted.

The summaries have been developed and the lay and professional abstracts go on our website.

We expect to have 62 studies completed, that is approved and ready to be summarized and posted by the end of this year. And as I said Evelyn is going to talk more about this. It's not that we are resting on our laurels, we continue to work and improve. I already have made some improvements in the peer-review process, just some learnings.

So now for three examples. This is a study, a randomized trial of commonly asked and widely disputed question in type 2 diabetes whether you should tell diabetes patients who don't take

insulin that they should prick their finger once or more times a day and use a glucose glucometer and a and a glucose strip to test your blood sugar value to adjust their diet or their exercise.

So many people felt that if you weren't taking insulin this was not really relevant and it didn't make a difference, other people thought that it must. Observational studies were mixed on this question. This was a three-armed randomized trial; 450 people in total followed for a year, and there were three approaches. One was don't use self-monitoring of blood glucose which is called SMBG. One was to use it as is typically used in practice and the third way was to enhance the use with a specialized feedback that should help people adjust their diets and exercise better.

And what they found that in neither of the intervention arms was there a difference in either blood sugar -- blood glucose control, rates of hospitalization, needs to start using insulin or quality of life. That the results augment some findings from previous research but are the most

definitive to-date. So the conclusion of the author was that our study results have the potential to transform current practice for patients and their providers by placing a spotlight on the perennial question of 'to test or to not test?'

I will say that SMBG is also a big issue because glucostrips cost a lot. I'm not exactly how much, but over a year -- pardon me? A dollar a strip. So that would be minimally $30 extra a month and CMS has had a lot of questions about covering this in fact.

This has garnered more attention from the media than I think any publication to-date, at least 120 news stories, 106 news outlets have demonstrated the interest. The Choosing Wisely campaign, as early as 2013, had recommended against daily home glucose testing in these patients. That is -- I want to be clear, this is patients who are not using insulin. Those who use insulin should definitely use self-monitoring with finger -- with glucose strips and finger sticks.

So this was one of the SGIM and Choosing

Wisely's top five tests and procedures that physicians and patients should question. So Choosing Wisely has been very receptive to this new information. It's been very helpful in their case.

Now another question about speeding the uptake in use of information. So Goal 2, so there's three studies now that have been -- whose findings have been built into UpToDate and those of you who are physicians know that UpToDate is the way of the physicians on the wards and in the clinic keep up with the latest research and check when they've got a dilemma on their hands about what to do.

So two of our studies on localized prostate cancer, the outcomes of the three treatment choices have their results have been incorporated in UpToDate and the Keren study, which you know well, the study about using PICC lines versus oral antibiotics at discharge after osteomyelitis; those three have been incorporated into UpToDate. So this is hopefully one of the ways that we do that very difficult step of changing practice.

And then in terms of speed the use uptake

in -- this is still in this -- we have also funded and still on Goal 2. We've got two new CME programs, five now all together on our website but you can take a look at these two on the website.

One is on contemporary treatment options for prostate cancer and then the second one is on the PROSPER study which is about the use of anticoagulants in elderly patients with atrial fibrillation who've had a stroke. And so, these are new CME activities, very nicely done on our website.

And toward Goal 3, changing the way that others do research. This is a report from the cancer outcomes research group at Mass General using a PCORI-funded project. They established a PFAC; a Patient and Family Advisory Council specifically for their outcomes for a research programs. This is the first PFAC I've heard of for a research program, but very exciting because they've got patients and family members helping them understand the kinds of research studies, as a cancer outcomes research group they should focus on.

So nice to see a research unit pulling

patients and family members into their planning.

This just shows the altmetric scores and you'll see the top one is the diabetes one and it's way out there in front, but others with very high scores in the last quarter.

Yes Sharon.

DR. LEVINE: Just looking at the previous slide. Now I guess it's two previous slides. The use of the word 'forced.' "PCORI forced us to get out of that old mode." I think that's a wonderful example --

DR. SELBY: Instead f saying influenced they said forced.

DR. LEVINE: Right.

[Laughter.]

DR. LEVINE: -- incentives to change behavior, I think it's great.

DR. SELBY: Okay and then every quarter we do -- we feature something and I wanted feature recruitment because of science staff, evaluation staff, and analysis people have put in a ton of effort on getting a better handle on recruitment so

I want to address to questions ones about the proportion and number of studies that have successfully completed enrollment and there are a lot of them now and then to what extent do they need to modify their project plans and milestones in terms of timing and terms of sample size in order to complete recruitment.

So the bars across the slide are the -- kind of the national averages gain from our checks with the literature and the other funders. On average about 10 percent of research projects are not successfully completed nationally. PCORI to-date that figure is less than 5 percent; 47 percent of studies meet agreed-upon recruitment timelines including some extensions; 69 percent of PCORI projects to-date have met recruitment timelines after some modifications.

And in terms of modifications, study timelines are typically extended to nearly double their original duration. When they are extended our average extension is 6.3 months, which is well under a doubling of the recruitment time. So it looks at

this point like we are doing at least as well as others and maybe somewhat better.

We've got 309 perspective studies and I don't have the exact number that are longitudinal cohort studies but I can tell you that the vast majority of these are randomized trials, the vast majority. So 137 of them are either in recruitment or haven't started recruitment yet, but 172 are no longer recruiting. And of those 164, so well over 90 percent completed as planned and that is they -- they completed it within their timeline although some of them are within renegotiated timelines with at least 85 percent of the plan sample size recruited. So 164 of them.

There were four in which recruitment was suspended by the investigators for one reason or another and there were four where the study was terminated by PCORI.

In terms of recruitment completion, you will see it in terms of the time it takes after the negotiations and I'll show you the percent that a required a renegotiation on the timeline. We had

29 percent of that completed early, 40 percent on time so a total of 69 percent completed on time, 31 percent late. And that's just on the rise of the distribution of those times and you can see that there were 11 that were delayed; 11 out of 164 delayed seven months or more beyond their negotiated time.

So 38 percent of the 164 required a negotiated extension of at least a month in recruitment and meeting the recruitment extension 5.3 months, 61 percent then completed on time and 39 percent actually took more time even after the renegotiated extension. So the average time to complete recruitment was 130 percent of the original plan across all of the projects.

In terms of enrollment targets; 96 percent of all projects recruited at least 90 percent of their target sample size and 75 percent recruited 100 percent or more and you can see there that that’s 83 studies that were 100 or more -- I'm sorry those are all those 83-plus-20-plus-21 are about 13 percent of PCORI’s studies achieved more than 120

percent -- 20 percent of enrollment target.

Only 10 percent of projects had to negotiate their sample size down to a median of 70 percent -- 76 percent of the original enrollment target range was 50 to 90 percent. And then fifteen of these studies -- so 15 out of 17, achieved that modified enrollment target and two fell short.

This is just a sample size in the 164 completed studies and you will see that there are a lot of them, the majority are less than 500 reflecting the fact these are almost all -- these are all I think broad awards, relatively small awards but there were a pretty fair number that went as high as a 1,000 or more.

So that's the end of the report and then let's see if there are questions.

CHAIRMAN NORQUIST: Let’s open it up, if people on the phone will just wait a minute and let me go around the room here first. So Bob Zwolak is first.

DR. ZWOLAK: So this is work I think we should be proud of. It’s absolutely delightful to

see all these publications and in particular from my perspective the trials. I suspect we'll see many more trials like this. The diabetes trial to me seems to be the heart of what PCORI ought to be about, I mean, real world trials that are important to patients. The concept of whether or not you've got to stick yourself everyday to check your glucose if you're not on insulin I think is critical.

So that's good, but that the trouble I have I think a little bit is you showed us probably about 20 slides analyzing the recruitment rate appropriately and encouraging our funded researchers to recruit timely, but if we think this peer-review process contributes to speeding the uptake of useful information then I think we need to look inward towards analyzing and improving our peer-review process just as much as we look outward at our researchers expecting them to recruit in a timely manner. I think that 8.6 months to complete peer-review is pretty bad, so I think we need to focus inward on that as well as focusing outward on our researchers to recruit timely. Thank you.

DR. SELBY: Thanks. We agree and as I said some work has been underway for several months and I think components of it already are speeding up but we continue increasing the number of reviewers for one thing, but there was a lot to learn as we just put this brand new program into place.

DR. McNEIL: Joe it's Barbara, is there anything the NIH can help us more on this issue of speeding up our evaluation process?

CHAIRMAN NORQUIST: You spoke just about the time Michael raised his hand -- so, Michael.

DR. LAUER: I'm not sure what evaluation process are we talking about?

DR. SELBY: So we're talking about the peer-review process of our final reports, which to my knowledge you don't do a lot of it at NIH.

DR. LAUER: We are -- you are way ahead of us in this disregard because what we're doing now which is new, is we are now insisting that people turn in their final reports and with it have a lay language summary that we then post on our website. What you're asking for is far more ambitious, so I

think we could learn from you as opposed the other way around.

I wanted to ask about your recruitment statistics which look really good and I'm wondering whether in the way you negotiate your contract with your awardees, do you deliberately build in a pessimism bias to overcome the optimism bias? Do you like deliberately say okay we're going to double the amount of time that's necessary or no?

DR. SELBY: I'm looking at Evelyn and she says no. But there are milestones --

DR. LAUER: Yeah.

DR. SELBY: -- you know, an important point Mike, is that our awards are contracts. So when we sit down to sign the contract we have milestones and our program officers monitor those milestones which is probably a more intense oversight --

DR. LAUER: Yeah.

DR. SELBY: -- than NIH uses at least in its R01 type of award.

DR. LAUER: Yeah, I would think so because this way --

DR. WHITLOCK: Right.

DR. LAUER: -- because you could end the contract.

DR. WHITLOCK: Right.

DR. LAUER: It probably makes the negotiations more realistic.

DR. WHITLOCK: I think actually what we think is that we've negotiated so aggressively that that's why we had to have some prolonged timelines on some of these because we really -- we have been so focused on getting the studies done and the results found out that I think in some cases investigators were -- I'm not sure what you meant by the pessimism/optimism bias but investigators were optimistic and we've had to now become more realistic.

But I will talk in the SOC update about the closer monitoring that we're doing so that we are trying to detect if there is any/either optimism or pessimism bias. We're picking up what's actually happening in the real world sooner so that we can, of course, correct earlier. So I hope that helps.

CHAIRMAN NORQUIST: Other -- on the phone?

DR. McNEIL: Well, I had asked Gray but Michael answered my question about whether the NIH can help and he obviously said we're way ahead of them. So that's the answer. Thanks.

CHAIRMAN NORQUIST: Way ahead, they're learning from us -- yeah, okay. Anyone else? Joe?

DR. SELBY: Sorry Gray, that's the end of my presentation.

CHAIRMAN NORQUIST: I don't think you have anything to be sorry about, I think it's very good. So I think the other thing we do need to say is that we really appreciate that the staff -- I mean, this is an incredible amount of work to put these slide and everything else together. So you know I want to thank your staff as well that have done the yeoman's -- or whatever the word is, job here to put all of this together. You know? And not including what comes after this, just wow.

DR. SELBY: On behalf of them, thanks very much and I certainly agree with you.

CHAIRMAN NORQUIST: Now to go forward; my

the next topic is the Methodology Committee Update. My understanding is that Robin and Steve are both on the phone and I'm not sure if they're on the phone yet, so I'll let see. Robin and Steve or are you by any chance on the phone?

[No response.]

CHAIRMAN NORQUIST: No, okay.

And we can't go to the next one because it's lunch, so I guess it's -- so I can't like go ahead of the -- we don't have anyone I guess here to help us with the Methodology Update. We have to wait on --

DR. WHITLOCK: Dave and Emily can you can you --

CHAIRMAN NORQUIST: Can someone text them or something, to just see if we can get them on the phone? The Methodology --

You can? Oh, okay.

So we're going to find someone else here to do it.

DR. SELBY: David or Emily, do you feel either of you feel prepared to actually give the

presentation?

CHAIRMAN NORQUIST: Yeah, we don't want to put you on the spot if you don't feel like you're ready.

DR. SELBY: Okay, well I'd invite one of your or both of you --

CHAIRMAN NORQUIST: I want you to feel inspired to do it. Can someone email or text Robin or Steve just to let them know?

DR. SELBY: That's a good idea.

CHAIRMAN NORQUIST: Oh wait a minute, I think -- I'm sorry just a minute -- hat we could do -- I'm sorry.

What we're going to do because we're now thinking we'll let you stay up there if you want to sit, but we're thinking since it is their committee we should not put them in a position where they don't get the present and Christine has volunteered an afternoon thing but that was only a 15-minute thing which is the Selection Committee. We could skip to that and do that section and that will allow Robin and Steve to do their part.

Is that okay?

DH: Yeah, that's fine.

CHAIRMAN NORQUIST: All right. Sorry w made you -- a little exercise to get -- but you can sit there if you want to.

So Christine -- what we're going to do for those on the phone is we're going to skip ahead to an item that we had after lunch, which is the -- okay, we have to approve so let's make sure we have enough. I think we have a quorum to approve, right?

DR. SELBY: Yeah.

CHAIRMAN NORQUIST: Okay all right, go ahead. So Christine this is the additional application for approval, right?

DR. McNEIL: What's slide number Gray?

CHAIRMAN NORQUIST: What's the slide number Christine? I'll quickly see if I can find it here.

MS. GOERTZ: There it is.

CHAIRMAN NORQUIST: Forty-four.

MS. GOERTZ: It's 44 Barbara, I don't know if you were able to hear.

DR. McNEIL: I got it, thank you.

MS. GOERTZ: Great, thanks.

CHAIRMAN NORQUIST: Yeah, I got it. Okay.

MS. GOERTZ: So every now and again -- well actually it's not uncommon when the Selection Committee meets to run across an application where either that the staff has requested extra time or the Selection Committee has questions that require some sort of additional information before we can move forward with the recommendation to the full board. And so, we have one application that falls in this category for consideration of approval for this particular meeting it has an application from our Cycle 3 2016 critical strategies for managing and reducing long-term opioid use for chronic pain PSA and I'm going to ask Evelyn to present the project.

DR. WHITLOCK: Thank you very much Christine, I'd like to advance to the next slide please. I'd like myself to advance to the next slide.

So we are presenting to you an additional project as Christine said, that would add to the

Cycle 3 2016 funding slate. As you will recall you approved one project of the comparative effectiveness, you will see the first title. You approve this already and we did some additional work with the applicants and are very pleased on behalf of the Selection Committee to bring to you today another project that the Selection Committee has recommended to you for funding.

This project is called Integrated Health Services, to reduce opioid use while managing chronic pain.

As you may recall, in Cycle 3 of 2016 there had been a posted amount the SOC approved $19 million. The previously approved award was $8.8 million. If you add in the new award which is $9 million, we will be close to but a little under still the total amount that was available in the original approval by the board.

So this additional project that we're recommending to you as I mentioned will answer the question “In clinics where providers receive a 4-hour training on the revised CDC guidelines, what is

the comparative effectiveness of two different active strategies to work with patients?" One is a shared decision-making strategy versus a cognitive behavioral therapy strategy that also has a component of motivational interviewing. And this is focused again on patients who are chronic opioid therapy users looking to manage opioid reduction as possible along with adequate pain management.

The population is any adult 18 years and older using at least 50 mg of daily medication equivalent dose or morphine equivalent dosage for 90 or more days and also have six or more prescriptions in the prior 12 months. And I'll give you a little more detail about the two active comparators, but the background is that all of the clinicians will have already received a 4-hour training on the CDC guidelines.

This is important because the CDC guidelines are comprehensive but there are areas where the implementation of these guidelines has been of concern to practitioners in order to be sure that they are adequately achieving the dual goals of

this funding announcement which is adequate pain management along with safety in opioid use.

So the outcome of interest, the primary outcome is opioid dose reduction which is the large focus of the CDC guidelines but the secondary outcomes are very patient-centered; physical functioning, pain interference in daily life, self-reported pain status, generalized anxiety disorder, depression, and other patient-centered outcomes including satisfaction with care.

It's a large randomized control trial with a sample size of a little over a thousand, the length of follow up will be 12 months. Now the two interventions are going to provide different ways that clinicians will be supported in helping their patients to both achieve opioid reduction as appropriate but also to manage pain. The intervention looking at motivational interviewing also has after two sessions of motivational interviewing, there will be eight sessions CBT that are focused on chronic pain management. For the shared decision-making arm there will be up to 12

sessions of shared decision-making.

The first at baseline -- at months one and two there will be three definite visits and then depending on how things are going for the participant, they can further meet with their clinician every one to three months over the next nine months. So these are both active strategies to assist clinicians and patients in this complicated and challenging process.

The total project cost is $9 million.

The impact of this could be very helpful for a number of clinicians who are struggling with this issue, it has the capacity to facilitate opioid reproduction in patients who are not receiving benefits or and are interested and/or are interested in dose reduction if there's a safety component because folks in this range are likely to escalate their dosage and are at risk for some of the negative consequences. It also can help folks that are trying to implement these CDC guidelines to know how to do in the real world. The intervention and the outcomes are patient-centered and there is a

strong engagement component with folks that are affected themselves as well as advocacy organizations experts and state health departments, and insurers and these have contributed across the idea of the study design, intervention, and the outcomes. And there are strong opportunities for dissemination, including through some of our partners like the Medicaid Medical Directors Network at the conclusion of the study.

So I'm happy to answer any questions, if anyone has them about this proposed study or to turn it back over to Gray for further moving forward in the board process. Thank you.

CHAIRMAN NORQUIST: So let’s open it for any questions about this to this particular project.

MR. BARNETT: So let’s assume this goes as planned, you get the results you expect to get. What’s your projected impact going to be relative to opioid use?

DR. WHITLOCK: Are you asking for a quantitative estimate or you mean would this help reduce opioid use? Is that what your question is?

MR. BARNETT: Well, in the [inaudible] case would it help reduce opioid use? Does it address the problem? And yes, if you had a projection of this is going to have a one percent impact -- ten percent impact -- if we put $9 million in --

DR. WHITLOCK: Right.

MR. BARNETT: What result will we get? How are we going to help the crisis across America?

DR. WHITLOCK: Sure. And I think as I'll show you later in Scientific Oversight Committee presentation, the investment PCORI has made in the opioid epidemic is across the spectrum. So certainly from prevention to management, this is in the management quadrant, to then treatment of opioid use disorder -- which we hope people don't get to, but this is in the management quadrant and I think that because this is a -- this group is considered at least moderately -- moderate to high users, then we're hoping to manage -- to help people manage their pain so that they can reduce their use, reduce their dosage so that it is safer. We can prevent the escalation of dosage which happens when there's

adequate pain management or people don't have another strategy.

So I think it's a key part of -- a central part of the strategy, which is as we help people manage pain more appropriately people need to know how to both manage opioids and adequately address the individual pain management. So I think it's an enormous part of the contribution to what's happening right now.

CHAIRMAN NORQUIST: I just want ask a question so I've got this right. I'm looking at the two comparators. So in comparison everybody [inaudible] of the arm in the CDC guidelines and the comparison is between using the shared decision-making only, getting CBT with motivational interviewing --

DR. WHITLOCK: That's correct. The shared decision-making, I think, in terms of what it actually represents maybe a little different than we usually think about it.

So the shared decision-making component as I mentioned we have clarified with the applicant to

be sure that it's an active component that would really assist patients in managing pain. The original funding announcement was very clear that we -- that opioid dose management needed to be in the context of pain management. That's the patient-centered approach. So the shared decision-making component will have at least three visits on a monthly schedule that will introduce people to the idea of decision-making, we'll show them videos about opioid use and what else can be done in terms of safe pain management. What people need to know about the benefits as well as risks of opioids.

And this will continue through a process of enabling both the patient and the clinician to be aware of the facts and then to work effectively in a strategy for that individual.

CHAIRMAN NORQUIST: Yeah. So actually where I'm going with this is you're comparing those two, let's say the arm with the shared decision-making comes out with a more positive effect, let's say, than the cognitive behavior therapy MI then the conclusion could be that you could do only shared

decision-making as opposed to having people get CBT or MI. Right?

MS. GOERTZ: I think there will be an opportunity to look at for both. So they were equivalent in their impact. Say both are effective. The look will be actually on the absolute impact from baseline to follow up for each of the arm, so there's additional information to be learned about the effectiveness of each of the strategies as well as their comparative effectiveness. Is that your question?

CHAIRMAN NORQUIST: Yeah, but you could up with a result that one has a much greater effect.

MS. GOERTZ: Absolutely could.

CHAIRMAN NORQUIST: And so, the implications for that -- there is another implication for that where there’s a very resource poor opportunity where you don't have access to CBT and MI which is a lot of places, quite honestly. I mean been trying to get legitimate cognitive behavior therapy motivational interviewing, may be very limited and so the potential benefit of such a

study might be that you could use a less costly -- let's say or less intensive where it may not be available, shared decision-making as opposed to cognitive behavior --

DR. WHITLOCK: So what you're potentially because you are looking at from baseline to follow up the effectiveness of each of the strategies not just comparing them that this may give a menu of options for settings depending on what their resources are and their services available are.

CHAIRMAN NORQUIST: Freda.

DR. LEWIS-HALL: I was going to ask it -- I guess a little bit of a different way, which is what is the scalability finding?

So at the end of the day if you -- if one finding versus another, I think Gray this is where you were going, what is the likelihood to be able to scale to what we would then defined as the most effective or most appropriate therapy?

DR. HICKAM: So this approach to shared decision-making is actually built on the model that was developed and disseminated by the Agency for

Healthcare Research and Quality, so it is built upon an approach for which there is some guidance and for which is going to be possible to state how this was carried out in the primary care clinics where this study will be conducted. So I think that it does give an avenue for being able to implement it after the study depending on what the findings are.

And maybe to go backwards to the previous question -- I mean I think this is exactly what this study is about, is to try to understand reasonable strategies that can be applied in primary care clinics for helping people who are on opioids to reduce their doses and dose reduction is an important outcome. It's the primary outcome of this study and we kind of went into the whole sort of power estimate, the sample size estimates needed based upon realistic estimates of how much impact these in these interventions would have. So it's powered to be able to detect about a 20 percent reduction in dosage on average across the patients in the study which is I think everyone would agree that on average meaning that some patients will

probably achieve better dose reduction. So that is a pretty reasonable goal for a study like this.

CHAIRMAN NORQUIST: So I think the answer is it is scale. I think that was the question specifically that is that shared decision-making should be easily scalable and much more scalable than let's say having a bunch of people who can do CBT or MI, if it comes to that.

Other -- I'm sorry Bob I didn't see your tent.

DR. ZWOLAK: Thank you. Bob Zwolak, board member.

My question was exactly about scalability of CBT and I think it's been answered. My sense is it's not available very widely in many parts of the country. Aside from that is assuming we're going to deal with that issue as we move forward with the congratulations that I have been from the state of New Hampshire, which is the focus of the crisis. I think the more that PCORI awards for valid and appropriate opioid research, the better.

DR. WHITLOCK: Thank you Bob and I just

want to say that not in this context we are doing work right now for childhood anxiety on the issues of digital access to CBT and I think this issue of access to CBT is an important one that I believe Alicia Fernandez has made quite clear in our SOC discussion so we need to continue to think about as CBT is a preferred alternative to a full range of conditions -- how is it made more accessible to enhance scalability.

CHAIRMAN NORQUIST: The only caution about that is there is some concern about the utility of digital -- I mean, delivered CBT so there will be those other issues like that.

MS. GOERTZ: We are actually testing some of that.

CHAIRMAN NORQUIST: But anyway, that's a whole other topic. So any other questions specifically to this one at this point? On the phone?

[No response.]

CHAIRMAN NORQUIST: Okay I need a motion to approve. Mike. And then a second? Thank you Leah.

We have to do a roll call vote, right?

MS. GOERTZ: You can do hands --

CHAIRMAN NORQUIST: We can do a hand and then a call. Okay so everyone in the room who is in favor --

[Hands raised.]

CHAIRMAN NORQUIST: Anyone opposing?

[None.]

CHAIRMAN NORQUIST: And anyone abstaining. Are you conflicted the two of you?

DR. LEVINE: Mary's --

CHAIRMAN NORQUIST: Mary's right here.

DR. LEVINE: Something I'm conflicted on.

[Off microphone discussion.]

CHAIRMAN NORQUIST: I had no one listed here as conflicted but I could be wrong.

DR. LEVINE: It was another opioid related --

CHAIRMAN NORQUIST: Okay, so you want vote now in favor?

DR. LEVINE: Yes.

CHAIRMAN NORQUIST: Okay, Freda, do you

think you're conflicted?

DR. McNEIL: Hello?

CHAIRMAN NORQUIST: Hang on Barbara, we're having a discussion about whether someone's conflicted here.

DR. McNEIL: I'm for it, just in case we get cut off.

DR. LEWIS-HALL: [Off microphone.]

CHAIRMAN NORQUIST: So -- what do you think Freda. Do you want to abstain?

Okay, so Freda is going to have to abstain because she's not sure if she's conflicted.

Yeah. That's the way to do it. We don't want any problems.

Okay, so on the phone? Barbara are you voting for, abstaining, or against?

DR. McNEIL: I'm voting for.

CHAIRMAN NORQUIST: Okay, Harlan are you on?

[No response.]

CHAIRMAN NORQUIST: Allen? Allen Douma.

DR. DOUMA: Approve.

CHAIRMAN NORQUIST: Okay, is anyone else on the phone? The only other person would be Rick.

[No response.]

CHAIRMAN NORQUIST: Harlan didn't answer.

So it's approved. Thank you Evelyn and your team very much and thank you Christine and the Selection Committee as well.

And I hear that -- I've been told that Robin and Steve are on the phone now, so we're back on time. So Robin and Steve, I don't know which one of you is going to go first. Who has the slides?

DR. McNEIL: This is Barbara, I have to drop again for PT. I'll be back.

CHAIRMAN NORQUIST: Okay, thanks. So Barbara McNeil is dropping off.

MS. NEWHOUSE: This is Robin can you hear me?

CHAIRMAN NORQUIST: Robin, yes. Is Steve on?

DR. GOODMAN: I'm on too.

CHAIRMAN NORQUIST: So Robin, I'm going to let you -- I don't know how you and Steve are going

to do this, so I'll let you go first.

MS. NEWHOUSE: All right. First we're going to introduce some proposed new standards and then we're going to take a few minutes just to do some reflections about the Methodology Committee since we began in 2011.

So let’s start with a methodology update and you should see slides that say Methodology Committee Update proposed new standards. And just to get started I wanted to thank the Methodology Committee for all of the work that they have done to contribute to the generation of these new proposed standards and you should see in your slides that now the names of the people on the Methodology Committee.

Just to refresh your memory. Steve and I are presenting on their behalf.

The next slide provides an update on our approach to the development of the methodology standards and, of course, these standards are required by PCORI’s authorizing law. And the Methodology Committee is proposing that the board

approve the posting of these new methodology standards for public comment.

Just a reminder that these standards are minimal standards for the design, conduct, and recording of comparative effectiveness research and patient-centered outcomes research. And the intent is to provide guides for researchers who use research results as well as conduct the research and these standards represent generally accepted best practices.

Next, we'd like to introduce our standards and also want to mention the approach to the development of the methodology standards. So all of our standards start with a evidence review so in coordination with the PCORI staff and the Methodology Committee members, we generally conducted a evidence review of the science related to each one of the standards and then we draft ordinary standards based on the science.

The next step is to gain feedback from the Methodology Committee to put the standard in a presentation format and we invite experts to comment

on those standards and deliberate in an interactive mode with externally selected experts.

The next step is we bring them back to the Methodology Committee for more deliberation and then when all revisions are done to our satisfaction, we vote and with a majority vote we have endorsed these methodology standards that we're presenting to you today.

The first set of standards is related to complex interventions and you should have a slide that says proposed new standards: studies of complex interventions.

CHAIRMAN NORQUIST: We have them.

MS. NEWHOUSE: Okay, thank you.

The rationale for the standard is to assure the design, conduct, and analysis, and reporting of studies that are using or testing complex interventions. They are certainly frequent. They have complex interventions. They have multiple components that are being tested and they're being used with increased frequency.

We suggested a set of new standards that

you should see on your slide now. The first of the minimum standards for complex interventions would be to full describe the interventions and comparator and define their core function.

The second is the specified, hypothesized causal pathways and their theoretical basis.

The third to specify how the adaptations to the form of the intervention and comparator will be allowed and recorded and the fourth to describe the planned data collection and analysis.

So that's the first set of standards.

The next slide includes the addition to a new standard for data integrity and rigorous analysis. Of course data management plans are fundamental to ensure the scientific integrity of clinical research and particularly with our open science dialogue this becomes very important to have a good data management plan.

So the recommended standard that you see before you is an addition to the data integrity and rigorous analysis standards. And this standard is in the study protocol, specify a data management

plan that addresses at a minimum the following elements: collecting data, organizing data, managing data, describing data, preserving data, and sharing data.

So at this point what we're asking is board approval to release these five standards to the public for comment. If the board approves, we would make those standards available on the PCORI website for public comment.

We would then after the standard process is completed and we receive all public comments, we would read and process those comments, categorize them, make changes to the proposed methodology standards as we've done in the past based on the public comments.

The Methodology Committee would then develop a revised methodology report based on those revisions and additions; and then we would come back to the board to seek approval to adopt the revised proposed standards and accept the new revised methodology report.

The timeline for this work would be between

November of 2017 until May of 2018.

And with that I'll close and ask for any questions or comments.

MR. BARNETT: So Robin the board would then be expected to vote on the new standards when would that be? The June meeting of next year?

That's the rough timeline.

MS. NEWHOUSE: I would say it would be one of the spring meetings.

MR. BARNETT: Okay, let's go ahead and open it up for any questions for Robin or comments on the proposed standards.

Leah.

MS. HOLE-MARSHALL: Good morning Robin, thank you for joining us.

MS. NEWHOUSE: Hi Leah.

MS. HOLE-MARSHALL: My question is that I'm really excited about the methodology standards for this set of studies if I understand it correctly. But my question is that most of the standards as I am reading through them, not being a researcher or a methodologist, is really about transparency.

So all of these standards aren't specifying what the analysis needs to include but rather that it needs to be expressly stated; is that an accurate characterization?

MS. NEWHOUSE: That's correct. And most of the work by the Methodology Committee, again, was to really construct the guidance for those minimum standards. What needs to be in a proposal to make sure that all the components that are linked to the rigor of the design and the conduct of a study are included and transparent. Then it's very difficult to create a standard that says you must do this when you think about an analytical approach, for example.

So our intent is to create this framework of a minimum standard so then through the scientific review, additional valuation can be conduced; investigators can state why they're using a certain design or approach. But these are the components that should be in the proposal to help make a judgment about the quality of the proposal when a complex intervention is conducted or you're presenting a data management plan or when you

present your data management plan.

And Steve, please feel free to chime in.

DR. GOODMAN: Yeah. I'd like to put a little different spin on that. If these elements exist, then it's all about transparency.

But the problem is with regards to data management plans and also with many proposals having to do with complex interventions, sometimes proposers have not thought of the elements that are in the standard, in which case the standard actually tells them they have to create what the standard demands -- that shows a plan for data preservation, or a plan, you know for storage et cetera.

If those things already exist, then yes it’s merely transparency, but what they really are is a guidance to make sure that they are created and then to be recorded.

So in a sense it’s about transparency but really for many of these we think they’re there because we don’t think the investigators typically, adequately, consider these things and then you don't even have formal data management plans in a better

-- they don’t have them that they're not revealed, but they don't have them at all.

So this is telling them what the structure of such a plan is and what they should create.

MS. HOLE-MARSHALL: Would there be any thought to -- it seems like such a huge leap forward, so I'm completely on board with it but I'm wondering if there would be any thought to -- as we learn more enhancing these standards with -- even if you don't have a particular it has to be conducted in this way, either minimal considerations or the reason that I'm asking is that I do think that we sometimes get into a discussion in the Selection Committee about methodology and methodology standards and sometimes what happens is the methodologist that reviews it becomes our guide and there are differences even within the methodologic communities so then we're still -- we’re not able to use some criteria to stay did they need it or not meet it?

We need to just rely on an individual expert which is appropriate and important, but also

they have their own bias.

So I'm just wondering if from your perspective this particular group would be amenable to editions later on about, you know, the significant things to consider even if it's not an actual standard or whether you feel like this is probably the best the science around the methodology can give us.

MS. NEWHOUSE: Go ahead Steve.

DR. GOODMAN: I was going to say it’s a spectacular point, we’re walking a tightrope here. It's very hard to be to prescriptive, for example let’s just talk about preservation. There are many, many ways that it can be done but we want to make sure is that is preserved in certain way in a functionally, retrievable, useful, readable and you know when the investigators are not available. There are many ways to do that. We can't write a handbook on that.

So you're absolutely right that there's always going to be some degree of interpretive space and it's almost impossible to write standards that

don't require a good state of interpretation, just like we have judges for the laws. And we pay very close attention to this when we write them in trying to provide enough detail so it satisfies the spirit of what we're trying to do, but not so much that the proposer's could be handcuffed.

If we got more specific, you would find yourself in another difficult spot which is that people could propose the standard -- the logistics of these often change, people could propose completely adequate ways to meet the standard and yet it would be exactly what we had put there in terms of the specific detail and then you'd be stuck with saying, “Well, what they're doing sounds fine, but it’s not exactly what the Methodology Committee listed as the process.”

So we’re trying to have in a sense laws that whose spirit is clear, but will stand the test of time as the specifics change. So I do understand your problem and I think if there is feedback to us about particular standards that are particularly difficult to interpret, because we don't want them

to the useless, then that would be a very valuable feedback.

In many ways this is an experiment, you know, an institution-wide experiment and we to constantly be iterating and refining to get standards that are the most practical and useful.

DR. ZWOLAK: Bob Zwolak. Thanks very much Robin and Steve.

I think these are excellent but to me the standards for the complex intervention seem pretty complex. I wonder if you could just bring this home with an example of a study that might be outside of these complex intervention standards that you could help improve. Just a simple real world example, either a past real example or a future hypothetical example.

MS. NEWHOUSE: Okay, so if you think about some of the interventions around complex illnesses like diabetes or heart failure. Many times the interventions have multiple components. Those multiple components may be to increase knowledge, maybe improve skills for patients, and a number of

other factors with the idea to improve outcomes, decrease blood sugar for example.

So the intervention could be things such as are typical in-person group interventions to improve self-management for diabetes. And a comparator may be an online intervention. That intervention, itself, has multiple components to try and specify what's being taught, what's the [inaudible], is it equivalent in both arms? Would be a way to fully describe the intervention and comparator.

Then in terms of specifying the causal pathways, you would use some kind of theoretical framework to understand the active ingredient and what the effect of that active ingredient was; whether it was education or a self-management plan.

And then in terms of the third issue, the adaptations -- it's not an adaptation to the function to improve self-management, for example. It would be an adaptation to the form, in that perhaps a method of measuring one of the outcomes -- there maybe a method of education, there maybe online education, there maybe more of the same

education in-person which might be a different form.

That was not a good example, because I used a comparator online and in-person for.

But you would have to specify exactly what is allowed and what is not allowed to assure that you had integrity and fidelity in the intervention.

And then describing the plan for data collection and analysis would specify what methods are used to understand the fidelity and to collect information about the outcome of interest.

Does that do it Bob?

DR. ZWOLAK: It helps a lot, thank you.

MR. BARNETT: Christine.

MS. GOERTZ: I just I want to thank Steve for his really thoughtful response to Leah's question and to the entire Methodology Committee. You know, Robin and the entire committee for really doing an excellent job of walking that line in creating standards that actually have enough detail and specificity so they that investigators have true guidance, but not having so many details and rigidity that it hampers their ability to conduct

the science that they're [inaudible].

So thank you for doing such an excellent job on that extremely difficult task.

MS. NEWHOUSE: Thank you Christine.

MR. BARNETT: If there are no other questions or comments, including from anybody on the telephone I'll pause.

[No response.]

MR. BARNETT: Okay, can I ask for a motion to approve the release for public comment of the new proposed methodology standards?

Christine motions, Larry Becker the second. Any further discussion?

[No response.]

MR. BARNETT: If not I'll ask for a show of hands, all those in favor please raise your hand.

[Hands raised.]

MR. BARNETT: Any opposed? No.

[None.]

MR. BARNETT: Any abstentions?

[None.]

MR. BARNETT: And then we'll ask the folks

on the phone. Allen, how do you vote?

DR. DOUMA: Approve.

MR. BARNETT: Barbara, how do you vote?

[No response.]

MR. BARNETT: I'm sorry, Barbara is off. Anybody else on the phone at this point?

[No response.]

MR. BARNETT: Then I'll turn it back over to Gray.

MS. NEWHOUSE: Okay, thank you all for approving it.

So Steve and I just wanted to take a few minutes and reflect on the Methodology Committee, where we started and just discuss some of the formative work that's been done by the Methodology Community, the engagement with the PCORI board and hopefully the method standards that we are providing to you as the PCORI board are helpful in improving the quality of the studies that are funded.

As you know our role is to create methodology standards for studies that are funded by PCORI and we started by identifying those gaps in

the research methods are so that they could be applied to improve the quality of any studies that were funded by PCORI, to continue to work toward that goal.

So in terms of some of the Methodology Committee's work in the past since we were appointed in January of 2011, has been both informative in a way that is a contribution to the work of the research priorities as well as the methodology standards. So just some examples of some of the formative work that we did very early that helped to inform the direction of not only the method standards, but some of the priorities.

So very early in our work on the Methodology Committee we started to think a lot about where those method gaps existed and we reviewed the evidence, we reviewed some of the priorities around methods and comparative effectiveness research and we found ourselves seeking to gain broader input.

So very early in our work we did outreach not only through contracts for the first set of

methodology standards, but also through workshops in open venues to do some work first to understand what is patient-centered outcomes research and to come to some really conceptual definition of exactly what that was and held some open sessions related to incorporating the patient's perspective in patient-centered outcomes research between 2012 and 2013.

We did some really foundational work to identify those methods gaps where we could establish minimum standards and those methods gaps became the first set of standards that were provided for approval to the PCORI board for posting in May of 2012, a little over a year after we were formed.

As well as trying to establish how best to set research priorities and explore the notion of patient-reported outcomes and electronic health records. And ended up having some foundational workshops in both 2013 and 2017 toward that goal.

In terms of the development of the methodology report and methodology standards, we developed the initial set of standards, as I said in 2012, with a following report that was approved in

2013. And at that point the methodology standards began to be used in all funded studies that PCORI funds.

Our work wasn't done and we have continually evaluated where some of the methods could be developed as we've learned from proposals that were submitted and as we've watched the standards, and as we've heard from the field and public meetings, and our online venues which really inform the next set of standards that we were able to present.

And most recently, the last set of standards were around designs using clusters for example.

We also work toward developing a set of training materials; both for continuing education in all of our standards, as well as, an academic curriculum that is publicly available on the PCORI website for use.

Also another area of mythological input that we've had to the PCORI board is the suggestion for methods consults and those consults were to be

helpful to address any methods concerns that were raised around study design or analysis. And so, these methodological consults are now being used regularly as these proposals are reviewed and selected for funding.

Another area where we had some foundational work is a dressing at the challenge of that electronic data infrastructure and some of the discussions we had in the beginning around advancing the use of electronic data in 2012, that actually resulted in a workshop that Steve will talk a little more about. And advance the idea of a common data model, the need for data infrastructure and linkages and set the tone and the thinking about the PCORnet initiatives as well.

There were also a number of workshops, such as our workshop on observational studies and a learning health system in 2013 and a data quality workshop in 2015 as well as a decision sciences workshop in 2015.

So when we look back I think we can be proud of the accomplishments and the contribution to

the development of methods for patient-centered outcomes research, but we continue to learn from the field and learn from studies about where methods can make a difference and we are continually discovering ways that we can think about our next set of standards where we can be helpful to the quality of the studies that are funded.

So in addition to these activities during this period of time, of course, the clinical trials advisory panel was launched and the Methodology Committee has oversight for CTAP, clinical trials advisory panel as well. In addition, and I know Steve has been -- this is another area that he'll mention, is supporting to PCORI's efforts toward open science and our interaction with the research transformation committee.

So certainly there are a number of future opportunities there are still standards that we are in process of developing and there will be many more and we are continually examining PCORI's portfolio to identify where those opportunities exist.

So let me just pause there and Steve would

you offer a few reflections?

DR. GOODMAN: I'll just make one point, which is in the rest of my -- in my non-PCORI life I spend quite a bit of time on issues related to research reproducibility. And of course, we all know that since we started this has sort of been a tsunami of concern and activity that has sort of washed over the whole scientific establishment and certainly has been a major concern of funders and journals.

And one of the main issues that many, many people focus is the lack of adherence in many settings what we would consider to be basic rules of scientific conduct and knowledge of statistics and design and all those things; and what's interesting is that many of the funders are searching for ways to address this and PCORI right from the start it is the only one that actually has any rules for how to conduct science. What the methodology standards represent is quite unique in the world, I believe among science funders.

And that's why I underscored the point of

this being a really grand experiment: how exactly to enforce them; how they're reflected in the science PCORI does. All these things, this is work that we need to continue to do but this arrangement of the methodology committee at one of the highest levels of the organization and trying to actually lead the grantees in terms of how science is best done is part of the solution to this really global concern in science. And yet we're the only ones who are doing it.

So I think we -- and I know we do look at this very sort of seriously and historically as an effort that no one else has yet tried to do. I suspect there will be these standards will have a life and their story of their implementation -- a legacy well beyond outside PCORI and I think it's important to look at them through that prism as part of a multifaceted and international effort to raise the level -- in a sense raise the minimum level of how science -- funded science is done.

So I'll just leave that thought out there and wait for any comments from the board on that are

other things that you've mentioned Robin.

MS. NEWHOUSE: Thank you Steve.

CHAIRMAN NORQUIST: So let's open it up for questions.

On the phone -- oh I'm sorry Leah.

MS. HOLE-MARSHALL: -- taking an opportunity to pit in a plug for consideration of the N of one trials mythology standards again. I know that's been a hot topic and one that is difficult and I really appreciate your ongoing effort. So put that in for consideration please.

MS. NEWHOUSE: Thank you Leah.

CHAIRMAN NORQUIST: Joe.

DR. SELBY: Joe here, hi Steve and Robin. I wanted to thank you for this work, I'm especially excited about these complex intervention standards. I appreciate the one on data management just as much, but I'll be really interested to see how our science staff takes these and talks to our merit review panel's about them and how we build them into our monitoring of our own products many of which just happened to be pretty darn complex

interventions. I also wanted to take -- one other thing I'm really and I'll say something about this afternoon, but I'm really excited about what I know you're thinking about doing which is to begin to look through peer review and through review of literature at which of our standards are not being adhered to in our own work and that of others, so I'll say more. I just think that's such a cool way -- excuse the non-technical language to find out which standards really need our focused attention on.

And the last think I wanted to say and I was reminded by Leah when she expressed admiration for Robin, that there is a formal reason to express our admiration of Robin which is that she was elected to the National Academies of Medicine in October of this year so --

[Applause.]

DR. SELBY: -- for years of contributions -- of important contributions to this field.

MS. NEWHOUSE: Thank you.

CHAIRMAN NORQUIST: So Robin and Steve --

go ahead Steve.

DR. GOODMAN: I just wanted to make one tiny point and certainly second the congratulations -- we sent something around to the Methodology Committee. We all take credit for her elevation and bask in the reflected light.

MS. NEWHOUSE: Thank you.

DR. GOODMAN: The point I wanted to make about the methodology standards is the methodology standards -- the trail from a standard to improved quality science is itself a complex intervention. There are many, many, many steps beyond our publication of these and I think our path going forward is to look and I think this in the spirit of what Joe was saying; it to look at all of those and assess and see which ones we can play a roll in because it's a quite complicated path from what's on that page and the initial review of proposals to actually something that's better at the end of the day.

So that this is a complex task that we really have to take quite seriously going forward,

because otherwise it won't be an experiment or if it fails we won't know why or to the extent it succeeds we won't know why or how it succeeded. So that's sort of a metapoint with regard to the complex interventions and standards.

CHAIRMAN NORQUIST: Steve and Robin thank you both very much and of course the whole Methodology Committee because I know you have done tons of work and will continue to do more.

So we're going to take a break for those on the phone until -- for about an hour. We'll be back in little over an hour. So thank you.

MS. NEWHOUSE: Bye, everyone

DR. GOODMAN: Thank you.

DR. DOUMA: Bye-bye.

[Whereupon, at 11:55 a.m. a luncheon recess was taken.]

AFTERNOON SESSION

[1:03 p.m.]

OPERATOR: Good afternoon everyone. Thank you for joining us. We would like to remind Board members to please turn off your mics when you are done speaking. Additionally, when there is a presentation being given over the phone please keep your mics off to minimize the echoes. We will begin momentarily.

CHAIRMAN NORQUIST: So for those on the phone, we're coming back into session for our afternoon session. I'm going to as the Board members -- well they're in the room -- it's okay if you want to stand up.

DR. DOUMA: Welcome back.

CHAIRMAN NORQUIST: Thank you. Allen Douma's on the phone. Who else is on the phone? Barbara, are you back?

[No response.]

CHAIRMAN NORQUIST: No. Harlan?

[No response.]

CHAIRMAN NORQUIST: Okay, Allen, I think

you're it on the phone right now for the Board.

DR. DOUMA: I don't see anybody sitting around me.

CHAIRMAN NORQUIST: [Laughs.] Okay.

Joe, I'm going to let you introduce Congressman Gingrey.

DR. SELBY: Good. Well good afternoon everybody.

As you know this slot is reserved for invitations to important voices in our community; whether that be patients, patient organizations, physicians, specialty organizations, payers, purchasers. This is the first time we've had a former Congressman visit us and Congressman and Dr. Phil Gingrey represented from 2003 to 2015 the 11th Congressional District in the great state of Georgia. During that time -- and I should say that before that he was a practicing obstetrician-gynecologist for quite some time and before that he even told me he was a family physician for a little while.

So he came to Congress with an informed

perspective on what it's like to be in the front lines delivering healthcare. He was the founder shortly after he arrived of the Doctors Caucus in the House of Representatives, which over the years has weighed in on consistently -- regularly on a wide range of health and healthcare related issues. He also served on the health subcommittee of the House Energy and Commerce Committee during his time there.

And since leaving Congress he has been a vocal advocate for strengthening health research, improving the quality, efficiency, and affordability of health care.

Now we had the great pleasure at a forum about two and a half months ago that was sponsored by the Bipartisan Policy Center here in Washington on the topic of the future of comparative effectiveness research. A panel that included Congressman Gingrey and former Senator Kent Conrad, Democrat. Dr. Gingrey is a Republican Senator Conrad is a Democrat. I just learned that they didn't meet during the time that they were co-

serving in Congress, but they certainly met and they did a great job on a panel and it was very interesting to hear Congressman Gingrey's perspective on comparative effectiveness research and PCORI after 7 years of PCORI's existence.

So Congressman let me say welcome to you. We really appreciate your perspective and the way you've voiced it at the Bipartisan Policy Center forum and look forward to what you have to say today. I'm sure we'll have some pointed questions for you during the question and answer period.

But it's a real pleasure to get to know you. Welcome.

CONGRESSMAN GINGREY: Joe, thank you very much. Chairman Norquist, thank you and members of the Board of Governors of Patient-Centered Outcomes Research Institute, PCORI. It is pleasure and honor to be with you. Thank you for asking me to come and share my thoughts.

I enjoyed being with the Bipartisan Center and share a podium with the Senator Conrad and Senator Conrad on the Democratic side, a long-term

member and I think I appropriately gave him credit for allaying a lot of concerns that I had back in 2009, 2010 timeframe in regard to comparative effectiveness research and what effect and hopefully no adverse effect that that section of the what -- 2,300 page bill I forget how many pages, but we physicians, mostly Republicans, on the House side were very concerned about comparative effectiveness research being a bludgeon -- if you will physicians would be not reimbursed possibly or even at the risk of medical liability if they didn't follow certain standards and guidelines that were handed down by the federal government -- by Uncle.

And so, I want you to know where I was in 2009 and did not support the passage of the Affordable Care Act. I have come to believe over that period of time -- nine, ten years now that clearly again thanks in large part to Senator Conrad -- the changes he made on the Senate side which became law in regard to the creation of PCORI and how comparative effectiveness outcomes research was used and that providers today, I think can feel

comfortable in knowing that this information is most valuable to them. Particularly, if it's a condition that they don't see a lot of.

You know if you're seeing five cases a day in your practice, you are very comfortable in the way you treat migraine headaches or the way you treat preeclampsia or how you deal with the chronicle angina. Whether it's just active watchful waiting or that patient ends up having a stent or bypass procedure.

But a lot of things that doctors don't see but maybe one case of month, they don't have time to keep up with the latest research on each and everything that they have to deal with and there are not specialists a block or two away. They may be lucky they’re 25 miles away and the patient can't afford to go to another state to get that care.

So they have to provide and do the right thing and they rely on comparative effectiveness research. But they may decide after receiving that information that it doesn't -- for this particular patient, for this person circumstance, whether it’s

them or their family or extended family or their genetics or their ethnicity that they need something else.

And the something else maybe a little more costly, it may be cheaper, but maybe it's a little more costly and if they decide that that's the way it’s best for this patient they shouldn't have to worry about not getting reimbursed or not so much that they can't afford to give out a little free care, but the patient themselves can't afford to pay for the medication or pay for the procedure or pay for the hospital stay. And they also need to feel very comfortable in what they're doing.

Particularly if their specialty society has recommended in their best practices and I gave some of that information out to the board members earlier at lunch in regard to the specialty of Ob-Gyn. What is recommended in so many of the other conditions that we face in that specialty; be they gynecologic or obstetrical.

So you make a decision even though it might not be completely congruous with what has come from

a study or several studies in regard to the comparative effectiveness outcome.

And so, that's basically where we are today that I think that the work you are doing and the studies that you are funding and the monies you have spent, are monies that are well-spent but we have to make sure that that information is in the hands of these practicing physicians.

Particularly those who may be in a rural area. They're busy seeing 30 patients a day, five and a half days a week, there no emergency room physicians. When their patient goes to the hospital, they have to go see them. There were no hospitalists. Now that's changed a bit, but back when I was practicing, you know, you did it all. So you have to have the best information that's available to you.

So again, I want you to understand that the whether the Affordable Care Act is repealed in part or are in whole and it looks more and more like it will not be repealed in its entirety; even though the president still has a lot of authority in regard

to rules and regulations. I know today that there are a number of good things in the Affordable Care Act that I voiced a lot of opposition to when it was just a team play kind of thing.

It's like the football game I went to this weekend and Clemson was killing my Georgia Tech Yellow Jackets, but I could say nothing good to my brother the Clemson fan about his Tigers. I could only say good about my Georgia Tech Yellow Jackets, but they weren't very good.

So the point is you know, there's a lot of partisanship in Congress, it's important that you get your information to members on both sides of the aisle, in both Chambers, and they know -- and I think no better place to start than the Doctors Caucus or any group of members who are prior to their Congressional careers, were involved in healthcare; be they physicians or advance practice nurses or hospital administrators -- that's the pace to start, because if they don't understand it, if they don't feel comfortable with what you're doing when you get to 2019 -- the end of the year and

PCORI's up for reauthorization and you got to tripartite funding stream that's fully and completely dependent on Congress and them reauthorizing, then it might not happen.

I mean these are times that are very uncertain. I mean from day-to-day, we really don't know, do we? On either side -- whether you're an extreme conservative or a flaming liberal as we conservatives like to say or somewhere in between; I don't think anybody really knows at this point what this administration is going to do.

And in 2018, indeed who is even going to control Congress. It could change again.

So the most important thing is you make sure that every member is well-educated about this and how it came about, and why it came about, and why it's important. It goes hand-in-glove with the electronic medical records and make sure that all of this information is available to our healthcare providers.

So I'm going to stop with that and I promised the group, the small group that I spoke

briefly to over lunch -- and pretty much said the same thing but I'm saying now, that I would give more time for Q and A because as most members of Congress, I have a tendency to drone on and talk a little bit too long and I like to stop now and give you the opportunity to ask me some questions that are on your mind.

CHAIRMAN NORQUIST: So we'll start -- one thing I just wanted to say, thank you very much Congressman Gingrey and fellow Georgian, thank you for coming.

The one thing I noticed that you talked about, it's an interesting issue about the information that physician's have and we do turn to our guild organizations but where we get that information is a key issue. So one of my other roles is that I'm the chair of the American Psychiatric Association's Council on Quality and under my counsel is the committee practice guideline so basically we set up practice guidelines for psychiatry and we struggle all the time with where do we get the information to do those guidelines.

And so, to have a quality and kind of accurate resource for that is really key for us every time and I'm sure the same an OB/GYN and other specialties too about where you get that information.

So I'm going to go around this way -- we don't raise our hands, we put tent cards up so I'm going to let Kerry Barnett who is our Vice chair here to go next.

MR. BARNETT: Thank you very much for being here and we appreciate your candid comments to us.

I just want to pick up on what you said at the end of your comments your thoughts about the importance with our potential reauthorization really not far away. The importance of communicating with key policymakers, particularly those in Congress.

I would love to get some advice from you as to what you think are the most effective messages for us that resonates on both sides of the aisle and also who are the most effective messengers for delivering those messages?

CONGRESSMAN GINGREY: I think that it is

important that they understand -- they, members of Congress and indeed members of the administration as well. Support groups or it's usually important advocacy groups. The firm that I work with as a senior advisor, mainly healthcare clients, advocacy groups -- I won't name any of the clients, but you know they're coming to Congress and explaining to the members what they do and why it's important and where the shortfalls are and what the funding needs are.

So those advocacy groups need to be on your side. You need to have their support and you also need to talk to the administration and talk to members of Congress and they make sure that they know that what AHRQ is doing is very, very important. Gopal we talked about this earlier. But it's not the same thing is what PCORI is doing. It's a different focus. It's similar. It's not electronic medical records, but the information that you get from the research projects that you fund each year since this entity came into existence under the Affordable Care Act is giving us very,

very useful information. And that the doctors -- healthcare providers utilize this information for the betterment of their patients and they're less likely, not more likely to be practicing below the standard of care and facing some liability claim by a patient who has been injured because they didn't have the information and they made the wrong decision.

So if you can convince them of that and I think it's a pretty easy sell, it's almost intuitive that this information is good. And also make sure that they understand that this is not a "you have to do it this way, it's this way are you going to be in serious trouble" or "your patient is going to be in serious trouble."

No, we just we just want to give you the information. We understand -- we know that your particular patient because of their unique situation; maybe comorbidities, maybe something in their family history that means that some other choice even though you've studied it and you've done a research project on it would indicate otherwise,

you're not going to be practicing below the standard of care and you're not going to not be reimbursed for the care.

CHAIRMAN NORQUIST: Debra Barksdale.

MS. BARKSDALE: Hi I'm Debra Barksdale and I chair the Engagement Dissemination and Implementation Committee here at PCORI. So my question is sort of related to -- and you touched on some of this -- in terms of dissemination and implementation of our actual research results, what are some of your thoughts on how we best can strategize some specific strategies that might work in terms of dissemination and implementation to some of our other stakeholders; particularly patients and you touched on medical societies and policymakers, but if you have any thoughts I would like to hear.

CONGRESSMAN GINGREY: Well, I think as you go forward and as you approach your deadline for reauthorization of PCORI in comparative effectiveness research, that you want to be thinking about where you spend your dollars. And I -- Joe

and Gray were very kind enough to explain to me how -- what your funding stream is, and from the general Treasury and the grants from the CMS and also from insurance -- the healthcare insurance industry. And you know, it's important funding but members will be very quick to say to you, "Well, don't we already do this? Isn't this a duplication?"

And you might get an opportunity to sit down with Mick Mulvaney, the OMB director -- maybe not, but maybe one of his underlings and it could be a legislative director or a chief of staff and member of Congress' office, maybe not necessarily member but they are going to have their talking points. You can be sure that they're going to be well-informed about what you do and what's your results have been and maybe they've heard something that's a little bit on the negative side.

I mean, there's always oversight investigation hearings about some programs that is reportedly not fulfilling its mission or wasting a lot of money, and you need to make sure that you explain to members of Congress that we are studying

the best way to treat Type 2 diabetes. We're studying the best way to treat a coronary artery disease. Cost-effective, yes but not on the cheap. We're trying to do the right thing.

So as you go forward over this next year-and-a-half, you need to think about which disease entities that you're going to give research grant money to study, so that you get the good information and the right results.

CHAIRMAN NORQUIST: Bob Zwolak.

DR. ZWOLAK: Thanks. Congressman Gingrey thanks very much for joining us.

I was interested and pleased to see that the handout you gave us at lunch had white papers and clinical guidelines from ACOG, the American College of Obstetrics and Gynecology. And it led me to wonder about your thoughts of involvement of the medical and surgical professional societies vis-à-vis PCORI as we move forward.

How can we make a win-win out of work PCORI does and the good work of the professional societies?

CONGRESSMAN GINGREY: Robert, I'm really glad you asked that question. That is one of the key questions of the day, because clearly each specialty society -- and again, it could be the vascular surgeons, it could be orthopedic surgeons, it could be general internal medicine, it could be psychiatry, it could be OB/GYN. You name the specialty. And they all -- well their membership, their dues-paying membership, and they have meetings throughout the year and they have an annual meeting, and they're putting out white papers just like I shared with you earlier in OBGYN space. You need to make sure that they're working with you and realize there is a cohesion there between what you do and what they do. You're not crosswise with them.

And as I sit here today, I don't have the exact talking points Robert that you would -- members of the board in particular, would have but it is hugely important that they are working with you and not against you.

Now let me just give you one example. It's a little bit tangential, but the issue of how often

and at what age a woman should have screening mammography. The U.S. Preventive Task Force -- again, this was back in the 2009-2010 timeframe when every OB/GYN was taught that between the age of 40 and 50 was really the most dangerous time for a woman to contract breast cancer and it didn't happen is often as it did to the women in the next decade of their life between age 50 and 60; or maybe even between age 60 and 70.

And so, the U.S. Preventive Task Force came out with a recommendation and were backed up to a certain extent by the American Cancer Society and said well, women between the ages of 40 and 50 really don't need screening mammography. It leads to false positives and needle biopsies that turn out to be negative, but create an infection and adverse side effects. And you know, that was totally contrary to what my specialty society, the American College of OB/GYN, had recommended. And I'm still kind of a senior status -- I guess you would say member, of the American College and I don't know where they stand exactly today on that issue; but I

personally feel even though it's at low incidence occurrence in that fifth decade of life of women. If you're going to save their lives, that's when you need to have early detection and the importance of early screening.

So that's just one example of where the government -- big government is making a recommendation that was totally contrary to what I believed and still believe today, and I think my colleagues it in OB/GYN and probably the majority of the membership of our specialty society, the American College of OB/GYN, feel very strongly that way.

And that could be very much applicable to other specialties as well.

CHAIRMAN NORQUIST: Thank you. Sharon Levine.

DR. LEVINE: I'd like to ask your advice based on your experience about timing of getting the message about PCORI and reauthorization in front of the Doctors Caucus and members of Congress, given everything else that they've got on their plate,

when is it too soon and when is it too late given the timeframe? Looking at the issues that are before Congress now and something that's in September 2019 --

CONGRESSMAN GINGREY: Sharon, it's a great question and I don't think it's too early right now and I think the sooner you become involved and get before them and get this information to them, the better.

Because things get pretty crazy in Congress and there's -- ever since I was there and I've been gone three years and I served 12. So for the past 15 years I've seen us, whether the Democrats are in control or the Republicans are in control, kicking the can down the road and waiting until the last minute and putting something together, which with a hope and a prayer you hope that it turns out right but usually it's rushed and members don't have time to read bills.

And so little things, this might to them be considered a little thing if you're waiting to the last minute to get before them. So the sooner you

can make your case, the better. It's not too soon to start right now Sharon. It's a great question, great point.

CHAIRMAN NORQUIST: Thanks very much. Leah.

MS. HOLE-MARSHALL: Good afternoon and thank you for joining us.

My question was really about your evolution in thinking from your early stance of not supporting PCORI to where you are today and if you could talk a little bit about whether there are particular studies that have convinced you or whether it's hearing from your colleagues rather than directly from maybe members of PCORI that have helped you to see that this -- not only your worst fears did not come true, but that perhaps it is actually a value and a service that can really support the work.

CONGRESSMAN GINGREY: Well, thank you very much for that question and as you know from listening to me these last few minutes and at lunch that maybe I'm bluntly honest and will tell you that I was against everything except allowing my children

to stay on -- my grandchildren rather, to stay on their parents health insurance policy until they're 26 years old. And also maybe ending annual and lifetime caps for coverage of certain diseases and mental health parity. There were a number of things, it's not just a tribute to your chairman, but I fully believe that Gray, I fully believed it.

But yeah, I was against everything just as the majority Democratic leadership was against every Republican amendment that came across the desk. But as far as this particular issue is concerned -- and that's why we're here today, to talk about comparative effectiveness research and PCORI and the work that you do -- I am very, very comfortable today in that when the bill was finally passed and the changes at that Senator Conrad put in there and that providers could feel comfortable in knowing that it's a win-win for them, the work that you do and the money that you spend on research gives them the best possible information that that money can buy.

But you're telling them we're not going to

punish you doctor if you make a decision to go in another direction because of clinical information that you and you alone have about this particular patient and you know what's best for this particular patient. You may have to explain yourself, but you shouldn't have to spend two weeks explaining yourself. It ought to be maybe a ten-minute phone call and then the patient is approved and reimbursement is there and you have no liability for doing the wrong thing.

And I feel today that that is a state-of-the-art and that's why I feel comfortable in being maybe 180 degrees from where I was back in 2009 when H.R. 3200 was being marked up in the House Energy and Commerce Committee in regard to that particular issue.

Now I'm still a little bit against some of the things to be perfectly honest, but I think that what you're going to see is the two parties are going to come together and work together and do what's right for the people. They're not going to let it just go to heck in a hand basket and let

people suffer; I don't think that will happen. I hope and pray that it won't happen.

CHAIRMAN NORQUIST: So I want to thank you. I hope this is a model for everyone to kind of start to have these discussions. Right? I mean I hope we can do that and I hope you're right, that we come to a better place than sometimes we see we are in the current -- we very much appreciate your advice.

I'm sure we'll be asking you more advice in the future as well, and Joe is there anything else you wanted to add at this point?

DR. SELBY: I just wanted to mention one little thing, that you mentioned the study about mammography and I think we see it exactly as you do and in fact we put a large investment into a trial that specifically gets at supporting women with all the information we can about their personal risks and then letting them make the decision. A preference sensitive decision.

So we have a large trial underway to see if that isn't actually a better way to deliver care. To provide the information after collecting it on

people about their genetic risk, their family history, personal history. Giving them the information and then letting the woman make the decision. So it takes perfect account of that, the variation among people and their fears about variety of risks and benefits.

CONGRESSMAN GINGREY: Joe, I think that's a great conclusion remark because I emphasized in my own practice 15 years ago, you know, where every two years that everybody that was a patient of mine in their 40s would get a routine screening mammogram. Today, what you're saying is if you give them the information and let them make the choice and certainly it depends on their genetic makeup, BRCA gene, and the different things that would make them at high risk and their choice maybe, “Look, I want to have a mammogram every year if I have to pay for it out of my own pocket. That's what I want.”

So again, in conclusion I thank the PCORI board members and all of you here today to give me the opportunity to talk about this. I am no expert, but you know, we're all struggling to learn as much

as we possibly can and to volunteer our time and effort. And the 20 or so of you members of the PCORI bored and you take time away from your practices, and what you do, and some of you are coming from California, and I'm from North Carolina, and all over the country to be here.

It's not easy. It's not easy, but you're here because you want to help. You want to give of your valuable time and I commend you for that. I absolutely commend you for that and thank you for allowing me to be with you today.

[Applause.]

CHAIRMAN NORQUIST: Thanks.

So we'll take a few minute break here.

[Recess.]

CHAIRMAN NORQUIST: So the next session here is our primary afternoon -- longer session for the afternoon and what we decided as a board to do is to have our strategy committee's report on the -- we're at seven years now and what we think we've accomplished and looking to the future. And so, we've asked the Primary Strategy Committees, our

Science Oversight Committee, the Engagement Dissemination Implementation Committee, and the Research Transformation Committee to each do a session.

And so, we're going to start in no particular order, it doesn't mean that one has a priority over the other, we are starting with Evelyn.

So the first one is Increasing Information: Science Oversight Committee and this will be led by Bob Zwolak who is the chair of that committee from the board and Evelyn Whitlock, who is our chief science officer. And I don't know how you want to go -- and Alicia Fernandez. Where did she go? She's the Vice Chair.

Okay, so the three of you will tell us how you're going to divvy this up.

DR. ZWOLAK: Thanks Gray. Certainly, Evelyn will do the heavy lifting of this session, but Alicia and I are proud to be associated with the SOC and with what we've done. Evelyn will outline the three major initiatives which are developing and

funding our research portfolio now that we have a very generous research portfolio. Managing it; optimizing it; making sure the studies get done and as a third step, partnering. Partnering with NIH, partnering with other agencies to force amplify our efforts and our funds to come out with the best possible research and it certainly is gratifying now that we have basically hundreds of studies in the pipeline and seeing the new results on a virtual day-by-day basis.

So with those short introductory comments, I'm not sure where Alicia is and if she has any other words to say. She stepped out just momentarily but perhaps we can have Evelyn go ahead. So Evelyn, thank you.

DR. WHITLOCK: Thank you, Bob. Well, I'm delighted on behalf of the Selection Oversight Committee to give you sort of the state of the science, if you will, at this point. I thank Bob and Alicia who fearlessly lead this, along with our dedicated members that have brought such value to this committee.

As Bob said from the original PCORI strategic plan there were three imperatives that our research agenda addresses and as you'll see from other reports from other of the Strategic Committees we don't do these in isolation. But certainly, the developing and funding the research agenda with high potential for impact has been a big focus of the Science Oversight Committee, managing that research portfolio once funded so that it will be successful. And then, partnering with other funders to foster patient centeredness research.

So I'm going to spend my time going through the strategic initiatives, just as a kind of an update of where we think we are at this point. Alicia, you didn't get to make any introductions but you'll get to wrap it up.

So here's kind of an overview of where the SOC sees us in terms of the state of the research enterprise in 2017. We maintain -- as Joe talked earlier, both broad and targeted work to address all five national priorities. We are increasingly looking at what I'm calling focus funding

opportunities, which are both our pragmatic clinical studies as well as our targeted funding announcements to make sure that the investments that PCORI is making are for critical clinical topics.

We have launched research synthesis activities and that part of our portfolio is looking at supporting personalized decision-making in healthcare, producing rapid and actionable results in communicating our current portfolio. We continue to engage with other partners throughout PCORI as partners, our Engagement Department, with others to look at seeking out new research areas from stakeholders, and working internally to identify evidence gaps within topics of interest to patients and other stakeholders.

As the results start to come, this is going to be really exciting at our annual meeting it is the time of results. Science finishes out its process and part of what we do under Hal Sox's leadership is we do the peer-review process which is a critique and then contextualizing results and doing a handoff to our discrimination and

implementation partners.

And we continue to try to improve our processes with pre-award and post-award and enjoy -- I wanted to be able to say this, I hoped Alicia you would say it, but she wanted to be sure that we say that we enjoy a close and constructive collaboration between the SOC and the Science staff. It's really been a pleasure and privilege for all of us to work on these together.

So this is just a -- Joe showed you sort of the cumulative dollars and this shows you in 2017 where the dollars went in a broad sense. So as you can see in 2017 about 25 percent of the research awards were to -- in the broad area or the investigator-initiated awards and about three-quarters were targeted for pragmatic clinical studies. So this -- and this reflects what we've seen over time, which is an increasing shift over towards doing more large targeted and pragmatic studies since 2014.

And we continue our quest for high-priority topics and versatile funding opportunities and I'll

remind you of what we've done since February 2017, when I gave you the SOC strategic -- thinking about -- making sure we were doing priority investments.

This is that multi-pronged strategy where we talked about increasing the PCS opportunities, adding areas of special emphasis, continuing to focus on new targeted funding announcements. Allowing things -- as you saw this morning, if we put out a targeted funding announcement we didn't get enough meritorious awards and there still was a scientific need; the SOC can approve reissuing that under the board's delegation of authority. And so, we have been successful in that kind of an activity.

We've also looked at sequential funding opportunities that come from multi-stakeholder meetings and that's been very successful.

We continue to monitor our research allocations within programs and revise as needed, and the SOC meeting coming up tomorrow we'll look at these opportunities and continue as it has done over the last several years to think strategically about when and in what the research investments are made

so that we can put out the appropriate funding announcement. And then, finally we have been working on increasing the quality and quantity of applications to all programs.

Now you wonder why that has the less than strong arrow and it's because I can't tell you yet what the impact actually has been from the evaluation efforts of all that we did in the last several years on improving the applications and include improving our merit review process. We don't have enough cycles under our belt yet, but we have evaluation plans in place and I can report back to you about those.

If you go to our website and you heard a good feature earlier about how wonderful our website is, you'll see that there are areas of our portfolio that are focused upon and one of the most beautiful things about being at this stage for PCORI is that so much investment has been made in so many interesting topics that there are lots of opportunities to look at our portfolio through various lenses to through various stakeholder needs.

And so, this shows seven areas where the portfolio has been pulled together: cardiovascular disease, cancer, pain care and opioids, kidney disease, multiple sclerosis, dementia and cognitive impairment, and transitional care but earlier -- it was actually late last year, early this year there were some real efforts to pull more portfolio views together in order to support a variety of Outreach efforts and we continue to do that work.

I want to show you just a couple of the portfolios.

I wanted to show you the big picture of the portfolios first, because this is an ongoing effort and -- but I want to show just a few portfolios here so you can see some exemplars of some areas we think are important and exciting most recently. So I think we all know how important the opioid crisis is and as of September of 2017 PCORI has awarded $62 million to fund 11 CER studies as of -- what's today? October 29th or 30th?

But as of today PCORI has awarded I guess the $71 million to fund 12. So we are -- we keep

working on our portfolio in this area and this will add to -- it will be close to almost 12,000 study participants to look at research in this most important area of opioid use and pain. You can see from this that we're looking at chronic pain, acute pain, or both in our study populations.

And as I commented earlier, we're looking across the spectrum of preventing inappropriate or dangerous use in the first place. To helping people in the early stage to not progress to more chronic use or dangerous use. And then, also addressing those who have progressed opioid use dependence.

We also have a new funding announcement we're working on. I wanted to be able to comment on it to the representative but based on a lot of stakeholder feedback, medication-assisted treatment for pregnant women with substance use disorders is a new area of focus for us that has received a lot of endorsement our SOC and we're working on now processing the letters of intent and moving into the next phase of the process.

In this last year based on funding

announcements that the SOC created and that the board approved, we have looked at the very patient-centered, important area of palliative care. And what we're trying to do through these types of studies is to make sure that we know how to help clinicians and patients and caregivers best approach this very important problem with those that have advanced illness. And this includes what kind of models work in the community?

A lot of palliative care is hospital driven, so what can happen in the community? How can people get advanced care planning, particularly in primary care that really works for them and really importantly how do we help people that have advanced illnesses deal with the very common symptoms that we know occur across a number of conditions?

And so, we have already funded seven studies that look at both the types of models of care and are looking at it after planning, but we we're in the process again of looking at the symptom management areas. And we have been really, I think,

gratified that the field has responded very strongly to these opportunities with very high quality, meritorious applications and so we're thrilled with the opportunity to contribute in this patient-centered area.

Similarly there is work over a period of time to continue to invest in this important area of Multiple Sclerosis at this point in time through our broad -- and through several targeted funding announcement including a reopening of one. We now have about 65 almost $70 million to fund 12 studies. This has been a really good opportunity because, as we've done the targeted work, we've been able to say we'll fund a set of studies at a single period of time and our Science staff are working to harmonize these in terms of increasing the comparability and impact of the results. So more similar outcomes, more similar approaches where necessary so this will be a body of evidence and not a set of individual studies.

And obviously, these are focusing on very important questions that folks with Multiple

Sclerosis have identified matter to them, including head-to-head comparisons of some of the newer disease-modifying therapies or therapeutic strategies. Looking at how to get care to people who live in rural settings or are unable to access specialty care for a variety of reasons.

And then, very importantly looking at symptom management -- the most common symptom in MS is fatigue and something that really affects people's quality of life.

Yes, please Freda.

DR. LEWIS-HALL: A quick clarifying question.

DR. WHITLOCK: Of course.

DR. LEWIS-HALL: On the MS studies, there has been a lot of recent work on biomarkers that divide MS into subtypes. Is any of that included as we -- you know, the best therapy for who is so is that included or are we doing kind of straight clinical --?

DR. WHITLOCK: We're doing straight clinical effectiveness but I will jump ahead to my

end slide where I'm going to be talking to you about at the strategic opportunities that Bob was referring to earlier, which is strategic in-fill.

So we are right now looking at adding a biomarker aim for a very -- I would say modest amount of money to a very large pragmatic clinical study in another area. And so, I think we do have those kinds of opportunities if they can be identified early in the course of the study so we can do the biomarker measurement at baseline before any of the treatments start.

But I do believe that that you've set me up beautifully, because I think that our opportunity to do supplemental aims with things like biomarkers, with things like additional heterogeneity of treatment effect analyses, additional methodological inquiries can allow us to leverage the existing investment so it's even more powerful.

So thank you for that, and I'll pay you later. Okay you're welcome.

And we haven't done in this area but I would love to talk to you about it because we're

just getting these going, so the time is now.

Please, Sharon.

DR. LEVINE: So does that mean it's not too late to do with these studies?

DR. WHITLOCK: Well, what I'm saying is I believe that's true. What -- you know, I don't have the start dates of each of these, but the awards are relatively recently and I just have to see where we are in the startup phase in terms of enrollment. But even if we couldn't do it across all, we may be able to do it in some.

I want to also point out that some of these are observational studies, so again, we might not have the same opportunity, we might. We have to look at them but I think it's -- the point is, thinking about those opportunities is going to really be a great thing for us to do. Thank you.

Okay, so I want to pivot over to our research synthesis program. We started designing in 2016 and what you see up here, and I talked about the three main focuses to get started. What you'll see up here is a bunch of acronyms: RFP and PFA and

MOU and IDIQ and what that really -- I had to give ourselves, I just had to let you know that we had to create all the infrastructure for funding in these things and we have created infrastructure across all of these initiatives as well as beginning to fund and I'm very pleased that this gets to the issue of both personalized choice and rapid actionable results and I'm going to show you what to expect in this next period of time.

So we began in early 2016 to talk about how we might more quickly get results that would represent a state-of-the-art systematic review information. We're working through a memorandum of understanding with AHRQ, we've commissioned four targeted systematic review updates. These are expected to be completed, they were begun in January and we're expecting them in the timeline that you're seeing. And they're around very important areas related to both actionable evidence for the public, but also areas where we have had areas for investment like some of our pragmatic clinical studies and this can help us figure out what are

some next areas we invest in including atrial fibrillation.

So these are going to be dual purpose. They will give us in-fill -- it will give us information that can immediately be disseminated. They will also give us information about remaining research gaps.

We funded an IPD meta-analysis on evaluating progesterone and pre-term birth and we are expecting results for that in March of 2018. And that's been going since we began the pre-work, but award was made earlier in 2017 --

DR. McNEIL: This is Barbara, can in interrupt you there?

DR. WHITLOCK: Of course.

DR. McNEIL: Hello? Are you on?

DR. WHITLOCK: Yes, Barbara. Go ahead.

DR. McNEIL: A quick question. I think that’s just a great study you’re doing with pulling out the primary data and trying to get a more coherent and accurate analysis.

The question I have is the timeframe that

you will likely have for this particular analysis what we could expect in general and the other meta-analysis, pulling out primary data from the various components of the original analyses. In other words, is the analysis that you're talking about really always going to be a two-year process?

DR. WHITLOCK: For an IPD meta-analysis?

DR. McNEIL: Yeah, exactly.

DR. WHITLOCK: Yeah. So right now one of the funding announcements that we have out -- it is to allow, to try and make the case that we can get this done in a shorter period of time. So we put out a funding announcement that will allow trialists to come together and propose and receive an award to work together to come up with a researchable question and the consortium agreements that people will actually make their data available. Then once they get that done, the second stage is to do the analysis in a fairly short period of time.

We have spent a lot of time creating the template for the trialist consortium, a model. It builds on the IOM report on systematic reviews and

the independence necessary for credible analyses but also the World Health Organization approach to guideline development.

So we have a very robust model in terms of scientific integrity and we are building the funding mechanism to support that.

I do hope and believe that it will allow us to produce results in the kind of timeframes we're talking about, particularly as the scientific community moves more and more towards open science as a concept of really being a public good.

Does that answer your question?

DR. McNEIL: Thanks.

DR. WHITLOCK: Okay. I don't think I can predict the timeline, the timeline I've been able to accomplish on the next two but we will still have I think fast timelines on some of these.

We have funded two projects in predictive analytics. We funded these in March or April or May or something. We have the first result out from the reanalysis of the preventing stroke recurrence, the IRIS study and I'll show you the publication from

that. We're expecting the second round of results on or before April of 2018 and we have a third study that's looking at chemotherapy related cardiotoxicity.

So and then finally, we are working on a variety of other shorter turnaround kind of products that may have interest for particular groups such as payers, et cetera, looking at evidence maps and other things. So I don't have any to show you right now but I'm hoping to have some maybe by -- I certainly will have some for your February retreat.

This is just to mention that this IPD meta-analysis, it represents more than 40 randomized control trials worldwide. It has already been written up in *BMJ* and in *PLOS Medicine*. So we've gotten credit and when I say written up, I mean PCORI has been written up as moving forward and doing something very powerful in the public domain by funding this IPD meta-analysis. So it's very exciting for PCORI to get credit even before the results are out.

Similarly, this is the citation from *JAMA*

Neurology, September 2017 which is the first paper in the predictive reanalysis of the IRIS trial.

If you look at the bottom it shows it's been able to target the patients that will drive the greatest absolute benefit from pioglitazone after -- in terms of preventing a stroke recurrence; however there still is a high risk for fracture which is the main side effect of the medicine and there will be an additional analysis coming out that will talk about further targeting towards the patients that are most likely to benefit and least likely to be harmed. So it’s very exciting and there’s been some good feedback from this as well.

We continue to work on -- as we go forward, we're trying to make sure that the investments that are done over the next couple of years are the most strategic that we can do. So we're working and have been working on anxiety in youth. This is the most common mental health disorder that affects children and adolescents. If not detected and treated it can really affect the life course.

We’re going to be talking about the various

initiatives to improve birth outcomes that relate to various stakeholder priorities including the Medicaid Medical Directors -- Medicaid is responsible for half the births in United States.

We're working on atrial fibrillation as -- and you'll hear more about that later. Type 2 diabetes, et cetera, but we are -- these are areas and we're not -- it's very important that you realize that we're actively still working on our PCS priority list. We're working with our program and advisory panel priorities. We're looking for just-in-time opportunities with partners and I will talk more about the in-fill opportunities that were brought up and that we're looking to repost our targeted funding announcements as appropriate.

I'm going to move now and you'll be glad to know that you saw the biggest part of the presentation, so I'll roll through the rest of it but I'm very excited about that part because they're still is such an opportunity to contribute good science to improve patient outcomes and we want to take full advantage of that.

So the SOC has been really integrally involved in making sure that the application process and the merit review process are as good as they can be. There were several work groups that were put together. There were external reports and you've heard about those and there were recommendations that were made.

We have implemented all of the recommendations, I think with the exception of a few that we definitely couldn't do and we renegotiated those. We are now in a position where we've worked with our evaluation and analysis group to begin to build in the questions that will allow us to determine if this has had the desired positive impact on researchers in terms of their perception and belief about our processes.

But even more importantly, and Joe referred to this, we are paying a great deal more attention to all of our projects as we move into these larger targeted and pragmatic clinical studies. These larger studies have much larger sample sizes and attention to recruitment and retention is critical.

So we are we are paying closer attention, we're monitoring our projects more closely, and to ensure that we bring these through to successful completion. This is just one example to show that we have fine-tuned the practices that look at monthly recruitment as a regular basis. Those will then roll up to the department and then roll up to the dashboard. So this will be much more carefully monitored going forward because of a lot of people's work.

As was mentioned, peer review is up and rolling and I'm not going to talk about the numbers. I think most of this has been said. We have been working very carefully and I want to say that the dashboard data that you've seen, we really believe will be getting better for two reasons. One, you saw all of the data inclusive of the startup. So the start-up, of course, was not exactly -- we were learning as we were going. Our contractor was learning as we were going, our staff were really learning.

And so, we believe that it's going to get

better. It's been really valuable. We've identified key parts of the process. We've identified -- to the extent that we can, the leavers that we can move -- we can change in order to make things go faster and more effectively.

And most importantly, I want to reinforce what Joe said and I think Hal would agree with me as well.

We're finding that the peer-review process is a fantastic opportunity to see how all the other aspects of our process fit together. It kind of brings it all together at the end so that the lessons that we're able to glean as we really do this per review process will be informative all the way back up the chain and I think that's a huge opportunity for us.

So more to come on that. We're very excited to be getting to this point where it's not all brand new for the first time and that things are starting to roll. And just in time because it here comes the tsunami, so we're very excited about that.

Now I'll end up saying that this is an area

that SOC has oversight with, but also the RTC. Because we are -- we have many opportunities to collaborate with other agencies, particularly around our newer initiatives, predictive analytics. We've been working on an international consortium to reduce research waste and ensure value. The Funders Forum we're calling it and because of PCORI's work in this area, we're meeting this Thursday with people from around the world, NIH, AHRQ, the VA, Health Services Research and Development, and the DOD among others, to talk about what can research funders do to make sure that the money that we invest actually produces public good.

This is really exciting and one of the things that you should know is PCORI is leading the pack, along with a couple of European funders because of methodology standards, because of the commitment to engage folks in research, because of the commitment to publish all results out to the public.

And so, it's an exciting time for us to challenge ourselves to do it even better.

Looking ahead, I'm going to start at the bottom and just say the things the SOC -- and then I'll ask Alicia and Bob to finish up, but these are the things that they wanted us to emphasize in this next period of time.

Probably first and foremost as a foundation, we need to make sure that all the investments that have been made to-date are realized and we contribute to applicable useful knowledge through overseeing our investments. We need to make sure that every investment we make over the next few years are as high priority as possible. And to that end, this idea of in-fill opportunities where we can leverage our current portfolio, get a bit more for just a bit more or get a lot more for just a bit more. Think creatively how we can bring these together is something that is exciting. We won't just cement the approaches to heterogeneity of treatment effects. The issues raised by predictive analytics because we think that we can make a contribution to the field and it's important for PCORI's future. It's all about getting the right

treatment to the right person at the right time.

We want to continue to engage stakeholders and build a pipeline for the future and we want to work hand-in-hand with others and PCORI to enhance all that it needs to do to get good results out so that they can be used and benefit the public.

So with that I'll stop and ask if my fearless leaders would like to make any other comments.

DR. ZWOLAK: All I want to say is that was a spectacular presentation. So thank you very much.

DR. FERNANDEZ: And just thank you and the rest of the science staff for the incredible hard work you you're doing and for your cooperation and collaborative spirit with us and everyone, thank you.

CHAIRMAN NORQUIST: So are there some questions and then remember we have this more general discussion after each of the committees, so maybe clarifying or what other questions. Sharon?

DR. LEVINE: So and my question is kind of a bridge between flag 54 and the top box on your on

your pyramid there. Top of Maslow's hierarchy of needs for research --

[Laughter.]

SPEAKER: That's right.

DR. LEVINE: And it has to do with -- and this is looking at it from the perspective of the recipient of the communication and dissemination and uptake. To the extent that there is an evidence synthesis that goes along with the publications -- is available to go along with the publication of research results. So it puts the research results in the context of what else is known. It will be much easier for whether it's professional societies or group practices or individual physicians to understand the meaning of a specific set of research results and the likelihood that a change in practice is really going to have a significant impact on patients and it will provide context.

So I guess my question is there are a 141 studies in draft, you've got 141 draft research reports. Yeah. How many of the evidence synthesis are -- where are the evidence synthesis [inaudible]

and will they be ready?

DR. WHITLOCK: So I'm going to answer that and I also let Jean answer that, because there is work that happening in the Translation Center in order to embed the single study results in the evidence context. But let me answer a couple of other things just to tell you that we agree completely and we're thinking about it across various aspects of the work we're doing.

First the peer-review requirements for the template for every individual result it is asked for and required that they put it in some context, so they're not allowed to just discuss their own study. They're asked really to put it in some sense of context.

Right, Hal?

Yes. So that's the first requirement for the final report.

Second, as you as you saw I talked very quickly about evidence maps and a couple of the areas we're doing evidence maps. I didn't lay them all out, but when is DCIS for example. We've got

some work going right now.

So what we're trying to do in some sense, and it's not completely systematic yet, but for some of these areas where we think we might have key findings get ahead of the game. Do some evidence synthesis, a map is kind of that. So that there is an evidence map that you can drop the results into and quickly do an update to help our friends and our colleagues in dissemination.

But there really is an understanding, we can't of course do it for all and I don't think all 142 even necessarily deserve that, so some of what I talked about in terms of the critique and contextualizing. We're doing -- as science finishes up an individual project, we're doing some work to try and help our colleagues know how strong is this result. You know, how important do we think it is using a set of criteria, how impactful?

So that when we do have to do some just in time work it's really focused in the areas where it will make the most impact, but you know a final area that we might do is that it may be that an important

study comes out, a guideline developer says “wow if we just had the full Monty -- all of the results updated, then we could really do something with this,” then we need to be open to those kinds of suggestions as well.

CHAIRMAN NORQUIST: So Evelyn there is one other slide you wanted to show us which is the questions that you want us to address, right? Yeah.

So that when we come together -- I mean we’re going to have to moderated discussion. These are specific questions that you want us to address, correct?

DR. McNEIL: Which slide is that Gray?

DR. WHITLOCK: Seventy-three.

CHAIRMAN NORQUIST: Seventy-three.

DR. WHITLOCK: This is one question that -- we have a whole lot of questions that we would love to talk with you, but we know other --

CHAIRMAN NORQUIST: We can’t do them all today.

DR. WHITLOCK: I know. This is one that’s been really interesting to us; how do we determine

when we've maximized our impacted investment in a particular area and what are the criteria that should be used, how should it be thought about because more research is an infinity. So when do we know PCORI itself as done enough? This is one question.

Bob and Alicia have other questions that if this one's not interesting that we can go to.

CHAIRMAN NORQUIST: We'll start with this and when we get there we'll see -- that's the idea of the discussion is that it will be open for others.

DR. WHITLOCK: Okay.

CHAIRMAN NORQUIST: So in the interest of time because I know Debra -- but Evelyn thank you very much. I mean outstanding job for you and your staff and I sit here at seven years and think just wow, if we had started with some of this seven years ago how much even further -- anyway so thank you very much.

Debra Barksdale. Can we go to the next slide?

So Debra Barksdale, chair of EDIC Committee, Jean Slutsky who is chief engagement officer.

MS. BARKSDALE: I'm going to start it.

CHAIRMAN NORQUIST: You're going get it started. Okay.

MS. BARKSDALE: Well, we are very excited to be able to begin to fulfill of strategic mission.

And we've guided this work of the staff over the past seven years. It started under the leadership of Sharon Levine and Gray Norquist. Whatever those earlier versions of this community were called.

CHAIRMAN NORQUIST: Centuries ago, I'm sure.

[Laughter.]

CHAIRMAN NORQUIST: Sharon, turn your mic off.

MS. BARKSDALE: Yes, but through all of that work is has led us to many of the innovations that you're here about today and we finally feel like we are coming into our own as a group and

really having something to say as more results come in.

I do just want to take a minute. I know Bob Jesse is not here but with us, but he was so instrumental in all of this work and getting us to this point as well. And I just want to thank Larry because he doesn't know it, but he sort of stepped in de facto and I really appreciate that.

So with the slide that you see before us the goal of EDIC is to speed the implementation and the use of patient-centered outcomes research evidence and EDIC had four major goals.

CHAIRMAN NORQUIST: Do you want to identify your other members?

MS. BARKSDALE: Committee members. Larry Becker, Allen Douma, Gail Hunt, Gopal, Sharon Levine, Brian Mittman, and Bob Jesse.

So next slide.

So the four goals for EDIC are to establish PCOR as a thought leader in CER and PCOR; to ensure stakeholders have mechanisms to engage; to ensure efficiency and quality of public reporting; and then

dissemination and implementation of PCORI funded findings. So with that I'll turn it over to Jean.

Oh, and let me just say even before we get started, regardless of what you think about this presentation we have the most fabulous staff that work to support us and put up with us. So we're very appreciative.

CHAIRMAN NORQUIST: I'm sure it will be an excellent presentation with that staff.

[Laughter.]

MS. BARKSDALE: So Jean.

MS. SLUTSKY: SO I've got double redundancy here, I've got my laptop because I thought I would be too short to see that. Evelyn's is [inaudible] design and I thought she could do it okay, so I'm here.

I just want to make a comment about Bob Jesse. I represented PCORI at VA Memorial last week and his wife and we sort of were joking about the fact that Bob was just a fountain of "Why don't we do this? Let's do this. Let's do that."

He had the most innovative and energetic

ideas about implementation and pushing the envelope and so, I think we were as an organization and certainly as a Strategic Committee far better for the input that he gave us then. We truly miss him.

So I just want to start out by thanking the EDIC because, you know, there's something to be said about selling the future when you want to talk about things that are about to happen so the EDIC really or just for those who you on the phone, EDIC stands for Engagement Dissemination Implementation Committee. So I will use the acronym just shortening the discussion today.

We developed the schematic to really show all the touch points of the work that we do under the oversight and auspices of the EDIC which really touches almost everything that PCORI does from a topic identification and research prioritization to the actual conduct of the study and analysis of the results, and then dissemination and implementation of study findings.

So we do this through our public and patient engagement activities, our engagement

awards, our communications activities and the newest and I think one of the most powerful parts, what the EDIC oversees is dissemination implementation of research results. And I'm going to talk about all of these quickly and hopefully when we have the question and answer at the end we can sort of integrate what all of these three strategic committees do because I don't think that the lines between them are bright and clear, but there's certainly overlap.

So first I want to talk about establishing PCORI as a thought leader in CER and PCOR.

So when we think about the work that we do, one of the things that we do is we support PCORI's internal work. So my department and the EDIC really provides those types of infrastructure that supports the work of other components within PCORI through our engagement officers, our tools and resources, and training for nonscientific merit reviewers. So we also support the internal/external communities through stakeholder meetings and workshops, our communications activities work, our engagement

awards, work on the science of engagement as well as on the advisory panels that support and comment on the work that PCORI does.

And finally, external activities we're really, I think pressing -- pushing the envelope in terms of public reporting both to the public at-large about the work that we do but also to participants in studies. How we've changed our website and use of social media. And then, dissemination implementation activities through dissemination awards and the shared decision-making implementation award.

So many of you may not have seen some of the new changes that have been overseen by the EDIC on our website, but our communications team working with science and our evaluation and analysis team, has really worked very hard to bring the website to life and to communicate what we're doing as an organization by using real world examples to show the impact of engagement. Also providing a platform for the voice and stories of patients, caregivers, and partners. And to work with stakeholder

communities to explain how our work is valuable to them.

And then finally, that these relationships can support dissemination of study results particularly for those who need them and have identified them before the studies even began.

DR. McNEIL: Jean, can I question about this? Your new website?

MS. SLUTSKY: Yes.

DR. McNEIL: Because it's obviously very important. Can you explain how the number of hits has increased over the past six months?

MS. SLUTSKY: Yes, we have that information -- I don't have it, but I'm looking at our communications team and we can provide that to the board if that's okay Barbara.

DR. McNEIL: Sure.

MS. SLUTSKY: Okay, thank you.

So when we look at the five years between 2012 and 2017, we've met with 740 unique organizations who've participated in PCORI workshops, work groups, and roundtables to support

topic generation and research prioritization. Some of you who may recall what we called our super Tuesday meeting, which was a stakeholder group -- just priorities for what is now a large opioid portfolio, multiple sclerosis portfolio, low back pain portfolio, where we had five simultaneous stakeholder groups setting priorities for these what are now major investments for PCORI.

So this is a huge touch point with those communities and individuals that care deeply about these issues.

I won't go through each of these individual slides, but to say that this sort of blows out the national Multiple Sclerosis Society interaction with us where this interaction actually helped put together a small multi-stakeholder refinement work groups that were joined by payers and industry and community-focused work groups and that led to that large multi-stakeholder work shop and led to two targeted funding announcements and 12 awards totaling $55 million.

Similarly, PCORI supports the Medicaid

Medical Directors Network, as we heard earlier from Evelyn. The Medicaid supports almost 50 percent of births in this country, so we work closely with them because their needs are often the needs of the broader clinical community and they are a very large dissemination outlook for us, as well, so we support them and they support us through the work that they do.

And then, establishing PCORI as a thought leader on engagement also means understanding the science engagement of engagement -- understanding what is happening so that we can build on existing sources of data, to describe engagement in our projects more deeply including how partnerships are initiated and fostered and sustained. And to also understand the influence and impact of engagement on research, what are we learning about it and what is happening because of it and importantly what wouldn't happen if we weren't doing engagement.

So how would things be missed and not done as well and then exploring how the influence is occurring so testing associations between different

types of engagement and specific impacts of engagement to better understand how people are making engagement happen. So how does this interaction occur and what about this interaction is specific to changing how research happens?

So the next goal I want to talk about is ensuring stakeholders have mechanisms to engage.

So the Eugene Washington Engagement Awards were started in 2014 and since that time we've made 277 awards these were intended for partnerships in research to identify research priorities and to serve as channels for dissemination implementation of our research findings. About seven months ago we approached the EDIC and pivoted the engagement awards program towards primarily dissemination implementation and making those communities ready for dissemination implementation of PCORI results and so we changed the awards funding announcement so that they would understand that this is a priority for PCORI to make sure that our research gets into the hands of people who need it, including communities.

And this is just a couple of examples and I wanted to bring these up because actually our opening plenary tomorrow is an engagement awardee who actually worked in the Mississippi Delta and you'll see on the lower right-hand corner -- actually the state of Mississippi PCORI an important organization based on funding for her work, Freddie White-Johnson, who you'll hear from tomorrow. Quite compelling. I've seen her slides and they really make you begin to appreciate the role of communities and research.

And then, on the lower left-hand corner you'll see Pastors for PCOR, which is the Chicago-wide organization of faith-based communities to tackle problems in the community such as hypertension, obesity based on evidence.

So these are actually activities that really have made differences in communities, relatively small amounts of awards but they are now clamoring to actually integrate results that come out of our research projects.

So I want to talk now about a third EDIC

goal, which is to ensure efficiency and quality of public reporting. This is a very unique aspect of the work that PCORI does. And Joe had showed earlier slides about how we're making our portfolio more accessible and this is just a slide showing the Project Explorer, which allows the external community or internal community to actually more easily search for our own projects that we're funding and it allows you to search on many different filters. And isn't that cool? And as you can see, you can just press a filter and then results will come up.

Another filter and a different result.

And then as Evelyn mentioned earlier, as our portfolio grows and we begin to have clusters of work, we're enhancing the website so that we can arrange the content and resources by topic. This was something that was really important to the EDIC to make the work that we're doing accessible to people who wouldn't necessarily know how to search for this information, but wants to get an understanding of what type of investment this

organization has made and why and how it fits into the over-arching condition profile.

So you'll see here cardiovascular disease, cancer, pain care and opioids, and these are just three. Evelyn showed a large constellation, but these are really written in language that is plain language so it's language that's accessible to many different types of external audiences.

And one of the things that the EDIC felt strongly about as the oversight committee for making sure that we educate communities about the work that we're doing is that we create fact sheets that highlight our activities and portfolios for us to take with us and to handout to audiences that would like to know about what we're doing.

These are just three, again, that match what's on the website. These are updated regularly. These are easy to understand, they’re one-pagers. They're available in both electronic format, as well as stock paper. So easily you can pull it off the website and distribute it yourself or are we provide it to other organizations.

I just want to mention a little bit of a promoting open access to journal publications and presenting findings from PCORI-funded research.

We worked with the EDIC to make sure that we are above most funding organizations in making sure that our research findings are accessible as possible to external audiences. So PCORI investigators may request PCORI coverage of open access fees when a manuscript presenting the main results of the paper has been accepted.

So what this means is we'll pay up to $3,500 to bring that major publication outside of a journal firewall so anybody can get access to that publication. So far we've received 26 open access requests from PCORI investigators and we've been doing this for about nine months now. And PCORI has accepted 22 of these requests based on our policy requirements. The four that we didn't accept were not major on results papers and we didn't want those investigators to use up their "wad," so to speak, kind of findings that weren't major findings.

We're also working with PubMed Central to

facilitate the deposit of all published manuscripts to enable full public access within 12 months of publication. So using these two mechanisms, all of these results will eventually be available to the public free of charge.

So we're also making sure that that these are available on our website, so you'll see this is probably clear in your printed materials that on the website page of each project you'll see that the publications are noted on there where you can access them and the initiatives to promote public access to peer-review journals, so the free publications are noted on there.

And then by legislation, we've developed plain language and technical summaries of every single research result once it's on gone through the peer-review process. And those plain language findings, and you can see one on the bottom there, are reported back to study participants because health literacy is a big issue and we try to keep the plain language at the 7th or 8th grade level. We present audio files for those folks that are

reading at the 7th or 8th grade level. It is difficult and we now have our first Spanish modules up on the website.

So we've talked about the tsunami before and this is just another reminder that the tsunami is coming.

So we now have four results posted to PCORI.org and then nine more will be posted within the next 90 days, so that'll bring us up to 13 and up to 145 results to be posted within the next year. A huge ramp up.

So it looks like this last year was spent on cognitively testing the formats for all of these translations that will go up on the website and then they are -- so the format is already set because we know that this is the same format -- if you go from one publication to another, but the plain language and the technical ones are also testing with focus groups of individuals who either have the condition or treat the condition, and then they'll go back to the PI for review.

So finally, I want to talk about our

dissemination implementation of the PCORI-funded findings even though we've talked a little bit about it in terms of public reporting, I do want to emphasize some new activities in this area.

So this is the schematic that we developed in partnership with the EDIC, which really characterizes how we go about onto dissemination and implementation and then we'll talk about our partnership with AHRQ as well.

So when we talk about focused dissemination, this is really meant to be activities to disseminate results of PCORI-funded research on current treatments. For example, recently there were two of PCORI projects on prostate -- localized prostate cancer that were published in *JAMA*. So we did several activities around these projects. One was a congressional briefing with the Men's Health Network for Congressional staff and then, we developed evidence updates on these two studies for clinicians and patients and co-branded them with the American Urological Association and Men's Health Network and developed continuing medical education

and continuing education on these two studies. And those are available on our website now.

I believe Joe just looked at them last week.

When we talk about focused implementation, this goes quite a step further and so working with the EDIC, they approved a targeted funding announcement for implementation of effective shared decision-making approaches and practice settings, which we brought to the board in August and you approved publishing that targeted announcement. That announcement went live, we've received letters of intent and we'll receive applications in January. And this is really an important aspect of what we've been talking about in terms of changing behavior and shared decision-making for particularly preference sensitive conditions for which there's no one truly right answer that evidence with patient values and in consultation with providers is important.

So another activity that we do which is Dissemination and Implementation Awards. These are awards that are meant to bridge the gap between

those research projects that we funded and dissemination implementation of the findings. These awards are intended to promote people submitting high-quality draft final research reports and so we work closely with our peer-review colleagues and our science colleagues to make sure that someone cannot apply for an award until they've actually submitted a high-quality final draft final research report.

So far we've committed $2.2 million and have issued five awards. These are in areas of diabetes prevention, benefit-based tailored treatment, and virtual care visits for Parkinson's Disease, and preventing venous thromboembolism. The EDIC is overseeing this project and for the first time we will be going to the EDIC for two projects and dissemination implementation awards that are greater than $500,000 and they will vote on whether or not to send these to the Board of Governors for approval and so on that vote will take place at tomorrow's EDIC meeting. So this is really exciting for us these are pretty targeted implementation projects and so we'll have an exciting discussion

tomorrow.

And our colleagues at AHRQ have been working closely with us because they're charged with dissemination implementation of PCOR findings as well and they are considering several broad initiatives that we have submitted to them for consideration. One is anticoagulants to prevent stroke for patients with atrial fibrillation or the PROSPER study and this is based on our submission of study results to AHRQ.

And another on cardiac rehabilitation. This is highly relevant to a PCORI study in progress right now. So we've had several meetings with AHRQ on this and together we're planning a stakeholder meeting on how best to disseminate the information from the PROSPER study, which is the first bullet. In addition, we're collaborating as Evelyn said on systematic reviews, and PCORI will disseminate findings from the systematic reviews that we're completing under a memorandum of understanding with AHRQ.

So in closing, how does this look in

practice? I'm going to close with a quote from someone who I was surprised to see that they actually where from an organization that doesn't traditionally work with funding organizations and hats off to Larry Becker for really helping us reach the purchaser community. But this is a Kimberly Jinnett from the Integrated Benefits Institute. And really the gist of what she's saying is, "I've been fortunate to have a seat at the table at PCORI-convened meetings to represent the voices of employers and those helping employers to improve employee health and well-being."

And I think that's an important testimony to the fact that, you know, as a funding organization we are really walking the talk.

So in closing here are the EDIC questions for you to consider.

So the first is the thoughts on the balance of dissemination versus targeted implementation and are there any initiatives that should be added or enhanced from what we talked about today?

And I'll just turn to Debra and Larry as

our ad hoc and co-chair, if they want to make any further comments.

MS. BARKSDALE: I just want to say thank you for a wonderful presentation, which I knew it would because I had a copy of it. And it's really impressive the amount of work that has gone on in this committee and the staff that support it, so again thank you. Are there any questions? Comments? Answers to our questions?

CHAIRMAN NORQUIST: Sharon, I think you had a question or a comment?

DR. LEVINE: I have a question/comment which is that as we move I keep focusing on this 145, 141 and I'm wondering whether -- we haven't really talked in a formal way about our engagement investment and whether we have we have reaped so much from them. I'm the first to say we have, that we can begin to shift some of that focus and resource particularly staff resource into the dissemination and uptake phase.

We've built a very broad community of friends of PCORI and whether we can begin to

repurpose some of that into dissemination and uptake.

MS. SLUTSKY: So that's a great question. One of the things that we're doing is we're winding down the Pipeline to Proposal program, and so that program will sunset a year from now so we just have the last pipelines going through the process and three of the major awards supporting that program will on sunset at the end of this year.

CHAIRMAN NORQUIST: Larry, are you going to comment or have a question?

MR. BECKER: So a couple things and I know Debra and Jean and I talked about this, so I think as much as we communicate this stuff I think there's another step we need to take and that is to measure the results of what we're doing. And that is -- I want to give you by way of an example -- let me give you one example. Let's take the Type 2 diabetes, people who are not insulin-dependent. In sales and marketing you call this awareness consideration [inaudible] and impact. So awareness you would say that you want to have -- I looked this up, there

about 29 million people who are Type 2 diabetics in this country and growing. So essentially you want 29 million people in this country to at least be aware of this research and the doctors.

And you want something like -- and I'm making this up, but you set a goal say for half of those people to consider what this research is saying and then you want a hit rate. You want some percentage of the people that consider it to actually take action. To actually do something with this result. And then what you measure that in [inaudible] Type 2 diabetes -- the test strips, I looked them up on the internet, they're $50 a month, $600 a year.

So we're talking about real money if you know everybody is aware, 50 percent consider and a quarter of those people actually take action.

And it's the kind of things that as we actually do this, are we having an impact and can we measure those things? We talked about opioid use earlier today. You can apply the same methodology to opioid use, you know, in terms of reducing it

based on some of the discussion we had. So we've got to figure out a way to measure what we're doing and measure the impact of what we're doing, and then we can demonstrate to people for the future that we got to just keep doing this stuff.

MS. SLUTSKY: Thank you. I think that's probably what I think Michelle's probably singing in her heart right now because we meet regularly with evaluation analysis group to make sure that we have metrics in our dissemination implementation projects that support their evaluation analysis activities, so that we can actually show that what we're doing has an impact but I think it's really important for you to keep saying that over and over again because I think that's a way for us to show our utility and it's important that we do things that have been shown to do what we want them to do. And even if they are unintended consequences, we ought to know about them, both good and bad.

CHAIRMAN NORQUIST: Yeah and I think the other issue, it's like in quality research, outcomes are the key but sometimes you measure process and

way to get that so there's process indicators -- like I think if you listen to what Congressman Gingrey talked about, how do we make sure in collaborating with guilds and organizations who are doing a lot of the decisions about practice guidelines. How do you get that information to them and stuff?

That's a process. Ultimately you want to see patients improve and change, that sometimes that takes longer so we some intermediate outcomes, if you will, on dissemination.

Joe did you want to --

DR. SELBY: This is just a little follow on and I thought you might mention this Jean, but I think it's appropriate here. In terms of estimating impact of our projects, we are actually -- I don't think you mentioned this unless I missed it, we are for some of our projects that look like they should have an economic impact among others were actually -- you know it better than I do.

MS. SLUTSKY: Yeah, so what we've done is we're doing some economic modeling on the impact of

some of our research findings on what impact they would have on time lost from work, readmissions to hospitals, the cost of treatments that are necessary or unnecessary. So we've got two in draft that we hope to be able to accept and final but both are showing that you know they would increase time on work and decreased time off of work.

CHAIRMAN NORQUIST: So I don't see any other tent cards and I want to move on to let Freda and the last committee before we take our break and then come back for more a more general discussion. Thank you very much Jean and Debra and Larry. Since you're the ad hoc, I think you are now -- for the wonderful work along with the committee and I think the staff is absolutely excellent. And again, it's the kind of feeling that had we started out here seven years ago, right.

So Freda, Allen I guess Allen are you on the phone?

DR. McNEIL: I'm okay.

CHAIRMAN NORQUIST: We're looking for Allen Douma who is supposed to be part of this

presentation but I don't know if he fell off the phone.

DR. McNEIL: I'm okay so far.

CHAIRMAN NORQUIST: Thanks Barb.

So Freda this is -- I guess you're going to lead it and Joe is going to help you with our Research Transformation Committee.

DR. LEWIS-HALL: We can do that. And I'll make the introduction quick to give lots of time for the presentation.

I just want to start out by saying in case we do run short of time, this is clearly staff appreciation day. So for the third committee in a row I have to say that our relationship has just been absolutely incredible. It has been a ton of work with enormous complexities but we have really been shoulder-to-shoulder, so I'm really grateful for that.

And then a special thanks to Allen, who can't hear me say that but someone can tell him later that I did, for always asking the most poignant, evocative questions ever and keeping our

feet to the fire. And then to all the other committee members who you see here on the slides, again much gratitude to all.

DR. DOUMA: Freda, it's Allen. Thank you.

DR. LEWIS-HALL: You did hear me say it.

CHAIRMAN NORQUIST: It's recorded --

DR. DOUMA: I did.

DR. LEWIS-HALL: So I'll stop there, I'm going to turn it over to Joe but I just wanted -- now Allen that we know that if you had any comments to get us started off.

CHAIRMAN NORQUIST: Before -- I just want to make one comment, everyday is staff appreciation day not just today. So I just want them to know that.

[Laughter.]

DR. DOUMA: Actually I don't have anything specific to point out. I think the future activities are the exciting part of everything and in particular, for the RTC I'm looking forward to us focusing on that a bit.

DR. SELBY: Okay, thanks Allen. I'll just

add a little historical reminder here. The RTC is the one strategy committee that it started later than the others, we knew about -- we knew about selecting the science we wanted to do from day one. We knew about engagement and dissemination from day one. It took us until we completed the Strategic Plan and then had the kind of the board reorg of 2013 that we had a third goal which was to influence science done by others and funded by others to become more patient centered.

And that is strategy number three or goal number three, and that's the mission of the Research Transformation Committee, to influence clinical and health research funded by others to be more patient centered. This is the excerpt from our mission statement, which is to advise the Board of Governors and PCORI on encouraging all research, included that funded by others to be more patient centric. And we do it through open science, the development of transformative research platforms, think PCORnet there, and the conduct of more patient centric and methodologically rigorous research.

And we identified -- as we were writing the charter for the RTC's five initiatives. One is open science and I'm going to speak to each one of these -- both what we've done, kind of the story --the history from the beginning to now and as Allen says on into the future. The entire open science initiative and area of consideration of PCORI, funding partnerships as Evelyn said. Several of us claim and recognize the importance of this workforce training, methodology standards, dissemination -- I would say share with both the Methodology Committee itself and also with EDIC and of course, PCORnet.

It's no secret that PCORnet has occupied a whole lot of our thinking and effort over our first three years of existence, but I'm going to talk about each one and I'm going to start with open science.

So in our Charter it says that the Research Transformation Committee serves as the central advisor to staff and the Board of Governors for developing and implementing our policy for data access and data sharing. So our view is that it is

critically important to patients and to clinicians that the investments made in research but certainly the investments made by us and hopefully those by our example, the investments made by others -- those investments lead to quicker and more completely to the release of not only information but data from the studies so that others can participate in using those data to the fullest.

And you know, there's one thing we know at PCORI is that the last seven years we've underutilized the data that have been produced by an order of magnitude at least -- and the work that Evelyn talks about the individual patient data, meta-analyses is an example of the need to get that data, to share the data, and to analyze it to get much more information out of it. And particularly around what works for whom.

So specifically in our plan, in the plan of the RTC, we stated that we would provide guidance to staff in assessing the options and the trade-offs for implementing a data access and sharing policy and to ensure alignment of the policy with ongoing

work in the research community.

And I'll just say here that we are very fortunate to have on the RTC three members who are really in the thick to put it lightly, in the thick of the open science discussion. Steve Goodman in his work on reproducible science, served on the National Academy of Medicine Committee on sharing open science. Harlan Krumholz is a leader in many ways, including some of the projects he directs personally, in terms of building data repositories and pooling and sharing data. And Francis Collins and the NIH -- if there's another leader in open science, it's certainly NIH and Francis who stays very abreast of that.

So it's been great to have those three on committee as we've discussed this area.

We started by developing principles for data sharing and then advise staff on operationalizing those. Staff convene an expert group and solicit input on the draft data sharing policy and requirements. The policy was drafted. It was put out for public comment after showing it

to go to the board here and getting the approval to put it out.

And we've seen the input from a range of stakeholders, considered for public comments and return it to the expert again with the comments from the public input. Identified areas for further refinement and recommended a pilot project which would invest $300,000 in bringing three PCORI awardees -- three PCORI awardees of larger projects, pragmatic trials, or targeted studies together with two entities that serve as biorepositories -- potential biorepositories, to begin working out some of the -- to begin actually putting -- going through our draft policy and learning from it.

The advice of the RTC was to move deliberately here. This is -- we are making stuff up out of whole cloth in many ways, it hasn't been tested so the pilot study and others are not moving even as fast as PCORI is. So we are testing these great ideas, fully expecting that we will run into some of them that need modification in the pilot project.

So in terms of future work in open science we will evaluate and learn from the pilot project. That will be done in March of 2018 and make recommendations for staff to craft a final policy for data access and bring it to the board for consideration for approval in May. We will monitor than the implementation and progress on data sharing using this policy and advise staff on modifications which we anticipate.

And we'll also monitor other emerging areas in open science. So data sharing is not the only area. There are other topics that we anticipate will come up and we'd like to consider whether PCORI be in the vanguard on those as well. As likely as not, we will go in that direction.

So moving on to funding partnerships. So here are the ideas, simply if you want more research funded by a wide range of funders to be more patient centered you've got train the researchers to do this kind of research. So the RTC encourages -- I'm sorry this is funding partnerships. This is why -- I jumped ahead of myself.

So this is the one that we share with the SOC in terms of being very supportive. The idea here is that if we co-fund with other funders we will in fact have a chance, particularly if we insist on it, to influence the way they do research. Ideally they will learn from it and continue funding additional research of theirs in the same way and I think we see this happening already.

But the RTC reviews existing collaborations to make sure they are aligned with PCORI's collaboration principles, which we outlined very early on and the board approved and are on our website. And to consider additional active partnerships and we do certainly recognize that others, particularly our colleagues in science sometimes generate collaborative partnerships on their own with us doing nothing.

So here's just a list of the ones that are under way. We have to with the NIH, one is preventing falls in the elderly. A large intervention study with NIA and one from National Heart Lung and Blood Institute and the National

Institute of Neurological Disorders and Stroke on interventions to improve hypertension and to reduce disparities related to hypertension in African American and rural populations. We have a great project with ARHQ on a large observational study -- a registry study on comparing options for managing uterine fibroids in women who would like to be able to become pregnant in the future despite the uterine fibroids.

The one you're very familiar with is that with the American Heart Association which began as a jointly funded crowd sourced project with patients and clinicians to identify critical questions in cardiovascular disease, which focused very impressively on atrial fibrillation and stroke. And then, in collaboration with our science staff and in collaboration with the SOC, we reached a decision to support a project co-funded with AHA on decision-making and choices to inform a dialogue about anticoagulation in stroke prevention in atrial fibrillation patients.

So this is a project that continues to

synthesize the data around atrial fibrillation, particularly stroke prevention in atrial fibrillation and then develops the shared decision-making intervention for atrial fibrillation patients and their physicians because physicians need information on this probably as much as patients do to get right and to get anticoagulation used in the ways that it should be used to prevent strokes.

Also in PCORnet we have several projects that encourage or require co-funding. So the recently approved partnerships to conduct research in PCORnet directed at PPRNs actually require the PPRNs to engage with a co-funder then bring a co-funder to the table. That may be an industry co-funder, it may be an institution such as an advocacy organization, it may be a foundation. So that announcement is in the field, applications are coming in. A lot of them bring industry co-funders but they also bring foundations and institutions and we will have awards coming up in the spring of next year. At least three, as many as five.

Also we have a co-funded project with the

Centers for Disease Control and Prevention that involves six of our CDRNs called Natural Experiments for Translation in Diabetes or NEXT-D; and those really caught on in the CDRNs and we also very active collaborative diabetes research group within PCORnet, thanks in part to bringing the community together around this co-funded project with the CDC.

And we have three co-funded projects, pilot projects with the FDA that are based on linking data -- either linking data to claims data that are in SENTINEL for drug studies or linking data from PCORnet with data on devices from the so-called TAVR Registry, transcatheter aortic valve replacement. So these are three nice projects that we're doing with the FDA.

So future work in this area is to continue monitoring particularly the outcomes of the PCORnet PaCR announcement with the PPRNs and the progress of those once funded. To continue seeking out opportunities to partner with other organizations and to endeavor to have at least two to five new co-funded the projects over the next two years.

Workforce training. Here the notion is as I began to say awhile ago that you've got to train people to do PCOR if you want to research funded by others to be more patient centered. And so our work as we set it out the beginning of 2014 was to conduct a field scan to understand the current landscape of workforce training and then to create a plan for how PCORI could contribute to an increased availability of training resources.

Building on that, we joined a technical expert panel that had been convened by the Agency for Healthcare Research and Quality to consider the framework and the competencies for training researchers to work in learning health systems. This idea actually came out of a National Academy of Medicine's PCORI funded series of meetings on learning health systems doing patient-centered outcomes research in learning health systems and at that time Rick Kronick was in Gopal's seat and he jumped up at the meeting along with me and we said, you know, if you want these people to be able to -- if you want these systems to do it you need to train

researchers to work in their systems.

The purpose of this announcement is to train clinical research scientists to conduct PCOR within these learning health systems focusing on generating, adopting, and applying evidence. Particularly using the data that are generated in the systems and the announcement that we put together -- that AHRQ put together with our input, insists that the program incorporate PCORI methodology standards in the training and also that all applicants and awardees develop the capacity to train trainees in patient-centeredness, in patient engagement, disparities, and health equity.

It wasn't a hard discussion with AHRQ, they were very open. Applications for this are due by January 2018.

And so, in the future we will monitor the impact of this as they as they take shape and consider other opportunities. In fact, we have another small opportunity -- relatively small opportunity for a workforce training award that we will be talking about in the RTC tomorrow.

The next is oversight of the methodology standards and I'm going to be brief here because I think it's very clear that although we had identified it as an initiative, the Methodology Committee itself as well as EDIC are hot onto this as well, but our mission was simply to ensure that there's appropriate integration of the methodology standards in PCORnet.

This work, again, has been led predominately by other committees but we certainly support the integration of the methodology standards into CME and workforce training activities and to support the identification of standards that may need more targeted dissemination efforts. So our strategy and I think we need to figure out -- fortunately we have Steve on the RTC, just figure out how we can actually contribute -- if and how we can contribute in this area but continues to monitor the question of disseminating the methodology standards especially these newly approved standards once they go through public comment and to encourage the development of processes to assess the

implementation of methodology standards in research.

Not only our research, but that funded by others. We believe it would be quite interesting to see whether our research follows the methodology standards more frequently than that funded by others, I think we hope that it does.

And last but certainly not least, is PCORnet, where we set out to ensure that PCORnet remains committed to patients, clinicians, health systems and plans to monitor the government's policies and practices to support development and evolution and evaluation of PCORnet's business plan for sustainability, to pursue external co-funding opportunities, to help ensure the sustainability for PCORnet, and a monitor on the demonstration projects.

In terms of the initiatives we've overseen on the RTC and approved. There are 14 demonstration studies underway. There are two major clinical trials, one is a demonstration project, adaptable and the other is a large NIH funded trial that PCORnet is a major contributor to. It's called

INVESTED, which is a study of single versus double strength dose of influenza vaccine for patients with congestive heart failure.

We also have eight externally funded or co-funded research projects. I mentioned there were seven on the spreadsheet, on the dashboard this morning, but we have added another one in the last order. So eight currently externally funded or co-funded research projects -- all with federal agencies.

New funding mechanisms. Several months ago you approved the Rapid Cycle Research Projects. These are jointly overseen now by RTC and the SOC and they are to provide a modest amounts of money up to about $500,000 on specific projects where an idea comes to us from stakeholders or board committees or staff and we have funded projects now in diabetes, cancer, particularly cancer outcomes in the use of targeted therapies. Hepatitis C, potentially -- specifically focused on adverse effects of new agents, and PCSK9 inhibitors. And then the PaCR awards, which I already mentioned the PPRN directed

projects that engage external co-funding.

The sustainability plan as you well know led to the creation of the People-Centered Research Foundation, which PCORnet follows closely and we'll get a report on which RTC follows closely and we'll get a report on tomorrow. That is the solution for sustainability produced by PCORnet that we follow and in following it our stance on the RTC is not to micromanage in anyway PCRF. It is an independent entity, we don't control it but we do fund it.

We find it through statements of work but our primary role in the RTC is to ensure that that PCRF just as PCORnet abides by these principles, which are the engagement of patients and other stakeholders. Commitment to building a national resource accessible via a central gateway to researchers inside but also outside the network. Encouraging and facilitating data sharing and sharing of resources and tools through an online commons, which I actually commend to your examination.

Insistence on a common data model as a way

to expand the capacity to do large-scale research to advanced data quality consistently. Insistence to work on streamlining and standardizing the mechanisms of conducting research specifically contracting data use agreements and centralized IRBs. Insistence on advancing the quality and availability of complete and comprehensive data sets; that is data sharing so that we have complete data and usually that's accomplished through linkages of disparate data. For example, between a large delivery system and its partner health plans.

And lastly, to comply with all applicable laws, regulations and legal requirements.

Future for PCORnet and PCRF and the RTC is to monitor to continue monitoring the transition of PCORnet through sustainability through PCRF, to evaluate PCRF's business plan and report on that to the board and to consider and make any recommendations to the board on any future infrastructure funding to PCRF.

So this just summarizes what we plan to do in these five areas and our questions for the next

discussion are among those five initiatives how should the RTC prioritize these? Both in terms of our time, but also in terms of PCORI's and PCRF's emphasis on these priorities? And are there initiatives that should be added or removed with the aim of influencing the others the way that other funders conduct their research to be more patient-centered.

So those are the two questions for the next session.

And that's it. I'll turn it back to Freda and Allen.

DR. LEWIS-HALL: So, again, that is a lot going on in a 30-minute report but we're really excited about all that has been done, but in particular slide 19 which really talked about where we want to be in the future.

So again, thanks to the staff and to the committee members and we really look forward to talking about some of these questions because they're going to be pivotal for us in the way we apply ourselves to our future work.

Allen, did you have any comments?

DR. DOUMA: Just that I agree with everything you both have said. There's a lot of work going on and I look forward to seeing a little more details about PCORnet and the Foundation but that's hard to do on the fly, so in the future we'll know more.

CHAIRMAN NORQUIST: Questions or comments from others?

It's a lot. I mean it's incredible so thank you Joe and the staff and Freda and Allen and everybody else on the committee. I mean, the amount that's been accomplished in seven years and still more to go.

All right I think people need a break, I can tell already. I think I do too, so we're going to take a 15-minute break for those on the phone and we're going to come back and we're going to go over these questions or more. We'll see where we go with this next part. Fifteen minutes everybody.

[Recess.]

CHAIRMAN NORQUIST: Okay, let's see -- I'm

still missing -- there's Bob. I want to make sure the chairs' at least and the vice-chairs of the three groups are back.

Okay, so the idea was -- one was to obviously hear from the three committees to get a sense of -- people have been asking us, a number of the board members said they wanted to hear what the committees were doing and then to have an opportunity to discuss across the committee. So the idea was not to have a free-for-all and just had a lot of discussion but at least tee it up with some very specific questions that would start to approach.

So Bob and Alicia and their group came up with the first questions. Bob maybe you want to lead it off and give us kind of a sense of what you're looking for or perhaps some help on this or what you're thinking is on these questions.

DR. ZWOLAK: On the slide we have MS and palliative care to which there were just absolutely remarkable response levels of really good applications and we funded. Several I think we went

over our recommendation, I believe in the palliative care category.

DR. McNEIL: Which slide?

CHAIRMAN NORQUIST: Which slide are you on? Which side is it? 130.

DR. McNEIL: Okay.

DR. ZWOLAK: And the one that's not on there is and is my particular favorite is opioids. I mean, as far as I'm concerned we could we could fund as much high quality research as we could get applications and I think the country and people would be better for it. But I guess the question comes up, how much how much focus is too much focus?

I think that's sort of the intent and when do we tell from the incoming signals when it's time to say it okay this is enough in that category?

CHAIRMAN NORQUIST: So ideas about your own -- the committee's own thinking on this? I mean, so one of the things to me is if it's an area in which we're the only ones doing the work, that's one thing but if there are others doing the work if there is some sense about what is being produced by others

that gives you a quicker sense of when it's time to stop unless you have a particular niche that you're in, right? And opiates, the one you mentioned is one that we're not the only ones doing work in.

I think in MS, too, we certainly shouldn't be the only ones doing any work and Multiple Sclerosis. I just -- what is our particular niche in that area and have we fulfilled it? I guess the other question is you won't know that until the studies are finished, right?

Evelyn -- yeah why don't Evelyn and Jean, we're going to put you on the spot up here too. Yeah if you would sit up here you we could have you -- to have the staff kind of perspective because you may have a better sense of this.

So anyway that's my two cents. Let's see if others have -- Larry?

MR. BECKER: So Gray it goes back to two things we've talked about over the years. So the first one is the landscapes, right? So that's to the point of what else is being done and the second one is time value to the research in terms of we can

start something, but it’s going to take us four years and other people are working on it. Will it endure when it comes out the other end?

So we need to be careful, but I think it's also a paradox with and -- I mean, we need to do this “and” we need to be able to implement and make change or induce change somehow and be reasonably sure that we can make an impact because we’ve got fewer than eight years to make this stuff happen and count so we can [inaudible] people -- an enterprise worth doing.

DR. ZWOLAK: Evelyn, do you want to expand on what I said about this particular question?

DR. WHITLOCK: Well, I walked in as you were talking so I might repeat something you said by mistake, but we had talked about various criteria. One was with the one that Gray brought up which is where are we in the research ecosystem? Are we the unique funder? Are we a major funder? And then contrary to that, is where is this -- how does this represent PCORI? Not only as how are we feeling in our partner resource system but at this point in our

history how does this represent who PCORI is so that it can be something that helps people understand who PCORI is.

So that was that was one thing that was said.

The second is that we talked a little bit about the balance across the portfolio and this is where I think it gets a little bit more challenging because what is an ideal balance in terms of putting a lot of money -- when is it too much money to have in a certain part of a portfolio? And of course, there are various views of the portfolio that overlap.

So that was the second area. Certainly what Larry said is a consideration, which is who else is funding in this area and what research gaps remain? I think where we are particularly deficient is how do we prior -- there's always going to be research gaps. There's no such thing as no more research gaps, but how important are those residual research gaps and do we have a way to prioritize? We are in some ways, when we repost a targeted

funding announcement it's all built on stakeholder input, the board has approved putting out a certain amount of money for that and the SOC is charged with reviewing whether if dollars remain is there other important research gaps that remain. So that happens.

But when you've got a portfolio and there might still be research gaps, we haven't figured out a process to say yes we know there's research gaps how important are those and how important are they considering all of the other research gaps the PCORI could address?

So I think those are the things the committees have talked about.

DR. LEWIS-HALL: I was trying to and I can't remember which meeting it was where you presented a landscape of what was happening in a particular space and it wasn't just a topic that we were unique in, but you know, this question was being answered here and this question was being answered there and we just had a nice lane that we were uniquely situated to respond in. In these

areas do you have that landscape in a way that we could really pull out where we were uniquely positioned to identify a need in that space, articulate the work in that space and fund it?

DR. WHITLOCK: I think for Multiple Sclerosis it depends on what you consider the space, because there's different ways of that space but we are moving into trying to do that. You may have noticed in my quick run-through that we do have an evidence map that has been commissioned on Multiple Sclerosis to see where we're sitting in terms of what's already known.

And so -- but the frame around that is a type of MS, so we had to have a frame around it and it may not be exactly the right frame. I think that's one of the hardest parts when you do a landscape is how broad do you go? How narrow do you go? But we are doing that with MS.

In terms of palliative care because it was developed so recently, we have a couple of things where we have crossed-looked at our portfolio what were major research needs that exist in the field.

Who else is funding? It's kind of cross-cutting issues so there are -- according to the researchers in the area, people that are really concerned with this area, there's not enough investment but we do know from that work that -- for example for children, there's just a huge underserved need and through all our calls up to this point we haven't gotten that evidence quite yet.

So it -- again, it depends on how you set the frame but we could work creatively with SOC or the board to help be sure we accept the frame right and then there are various ways to look at that and then think strategically about what could be done.

Does that answer your --?

DR. LEWIS-HALL: I just want to make one other point because I think areas like opiate addiction, there's going to be a lot of work coming from all angles in this space and I think in that space as much as needed I would endorse doing this with a really good landscaping exercise so that it was well-coordinated and we weren't being redundant.

But I agree that this is a time and a place

that we could be all in make a unique contribution. I'd just like to be sure that is unique.

CHAIRMAN NORQUIST: Russell.

DR. HOWETON: I mean, if we accept there will always be research gaps and as a matter of fact I would assume that even across our portfolio, in every slice of it there will be gaps and we would be doing good almost anywhere we chose. Is it wrong to have a little bit of realpolitik and considerations? If we go to your favorite -- opioids at a time when we would like to be refunded, if we are focusing on the things that are important that those who are thinking of us is that necessarily wrong?

And that issue will be on the agenda for years to come, right? We know that.

And if there are viable gaps there, to your point, which I feel certain that we would be able to find a viable gap -- maybe that's a basis for consideration.

DR. WHITLOCK: I mean I think if we think of Congress's representing constituents then you know people who are concerned about opioids are

representing -- their representing locales where it's hugely important and it's a very bad situation. We held a congressional briefing with Anthem recently and you know, the representative from West Virginia came and spoke and it's tearing her state apart.

And so, I think it's not that we're playing to their favorite they're actually representing their communities.

So I wanted to add a couple things to that and we are -- the chair of methodology committee Robin Newhouse has let us know and we have a call set up with her because they've had such a strong community response to some of the initiatives that her institution is doing around opioids, that it's a natural opportunity for engagement around research needs and community needs.

And so yeah there are natural opportunities like that, but the second thing I wanted to say is I think that another way to figure out and it's not exact, it doesn't work as well as a landscape review but I think that the importance of our partnerships

with other funders is really key.

So I'll give two examples one is our partnership having representation from NIH on the Selection Committee and right now we have -- we're working on something that is in the opioid use disorders and that will be looking at whether something that might not be -- not quite be in the PCORI wheelhouse as currently defined. It May because it has such large significance, could be worked through other channels in order to make sure we're bringing that information to the public good. So having partnerships with other funders and the Funders Forum is happening later this week where we're going to be talking to partners in the U.S. as well as around the world, about how can we reduce duplication, enhance efficiency, enhance focus just as another way of going forward.

So I think it's the partnership part that helps as well. We always wish we knew what everybody was doing at the right time, but when were there is overlap with these other partners and people are trying to collaborate it gets us closer

to being able to achieve that idea.

CHAIRMAN NORQUIST: Maybe that's part of it is ongoing relationships with the other potential funders because there are a lot of people who would want a piece of the action, so to speak. Especially with some of the private funders now and how to we make sure we're all kind of doing and even partner in funding. Joe?

DR. SELBY: So this is just a strategic question. I don't really have a choice but I don't have a side in the choice, but I think the whole reason Evelyn raised this was in part the fact that we are now at a point in our history where for the first time the funds field -- there are some limitations on the funds, so lets you know -- we feel like we could be all things to all people, so now there's a choice between really going very deeply into an area where there's opioids and mental health, Multiple Sclerosis, palliative care versus being open to a large number of other stakeholder groups as the only place in the country that addresses these kinds of patient-centered practical

questions.

And part of the question I think is about balancing that tension between wanting to stay open to a wide range and getting deeply involved in some areas and I would just say, especially since there are other funders operating in any all three of those areas that I mentioned.

DR. WHITLOCK: That's well said and really is part of the dilemma and I'll give another example.

So I mentioned earlier just in a quick drive-by that we've been doing a lot of focused work on childhood and adolescent anxiety and I think I quickly went through the New York Times -- there was a New York Times magazine study in October about this, about how prevalent this condition is and how to debilitating it can be.

But a part of getting going in this was it came through stakeholders and as we begin to work at it, we checked in with NIMH and one of the first things that we were told is that this is a really important area but right now the focus is not there

for NIMH. And so, we are doing something that's very collaborative and important and we should keep talking with NIMH through the process as we do that.

So that's an example, but I believe that you know, this is my impression from the stakeholder meeting that we had from the needs that are out there at the family level, at the community level, at the school level, at the practitioner level, that we could do a whole series of investments in this with a lot of resources right now and we would be making a huge investment in a very important area but we would be leaving some other things aside and we would be going deeply into that as opposed to listening to the next important thing. And that's what Joe was saying is trying to make those strategic choices and thinking about how does the board want to think about those things at this point in its history.

CHAIRMAN NORQUIST: The other thing I also add particularly on that topic is I think picking topics also if -- you're right, we don't have all the money in the world. It’s limited to the ones in

which you can make a quick impact on making a difference in what the treatments are. Because some of these areas like for example, the treatment of anxiety disorders in children gets very complex and there might be a lot of investment in it but the payoff potentially for new -- for interventions that are going to make a significant difference in some children may not be as great -- and I'm just this up, if you pick some other area where there might be a more immediate opportunity. That might be another way to think about where that prioritize, you know?

I'm not sure what the answer is to that but we are going to have at least for the foreseeable future even if we we're authorized with limited funds, we won't have the level of money that NIH has.

On the phone -- I wanted to give people a chance on the phone, I'm not sure -- I knew Barbara was on. I don't know -- Allen are you back on? I think Harlan at one point had rejoined us, I'm not sure he's on.

BM: I don't have too much more to say Gray.

I guess I'm most impressed by the MS stuff, but go ahead someone else can talk.

CHAIRMAN NORQUIST: Barbara you can finish your thought there.

DR. McNEIL: The thing I worry about MS the most is that so much is happening all over the country with industrial activities and small pilot studies with new drugs, I just want to make sure we're on top of everything and then when we get our final results which we'll have much more patient friendly and patient specific data than almost any other trial to-date. That we not run behind on what the newest drugs are. I have no answer to this problem but I think it is one we have to keep our eye on.

DR. DOUMA: I really want to reinforce that particularly with MS, the definition for itself has been changed significantly over the last five years as MRIs [inaudible].

CHAIRMAN NORQUIST: I don't think we have an answer. I mean I didn't think you really thought we'd have to final answer here Bob or Alicia, but I

think it's something to keep an eye on and I think certainly the staff and the SOC can help us as we put some guidelines perhaps around how we start to approach these. And we get into this issue of do we stop funding and move to another topic, do you know what I mean?

[Simultaneous discussion.]

SPEAKER: Go ahead.

DR. McNEIL: Suppose we're halfway through or whatever the way through one of our studies with Drug A and we then learn through a very small Phase 3 randomized trial by Genzyme, but there's a new drug that is considerably better on most of the outcomes that are relevant, I think we should thinking about what we do at that point.

Because I think at that point we don't want to go fund to the end a dead study, on the other hand I just don't know what to do. I think it's a real big problem with MS. More so than with any other disease we're studying.

DR. SELBY: So I'm glad you raised that Barbara, I think this is this is drifting a little

bit from the questions on the screen here and the question we raised in the committees, but it is a fundamental question about what people thought PCORI was going to be and what PCORI is today in terms of its funding portfolios.

Because Barbara is talking about the area of new treatments, relatively new treatments and we are in 2017 in the midst of one of the biggest onslaughts of new treatments that we've seen in forever. And in every -- you know, there were a lot of people who thought that PCORI would be there when new treatments appeared to try to contribute to patient, clinician, system, and formulary decision-making and we've already established that, you know, it takes a lot longer to actually do CER than policymakers can wait and yet people who do cost-effectiveness analysis, they are -- and other types of decisions supports that without the evidence from CER studies, acknowledge that they're doing this on a bit of a guess, on some assumptions that could only be filled in by the types of research we do.

But as Barbara said, one of the things that

you really get frightened about when you're comparing new drugs is that they're going to be outdated so we just had a lengthy meeting with NIH and NHLBI on Friday, a fabulous meeting trying to identify the right study in the area of the second line treatments for Type 2 diabetes and I think one of the biggest fears of some of the people in attendance was that by the time this study gets finished, there could be yet newer agents that could be supplanting the things we just proved the superiority of.

DR. WHITLOCK: But I will say that one opportunity that moving into this area called predicative analytics gives us is the trials are done and the IRIS example I showed you was a good example. It was in the *New England Journal of Medicine* maybe a year-and-a-half ago and for the appropriate trials, you've got you've got trial evidence, you've got the average treatment effect. It's very difficult to know how to target the treatment particularly when there are about equivalent risks and benefits but they don't

necessarily accrue to the same individual.

So those are examples where to Gray's point, we can do something that will -- it may not answer the A versus B but in the same way what a answers is A or not A. Is this a good agent for this person? So it gives you that information and that's the actionable and that's relatively quick to produce compared to a lot of the other things we can do and it's also a resource that is under utilized in the field. We have a lot of average effects, we have very little of this kind of very sophisticated heterogeneity of treatment effect and I think it is a way that we can even in this time of reduced -- maybe reduced, you don't know, resources we want to continue to look for those kinds of opportunities as well.

CHAIRMAN NORQUIST: So Freda and then Bob, but I think the one thing to remember not all interventions are the new drugs. I mean, there are plenty of -- tons of other interventions and stuff that are not necessarily -- so Freda.

DR. LEWIS-HALL: Yeah. Actually I just

wanted to amplify your point because strictly medical terms, “everything ain't for everybody.”

And so, I think one of the challenges that we have collectively is sorting through all of the new devices and many other forms of therapeutics and how to decide what patient, on what therapy, at what time, and let's add on even more complicated and what combination of combinations is indicated.

So I think that there's no one that spends time in that sweet spot, if that becomes our unique capability to help sort through that then I think that that is an enormous contribution to patients in the public care forum.

CHAIRMAN NORQUIST: Thanks. Bob.

DR. ZWOLAK: So before we leave this it seems, at least what I'm hearing, is that people on the board wouldn't exclude SOC coming back with a potential recommendation to relook at opioids, palliative care, potentially carefully MS as long as we do the appropriate landscape and impact because right now I don't think for any of those we have existing or potential upcoming announcements.

Right? We've expended our allotted funding for those --

DR. WHITLOCK: That and some. And some. But I think it also becomes important and one of the reasons it comes up here is there's a very pragmatic thing. It's not even whether we ask for more targeted announcements, it's whether we signal to the field that they shouldn't come in under general announcement.

So I think there was a point in time that preceded me where folks said we've seen enough of this type of application because we had seen quite a bit, and so, one of the questions that were being asked by applicants to these particular announcements -- particularly those who scored pretty well but we're not funded, is can we come back in? So people need practical guidance as to what PCORI is looking for.

CHAIRMAN NORQUIST: I think that's an excellent point, that it’s also when we're ready to shut off in a certain area and move on to another area. That needs to be clear to the field, as well.

I think absolutely. Christine.

MS. GOERTZ: Just in addition to weather we have targeted announcements, every now and then an application is presented to the Selection Committee that has a good score but there's not a lot of excitement or interest about funding it because there's overlap of what's already in our portfolio.

So just taking it to that next level and trying to figure out how can we also communicate to the investigative community those things that -- where -- because there are sometimes when we already have several applications and we actually want another application or two in that area and there's some instances when that's not the case. To kind of figure out how -- you know when it is true and how to communicate that is I think really important also.

DR. WHITLOCK: I think that's great point because we are very standardly now when we bring you forward something in an area we're showing you what else we already have funded and how it does or doesn't fit or if it's duplicative. So that's a

really good point though, it's making that externally facing.

CHAIRMAN NORQUIST: So Bob, to answer your question, no. I don't think the board would be adverse to you coming back as long as it's in the context of whatever the stakeholders are telling us are the priorities.

Joe, to make you feel better when we started the comparative effectiveness trials of the antipsychotics over 20 years ago we were told the same thing -- when this is over it probably wouldn't be worth while because there'd be new -- but guess what, no, there's nothing yet. We're still -- the same results are very relevant today 20 years later, unfortunately.

CHAIRMAN NORQUIST: Okay so in the interest -- Harlan.

HK: Gray can I ask one question. Of course I'm always reluctant to sound like a broken record, but one of the themes of the discussion that have been had around CER has been within certain topic areas that are defined by condition. And I

know that I've said this a lot, but I just want to make sure that we are not doing it now and we're waiting for 2.0; which was defining it by the properties of the study. That is rapid-fire CER focused on things that people feel -- or function, all the symptoms, all the stuff I've been saying over and over again.

Are we just going to clean it off and say 2.0? Because to me again, I always thought that was a sweet spot. There were a 100 of those and we make a big advance and that's a little different than the idea of just focusing by condition. It's focusing on the sort of properties of the problem and ones that can be solved rather rapidly and providing evidence that is immediately actionable.

I'm perfectly content with putting it off, I just feel the need to bring it up one more time.

CHAIRMAN NORQUIST: Thanks Harlan.

So let's move to the EDIC questions here which Debra and Jean, which of these two do you want to focus on here at this particular point?

The first one? Maybe a little more

specific.

MS. SLUTSKY: Sure. So the first one really represents the tension between disseminating broadly our research findings versus really doing a deep targeted implementation and how should that balance be made. Some of that is because we don't know what research results are going to be coming in so, you know, it's a little bit of the unknown but it would be nice to get through a reading of the board on what do you think that ratio should be between you know broad dissemination and awareness of our findings for different audiences and then really doing a deep dive and implementation in communities and broad regional areas.

MS. SLUTSKY: Jean, this is Barbara.

CHAIRMAN NORQUIST: Barbara, we're going to let go and then Larry is going to be next. Go ahead Barbara.

DR. McNEIL: I didn't see his hand.

[Laughter.]

CHAIRMAN NORQUIST: You didn't see his card, go ahead.

DR. McNEIL: So [inaudible] is getting self-focused and just laser sharp, I guess I don't understand the concept of broad dissemination versus targeted dissemination for the better care of patients. I just don't understand why we would ever do the former instead of the latter.

MS. SLUTSKY: So when we refer to broad dissemination, it's really awareness of particular findings and the secondary deep dive takes place by other entities. Whereas a targeted implementation as we go hand-in-hand with communities and broader health systems, physician organizations, patient organizations to actually get the findings implemented and used which is the much more resource and multifactorial activity versus broad general awareness with a much more passive dissemination, which may be appropriate for a large amount of our findings which are not as you know --that are smaller studies as opposed to some of our more definitive findings.

DR. McNEIL: I'm sorry, [inaudible].

MS. SLUTSKY: I'm sorry?

DR. McNEIL: I just [inaudible] through your argument a little bit to make sure I understand exactly what you're saying.

MS. SLUTSKY: Sure. So --

DR. McNEIL: [Inaudible.] What would we do? [Inaudible] put that on the front page of the Globe, we'd go to the various neurologists [feedback] and professional societies. I guess I need to understand more what your differences are.

MS. SLUTSKY: So for example let's take -- let's say we find a have a finding that shows that one intervention is vastly superior to another and it actually is safer than another intervention. It was done on a pretty representative population, the methodology was really strong, and it is going in the direction of other previous studies so we believe these findings are pretty accurate.

I would say that that would be a study finding that would really be justified to do a deep -- to spend a lot of resources doing a very deep intervention in the communities that are affected by this condition. For in terms of broad dissemination

let's say we have a smaller study that shows equivalency, it's not necessarily as representative of a population, it adds to the body of literature but we don't feel that it's definitive and probably wouldn't be justified to do very deep expensive implementation strategy until we had more findings that would support it.

DR. SELBY: So Jean, I'm still in Barbara's question, too. Are you saying do we want to be selective in our choice of findings to disseminate and then really and really aim for big ones and invest either alone or with AHRQ in big efforts rather than do something in a larger number of areas that is -- in other words, is the choice really about concentrating on the most meaningful findings, the ones that could change practice the most in a few areas versus trying to do some level of dissemination for a larger number of findings?

MS. SLUTSKY: No, so I'm saying that we should do broad dissemination of all of our findings because that's our mandate, but what I'm saying is we don't have enough resources to do deep

dissemination for all of our findings. So that we should be we should be selective when we do that that very deep implementation strategy and what I'm just trying to get a feel for is -- does the board feel comfortable with that because we have a zero-sum game here in terms of the amount of money that we have available to do this right now.

CHAIRMAN NORQUIST: So Larry has had his card up for awhile. Larry.

MR. BECKER: So mandate, disseminate because we have to. I think there's an intermediate step between dissemination and targeted implementation going deep.

So I'm an N of one, I come from a community that's an N of one and I sat on the planning team for 16 years. And my belief as N of one is that every community is different and every community that's where change happens is at the community level.

So I think that the step in between is to develop a robust toolkit that helps communities actually take the information and build all the

things that they need in order to get the right people at the table, have the right kind of conversations with the right data, having the right level of communications materials as they begin to fan it out across patients and clinicians and public -- you know, social workers and, and, and -- we build that construct because every community is going to have to do things like practice guidelines, educating physicians, changing health insurance designs, employers are going to have to get involved. A whole series of things and I think to help communities to sort of coalesce around these changes, I think we could do a world of good to give people that toolkit.

MS. GOERTZ: Jean, I think that's -- I think in order for me to answer that question about the balance of dissemination versus targeted implementation I would have to have a little bit better understanding of how you're defining each of those -- you know, what is -- what's in each of those buckets, which activities are in each of those.

I'm not opposed. I think that's a good idea. I think that there are not infinite resources and we've funded a lot of studies and I don't think we could do a deep targeted implementation on each of them and it's probably not warranted, but understanding what types of activities we would engage in but also the criteria for deciding which of those buckets a particular study would go in.

I think for me I need to answer to those two questions before I can give very much more feedback.

MS. SLUTSKY: I understand. Yep.

CHAIRMAN NORQUIST: Sharon, did you want to answer the question or was that you were --

DR. LEVINE: I just want to make it more complicated.

CHAIRMAN NORQUIST: Oh.

[Laughter.]

CHAIRMAN NORQUIST: Oh, what the heck. Before we make it more complicated, did you want to answer it because Freda looks like she wanted to --

MS. SLUTSKY: So we are working on the

criteria and it's not as easy as one would think. And having done this for a good part of my professional career, but when you know what Larry described is that intermediary activity. That's a very -- it's fundamental to broad targeted implementation. It is very resource intensive because you need to target the materials for the different components in the community. So the purchasers hear things differently than patients and clinicians, and so at some point we're going to reach a friction point between, you know, how we invest our dissemination implementation funds.

This is really the beginning of the discussion and we sort of started this at the EDIC. but it's not that dissimilar to the discussion that we just had with the SOC. Should we go deep or broad in terms of the scientific investments that we make.

CHAIRMAN NORQUIST: So Freda and then we'll let Sharon make it even more complex. Freda.

DR. LEWIS-HALL: Mine is just reiterating, I really think it's framework since we are talking

about balancing and I can't really answer the question either because I'm fairly confident that for all of the studies and their implications that highly disseminate is going to be completely different.

A finger stick finding that has outcomes and implications and is really around you know tens of millions of people is going to have one implementation over findings in pediatric palliative care, which may have a very different way in which you would be a change agent.

So there are a few change -- communication change models that essentially backup from the desired outcome and you prioritize that and then you just back into who you need to tell about. It is "Kardashian girl style," like everybody needs to know what we have for breakfast or is it, you know, kind of specialty care guideline where only a few people with specific expertise need to know.

So I don't know if we are thinking about deploying those but I think that would help us get to the answer but would also help us conserve

resources because everything will be fit for purpose.

MS. SLUTSKY: Yeah, and so first of all I wasn't really expecting people to say now what they thought that balance was, but to begin the discussion that we're going to face that issue because we're at the tip of getting our results and so we don't want to spend our -- to use sort of crass language, we don’t want to spend our wad now when we don't know essentially what’s going to come out three years from now.

And so we do have to set some framework for criteria as you as you say.

CHAIRMAN NORQUIST: So Sharon.

DR. LEVINE: Yeah I mean, I'm just think we've had -- Joe and I, I had talked to Joe about this a little earlier. I think we've had a very sobering example of the failure of broad dissemination with a lot of stakeholder -- in early stakeholder engagement, at least on the part of the specialty societies with five years of work in Choosing Wisely. And two papers in *Health Affairs*

in the November issue showing barely measurable change in the performance of procedures that the professional societies and in theory their members agreed were largely to be avoided.

And so, understanding the failure of that. There's a lot of excitement including my excitement when this thing launched thinking, you know, finally professional societies are stepping up, their taking accountability, they're looking beyond financial interest in a fee-for-service world and five years later there's not a lot to show for it. I think there's an opportunity to understand the failure of that and to be certain that we think differently about what it's going to take.

MS. SLUTSKY: I agree. It's ironic that those came out just right before this board meeting and I think in particular Eve Kerr's commentary was very enlightening almost more so than the original research article, but I think there are lots of things to learn from that and certainly things that we can employ over things to avoid doing.

DR. McNEIL: So Jean, this is Barbara can I

ask one question?

CHAIRMAN NORQUIST: Sure, go ahead Barbara.

DR. McNEIL: Maybe it's just my style but I find conversations like this extraordinarily difficult because I actually am not sure there's any such thing as principles that we can place right now. I would find it much better for my particular style if we said, okay, in a couple years let's look at the three studies that we think are going to have -- that represent different kinds of studies and the impact that they -- the results they might show and let's think about how we might want to disseminate those results.

Rather than making big diagrams and charts and sublevels, I just think that's going to waste a lot of our resources and when we get down to some really key result it's going to become very ad hoc.

For example, suppose one of our MS -- I'm somewhat preoccupied with MS, suppose one of our MS studies had a blockbuster result.

That's going to go through the world like wildfire. I don't care what principles we have to

talk about it, it's just going to happen.

So, I think it would be nice to have some -- look through our portfolio find -- and the insulin one, the finger stick on is another good one. And figure out what it would take to make the most of our results and just being really pragmatic. That's just my thought.

MS. SLUTSKY: Thank you.

CHAIRMAN NORQUIST: So other comments about this? I mean I think that to me it's always the issue of ultimately how you change behavior because I think that's the problem. If you just tell people to do something they're not necessarily going to do it, unless they're -- I think we heard it even earlier from the Congressman about his concern about what the data meant and what it meant for them to do something differently.

And I think it's the way you help people change that and I guess that's the question and I think the other thing we haven't talked about -- we talked about it with the SOC who do you partner with to this? We don't have to do the whole thing,

right, to do these implementation -- you have AHRQ and a variety of other groups who would hopefully like to partner with us to see if there's some way to actually make a difference in what people do once you know what you're supposed to do.

MS. SLUTSKY: So just on that point, we actually have set up partnerships not just with AHRQ, but with the purchaser community, several patient organizations, but again you know, depending on how broad we want to go.

And I take Barbara's point that you can't totally see into the future but we have to plan for having to make those choices as we go ahead.

CHAIRMAN NORQUIST: And I would also -- I know you're doing those, but to encourage you to work with guild organizations, the others, providers, the clinicians and stuff to also engage on this.

Other comments? Debra, did you want say anything else?

DR. DOUMA: This is Allen, I'd like to ask question.

CHAIRMAN NORQUIST: Go ahead Allen.

DR. DOUMA: When we're trying to make decisions about whether we do a blowout or targeted dissemination or just between two targeted disseminations, in the back of our mind I think we're all thinking that the outcome of that dissemination is the key to making a decision.

There are two different components to that to measure one how well is dissemination going to influence practice? And the other one being what is going to be the outcome of the health of people [inaudible]?

Do we have any thoughts about how we are going to compare different outcomes less negative or more positive outcomes between one and another?

How do we compare [inaudible] versus disability et cetera?

MS. SLUTSKY: Were you saying how you compare death versus disability?

DR. DOUMA: Those are the two potential outcomes from distributing any study, targeted or otherwise. And if we are going to compare the

outcomes of A versus B and what [inaudible] of what we do, how do we compare the different outcomes of whether it's death or disability or paying, et cetera?

MS. SLUTSKY: Yeah. So that's an interesting question. I mean, I think one of the studies we're partnering with AHRQ on dissemination and implementation of is the PROSPER study which is the anticoagulants use in patients who have atrial fibrillation and Joe knows the study better than I, but the initial study question was whether or not anticoagulants prevented more strokes than without anticoagulation and the patients who were partnering with the study were more concerned about days in institutions versus staying at home.

And so, the study was -- the protocol was changed to look at that outcome and the outcome showed that patients who were anticoagulated spent less time in institutions than patients who had no anticoagulation.

So I mean I think it's in the eye of the beholder, I mean in some patients may find that a

pain-free existence is more important than early mortality and some patients may find, you know, late my mortality is more important and would be willing to accept a level disability and I don't think we'll know that unless we engage them.

DR. SELBY: I was just going to add that I think Allen, those are the kinds of results we actually expect to get quite a few of, you know, between finding treatment heterogeneity and just finding places where outcomes don't necessarily go in the same direction. The dissemination tool or one of the main ones then become shared decision-making, so I'm just much more than I thought in the early days before we had any results, I'm just seeing that an awful lot of our results are going to head towards the shared decision-making factory -- if you will -- get incorporated along with other evidence into improved tools and then we're going to have to figure out how they get used and by whom and how they take their place in healthcare.

But if you really want to better inform patients and if patients have different preferences

and if drugs -- and if treatments do go in opposite directions sometimes then, it's not just a simple guideline change that's going to -- I mean I think the model of -- you change the guideline and then practice changes and then the outcomes are improved is going to be the exception rather than the rule.

DR. DOUMA: The only trouble with that thinking and I agree with it, particularly the importance the variation and the use of outcomes through the shared decision-making. But if we say that everything depends on shared decision-making after the fact, that means we can't use any of that information in order to make decisions before.

And that's frustrating because we are losing the ability to have data to make decisions.

DR. WHITLOCK: I think this might be relevant -- as I said in my SOC slides that ending the science process is a matter of qualifying and contextualizing the evidence as a final step in the process -- peer-review is part of that.

But we also have a process that we developed in conjunction with Michelle called our

exemplary process where we have a set of criteria and I thought of it because somebody else asked for criteria about what would maybe go for targeted implementation and so we have a set of criteria that we go through to look at the findings and to consider how important the -- and again, these are judgments but they have criteria based on how important we think the findings are and how impactful we think they might be.

And it might be that those kinds of criteria could be more broadly used or at least be looked at as a set of criteria that could be applied more consistently across the organization.

Now I know you can't see the criteria, so that's a thought exercise but I just wanted to bring that up as a potential way for us to think about maybe being more consistent and explicit across the process.

SPEAKER: Those criteria we have shared them with the EDIC and before weekly did the exemplar process so -- and we have looked at these criteria but often one doesn't anticipate that a

particular study even though we've pulled it out as an exemplar -- some studies have had more impact than we ever would have thought they have, so it's that's why science is so exciting, it's because something that you think might be a dud turns out to be a beautiful rose in the sense that it has much more impact than one would have thought.

So anyway, sorry for the confusing question but it will come back to you again, I'm sure.

DR. SELBY: Just when I thought. Evelyn I thought you were maybe going to go all the way to prediction modeling in your comment that --it's strikes me sometimes for some of the duds or even for some of the beautiful roses there's still more that we can do, maybe with a little extra investment, to push that data further to try to inform shared decision-making at an even deeper level in terms of what might be the better choice for one individual compared to another based on their clinical characteristics and then -- and then they apply their --

DR. WHITLOCK: If I answer every question

with that then it'll seem like I only have one answer.

DR. SELBY: I'm sorry to undercut you there.

CHAIRMAN NORQUIST: All right, so we'll come back -- thanks, so Freda of the two you have here -- or Joe since you were presenting on this. Is there one in particular that you want to --

DR. LEWIS-HALL: I think the second one is much broader and they require kind of more time, so doubling down on this first one to help us prioritize [inaudible] -- Joe.

So the first one, I think would be most helpful.

And just as a background for this, we got a lot done in each of the spaces but from my perspective we ended up spending a lot of time on PCORnet, it was the gorilla in the room every single time. So that having been said, the question is do -- you know, do we keep our shoulder on that? Do we lighten up a little bit and reprioritize some of the others?

You know, just interested in your thoughts especially looking out at what might be more important.

CHAIRMAN NORQUIST: And I think in fairness as Joe said also, the methodology standards -- you got a whole committee who is kind of working on now and so I think that is in our mandate to do, so that's kind of a given so we're really talking about four. Yeah.

Larry has a comment and Sharon.

MR. BECKER: So I actually have a question.

If this was a horse race and those five things were in the horse race, which ones are deficient and we need to push them further to make something out of them, and which ones are really close to this to finish line that if we just pulled a little harder on them we could get them to the next big thing?

Because I don't have the sense of, you know, lining these five things up and say where can we do the most good?

CHAIRMAN NORQUIST: And I'll just had

another pieces --

DR. McNEIL: This is Barbara --

CHAIRMAN NORQUIST: Wait just one second Barbara. The only thing I was going to say is [inaudible] I mean what is it that we add value to on?

Okay Barbara, your turn.

Barbara?

[No response.]

CHAIRMAN NORQUIST: Was she signing off? Okay, well we've lost her.

DR. SELBY: She must have been signing off.

CHAIRMAN NORQUIST: She must have been signing off. Alicia.

DR. FERNANDEZ: Thank you. I think the RTC has done phenomenal work and I really just admire the range of things that you all have covered and the creativity that has come out of that committee.

I think when I look at this, I think what I would encourage you to do is to continue to take care of the elephant and I'm sorry about that but it's because of the size and importance of our

investment and the need for that to succeed in order for us to feel okay. The other thing I would ask you to do is to add an initiative which would be to think through even more, how to make -- how to conduct quicker science based on the instruments on hand including PCORnet, but not limited to PCORnet.

And I think your committee has the talent and the creativity to be able to think that through broadly.

So those are my two things. Sorry not to get rid of the elephant, but I really think we have a wonderful pet and we need to watch it grow.

CHAIRMAN NORQUIST: So you're additional initiative is speedier science; is that what you're saying?

DR. FERNANDEZ: What I admire is this ability to think for the science done a little bit differently and there are two areas there.

One is if PCORI went away, would anyone do patient-centered science in the way that we have asked them to do? Or not really, because it was because you know they had to do it to get the money.

And I think that anything that we can do to really examine in a more evidence-based way to see how that actually worked out -- you know, in a real way because I hear good and bad and different.

So harnessing some knowledge from that bold experiment I think would be one thing.

But the second thing is this notion of how does one do quicker science while retaining all of the best elements of U.S. science including merit review, appropriate fiduciary oversight, so on, and so forth. Is there some different way that this can be done? Maybe there is, maybe there isn't but I think I would put that on their agenda. I cannot let them let go of PCORnet.

CHAIRMAN NORQUIST: Yeah and I guess I would say just a little bit -- that I would add just as a friendly amendment toward Alicia is it speedier science or is it getting to results quicker? As if I'm in the sciences, whatever it is but how -- is there a way to get to results on a specific question quicker than we spend now because I can tell you that's -- this is what we hear all the time when we

go to the stakeholders.

Why does it take you so long -- you know what I mean? This answer that some -- exactly but can you get a valid answer or one that's accurate enough to help us made a decision about what to do quicker, if not -- if not okay, if not maybe there's some areas you can't -- Russell? Larry?

DR. LEWIS-HALL: We never answered his question.

CHAIRMAN NORQUIST: Want to answer his question?

DR. LEWIS-HALL: Well, I'll answer it from my perspective and then maybe other members of the committee can weigh in. I agree with Alicia, I think PCORnet is one of those things that is -- you know is on a trajectory. It would be -- I think a shame to allow ourselves to lose steam on it now.

And I think the funding partnerships serve a number of purposes, it's not just the collaboration around the money. It really encourages the other point that Alicia made, which is if we want people to keep doing this in

perpetuity, in a different way partnerships is one way to do it. Because it's not just well, you've got to do it because we're paying you to do or we're giving you money to do it, but we've agreed on it and we're sponsoring it together.

So I think that those two are on the trajectory. If you asked me which one I wish we had more steam for, it would be workforce training.

I think we have an opportunity to do a little bit more in that space and I think we're going down there at the right road with some of the partnerships that we've created and some -- kind of the wind at our backs if you would, that are being shared with other groups. But if I had a sense of urgency of any one thing that I feel I'm nervous will get left behind is that workforce training, because I look at myself in the mirror I go "okay I don't have long in this game," so who's going to be behind us to get the work done? And I'm not sure it's a big enough crowd right now.

I don't know Joe if you want to jump in or Allen?

CHAIRMAN NORQUIST: Russell has a -- so Russell you're next.

DR. HOWERTON: Well, I think you mostly said my -- I would think of these things in terms of what would be durable even if we were not. And leaving methodology aside, I think you've called that out.

I would like the funding partnerships, in my view, as the least likely to be durable long-term if we were not because those partnerships will wear out but the concept of open science and if it could be durable would be a long-term change as would PCORnet if it were durable without us. It would be profound long-term changes and I would go to workforce training as the next longest thing.

CHAIRMAN NORQUIST: Joe.

DR. SELBY: Well, I wanted to thank Alicia for the new assignment. I didn't actually expect to get any of those, but by golly I think that's why I want to ask you a further question of it but first I just have to say because I've been wanting to say it for about five minutes.

So wait Freda and I can continue to say that the elephant ate the agenda, right? You keep saying that, in RTC.

CHAIRMAN NORQUIST: I'm not sure --

DR. SELBY: Every time we have an agenda, we have three or four things down and then PCORnet eats it up. Like the dog ate the homework.

CHAIRMAN NORQUIST: The only thing I'd sat about that is don't forget about the other animals in the room while you're working on it. You know, I think it's sometimes --

DR. SELBY: Alicia would this include in your mind the question that comes up from time to time in terms of speedier researches, should we have other mechanisms for funding research? Should we have you know, sort of more, partially intramural approach plus some, you know, some contractors that can move quickly on the topic of our choosing?

DR. FERNANDEZ: I think we should consider any and all mechanisms and I certainly think that we should consider new mechanisms, whether they should include an intramural research program -- I don't

know, and I think that there are considerations there in terms of focus and resources and so on.

I think the key question is how to keep -- is how to keep the best elements of peer-review and yet have it work more quickly.

There are for example, both positive and negative aspects to the rapid review work that we have been doing for PCORnet and we've talked about that, but I don't think the entire board has had a chance to hear about those and we should probably come back to you and tell you what we think is going well, what we think is going less well with those.

But I do think that the RTC is the right forum in which to start thinking about this in a creative way and whether that is contract science as Harlan has urged us to do. Whether that's an intramural program, whether that is a smaller, shorter of peer-review with shorter grant times for observational questions, more similar to an R21 mechanism at NIH than an R01 mechanism. I don't know.

But I think that we should put them all on

the table and see what they come up with and they're the right group to do it.

CHAIRMAN NORQUIST: Christine.

MS. GOERTZ: I'm just wondering and maybe we don't have the bandwidth to actually do this, but given that PCORnet is the -- you know, the elephant that eats the agenda and that these are -- you know, other topics that are really, really important. I'm just wondering as we think about -- do our strategic planning for the next five years if it makes sense to put PCORnet in its own box or its own committee and then free up the energy to be able to address some of these other issues that -- I think they're really important.

I am not sure we can just take methodology standards, dissemination put it in a parking lot because we've got -- I think that it does require concerted attention as we move forward not only at the Methodology Committee level, but at the board level.

I think that workforce training is critically important if we're talking about the kind

of legacy that we can leave is training people to do this kind of science and getting them established as possible in their careers so that they have some opportunity to continue to succeed regardless of the what happens with PCORI is it could make a huge difference. So just something -- a dead cat to throw on the table for our discussion.

CHAIRMAN NORQUIST: Sharon is your card up? Leah? Sharon.

DR. LEVINE: So we looked at the issue of intramural research early, very early in PCORI's life and made the decision at that time that our resources were better spent supporting others in researching, using the money to not to try and replicate research infrastructure but to using contracts and grants to actually try and to get the work done.

Keeping PCORI a lean and mean organization. It seems funny to me at this point, to put that back on the table and maybe I'm missing something, given it seems to a substantial diversion of resources from this -- at moment in time to build that

infrastructure to do that work and maybe I'm missing something but --

DR. WHITLOCK: Joe signaled to me to speak because the SOC is cued up to talk about this tomorrow, but I think the idea is perhaps there are several things that intramural and maybe it's too grandiose in some ways to call it intramural research.

I think what it's talking about is potentially allowing us to think about what are some of the analytic projects that we might do that would be led by our current science staff in ways to gather the lessons of what has been learned from the PCORI experience. And there's a whole host of lessons to learn.

There’s lessons about engagement that I think Jean’s department is looking at, but there’s many other lessons about the methodology standards, about you know what you might do when you bring groups of investigators together -- you know, a variety of things about the portfolio that we funded.

So I think it's really an idea of it goes hand-in-hand to some extent with the concept of we have a very large investment, there may be some additional synergistic things that are relatively modest in the scheme of things but that allow us to gain even more from all of the activities and all the investments that PCORI's done and also enhance the scientific life of some of our staff who are overseeing these portfolios to completion. So almost as the transition activity.

So those are some of the things we're going to be talking about.

DR. LEVINE: So it's not launching new research projects in MS?

DR. WHITLOCK: No, it's not. And so, I think intramural research is maybe a little bit misleading when you think about maybe perhaps how it might be done through NIH.

DR. SELBY: I second that. I really meant more giving our researchers a chance to roll up their sleeves now that they've acquired, you know we've been at it for seven years now and a number of

our researches have acquired a fair amount of insight into areas that we've invested in. If we're going to put more money into these years and try to thread the needle to hit certain gaps, having them more involved in the projects whether they're done through -- you know, with competitive mechanisms or whether they're done through CROs and more explicit RFPs.

DR. WHITLOCK: Supplemental awards.

DR. SELBY: Supplemental awards or small analyses that could be done here or one other consultant.

CHAIRMAN NORQUIST: So Leah and then Bob.

MS. HOLE-MARHSALL: Russ said most of what I wanted to say, so I put my tent card down but I thought I would just underline it too. I mean, I think PCORnet is here to stay -- as others say, as others have indicated but I guess what -- the only thing I would add is that I think it can be used as the leverage point to talk about these other very important initiatives and they are all very important. So I'm not sure if prioritizing is the

right word rather than just right-sizing what we can do in each of these spaces and whether there's a struggle about that.

Maybe that's something that we can help with but really in terms of not getting something done here, they're all pretty crucial.

And then I would just add, I think my cautionary thing came up to when Alicia said I'm going to add another one. I feel like if we're already here and you guys are already saying your plates are full, adding another one is difficult and maybe what we could think about is how to leverage the things that we're already doing with that in mind.

So PCORnet -- its original purpose was to make it both more open for more people to use, right? Open science and faster so you know really thinking about those options and then where there are areas to leverage that for instance or leverage current investments, I would agree that quicker is also important but not maybe make it a primary area of new focus about how can we do the work we're

already doing completely different.

CHAIRMAN NORQUIST: Bob.

DR. ZWOLAK: So Leah brought up my concern right when I when I heard Alicia and a new charge; my mind went directly back to be PCORnet and the concept that PCORnet was supposed to be our vehicle for research to be better, faster, cheaper and maybe I'm just not exposed to all the details of PCORnet but my soft impression is that I'm not sure we've gotten there yet wit better, faster, cheaper in PCORnet.

So perhaps my version of the Alicia comment would be to not to look at other mechanisms of better, faster, cheaper but the poor some accelerant on the PCORnet fuel to see if we can push them to make PCORnet push the foundation to make PCORnet better, faster, cheaper.

CHAIRMAN NORQUIST: Kerry?

MR. BARNETT: Well, I just want to second Leah's comments.

Well, I'm not comfortable with the notion that it's necessarily a zero-sum game among these --

I think what some of these may need is a lot of staff time. I think what some of these may need is not that much staff time, but the creation of external partnerships, and I think in some cases what's really needed is writing a check.

And it's really more of a matter of finding the synergies among them, looking for areas of leverage and if there's a feeling that that we don't have enough overall resources allocated in this area and we believe that these are essential programmatic elements for us, and I think we to begin by looking elsewhere in the organization for a possible resource. But I don't think we should start with this notion that we have to trade one off against the other, we may wind up there but I don't think that's necessarily where we want.

DR. LEWIS-HALL: Yeah. I think prioritization didn't mean we're going to do two of them and we're not going to do the rest.

Your word Leah was great, which is kind of right-sizing the amount of time, you know, money and effort that went into each one and I think several

of you said the word leverage. I think where we are in the evolution of PCORnet, we're at the point now I think where we can really begin to leverage it.

We were testing it, piloting it, getting it set up and doing all those things. It was pretty hard to leverage the weight of it but I think that we're now corner turning on you know the pilots delivering the various participants being better able to take on a little bit more.

So leverage and right-sizing I think along with the other charges that I have down as ways to put them in.

CHAIRMAN NORQUIST: So let me just check on the phone.

DR. DOUMA: Gray.

CHAIRMAN NORQUIST: Yeah, Allen.

DR. DOUMA: Yeah, I'm in agreement with how important PCORnet is, and earlier in the presentation Joe talked about we didn’t [inaudible] micromanage

Well, micromanaging is in the eye of the beholder and one of the things I think we need to do

pretty soon is to become more efficient in our monitoring by becoming more specific about what we're actually going to monitor. And get rid of the concept that we're micromanaging because we already decided it's on the table, it's not micromanaging and if it's micromanaging it's off the table.

Otherwise, we could go round and round in circles for a long time.

SPEAKER: All I wanted to say was, building on Leah's comment and also on Freda's that in some ways am I an observation and some ways these strategic committees are now sharing imperatives.

And when we are putting together the presentations there were many times where we're now doing shared initiatives and I and I think about doing research, you know better, faster, cheaper, and I think across the whole organization we're trying to do everything better, faster, cheaper; but some of the work that we're doing in research synthesis isn't intended to get a result out there more quickly. And so, you can't really segregate these things anymore -- it's not just the RTC, it's

that the RTC will continue to carry that banner but the other strategic committees are also listening and picking that up as well.

And so, I think that there should be -- that's encouraging that the priorities of all of the committees are being shared and I'll give another example where you know, PCORnet while it's under the RTC, some of the core outcomes -- that work that's being done, is trying to leverage PCORnet.

So I just wanted to just to make that observation. There's a lot more shared at this point in time which is a good thing.

CHAIRMAN NORQUIST: Yeah I think that's a very good point, that it's not one committee -- especially if you think of the opportunity for PCORnet to look at some implementation opportunities across these large networks and stuff. That may be a seat where we learn a lot about how to actually implement some of this --

DR. SELBY: I agree. We had a real eye-opener and it never crossed my mind that that I Evelyn would have slides in there about co-funding

with other partners, but she actually not only had a legitimate topics -- the SOC played a big role, but she had topics that the RTC had never even touched. So I really second that.

Going back to Alicia's initial comment about the RTC, it almost strikes me that and we're going to talk about this tomorrow as we debrief from this presentation today in our committee. We could perhaps think about with an eye toward influencing others to research, we can see ourselves as a bit of an incubator.

Where we may generate some ideas that we would take almost immediately to the SOC, the EDIC or others.

CHAIRMAN NORQUIST: Okay. I think we've done these and I think it gets something for each -- all three of the committees are meeting tomorrow so there's an opportunity and we do hope that there is continued interface across all of them. All of them are very important in what they're doing.

So at this point no one is present or waiting on the line, so we'll not be initiating our

public comment period, but we always welcome feedback at info@PCORI.org or through our website.

Joe do you want to say anything for closing remarks?

DR. SELBY: No. I think it was a productive day and had a forward look to it that we'll continue to foster in board meetings in the upcoming months.

Nothing else -- expect one thing. Maybe we can handle this after we go off --

CHAIRMAN NORQUIST: Well, I thought you were going to say and as always we want to thank the staff for the incredible work that you all do every day, right?

Except maybe the weekend unless Joe's got you working on the weekend, too. I know some of you are, but I also want to thank the board members too who are here and we look forward to also and for those of you who are not here, but many of us will be here for our annual meeting which starts tomorrow evening.

So let me close by thanking others who

joined us on the webinar teleconference, a reminder that the materials presented will be soon be available on our website and today's webinar was recorded and will also be archived within the next week.

We always welcome your feedback at info@PCORI.org or through our website and thanks again for joining us and have a good evening.

[Whereupon, at 4:52 p.m., the meeting was adjourned.]