PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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AGENDA

AGENDA [Continued]

P R O C E E D I N G S

[8:35 a.m.]

CHAIRMAN NORQUIST: I want to welcome everybody to our Board meeting here in Atlanta and thanks for everybody for attending. For those of you who are listening to us on the phone, you can access our materials at our website, which is www.pcori.org. Any of the things that we talk about or are shown here, you can watch along with us on that website.

The webcast is also being recorded and, if you want to take a break during that and see it later, it will be archived also on our website, but will not show up for several days after.

Today's meeting, like all of our in-person Board meetings includes a public comment period and today it will be between 3:00 to 3:30 p.m. Eastern Standard Time. You can find out how to register, provide public comments, on our events website. Of course, we always welcome feedback by e-mail at info@pcori.org.

We're live Tweeting today's activities on

Twitter for those of you who use that, so join the conversation at #PCORI. So those are the formal kind of introductory remarks. I want to welcome everyone. I also want to thank -- we don't do this often, but I think we need to thank Mark, Michael, and Kim for the fantastic work they do to put this meeting together. And I think we need to remember that. That a lot of making this run smoothly is due to Mark and his team, so I want to thank Mark and them for doing this.

[Applause.]

CHAIRMAN NORQUIST: He's the unsung hero and his team of getting us working. Anyway, the other thing I'm -- this is obviously my first meeting to chair, so I'll get used to this in a little while, but several people have asked me what is your vision as the chair and all that?

My vision is to do what the Board wants to do. One of the things of a chair is that, in some ways, you don't get to have your vision. You get to have the vision of the group, which is what I want to have. However, I would say that I do hope

-- I'm one of these, I think, on the Board who believes in doing something big and having a real splash. So I hope that we can kind of come to that. That we don't do small, little things. I think those are important, but I hope we do some big things and things that we'll be proud of and that will have people saying, yeah, we want to buy some of that because I think that's really key.

And the other thing that I would say, and I've said this in public, is that we have to get past the point of this deadline of 2019 and operate in some ways like it -- we know in reality there is some kind of deadline, potentially, but we have to operate in some kind of way that we're going to go on past that. So, if nothing, but in spirit alone.

So, with that, Joe, I'll let you get started. I guess I have to ask for the formal approval of the minutes from the last meetings, so first let me ask if there's any comments or corrections on the minutes for the last Board meeting? That's the face-to-face meeting, of course.

[No response.]

CHAIRMAN NORQUIST: I'm sure you've all read them in detail. All right, I don't hear any comments, would someone like to move to approve?

UNIDENTIFIED: Move approval.

CHAIRMAN NORQUIST: And second?

UNIDENTIFIED: Second.

CHAIRMAN NORQUIST: Okay. Anyone opposed?

[No response.]

CHAIRMAN NORQUIST: Anyone abstaining?

[No response.]

CHAIRMAN NORQUIST: Okay, and they're approved. Joe?

DR. SELBY: Thank you, Gray. Thank you for the last two months. The pleasure of working with you and with Steve over the last couple of months, you've really made it a seamless transition, even though you are putting your own stamp on it and it has a slightly different feel, like and 8:30 start. Thank you for that.

CHAIRMAN NORQUIST: Yeah, let me just say -- and I would have gone -- this is in deference

to the people who live on the West Coast -- and some people who are actually listening don't like to get up at 5:00 in the morning to listen and as one of those who does not like to get up at 5:00 -- so at some point we may move it a little later, too, but not too late. Thanks.

DR. SELBY: Okay, so I want to just, in these opening comments, touch on three important items. The first one, I think, falls smack in the middle of the do big things that you do mention. And this is the National Clinical Research Network update where even though a lot is happening in this area, we're not going to have a dedicated section of the agenda today on this topic, but I want to give you some information there.

I want to update you on the very important changes that are going on -- continue to go on -- in our PCORI merit review process and contracting processes. And then I'll just preview today's agenda.

So, I think most of you know that we received a large number of applications for both

the Clinical Data Research Networks and the Patient Power Research Networks. The reviews -- 28 applications were reviewed for the Clinical Research Network and 61 applications were reviewed for Patient Power Research Networks last week. About half of the Patient Power Network applications represented organizations and patients with rare diseases.

We had applications on the CDRN side from a very wide range of sources, which was exactly what we wanted. So we received applications from integrated healthcare delivery systems, from military health plans, hospitals and providers from academic medical centers allied, typically, with hospitals and physician practices. Sometimes within entire cities. Community clinic networks came in. There were networks dedicated solely to pediatrics, linking pediatric hospitals and networks based on health information exchanges.

We have excellent geographic representation among the applicants. Underserved populations are well covered in many of the

applications and the size of them was already a million on the small side -- up to 12 million patients. So you can see that with eight awards, which is what we anticipate, we'll have many millions of patients covered on day one.

This is the timeline from here on out. As I said, the applications have been reviewed and scored. The staff and the Board, through the Program Development Committee will now review those priority scores and applications to select final slates taking into account a number of considerations, including balance of the type of applicants on both the CDRN and PPRN side.

On December 17th, in an open Board phone call meeting -- teleconference -- we will present the recommended slates and the characteristics of the proposed awardees to the Board for approval and we're already making detailed plans with our coordinating center for the steering committee kick off meeting, which is a three day meeting in January.

This is what we will count as success 18

months later, that we have a network able to conduct high-quality observational comparative effectiveness research that external data partners, that is, other networks that would like to join with us, are able to by virtue of the way we've designed this network, it is feasible for additional sites to join the network and expand it further across the country.

CHAIRMAN NORQUIST: I just wanted to say, those little dots don't represent where the awards are, that's was just a visual thing.

DR. SELBY: Absolutely. Totally visual.

CHAIRMAN NORQUIST: Just to be clear about that.

DR. SELBY: Yes. Just a pretty picture. That researchers that are not based at one of these network sites are nevertheless able to work with and collaborate with the network -- researchers with good ideas. And that this network will be prepared to conduct large pragmatic interventional trials. In fact, and this is a recent decision, we're pretty much convinced that it will be a good

exercise for the whole network to put up one pragmatic trial during this 18 month period. So, during 2014, we will work particularly with those network members who are more advanced and don't have to do some of the very basic work of constructing a database. Put them to work laying out and organizing and implementing the first interventional trial.

The challenge here is going to be to keep all the CDRNs and PPRNs engaged, despite their significant diversity in a number of characteristics: size, prior experience, data, data readiness, and the length of their existence, but that's one of the reasons we actually think that having some of the more advanced members go ahead and tackle the complexities of putting a trial together across sites is a good activity for 2014.

MS. HUNT: So, can I --

DR. SELBY: Yes?

MS. HUNT: Gail Hunt, member of the Board. Could you talk just really briefly about interoperability among these different -- the

CDRNs, in particular, that we're going to be funding?

DR. SELBY: Yes. Well, interoperability means to me, and I'm no informatician, but it means that you are prepared and able to share meaningful data. Data that not only fits with another site's data, by virtue of having the same variable names, but in addition, that the variables mean the same thing and that you have compared the quality of the data so that when you mix data from the two, you are not mixing apples and oranges.

So we had a meeting earlier in November, held at the IOM for a day and a half with a very large proportion, I'd say, of the informatics community in attendance to talk about this exact topic. And we see a way forward. It is complex, but I will say that we have the informatics community behind us. There's a lot of excitement. I can't tell you how much excitement there is about this entire process, and I'm very proud that we took it up and I'm proud that we were encouraged to double the size of it from what I originally

thought we were going to invest.

So, it's right sized and it has a lot of support. And interoperability is one of the key tasks of the first 14-month period.

DR. DOUMA: Joe?

DR. SELBY: Yes.

DR. DOUMA: A quick question. I think it would be helpful for some of the people who are watching in and it would be helpful for me, I must admit. Would you define pragmatic interventional trial?

DR. SELBY: You know, I don't think I will, Allen.

[Laughter.]

DR. SELBY: Any time you try to define it, somebody in the room will say, that's not right. So it's not one of those perfectly well defined -- but I think pragmatic -- and no, I'm not defining it -- but the word pragmatic connotes that the results are practical. It's just exactly what we always say PCORI will fund, research that is useful for patients. So the comparisons would be useful

comparisons and they'd be conducted in real world settings, real world populations, real world delivery features.

DR. ZWOLAK: Joe?

DR. SELBY: Yes, Bob?

DR. ZWOLAK: Bob Zwolak, Board member. I'm only a neophyte in this, but having tried to blend a couple of big databases, that the devil really is in the details of these definitions. I mean, even the definition of something like a heart attack, a myocardial infarction, you can spin your wheels for months about things like that.

So it’s hugely important that all be settled out effectively.

DR. SELBY: You're absolutely right. Fortunately, people have worked on this before and there is a certain amount known, but you couldn't have said it better. The devil is in the details and that's why these awards are really quite sizable, as you know -- $7 million for 18 months, each of these awards.

And Francis?

DR. COLLINS: Joe, I'm glad you're bringing this to our attention right at the beginning of the meeting, even though we're not going to spend time at this particular Board meeting talking in detail about the network, I'm sure we will at the next one after the awards have been made.

And I just want to flag, for anybody who's not completely absorbed the significance of this, this is a very dramatic sea change in the way in which we may be able to conduct both observational and interventional trials in the United States with access to very large numbers of patients and the opportunity to do clinical studies that are patient-centered, that are remarkably inexpensive because of building an infrastructure that's already there and you don't have to start it up and tear it down each time.

And as we go through our conversations today about PCORI's plans, I think we should constantly keep in our mind the fact that we are about to initiate a really powerful platform for

doing research which, within a year, a year and a half, will be a major factor in how we design studies that we think are most needed to influence the practice of medicine and be sure that patients get the care they need. And so, any sort of long-term planning that goes beyond the next 12 or 18 months ought to consider the arrival of this remarkable engine.

It is going to be, undoubtedly, a bumpy road. We're trying to do something really hard. Nobody should imagine this is going to roll out and just be smooth as silk. There will be all kinds of moments where we worry about whether we've taken on something that's just not possible and there will be a lot of fixes that we have to do, but if PCORI is looking for a way to change the landscape permanently and dramatically, this is it.

DR. SELBY: Thank you, Francis.

Okay, now I'm going to move on to the second topic. Many Board members have come to us with comments both positive and, also, some expressions of concern about the PCORI Merit Review

Process. It's a novel process, as everyone knows. The incorporation of so many patient and stakeholder reviewers. The revision of review criteria or the introduction of new review criteria, not like those used in the reviews at NIH or ARC has made it a little less than completely smooth getting started, even though people love the process, on average, and say they'd love to come back and review again, but we have seen some deficits in the past and heard about them and I just want to update you on efforts underway at PCORI to improve that.

So we surveyed the reviewers from this process every cycle and we do it immediately post-review, so we get a 90 percent or higher participation rate. Several weeks later we do telephone focus groups with samples of the reviewers and we also analyze merit review scores -- the scores that were submitted before the discussion happens and the revised scores after the discussion. We also do personal follow-up with reviewers on specific concerns.

We held a webinar at the end of October on the PCORI Merit Review process for would-be applicants. And in response to these comments, this wide range of comments, we've streamlined our processes in several ways.

So the first thing to be said is that at PCORI science -- and when I say "science," I mean the science sector at PCORI -- now runs the review process. Now oversees the review process. In our early days, lacking sufficient science staff, it failed to contract to run that, but science has taken it over under the direction of Dr. Lori Frank and my understanding is that feedback from the most recent round of reviews, which was last week, was that there was a marked improvement in the entire process.

I think we continue to see other areas in which we can improve further, but contracts, engagement, and science are all three working together on this. Engagement has gotten very involved in the training -- just helping applicants and helping reviewers understand what we mean by

engagement, our vision of engagement.

We are moving toward standing review panels so that good reviewers have been invited to populate these panels in an ongoing way. And we also continue to revise and improve our training communications and implementation of the review process. So big improvements have already occurred and I think the main news is that this team sees a number of other improvements and fixes for those, as well.

So this is just a summary of that. Reviewers have said that sometimes the meaning of the review criteria is unclear. We've made the review criteria more concise. We've actually reduced the number from 8 to 5. We've made them more concise and enhanced the training materials. The time burden of the review is too great. Many, particularly, patient stakeholder reviewers made that comment.

We improved the template for the written critique and enhanced the training. And, again, reducing it from 8 to 5 review criteria has

simplified the review as well.

There have been some comments that patient stakeholders and scientists seem to score the applications differently. Our initial analysis at cycle 1 indicated that before the discussion there was a huge discrepancy between the scores of scientists and those of patients and non-patient stakeholders. But after the discussion, these review scores came together remarkably, so there was correlations between scientists in each of these groups well above .9. So, almost complete agreement after the discussion, so it just says that those were, in fact, rich discussions. And we don't have data yet on subsequent cycles, but I'm quite sure that we'd see the same thing.

Ongoing analysis will help us better understand any differences, so we continue looking at these. There was some statement that we need to reinforce all of the perspectives valued equally. These were not the majority statements, but occasional people felt that one group or another was not appropriately listened to and so we

continue to work on the dynamics of the review and monitor it and make revisions to how the applications are presented and discussed in the study section.

And lastly, there was a number of comments about how we communicate with those who apply to be reviewers and those who are selected. And it's true that we had some flaws in that and we have improved the communication processes with reviewers. And so I think we have addressed that well.

And lastly, you all know that we have been concerned about the time it takes to get our contracts in place, so these are the three award cycles that have been awarded already. And the target here is, did we get a contract signed within 90 days? And you'll see that for the first cycle, we got 0 percent signed within 90 days. For the second cycle, 16 percent were signed within 90 days and for the third cycle -- and I'll tip my hat to Regina and her wonderful and growing internal staff -- at just 60 days. So not 90 days, but at 60 days

we have 65 percent of the contracts signed.

I'll also tip my hat to our new general counsel, Mary Hennessey. So that has really made a lot of difference and I think this is the pattern you'll see going forward. And, very good news, we launched a major search with search firm to identify a director of contracts management and this is the person who would replace Martin Dueñez, who left us in early summer.

And after this extensive search we found that the ideal person was right under our noses all the time, that's Scott Solomon, who had joined us a little over a year ago. And Scott had been working hard on contracts. He was our contracts expert and Regina -- and with the concurrence of all us -- eventually decided that Scott was the perfect person and he's started his work over a month ago now, so he will have administrative oversight of our awards, from the pre-award stage throughout close-out. He will manage the review processes in close collaboration with Lori and her team.

He will work closely with Bryan Luce and

the entire science staff in developing funding announcements, the PFAs collaborate with the communications team in publishing our announcements and in all the communications with potential applicants and work closely with our general counsel and directors of finance in negotiating the terms of agreements. So we're very delighted to have Scott take on this role and, as I've said, he's already been at it a month and doing a great job.

And we've grown a bit, so we are now at exactly the point we said we'd be at the end of 2013, so we are at 88 staff. And these are some of our newest arrivals. They span all of the sectors and I think the biggest growth these days and continuing into the near future will be in contracts and in science.

And then, just in closing, I want to -- and then we'll take some more questions, if there are questions, but I just want to preview the agenda today. The first agenda item is a presentation and discussion of the strategic plan

and we will ask the Board for approval of the plan, after which we will post the plan to the website and it will be available for the public to react to and make suggestions or comments.

And then, we will go directly to discuss two strategic issues that flow directly from the plan. The first is our research funding plan. So how shall PCORI allocate its funds over the next six years? How shall it make commitments of research funding over the next six years? And there is an approval there.

The second is a set of observations and proposed directions forward that relate to an analysis of our current research portfolio. We've looked at the research we're funding, and we want to show that to you and we have some comments and want your input into the ways we see both that we need to maintain and strengthen what we've got and directions that we need to go to get some additional types of research into the portfolio.

We go from there to the budget. We have worked over the last two months on putting the

budget together. You've seen previews of it a couple of times and this, the entire budget, will be presented, we'll discuss it and hopefully approve it.

And then you will hear from Bryan Luce. We have two advisory panels, both mandated in the legislation. A clinical trials advisory panel and a rare diseases advisory panel, and both of those are up for approval today. And they both bring support from the relevant board and methodology committees.

Then we have a policy modification or addition to our decision metrics. And again we will ask for approval. And then you'll hear from Robin Newhouse with the great news about the methodology report, that the revised report is complete and ready for posting and will ask the Board to accept.

So, two points about this, it all, I think, starts from the strategic plan -- the entire agenda. And there are a lot of approvals on today's agenda, which I think really reflects where

we've gotten to that we are making a lot of decisions now guided by you.

So that's it for these comments and I'd just ask if there are any questions?

CHAIRMAN NORQUIST: So, let's open it up for questions and, particularly, why don't we start with if anybody had any questions or comments about the merit review process, because you had a lot of discussion on it. Anybody? No, okay. Any other particular questions to Joe at this point?

MR. BARNETT: Just a quick comment, if I could?

CHAIRMAN NORQUIST: Yes, Kerry?

MR. BARNETT: Okay, I just really wanted to --

UNIDENTIFIED: You have to ID yourself.

MR. BARNETT: Oh, Kerry Barnett. I just really want to acknowledge the incredible progress that's been made on the contracting -- creating the contracting infrastructure and taking us from a point where we really lagging in that area to where we are today. And I really want to acknowledge the

great work that the staff has done. That was really threatening to pull us down and prevent us from being successful, so thanks for the focus on that.

CHAIRMAN NORQUIST: Okay, Joe, I think you can move on it a little early here to the next agenda item.

DR. SELBY: Yeah, the other thing we didn't say doesn't actually show in the agenda very clearly is that you're getting a very heavy dose of Joe this morning. This isn't the future, but it happened that way this time.

So, now for you and those listening, as well. We have been working on a strategic plan for quite a long time. We had a strategic plan that we introduced in May of 2012. That was version 1 and we now want to present to the Board the final strategic plan, or the -- final is not the right word -- the strategic plan that we've gotten to. This quote would suggest that I'm going to ask for your approval of a worthless plan, but it's really up there mainly to say that the planning process

has been a remarkable process and it has been lengthy, as you know, but it has really transformed the way that we talk to each other at PCORI.

I think that there's certainly no one at the director level or above who doesn't understand what our three goals are and how our activities fit into that and I think, really, it's pretty much diffused throughout PCORI. So it's been a very valuable process and really does give us a foundation to move forward on.

This is the way it has evolved: in July of 2011, just exactly at the point I arrived, the Board approved a mission statement that it had been working on for a long time and we'll look at that in a minute.

In May of 2012, we approved both a vision statement to accompany the mission statement and a set of strategic imperatives and that was our first strategic plan. In February of this year we reviewed and discussed a strategic framework and logic models for how we would get from the imperatives to a set of goals. And we also began

discussing metrics and milestones.

In May we actually reviewed and endorsed a strategic plan for finalization, but it was definitely not finalized at that point. We discussed implementing a set of strategic priorities in 2013 and we began to discuss metrics and a dashboard that were in development.

In September Board meeting we reviewed and discussed the highlights of our first dashboard, that is the dashboard for 2013. And today we're going to consider the full strategic plan, Version 2.0, for approval. And we will continue to reassess this plan annually and we will discuss a set of questions which come right from this plan at this meeting today and at future meetings.

So this is the mission statement that was developed by the Board in July of 2011 and I just would say that I got the impression when I arrived that you'd been working on this a long time and you actually had a bit of mission statement fatigue, but this has been a remarkable statement that is really stood the test of time and served us very

well. That we would focus on research that helps people make informed healthcare decisions, improves healthcare delivery, improves outcomes by producing and promoting high integrity information. And these last words, I think, were really formative for PCORI -- very distinct from research in other quarters that comes from research guided by patients, caregivers and the broader healthcare community.

So, out of those words came our whole notion of engagement, the whole engagement sector of our staff, and the ways that we require research teams to be put together, the ways that we review it. The vision, as I said, came in May of 2012 that patients and the public will have information that they can use to make decisions that reflect their desired health outcomes. So that's our mission envision.

We identified three strategic goals and these are the goals I think that we all at PCORI focus on at this point. The first goal has to do with conducting research that we would

substantially increase the quantity, quality, and timeliness of useful, trustworthy evidence available to support health decisions.

And so there's a couple key words in here: quantity speaks, among other things, to doing research efficiently. It has a lot to do with our infrastructure that will enable us to do research in a more timely way and in a higher volume.

Quality speaks more than anything to our methodology committee and to the interaction and contributions of the Methodology Committee to all the research that we fund.

And useful is a word I'm going to come back to. Useful is a word that goes back to the notion of what is pragmatic. It goes direct to the heart of what we want to fund. And I think it also goes very directly to how we're going to measure whether we are succeeding. It will be one of our critical metrics over time, whether we are producing useful results.

The second goal is to speed the implementation and use of patient-centered outcomes

research evidence and this speaks directly again to engagement. We believe that engagement done well will facilitate implementation of worthy findings, but it also speaks to the importance of the dissemination that's in our purpose and in our mandate that we do in collaboration with ARC.

It speaks to the development of the dissemination and implementation plan that will take place in the first part of calendar year 2014. And it speaks to, again, metrics. Some of the metrics will focus on whether we have succeeded in implementing our research findings.

And the third goal, and this is one that we added. It's not necessarily in the legislation, as the first two are. To influence clinical and healthcare research funded by others to be more patient-centered. And this speaks to everything from getting the methodology report disseminated so that researchers elsewhere have our standards at hand and can implement them.

It speaks to evaluation of the way we do research and whether that is superior. And it

speaks to partnering with other funding agencies and co-funding activities. So all of those fall under this third goal of influencing the way research is done by others. It also speaks to our infrastructure because we've said that our infrastructure will be funded by others, not just by -- will serve research funders other than just PCORI.

So, these are all interconnected. You have to increase the amount of research and the quality and the usefulness of research if you want to speed implementation. Speeding implementation helps to influence the way that research is done by others and that leads to even more high-quality, timely, useful information.

So those are our three strategic goals. And all of what we do is in the service of these three goals.

So this is a schematic that's going to expand. We start at the right. The impact is another way of expressing our mission and vision. So we want to have better informed health

decisions. We want improved health outcomes. We want better healthcare. Those are contained in our mission envision.

How do we get there? By achieving the three goals that I just outlined of increasing information, speeding implementation, and influencing the way others do research. Those are our three goals.

Now I want to introduce the five activities -- the five groups of activities that take us towards these goals. And those are engagement, rigorous methods, the research we conduct and fund, dissemination, and infrastructure. So these are the ways we organize our work.

So here they are again. Engagement means we engage patients, caregivers, and all other stakeholders in our entire research process from topic generation to dissemination and implementation of results. And I think you all know that we are busy doing that and we certainly do start with topic generation, go right through

review and conduct of research and, hopefully soon, to implementation of results.

That we develop and promote rigorous patient-centered outcomes, research methods, standards, and best practices and you will hear later today about our latest progress in this area, namely the production of the revised methodology report.

We fund a comprehensive agenda of high-quality patient-centered outcomes research and we evaluate its impact and we will talk in just a bit about that portfolio of research that we are funding. And we disseminate the research to all stakeholders and support its uptake and implementation. And lastly, the fifth imperative is that we promote and facilitate the development of sustainable infrastructure for conducting patient-centered outcomes research.

And here we mean by infrastructure, in addition to the data infrastructure, we again refer to a body of analytic methods for which we fund research and also a workforce. Not just of

researchers, but of patients and stakeholders. So those are the five imperatives under which we conduct all of and organize our activities.

This is not -- we're not going to go through this. This is simply a page from the strategic plan that is available in the plan for each of our imperatives and it shows that under each imperative there are a set of strategic priorities and under each strategic priorities there are sets of priority activities. Priority activities for 2013 and priority activities for 2014, 2015. So there are tables, as I said, in there for each of the strategic imperatives.

I should say, too, that you have the strategic plan in your Board materials and this is the plan that will be posted, assuming that the Board approves the plan today.

So, back to this flow chart. And there is a missing step between how we organize our activities and how we get to our goals and these are what we call outputs. These are what the activities or the imperatives generate. For

example, building a skilled patient-centered outcomes research community. Not only of researchers, but of patients and stakeholders. Of growing the set of methodologic standards, of growing a portfolio of patient-centered research studies, of communication and dissemination activities, and of patient-centered research networks.

So those are the outcomes. And the key thing about the outcomes is that the outcomes can be measured and the outcomes can be monitored and we can report process to you on these outcomes. The outcomes start early on with simple counts, but they -- and we'll talk about this in just a second -- they become more interesting and more compelling over time.

I'm not going to spend much time on this slide, only to say that there are a bunch of these slides in the strategic plan and they show, one by one, how the imperatives and activities, the strategic priorities within each imperative lead to numerous outcomes. And those outcomes then lead to

a goal.

So it's simply to show that this has been thought through and, in fact, there are connections between the outputs and the goals and they link back to the imperatives and our activities.

This is the dashboard that was put together for 2013 and it now shows two cycles, two quarters, of data. The dashboard is made up of strategic priority activities pulled from the plan. Those activities that we thought were most central and that we wished to monitor. So we will see one more reiteration of this dashboard at the end of calendar year 2013 and we will then switch to a dashboard for 2014, which will be more dynamic. It will show progress over time and it will be focused on a different set of outputs. Many of the outputs on this 2013 dashboard were simply things that had to happen to get us started. For example, the development of an engagement plan.

Or the training of a workforce or the establishment of advisory panels. Those will have been done and 2014's dashboard will be more

uniformly a set of progress charts over time.

So I wanted to say a word about identifying metrics that we can follow over time that are, in fact, meaningful. A number of you at various times have said, this is all good, but it doesn't really tell us that we're making progress, the progress that we want to make. It's more in the spirit of just counts. So I mentioned word "useful" has a lot of importance and we, in fact, have been working with a group of entities, in fact. ARC has been involved. The National Health Council has been involved. The National Pharmaceutical Council has been involved and others, towards defining the word "useful."

And there are two ways to do it and we propose to use both in getting towards a set of metrics. The first is to identify "useful" in a priori fashion that we can agree on. So you might define "useful" as research that is based on who asked the question? How reliable is the information? And how actionable is the information? So that could be a definition of

"useful," that it's a research question that was requested by key stakeholders, that the study was done well with good methods, that the results are reliable and trustworthy and that the findings lead to action.

So that is a potential definition of "useful" and, as I said, we continue to evolve this definition. But, at a point in time, as our results begin coming out, we'd like to apply this definition to the results and see if we can't reach agreement with you on which studies were useful and which were not. It'll help us with our research portfolio going forward, but it also gives us a metric for a meaningful and compelling metric than simply the count of publications or projects completed.

The second complementary way to use measure usefulness is to ask people who would use it. So to ask patients and caregivers about particular studies. To ask the research community. To ask clinicians, professional organizations, payers and purchasers, and that we intend to do.

So developing a set of questions in a survey that is repeated periodically to see if these key stakeholders agree that our findings are useful. So this is just offered by way of saying that the metrics will continue to evolve. We appreciate the point that counts alone are not enough, even if they're increasing over time.

So this strategic plan leads to a set of strategic questions. Answering the strategic questions helps us to implement the plan. Implementing the plan leads to more strategic questions and that leads to revisions in the plan. All of this being influenced both by the legislation and by input from stakeholders. So it is not a -- we're not done. This is an ongoing process, but our sense is that getting this version of the strategic plan to the shape it's in and, as I said, you have it in your Board books and if approved we'll post it immediately -- has been a really critical and help step.

And lastly, I've said that the plan has brought a number of questions into focus and these

are some of them. The question about, what is the optimal mix of targeted and broad funding opportunities? We'll touch on this a little bit today, but I think it's just an ongoing question. We'll be talking about this repeatedly over the years. And I think our answer will change over time, but it will always be an answer that fits with where we are and where we need to go.

How we allocate or commit our research funds between now and 2019 is a topic we're going to discuss in just a few minutes. The proportion of funding that PCORI should invest through co-funding with other agencies is really a very interesting and critical topic. A very strategic question and it's one that I want to put on the table just as soon as we can. It's one that we're looking squarely at right now.

This next topic, the balance of our research funding that we commit to decision support research versus primary assessments, primary comparative effectiveness research questions is a question we're going to address later today for the

first time. And it is one that has come to our attention as we begin looking at the portfolio that we funded.

The appropriate relationship between dissemination activities and implementation activities is one that we're going to need to discuss as we develop our dissemination plan. We've touched on it a few times in the past, it's one that -- like the word "pragmatic" -- suffers a bit from definitional variation, but it's one that we're going to have to resolve.

Should PCORI dedicate specific funds to attracting and supporting new investigators? It's a sentiment that I've heard expressed a lot on the Board, up to this point, yet we have not taken steps to do this.

ARC is in the business with PCORI trust fund dollars, growing the workforce to do PCORI and so I think it's something that we could benefit from having a strategic discussion about. And a subject that continues to reverberate on the Methodology Committee and among Board members and

with staff is how can PCORI best position itself to be supportive to the values and the notions of open science? So these are some of the questions that occur to us that we need as a board to tackle and we will do it in short order, starting with two of them today.

So, with that, Mr. Chair, I will suggest that we entertain a motion to approve the strategic plan document. And if it's approved, as I said, we would post it, but I'll turn it over to you to see if there's support and then discussion.

CHAIRMAN NORQUIST: Right, I think if we're going to have discussion, we need to at least have a vote to approve and second, and then we can have the discussion. So, do I have a motion to approve?

[Moved and seconded off microphone.]

CHAIRMAN NORQUIST: Okay, so then we can start the discussion. The one thing I was going to say on the last point, Joe, where you were talking about the open science issue, I just wanted to let everybody know -- because we had some e-mail back

and forth about this, that Steve Goodman has agreed to chair an internal committee on this subject, so that will hopefully bring together our thoughts about this.

So, it's open for discussion. Steve?

VICE CHAIRMAN LIPSTEIN: Yeah, Steve Lipstein, member of the Board. Can you go back one slide, Joe? Are you capable of doing that? Good.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: That didn't come out the way I meant it to.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: I meant, technically. All right, that's good. These questions have emerged after three years of PCORI work and what I've learned about these questions by serving on the Board is that there's lots of opinions about them. And that there's no right or wrong answer to almost any of them. And so, it begs the question of how do 21 people come to agreement about the approach that PCORI should take in response to these questions.

I think a credible process is really important because one of the frustrations that we've heard from investigators is that PCORI doesn't answer these questions or necessarily do things the way other research organizations do. We have other requirements for both merit review, we have other requirements for the kinds of projects that we are funding and so we didn't just take our assignment and proceed with a mandate to increase funding for what I'll call traditional CER. Just putting more money into it and using the same allocation methodologies that others had used in the past.

So I think these are really difficult questions. I wouldn't want to -- I think would want to communicate that they are not easy and that there are lots of different points of view on this. And rather than just open up a conversation where all 21 people express their opinions about what the right answers are. I think it would be useful to figure out how do we go about a process that we can all find credible, to identify the right answers?

DR. DOUMA: Allen Douma. Thank you very much, Joe. I appreciate it. Each time we look at this it gets more robust and more fascinating and the questions are certainly challenging and that's why we're here, I think.

I just would like to comment, in the three strategic goals, I think they're excellent goals. You've done that very well. But the first one, it talks about evidence which supports health decisions and I think that's critical, that we recognize that they are health decisions across the board. And I thought we had agreement already and I would and I would like to partition, if we don't -- that our mission talks about healthcare decisions -- and perhaps we could just have health decisions, which is bigger and broader and more important?

DR. SELBY: Are you referring back to the mission?

DR. DOUMA: Yeah, I'm referencing the mission, yeah. Where it says healthcare decisions -- and that's part of what patients and people are

interested in, but it's actually the vast majority of decisions made by people, whether they're patients or not, are outside of the healthcare delivery system. And so it's just a message, you know?

DR. SELBY: Yeah, okay. Yes, and I think that our research portfolio does show that we support research around health, as well as --

DR. DOUMA: Right, and it does and we're operationalizing what I'm suggesting --

DR. SELBY: Yeah.

DR. DOUMA: -- but our mission, but those who see it for the first time, in particular, might be a little confusing.

DR. SELBY: Interesting. Okay.

DR. WEISMAN: Harlan Weisman. I just wanted to respond to, Steve, your question about the questions. And I think because they're sort of open ended questions without a yes/no kind of answer that you can give. Rather than saying that I think you're right, there is no right answer. At least a proportion of them -- there may be variance

on this -- are maybe continuous questions that we ask ourselves as we make decisions about what we're doing at any given moment, rather than saying they're fixed and we lay them out in concrete and abide by them forever, but that they're important questions that linger over us and we continue to examine them.

CHAIRMAN NORQUIST: Other comments? Yes, Christine?

MS. GOERTZ: Christine Goertz. So is the thought then that these questions would go back to the committees for thoughtful vetting with a recommendation to the Board? Or is the Board going to have an opportunity -- are we going to all address them, or are we going to ask staff to? I mean, what is the next step then, as we look at those?

I think my recommendation would be that we queue them up within the committees, to have a more robust discussion and then come back to the Board with, at least, some thoughts, if not some recommendations.

CHAIRMAN NORQUIST: Yeah, I think that's what Steve's point was. What is the process to get to the answer here? And I agree with Harlan, some of these are going to have close to a final answer, like the funding, or it's going to be decided for us. If we sit around and make no decision, we'll have made a decision. That's where I was.

And I think that's -- one of things about what we need to discuss is being more efficient at what we're doing and one of the ways to do that is through the committees. To tee these up with -- which are made up of our Board members -- to bring those to the full Board.

I think at some point, yes, the full Board has to have come to some agreement on these as best they can. We may not have 100 percent agreement, but we do have to move forward, but we do need some work to tee these up, to get us into a more efficient conversation. Sharon?

[Laughter.]

DR. LEVINE: Sorry, I'm technologically challenged. I mean, I think the process -- if we

agree that these are the strategic questions we need to answer and I think I agree with Harlan that some of the answers may change over time, based on the work we accomplish in any given year. But the process of addressing them will be different for each of the questions.

The first step is, do we agree that these are the questions? And the second is, which of these appropriately fit into our existing committees. You've already identified, Joe, that Steve Goodman is going to take on the last one and develop a thought paper for us to respond to. And so I think part of the work is to say, okay, how do we deal with each of these?

Certainly the second question is one that's temporally connected and will change over time, but I guess to me the first thing is, do we agree that the process of answering these questions will enable us to actually do our work most efficiently and I would certainly support that that's the case.

DR. SELBY: This is Joe Selby. They were

not put forward, though, as the questions, just as examples. I don't want anybody to walk away thinking that this is all the work that we have to do.

DR. LEVINE: Okay, but we have to start somewhere.

DR. SELBY: Yeah, right.

DR. LEVINE: And getting a perfect set of questions isn't going to help us.

CHAIRMAN NORQUIST: Exactly, we should start with the questions that we have and let's get these, and then we can go on. But if we start developing more questions, we'll never get started. So these are the ones that have come up.

Let me bring the group back a little bit to the higher level discussion, which is the strategic plan and that we're approving that because these questions flow from that because if we don't approve the strategic plan, then we have no questions, we have -- I mean, so we need to come to some conclusion on that.

We have a motion to approve the strategic

plan and a second, at this point is anyone opposed to the strategic plan that we have in place? Or more discussion about that?

So it looks like we're ready for a vote to approve it. All those in favor?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed or abstaining?

[No audible response.]

CHAIRMAN NORQUIST: Okay, Jeff, you can put it up on the website for comments, all right. And we'll start answering the questions and the other things.

And I think the other thing that you will see is because we have a strategic plan that we will try in the future for our discussions at the Board, and a lot of other things, to make sure that we're very clear every time where we're having this discussion. How these things link back to the main strategic plan and that it will help us in our way of thinking about how we're moving forward. Steve?

VICE CHAIRMAN LIPSTEIN: Gray, just

because you can't see, when we approved the strategic plan, everybody behind you smiled.

[Laughter.}

VICE CHAIRMAN LIPSTEIN: And so, everybody seated behind Debra and Bob Zwolak just breathed -- I mean, they just took out this collective sigh and they deserve just an enormous round of congratulations for all the work you put into the strategic plan, Version 2.0. Good work.

CHAIRMAN NORQUIST: The only problem with that is, be careful, now you have a work plan and you have to really do something.

DR. SELBY: Let me just say, first of all, thank you for all of your input over these months, your patience with this process. Let me say thank you to Michele Orza, who really was the steam engine behind this, who just kept plugging away. Her desk always has a stack of the flow charts on it.

And thanks to the entire staff, not only for their patience in putting this together, but for actually all of the work that they've done in

implementing parts of this already.

The staff and PCORI is the most dedicated group I've ever seen and worked with and it's a pleasure to bring this plan back to them approved.

CHAIRMAN NORQUIST: Arnie?

DR. EPSTEIN: Sure, Arnie Epstein, Board member. A short, friendly edition. Joe, as you were articulating the strategic plan, I thought you did a really, really good job in lucidly arborizing the plan for all its richness. And I wonder whether if, on our website, with the plan, we could get an audio explaining it? I'm dead serious about it.

CHAIRMAN NORQUIST: No, no, actually the whole Board meeting is --

DR. EPSTEIN: A lot of [inaudible] came out --

CHAIRMAN NORQUIST: Yeah, the whole board meeting is recorded, so it would be on there. We could probably go -- we could pull off this particular section. It's kind of a cut, if people are looking at -- that's a very good point, yeah.

Yeah, I have to say, I also was very pleased -- this is one of the things we've been working on, is to have more concise, kind of focused discussions and, Joe, I thought you did a very good job with that also. I think it makes it better.

Well, Joe, we have 30 minutes that we can plan -- what do you want to do at this point? Do you want to dive in the --

DR. SELBY: It's the Board's pleasure.

CHAIRMAN NORQUIST: See, we could have started at 9:00. You see, I could have --

[Laughter.]

CHAIRMAN NORQUIST: Next time we will, okay.

UNIDENTIFIED: The suggestion was made that we move along.

CHAIRMAN NORQUIST: Yeah, I think we better start getting -- maybe we should start moving it along.

DR. EPSTEIN: Steve, do you want to make progress on the question you raised -- which is, we

have a lot of strategic issues facing us. None of them have clearly right answers. There's no clear consensus on the Board right now, how do we think about a process for them to drive us towards wiser, more consensual decision-making?

VICE CHAIRMAN LIPSTEIN: Yeah, so if you go back to the previous slide again, Joe, I think that Arnie's bringing up a very good point and one of the things that we will take up later in our agenda today is enhancements to our own governance process.

And one of the things that we've worked on between last meeting and this meeting, which we will share with all of our colleagues listening in today is that we want to reorganize our committee structure around the strategic goals, and we'll talk about that more. But you -- a lot of these questions almost apply to each of our strategic goals. Some of them are specific, as it relates to dissemination and implementation, but I think, Joe, what Christine suggested is that some of these questions can be assigned to individual committees

of the Board and that we, as a full Board, would like to hear those deliberations at our next meeting.

And as Sharon said, the answers to these questions may evolve over time, but if they evolve over time in the context of our strategic goals, if we never lose sight of those three goals that you articulated, then these are good questions to guide our deliberations. So, I thought, Arnie, that's what Christine was suggesting, and Sharon was suggesting and it makes sense if we keep our committee structure aligned with those strategic goals. Does that make sense to you, Joe?

DR. SELBY: It makes perfect sense. Actually, I haven't looked at all -- going down this, I think I could apportion almost all of them to one of the committees or another. And I think each of the questions has at least one committee that could take it on, so I think Christine's idea is just right.

CHAIRMAN NORQUIST: Any other further discussion about this? So, you know, one thing we

could do because you've got 30 minutes, you could take one of these next to --

DR. SELBY: Okay.

CHAIRMAN NORQUIST: I would propose that we take the decision support because I think the other one may be a --

DR. SELBY: [Off microphone.]

CHAIRMAN NORQUIST: Yeah, the other. So what I would do is start with the -- we're going to move to the Tab 4 or whatever we call it, which is strategic issues, and we're just going to discuss in the next 25 minutes the decision support research. Go one. And then we'll come back in the allotted time because I think the research funding planning will take a little longer.

DR. SELBY: That's great. And so, just before we leave this slide, I want you to just look at the fourth bullet because this next discussion is directly linked to bullet number 4, about the optimal balance of research funding dedicated to decision support and to primary comparative effectiveness research. So now, bear with me as I

see if I'm capable of moving all the way ahead.

Okay, so this is a topic that I would say wasn't on our minds until we began examining our funded research portfolio. And it has over the last few months gradually risen to a very high place on the list of strategic questions on our minds, from day to day at PCORI.

It starts from the observation that in -- you know, we funded three cycles of research, 127, I believe, or 128 comparative effectiveness research studies that take out the 19 methods studies we funded and there are 127, I think, CER studies. And in this group there is a relatively large number of studies that evaluate decision support. Decision support either for patients or very often decision support for patients and family members and clinicians together that is shared decision-making.

And the questions that we want to put to you, the Board, as we're going through this presentation and then discussing it is, is there a sense on the Board of an optimal ratio at this

point in time of decision support studies versus studies that are really about one treatment versus another. One diagnostic approach versus another. One preventive approach versus another. So two distinct types of research and I'll give you a little more detail on what this second type of research looks like in just a minute.

The second question is, are PCORI's proposed strategies for increasing the numbers of primary comparative effectiveness research questions in our portfolio sufficient? And are they likely to be effective? And then, are there other questions?

I'm sure there will be other questions and points of view and suggestions that arise, but those are the strategic questions about our portfolio and the balance of these two types of studies. So, I just want to point out that in our purpose, we actually are instructed to both conduct research, but also to conduct evidence synthesis and to disseminate research findings.

And I'll say that in the highlighted words

here, the research, in my mind, speaks directly to these primary comparative questions in evidence synthesis and dissemination, taken together, is one way of describing this second type of decision support research. And I'll show you what I mean, but just to say that I think both are very squarely within our remit.

So, this is what we're seeing a lot of and it starts by the researchers and patients and stakeholders synthesizing the available evidence in a particular area. It's a pretty narrow area. It's the evidence around one particular set of clinical questions for a particular condition.

And this is not a formal systematic review, it's a rather less formal, more ad hoc process, but, at any rate, the evidence is marshaled and it's reviewed and out of the review that always has the engagement of patients and caregivers and other stakeholders, along with the researchers, some form of intervention, usually in the form of a tool to support decision-making, is developed.

And then the comparative part of the whole study comes along and the comparison is either between using a decision support tool and not using it or between conducting shared decision-making with versus without the tool or sometimes it can be a comparison between two types of tools. So that's the format in a number of these studies.

So when we look at our first 128 studies, we find -- and this is now stratified by our 4 priorities -- we find that, if you look at the communication and dissemination line, the third one down, in that announcement we specifically call for studies on shared decision-making and decision support and the development of tools. So it isn't surprising that 55 percent of the studies that we're funding in that priority are decision support.

But also notice Line 1, the clinical effectiveness area. Their 40 percent of the studies were judged to involve decision-making, development of decision support kinds of information. So 30 percent -- and I will say that

this is a very conservative, rigorous definition, so these are projects that are really all about decision support.

A second analysis was done by another person at PCORI and the number proportion came out to 40 percent, rather than 30, so a lot of these types of projects are being funded.

So I've begun actually talking with researchers, patient organizations, clinician organizations about this and just asking them, which is the greater problem? Is it that the shelf is not full, that we don't have a lot of information? That there are large gaps in knowledge and that the evidence is of poor quality? And that what we really need is more and better quality comparative research information?

So that's one way to see the problem and one way to see PCORI's mandate is, we really need to conduct more primary comparative effectiveness research because the available evidence is just not that good.

But a second way to look at it is, in

fact, that the shelves are really quite full. That there's a lot of information on the shelves, but it has not been synthesized or presented in useful ways at the point of decision-making, so that clinicians and patients can take advantage of the evidence and that shared decision-making needs to be expanded, supported, incented, understood, improved and that that is the greater lesion in the current process.

And when I ask audiences, I've always gotten the answer that it's both, but I would say, as often as not -- maybe even more often -- the audiences will weigh in that the second problem is greater than the first. That, actually, it's getting the available evidence off the shelf and into practice and into decision-making.

CHAIRMAN NORQUIST: Leah?

MS. HOLE-MARSHALL: Leah Hole-Marshall, Board of Governors. I guess I would also just add that it's probably not either/or.

DR. SELBY: Right.

MS. HOLE-MARSHALL: Even in the first

case, you need to synthesize both what the gaps are, what we do know and what we don't know, in a way that allows patients to make decisions.

DR. SELBY: Yeah.

MS. HOLE-MARSHALL: So I don't think, oh, if you go with the first one you don't need any decision support, if you think that's the issue.

DR. SELBY: Right. So agreeing with Leah, our assessment is that both evidence generation and evidence synthesis decision support are central parts of our PCORI's program. That our mandate calls for both and there are major deficits in both, but in fact both need to be addressed.

And so, these are the proposed actions we want to speak with you about. In the first area, given that we've funded such a large amount of this, we want to strengthen our management of the portfolio in decision support research. And I will get into what that means in the next slide.

But the second is, we do feel that at this point that it is pretty clear that PCORI needs to do something to increase in its portfolio the

numbers of genuine primary comparative evaluations of prevention, diagnosis, treatment, management options. And I want to add here that's in all three priorities. That's in the addressing disparities, that's in the improving health systems, as well as in the clinical effectiveness priority areas.

So, proposed steps for strengthening our decision support portfolio include, first of all, doing a careful assessment of the current portfolio and that is underway. In fact, this is the first product of that. Looking for common approaches, looking for common themes, identifying remaining questions and gaps. We want to carefully assess and make ourselves aware of funding by other potential funders in this space. So we want to learn better than we know today, who else is funding work in this area of decision support?

We intend to conduct a landscape review and we are planning a workshop in collaboration with the Methodology Committee and we're hoping for some time about May to June of 2014, where we bring

together decision scientists, we want to bring some of our own funded researchers to this meeting and use this meeting, as well as the landscape review, as well as our own work, to develop a framework that will guide PCORI's solicitations going forward, so that we actually solicit work that we need more of. And also guide the management of our current portfolio.

So we want to get our intellectual arms around this area. We want to become -- and we need to become -- really a knowledge center in this area of decision support. We want the last bullet there -- we expect that this framework will lead us to modify our funding announcements so that the announcements clarify better than they do today.

What we're actually looking for going forward and what we think the gaps are that need to be filled so that this decision support work can be effective and can impact practice. Francis?

DR. COLLINS: Francis Collins, member of the Board. In terms of what we've already funded, these 37 projects, which is really quite a

breathtaking list. I'm curious if there's any early sort of sense from what Hal is doing, and others, about the way in which these were chosen in terms of the likely impact they're actually going to have. And particularly is, I'm hoping, in the review process there's a clear sense about whether such a decision support tool could ever be exported to a broader audience than the investigator who's basically putting it out there? Because that often is where good intentions run off the track.

Can you say anything? If you look at these 37, what's the likelihood that they would have actually resulted in a tool that could be more broadly adopted, than in a very narrow way?

DR. SELBY: Well, that's a central question because -- and I'll invite Jean, if she has any thoughts to weigh in here, too, but it really is true that a lot of these studies produce tools that work fine locally, but they don't necessarily generalize.

One of the reasons may be -- it may not be the tool as much as it is the environments. There

are not a lot of environments in this country that welcome decision support tools into their day-to-day practice. It's potentially time consuming. It probably could be done in efficient ways, but those have not necessarily been worked out. And I think the incentives that most clinicians practice under doesn't necessarily support the implementation of decision support tools.

So I think our sense is that part of the research agenda in this area is, how does one create an environment in which -- in a business case for the use of decision support tools? If that could be answered, then PCORI could be asking itself, given that you've just developed 37 decision tools, how do you in fact disseminate these tools? And what kind of commonalities can we identify among the tools we generate that might make them fit into a bigger package?

So, good question.

CHAIRMAN NORQUIST: Jean, do you want to add anything?

MS. SLUTSKY: So that's a really

interesting question and shared decision-making and decision support tools is a very complex area and there are international standards which guide how these should be developed.

And the currency of these tools is also something that's been a lot of up for debate, so the fact that some of them are underpinned by narrative reviews, rather than systematic reviews is also of concern. So I think looking at the portfolio and how well it's done, you know, ARC has supported decision support, both as an investigational tool, but also actually soliciting specific tools where there's a lot of uncertainty in the evidence, particularly how it leads to application to patients that are outside the confines of a particular body of evidence.

So, I think as PCORI moves forward it will be really interesting to look at how well these studies -- or if they're sort of the biomedical part of shared decision-making? So investigational. Or if they're really ready to be maintained and implemented and meet international

standards?

The other thing I'd like to say -- and Leah can probably comment on this -- is Washington state actually has had a law for many years implementing shared decision-making in their Medicaid programs, so there is model legislation that states can use if they want to implement shared decision-making, so it is a very real issue on the state level, particularly with Medicaid populations.

CHAIRMAN NORQUIST: Let's go in a clockwise -- we'll just go around this way. Freda?

MS. LEWIS-HALL: Freda Lewis-Hall, Board. I actually just had a follow-on question which is, understanding the complexities of this and being in the situation of not yet having feedback, do we know exactly what metrics we're going to use to measure the effectiveness of this work ultimately?

DR. SELBY: I think the answer today is, no. But that's part of the active portfolio management, part of bringing these researchers together that has to happen.

DR. DOUMA: Allen Douma. I want to thank all of the staff and Joe, in particular. I think this is an incredibly important area. I think it is as important or perhaps more important since it's where the rubber meets the road with regard to changing and improving health and healthcare delivery behavior.

I think it's also an obvious place, in looking at our networks, how those can be decision support tools can be implemented at the real level and then seeing what it is our networks are telling us about how effective they are is a tremendous advantage that PCORI will have in the not too distant future.

It's also just to reinforce these decision support tools have been developed in the non-clinical arena a lot. In primary prevention, in secondary prevention, self-care, and in a lot of other environments, particularly in the corporate cultures. So we need to make sure that we look at expanding ourselves beyond our normal kind of clinical care research model.

I'm looking forward to this. This is one of the most exciting things you've brought forward. Thank you, Joe.

CHAIRMAN NORQUIST: Ellen?

MS. SIGAL: So, thank you. Ellen Sigal, Board. I share the enthusiasm for this because we will never have perfect information and understanding in the lack of perfect information, how to make informed decisions is very important. And measuring this is important, but I do want to stress one thing.

I believe it is the charge of the PCORI Board to actually advance the science and advance information so we actually have better information in many areas and I want to make sure that we just don't forget about that, as well, because there are things that we can and should be doing that would really be helpful. So, just a point.

DR. WEISMAN: You know, I wanted to voice -- Harlan Weisman. I wanted to voice my support for the work because it's fundamental to the vision you started us off at in the strategic discussion.

Patients and the public can have information they can use to make decisions that reflect their desired health outcomes. And decision support seems fundamental to the vision, but there are other aspects of what we do that are going to be equally important, like the infrastructure work.

You have to have the information available in order to support the decision, which is -- I also think that there are, besides tools, it's important to decide, what is that process by which people make high-quality decisions about their health, either with a clinician or if they're looking at managing their own health, how do they go about getting that information?

And I keep remembering the outcome of the open session we had the town hall that we had in New York, where there seemed to be a convergence on the idea of what clinicians and patients -- people -- wanted was the ability to sort of plug in the issues. Who I am, as specifically as possible and find out as much information about options that are available to me and the likely outcomes based on my

particular circumstances. That's another thing we talk about.

It's having that kind of information -- what does that look like? So before you design tools or select tools, I think it is important to decide what is that state look like in which decisions are being supported and what are the behavioral aspects of this that are going to be important, as well. In other words, changing the framework of one, just relying on experience or where they were trained to one in which there's an openness to seek better quality information.

But I do think it's highly important. There's one other aspect and that is, decision support is not only knowing the available information, but how one incorporates new information as one goes forward. And we do have this notion of a learning healthcare system in which the infrastructure grows and becomes better, as we go. So, one is to be able to synthesize available information at the time and get an outcome, but on an ongoing basis be able to revisit

it.

And to come up with how newer information impacts what we believe we've already learned. It's sort of a Bayesian way of looking at the world, as opposed as a frequency way of looking at the world. A lot of the research that we look at is a frequentist way of looking at the world, but I think the way people make decisions is much more of a Bayesian approach. And I don't know how much of the work we're funding looks at it in those kinds of terms?

DR. JESSE: I think I'm going to ask the same question, but in a little bit simpler fashion. And that is, it's 29 percent of the portfolio now for decision support and the question is, how does that reflect the number of applications? Meaning, are these much more difficult grants to construct and get funded? And, secondly, what's the right mix?

DR. SELBY: Well, the second question is the one I put to you. What's the right -- that's for you to help us decide.

We don't have data at this point about the proportion of the submitted applications that are decision support. But our guess, I think, is that it may be slightly easier to get these through the study sections because they come across as extremely patient-centered and preference sensitive. They have a sound and they can be described in ways that appeal to merit panels that have been really trained to look for patient-centeredness.

And so, our -- and it's a great question, one we want to go back to. Another way of saying that is to ask whether there may be applications out there that did not score well. Comparative clinical effectiveness research applications that did not score well because they came across as very technical comparisons between two treatments, let's say.

So we really do want to look at the portfolio of applications more closely, too.

CHAIRMAN NORQUIST: Leah?

MS. HOLE-MARSHALL: Leah Hole-Marshall.

First, I really appreciate this. This is the type of discussion that I envisioned when we talked about active portfolio management, to look for trends and talk about how that fits our vision, so thank you very much for that.

Second, just anecdotally, it doesn't surprise me that this would be the case around decision support. And I do agree with Ellen around not losing sight of the fact that primary research is important, but I'm not necessarily uncomfortable with the current outcome. And I would say that we need to keep in mind that decision support tools are a form of dissemination. And so, because a part of our mission is not just research, it's dissemination, we're actually accomplishing two of our goals by funding research that is about how to insure the synthesized research is disseminated at the patient level.

So, I mean, I think that it's very important and I think the barriers to implementation, at least in our state that we've seen, are not the ones that people think of as

common in terms of their taking too much time or that patients or providers don't want to engage. It's just a system change and it's extremely difficult to introduce change into a system.

But I'm happy to see this. I'm not saying I know what the exact right number is. I was a little concerned about modify funding announcements being a proposed action step before we know whether there's a problem. So, again, I completely appreciate this being put before us. I'm not saying this is great, don't do anything, but at this point, I'm not certain there's an issue. I think it's something we have to monitor.

CHAIRMAN NORQUIST: Sharon?

DR. LEVINE: Yeah, just one comment, which sort of builds on what Leah said, but perhaps with a different perspective, which is that one measure of whether or not this is going to make people's lives better is the ease and utility of use in the context for which it is designed. And in a perfect world, every one of these shared decision-making applications, to me, ought to be looked at from,

okay, how likely is it? Whatever the results are that this actually going to be feasible and useful in the context in which it's designed for.

Whether it's a patient at home, a patient and family member, in the context of a clinical setting. And I still think, based on my own experience, that the biggest challenge is -- if you want the business case, has to be, does this make it easier to do the right thing?

Or is this just additional work and so, from a design perspective, challenging the applicants around, so how is this going to make people's lives easier and better and more likely to adopt the tool? There's a tradeoff between elegance and utility.

MR. BECKER: Larry Becker. So, I want to build on what Sharon just said, and that is that I think all this stuff is really good and it's an opportunity to leverage another part of our mission statement and that is around the high integrity and the trustedness of the information. And it's an opportunity for us to role model and influence like

we have around patient centeredness. Around using, for example, the Methodology Committee's work in terms of demonstrating the process, the integrity of this data, and having it start to set a standard because there's so much information out there.

When I want to look at information about me and all the studies out there, well, which ones do I trust and which ones can't I trust? And which ones should I follow and which one shouldn't I follow?

So maybe this is an opportunity for us to put our brand on high trust and let others begin to follow that, so that patients, clinicians, everybody can understand the information that's out there.

DR. EPSTEIN: Two quick comments. The first is -- I'm going to sound a lot like a primary care internist who sees his patients every Friday morning. But the litany of discussion here has been all about shared decision-making and bringing data to patients. And docs are more than half the triad in a lot of situations -- the dyad.

Joe, you look like you have a question? I said triad, I meant dyad.

DR. SELBY: I just didn't quite hear what you said. Did you say docs are more than half --

DR. EPSTEIN: I think I -- getting information that's useful for docs strikes me at least as important.

DR. SELBY: Yes.

DR. EPSTEIN: Shared decision-making happens all the time, but especially about big events. Could I get back surgery? But not about whether I get my BUN checked and not about, I've had viral bronchitis for 10 days, do I get a chest X-ray or -- most of the time it doesn't take place that way. And we need information and I'm thinking, just quickly, we have new guidelines out just this week for cholesterol management that's going to affect hundreds of millions of people in our country. Literally, that magnitude.

And I'd love something that could help me because on several of my patients, I know I have to rethink where they are and the guidelines that I

saw that came out are complicated. Anyway, I'll stop that. I'll get off that.

DR. WEISMAN: And are probably wrong.

DR. EPSTEIN: And probably wrong. That's reassuring then. The fact that I can't use that information is -- you've made my day, Harlan. I hope it's clearly wrong. They do that.

Second, Joe, I wonder whether it's not too early now -- as you carefully assessed PCORI's current portfolio -- to try and get some sort of criteria for what is a successful product and what isn't. Was it take-up rate? Was it -- and so forth?

But I think it's not too early for us to look at the first 10, 20, 30 studies that we've published and give ourselves a grade. And then from the grade, obviously, instructions for how to move left to right.

MS. HUNT: Yeah, Gail Hunt, member of the Board. I agree, really, so much with what Arnie said, and also Sharon and Larry. I think that we -- of course, I think that the patient and the

caregiver, and it is a triad involving them with the doc. That's really an important issue to take into account, but I'm struck that we need to be focused so much on the environment of the system that the primary care doc is working in.

You'll remember when we had that meeting in Palo Alto, we had primary care docs who got up and said, if you don't have something in it for me, if you don't make it clear that this is going to make my life easier, I'm not going use it.

So that's something that we really need to be thinking about with decision support.

DR. ZWOLAK: Bob Zwolak, Board member. I wrote down my thoughts as we started around the circle and almost everybody has said mine, but as a clinician, I think I need to say something.

First, my simple opinion about the balances that we probably should swing a little bit back towards primary evidence development. I think we might be modestly overbalanced towards decision support. When I think about decision support pragmatism and the current business models come to

mind immediately.

I do think it would be very challenging to introduce extensive decision support into today's clinical practice models. Our enthusiasm at PCORI for portfolio management may provide us with an opportunity to really shape the projects that we've funded towards an operational approach in our increasingly pressured world of clinical practice to make these studies useful in a way that, so far, they really haven't been extensively, I don't think.

DR. SELBY: Wow.

CHAIRMAN NORQUIST: Wait, wait, wait. Freda has one more comment.

DR. SELBY: Okay.

MS. LEWIS-HALL: So, one of the things that I wonder -- this speaks to the balance. I'm Freda Lewis-Hall, Board. Right now it feels like we have some in a therapeutic area looking at evidence development and another one decision support and another one engagement, so it may be an interesting notion to pull a thread through a

single therapeutic area or around an issue that would allow us to really look at some of the pressure points between -- you know, what is the challenge in generating the evidence? Are there unique challenges in having input into decision mechanisms?

If we did -- not to say it out loud, but if we did cholesterol, just as an example, what are the evidence gaps? What are the dissemination issue? What are the support tools there, so you could actually look across the continuum because right now I'm not sure that we really have a line of sight across any single issue or population for the various activities and content that we're developing.

DR. SELBY: Okay.

CHAIRMAN NORQUIST: So, Joe -- you might want to turn this off so you don't get feedback -- it sounds like, if I've correctly heard every one, which is not always the case, but no one's saying get out of the business. I think what we have to decide, which you've outlined here, is what is our

niche in this?

And understanding what others are doing and, I think, if we look across in disease or condition or whatever, what would be our niche in that and what's missing?

I think you've laid out a plan of how to go about that. It has to be a thoughtful way, I think, to bring back to us a proposal on this, I think the key question now is, what is the exact process? Would this go back to PDC? Does it go back to an internal group? Obviously the Methodology Committee is obviously involve in that.

So, if you could say a little bit about that? And I think that's what we're asking. I think everybody's saying, yes, we need to take a critical look at this and decide what our niche is.

So let’s be clear what the process is. And I think that's what you're asking for approval is to go forward with your process, right?

DR. SELBY: Uh-huh.

CHAIRMAN NORQUIST: Okay.

DR. SELBY: Well, this is actually not a

request for approval at this point. It was a request for input and that was the most remarkable round of comments that I think I've ever heard at a PCORI Board meeting. And I'm glad that we archived them. I'm going to sit down and actually watch this again and when I sit down, I'm going to invite this fellow, Dr. Hal Sox, who, as you know, joined us as a senior advisor and independent consultant about a month and a half ago and Hal has taken on, as one of the tasks that we've contracted with him for, to help us get our arms around this. And he's been looking at the individual projects and shown us some initial data on this.

So I'm dead serious that watching the comments that just came around this table will be our very next step. And we will be working toward developing that framework, commissioning the landscape paper, and particularly heading toward that conference where I think questions like Harlan's and Bob's and Sharon's and Leah's will be addressed, will be taken up.

You know, what kind of set of incentives,

what type of environment could be conducive to using decision support tools? If they're going to use them, how do you make these decision support tools helpful rather than just time consuming and painful additions?

So, understanding that, how do we guide the set of projects that we've funded toward some more uniform and useful end products that can take root in places other than where they were developed? So I think the answer is that we are moving forward with this set of strategies that I showed and we will keep you in close touch.

And it's a good question, where this gets discussed? It strikes me that it's something that has a lot of resonance in the COEC, as well as in the PDC, but we'll probably keep both groups apprised.

CHAIRMAN NORQUIST: Can I suggest that you also come back to us with a timeline on your expectation --

DR. SELBY: Okay.

CHAIRMAN NORQUIST: -- when you come back

with us on this, since we've been accused in the past of not completing things and finishing. I know you do that, but let's come up with a timeline so the next time that the Board -- if you could get the staff together and kind of come up with a timeline and give us an answer on when you kind of expect to get back to us with some of this? So that we're not, a year from now, having this discussion, saying now we've got 50 percent --

DR. SELBY: Yes.

CHAIRMAN NORQUIST: -- that we don't want, or something. Right? Okay.

DR. SELBY: Yes. No, I think our staff are sufficiently concerned that they're not going to let this set. And David Hickam and Bryan are working particularly closely with Hal on this, as well.

So, now a nod toward Ellen.

CHAIRMAN NORQUIST: I will check.

DR. SELBY: Okay.

CHAIRMAN NORQUIST: Are we going to take a break?

DR. SELBY: Yes, oh, yes and no, no, we're not quite finished. Not far though.

But I just want to -- I heard Ellen, I heard Bob say that we may need to swing back a little bit. We on staff feel that we very clearly have to do something. Part of answering Bob. Jesse's question about -- I think it was yours, Bob, about the portfolio coming in or the mix of applications coming in, but we want to work very closely with the PDC, and we've certainly discussed it with Christine and others on the committee.

And, very promptly, by January of 2014 we hope to issue broad standing funding announcements. Standing, I mean, these are recurrent every three or four months. Or at least three times a year. Funding announcements that are devoted solely to large, pragmatic, head-to-head comparison studies, mostly randomized trials, that they feature substantially increased funding levels and that they invite longer studies.

Part of our sense, Bob, is that the $1.5 million maximum direct cost and the year length

have been features that discouraged genuine head-to-head comparative studies. So we feel that very quickly -- I mean, we've tried the broad mechanisms, we have the targeted mechanisms, too, but the targeted mechanisms do not necessarily lead to the large number of comparative trials that we'd like to see.

Just one second and I'll -- so in these announcements, we will emphasize the need to address high priority questions and by high priority questions, we mean questions, for example, that are on the IOM CER top 100 -- particularly the top 25 -- for possibly questions that AHRQ processes have led to be identified as future research needs.

Questions submitted by our stakeholders, like National Business Group on Health and AHIP, who have provided lists of questions that are very compelling questions. So we will feature these questions on the announcements. They would not be, you know, applicants won't be limited exclusively to those, but we want to point out to

them that they need to make the case that this is a genuinely high priority comparative question.

And we will emphasize the importance of very strong engagement. And in this case, not simply with individual patients or individual clinicians in a single site, but with national organizations -- national organizations of patients, clinicians, specialists, payers, or purchasers, who say this indeed is the high priority question. This is the question which, if answered, would allow us to change practice.

So, that's the kind of questions we'd hope to fund with these. And, as I said, we hoped that we can get an announcement in early calendar year 2014 and then follow it up with serial solicitations.

DR. SELBY: So --

CHAIRMAN NORQUIST: Wait a minute, Joe. That was one -- this is going to take a lot longer and we've passed our break time, so I've been trying to be cognoscente of the fact that people want breaks, and stuff. And this, I can tell, is

going to go into much more than the next 5 or 10 minutes, so let's take a break --

DR. SELBY: Okay.

CHAIRMAN NORQUIST: -- for 15 minutes and we'll come back and start the discussion here. So we'll start back at 10:30.

DR. SELBY: Good.

[Recess.]

CHAIRMAN NORQUIST: Thanks, and welcome back everyone. We're back from our break. We are going to continue on the conversation where we left off, I've been asked to remind people who may have joined us since we started this morning that our webcast and teleconference, you can register for it on our site at: www.pcori.org/events. All of the materials that we are talking about and discussing are available on our website and for those who do not want to listen to the entire thing, but perhaps pick it up later, this will be recorded and archived, but won't be posted until probably the end of the week or maybe next week.

Okay, Joe, you can pick up where you left

off.

DR. SELBY: Thanks, Gray. So, this is the very early proposal for a remedy or for a set of actions to address the relative lack of primary head-to-head comparative studies. And I went through it right before the break, I won't go through it again.

This needs to be worked substantially with the PDC over the next few weeks, but we do have a pretty clear vision of where we think it should go and the primary features were that we would solicit across a broad range of high priority topics that have been obtained from a variety of sources.

Larger, head-to-head comparative studies, they can be longer. They can be essentially as long as they would need to get the answers that patients need. And that we would really emphasize the need for these to be done in close collaboration with key stakeholder groups, so that they'd have the best -- first of all, to provide evidence that they are the right questions. And secondly, so that the chances for dissemination and

implementation would be strengthened from the start.

So, I'll just open it for comments at this point -- not looking for a decision here.

CHAIRMAN NORQUIST: Ellen?

MS. SIGAL: Ellen Sigal, Board. So, Joe, I'm very pleased we're doing this. I think this is incredibly important, but I have a caveat. So, because the head-to-head trials are important and there's a lot of data out there that needs to be resolved and may be resolved from pragmatic trials. And one area of concern is recycling a lot of old lists that may not be relevant at all. Even the IOM study that was done a few years ago, and things that we submitted in behalf of the cancer community. There could be a lot already in progress, so I would like, if we can -- and I understand that we don't have enough time if we're going to do this in January -- to at least take off things from these recycled lists that are in process or we can't get answers to or perhaps, really, are not meaningful.

And, of course, we're going to encourage people to submit their own, but, you know, just again, concern about recycling old lists that may not be relevant at all and it could put people off on paths that aren't going to be meaningful for us and then we're going to spend a lot of time after we get proposals saying, oh, this is already done. We have this. We don't need it. So anything we can do to crisply address the things that perhaps could be used that would be primary for what we're interested in.

DR. SELBY: Thanks, Ellen.

CHAIRMAN NORQUIST: Bob?

DR. JESSE: Bob Jesse, Board. We had a little conversation about this last night, but I thought I'd bring it up again. But Jon Perlin presented at the ACRE conference the work that they had done as a comparative study for the management of MRSA in hospitals. And it was a large, relatively rapidly done study, but done incredibly inexpensively -- a little over a million bucks to do the whole thing.

And I think we ought to be thinking of ways to dissuade the research community that these all have to be huge and very expensive trials because historically what these things have cost is going to be pretty limited in what we're going to be able to look at if they remain that way.

And maybe one of the challenges that the Methodology Committee could take on would be to set up some principles that would allow these kinds of studies to be done on a rapid turnaround, through the research networks at a much more reasonable cost than we historically have done.

DR. SELBY: Thank you very much. We couldn't agree more. You mentioned the network and we do see the network as an eventual source of these questions and sites for these kinds of studies. I think to be worked through with the PDC is whether we ought to really emphasize, even in these initial ones, that they ought to be embedded in systems. That they ought to come with expressions of support from the systems where the studies would be done. And reassurances that slow

recruitment won't be the reason that the study takes five years.

I mean, if the occurrence of the critical outcomes takes five years, that's one thing. If the study takes five years because it took that long to recruit, we can't afford to support that kind of sluggish recruitment.

DR. JESSE: The risk is, you get a very elegantly well done, well performed study that's irrelevant.

DR. SELBY: That's right. Exactly. Thank you.

CHAIRMAN NORQUIST: Larry?

MR. BECKER: Larry Becker. So, in conjunction with those two comments, particularly Allen's, I think we funded a paper, or at least one of our methodologists did a paper, on the value of information. So we ought to use our own cooking, we ought to use that. And we ought to apply whatever we do against those standards.

DR. SELBY: Thanks.

MS. SLUTSKY: So I'm glad Bob brought up

the MRSA study. We funded that through the DEcIDE Network, which really tracks back to if the CDRN is up and running. That network that we funded the MRSA study was almost eight years old, so it was a very efficient way of doing what I think of as a pretty elegant study.

DR. COLLINS: Francis Collins, a member of the Board. I just want to endorse the comments that are being made here about being thoughtful about how to take full advantage of platforms that are emerging, both the network that will announced by the end of this year, and other networks, as well. But I'm sure there will be important primary CER studies that don't fit those networks. And as we figure out how to put forward this announcement, we ought to try to make that clear so that it is understood that if you're going to do a head-to-head comparison in a pragmatic way that could be done in one of the networks, and you're not doing that, that might be a problem.

Whereas, if you are actually looking at an area that the networks don't represent very well,

we might be particularly receptive to a free standing application of that sort. I'm just trying to clarify this because I don't think the community will necessarily get that unless it's laid out more clearly.

MS. GOERTZ: Christine Goertz. Just to say that we do actually have this on the agenda for the PDC meeting tomorrow morning, to discuss in more detail. It will be our initial discussion on that, so I'm looking forward to that because I agree that this is an important area and if we are going to try to get something out by January, we're going to be pretty busy pulling this together during that period of time.

CHAIRMAN NORQUIST: So, let me -- Gray Norquist, on the Board. So, Christine, it sounds like for the PDC this is a big issue because you have two general things. One is the topics that are going to be supported. We're not going to be completely all over the place, I assume, in reference to what Ellen was talking about.

And then, also, this explanation -- that

announcement's got to be pretty clear about saying it would be if you could be do it in a very concise kind of way in an existing network, but it may not be possible and what would that be? So this is November whatever it is, 18th -- 19th, thank you. This is going to be tight. Do you think we're going to make it by January to do this? And if so, when would the Board be able to kind of, in general, hear about this before the announcement?

Because, Joe, you were saying you plan on this being January -- I guess, the beginning of January is the announcement.

DR. SELBY: Mid-January.

CHAIRMAN NORQUIST: Mid-January, okay. Any ideas, Christine? I mean, I'm putting you on the spot here, I know.

MS. GOERTZ: Yeah, I actually think that that's definitely a stretch goal, as far as the date goes, especially given the holidays and the fact that we haven't really talked about it. I think we also need to talk about the impact that this will have from a budget perspective if we're

pulling -- if we're going to have this as a general announcement in addition to our other general announcements.

How will that impact our funding line for studies that aren't primary CER? So I think there are a lot of issues that we'll need to cover. And hopefully we'll be able to -- I would recommend that we really focus on a timeline, as well as fleshing this out and having a more detailed discussion about it tomorrow in the PDC so that we could come back to you then, later, Gray, with an answer to your question that would be, I think, a little bit more accurate than I think anyone would be able to give you now.

CHAIRMAN NORQUIST: So you'd be able to tell us on our next Board call if you're meeting in your face-to-face. You should come to some idea about this on a timeline, is that right?

MS. GOERTZ: I think so, don't you, Joe?

DR. SELBY: Yes.

CHAIRMAN NORQUIST: And I think the good news for the -- the key issue here for me are the

people sitting out there waiting for this announcement to come out to do something. So we can signal them that certainly we will have this coming out in January -- we're planning for, at best

-- and we'll do the best we can to arrive at that, right? Okay.

DR. SELBY: Absolutely, that's right, Gray. One of the reasons we hoped that it could come out in January was because it would give applicants an extra month of preparation time between the announcement and the due date. And the due date would be the same as the other broad announcements, with funding in September.

So, thanks. These were the three strategic questions and, my goodness, I think the Board has weighed in on all three of them, but just before we close this presentation, ask whether there's any remaining comments?

Again, a fantastic discussion. Okay. Now I've got to go backwards.

DR. SELBY: Well, Gray was definitely

right that this topic I'm going to introduce now is really -- it's a strategic question that we could address at any point, but it has links to the 2014 budget, as well, so it makes perfect sense to discuss this topic as we lead into the discussion that follows, which is the budget.

So this is about how we make our funding commitments. Not how we spend the money, so much, but how we make the commitments for funding over the next 6 years. As we'll see, expenditures follow the commitments. They follow them, though, with a substantial lag and we'll get into that in a minute.

You don't start spending if you commit $100 million, you don't spend $100 million in the next 12 months, and there's not a lot you can do to speed the expenditures up, other than keep making commitments and waiting a bit.

So, this is the strategic question. By virtue of the way the legislation was written, with its review of PCORI in 2018 and a Congressional decision on whether we continue beyond September

30, 2019. PCORI faces some uncertainty in our planning. It's a simple fact of life. I think the framers of the PCORI legislation had some uncertainty about whether and how PCORI would perform and they reflected their uncertainty into a decision point in 2018 and so that leaves us with some uncertainty. It's not a bad thing, it's a good thing. It's a prudent thing. But we now have two possibilities for what could happen in 2018, in terms of decision-making and we need to plan our commitments in a way that, really, takes account of both possibilities and optimizes outcomes as best possible under either scenario. And that's what this discussion is solely about.

Some background, we are authorized through 2019 and the approximate amounts of our funding each year -- not the exact amounts, certainly, but the approximate amounts -- are known. The PCORI trust fund allows us to carry forward unexpended funds from year to year.

With these several advantages, PCORI is really in a very nice place to allocate our

research funding commitments strategically. We are able to commit future year's revenues at any point in time.

If we could assume, we can't, but if we could assume that PCORI's funding was going to guaranteed beyond 2019, in other words, that the decision would be made to continue PCORI and the trust fund beyond 2019, we would likely aim to commit about the same amount that we took in each year. So, after two to three years, our revenues, our expenditures, and our commitments would all be the same. That's kind of a steady state, but we can't assume that.

So, given this uncertainty, we'd like to work with the Board to plan PCORI's research funding commitments, as I've said, to maximize the useful results during this timeframe and to, really, this is all about insuring the best stewardships of the funds that have been entrusted to PCORI.

So we could consider a variety of approaches and what I'm doing here is, I'm going to

rather briefly mention two what I call options that are at the extremes of what we could do. We find problems with each of those and we have a third middle path, which seems to us to really split the difference between what happens if we continue and what happens if we don't.

So, I just want to emphasize though, before going through the three options that in no case are we talking about making any commitments greater than the revenue that we anticipate between now and September. So we're not talking about committing revenue that isn't already built into the legislation.

And in no case are we talking about making a new commitment after September 30, 2019. So I just want to be perfectly clear about that. So, one option would be to say, well, because there is a possibility that the trust fund will close down. No monies will flow into it; no monies will be able to be removed from it after September 30, 2019.

PCORI ought to just simply aim to expend all the revenue we expect up to that point in time,

by that point in time. So we simply spend our last dollar on September 30, 2019.

We find grave faults with this. It essentially means that we can at this moment in time fund nothing longer than a five-year study and then next year it will be four years, the next year three, two, one, so we know that some critical studies take longer to get accomplished and we'd be tying our hands and not be able to use the resources for the meaningful studies.

It also means that we would have to ramp up the spending dramatically and spend something like $800 million a year for the next two or three years and that seems supremely imprudent and it's really just impossible to do well. So we dismissed Option 1 very quickly.

The second option would be to do as I suggested a minute ago to just set the annual research funding commitment equivalent to the revenue that year. What that would do is it would leave a very large amount of money, particularly since studies can be four, five years long, it

would leave a very large amount of money committed, but not spent on September 30, 2019, and that does not appear to us to be entirely prudent either, to have an immense amount of money still unspent on September 30, 2019.

And the third option, the middle path, is to commit funding at higher levels in the next three years and at tapering levels then through 2019. And I'll show you a graphic now. So this graphic has a lot of information in it.

The first thing it does is it makes a clear distinction between commitments, which is just the awards we make in a particular year and the expenditures. And if you look especially at the years 2012, 2013, and 2014, you see that you can make a very large amount of commitments early on in the life of an organization like PCORI and not spend a lot of money. And that's because it takes a while to get these projects up and running and these projects are three-year or longer projects, for the most part, and they don't spend all of the money that we've committed that first

year.

So take a look at 2014, which is the year we're going to be discussing the budget for in the next presentation.

If we committed as much as it shows here, $528 million in 2014 -- putting that together with the commitments from the previous 2 years, we would still only be expending $129 million. This has all kinds of ramifications. One of the biggest ramifications is the way it makes our program activities look in relation to our expenditures. And an important point is that although we don't count the commitments, when we show you the pie chart in a little bit of the program activities as a proportion of the total expenditures, program activities are going to look high. And the reasons are right there in that 2014 year that, although we are spending a lot of effort prioritizing topics, writing funding announcements, reviewing applications, making awards so that we can commit a large amount of money, that doesn't show up as research expenditures. It shows up as program

expenditures.

And so you'll see that by the next year expenditures begin to approach commitments and by 2017 the expenditures are actually higher than the commitments.

Two other things about this graphic that need to be shown. We have proposed spending more in the three years, 2014 through 2016, and then tapering the spending over 2017, 2018, and 2019. And I'll draw your attention to the year 2014 again and this commitment of $528 million. This is a lot of money. It's a pretty substantial ramp-up from 2013. Staff has looked at this carefully and we see three scenarios by which we can expect, anticipate, estimate that we can expend this money prudently.

But two factors come into play here. Number one, we can put the announcements out that will generate $528 million worth of work, but if we don't get high-quality applications in response, we could fall short of the $528 million in commitments.

We are not driven by the number, we are driven by the interest in getting a lot of high-quality research funded as early as possible, but if we do not get the high-quality research, we're not driven to spend this money.

The second is that other kinds of delays can come up. To spend this much, we'd have to get a number of targeted announcements, we'd have to get the broad announcements attracting good quality research and this third line of funding, these large pragmatic studies, would have to roll out in a very timely fashion. We're particularly handcuffed by the fact that our year got shortened to nine months as we made this transition, so we're talking about by a little over 10 months from now.

So, this is our proposal, but in conversations with Christine and others, we are not wed to exactly this number. What we're wed to is the concept of spending more in 2014, 2015 and 2016, assuming high-quality research, than we do in the latter three years.

And that brings me to the third fact on

this informative graphic and that is that this, what we believe is the most prudent approach to allocating our funding does result in us having made some commitments that call for expenditures of PCORI funds after we close down. So you notice we make no new commitments after 2019, but there are some remaining expenditures.

So imagine if, in 2017, we funded a five-year study, which is what we'd want to do; it goes on to 2022. So that's the fact that we haven't discussed before. It's a fact that we think that there are several solutions to. We don't see this as without a solution, but in the case that the funds would stop going to the trust fund and being removable from the trust fund on that date, it's something that we need to work out and we need to work out soon because we may be making commitments as early as 2014 for studies that could continue at least into 2020.

So, we have initiated conversations with both the GAO and with the Treasury to address exactly how we would handle this situation, which

we think is the consequence of being a prudent funder. We'll also stay in close consultation with Congress and our Congressional staff on this, as well.

I don't really think that we need to discuss the possible mechanisms for handling this until we have those conversations, but we do want to be on record as saying that there will be some expenditures beyond 2019.

Why do we think this is the most prudent approach, this idea of spending more in a higher level of research funding in 2014 to 2016? Well, there's several pros. Number one, it gets more research started early on. And in general, assuming it's high-quality research, we think that's a good thing. There will be more results for the evaluation in 2018. If the GAO has no results on which to evaluate us, they're going to be hard pressed to decide whether we should continue or not.

So, getting a larger body of research completed or near completion by 2018 seems like a

very worthy notion. Getting the funding started earlier really allows us to invest in more longer-term studies, when longer-term studies are appropriate. Having more research underway allows us to identify research gaps quicker and identify trends earlier, so that we can evolve our research agenda heading towards more promising research areas over time. So the point there is just having more research underway gives us more insights, helps us shape the remainder of the agenda optimally.

And the fact that we continue making awards up through 2019 keeps this pre-award infrastructure at PCORI in place against that possibility, which we certainly hope turns out to be the case, that PCORI is continued. So, you know, if we had an approach to funding commitments that said we'll have every penny spent by 2019, that would mean we'd shut down the research infrastructure in, say, 2017. And we don't really want to do that. We think it makes more sense to maintain an infrastructure through 2019 so, if we

continue, they'll be in place.

And the only con -- and we don't necessarily see this as a con, but it is something that needs to be appreciated -- is that is does leave some funds committed, but unexpended on September 30, 2019.

So we'd -- just to tee this up, Gray, we would recommend to the Board not that the Board approve this entire spending plan. We think, really, we'd like to have these conversations with the GAO and with the Treasury before we talk about the entire spending plan. What we'd like to get today is approval from the Board for a commitment in 2014, which is $528 million. We'd like to leave flexible for the moment what we do with this plan beyond 2014, until we're fully able to explore our options. And we'll be working, as I said, with the GAO and Treasury.

So, I'll just close by saying that, yes, $528 million in commitments in fiscal year 2014 is a stretch, as Christine likes to say. And we're open to your comments and thoughts and suggestions

on this, but we think that setting the -- I think I've showed you the pros for why we think taking our best shot at making funding commitments early on in 2014 is a very good goal and if per chance we don't commit all $528 million by the end of September in 2014, the efforts to try to get there will position us to make those commitments very shortly after, in 2015. So that's our proposal and I'll turn it back to you, Gray.

DR. WEISMAN: One question?

CHAIRMAN NORQUIST: Yeah, well -- sure, go ahead.

DR. WEISMAN: Wouldn't the appropriate place for this vote be in the budget discussion, as opposed to now?

CHAIRMAN NORQUIST: We're moving into the budget discussion as we speak. This is the whole point, we go into a seamless -- yeah, we're not going to vote right now on this. We're going to go through the budget and then we'll do this. He's just bring this up to give you some background as we get ready to vote on that. So, I think --

DR. SELBY: Well, actually, we were, but if you'd like to review more parts of this --

CHAIRMAN NORQUIST: Well, no. I think it's more a part of --

DR. SELBY: If you'd like to fold it into the budget discussion --

CHAIRMAN NORQUIST: Yeah.

DR. SELBY: -- we can certainly do that. But I think it's very important to have this number in mind as we go into the discussion --

CHAIRMAN NORQUIST: Right.

DR. SELBY: -- because in many ways it drives the budget.

CHAIRMAN NORQUIST: No, I think they need to see the whole budget as we have the whole discussion about that, but in this context this is a major part of it and I think that's key. I think the key thing here is that we're not going to make any decision about how we operationalize whatever the plan is until we've fully vetted this with the GAO, the Treasury, and the appropriate Congressional committees, right.

So we're all agreed on that, right. And then -- but we do have a budget implication here and we certainly are allowed to make some commitments, I would think, at this particular point in time without that whole plan and what we're allowed to do, basically, being worked out. So that's why this amount of money is up in front of us now.

MR. BARNETT: Yeah.

MR. NORQUIST: So why don't we move -- I'm sorry, Kerry, did you want to -- is this a point of clarification? We're going to move around.

MR. BARNETT: Actually both.

CHAIRMAN NORQUIST: Okay, go ahead.

MR. BARNETT: Just a comment I wanted to make quickly is, we believe that as of the end of September 2019 that there will be a mechanism that will allow us to withdraw whatever funds are in the trust fund at that point that have been committed, but that haven't yet been spent.

We believe that there will be a mechanism in place to do that. But there's some risk. We

don't really know quite for sure and that's the purpose of discussions with Treasury and the GAO. But I don't want anybody to proceed in this discussion to assume that as of that magic date, any funds that are in the trust fund are automatically unavailable to us.

We do know that as of that date there will be no new funds that are put into the trust fund and we're pretty sure that any uncommitted funds that are in the trust fund as of that date will be drawn back into the Treasury, but there is some important clarification that we need to get.

The question that I wanted to ask very quickly is just to make sure we're all on the same page. Joe, when you talk about that expenditure of $528 million, that's over what specific period? From what month to what month? Because there's some confusion around whether that's calendar year 2014 or fiscal year 2014. We sort of talk about it differently. Could you clarify that, that would help everybody.

DR. SELBY: First of all, I've tried

really hard to distinguish commitments from expenditures.

MR. BARNETT: Yes.

DR. SELBY: So these are not expenditures.

MR. BARNETT: Yes.

DR. SELBY: These are commitments --

MR. BARNETT: Are commitments, right.

DR. SELBY: -- and expenditure far short of that, as I showed. These are commitments that we are proposing would be made by September 30, 2014.

MR. BARNETT: Okay, so this is --

DR. SELBY: So in the next 10.

MR. BARNETT: So this is beginning on October 1st --

DR. SELBY: And I'll point out that anticipate something on the order of $200 million of that being committed at our September telephone Board call, through the variety of announcements that will be put to the Board for approval on that day.

MR. BARNETT: So, to be clear, it does

cover a 12-month period, but that's a 12-month period that began on October 1st of 2013.

DR. SELBY: That's right

MR. BARNETT: So we're already a month and a half into it.

DR. SELBY: Right.

MR. BARNETT: Good. Thank you.

DR. COLLINS: Francis Collins. I'd like to make two comments and one about the longer term and one about the fiscal year '14 number. First, the longer term.

I think it's very helpful for us to have this horizon scan in terms of what is the most efficient way to take the funds that PCORI has available and advance the understanding of what works and what doesn't work. That's what we're all about. But if you could back up one slide, I think the option that's on the table -- your Option 3 -- is perhaps --

UNIDENTIFIED: Is this the slide?

DR. COLLINS: Yeah, well, that's the diagram, but actually the one after that which is

the pros and cons -- so, go two forward. Oops. Two forward. There.

I think there's another con here that ought to be thought about and Joe and I have had conversations about other models here and I'm glad we're not deciding this today because I don't think -- from my perspective -- that we've hit on the ideal one yet.

One of the concerns that I would have is, if we drive the decision-making about how to expend our funds solely on how are we going to have something to put in front of GAO in 2018, we may miss some real opportunities in 2018 and 2019. When I think actually our engine for doing these kinds of studies will be getting better and better and so I'm troubled when I see that diagram, seeing the fall off of commitments that could be made in '18 and '19, just at the point where we might have some really great studies that we'd like to do and, oh gosh, we've already kind of made the commitments earlier.

I would prefer, when we have a longer

conversation about that, to take that more into account. And for the con here to actually specifically mention that as a potential risk of the model that's being proposed.

Now to come to 2014. I don't know how $528 million was arrived at, but that's a heck of a big number. And I take your point about, well, okay, if we don't get really good quality research then we won't spend all of it. But, of course, we will be trying to rev up responses in that timetable in order to account for those dollars getting spent wisely.

Going back to what Gray said at the very beginning of the day. We are not here, I think, to try to just do incremental stuff, if we can avoid it. Are we all confident that there's $528 million of groundbreaking research that we could actually be likely to support in 2014, or is that number just a little overambitious and should we think about this as a longer, sort of, two year effort instead of a single year effort. Christine and I had a brief conversation about that -- I think

that's putting a very large number out there without having a confidence, at least for me, that we know it could be spent well.

CHAIRMAN NORQUIST: Christine?

MS. GOERTZ: Yeah, Christine Goertz, Board member. Just a follow-up on the comments that Joe made about some of the concerns that I had and piggybacking on what Francis has said.

I agree completely that the thought of spending -- the process that it would take to spend $528 million, well, is not completely in place yet. That I think it would be very difficult because literally, from my perspective, we would need to get about $100 million worth of targeted funding announcements out the door sometime in February and I'm not sure that we're completely -- it may be difficult to do that, let's just put it that way.

And also, we haven't really talked about what the implications are for moving towards more pragmatic trials. How will that impact our general funding announcements, because if we leave our general funding announcements more or less at the

level that they are now, but then put an additional $60 million towards pragmatic trials, basically we may be increasing the funding line for our other general announcements because we've taken a big pool of what might have been included in those and put it aside.

And so, maybe, maybe not. But I think it's a discussion that we have to have that we haven't had yet. And so, my thought is, I think it would be possible to commit to spending $1 billion over two years well, it gives us more opportunity to ramp up, as we'll discuss when we talk about staffing. We're planning a fairly large staff ramp up, so right now -- between now and February, when we need to be getting these funding announcements out, we're going to be hiring a lot of staff. We're going to have a lot of other things going on where we may be able to do this more simply and at a higher level of quality if we just give ourselves the possibility of a little bit more time.

Now, I'm not in any way suggesting that we don't move full speed ahead and to move as quickly

forward as we possibly, possibly can. I think that that is critical and that we absolutely need to do that, but I think that as we move forward as quickly as we possibly can that funding very high-quality, high-impact research needs to be our very top priority, rather than feeling that we're somehow caught having some sort of a spending goal that we have to achieve.

DR. SELBY: Could I just say briefly -- thanks, Francis and Christine, for those comments and they make a lot of sense and, frankly, we were bringing this to the Board just for this kind of input. So it's very useful. I particularly do like the idea of thinking about the two-year interval and thinking about spending in a two-year timeframe.

And, Francis, I also appreciate and think we need to deliberate more on your concern about having expended nearly all of our resources before we get to 2018 and 2019. So both of those comments are really helpful.

CHAIRMAN NORQUIST: Do you have a comment,

Allen?

DR. DOUMA: Allen Douma. I just want to reinforce what we've just heard. I think it's really important that we determine how we're going to get bang for the buck. What we're going to spend it on before we figure out how much. And I think that's a part of the discussion and the rest of the budget, perhaps we need to have more dialogue about, as well.

Just one thing, in showing the bar graphs there, going forward I think it would be helpful if we had all of the other expenditures, not just the research, on a year-by-year basis, as well. Because then it's going to make us address how are we going to spend money on the support system in 2020, 2021, et cetera. So, if you could just add that number in there -- realizing that number will change toward the end of the five-year or seven-year timeframe, as we're winding down a little bit, but guesstimates are better than just a blank.

CHAIRMAN NORQUIST: Ellen?

MS. SIGAL: So I agree with everything

that's being said, but one concern I have -- and it's just a practical concern. If we wait too long, I wonder whether we can get any answers to anything that we have established in the last two years because everything that we're looking at now we're already getting squeezed because most of the things are going to take three to five years to get an answer, so I just would caution us to be very careful about if waiting too much at the end and we'll -- you know, if the research goes on, I guess that would be important, but then we won't have the infrastructure to implement any of them or to disseminate, so it's a complex issue we have to deal with and we can't do that now.

CHAIRMAN NORQUIST: Steve?

VICE CHAIRMAN LIPSTEIN: Steve Lipstein. So the conversation is fascinating and interesting because I can recall over the last three years where we've believed we've been spending too slowly and now we're having a conversation about spending too quickly.

And so I guess, Joe, the challenge and

what I think Christine is suggesting is that if we look at this two-year frame, we can spend just right. You know, not too hot, not too cold, not too fast, not too slow.

But the interesting and unique feature of PCORI that we have to keep in mind is that, unlike most research institutions that go on in perpetuity, we don't have the opportunity to level fund because if we level fund, we may actually end up at a disadvantage or not fulfilling our responsibilities. So because we have to bolus those funds probably in the next window of years, '14, '15 and '16. How we titrate this to get it just right is important and I think if we follow the wisdom here, which is that PCORI's going to do good research, consistent with our methods and the scientific rigor that we put in place and the engagement rules that we put in place over the last three years, we can spend it just right over the next couple of years.

So, as long as we let that be our guideline, I think we'll do okay. But we have gone

through these phases of too slow, too fast. I think we've built our platform now that will allow us to do it just right.

DR. LEVINE: Just a clarification question, Kerry, for what you said earlier. Can we, with money that we have in the early part of 2019 -- can we make multi-year commitments?

MR. BARNETT: I mean, we all have to understand that there's no other organization out there like PCORI. So whenever these questions come up, they're almost always a question of first impression, as judges like to say.

So it's hard to know what the definitive answer is going to be and we're having these dialogues with Treasury and GAO, but when we ask the questions of them, it's not as if they go to a manual and look up the answer. They scratch their head and say, well, golly, we're going to have to figure this out.

We believe that logically the nature of PCORI is such that there's an expectation that we're going to use this money appropriately by

making commitments and then wisely stewarding the money over the course of that set of research activities. And so we think it's sort of built in to the concept of PCORI that we would be able to make these multi-year commitments and then service those commitments, even after September of 2019.

We have drawn money out of the trust fund in order to create reserve to meet liabilities that we have, as an organization. We already have that in place now, so we think that's an important precedent that shows that if we can point to the commitment -- to a contract, to a liability -- that we should be able to take that money out of the trust fund and hang onto it in order for us to be able to service that commitment.

DR. LEVINE: So the second part of that is, so who would be doing the stewarding of those grants in 2020, '21, and '22?

MR. BARNETT: Well, it is important to note --

DR. LEVINE: Where would they live?

MR. BARNETT: -- that with the sunset that

we keep referring to is a sunset on the trust fund. There is no sunset on PCORI as an organization. We are a separate, independent organization that's been incorporated under the nonprofit law of the District of Columbia, so our existence continues on. I mean, that's really important to note.

So either we or a sister organization or a grantee of ours could play that role of stewarding those resources throughout the life of that commitment. And that's a decision that I think we're going to be confronted with several years from now to begin to make some real call it estate planning decisions about how we're going to carry that out over time.

CHAIRMAN NORQUIST: So let me just reiterate -- and when we say "we," we don't know exactly -- I think all of this, we have to clarify with the GAO and other appropriate entities to make sure that we all are holding the same opinion, as they would say, whatever the Supreme Court may be in this case, right? Larry?

MR. BECKER: So, Larry Becker. So

summarizing what I think I've heard around the room is, we should fund as much high-quality research as we can with perhaps the caveat up to $528 million.

CHAIRMAN NORQUIST: We'll see if that's what everybody -- but we should always be funding high-quality research, regardless of what the --

MR. BECKER: Right.

CHAIRMAN NORQUIST: Okay. So we're going around here. Debra, Kerry, you're next, then.

MR. BARNETT: Yeah, if I can just comment on that? I think we're saying a little bit more than that. I generally agree with what you're saying, Larry, but I think we're saying a little bit more than that.

We're not saying to staff, as part of this budget setting process, go off and spend as much as you want, as much as you can do so effectively, but it's capped at $528 million. I think what we need to do as an organization is set some expectations as to the pace, as to the rate of spending.

My concern about our financial performance over the last several years is not that we've ever

been in danger of overspending, it's that we've consistently underspent. We have wildly underspent, if you want to think about it that way. And what that has reflected is that our eyes have been bigger than our stomachs. When we've created our strategic plans looking forward, we've talked about as set of activities and then we haven't been able to put in place that same level of activity and, frankly, I think we would all prefer that we had gone further faster.

Not to start just pushing money willy-nilly out the door. Certainly, none of us favor that. But I think what we need to do is create a set of expectations for staff and for the organization that this is the level of activity in spending that we think that we can sustain as an organization, and that's what we're going to set out to do.

And that's why I think we should all be very, very sensitive to the comments of Christine and Francis about making sure that we set that level of expectation as something that we think is

truly doable. Whether that's $528 million or 500 or 400, or whatever the number might be. But let's kind of set those expectations and then let's make sure we all hold ourselves accountable to meeting those expectations.

MS. BARKSDALE: Joe, could you go back to the bar graph? First, I just want to say I really appreciate this plan and the thinking that went into it to try to project a world that we don't know in 2019, or even tomorrow.

My question is, I see the 528 for 2014 and then 503 for 2015, are those new commitments for 2015 or is that some culmination?

DR. SELBY: Yeah, thanks. If you just look at the blue, every one of those blue bars is the commitments -- the new commitments made in that year. So here -- one little thing to help your thinking maybe is that if you added up all of the blue bars and then you added up the dollars in all the red bars, they come to the exact same amount to the penny.

So we make the commitments in each of

those years and then those expenditures we project that's what would happen given those commitments. Does that answer your question?

MS. BARKSDALE: Yeah, thank you.

DR. SELBY: Yeah, the simpler answer to your question is, yes. The dollars in 2015 are new contracts awarded.

MS. BARKSDALE: Thank you. In my mind, an approach like this makes sense given that after 2019 or 2020, whenever, if PCORI ceases to exist as we know it, there could be some challenges to the goals -- the mission that PCORI has set. Particularly if there's some other entity that would be ultimately managing the grants, the funding. So that's my two cents' worth.

DR. SELBY: And that's exactly what we want to discuss with GAO and Treasury is how we do service -- as Kerry says, service those commitments, those years.

DR. ZWOLAK: Bob Zwolak, Board. I listened with interest at Francis' comments and I absolutely think we have to spend responsibly, but

I think we need to be aspirational in terms of our research support goals and in terms of our staffing goals and whether this is exactly the right shape of the curve or not, but I don't know. And I think that the curve will depend on each six month's or each year's spending as we move forward and spend on research responsibly.

The shape of this curve will change, but in general I support the idea of sort of the spend forward -- or the commit forward. It's not -- it's a spend backwards, but it's a commit forward.

MS. GOERTZ: Christine Goertz. Just one point of clarity is that when I'm thinking of a two year research commitment budget, my suggestion is actually that we are always on a two year research commitment budget, so that we're always looking two years ahead as we're funding in the future. And I think that will -- it's very important this year and would continue to be almost more important as we're looking forward towards this sort of a ramp down, but as we may be putting together a total PCORI annual budget, but always thinking about what

our research commitment spend is going to be, not only that year, but he following year, as well, because it's just really difficult to do it the way that we're doing it now where we're already in the fiscal year when we're trying to figure out what our research commitment is.

DR. WEISMAN: The reason I asked about the motion and whether it was more appropriate to have it in the budget discussion was that high-quality research which, clearly, we're all about, is only one of five of our imperatives.

The other four imperatives are equally important and are really dwarfed by this and that may be totally appropriate because research cost a lot, sort of, compared to effectiveness research where what we want to do is very expensive. But I wanted to make sure that -- not so much in dollar amounts, but in effort amounts. And are we maximizing what we could be doing in engagement, dissemination, the creation of research networks, information systems, all of the infrastructure things that we think are important?

Part of that is in research, part of that is in creation and if we only have -- you know, Ellen, earlier was suggesting that we can't forget the research, which I totally agree with, but we also can't forget the other things. And that context of how we spend and when we spend I think has to be incorporated into this thinking.

DR. SELBY: Thanks. I think that was Allen's comment, too. And, really, the discussion we're moving into now, the discussion of the budget, it really opens up what you're suggesting that we're going to be talking about our expenditures for every imperative.

So, Steve, I think we can move --

VICE CHAIRMAN LIPSTEIN: Can we open that up?

DR. SELBY: But I wanted to just say one thing. I think it's important for us to be very clear that we put on the agenda that we posted on the website that there would be a vote associated with this discussion item, to approve the $528 and we've heard a suggestion from Harlan that we

abstain from voting at this point and build that into the budget discussion.

VICE CHAIRMAN LIPSTEIN: We'll table it, not abstain it.

DR. SELBY: Thank you, buddy, I was searching for the word.

VICE CHAIRMAN LIPSTEIN: We will table it. And let's move into the discussion. Gray had to step out briefly, and asked if I would moderate in his absence, so can we go into the budget presentation?

DR. SELBY: Yes, and Regina Yan is going to make that presentation. I just want to thank Regina and Pam and, really, all of the chiefs and directors for their part in putting together what I think is a very tractable budget to guide our discussion.

MS. YAN: Okay, we're presenting to you today the draft or the proposed 2014 budget for your consideration and approval. And I'd like to thank all of the Board committees, members who have been helping us the last couple months, looking at

different versions of the draft, giving us comments, suggestions, and very critical questions that have helped and guided us to this point today.

One thing I would also like to say, that throughout the fiscal year there will be a quarterly financial report to the Board, as well as a mid-year budget review that we'll be doing with the Board, so in case there's any major changes to our assumptions there will be a chance for us to make a modification or adjustments, as needed.

As we developed this budget, the strategic question that we're looking at is whether we are making appropriate resource allocation to support our strategic plan and also our organization priorities for 2014.

Our fiscal year budget requires the approval from the Board of Governors and, in September, the Board has approved a change of our fiscal year from calendar year to a fiscal year ending September 30th and that will allow us more reasonable timeline to finish our annual financial audits and to meet the deadline for annual report

to GAO. So our fiscal year 2014 actually has already started on October 1st. Since October to December, a budget has been approved previously under the old fiscal 2013. That's the budget we are using right now, until the new budget is approved by the Board.

The strategic plan and our priorities are the foundation of our budget and operating plan. This year all the departments prepare a detailed operating plan with all the major activities and all those activities have to tie to our strategic priorities and based on that, we developed the budget. Because we want to make sure that our resources match our activities and that matches our priorities.

And there a several key drivers of this proposed budget. One is our projected funding commitment for 2014 and 2015 because that drives the resources and personnel required to develop all of those PFAs and to support the merit review. And also the resources required to support our growing portfolio. Right now we have already made 200

research contracts, so we already have 200 funded projects that we need to service and we need to support. And with the active portfolio management, we want to make sure that there are sufficient resources there to support this portfolio.

And so far, the last couple of years, we've have devoted a lot of resources into supporting making the funding commitments. And now we have a pretty sizable portfolio, we need to devote more resources to now monitor our portfolio.

Another key driver is the level surfaces we want to provide our applicants, our reviewers, and awardees. We have online training, so developing to all of these stakeholders, we have webinars, we have online help desk and, with the suggestion of the Board, that you've urged us to also open phone lines to answer questions. So all of these required human as well as system support.

And lastly, this is also a very critical year for us to solidify our infrastructure, both in personnel, as well as systems, to really support the work that we're anticipating in the coming

years. Particularly in the IT systems. We all know very well that when we don't deploy our IT systems adequately, it creates all kinds of problems and we have already, with our own experience, experienced some glitches in our system, so we want to make sure that as we try to complete the development of our systems that we have adequate and skilled personnel to support it.

Here is a general overview of our 2014 proposed budget and our projected revenue for 2014 is $412 million and that includes the appropriations, the funds in the trust fund, as well as the PCORI fee that we're collecting.

And the projected funding commitment is $528 million and we've already had a lot of discussion on that and it is a stretched goal. And we are also in 2014 planning to make a commitment of $15.5 million in our engagement awards. And, obviously, these are multiple-year awards, so we expect the payments to be made over time.

In preparing this budget, particularly in

building the human resources, as well as our systems, we are looking at this multiple-year projection of our funding commitment, as well as our spending to determine what kind of infrastructure we need to build to properly support it.

This is a general overview of the major breakdown of our 2014 budget. For 2014, we're looking at a budget of $182 million, all of which -- $106 million -- will be in research spending against this, with our budget because we award contracts, so in our budget we don't reflect the commitment, but rather the spending that we are projecting anticipating during that period.

So the 106 would reflect the research spending, research award spending, as well as the projected spending in our engagement award. Obviously there we also have of our evaluation activities there.

And $46 million in program support -- I will go over the details later -- and $30 million in general administrative support. Some may say,

well, you know, it looks like the program support and administrative support occupy a very big piece of our pie, but again, since this budget is kept during the spending, there's a lag time in our spending based on our commitment. We also want to show you next year, based on the commitment that we've made last year and this year, we'll be looking at a substantially bigger piece of pie as far as the spending is concerned.

So, assuming that if our program support and our general administrative support experience marginal increase, the pictures look quite differently next year, based on all the commitment that we are making so far.

Here is our 2014 budget in broad categories. I want to kind of go over it with you very quickly. Under program expense, we have research expense, which is $101 million. And also a projected expenditure for engagement awards is $4.6 million, so our total research and engagement spending is at $106. And for program support, again, the program support refers to all the costs

associated with directly supporting the program -- to make the program happen. That includes our cost in our science department, program development, all the cost associated in topic generation, PFA development, supporting merit review, and also evaluation, that's $23 million.

Methodology committee, $2.7 million; engagement, 7.6 -- that includes all the workshops, roundtables, and various activities that they have; and contract management, 12.5. For contract management, the 12.5 includes all the costs associated with running the merit review process, including training of all of the applicants and the reviewers, as well as running the merit review meetings. We do it four times a year and we have one going on this week. We just had one 10 days ago and every time we're bringing together over 200 reviewers and that is a very big operation. And this line item also includes our reviewer stipends.

So the subtotal for program support is $46 million. In addition to that, our administrative and general management expense is $30 million and

that adds up to $282 million for our proposed 2014 budget.

And obviously this is also a critical year for us in building our infrastructure and our personnel is a very key part of our infrastructure and of course, we're just not starting it now. We have been doing this last year. You know, we have already pretty much doubled our personnel in the last six months. We need to continue to do that in order for us to have sufficient human resources to support the work that we have to produce. And this year, in addition to making commitments, again we have to service the portfolio that we have, as well as focusing on performance measurement that we have to report back to you, on a quarterly basis, the results.

So on November 6th, this is all of the head count that we have. We have 88 employees and we propose that at the end of September 2014, which is at the end of fiscal year 2014, we have personnel of 164.

VICE CHAIRMAN LIPSTEIN: Regina, just

before you move off this slide, I would just like to have a piece of information -- what's the [off microphone] count for contracted personnel right now?

MS. YAN: That's the next slide.

VICE CHAIRMAN LIPSTEIN: Oh, never mind.

MS. YAN: Okay, here is a slide on employee and also contractors. Again, the dates are a little bit off. The one I showed earlier is from November 6th, so if you look at 2013, we have about 83, and we have about 50 contractors. 133 head count. In 2014, we are looking at 164 employees which will bring the contractor head count to 13.

One thing that we do in preparing this budget and also looking at how many employees we have, is that for ongoing functions -- functions that we think that we will need for at least a couple of years. For example, the scientific review officers. Right now we are using contract SROs, which is important to us. They have helped us -- allowed us to do our work the last year and a

half. But we know that we will continue to need that function, so right now for 2014, we're actually building in 10 employee positions so that we can have staff SROs to support our merit reviews, so we can reduce our contract support. And we will only use contract SROs for overflows.

And so that's what we do with all the contract positions. And, of course, you know, there are still important functions that contractor play, particularly for discreet activities that we need.

So -- but the thing is, if you look at the dollar amounts, 2013 and 2014 -- if you look at the employee and contractor clause, the total is about the same, but the difference is that because we will be converting some of the functions into employee positions, so we can really reduce the contractor counts and increase the employee counts with more or less the same amount of funds.

I think the most important thing is, we have to think of what is in PCORI's interest, as far as the function is concerned. So, with that,

we will seek your approval of this proposed 2014 budget.

VICE CHAIRMAN LIPSTEIN: Regina, before I turn this back to Gray and let him get his sea legs about him, could you speak to what you and the staff believe are the key execution risks in this budget. So, we've talked a little bit about this in terms of whether or not we can stay to the pace of a funding commitment and, as Kerry mentioned a minute ago, in years past in underspending our budget --

MS. YAN: Yes.

VICE CHAIRMAN LIPSTEIN: -- it means that we haven't been able to go at the pace that we would have initially set at the beginning of the year, so before we get into either a motion to approve the budget and then discussion, can you speak to what you believe are the execution risks?

MS. YAN: Yep. I know there's a lot of questions about whether we will be able to manage this pace of growth. And what this pace of growth means to us and what kind of negative impact it

could -- because when growth is so rapid, sometimes it can be quite destabilizing. We recognize that. This is not a new problem for us because we lived through it this last six months, but we are dealing with it and recognizing the challenges.

One thing is that, compared to six months ago, now we have four executives versus two. So we have at the leadership level additional capacity to manage these changes. Another thing is also that in the last six months, we have already pretty much doubled our size and we also have filled some key positions, some key managers positions, and those managers will also be managing some of this process, so as a result, some of this burden will be spread, so we have actually more people who can process the hiring and also the employee on-boarding and training.

And we are also rolling out employee on-boarding programs, as well as staff training programs. We are working very hard in building our systems, making our policies and processes more explicit. We hope that these will help address

some of those risks, but you're right that, you know, we need to be aware that we may not always be able to deliver at the level that we wish to, but it is something that we're keenly aware of.

VICE CHAIRMAN LIPSTEIN: Before we open this for general discussion, are there questions? Does anybody want to ask a question of Regina to clarify information that's been presented or greater clarity? So there's one at Allen and there's one at Arnie and there's one at Francis. This is the question time. So, Ellen, did you have your card up, too, for a question?

MS. SIGAL: Yes, but it's not a clarification, although I think it's really on the absorption of the personnel, so do you want me to defer that until later on?

VICE CHAIRMAN LIPSTEIN: Yeah, I'd like to just get clarifying questions off for now. Allen, do you have a clarifying question?

DR. DOUMA: If you could go back, the one you showed the staffing, the numbers, and the monthly spend? My question -- I have a two-part

question. One is --

MS. YAN: That one?

DR. DOUMA: No, the one you just -- that one. Yeah, the monthly spend, is that salaries, benefits, overhead? What's included in that number?

MS. YAN: That's mainly salary.

DR. DOUMA: Mainly, meaning only salary?

MS. YAN: For the personnel, for the staff.

DR. DOUMA: Okay. It would be useful to have all of the other things rolled into one.

MS. YAN: Okay.

DR. WEISMAN: In terms of your fully loaded cost of an FTE, do you have a formula that would work? I mean, is it like 25 percent more than salary? Or 30 percent more? What --

MS. YAN: You mean including the benefit and all other costs?

DR. DOUMA: And overhead?

DR. WEISMAN: I'm talking about an FTE to PCORI, which is salary, benefits, all the things

you said, plus --

MS. YAN: Facilities and all of those things.

DR. DOUMA: And retirement, et cetera, et cetera.

VICE CHAIRMAN LIPSTEIN: So, I think what they're asking for, Regina -- and you may not be able to do this now -- is just fully loaded staff costs in the second column, so they can compare that to fully loaded contractor cost in the third column.

MS. YAN: Okay.

DR. DOUMA: And a second follow-up is, when you're talking about 2015, we have a number for 2014 $2 million, whatever, and that then will build based on what we were just talking about, but a lot of these people are going to be hired in 2014. Do you have a number which is, what -- if all things being equal and there's no new hiring in 2015, what the costs would be?

MS. YAN: For 2015?

DR. DOUMA: For 2015, because we're

building in a growth from '14 to '15 simply because we've got another 50 or 100 people on board.

VICE CHAIRMAN LIPSTEIN: Right. So what Allen, I think, is alluding to is that, as you staff up you're not going to have a full year operating expense --

DR. DOUMA: Right.

VICE CHAIRMAN LIPSTEIN: -- because you going to be bring up people during the course of the year where, beginning in 2015, you will have a full 12 months of expense. Is that your question?

DR. WEISMAN: Do you know the ramp rate? Is there --

DR. DOUMA: Yeah, assuming we're not going to hire another 50.

DR. WEISMAN: Is there an assumed ramp rate in the 2014?

MS. YAN: Shall we --

DR. WEISMAN: [Off microphone] we want to have everybody in progressive order, so --

MS. YAN: Do you want us to answer all the questions now or --

CHAIRMAN NORQUIST: This figure is monthly.

VICE CHAIRMAN LIPSTEIN: Yeah, yeah. So let me just restate the question, since Harlan didn't have his microphone on. What he wanted to know is, in your budget for 2014, did you assume 12 months of salary for the 164 positions or is this a phased-in number?

MS. YAN: It's a phased-in number.

VICE CHAIRMAN LIPSTEIN: Okay, thank you. Arnie?

DR. EPSTEIN: Yeah. Arnie Epstein, Board. I don't want to overcall the importance of benchmarks, but I'm just trying to understand how we stand, compared to other funding agencies? And we've got administrative expenses of 16 and how much discretion is there when different agencies lay out their categories?

Stated differently, is contract management always program support, as opposed to administration or are there benchmarks? And how do these numbers compare, really? Understanding that

we may not want to match everybody else.

VICE CHAIRMAN LIPSTEIN: Right. So, Arnie, I want to add in here a little bit. So, what's really key about the benchmarks -- and I want to encourage both the Board and those listening -- is you would have to benchmark us against a research institution that was in its third year of existence. So if we go back, there are references here to the Robert Wood Johnson Foundation or the Commonwealth Fund or other private institutions. If we go to their third year of existence, when they were ramping up their infrastructure, you would have found much different benchmarks for some of these categories of spending.

The same is true if you wanted to benchmark us against federal agencies that rely on the entire federal government for overhead support, where we're a very self-contained organization that is separate from the government structure. So, we've talked about benchmarks exclusively, and Kerry, you may want to comment on this, but there

really isn't an external benchmark that you can look at that would be -- well, you're a scientist -- you'd have to control for the variables that differentiate one benchmark from the next.

So, Kerry, do you want to speak to this since your committee talked about this a little bit?

MR. BARNETT: Larry's the guy who I think really drove this, but that's exactly right. I mean, I think everybody throws around different benchmarks and the question is always, well, what's the denominators? Everybody's talking about a common denominator and it has everybody throwing the same things in the numerator. Go ahead, Larry, you're the expert on this.

MR. BECKER: I don't have much more to add, but I think Steve's exactly right. I think that trying to get to apples to apples, do you throw in facility expense? Or benefits would go in, so what are we benchmarking? And I think that we've done as good a job as we can, given where we are to get to a sense.

I think the real question that's being asked is, is $2 million in the lower right-hand corner a number, when you look at 2015 and you look at 164 staff, what does that number really look like ongoing? And what does that represent in terms of a percent of our expense?

VICE CHAIRMAN LIPSTEIN: And, Arnie, the other thing that I would add is that in the budget there are a couple of productivity benchmarks. There's one science officer for every 20 projects and there is one engagement officer for every 200 projects. And so what staff tried to do was find productivity benchmarks that would be relevant to the work that we have to do over the next year, as opposed to just looking at categories of spending.

And so, I don't know if somebody can speak -- maybe Joe -- somebody can speak to where those two productivity benchmarks came from, but they drive the staffing. The one science officer for 20 projects and the one engagement officer for 200 projects, they drive the staffing model. So maybe somebody could speak to where those two come from?

DR. SELBY: So those come from conversations we had with AHRQ, NIH, and with the Commonwealth Fund, and indirectly with information that came from Robert Wood Johnson Fund, as well.

And, essentially, our staff to spend ratio once we get to 2015 looks lean -- it looks quite lean, compared to all four of those. But, again, it is an apples to oranges kind of comparison in many ways, but it is very safe to say that the current projection of 164 staff is really quite lean.

You know that in the last two months we've trimmed back from 186 to 164, and even the 186 looked lean. So I think, in terms of staffing, which largely drives the piece of the pie that's not research funding, it's not out of line. And the reason that in 2014 is looks so out of line is precisely what you said, that we are a startup and none of the others are startups and we're making huge commitments and we don't get expenditures until out years.

The other thing is, I think -- and Pam or

Regina might be able to respond to this a bit more; it's to Arnie's question -- there are some standards for nonprofits in terms of calculating what is administrative cost and I think adhere to those standards in making our estimates or defining administrative costs. But that having been said, there's lot more debate today than there was a few years ago about whether there is an optimal ratio?

And it has a lot to do with what else research funding organizations do. And there's a very wide variety in terms of what these ratios turn out to be. It needs to be said here that we have decided from early on that one of our strategies for Goal Number 2, for speeding the implementation of research is engagement. So we have an engagement department which I think few other funding agencies formally have and it's not flush, it's not huge, but it's big enough to do the job and it does contribute to program costs and we're very proud that we have it.

So you can say that our program costs are always going to be slightly bigger than they'd be

if we hadn't decided that a key strategy was engagement.

MS. YAN: I just want to add a word about the staffing model on science, back to your questions. One thing is, you notice there's a significant discrepancy between the ratio for the science staff and the engagement officer they were proposing.

One thing is for science staff, the way we're looking at is they spend half of the time in PFA development and then the other half of the time is managing the portfolio, so that there's two substantial pieces of work for them. For the engagement officers on the pre-award side, on the PFA development the work load is not as heavy as the scientific officers.

VICE CHAIRMAN LIPSTEIN: Great. So Francis, then Sharon, and then Robin.

DR. COLLINS: So, Francis Collins, Board. A clarification question again about what's being presented and, obviously, we are already well into FY14, so it's good we're having this discussion and

we do need to make a decision.

Given the conversation, Regina, that we had a few minutes ago in the earlier discussion about the uncertainty about whether in fact we can be confident that there is $528 million worth of high-quality research that we can get out the door, as far as commitments, and therefore expenditures will start as well in FY14. I'm a little worried about blessing this precise plan, especially with Christine's comment that she's not confident from the PDC perspective that we can get PFAs out the door that will add up to that kind of number.

But obviously this is a plan that we work with in reality, so my question is, if we actually can't manage that? If the idea instead of working with two-year budgets -- which I like a lot and I wish we had that at NIH, believe me.

If that is sort of an idea whose time has come, does that influence our ability to make a decision today about the FY14 budget or can we work with what you've put forward, with that contingency in mind?

MS. YAN: One thing about the $528 in our 2014 commitment is that we are already doing merit review right now and in a few weeks, on December 17th, we plan to present to the Board about $196 million of awards. So out of this 528, 196 is ready to be presented.

And then, in June 2014, we have another award cycle coming up. So right now at this moment, if you look at the end of 2014, we only have one more funding cycle that we need to announce, which is the one in January/February. As I understand, it's going over the numbers and some of the targeted initiatives with Bryan and Kara and I think out of the 528, there may be between 60- to $95 million that still need to be determined.

So we should know pretty soon whether some of those will go forward and if we are not being able to announce all of those, then we are doing four cycles a year. So if some of those won't be awarded by September, then the next on is December 2014.

DR. SELBY: If I could just --

MS. YAN: So I think that the two years research plan is very much welcomed by the staff and I think that's a great planning tool for us

DR. SELBY: And just to respond to Francis' question, with a little additional information or impression, at least. You know, we're driving toward being able to commit $528 million. We're doing the work to get toward that.

We're doing all of the expenditures that we project -- that then take staff support -- will happen. Since many of these commitments that we make in 2014 really aren't the expenses of 2104, they're the expenses of future years. So I think the answer to your question is, even if we do not commit the full $528 million in 2014, I think this budget that's been put on the table is the budget that we need to put into place.

A logical consequence of saying we may not hit $528 million is not that we should lower the budget.

CHAIRMAN NORQUIST: Sharon?

DR. LEVINE: Just a quick question. On

page 149, where you've got the administrative expense budget highlights, does that represent the sum of the specific line items that are in each of the program development areas? So, you've got $30.1 million for administrative expense budget highlights

VICE CHAIRMAN LIPSTEIN: That's the 16 percent group.

DR. LEVINE: Right, right. So is that the sum total, does that incorporate the line items in, for example, science program development and evaluation? Does that $30 million include those line items that are under the research program? Or the Methodology Committee?

VICE CHAIRMAN LIPSTEIN: No.

UNIDENTIFIED: Because they're just administrators. It doesn't include programs.

DR. LEVINE: Well --

MS. YAN: Yes, science and engagement and the Methodology Committee, as well as contracts management, they are under program support. So the $30 million is only referring to the general and

administrative support.

DR. LEVINE: Okay, so where it says communications and administrative under Science Program Development and Evaluation, that's a separate number?

MS. YAN: Yeah, that refers to the communications activities that are directly associated --

DR. LEVINE: With the program.

MS. YAN: Correct.

DR. LEVINE: Okay, and then just a question as to where the dissemination and implementation budget is in here?

MS. YAN: That is the science budget. It's part of the science budget. Where you look at $23.25 --

DR. LEVINE: Okay.

MS. YAN: I want to quickly go back to a question that Arnie asked about the three major categories of expenditures that we use, which is program, program support, and general administration. Since we're not a government

agency, these three major categories are pretty much a standard categories a nonprofit would use.

VICE CHAIRMAN LIPSTEIN: Allen -- I'm going to go to Robin, but I'm stealing Allen's, and since Allen's question I know is going to be relevant to what Sharon just said, because one of the things that we talked about yesterday was, some of the line items in the budget appear to be place holder numbers, where you don't yet know how you're going to spend the money -- communications being one of them.

So, I guess the question -- because Sharon brought it up in the context of, there's a communication line item in almost every program area. How much of that is just place holder, how much do you know what you're going to be spending money on, and how will the Board know what you spent your money on? Is that a good way to rephrase it, Allen? Did I do it right?

DR. DOUMA: You've done a great job, thank you.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: Yeah, okay.

DR. LEVINE: Pre-phrase it.

MS. YAN: I will have Pam, my partner here, help me answer the question, so we've talked about that.

PAM: Actually, the answer is that we have just applied percentages based on historical data. We've just concurrently finished switching over our records to cost accounting, so what we didn't have last year is any breakdown of expenses that would specifically allocate the communication cost, which came out of the communication budget to specific workshops or projects or whatever.

So that's something moving forward, now that we have some data we're going to be able to, as we work through '13, be able to be very specific about those costs, by project and event.

MS. YAN: Some of the corporate communication expense, for example the redesign of our website is part of our general administrative expense.

VICE CHAIRMAN LIPSTEIN: I'm going to keep

going in order. I'm going to go to Robin and then I'll come around, okay?

MS. NEWHOUSE: Hi, Robin Newhouse, Methodology Committee. And this is really -- Regina, we've talked. So this is really just verification for the Board. And the Methodology Committee budget is smaller than it was last year, but part of the reason for that is that we're doing so much in partnership with the Board. For example, the patient reported outcomes workshop and some of the work we've talked about in the decision support that's already come up.

So it's been taken out of the Methodology Committee budget and now is shared in other places. But also today I've heard a couple of opportunities for the Methodology Committee to engage in some of the strategic priorities. Two of which were around peer review of decision support, protocols and guidance around efficient pragmatic trials in coordination with the network. So the way that it was explained with the Methodology Committee was that these kinds of issue and items will be covered

also under other budget items. That we don't have to budget them under the Methodology Committee, that they'll be covered under other initiatives.

I felt confident after a discussion with you that these kinds of innovative and important work that would be designated in coordination with the Methodology Committee would be covered under other means.

MS. YAN: That's correct.

MS. SIGAL: So I'm supportive of what you're doing. I understand the need and I agree that this is much better to have the personnel rather than contract a third party. However, I am slightly skeptical and worried about how this is going to be done in one year? I think it's almost physically and maybe emotionally impossible, so a clarifying question and then let me get to some other issues on it.

So, we are out of space, so we need more space. So, just the physical place we're going to put these people is important. I assume in your budget you do have the cost for the build-out and

for the rent and for the computers and the personnel cost -- all of these things -- in there as a line item, so it's not just the additional personnel, it's the cost that will be incurred because of it.

But I guess, assuming all of that is worked out and you know where you're going to put them, I just think you're going to have to really, really think hard about how you're going integrate these people. How you're going to train these people? How personnel systems are really going to be managed, because this is really going to be a challenge.

And just having more supervisors or more executive isn't going to do it because everyone is incredibly busy right now and I wonder if there isn't -- God knows, a contractor, but someone that can help you with the integration of this because that can be a disaster, just even hiring people -- going through the ability to check references, just get them on board, training. So I'm just worried about this incredible amount of people in this

short a time. And just whether this can physically be done and, frankly, they can be integrated so they are useful to the organization?

MS. YAN: One thing is, we have incorporated the associated facility cost for the additional personnel in our budget. So that is in there. We are very cognizant about the challenges. Obviously, we are talking to a landlord in a building about additional space. We, as far as assimilating employees concerned, we are planning staff training, staff retreats, we also have a contract recruiter that we are using to help us recruit new employees and we are not putting into our staffing plans recruiters on staff, mainly because we expect in 2015 that the pace is going to taper off, so we will -- in this case, you know, we think using contractor support will be appropriate.

MS. SIGAL: Well, I just would remind you that recruiters get paid by putting a lot of people in, and so the due diligence that one has to do has to be done by staff because it's not that they're going to give you bad people, but they get paid by

placing people. That's what they do.

And just reference checking and just all of that is just extremely consuming and I just wonder if this is really achievable in the period of time that you want.

And then, again, getting back to the physical space and the cost associated with it. As I understand it, there isn't immediate expansion space that you have in the short term for this.

MS. YAN: It is indeed a Catch-22 because on the one hand we tried to really put some urgency into the work that we're supposed to do and then, at the same time, trying to do it.

VICE CHAIRMAN LIPSTEIN: So, Ellen's expressing a concern and we'll hear some other concerns, but I'm still trying to get the round of questions -- Joe, are you clarifying questions?

DR. DOUMA: I'm not clarifying, it's broader than that.

VICE CHAIRMAN LIPSTEIN: Bob Zwolak, do you have a clarifying question?

DR. ZWOLAK: Yes, I do, thank you. Bob

Zwolak, Board member. If I understand things, I see the budget of $180 million for fiscal '14 as one bolus of money and the goal of $528 million in commitments as sort of a different bolus of money and the question I have is, if we don't hit the 528 in commitments, how much would that impact this 180? Because I see this 180 as sort of being -- either it's going to be spent on commitments we made for science previously, plus our staffing, so I'm not -- could you explain how much of the 180 would be impacted if we don't hit that 528 goal in commitments? And I speak, I think, in favor of the budget as proposed.

DR. SELBY: So, Bob, I was trying to answer that question. I think Francis -- I think it was -- asked a version of that question, which is, if we don't hit $528 million in commitments, how does that influence the spending that we have to do, which is a combination of spending on, as you said, research we've already funded and spending on program staff.

And our answer is that it impacts it

essentially not at all. We still need to make that effort to commit the $528 million and that takes a lot of staff time. For the PFA development, for the topic generation, the prioritization, the PFA development, the landscapes, the scientific review process, all of that work goes forward even if the actual amount committed by September 30, 2014 is less than $528 million. All that effort is what will then bring more commitments into early 2015, so that by the end of 2015 -- two years down the road -- we have committed the amount that we've all agreed that we want to commit.

So my answer is that it does not influence this budget.

VICE CHAIRMAN LIPSTEIN: So let me say that -- I'm going to summarize that and then go back to Allen who has a clarifying question on that one.

What Joe's saying is the $182,500,000 is not variable with the level of committed funding.

DR. COLLINS: Can I ask a clarifying question about that because that surprises me?

VICE CHAIRMAN LIPSTEIN: Yeah, so, this is good because it surprises Francis and it may have surprised Allen. So Allen, why don't you go first and Francis, you go second?

DR. DOUMA: Yeah, Allen Douma. I think everything on this list wouldn't change as a result of what we're talking about except the research expense, naturally, would change. If our commitment is only $300 million, then our expenses are going to stay at $100 million, so that number will go down.

What Joe is saying is, our costs to get to the $300 million commitment, versus $500 million commitment is the same.

DR. COLLINS: Okay, I'm getting confuse.

VICE CHAIRMAN LIPSTEIN: So wait a minute. Joe, you were nodding your head. Do you agree with what Allen said?

DR. SELBY: Except for the $300 million. I think there's no chance that we'd only get the $300 million, but, yes --

DR. DOUMA: That was only illustrative.

DR. SELBY: Yes, that's right. No, Allen got it right.

VICE CHAIRMAN LIPSTEIN: Okay, Francis

DR. COLLINS: I'm still confused because I thought I heard Joe say it would have absolutely no impact on the 182, what we spend in terms of making new commitments this year. I assume if you make commitments in September, that some of that will involve also expenditures because you're starting up a project. It's not as if all of those commitments will spill over into FY15, but correct me if I'm wrong.

DR. SELBY: Okay, this is -- we know that we're going to commit a very large amount in -- we're thinking only about the 12 months that are fiscal year 2014. This is not a two year budget at this point. So if you -- and a good part of Christine's angst comes from the fact that all of these 2014 commitments -- a good chunk of these 2014 commitments are really scheduled under the best of circumstances to be approved in September of 2014. The very last month in 2014.

So the answer, Francis, is no. Much of these $528 million worth of commitments will have no expenditures in fiscal year 2014.

DR. COLLINS: Much, but not quite all. I heard you say it would have absolutely no difference, but --

DR. SELBY: Yes --

DR. COLLINS: -- surely you will expend some dollars.

DR. SELBY: I'm not even going to back down from that because --

VICE CHAIRMAN LIPSTEIN: Just round down, just round down.

DR. SELBY: -- because the amounts that are going to be reduced are not the amounts in December 2013. We basically know what we're committing in December 2013, unless this Board does something really dramatic.

And similarly, the amounts in play for the next funding cycle are pretty much related to broad funding announcements and targeted funding announcements that we've already got well under

way.

So the real big question marks are about those commitments in September 2014, so.

DR. COLLINS: But just a straight answer here because I still see puzzled looks around the table. It's not just me. If you make commitments to new projects in September 2014, will you also be actually spending dollars in September 2014 for some part of those projects?

MR. BARNETT: No.

DR. SELBY: Okay, if you think about what a commitment means, it is a Board vote to approve projects. Then we go ahead with conversations and with our remarkably short award to contract intervals -- yeah, we're still into 2015 and that's when expenditures start.

MR. BARNETT: And then some period of time for the investigator to rev up and get ready to track the funds.

DR. COLLINS: Okay, this is so different than the way some of us do business.

MS. SIGAL: Yeah, yeah.

VICE CHAIRMAN LIPSTEIN: So I think we've beaten Francis into submission here for a second. Larry, you wanted to respond to Ellen's point?

MR. BECKER: Yeah, Ellen I just wanted to say, I've been working with Mitch and with Regina on the recruiting because I question, too, the ability -- do they have the resources, A, to attract the people, figure out who they were? And in one of the things I said to Mitch was, he needs to be the organization's conscience -- that we don't compromise, you know, on the third candidate on the science request for proposal or request for requisitioning for a job.

The second thing was, we talked about making sure that they'd comprehended enough staff time to interview all of these people that they're going -- and that's going to take a lot of time to look at the process. See how many hours it's going to take to interview and walk through what the ratios are of how many people? I actually got some linked-in data as to what the benchmarks are around doing exactly that, so that they could work. So

that's one set of benchmarks.

So I think that it's really important. I think though the points you made are absolutely critical to us getting up to speed from having a place for people to sit the day they walk in, to having a series of responsibilities and deliverables when they walk in the door. So, I know they're thinking about them and I know that they know that it's a huge task and a huge challenge to get roughly 80 or so people on board running it at full speed.

DR. DOUMA: Allen Douma. When I said -- Dr. Douma, yes -- when I said mine wasn't for clarification, as I hear more conversation, it really is clarification.

One of the things that -- as a Board and a committee member in particular, it's hard to know where the weeds start where the Board's efforts should be. One of the things that I haven't seen -- and it's germane to this conversation about staffing -- is basically the documentation of the work efforts for each of the new FTEs, in order to

determine how many FTEs do we need and where? I'm not saying the Board necessarily should see that, but I'm hoping that we have that kind of documentation before we go out and recruit people, before we decide how many people we want.

And unless you've got the work effort defined ahead of time, you don't know who, how many, nor can you eventually track their productivity, as well, when they come on board. So, to the extent that we don't have that now, I strongly urge that we do.

I know we've had a lot of conversion going on this last year, but I hope that we really focus in that, as well.

MS. YAN: I just want to let you know that we actually have done it as we prepared the staffing plans. We had looked at other tasks that need to be performed and the man hours required. That's how we came up with the staffing plan.

DR. DOUMA: But presumably that wasn't done in communications, since we're not sure what that's going to do -- what we're going to do yet.

MS. YAN: I don't it's true that we don't know what they're going to do.

DR. DOUMA: Oh.

VICE CHAIRMAN LIPSTEIN: So, Christine, before I turn to you, are you ready for discussion or is this a clarifying question?

MS. GOERTZ: I think it's a clarifying question, thank you. Christine, I'm wondering how we're writing these contracts or how are we handling the 2019 potential sunset of PCORI with these staffing hires? Are we having limited contracts with them or how are we doing that, exactly? Do we just tell them? What's the plan?

MS. YAN: We are all at-will employees.

VICE CHAIRMAN LIPSTEIN: What that means, Christine, is everybody who works for PCORI is an at-will employee, which means that we don't have contractual obligations. So, just as we prepared when we were worried about the Supreme Court decision. We do have personnel policies and procedures that govern this activity, including separation from PCORI -- if it's not for cause.

MS. GOERTZ: So does that mean that we would have, like, buyouts? I was also an at-will state and here's what I found. It's not that easy to just let somebody go at will and so, I'm just wondering, what the plan -- so is there some sort of severance package then that each one of these employees would get?

VICE CHAIRMAN LIPSTEIN: Mary, do you want to comment here?

MARY: I think what they said, you know, covers it, that employees are at-will employees and that if PCORI's plans will evolve over several years with adequate notice for planning purposes and that Joe, working with the senior staff, will develop a plan that's a responsible one for management of staff.

VICE CHAIRMAN LIPSTEIN: Any other comments on the question about employees? Yeah, Ellen?

MS. SIGAL: So, Christine, thanks for bringing this up. I had not thought about this, so, yes, we can get many people to come for four or

five years, maybe, but people who have very secure jobs and who are really good, this will really limit the talent pool. Most people may be concerned about what happens after PCORI, so just another head's up for us to think about. The very best in the field may not come.

VICE CHAIRMAN LIPSTEIN: So the reason we wanted to get the clarifying questions out of the way is there is a proposal that this is the 2014 budget and that I be approved at today's meeting. And I know this has gone through the finance and administration committee, so is there a motion to approve the budget?

DR. LEVINE: So moved.

VICE CHAIRMAN LIPSTEIN: So moved. Is there a second? There's a second.

So, Dr. Norquist, this is where it's really great to be the vice chair. We have a motion to approve --

CHAIRMAN NORQUIST: I think I'll leave the room.

VICE CHAIRMAN LIPSTEIN: There's a motion

to approve the budget and a second and we've gotten through our clarifying questions and now I was going to ask for discussion, but it's also 12:20 and you're good at keeping us on time and I, obviously, am not.

[Laughter.]

CHAIRMAN NORQUIST: Yeah, so why don't we do this -- because we're already 5 minutes after -- why don't we spend 10 minutes and we'll see where we get within the 10 minutes and then at 12:30 we'll break for lunch? Because we do want to eat food that's edible and we'll see where we get from there.

So we have a proposal to accept the budget as proposed. And we have a second, so we're open for discussion.

Now, one thing I would say is that all of these -- the relevant sections of the budget have gone through the appropriate committees, so finance committee has seen their part, the COEC has seen its part, the PDC has seen its part. I will say that the COEC went through each line. But at the

end was -- you know, I think for us the understanding about -- and people on the committee should correct me if I've gotten this impression wrong -- but that we see this as kind of a place holder for a number of activities. We would like to see ongoing evaluation as we go. We were in favor of a mid-year look and if need be a reallocation.

I mean, we would even say -- even in the COEC. So some of the activities that are proposed, let's assume we don't get quality proposals, or whatever, and we end up with not an amount in there that we were willing to say, hey, bub, this could be reallocated if some blockbuster kind of research study. Maybe we should reallocate at that point.

So we were in favor at a mid-year kind of look at the budget. I think the FAAC had a similar, and PDC, but let's just check on that. So, Christine, did you want to say anything about that specific issue and then we'll open up, and Kerry, also.

MS. GOERTZ: Christine Goertz. The PDC did

vote to approve original recommended approval to the Board on the staffing plan. It related to the science budget. We had a lot of discussion about the budget, but did not formally vote on it.

CHAIRMAN NORQUIST: Kerry?

MR. BARNETT: Well, yeah, I would just say that every time we go through this process there's always an effort to engage the substantive committees in the pieces of the budget that relate to those activities. And I think the substantive committees never feel like they've really had enough time to really kind of marinate in all of the details of the budget that relates to that committee.

And in some ways that's unfortunate and in some ways that's just ultimately the nature of the organization that we're evolving into, where the budget is generally driven by staff. And I think that committees and the Board, in general, have to feel generally comfortable with the overall direction.

The key, I think, is that -- and this is

picking up on Gray, what you said. The key I think is that we have these checkpoints along the way, at every Board meeting where we have a pretty good sense not just of how expenditures are matching up with budget lines, although we have to do that, too. But, really, how far along we are in these activity streams to actually achieving those outcomes that are contemplated in the budget at this early stage. And to me, by far the most significant of those is this issue of the $528 million. And so I think we're just going to need to build in these checkpoints and ask Joe and Regina and others to report back to us regularly on this capacity building process.

And if we feel, as a Board, that that's not coming along at the pace that we think it needs to come along, I think we have to call a time out and revisit some of these pieces. So we really need to think about this budgeting process as an ongoing thing, as opposed to, we're just going to vote yes today and then not pay any attention to it for another year.

DR. SELBY: I just want to say that I believe Regina actually said in her opening comments that we hoped you'd approve a mid-year review of this. In addition to that, the dashboard will have a lot of data on it, both on commitments that we've made, but also on other aspects of our budget.

But we have uncertainties. We really agree with Larry and Ellen's concerns about staffing and what it takes to staff up that much. And that really will drive changes in budget, if we staff up at a different rate. And we also agree with Gray that funding opportunities may appear out of the blue that could -- so we think the budget could go in either direction at the six-month point. And we hope you'll build that into your vote and approval.

CHAIRMAN NORQUIST: Ellen?

MS. SIGAL: So I was going to say --

UNIDENTIFIABLE: Please identify yourself first.

CHAIRMAN NORQUIST: That's okay --

MS. SIGAL: Ellen Sigal, Board. So I was going to initially suggest an amendment to the budget that we slow down the staffing fund, however, if we have the flexibility -- which, of course, I hear we do -- to do that and to have metrics in place to really check to see whether it's achievable or whether we can do it, then I guess I would be comfortable in not amending the budget.

But I would just suggest that I think this is very impractical and difficult and we may find ourselves with some huge problems, if we do this at this pace. And it's just the idea of getting the right people and getting them integrated. And then, of course, we have the issue of what we're spending the money on, too. So I guess I'm okay not amending the budget, but I just would look at benchmarks and caution.

DR. DOUMA: Allen Douma. Yeah, the fact that we're going to be relooking at this and we're a learning organization and that the crunch of the budget because of the change of fiscal year, I

think we need to be looking, in particular, at what's going on in the next six months.

I don't think we did -- and Kerry, I think, it is real here, it's not just perceived. It didn't have the opportunity to review at the level that we might have, particularly in the communication arena.

But in saying this, one of the things that I would urge us to do in moving forward in the next year is to focus more on what are the outcomes that we're looking for. What are then the resources we need to reach those outcomes and out of defining those resource needs, then we come up with a budget. We will be able to that much better in the coming year. Now, we do -- it's almost we've come up with the dollars and then we're going to figure out to spend them wisely. Well, I would suggest that we want to avoid that in the future.

MS. YAN: I just to say that that's exactly the process the staff took in developing the budget.

CHAIRMAN NORQUIST: So, other questions?

Christine, is your card out? Yes?

MS. GOERTZ: Yeah, Christine Goertz. I would propose that we amend the spending plan to target $1 billion over 2 years over fiscal year 2014 and fiscal year 2015.

CHAIRMAN NORQUIST: So, your amendment is really to do it on a two-year budgeting, is what you're saying?

MS. GOERTZ: Correct. The science spending plan --

DR. SELBY: The Commitment Plan.

MS. GOERTZ: They call it the Commitment Plan.

CHAIRMAN NORQUIST: Yeah, the Commitment Plan

VICE CHAIRMAN LIPSTEIN: Yeah, could I intercede? She's okay with the $182.5 operating budget.

MS. GOERTZ: Correct.

CHAIRMAN NORQUIST: Got it.

VICE CHAIRMAN LIPSTEIN: She would just like to modify the commitment target to be a 2-year

commitment target of $1 billion versus a 1-year target of $528.

MS. GOERTZ: Correct.

CHAIRMAN NORQUIST: So we'd need a --

VICE CHAIRMAN LIPSTEIN: And I would accept the amendment if you need a motion to accept the amendment.

MR. NORQUIST: Yeah, if she -- so that would be a second? So I guess the first thing is that we have to approve the -- yes, Kerry?

MR. BARNETT: Just a comment on that. I will support that for the reasons that we've talked about both online and offline, but I wouldn't want that to be perceived as a statement on the part of the Board that we want you to slow down. It's not that at all. We want you to build the capacity so that we really are making these wise investments as early on in that cycle as possible.

The worst thing that could happen is that staff hears the message, oh, we can move slower in the early stage of the biennium, figuring we'll just spend more money in the latter stage of the

biennium, which I think would really be a big problem and a big mistake.

CHAIRMAN NORQUIST: Yeah, I don't think anybody -- the point is appropriate level of -- we don't want to rush out and just fund things we don't want to fund. So, yeah, Allen?

DR. DOUMA: Just an addendum. I'm following up on what Sharon said. Since dissemination and implementation is one of our key strategic goals, I would hope that we can bring that out of the budget and have its own descriptors and what we're going to do and, in fact, which committee it's going to fall under at some point.

VICE CHAIRMAN LIPSTEIN: Just to respond to Allen, I think, as all of you know, we're going to be proposing later today that the committees be organized around the strategic goals and so, pulling that out for the committee that will be speeding up implementation and dissemination -- no, implementation and something else. I forget the right word, but I think we will act on that recommendation.

CHAIRMAN NORQUIST: Okay, so I think we have to vote -- I'm sorry, Larry, do you have --

MR. BECKER: [Off microphone] or do you understand in two years we've got it?

CHAIRMAN NORQUIST: That's what she's doing. The two years together on the forms is a bit -- it's a little more than that.

MS. GOERTZ: I guess it's, you know, what, $1.2 billion?

MR. BECKER: Yeah, you've got it. It's slightly more, like $1.03 billion.

VICE CHAIRMAN LIPSTEIN: $1.03 billion.

MS. GOERTZ: 1.03, that's right.

CHAIRMAN NORQUIST: So, I think technically we have to vote on the budget first, before we vote on the amendment or do we vote on the amendment first?

MR. SELBY: The amendment's first.

VICE CHAIRMAN LIPSTEIN: Actually, you can vote on the budget with the amended --

CHAIRMAN NORQUIST: We can vote on the budget with the amended -- okay, is there any other

further --

VICE CHAIRMAN LIPSTEIN: [Off microphone] will be voting on a [inaudible]?

CHAIRMAN NORQUIST: No, no, we're voting on a one-year 2014 budget and a two-year commitment plan for research. Okay, let's be clear about that.

UNIDENTIFIED: So you're assuming that the use of --

CHAIRMAN NORQUIST: Right, the budget we're voting on now is the fiscal year 2014 budget and then the amendment is for a two-year commitment for research.

DR. WEISMAN: Can you just -- I'm really confused by the meaning of that, though. Does that mean that within 2014 they can commit funds that extend for two years?

CHAIRMAN NORQUIST: Yeah, I think that's what -- I mean, you're saying like if they were up to 500 that part of that 500 is obviously -- could theoretically --

DR. WEISMAN: But they already have that

right.

CHAIRMAN NORQUIST: Yeah.

DR. WEISMAN: So if the two-year commitment is a commitment by the Board to say, go ahead and commit to spending that will last, that might actually be in the 2015 budget. I'm confused -- can you say, Christine? I don't understand what you want to achieve, Christine. I'm confused.

MS. GOERTZ: Right. Right now the way that the proposed commitment plan is that we would spend $528 million in 2014 and $500 million in 2015. And what I'm proposing is, instead of having it sorted into those two buckets, that we would say that our funding commitment over the next 2 years is $1,028,000,000, with the caveat, as Kerry expressed, that we would not in any way slow down. That we would make every effort to spend as much money as we can well in 2014, but given the fact that we have a shortened fiscal year, and such, that it may be more realistic and allows us to plan a little bit better for it to have a two-year funding commitment.

DR. WEISMAN: But don't we -- I mean, we always have that right to do that, but don't we have an obligation for a fiscal year approved budget, which means only the fiscal year 2014. I mean, the spirit of the Board is, we understand that once a budget is approved -- and Gray indicated this -- that the facts of the world change and it may not all occur the way we anticipate it, which means some things might carry over.

But why is that -- we always have the right to -- I don't know what to promote? Just a formal administrative approval standpoint. It sounds like we're approving -- you want us to approve a two-year budget. I'm not sure we can do that.

VICE CHAIRMAN LIPSTEIN: No, no. Look, I think we need to be clear, so there's no confusion. We're asking for approval of a fiscal year 2014 operating budget of $182,500,000. It was on the slide.

What is becoming flexible and variable is

the pace of the committed funding over two years for actual research programs. And all that is meant to do is to provide staff with flexibility to go at the right pace. At the right pace. Not too slow, not too fast, just right. But we are not authorizing more than $182-1/2 million worth of expenditure between now and the end of 2014.

And that certainly fulfills our fiduciary responsibility.

DR. WEISMAN: Right. I'm just trying to understand it in a very formal management sense --

CHAIRMAN NORQUIST: Let me --

DR. WEISMAN: -- because when you go back to the budget, the 182.5 --

CHAIRMAN NORQUIST: Wait, wait, wait.

VICE CHAIRMAN LIPSTEIN: If you go back to the budget --

CHAIRMAN NORQUIST: I think that -- wait, wait, because we're getting ready to get into a whole other discussion that I can see our lunch hour is quickly disappearing. That maybe what we need to do is vote on the budget. We can come back

to this other issue about the commitment.

DR. SELBY: Yes.

CHAIRMAN NORQUIST: So why don't we be clear about we're voting on the 2014 budget, let's get that out of the way and we can come back to this other issue. Christine, if you will, on the amendment? Because I saw other cards going up and stuff, so if we can just agree on that part, let's -- we have a motion and a second on the table about the budget. Any further discussion about 2014 budget, not the amendment that could come to this at this point? Yes? Or you signaled something there, Arnie. I didn't know what that meant.

DR. EPSTEIN: [Off microphone.]

CHAIRMAN NORQUIST: No. Okay.

DR. WEISMAN: I don't think it should be called an amendment because then it changes the budget. It should be called a resolution.

CHAIRMAN NORQUIST: Okay, a resolution. We'll call it whatever when we get to -- all right, so all those in favor of the 2014 budget?

[Ayes.]

CHAIRMAN NORQUIST: Any opposed?

[No response.]

CHAIRMAN NORQUIST: Okay, we have that budget. Now, if there's going to -- why don't we do this? Let's take a break and think about this. We'll come back at the beginning of it. Let's have lunch, okay? And we'll come back at, if we will, 1:30, is that all right? That gives us 50 -- I know Gene used to like to kind of cut it -- we'll make it 20 after, okay? We'll do 45 minutes and we'll see where we are, okay? Thanks.

So, for those on the phone, it's 20 after 1:00 Eastern Standard Time we'll start back.

[Whereupon, at 12:36 p.m., a luncheon recess was taken.]

A F T E R N O O N S E S S I O N

[1:25 p.m.]

CHAIRMAN NORQUIST: Welcome back to the afternoon session of the PCORI Board meeting. I want to remind people who are on the phone, if you want to see the slides and see the information that we are seeing here, you can see it on our PCORI website at www.pcori.org. The webcast is being recorded and if you want to see what you've missed, perhaps this morning or this afternoon, you can see it on our website probably by the end of this week or next week.

And we're also using Twitter today, so if you want to join the conversation, you can join us at #PCORI.

So, let's pick up where we left off. We had approved the budget and then there was a motion that we have tabled here and I'll go back to Christine, if you want to come back to this. So I'll recognize Christine Goertz.

MS. GOERTZ: Thank you. I'd like to recommend that we go back to Joe's original motion

that was tabled to approve the funding plan for 2014.

DR. SELBY: Almost there.

MS. GOERTZ: Right there. And I would move that we make a commitment of $1,028,000,000 in research funding for fiscal years 2014 and 2015.

UNIDENTIFIED: I will second the motion.

CHAIRMAN NORQUIST: Okay, so we have a motion and a second and now we'll open it up for discussion. Yes, Allen?

DR. DOUMA: Every time we've talked about this in the last hour, we've all raised the caveats that we're going only do really good stuff and value stuff, et cetera. Do we need to have that formally in this amendment or is it just such a given that we don't even have to put it in there in words?

CHAIRMAN NORQUIST: I hope that's part of what we always do in everything that we do. So to put it in there would imply that we don't do that at other times in my mind, so I would hope that that's a given that we would have that in there.

Any other discussion about this motion? And I guess we're calling it a resolution kind of amendment, or something. I'm not sure. Okay. Yes? I'm sorry, Bob?

DR. JESSE: Bob Jesse, Board. So I'm inherently in favor of this, but I'm just a little bit confused about how the whole budget is one year and one part comes out as two years. Are we just projecting out into the second year and then we'll revisit that on a year-by-year basis?

CHAIRMAN NORQUIST: Go ahead.

DR. SELBY: I would just suggest that the commitments are only indirectly related to the budget. They do not fit into the budget sheets, per se, how much we commit. That does not have a place on the budget sheets. It's an indirect driver of how much work there is to do, but it is not related to the budget. So I think it's quite possible to say that we will budget this much for 2014, but that that budget should support the first year of a two year commitment plan and we're now voting simply on the commitment plan, not related

to the budget.

MS. GOERTZ: And Bob, basically you would see that spend then in future budgets. So you will see that, so that the 528 or whatever, you'd see most of that, I think, in the 2015 budget, actually, as a spend, which is one of the reasons that Joe showed that end in 2015. Our research spend is so much greater than it has been before, so we would basically be -- correct me if I'm wrong -- but I think we're voting on the spend for this in the 2015 budget next year.

DR. JESSE: So maybe -- it sounds like what we just said is we're not voting on the spend, we're voting on the ability to commit the funds into an out-year budget, not the budget itself.

DR. SELBY: Fine.

CHAIRMAN NORQUIST: Other discussion? Okay, so then I'll call the question. All those in favor?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed?

[No response.]

CHAIRMAN NORQUIST: Okay. So the next part of our agenda is the Clinical Trials Advisory Panel charter and the Rare Disease Advisory Panel charter. So, Bryan, do you want to go in that order or do you want to go -- so, are you going to start with the clinical trials or the rare disease?

MR. LUCE: Clinical trials.

CHAIRMAN NORQUIST: Okay. All right, so we'll start with the Clinical Trials Advisory Panel. In both of these you're asking the Board to approve, is that correct?

MR. LUCE: Yes, that's correct.

CHAIRMAN NORQUIST: Okay.

MR. LUCE: So the first panel I want to discuss is the Clinical Trials Advisory Panel. This, I'd like to remind the Board, was discussed fully last meeting in September and was largely agreed to with the exception that the Board felt that we should revise it slightly to reflect that it works directly with the Methodology Committee. That we did.

And the revised draft charter reflects

that it has been approved by the Methodology Committee and the program development committee, so unless there's further discussion, I would expect that you're ready for a motion to --

CHAIRMAN NORQUIST: So we're asking for a motion to approve the charter for the Clinical Trials Advisory Panel.

UNIDENTIFIED: So moved.

CHAIRMAN NORQUIST: Second?

DR. GOERTZ: Second.

CHAIRMAN NORQUIST: Okay, now we open it for any discussion about this. Christine, did you want to say, since the PDC is --

MS. GOERTZ: Yeah, just that this has been very carefully considered by the PDC and we did vote to recommend that the Board approve this charter.

CHAIRMAN NORQUIST: Any questions? Discussion? Okay, then we'll call the question then. All those in favor of approving this charter for the clinical trials?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed? Abstaining?

[No audible response.]

CHAIRMAN NORQUIST: Okay.

MR. LUCE: Excellent. So the Rare Disease Advisory Panel charter, is this the first time you've seen this, that the draft charter is in your packet? You'll recall that the applicable legislation required us to appoint an expert advisory panel for rare diseases, specifically, it says in the case of a research study for rare disease, the institute shall appoint an expert advisory panel for the purposes of assisting in the design of the research study in determining the relative value and feasibility of conducting the research study.

The legislation calls for the composition of the panel to include patients, caregivers, representatives of rare disease efficacy organizations, practicing and research clinicians, scientific and health services, researchers, health services delivery, and evidence-based medicine.

And other possible membership, such as policy makers, life science industry insurers, representatives of employers, and so forth.

There's some background here. The staff developed a draft charter consistent with the legislation and assembled a rare disease roundtable, made up of representatives that included patients and patient efficacy organizations, researchers, government agencies, industry, and payers. Pretty much reflective of what the legislation envisions and requires.

We had just a terrific meeting in September with that group, a very active, encouraging meeting. They discussed the charter, made recommendations, we revised the charter and sent it back to those individuals in the roundtable and got their feedback and then have revised the charter consistent with many of those comments.

I want to note that the legislation envisions tailored panels for each rare disease study. What we are recommending is that the draft charter constitute a standing, overarching panel

and that it allows for additional ad hoc advisory panels tailored to specific diseases. So, in point of fact, for each study, for instance, the overall arching rare disease panel would appoint an ad hoc panel that would be specific to that rare disease.

So the charter really goes beyond -- it includes what the legislation mandates, but it goes beyond it significantly.

So, the charter itself says that it will advise and provide recommendations on the conduct of patient-centered comparative clinically effectiveness research in rare diseases and coordination and engagement with the rare disease research community. As with the other panels, it does not serve and will not serve in an official position making capacity.

As was true with the Clinical Trial Advisory Panel, we are recommending two-year staggered terms, with a maximum of two terms. The composition, we're recommending 12 to 15 members, since it's an overarching panel and that no fewer than 33 percent to be the persons who are rare

disease patients, caregivers, and representative of such advocacy organizations and the remainder to include the representation by our broad array of stakeholders consistent with the legislation.

In terms of structure, as I mentioned, in terms of ad hoc panels, the overarching panel will assist PCORI in identifying experts to serve on condition specific advisory panels to assist in evaluation, designing, and conducting specific PCORI funded research, probably mostly trials, we expect and to determine the relative value and feasibility of conducting the research study.

CHAIRMAN NORQUIST: Yes?

MR. BECKER: Larry Becker. Maybe you could help educate me because I don't know, how do you define a rare disease?

MR. LUCE: Do you remember exactly the actual definition?

VICE CHAIRMAN LIPSTEIN: So, basically, there are two lists that are maintained of rare diseases. One is kept by the NIH and is roughly defined as diseases that have a point prevalence of

fewer than 200,000 people in the United States.

There's also a separate list that's kept by the National Organization of Rare Conditions which aligns pretty well with the NIH list, but includes some additional diseases. So we basically stated that it could from either of those two lists.

DR. LEVINE: So the FDA has modified its rare disease umbrella to include subpopulations of more common diseases that are represented by some rare variant, which has included some work in oncology and others. Are we extending ourselves or are we using those two lists and kind of what's on them, for now?

MR. LUCE: That's not addressed specifically in the charter. We did not consider it. It did not come up in that working group that we put together, but I would think that that would be a matter for this Board to decide.

UNIDENTIFIED: Good point.

MR. LUCE: And/or the panel itself.

CHAIRMAN NORQUIST: Are you about

finished? Because we're going to have a discussion here about this. If this is a question -- a clarifying question? Okay.

DR. WEISMAN: So I actually had a similar question as Freda, but I'm wondering -- because you said $200,000 which is identical to what the FDA uses for orphan drug designations. So is it the same? Are they -- if you looked at what the FDA would consider an orphan disease and a rare disease, would they be overlapped, in which case it would be covered with what Freda was asking?

VICE CHAIRMAN LIPSTEIN: I don't specifically know the answer to that. Do you, Freda?

MS. LEWIS-HALL: Yes. So it essentially uses -- Francis may know if there's any variation -- but I think that the FDA uses the point prevalence of less than 200,000 and then has evolved its definition as subpopulations have been identified in more common illnesses.

MR. LUCE: That's correct.

MS. LEWIS-HALL: So I think that if you

actually -- and I haven't done this. If you sit the lists next to each other, there's a considerable amount of overlap and there may be a few things that fall outside of that overlap space.

MR. LUCE: Freda is correct and all of this is documented on the web, if you just want to quickly jump in there, you can see the definitions. And I think there has been an attempt to try to make these mostly concordant because it would be nice when somebody said "rare disease" that it meant the same thing.

CHAIRMAN NORQUIST: Are you finished? Are you going --

MR. LUCE: I'm done.

CHAIRMAN NORQUIST: All right. So we need to ask for a motion to approve the Rare Disease Advisory Panel charter.

UNIDENTIFIED: So moved.

CHAIRMAN NORQUIST: Second?

UNIDENTIFIED: Second.

CHAIRMAN NORQUIST: Okay, so now we can have a discussion. I guess one piece of this --

let me just take on from the last -- is that we could insure, based on what Freda's saying, that our definition fits as broadly as you want it to, since you're using both. And then this. It seems like we could just make sure that that's part of it. Ellen?

MS. SIGAL: Ellen Sigal, Board. So I just want to embrace what Freda and Harlan said. I think the definition of rare disease is to be looked at very carefully and what we mean by it. Because I know the subpopulations and subtypes, and diseases like cancer are huge and it would certainly fit the criteria for what NIH or others or FDA is currently considering because there are no treatments for these people and it's a real issue. And they don't respond to treatments that conventional tumor types will, so it's important that we be as inclusive as possible.

CHAIRMAN NORQUIST: So, another vote for keeping it as broader a definition as possible. Okay, Harlan, were you up again?

DR. WEISMAN: Yeah, I tailored my last

comment to be the clarification comment, but in the legislation they talked about the sort of central groups and then other groups that could be added, and probably by Freda's comments and mine as two industry representatives on the Board, this is of great interest, particularly PhRMA. They have over 400 products currently in orphan drug development and I think some of the challenges of studying therapies and clinical trials include just the availability of being able to run the trial and have enough patients sufficient to study it.

So the methodology is something that really needs to be addressed and I know industry has a great interest. And, in fact, I'd mentioned to Joe that PhRMA, in particular, had said that they're very interested and maybe doing something jointly with PCORI in some fashion.

How does industry do patient-centered outcomes research, as opposed to other types of things in a way that fit the model that would be appropriate from PCORI's perspective. But I think orphan diseases -- rare diseases -- are a great

example of where a lot of help would be needed in development.

MR. LUCE: We certainly envision working closely with the Methodology Committee where we will also have industry representatives on the panel to help guide that effort. It would be helpful for me to know whether the Board would like us to be expansive to modify the actual charter relative to what you're talking about. Or to suggest that the panel itself deal with the issue of defining the rare disease definition.

DR. WEISMAN: You probably have enough with all the hundreds that are out there that it probably doesn't matter one way or the other.

MR. LUCE: Yep. Okay.

DR. WEISMAN: Except for what Allen said. But I would think that some of the rare childhood cancers and other ones that are now included would be included by other people's definitions of rare diseases.

CHAIRMAN NORQUIST: Right.

MR. LUCE: So, one comment -- not that it

requires any change at all in the charter -- is that we should closely at the PPRNs that end up getting supported because many of those are going to be about rare diseases and you would want very much for there to be a connection there between what this advisory panel is up to and what we're going to support through that mechanism.

The comment -- the way in which the composition of the panel is defined -- no fewer than 33 percent to be rare disease patients, caregivers, or representatives of rare disease advocacy organizations -- I totally support that.

I'm a little worried that the rest of the panel is less specified. I would not want this to end up in a circumstance where there was a lack of scientific expertise on this panel. And while that's not called out here as a need, I would flag it as a need if this group is going to be as effective as we would like.

I would not want to see one or two people with scientific expertise trying to sort of help steer this ship.

MR. LUCE: I understand the Board will actually appoint the advisors on the panel, so you'll have an opportunity to review that.

CHAIRMAN NORQUIST: I'm sorry. I missed you over there, Sharon.

DR. LEVINE: Just a clarification. Is that 200,000 people in the U.S. or worldwide?

MR. LUCE: U.S.

CHAIRMAN NORQUIST: Christine, did you want to say anything since the PDC had reviewed this charter, also?

MS. GOERTZ: Christine Goertz. Just that the PDC did review this charter and voted to recommend approval.

CHAIRMAN NORQUIST: Ellen, is your card up again?

MS. SIGAL: No, I'm fine.

CHAIRMAN NORQUIST: Oh, okay. Any other comments on this, Steve? Is that you?

VICE CHAIRMAN LIPSTEIN: No, that's --

CHAIRMAN NORQUIST: Oh, that's still Sharon over there, okay. I can't see you.

Okay, then we'll call the vote on it. All those in favor of approving this charter?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed or abstaining?

[No audible response.]

CHAIRMAN NORQUIST: Okay. Bryan, can you remind me what is the process now? We have the charters approved, what is the next part of the process here about what we do? Thank you.

MR. LUCE: Do you have that slide?

CHAIRMAN NORQUIST: We just happen to have that slide.

MR. LUCE: So that now that they have been approved, we will open up in the coming months for the application process for the panels. We anticipate, as you can see, the first advisory panel meetings in spring of 2014. We're particularly interested in both. We already have a couple of rare disease studies in our portfolio and, as we've discussed earlier, we're planning on getting into the pragmatic trial business seriously

and we will want the Clinical Trial Advisory Panel on board as soon as possible to help us.

CHAIRMAN NORQUIST: But can you help me a little bit more in the details for those people who are listening about what the application process is or what -- because some people may say, well, I want to apply. What I mean is, can you just give us a little bit more detail about that?

MR. LUCE: Do you want to? Go ahead.

MR. HICKAM: So, there will be a public call for nominations. So there'll be sort of a nominations period, a defined time window when nominations for both panels can be submitted.

CHAIRMAN NORQUIST: But a person could self-nominate or someone could nominate them from an organization for both of these particular panels.

MR. HICKAM: And, in fact, I think we would expect that the normal model would be self-nominations, yes.

CHAIRMAN NORQUIST: Okay, so we should have something up soon on our website that posts

what these particular two advisory committees are about. What their functions will be. And the process, the deadline, and everything for nominations, right? Correct. Yes, Ellen?

MS. SIGAL: I think it's fine to self-nominate. I just think it's important that you at least go to the rare disease communities, the organized groups, and speak to them, as well, and let them help you get the message out because there are in every, you know, disease there are these -- and there are all sorts of organizations that can help.

CHAIRMAN NORQUIST: Right, so I that that's the standard. We would do that. My point is just that we would allow people to self-nominate, but we would certainly go out and look. And I just want to be very clear what the process is for people who are just listening to this and may want to know what that is. Okay, anything else? Okay.

Joe, we're back on schedule, I think. So we're going to talk next about modification to the

decision metrics, is this yours, Regina?

DR. SELBY: Well, Regina's going to come back up here and lead the discussion.

CHAIRMAN NORQUIST: Okay, thank you, Bryan and David.

MS. YAN: We have a Board approved decision metrics which aligned what are the least items that will require Board approval and what kind of authorization level does staff have, including the executive director?

And we review it from time to time to update it and to provide clarification. So we have done a recent update. We have done couple updates on simply clarification of terms and language and there is one item regarding the Rapid Response Fund that we have added an additional section to the decision metrics to clarify the executive director's authority on those funds.

There are several simple clarification update items that we have made -- we're proposing to modify the decision metrics. One is adding the role of general counsel to the decision metrics,

particularly clarifying the general counsel's role in supporting decision-making regarding conflict of interest policies, by-laws, and also the institution policies.

And we are also adding the chief officer for engagement and chief science officer into the group of the executive staff. Early in the decision metrics it wasn't clear as to whether the Methodology Committee was making certain decisions or the staff was providing support, so we clarified that, as well.

The main modification we are proposing to be included in the decision metrics is regarding the executive director's authority on the Rapid Response Fund. Previously, in the decision metrics we have about procurement -- about procurement of goods and services. And a few months ago this came up in a discussion with the FAAC, which is whether the decisions of awarding funded projects under the Rapid Response Fund, which we have a budget line item in the budget. Actually, false under-procurement of goods and services or whether it is,

indeed, a little bit different.

So with the discussion with FAAC, we feel that these probably were in it's own section within our decision metrics. So, as a result, we have broken it out. Right now, in fiscal 2014, we have $5 million in the budget as a line item for the Rapid Response Fund. In 2013, we actually had $9 million, but that was not used.

I know Joe has a mind to utilize these funds and we want to make sure that there is a clear procedure in that. What has been proposed and has been discussed by FAAC is that -- for the utilization -- such funds, if it's under $500,000, Joe will consult with the chair and vice chair and he will have the authority to award such funds. And then, on a quarterly basis, he will inform the Board on how the funds have been utilized.

If there's anything that's above $500,000, then it will have to be approved by the Board, a vice-chair and a chair of FAAC. These process is identical, actually, with our procurement of goods and services. The authorization level is the same.

Joe, is there anything you would like add to this? Or Kerry? That we've discussed this?

CHAIRMAN NORQUIST: Anybody? Discussions? Are you -- so we need a motion to approve this modification.

UNIDENTIFIED: So moved.

CHAIRMAN NORQUIST: Second.

UNIDENTIFIED: Second.

CHAIRMAN NORQUIST: Okay, so discussion now. Questions to Joe? Yes, Christine?

MS. GOERTZ: I'm just wondering, since this is a budget line item, is that $500,000 cut point, is that a commitment, or is that an actual expenditure? So.

[Laughter.]

DR. SELBY: It's a commitment that would rapidly turn into an expenditure. Maybe almost immediately, you know, for small ones --

[Laughter.]

CHAIRMAN NORQUIST: Unless it was on September the 30th. Leah?

MS. HOLE-MARSHALL: Thanks, I think --

Leah Hole-Marshall, Board. I think this is a good addition and draft and I appreciated also the consultation so that we would have more awareness of the activities, but less request for approval. So I didn't hear that in the presentation and I didn't know if that was reflected for all of the significant changes or just the one about the discretionary fund?

MS. YAN: Just the discretionary fund.

MS. HOLE-MARSHALL: Okay. So, as you're putting that together, would you consider other things that aren't required to have consultation, but that might be included to make that update to the Board more substantive. So, if there are other substantive decisions -- I'm not suggesting a change to the metrics to require consultation -- but just think about what that update might look like? Because I actually think that would be very helpful for us to have some information about activities without it being a request for approval.

DR. SELBY: Well, if I understand your question or suggestion, Leah, the one of these

modifications that had to do with decision-making and expenditures, per se, was the only one for which we said, each time we make a decision I will confer with the chair and the vice chair and if it's over $500,000 with the expanded group and we'll provide the list.

The others, I think it would be fair to say they're really just slight modifications to the metrics that recognize, for example, that we've added a general counsel, added a chief officer for engagement, and added a CSO since the metrics was originally written. And so, they're just updates to it. Maybe I didn't understand your questions, but --

MS. YAN: Actually, the other modifications were not new decisions, but simply clarification. For this one there is a new section that we're putting into the decision metrics. And we are proposing that Joe actually provide quarterly reports to the Board regarding decisions made for the Rapid Response Fund.

CHAIRMAN NORQUIST: Did that answer your

question?

MS. GOERTZ: Yeah. So the suggestion was just, as you start to put that quarterly update to the Board together -- especially for Rapid Response -- look at the decision metrics and the decision that have been made. If there are significant other ones that could be included in the update, consider doing that.

Again, it's not to ask for approval, it's just a way that the Board might be more informed about activities that have occurred.

MS. YAN: I guess that we brought up the executive director's report to the Board.

CHAIRMAN NORQUIST: Other comments? Go ahead, Steve.

VICE CHAIRMAN LIPSTEIN: It is a great recommendation. It doesn't just apply to staff. So, for example, the Executive Compensation Committee made a decision during the quarter that didn't require full vote approval, just to update the Board on that, too. So it applies to anybody who has decision-making authority. I think it's a

great suggestion.

CHAIRMAN NORQUIST: Okay. We have a motion with a second. All those in favor?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed? Abstaining?

[No response.]

CHAIRMAN NORQUIST: Okay, thank you, Regina. So, Robin, I think you're up for the methodology report. And where we are, we're asking for acceptance of the revised report, which everybody should have a copy, and for those -- I guess it's not on the website yet.

DR. SELBY: No, it isn't.

CHAIRMAN NORQUIST: But it will be, quickly. As soon as we accept it. And you're also going to be asking us to adopt these revisions to the standards. So you're going to go through kind of what changes you've made since the last time we saw the report and the response to some of the public comment, a few changes. Is that correct?

MS. NEWHOUSE: Yes. This is Robin

Newhouse and also David is going to join me, David Hickam. And then Bill Silberg is also going to join to talk about the implementation, the dissemination plan. And do we have Brian Mittman on the phone? If not --

CHAIRMAN NORQUIST: Brian, are you on the phone? No.

MS. NEWHOUSE: Okay, he was going to try to join us. So, can we have the methodology report slides, please?

Thank you, but I'll start by saying that this work -- we're very proud to present this on behalf of the Methodology Committee, but it could not have been conducted with our multiple colleagues and you, the Board, that gave us so much feedback during the draft report period and during this final report period. We also thank Bryan and Joe for their review, as well as those of you that conducted a review most recently over the past month.

And, also note the past work of Sherine Gabriel, our past chair of the Methodology

Committee and Sharon-Lise in creating the draft report, as well. And to Mark Helfand for his wonderful leadership on the editorial team for these stories that are included, that we'll talk about. And David Hickam for his wonderful leadership of the editing of the Methodology Report. So, I couldn't go farther without acknowledging that significant work from all of our colleagues.

So, Gray has already told you the goal of this presentation is to get your support for the release of the Methodology Report publically. So we'll start by telling you a little bit about the Methodology Report. We will also cover the timeline and the dissemination and implementation activities which -- Bill, I'll be calling on you for some of the specifics. I'll give the high level overall.

Okay, so the Methodology Report, just to remind us of some of the history, was back in May the draft report was accepted by the Board and released to the public. Between July and September

there was an open public comment period for the report and the methodology standards.

In November 2012, the methodology standards were adopted by the Board and then they were posted publicly on the PCORI website. During the period of January through September 2013, the report was revised by the Methodology Committee and the PCORI staff under our oversight and with David Hickam's help.

In September 2013, the Methodology Committee reviewed the report and we approved the revised report. So now we're asking you to approve and endorse the report for public release.

Just some highlights of this revised report. First of all, there are a number of public comments: 1,487 unique comments that came from 124 stakeholder groups. And you can see by the distribution that researchers were those that were providing the most comments, followed by representatives of industry, and then other clinicians, organizational providers, and policy makers were about 23 percent.

We also had comments from patients, caregivers, patient advocates, and a number of comments that were unspecified. So these comments fell into three broad categories. First of all, suggestions for PCORI that were unrelated to the report. Second, general comments about the report, including suggestions about the translation table.

Let's see, what did I miss? Did I say something?

UNIDENTIFIED: No, you didn't say something --

UNIDENTIFIED: Yeah, this is for PCORI, though, unrelated to --

MS. NEWHOUSE: Yeah, unrelated to the report. Well, we do encourage lots of stakeholders, via multiple mechanisms, right? And then comments related to the methodology standards, in particular. So Appendix C of the report contains a full explanation of the response to public comments, with some detail.

The other impressive part of this report are some of the research stories that are included

that really bring to life the methodological standards and there are four types of stories that are included.

First is, compare to effectiveness research wins, which are stories that are evidence of the important changes from comparative effectiveness research that impact patients and patient care.

The second are research in practice. Interviews and insights, the value of challenges in implementing comparative effectiveness research. And the experience with comparative effectiveness research. There's also a series of patient voice stories that are from patients that are sharing their own experience in comparative effectiveness research, navigating choices and weighing options, as well as a number of research stories. And studies that capture the impact that these methodological standards have and the potential impact.

Also included in the report is a dissemination and implementation plan. And that

work on behalf of the committee was led by Brian Mittman and we'll be calling on Bill to help us with the specific details included.

So there are five phases in this first year of release of the report. The first relates to how do we operationalize these methodological standards, including operationalizing it for use for reviewers, for those that are submitting proposals.

The second phase involves a number of training activities around methodological standards. The third phase is intended to create awareness of methodological standards. The fourth, implementation tools in the development, and the fifth, ongoing monitoring and evaluation of the implementation plan.

So that give you a very high level overview of what's included in the Methodology Report and a little snapshot of the implementation and dissemination plan and timeline. So we'd like to spend the time opening the floor for discussion about the report and answer any questions that you

might have after the review.

I'll also ask Bill or David if you'd like to comment on anything specific that -- some detail?

MR. SILBERG: The only thing I'd add is that the dissemination and implementation plan, starting with dissemination, is really a team effort that David and Brian Mittman have had extensive amount of influence in crafting. My team started with some sort of operational elements with Brian and David's guidance. And we also heard extensively from the members of the committee about ideas that they had for the best way to reach out to the multiple audiences that we want to make aware of the report and standards. And that we want to, as you've heard for a long time, in effect make this report and these standards their own to help to refine them and improve them over time and insure that the work that we do with them together is designed to make the implementation process as relevant, smooth, and as much of these folks daily work flow, if you will, as possible.

So the different phases that you saw are not really discrete or distinct phases. As Brian has said many times to the Board, to the MC -- to the Methodology Committee -- and also in discussions we've had with the COEC. There are multiple components to each of these phases and they all reinforce each other and will align and overlap a substantial amount.

The focus really is on working with the experts we have on the committee and on the Board, to help identify the organizations and prominent individuals we should be working with to think about the sorts of tools and tactics that will be most effective to develop in order to get the report and standards out and used, and as well as what sorts of on-going training, opportunities, curriculum, development, appearances at meetings. What kind of particular material might we develop for patient and other audiences -- other non-research audiences, for example -- that might be helpful to make this material real?

So I think you'll be hearing quite a bit

over time as these different elements begin to come online. I would say that we are beginning today with the start of what is sort of the spot announcement, if you will, making the report available. Beginning to promote the report to various audiences, pulling together the beginnings of slide decks and other sorts of ancillary and support materials that we can begin to work with committee members and others to get out to the audience that, really, we hope will take this up.

MS. NEWHOUSE: All right, Ellen?

MS. SIGAL: Thank you for the report. I guess on the dissemination issue there are two -- multiple people -- around this table that can have a profound influence, but the implementation of NIH or researchers in academic -- researchers are going to be incredibly important -- and free to industry as well, so maybe I would like to hear about what our plans are for those very big audiences?

MR. SILBERG: So, without Brian on the line, I always defer to him for expertise. But the general framework that he has outlined is to work

with our contacts with those various audiences, members of the Methodology Committee, members of the Board, to be sure that the organizations, the industries, the sectors that we want to focus on are clearly identified and the reasons that we're identifying them, if there's some prioritization, if you will, with who to go to first, second and third.

That's part of that discovery process, if you will. As part of that, we also want to be sure that we can leverage individual relationships, professional relationships with all these groups and organizations and really begin to have discussions about how they would tell us it would be most effective for us to work with them to begin to get the word out and do so in relevant and useful ways.

So that work has started with the development of some communications material that we have put together under Brian and David's guidance to share with the committee and also with the Board, to begin to have them help us identify who

these folks are. Start to come up with suggestions for the kinds of tools the different groups might find especially interesting.

But, you know, we said for a long time that this is kind of a case study of how our other dissemination and implementation work needs to proceed. Being sure that you are developing and closely collaborating with the communities of interest that you are trying to reach and, hopefully, trying to get to make your work their own, in relevant ways.

So we see this as a way to begin to work into other dissemination activities, but because we have a very specific product now, that clearly can have some substantial influence we think we'll learn a lot by doing this outreach and beginning to identify these channels.

One of the points Brian has made is that it's going to be very important and I'm sure many people can appreciate this. As we have these discussions, to really think very carefully about the tools that will be needed. It's not enough to

simply send a large monograph to an organization and say, here, do this.

It really is very important. Brian and David have both said this and members of the Methodology Committee have emphasized it again and again. We are looking at trying to figure out how to make this material, this information, part and parcel of established processes. Processes of how research is done, of how researchers are trained, of how information is disseminated out of research, currently.

And so, Brian has already come up with a list of potential tools, checklists, slide sets, that will make this work real and understandable. So I think we have a lot of work ahead of us, but I think the key point is to be sure we are working with those groups and always asking them how can we make this most useful to the folks that report up to you?

MS. NEWHOUSE: Harlan.

DR. WEISMAN: Well, first, congratulations to you, Robin, and the rest of the Methodology

Committee members. And I think it's an excellent document and, actually the draft -- I look forward to deferring to the final or to the revised report, but I actually refer to sections of it in some of my day job responsibilities. So I think it's very good and should be used.

It's also the first example of seeing how PCORI disseminates and monitors implementation. So, to me this is a really, really big deal because we keep talking about dissemination and implementation, but now we can really walk the talk, so to speak. And I think, I as a Board member would certainly like to -- not just have it be a passive thing going into the background, I think it's really an important demonstration of doing it right and experimenting and learning.

But, in particular, in terms of influencing research -- well, clearly we can influence what gets submitted to us and what we fund because we've already said, you should refer -- even going back to the draft document, you should go back and refer to it. We can influence that,

but the best way -- in my mind, besides the training you mentioned -- it is influencing and -- I think Ellen got to this point -- funding agencies that fund research that would include the kind of research we're interested in. And seeing what it would take to get them to fully adopt this as a standard.

Because it's a standard, I assume, not just for PCORI, but it's a standard for all -- you know, we want influence research in this field. So funding -- you know, making sure it gets somehow incorporated into grants is important and those interactions, I think, will be very important.

And finally, besides money, researchers are interested in publishing. And I think it would be vitally important to see whether something like ICMJE or one of the -- some group of journal editors say that they will require these standards to be demonstrated.

With that in mind, are we creating templates? You know, there's also the national and international meetings where scientific

presentations go, where their abstract presentations. And a lot of these things get standardized as a standard format for abstract submissions or paper submissions. Are we trying to help make that easy?

Maybe you could expand on those kinds of efforts?

MR. SILBERG: And to agree fully with your point about wanting to influence others and having those discussions, that's on the list and is one of the points that Brian has made repeatedly is working with the thought leaders and the decision makers, those different levers of how research is done, to try to get this work out there and adopted.

I guess the last point you raised would fall under the general heading that Brian has referred to as tools. A variety of tools for a variety of audiences to try to make one, the standards, very intuitive in terms of how they would apply in various situations.

As well as for those who are, if you will,

trying to -- if we get to this point, hopefully -- scoring applications or work that comes in for how they follow the standards. Trying to make that process as intuitive and easy as possible. So, knowing a little bit about journal publishing, you know that, as you said, journal articles are developed in a certain format. Clinical trials are reported in journal articles in a certain way and that's all been adopted as part of the publication process.

It would be terrific if we could have something similar for the standards. We have had some initial discussions with a couple of editors about this, and I think that is a topic, along with our general dissemination challenges and opportunities, to have further discussions with a broad array of editors and publishers about, because, as you know, there's some traditional processes that we would need to try to fit into.

But the opportunity to begin to talk to the folks who do this work now and see how we could fit our work into it is, I think, is -- as you say

-- is absolutely critical.

DR. WEISMAN: How will the Board be updated on the progress of the dissemination and implementation plan?

MR. SILBERG: You know, I think part of that will depend on, as we go back -- I'm sure this is a topic that will be important to talk about at the face to face meeting tomorrow.

How we begin to talk about the phases, specifically, what the milestones and benchmarks for each phase would be, as outlined. And not just checking the boxes, but trying to begin to come up with some sort of appropriate metrics for saying that we think we are actually getting somewhere. Not just that we sent the report out to 300 specialty societies, which is nice, but what sorts of very specific -- based on the advice that we get from members of the committee and the Board?

What sorts of very specific tools and metrics were we told would be important to develop? Have we developed them? Are they being distributed? Are they being used? And what sorts

of feedback are we getting? And I think that's going to be an ongoing process of developing these metrics and these reporting mechanisms.

And I'm sure many of them, as we'll find, as you pointed out, hopefully will inform our broader dissemination work as our other research results come on line. Many of the same mechanics, if you will, and logistics, I think, would apply.

So it will be an easy way to learn how we try to do this with a very specific product that we now have in hand.

MS. NEWHOUSE: Leah?

MS. HOLE-MARSHALL: Leah Hole-Marshall, Board. First, congratulations on this significant step to you and everyone both on staff and on the Methodology Committee. I think it's wonderful. I did think the vignettes were a great add. The benefits of having a long plane ride, as I did read each page.

So it's actually specific to this and I'll echo Harlan's comments and not repeat most of them, but I have something a little bit more specific.

And the first is that in the executive summary it's called out that most of these standards -- so there may be some that are minimal, meaning they're necessary for high integrity research. We also currently have within our funding announcements a requirement to comply. But I don't actually think we have a current mechanism to identify whether the proposals coming are in fact complying. And a mechanism to enforce certain things like the detailed study abstracts or study summaries being posted, et cetera.

So what I would like us to start with being our own best example. And if we do accept this, take on the responsibility that as we move forward with funding, we can answer the question about whether we're in compliance with our own standards. And be expecting that before we vote to approve any funding, that that will be a question that is asked. And if we aren't, where are we along that route?

I think that would be an excellent example for other funders. We can work to influence other

funders, but we have to start with us. It's in our paperwork at this point, but I don't think we've fully implemented. And we are in a state of evolution, but I think we need to hold ourselves to a higher standard.

And then, secondly, I commend the good work and hope that, as it was noted in here, continuing standards that aren't just minimal, but are aspirational are continued to be developed. So, if there's any assistance that the Board can provide to the Methodology Committee, or if that's a controversial statement, I hope as a board, we'll talk about it, so that we can work together as partners in continuing to advance the standards.

MS. NEWHOUSE: Thank you. And I also want to mention with David and Stanley, it's help. Stanley has created a preliminary check list and then embedded the methodology standards into the proposal template, so that it makes it easier for people that are submitting proposals to comply.

And also I just want to note the part of the first part of the implementation plan is to do

an assessment, via survey, to understand what the most important standards are for us to focus on, as well, so we can set some priority for how to move forward.

But, yes, trying to create a plan that helps people understand what needs to be included in the proposals is important, so, not only for the reviewers, but for those applicants that are submitting. So we're looking to pilot ways to make that easy and very adoptable.

MS. LEWIS-HALL: So, two comments. And one is, also, that I noticed when I went back and read at least of the funding announcements that some of our examples and the way that we currently talk about the methods, standards are not consistent with what we're about to adopt today, so we do need to clean that up. But that's a legacy of where we were before.

But what I think I hear you saying is that we don't -- because we don't know if we're clear enough right now, we can't expect researchers to actually comply with these currently, even though

they're minimal standards.

MS. NEWHOUSE: No.

MS. LEWIS-HALL: Okay.

MS. NEWHOUSE: I didn't mean to indicate that at all. They are expected to be incorporated into the proposals or they have to have some rationale for why the standards are not -- and that that rationale is clear. What this implementation plan is doing is just trying to make it very clear what needs to be included in each part of the proposal template.

And then the evaluation of whether we achieve that adoption. Whether it's included should be part of the evaluation.

MS. LEWIS-HALL: Great. Okay, thanks.

MS. NEWHOUSE: Let's see, Francis and then Steve and Gail?

DR. COLLINS: So NIH very strongly supports the process that's been carried out here and, of course, Mark Lauer played a significant role on the Methodology Committee and provided a lot of input, from NIH's perspective. And so we

very much plan to encourage NIH applicants for studies where these would be relevant, to pay close attention to them.

We feel, however, that it's better that we use the word encourage, rather than require because -- well, I guess, two things. One is that scientists tend to resist anything that's required that they didn't come up with themselves and you may end up actually having a negative effect, if you make this too heavy-handed and make it sound rigid and legislated.

And I guess the second reason is, I would really not want this to squash creativity. There's always a risk there in terms of coming up with new methodology ideas. And there's always a danger if reviewers, for instance, are told, you have to have every application match exactly what's in this document. That somebody comes along with a new idea about a new design will get dinged, not because it wasn't a good idea, but because it wasn't what had been done previously. So, just a slight word of caution there about everything that

I'm sure the Methodology Committee would agree with. That we have not reached the end of the science of methodology. That there is still room here for innovation and creativity and we should be encouraging that.

I just want to say, I would very much welcome the tools that are being talked about to make this rather thick document accessible to busy investigators who will want to understand how does this help them? How does it give them a better chance to make a proposed SOL that is likely to be seen as rigorous and appropriate, as opposed to just one more very long bunch of paper that they are required to go through, which may not sink in particularly well.

So the more you can do that and sort of field test those tools with the audience you really want to reach to be sure you're getting through -- and we'd be glad to help with that -- the better this will go.

MS. NEWHOUSE: Thank you. Steve?

VICE CHAIRMAN LIPSTEIN: So, I have, I

guess, a question of the folks in the room who are the most familiar with methodology standards. And as you read through the report, would you characterize this as the 101 course for methodology standards that you would want every medical student, nursing student, public health student, other health professionals who are taking research methods courses, that you'd want this to be mandatory reading?

Or is this more in the category of generally accepted accounting principles, so these are the standards that are widely in use throughout the research world today?

Or, I guess, the third category would be best in class. Are these the best in class methodology standards that are employed by the top 10 percent of investigators in this world of research?

So I know that I'm getting you into a categorization, but -- you know, I guess Arnie, you work at all three levels. You teach, you research, and you're familiar with investigators, so where

does this fit into that classification?

DR. EPSTEIN: So, I haven't re-read this version. It just came out, but I read the earlier version. It's quite detailed and I would have characterized them as lowest common denominator.

That is to say, the committee deliberately chose standards for which there was a pretty broad consensus to try and reduce -- and I agree with everything Francis said -- the pushback from other people doing it. And as you get further up the tree to more sophisticated or more restricted areas, you'll get more discourse.

So this is LCD and I think it's fine. I also don't think it's a primer. It wasn't intended to be a primer. Primers are put together to teach people in a different way and this is more of a catalogue. But Robin, I've just characterized you work and I should give you a chance to --

MS. NEWHOUSE: Yes. No. Well --

DR. EPSTEIN: -- have a friendly amendment or a not so friendly amendment.

MS. NEWHOUSE: No. And these standards

were chosen -- just to remember -- not that they were completely prevalent, not that they were aspirational, but where the methods could add the most rigor if, in fact, they were adhered to.

So certainly there are a number of standards to come and when you ask, should every Ph.D. student read this? Yes, of course.

Now, that is a part of our implementation plan, that this is widely disseminated, but I would say that it's not a complete primer, but certainly includes methods that should leverage the success of improving the rigor and comparative effectiveness research.

VICE CHAIRMAN LIPSTEIN: So, if I mention the word "research" -- Ph.D. students are candidates, so in undergraduate medical or nursing curriculum, broadly stated, do they teach research methods in the general curriculum and, if they do, is this relevant?

MS. BARKSDALE: Debra Barksdale, Board. I'll take that one.

VICE CHAIRMAN LIPSTEIN: Have fun.

MS. BARKSDALE: Absolutely. In our baccalaureate programs, we do teach students research, as well as in our masters and doctor of nursing practice, and certainly in our Ph.D. programs. I see this as having the most impact, probably, in our doctoral programs, whether that be doctor of nursing practice or Ph.D.

MS. NEWHOUSE: And I also will mention, then, when we're out in the community -- and I think Allen and I talked about this in the hall a little bit earlier -- when there are people that are knowledge users and they're making decisions in their health system, this also relates to the evidence-based practice, competencies, and organizations of, can I believe this evidence? Will it work here for the patients? Does this apply to my patients and my patient population?

So the whole idea of being able to interpret the evidence, to incorporate it into your own practice setting -- even though they're not evidence generators on the research paradigm, they're the users of this research. So it has an

impact for them, too. So it's actually taught from the other end, not the research and methods component, but more the adoption, the pragmatics, and the utility side.

Oh, Gail?

MS. HUNT: Thanks. Gail Hunt, Board. First of all, I wanted to say that I think this is a great improvement, with the little case studies. I think they really do a great job of explicating the concepts. The other thing is, I understand -- because I read the part in the appendix that talks about what's the audience and so we've just had a great discussion of who is the primary audience for this?

So it is not the patient, typically. I mean, there are going to be exceptions, but basically, it's not going to be the patient or the family care giver, but I do think that when we're thinking about dissemination, we should keep those people in mind because, in the end, if we're talking about shared decision-making, it's not just the primary care doc, it's that triad of people who

are making the decisions and so how it plays out and how it actually filters down is something that they should definitely be taking into account.

And just lastly, I'd like to say, I remember when Christine and I and others were working on the pilot projects, the Methodology Committee report was just at a very early stage, but the RA said that they were going to be required to take those methodology concepts into account when they wrote the proposal. And the exception was that it was only in draft, so now it's not going to be in draft anymore, it's going to be final. So people who are replying to the RFP, I think it's more than encouraged them to take these standards into account, especially after we discussed this kind of basic -- I think we need to say they need to take them into account in terms of replying unless they've got some exotic special exception.

MS. NEWHOUSE: I'm glad you brought up the perspective of the patients in the questions, in the comments that you just made because the whole

idea of these stories is to help bring these standards to life; to help people understand and the patients understand what impact one has on not only the generation of the science, for example, missing data or a subject dropping out, how that effects ability to draw conclusions.

So the stories are written in ways that help people to understand why the methods are important. So they are also a target of the methodology report.

So, in the second comment, just about the use of the standards in the proposals, and that is the intent, that they comply with the use of the standards when they submit proposals. But as Francis said, we wouldn't want to block innovation. And there could be a rationale why the standards wouldn't be used in specific situations, so we'll rely on our peer reviewers to make some judgments about whether that's an appropriate rationale, or not.

Let's see, Christine?

MS. GOERTZ: Christine Goertz, Board

member. I want to congratulate the Methodology Committee and the PCORI staff that worked on this. It's just really an excellent document and I recognize the tremendous time and effort that's gone into this, especially on the part of many people who already have full-time jobs. So thank you for all of your work on this.

I'm curious about when you think you'll have criteria for evaluation developed? I note that your ongoing monitoring evaluation -- I'm assuming that this is basically your dissemination implementation plan for 2014, not overall. But it seems a little bit tight to me to try to even do any kind of evaluation in this year, given the fact that some of the key things that I think you'd want to evaluate -- such as your implementation tools and your increasing awareness -- are not going to happen until further out, so I'm just wondering how you're going to be benchmarking that?

MS. NEWHOUSE: Well, we do have to establish some evaluation metrics and, you know, I remember early in some of the discussion about the

evaluation metrics, the fact that we have a tool, yes or no, is not really what we're after.

We're after, are these standards used in the proposals? Do they improve the rigor of the studies that are funded? In fact, do they improve the usability of the results, which will take some time to establish?

But we will be developing some metrics that relate to the quality of the studies that are funded.

MS. GOERTZ: Now, is your plan that this initial monitoring plan would just happen within PCORI or that it would go beyond, as Francis had said, earlier, that NIH was very supportive of the process and wondering are even thinking of trying to monitor beyond PCORI at this point, or would that be something for future years?

MS. NEWHOUSE: Well, that was discussed, but I think in terms of reach, we should take one step at a time and make sure that we have tools that we can use. Tools that can be disseminated and implemented in other settings, so we've got to

do a fair amount of evaluation, I think, in the preliminary implementation plan.

Tailor what we're doing, carefully evaluate it, move it forward in another step, but the goal was that these standards were broadly adopted. So I wouldn't say this is something we'll be looking for in the first six months, but I would say that that's an evaluation criteria that we will be looking at over time. And the increase in adoption over time.

MS. GOERTZ: All right, thank you.

MS. NEWHOUSE: Let's say Allen and then Bob.

DR. DOUMA: Allen Douma. I think it's great. It's nice to see something come to fruition and now we can start proselytizing who we are and how good we are.

The measurement -- the question about benchmarking is probably not only critical going forward to measure the impact of what we're doing, but it's also going to be a real challenge to differentiate the difference between if I'm a

researcher using these methodologic standards which are identical to yours, how do we benchmark that? And the fact that I don't adopt yours doesn't mean anything because I'm already doing what you want me to do in the first place. So it's going to be a real challenge to the communications people.

The various phases, if you look at the components of each, they're fairly broad and can be very big. It all depends on how many, who, et cetera. My question is what is the budget for us in 2014 to do these things? And is there any prioritization over spending in phase one versus phase two, three, four, five?

MR. NEWHOUSE: Well, and as Bill mentioned, there are phases, but they're overlapping phases. And we do have budget in the Methodology Committee for the Implementation Plan. So I'm not sure if this is the only place it's budgeted. It's probably budgeted with you as well.

MR. SILBERG: Yeah, we'd have to look at the specific numbers. I know that the -- I believe, and maybe Dave can comment on this, I

think there's different -- there are some elements where the funding would primarily sit with the science group and the Methodology Committee and there might be some other communications support that will probably be built into what the broader communications team would do. But you may have a better sense of that.

MR. HICKAM: About half of the budget for the Methodology Committee in 2014 is for implementation of the methodology standards. There's also a component of the budget for development, doing necessary work to develop some additional new standards, which is part of, again, we haven't really talked much about it, but, you know, there's going to be sort of ongoing development of this material which will, you know, lead to updating of the standards and of the report itself.

DR. DOUMA: I guess the real question, back to Robin, is do you think you have enough money?

MR. HICKAM: I think it's a reasonable

plan for this coming year. I mean, I think it's feasible.

MR. NEWHOUSE: And I agree in year one. I do think, as I said, we'll have to carefully evaluate, tailor, move forward, carefully evaluate, tailor, and move forward. If we find something that has a very high return on investment in time, then I think we'll have to come back and say we've got something here that we need to move on. And I feel very comfortable that that's something we can accommodate.

All right. Let's see, Bob?

DR. ZWOLAK: Bob Zwolak, Board. I speak up very briefly to congratulate the group on finishing this and, in particular, the translation table, which I thought was going to be impossible, morphed a little bit into a translation framework, which I thought was very nicely done. I hope we dissemination this as widely as can possibly be accomplished. I hope we incorporate it within reasonable in our efforts to look at new applications and to measure how well it's done.

And on a lighthearted note, I would note that you were very responsive to all the feedback that you got, including my modest comments made their way into this document.

[Laughter.]

MR. NEWHOUSE: Very good. Thank you. Yes, we're very proud of the work and the translation framework and the work that will be conducted over the next year to the translation table, realizing that these are very complex decisions about design and methods. And one table couldn't fit all, so providing the framework gave a sense of the phases of decisions, but a table, which will follow with more work, really helps to identify the individual problem that one faces and the tradeoffs that one uses to make the decision about the design and methods. So thank you.

Let's see. Harlan, yes.

DR. WEISMAN: Thank you. Just one -- it's really a question maybe for you and maybe for Gray. In approving this, one section that we've never overtly addressed as far as I know is Appendix C,

which were the recommended actions and research recommendations by the Methodology Committee. And they've been hanging there since the original draft was published in 2011, and I'm not sure what anybody is to make of them. I think some of them when I read them maybe are being covered and addressed in other ways.

But I guess one question is what was the Methodology Committee hoping would happen as a result of making these recommendations, I assume to the Board? And second, expectations on what the Board would do with it. I mean, do you want yea or nays on these things? What's officially been done? What do we do with this?

MR. NEWHOUSE: Well, I know that --

DR. WEISMAN: It's been a while.

MR. NEWHOUSE: Yeah, this has been a while.

MR. HICKAM: Perhaps I might make a preliminary comment.

MR. NEWHOUSE: Yes, please.

MR. HICKAM: This list of recommended

actions and recommended research was actually -- was shortened because many of the previous recommendations had already been acted upon by PCORI. But you're right, there's certainly a connection between this current list and the prior list that came out in the draft report.

DR. WEISMAN: So what do we do with it?

MR. HICKAM: I think that's something for the Board to decide.

MR. NEWHOUSE: All right. So I would say with that question being raised we ought to go back to the Methodology Committee and look more in detail. There certainly were some recommended actions that the Board endorsed and we moved forward. But these additional recommended actions, I think that we would need to evaluate what has happened in that period of time and what else needs to be done and come back.

DR. WEISMAN: Thank you.

MR. NEWHOUSE: Let's see, I see Christine and Leah.

MS. GOERTZ: Thank you for bringing that

up, Harlan. Actually, Robin, I think this would be an excellent thing for the Methodology Committee and the PDC to work together on, looking at how we can implement those. And, in many cases, I think it is, as Leah had suggested earlier, we need to update our funding announcements. And, you know, some of it is actual, you know, doing -- you know, making changes in the way that we do things and some of it is just clearly -- is just simply being more clear about what our expectations are in our funding announcements.

MR. NEWHOUSE: Thank you. We look forward to working with the PDC. Leah?

MS. HOLE-MARSHALL: So I still feel like there are some that feel like, well, these are not always applicable or, as Francis mentioned, they will stifle innovation, and I just don't see it. I'm not a researcher, so I am well outclassed by the methodologists that are in the room, but things like select appropriate intervention and comparator and provide sufficient information or report to allow the inassessment of the study's internal and

external validity which are representative of the standards that were selected here are so fundamental, I believe, to producing what's in our mission, which says high integrity, that I think it's a floor. And so if there are some that aren't really a floor, as we develop the tool I would be very interested in separating those out so that we're all very clear and we clearly communicate to researchers that you're not going to get funded if you're below this floor. And I think most of them would fall in that we want you to be very transparent about the project and the information, so anyone else could reproduce it.

So I just -- I would plead for that because I still don't feel like we're all in the same place about how crucial this is to getting studies that are actually adequate to say they're of high integrity. And I think, you know, an elephant in the room for us is we have all done our own look at what's been funded so far and each of us has questions about that in some ways. And part of it is they don't meet our current standards.

So I just think -- I mean, you know, if it were up to me I would stop any further funding until we got this right because I just think it's that important. And I know that that probably would not be -- that'll be a minority opinion on this part, but I just -- I feel so strongly that our work cannot be completed without doing this. So I really --

DR. WEISMAN: We can't put anything in here that you wouldn't want to do because it's basic. It's basic stuff.

MR. NEWHOUSE: So you may be speaking about some of the crosscutting standards that really relate to everything and then design registry studies may not relate to all.

MS. HOLE-MARSHALL: Right, but even in the standard you call that out, the ones that are -- for instance, if it's registry, you know, but if they're proposing a registry even the standards that are specific to registry appear to me to be pretty fundamental.

MR. NEWHOUSE: Right. Okay.

MS. HOLE-MARSHALL: Thank you.

MR. NEWHOUSE: Arnie.

DR. EPSTEIN: I'm going make a plea for the kind of discretion that Francis spoke to and it has to do with the nature of scientific standards. I call these LCD, lowest common denominator. You call them floor. They are an enormously thoughtful group of guidelines or standards, however we're going to call them, put together by 15 or so of the country's best methodologists, getting input from scores and scores and scores of others, so that's a lot.

But you can see this -- let me give you an example. If you go to the standards in Appendix A, they list a number of standards for missing data. And they're really very thoughtfully put together for how one should specify missing data and use different methods of approaching it and compare them and do the sensitivity analysis and on. On the other hand, there is no and nor can there be a precise standard for, well, when do you pay attention to that? If I had a million data

elements and one was missing, do I really have to write you 34 pages for that one element? I don't think so.

But that's hyperbole. If 20 percent of the data are missing do I have to pay a lot of attention to this? You bet you. And in between there's going to be a little bit of discretion here. And I don't think we can take that discretion away from reviewers who are going to be knowledgeable of standards and make a considered judgment that, at the end of the day, this was a reasonable approach, they paid that much attention to it. Even if they believe those standards, there's such a thing as using a metered approach to address the size of the problem with a response that's commensurate.

MS. HOLE-MARSHALL: So, again, I would plead if that is the case that we figure out which ones are, in fact, minimal, that must be there. And figure out the other ones where discretion is permitted.

I mean, describe statistical methods to

handle it. Statistical methods for handling missing data should be pre-specified in the study protocols. That seems pretty minimal to me. It doesn't say what kind of documentation you're going to use. It doesn't say that you have to use a certain standard or statistical method. It says you have to pre-specify it.

DR. EPSTEIN: Yeah, I didn't go through them one to another. I just picked something where it said, here, this will make the point. It may be that you could go through and find some that no one could find an exception to. I just don't know of any.

MR. NEWHOUSE: We can certainly have a discussion in the Methodology Committee and see how far we can get, realizing that we do have to have some latitude for investigators to create some alternate approaches. Thank you.

Other questions?

[No response.]

MR. NEWHOUSE: Thank you.

CHAIRMAN NORQUIST: Thank you, Robin, very

much. And so I think that last discussion was very important. I wanted to see if we were going to come to a conclusion. I think the best conclusion is to put it -- at this point in the process put it back to the Methodology Committee to see if you could identify, for example, little stars by some of these that everyone would accept as something that would -- you know, and come back to us at some point. Because you can clearly hear some people who want that and then certainly we don't want to be too prescriptive so that I think even if you came in on a grant would say, wait a minute, I'm not necessarily going to do this one, you know. But be very clear.

And the other thing I would say, Bill, is that I think all of the audiences are relevant to this report. It's how you package it for the audiences. So I could see this and the answer is, yes, and since I teach in a medical school and teach medical students is that there are some who are on a research track and who would like a higher level, but there's -- every one of the medical

students should understand the importance of some of these methodologies as they read papers that are informing them about what to do, what the limitations of that research is. And so some of the examples and the other things are critically important just for anyone and practicing clinicians and stuff.

And I think overall it highlights the importance of what we're doing at PCORI in a variety of ways. So from a dissemination vehicle and also as a PR vehicle in some ways I think it could be helpful, but it's the packaging. And we'll have to have several different packages, depending on who our audience is, as I'm sure you well know better than I do

Okay. Allen, you had one last comment?

DR. DOUMA: Yeah, one last comment. Now that we have this as a basis on which we can go forward and hang our hat on, it's important that we also relook at what's out there and what kind of -- particularly education and training programs vis-à-vis CER. And I bring that slightly up in the

context I just got an e-mail from my wife Ellen Silvius [phonetic], who said there's a really good program funded by the NIH that's being used at Ohio State University, her alma mater. So you might want to look that one up.

CHAIRMAN NORQUIST: All right. Thank you. Arnie, is your card still up or are you just --

DR. EPSTEIN: Oh, I'm sorry.

CHAIRMAN NORQUIST: Okay, thanks. All right.

Robin, again, our thanks greatly to the committee, who, I know, put in a lot of hard work and, of course, your work is not over, so thank you.

MS. NEWHOUSE: Thank you.

CHAIRMAN NORQUIST: And David and Bill, too, thank you very much. Okay.

Oh, I'm sorry. Yeah, so we have a motion. So we have the motion on the table? I was out of the room when the -- was there ever a motion to approve or accept this? If not, could we have a motion to accept?

UNIDENTIFIED: So moved.

CHAIRMAN NORQUIST: Second?

UNIDENTIFIED: Second.

CHAIRMAN NORQUIST: Okay. We've had our discussion, I hope. No more -- all those in favor?

[Ayes.]

CHAIRMAN NORQUIST: Anybody opposed? Abstaining?

[No response.]

CHAIRMAN NORQUIST: Okay, thanks. That's it. So, Joe, we have, what is that, 10 minutes before we're supposed to -- should we take a 10-minute break?

DR. SELBY: I wanted to just -- I think that's a great idea, but there's just a couple things. Just to be on the record, I think that's a great idea, Mr. Chair.

And there are a couple announcements that I was reminded that I should make in the public session, so I'll make them now.

MR. BECKER: Oh, okay, [off microphone] there's one we skipped over, but go ahead.

DR. SELBY: An agenda item we skipped over?

MR. BECKER: Yeah, [off microphone].

CHAIRMAN NORQUIST: We skipped over it?

DR. SELBY: It's totally my fault.

CHAIRMAN NORQUIST: How did we skip over that?

DR. SELBY: I think it -- I'll tell you later how we managed to skip over it, but we did. And it's my fault.

CHAIRMAN NORQUIST: Well, so much for the 10-minute break. Sorry.

DR. SELBY: Larry, go right ahead.

MR. BECKER: So I just want to remind people that we have a responsibility annually to make our declarations about conflicts of interest and that Mary has taken on that process as our general counsel. And she will be beginning that process shortly, and it all travels up to a process that Bill Silberg has to get our annual report out and so forth. So I would ask all the Board members as well as the Methodology Committee members to be

on the lookout for those documents and to respond in a timely fashion to Mary when she so approaches you. So thank you.

CHAIRMAN NORQUIST: He pointed it out to me it was in red on mine, but it was after some other -- just before we got -- I was out of the room. I realized that was when the methodology report came out, so anyway. It's your fault, Steve.

[Laughter.]

CHAIRMAN NORQUIST: That's good, I can now -- that's the good role as the chair, I can blame it on the -- yeah, yeah, yeah. No, it's my fault actually. I mean, it was bolded in red and I missed it, so.

Was there anything else, Larry, that you need us to do? Okay. All right.

DR. SELBY: So now I just want to make a couple announcements for the public that's listening in as well as for Board members of upcoming open Board teleconference meetings. There will be two of them in December and one in early

January. And this actually reflects back on some of the conversations we had today.

So on December the 3rd, Tuesday, at noon Eastern, we will have a one-hour Board call. And on that agenda will be a proposal to the Board to reauthorize the standing Advisory Panel. So there are four advisory panels, three that are related to research priorities and the Patient Engagement Advisory Panel. We only approved charters for 1 year 12 months ago and it's time to reauthorize the charters and we will then initiate the process for refreshing the membership of those panels in the first months of calendar year 2014.

Also on tap for December 3rd is a request to the Board to approach at least two and possibly more targeted research topics coming from the PDC. So that's the December the 3rd Board meeting.

On the December 17th open Board meeting we will have the slew of slates to approve.

[Laughter.]

DR. SELBY: One of them is the result of the targeted funding announcement on asthma,

treatment of uncontrolled asthma in minority populations, so there will be a slate of proposed awardees related to that announcement.

The second is to approve the fourth cycle of the broad funding announcements.

And the third will be to approve a slate of CDRNs and PPRNs to create the National Patient Center and Clinical Network. And so that's the December 17th Board meeting. That'll be a 90-minute meeting beginning, again, at -- it's a Tuesday and it's beginning at noon Eastern.

On the January 14th Board call that will be another open webinar. We hope, we anticipate having additional topics for targeted PFAs coming from the PDC to the Board.

So all three of those are currently booked as open webinar meetings. Thanks.

CHAIRMAN NORQUIST: So we have five -- I'll tell you what. Do we have a public comment here or is it online?

DR. SELBY: We have a public comment here.

CHAIRMAN NORQUIST: Why don't we go ahead

and do that.

DR. SELBY: We have a public comment person I believe in the room. Sue?

CHAIRMAN NORQUIST: Correct, Sue?

DR. SELBY: Is that right? And then we will wait until the 3:00 hour because that's when posted that we would be having --

CHAIRMAN NORQUIST: No, but I'm saying we have the public comment in person for now.

DR. SELBY: Yes. I think you're right.

CHAIRMAN NORQUIST: And then by that point it will be 3:00 and --

DR. SELBY: Yes. Let me just double-check with Bill Silberg and make sure he's in agreement.

MR. SILBERG: As far as I know, [off microphone].

DR. SELBY: And as far as you're concerned it's okay to go ahead and have that even though it's not quite the 3:00 hour?

MR. SILBERG: The folks who are listening it's probably about five minutes?

DR. SELBY: Yes.

CHAIRMAN NORQUIST: Sue, were you going to -- okay, thanks.

DR. SELBY: Good afternoon, Sue Sheridan.

MS. SHERIDAN: Good afternoon. Thank you, Dr. Selby, Dr. Norquist. This is our public comment period where we're going to invite those in the room who are interested in offering a public comment and then we will go to the phone lines to -- open that up to the phone lines if there's anybody that wants to share some comments.

I'm going to ask that we limit our comments to three minutes for those of you in the room and on the phone. And that we'll also take written testimony, so if there's anybody listening that wants to submit some comments, please do so via our website at info@pcori.org.

I want to share that all testimony and additional materials submitted to PCORI will be provided to our Board members, our staff, our Methodology Committee, or whoever's appropriate to address and answer those questions.

So I would like to first see if we have an

operator on the line.

[No response.]

MS. SHERIDAN: Okay. We're going to start with our public comment from the room. I'm going to invite Sara van Geertruyden from PIPC.

MS. VAN GEERTRUYDEN: Thank you. It's good to be here. My name is Sara van Geertruyden. I'm the executive director of the Partnership to Improve Patient Care, also a member of the PCORI Patient Engagement Advisory Panel, which has been a great experience.

I want to thank Dr. Luce and Dr. Sox, who recently participated in PIPC's forum on November 5th, which was -- it was a great discussion. We got some really interesting questions from the audience and I think it was a really good opportunity for stakeholders to engage with PCORI in that environment.

I also want to thank Bill Silberg. He recently participated with us in a roundtable that we did. And Orlando's going to be coming to a roundtable with us later on this week, so PIPC

could be more pleased with PCORI's participation with us and engagement with us, so we're very grateful.

We hope to pull together some consensus recommendations based on those roundtables related to your work to try to identify best practices for dissemination. We hope that that is helpful to you as you're putting together your action plan.

So one thing, we also recently put out a new whitepaper, and I have some extra folders back here if anybody wants to pick one up with some of our whitepapers, but we recently did a whitepaper looking at priority setting. I know that that's something that the Board has been struggling with, especially as you're making that shift to targeted funding announcements. So just to sort of go through some of the recommendations that we've identified as best practices in the literature.

The paper calls on PCORI to establish a targeted research agenda based on a broad and structured solicitation of topics from patients and providers. It directs PCORI staff to evaluate and

distill the suggested research topics to ensure research topics meet PCORI's mandate of patient centeredness and the statutory criteria for research. It develops a rationale and also asks PCORI to develop a rationale and topic brief for research topics to provide both the PCORI and the public with a clear and transparent understanding of PCORI's research agenda; to utilize the relevant clinical expertise both within and beyond PCORI's advisory panels to help rank the topic list; and to ensure the opportunity for public comment on the draft priority list and research agenda and to provide for input and approval by the Board of Governors; and then finally, and probably most importantly, to promote transparency of the priority setting process in its entirety.

So anyway, as I said, you're more than welcome to pick up a folder. We have these whitepapers in the folder. And we are really looking forward to -- you know, I hope that this information is helpful to you. I know PIPC has been encouraging PCORI to take this direction and

to targeted funding announcements, and I hope that the information we provide to you is useful to you as you're coming up with those processes.

And I also think that, you know, building on -- I was listening to this morning's discussion about PCORI's sunset date in 2019. And I think, you know, part of the legacy of PCORI is going to be these processes, which hopefully would be -- you know, to the extent that they're clearly defined and understood, could be picked up by other research entities as well. So thank you.

CHAIRMAN NORQUIST: Thanks very much.

MS. SHERIDAN: Thank you, Sara. Do we have an operator on the line yet?

OPERATOR: Yes, ma'am. I said hello earlier. I'm not sure if you didn't hear me?

MS. SHERIDAN: I can hear, yeah.

OPERATOR: Can you hear me, ma'am?

MS. SHERIDAN: We can.

OPERATOR: Okay. When you asked for me earlier I did come on and say hello, but I'm not sure you heard me.

MS. SHERIDAN: Oh, sorry. Hello.

OPERATOR: Hello.

MS. SHERIDAN: Do we have anybody on the line that would like to make a comment?

OPERATOR: If anyone would like to make a comment, just hit *1 on your telephone keypad.

No, ma'am, we don't have anyone in queue.

MS. SHERIDAN: Okay, thank you.

OPERATOR: You're welcome.

MS. SHERIDAN: Bye-bye. With that we will -- unless there's any other comments in the room, we can conclude this public comment period.

Oh, Larry?

MR. BECKER: [Off microphone.]

CHAIRMAN NORQUIST: Yeah, we can certainly wait five minutes here. We can take a little --

VICE CHAIRMAN LIPSTEIN: Gray, [off microphone] with the agenda and if people will want to [inaudible] suspend the agenda or do you want to just --

CHAIRMAN NORQUIST: What does the rest of the -- wrap up and --

VICE CHAIRMAN LIPSTEIN: Yeah. [Off microphone.]

CHAIRMAN NORQUIST: No.

MS. SHERIDAN: They're going to listen.

CHAIRMAN NORQUIST: No, no, what we're going to do is wait five minutes to see if there are any comments. If there are not, then we'll adjourn. But if there were other perhaps comments or things that people wanted to make in the meantime while we're waiting, that's okay.

DR. JESSE: It seems we had a whole lot more people commenting in the public comments earlier on. Do we actively solicit people to come in and comment or do we just put on the announcement in the meetings that there's going to be a time for this?

MS. SHERIDAN: Yes, we do actively solicit and we let our stakeholders know that the Board meetings are going on. And I've been asking myself this question. I think the phenomena is that we have so many engagement events now that we're really capturing comments at our workshops, at our

roundtables. We're evaluating them. We have constant outreach with them. So I think that we're fulfilling a lot of the questions in other venues.

DR. JESSE: So that being said, maybe if we have this time and we have a void it would be an opportunity to feedback some of those comments to the Board, at least in broad categories?

MS. SHERIDAN: And I think that's a great idea because there's a lot that goes on with our public, with our stakeholders that we really don't have an opportunity to share with the Board. We do the COEC, but as we do these engagement events the feedback that we get, that we collect and evaluate, I think would be of interest to you.

CHAIRMAN NORQUIST: The other thing that we may want to do that we have done in the past is invite specific people to sometimes come or, like we did before, we had the research people together with their -- I think a lot of people enjoyed that. So that might be another thing we think about. Because I think it's true, our activities have completely changed a couple, three years ago. And

now we have all this engagement, but we might want to think about a way to get feedback. And also I think it's a good idea to give us some summary or other comments we've gotten from some of these activities, so that's a good point.

DR. DOUMA: Do we know how many people are online or on the phone right now?

CHAIRMAN NORQUIST: Just listening?

DR. DOUMA: Either -- whoever. I'm just trying to think what's the audience that is not responding?

UNIDENTIFIED: What's the denominator?

DR. DOUMA: Yeah, what's the denominator? Exactly.

OPERATOR: There's a total of seven.

DR. DOUMA: Seven.

UNIDENTIFIED: Seven people are listening.

DR. DOUMA: Okay.

CHAIRMAN NORQUIST: So now we're at five after, so we can ask again.

MS. SHERIDAN: I'm sorry, Operator, I didn't get your name, but is there anybody else on

the phone now?

CHAIRMAN NORQUIST: That wants to ask a question.

MS. SHERIDAN: That would like to ask a question.

CHAIRMAN NORQUIST: Or make a comment.

OPERATOR: There is no one in the queue.

CHAIRMAN NORQUIST: And make a comment, sorry.

OPERATOR: Ma'am, did you hear me? There is no one.

MS. SHERIDAN: Okay. Thank you very much.

OPERATOR: You're welcome.

CHAIRMAN NORQUIST: I think that brings the formal agenda of our open session to a close at this point. And I don't know, did you have anything else you wanted to say?

DR. SELBY: Well, I just would like to summarize briefly where we go on several of these topics, but not without saying first thank you very much for really useful discussions today on every single topic. That was just great. And thanks to

the staff, to the Methodology Committee for all of your work these last two months since the last Board meeting.

On the Strategic Plan the next steps are to post the Strategic Plan and then to get back to work on the 2014 Dashboard, which we will put into play. You will see the first version of that just after the 1st of January.

And then to take those strategic questions which we've identified and tackle them really I guess and we'll prioritize them and tackle them in the order of highest priority. Gray had suggested earlier today that they might be very good topics to vet, in part to have some initial discussions on in the Board retreat in February. So that's it for the Strategic Plan.

On the question of decision support research and primary comparative effectiveness research, we have two ways forward. The decision support work really revolves around getting our handle on the research, looking for themes, looking for ways to systematize or make more uniform the 37

projects that we've got funded, aiming toward products that we could make available publicly and disseminate. And the second part of that activity is getting this conference underway so that we really identify what the outstanding research questions are, how we want to modify the -- whether we need to modify the announcements, how we want to modify them, and what questions do we have remaining on the table. We will keep the Board posted closely on this per your request.

And the second part which we take up tomorrow morning bright and early with the PDC is getting on with the idea of announcements that specifically solicit larger, probably longer, higher cost comparative effectiveness research studies. And we will also begin blogging about this and in other ways communicating it to the research community because it takes time to -- one, people need to appreciate that this is coming so that they have time to get ready for it.

And then on the issue of the budget and of the question of the research commitments, we simply

need to go forward on trying to get as much high-quality research solicitations out the door in a timely way with a hope of getting a good part of the ways toward $1 billion in commitments by the end of fiscal year 2014 and certainly all the way there by the end of fiscal year 2015.

And on the advisory panels the next steps now are, as David Hickam outlined, to -- along with the advisory panels that are being refreshed in early 2014, these two new advisory panels will be solicited for members. And we'll be back to you with a proposed composition in the springtime.

I think that's it. I think that's it. And you've heard just recently about the dissemination plans for the methodology report. So again, thanks.

CHAIRMAN NORQUIST: Thanks, everyone. And Joe, one thing I would ask -- because one of the things that's come up before, if it's possible to get a concise summary of the meeting minutes, with the clear decisions and action plans kind of being laid out, out quickly so that we could have that.

I mean, we usually come back and do the minutes, but if we could get that quickly so we can keep on target and have it very clear. And then I think Francis had something he wants to add.

DR. SELBY: Good. That's a good idea and we can do that.

DR. COLLINS: It's Francis Collins, Board member. I don't know that we've heard what exactly the current plan is as far as dissemination as it relates to PCORI's interactions with AHRQ. And I know, Joe, I think you were speaking at their Advisory Council last week. Since we have just a minute here, is there something you can tell us about how that coordination plan is shaping up?

DR. SELBY: Well, it's been a topic that's been right near the top of Rick Kronick's priority list since he's arrived at AHRQ, how do we talk about, how do we plan, how do we implement dissemination? One of the things I said at the FAAC last Friday is that it's our -- we certainly recognize AHRQ's assignment in the legislation of that responsibility. We recognize their experience

and their expertise and, to a great extent, the infrastructure that they have in place. But we also -- and I said this, I think, probably based more on a sense of the Board than -- and particularly of the COEC than of a formal vote, but that our sense was that probably the amount allocated to AHRQ for dissemination, given that dissemination is a key part of PCORI's purpose, is small. And so that we're developing this dissemination plan in close collaboration with AHRQ over the next -- over the fiscal year 2014. And we're going to need to figure out whether, in fact, there are enough resources and whether we ought to deploy more resources to dissemination.

And I think, you know, there, also, we get to this hazy line where some of this conversation we've had this morning about decision support really blends right in to dissemination. So I look forward to working with Jean and Rick and AHRQ and with the recipient, the awardee, for the RFP on dissemination, on developing the dissemination plan, and with the Board to flesh this plan out in

the next few months.

DR. COLLINS: Is that something that the Board could expect to hear more about in maybe a subsequent meeting?

DR. SELBY: You bet. Yes, I think, you know, we will -- Anne, when will we have the award announced?

DR. BEAL: [Off microphone.]

DR. SELBY: No, the award announced.

DR. BEAL: Sorry, the end of this calendar year.

DR. SELBY: Okay. So we will have news of an awardee that will lead the development of this plan by the end of 2013.

MS. SLUTSKY: So I would like to add, first of all, Rick's sorry he can't be here. He's attending a family event this weekend that bled over into Monday. But I think if he was here he would probably tell you that in -- he would say that he's been at AHRQ for a little over 2 months, and then taking out almost 21 days for the furlough, that it's sort of a smaller gestation.

But one of his goals when he first came to the agency was to identify aims for the agency and brief the Secretary and her senior staff. He did that about 10 days ago. I don't know if you were present. One of the aims was to get her concurrence about the use of the PCOR Trust Fund primarily in the area of dissemination for fiscal year '14.

He did get her concurrence in a very broad spectrum and met with our National Advisory Council on Friday. Joe was actually there in the afternoon and Mike Cash in the morning. And now that they've been briefed he's going to make the broad outlines of that fiscal year '14 effort publicly available. And I think at the next meeting or even at a conference call he'd be happy to share that information, which I think you'll find is extremely complementary to what PCORI is thinking of doing.

DR. SELBY: I think he's also one of the few people that said that the furlough was a good thing because it gave him a chance to catch up with his staff.

UNIDENTIFIED: Outside of work.

CHAIRMAN NORQUIST: Not encourage that. Okay. So let me thank everyone who joined us today, both in the room and on the webcast. And remind people that you can get information on our website, pcori.org. We always appreciate feedback at info@pcori.org. And the upcoming webcast that Joe mentioned, you can find out about how to register soon for those webcasts on our website.

And that's it. We are adjourned. Thank you very much.

[Whereupon, at 3:14 p.m., the PCORI Board of Governors meeting was concluded.]