PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
May 6, 2013

Eaglewood Conference Center
Itasca, IL

[Transcribed from PCORI webcast.]
APPEARANCES:
BOARD OF GOVERNORS

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Kerry Barnett, JD
Lawrence Becker
Carolyn Clancy, MD
Francis Collins, MD, PhD
Leah Hole-Curry, JD
Allen Douma, MD
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Robert Jesse, MD, PhD
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Steven Lipstein, MHA (Vice Chair)
Grayson Norquist, MD, MSPH
Ellen Sigal, PhD
Eugene Washington, MD, MSc (Chair)
Harlan Weisman, MD
Robert Zwolak, MD, PhD
AGENDA

1. Welcome and Approval of February and March 2013 Board Minutes
   - Consideration of February 2013 Board Meeting minutes
   - March 12 & March 26 Board teleconference/webinar minutes for approval

2. Executive Director’s Report

3. Strategic Planning Update
   - Presentation of updated draft strategic plan for Board input before finalization

4. Recess

5. Targeted PCORI Funding Announcements (PFAs)
   - Consideration of recommended targeted research topics resulting from PCORI’s ad hoc workgroup meetings for approval
## AGENDA [Continued]

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Lunch</td>
</tr>
<tr>
<td>6. Advisory Panels Update</td>
</tr>
<tr>
<td>- Report on Kickoff and Training;</td>
</tr>
<tr>
<td>- Next Steps</td>
</tr>
<tr>
<td>- Presentation of proposed advisory panels charter amendment for approval</td>
</tr>
<tr>
<td>7. Active Portfolio Management</td>
</tr>
<tr>
<td>- Presentation on plans to maximize efficiency and impact of PCORI-funded research</td>
</tr>
<tr>
<td>8. Recess</td>
</tr>
<tr>
<td>9. Public Comment Period</td>
</tr>
<tr>
<td>10. Methodology Committee Report</td>
</tr>
<tr>
<td>- Update on Methodology Committee activities</td>
</tr>
</tbody>
</table>
## AGENDA [Continued]

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Cycle II (December 2012) PFA Awards</td>
</tr>
<tr>
<td>- Presentation of slate of awards for approval</td>
</tr>
<tr>
<td>12. Institute Policies</td>
</tr>
<tr>
<td>- Presentation of draft institute policies and procedures, including administrative policies, for approval</td>
</tr>
<tr>
<td>13. Wrap up and Adjournment</td>
</tr>
</tbody>
</table>
P R O C E E D I N G S

[8:06 a.m.]

CHAIRMAN WASHINGTON: Good morning everyone and welcome to this board meeting of the Board of Governors of the Patient-Centered Outcomes Institute. I’d like to first welcome my colleagues on the Board and colleagues from the Methodology Committee. And then, acknowledge all of those who joined us in person this morning. Welcome.

And likewise, welcome to all of you who are joining us by webcast and telecast. If you want to register online or by phone, you can do so by going to www.pcori.org/events. And please note that all the materials that will be presented today and are being considered as we make decisions are available on our website at www.pcori.org.

This webcast is being recorded and archived; it will be posted later this week. I also want to bring to your attention, those of you who don't know it, there is a public comment period later today and we will be welcoming comments from those of you who have to offer them.
I learned this morning that we're also live Tweeting today. And so, join the conversation at #PCORI. We always welcome your feedback by e-mail at info@pcori.org. And so, with that introduction, I see my Chair beaming here. Did I say something or are you just coming ready for this meeting this morning.

DR. KUNTZ: [Off microphone.]

* CHAIRMAN WASHINGTON: I think he knows about my association with the luddites, so that’s what you’re referring to, I imagine. Okay.

Well, the first order of business is to approve our minutes from the February and from the March Board meetings. And so, let’s start with the February first. Any comments?

UNIDENTIFIED BOARD MEMBER: I move to accept.

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: It has been moved and seconded, all in favor?

[Chorus of Ayes.]

CHAIRMAN WASHINGTON: All opposed?
CHAIRMAN WASHINGTON: Okay. And no abstentions?

CHAIRMAN WASHINGTON: Okay, the motion passed. And then the Board minutes for March 2013. Any comments?

UNIDENTIFIED BOARD MEMBER: Move to accept.

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: It has been moved and seconded. All in favor?

[Chorus of Ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay, no abstentions, the motion carries.

I’m going to turn the program over to Dr. Selby who will lay out for us what’s ahead for the rest of the morning, early afternoon.

DR. SELBY: Thank you Dr. Washington.

Good morning everyone, Board members, Methodology
Committee members, staff -- PCORI staff, growing numbers and guests, here and on the webcast.

SO, I’m going to start with as I usually do with an update that will both briefly review our past three months since the February Board meeting, a lot has happened and point the way forward to the rest of this meeting. And also, address some questions that Mr. Lipstein asked at our Board meeting in February, so that is the second item here; the Legislative mandate. Steve asked us to review the mandates from PCORI authorizing legislation and update the Board on where we are. And the process was valuable and does, in fact, point to some activities that are just getting underway and we will be focusing on in the coming few months.

I have some outstanding news about additions to the Office of the Executive Director, but you’ll have to wait just a bit to hear that news. And also, I want to celebrate the arrival of a number of additional key staff members.

So, I’m going to go through the activities
pretty quickly, in the interest of time and because you are familiar with them, in general, but there are a few points worth highlighting. The first point is simply that our activities, our budgets, and everything that we do at PCORI are now organized by our Strategic Plan, the five pillars of our Strategic Plan and that’s the way I will present the activities to you.

So the area of engagement is an area that we’ve been involved in since day one. Increasingly we’re coming to think of engagement as an activity that is done in tight linkage with our research. We trained -- and this is a very exciting program, we trained 17 mentors, there were actually about 10 mentors before, these are patient or stakeholder reviewers who join our Merit Review Panels along with scientific reviewers. After the first round of reviews Martin Dueñas and contracts management staff identified 10 mentors and later 17 more. From these patient stakeholder reviewers who were particularly skilled and experienced, and they lend their support through the review process to less
fully trained and experienced patient and stakeholder reviewers.

It has been very successful during the second round of our peer reviews. We held our first of several planned regional workshops. These are attempts to take PCORI on the road, so to speak, and to get to parts of the country that we're not hearing from much by way of research applications, by way of peer reviewers. And so, we went to Wichita, Kansas and had a day and a half meeting with 63 patients and a wide range of other stakeholders, focused particularly on issues of rural health and really discovered that there are people in the Plain states that understand once we explain PCORI it resonates. They've got a set of research issues that are in some ways unique to their region and enhanced our conviction that it's important to get out. That it's important to get these folks involved in PCORI research activities. Roundtables is something we do frequently, bringing a patient constituency, a physician constituency, to PCORI to have a discussion about particular
interests. In the spirit of generating research ideas, in the spirit of stimulating response that comes from stakeholders partnered with researchers.

And lastly, although I could go on, and on about the engagement activities we're looking forward with excitement to engagement awards, which will be small grants. An announcement will go out, we believe in July, and these are targeted to patients or to stakeholders or to researchers but it is all about new partnerships, forming partnerships. To begin to develop research teams, multi-stakeholder research teams. We initially budgeted $650,000 for this first year and as the excitement has grown, so has our conviction that this really will seed meaningful patient-centered research experience. We're going to increase that to $1.2 million.

This is just a map that we look at a lot and it just shows a kind of swath up the Great Plains from Texas to the Canadian border, where we don't get many research applications and therefore we don't wind up funding much research with the
exception of Colorado, which does quite well. Very little activity from the state to date and this is funded research through our first 126 awards. So this is what we would like to see gradually change by among other things, getting more applications submitted, improving the quality of the applications, getting more people from these regions on our review panel studies. Just appreciate the issues that come from this region.

You are going to hear later today from Dr. Sherine Gabriel, updating us on the Methodology Committee's activities, but I just wanted to say that the methodology report revisions are underway, incorporating public comments and we will hear about the progress on that today.

PCORI issued its first PFA specifically directed to Method research in November and those applications are in, I believe it’s in the 120-range and they will be reviewed in mid-June and we will have our first Method awards, Patient-Centered Outcomes Research Method awards in late June.

And I just want to report briefly on a
meeting, sponsored by PCORI held at the IOM and in collaboration with the IOM, on observational studies and use of observational studies in the learning healthcare system. Our Methodology Committee was heavily involved in putting this together and really did the heavy lifting on thinking about this. It was particularly Steve Goodman, along with a number of Methodology Committee members helping to planning and the presentations, but it really drew a diverse crowd of methodologists from across the country, and by all accounts was both an extraordinary meeting. It also drew one Board member, Larry Becker, for the entire darn meeting. That was impressive. And he said he enjoyed it. But it really did point to some exciting areas in the development of observational methods that we hope will make a major contribution along with randomized trials, to building the evidence that PCORI will support and then disseminate.

And I'm happy to say that there's a ton of activity in the area of funding patient-centered...
outcomes research. You'll hear this afternoon about our proposed slate of Cycle II awards, 51 awards totaling nearly $89 million and that's coming up this afternoon.

In the last three months, we have posted five day long, multi-stakeholder work groups focused on each one of the five proposed areas for targeted PCORI Funding Announcements. Those are asthma, back pain, uterine fibroids, falls in the elderly, and obesity. And this afternoon you will hear a report from these workshops and a proposal to move forward with -- immediately, with two of these funded announcements. I can hardly say enough, and I'm not going to try, you will hear from Dr. Rachael Fleurence this afternoon on our experience with our first round of four advisory panels. Three advisory panels related to priority areas that did prioritization and a fourth advisory panel dedicated to patient engagement, the practice of patient engagement. These panels, their composition is extraordinary. Their dedication and the extent to which they understand PCORI's mission
and are joined with us in addressing it was really, impressed all of us. A wonderful two days. A lot of national leaders in the area of patient-centered outcomes research, a lot of extraordinary patients and other stakeholders.

And you will hear this afternoon from Lori Frank about our PCORI Pilot Projects, part of what we call active portfolio management. But I just want to say that those 50 pilot project that we funded, under Lori's leadership and with the collaboration of Academy Health, we are really doing what we hoped which is drawing themes out them and bringing these investigators together across projects. They in turn are collaborating on dissemination. We have a large panel of pilot projects talking about patient engagement at Academy Health and seen another proposal generated, really by these investigators, talking about PCOR and PCORI in a proposed panel at APHA.

So, it's really nice to see these projects which are dedicated to patient engagement, really coming together to share learnings and to pull out
the themes about how you engage patients and other stakeholders in the research process.

You all know and aware that on April 23rd we released announcements for PCORI infrastructure Awards. We call this the National Patient-Centered Clinical Research Network. It's the Board's vision in many ways, a vision of a legacy, of an efficient national infrastructure for conducting patient-centered comparative effectiveness research; $68 million total funds both clinical data research networks and patient powered research networks. Letters of intent are due June 14th and applications are due September 23rd.

I want to thank the Board, many Board members for contributing to the thinking behind this and there's a lot more thinking to do. This is going to be a major PCORI investment, a real flagship. And it's challenging, others have tried. We are building on their efforts, but we indeed have a lot to think through as this goes for it. And dissemination activities, our Strategic Plan really tells us that dissemination is crucial to
achieving our goals. We continue to publish and you can find our publications on the PCORI website. The scientific publications committee met yesterday. We have a number of papers in review, including a paper on our review process or I should say in development, not in interview. On our PCORI review process, which is unique, the scientific community needs to know about it. On how we prioritize research and on how we engage patients and research. Papers on this topic are in development. We really feel that it is important to get the notions of how PCORI does research, what it's looking for out to the research, as well as the stakeholder communities. Papers in development also on PCORI opportunities specifically for nursing research critical to patient-centered research.

And then, you were here in the not-too-distant future about are work on the dissemination and implementation blueprint. Part of our Strategic Plan during 2013 is to develop a comprehensive approach to the way that PCORI will
both disseminate and implement its research findings. So it will be done, it will culminate with a multi-stakeholder workshop in October and we will have a final plan for presentation to the Board before the end of 2013, and ready to begin the work of dissemination and implementation.

So that was a whirlwind summary of activities.

CHAIRMAN WASHINGTON: Could we pause for a minute Joe and catch our breath here? Just for a minute.

DR. SELBY: Well, I’m still breathing. Aren’t you?

[Laughter.]

CHAIRMAN WASHINGTON: That is quite a bit. Also, just pause for a minute in case there’s a question regarding clarification. Please, Ellen

MS. SIGAL: Ellen Sigal, Board member.

So, hugely impressive work. Question about some of the states or that haven’t been involved. It’s a little strange. Some of them have a lot of academic research going in and have we reached out
to these academic institutions and these groups, I mean that was a little surprising to me.

DR. SELBY: We have reached out. We are reaching out. We have more outreach to do, I think. I’m not sure which state you referenced.

MS. SIGAL: Texas.

DR. SELBY: Okay. It -- Texas is a question mark for me as well. In a number of these states Ellen, it does seem to be more that we’re not getting applications submitted than that they are not doing well when they get reviewed.

VICE CHAIRMAN LIPSTEIN: Ellen, you know, it’s a timely questions. This is Steve Lipstein, by the way. I’m a member of the Board.

Joe just recently was the keynote speaker at a CER symposium at Washington University, which was targeted at states from around the Midwest and during the Q&A period, we were just talking about this on the phone. During the Q&A period, a number of people commented about just the research environment in general right now. Feeling like whether it’s a result of the sequester and some of
the pressures on NIH or the limited funds that PCORI has, that it’s getting more and more difficult to succeed in these applications for funding and on top of that in our mandate, where we’ve required a lot of research have a lot of patient involvement, what we call patient-centeredness here at PCORI. It adds to the degree of difficulty both in preparing an application and submitting it.

And so, part of it, I think we’re still in a phase in our development where we have to work with the research community and particular help them understand how to do what we expect them to do. What we want them to do. And so, I thought Joe did a great Q&A session with these researchers from around the Midwest and we’ll see if it begins to bear some fruit. But it really is going to mean us going on the road a lot more, I think, and answering those kinds of questions.

But what I’m hearing, and I’d be curious what other on the Board have heard, is that the research community is just feeling like the degree
of difficulty in both applying, preparing
applications for funding and then securing the
funding is just increasing from all sides.
So I don’t know if others have heard that
as well.

CHAIRMAN WASHINGTON: Thanks Steve.

Harlan.

DR. KRUMHOLZ: Harlan Krumholz, member of
the Board. I just want to really support what
Steve says. I think this may be one of the most
important things that we have to do in the upcoming
piece and Joe and I have discussed this as well.
But just to bring this into our awareness, I see a
lot of talented investigators standing on the
sideline. When I ask them why they’re not applying
to PCORI, they say they’re not really clear what
we’re looking for. They’re not clear how to access
us. And I know as staff that must be hard to
believe, because you’re feeling like it seems like
the whole world is accessing you all the time.

But I think from the researcher
perspective, you know, we need to engage them in
ways that we haven’t. And Steve, even going beyond, you know, the talks, we have to find ways digitally and beyond that I talked to Joe about the possibility of posting successful applications online so people can see templates. I think that we need to have video clips where people can come on a get a quick orientation. And I think we need to go through our networks to tell people that we are looking for talented researchers. We, of course, want them paired with stakeholders and patients and caregivers, you know, we want to have the sensibility that we’ve been talking about from the outset.

But I’m very concerned that a lot of talented people are not finding their way to this, even with the concerns about funding and other sources. And I just want to strongly endorse what Steve said and hope that maybe that’s something that we all can as a Board -- final thing, I felt the Methodology Committee can also play an important role in this, as they are such an important group for setting standards. They’re
also leaders within the research community and I think tapping their expertise to figure out how best to engage the research community and to get people to lean forward and participate would be very helpful.

CHAIRMAN WASHINGTON: Thank you Harlan. Two more commenters and then we’re going to move on. That’s Norquist and Zwolak.

DR. NORQUIST: Yeah, Gray Norquist, Board of Governors.

So, I agree. What I’ve been saying for a long time, and one of the things is that we haven’t had the staff to really reach out and do this. because at NIH, I mean, when I was there we had a lot of program staff. They’d be on the phone, they’d talk to people, people would call them. “This is what I want to do, what do you think?” And now we’ve had a few reviews. We actually know what we’re going to fund. I think that’s important. The other thing that I would think about and what we did, is we used to -- you know, once you got a cadre of people doing your kind of
research, they can help others. You know what I mean?

And so, somehow we need to have our “own programming,” which we have our own grantees who are successfully funded reach out to others and have meetings regionally, and that’s an idea that I think we need to think about because we will never be able to do all of it. But once you get a group who knows how to do it, they can kind of proselytize this to others, too.

CHAIRMAN WASHINGTON: Zwolak.

DR. ZWOLAK: Bob Zwolak, Board.

Amplifying those comments. If you look at that map, it appears that Canada starts just north of Massachusetts. And there’s an awful lot of white north of Massachusetts, so I think we need to invite -- Joe or potentially the staff, and I’ve also encountered as I told you, many people that are still perplexed a bit about what constitutes a successful application. So, the idea of posting some successful applications or some more clues, I think, will help people. And if nothing else,
we’ll have to drag Joe to New England sometime this summer.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

CHAIRMAN WASHINGTON: Joe, I would say this is a case where I would ask you to reflect back to the Board and say, you know, we could use your help, too. In that we have Board members who are all around the country, all the time and I think we should begin to take advantage of you.

And it reminded me, we’ve been talking about a national conference of some sort that also would generate activity and attention across the nation and we should resurrect that idea and think about how we’re going to move it forward.

DR. SELBY: Could I -- I completely agree with all of the concerns and the suggestions and we’re actually actively digging now through these funded applications just to put, if not whole applications, at least the examples of how the successful ones did their patient and stakeholder engagement, which I think is the part that
perplexes applicants the most.

    CHAIRMAN WASHINGTON: Joe, I sure --

    DR. CLANCY: So why not the whole

application? I mean, absent financial stuff? I
mean, on the federal side, this you can get it.

    DR. SELBY: We could have an offline --

    DR. CLANCY: Yeah.

    CHAIRMAN WASHINGTON: Joe, Jesse is

waiving his hands.

    DR. SELBY: Okay, when Jesse waives.

    CHAIRMAN WASHINGTON: Last one.

    DR. JESSE: Thanks, Bob Jesse, Board.

    So, it’s one thing to ask successful

applicants about the experience, I think a lot of

us are hearing from unsuccessful applicants about

the problems they encountered, the frustrations

they encounters and are we polling that group at

all to try to refine the process?

    DR. SELBY: When I said examples, I meant

examples for applicants who are hoping to get

awards, so they’re not -- we’re not just talking to

the successful ones, but we’re trying to show what
in the judgment of Merit Panels was considered to
be really top percent of engagement. But I take
your point and we could --

DR. JESSE: There’s a fair amount of
frustration on the part of unsuccessful applicants
with the process itself. And it might be useful to
burrow into that a little bit.

DR. SELBY: Yes, and I mean, that’s a
mix -- among other things, our inability to fund a
high proportion of what we receive. And, a
learning curve for applicants in what we’re looking
for, so, you know, it is partly is on the research
community to change. We are talking about doing
research differently so there’s that as well.

Okay, so I will thank you for those
comments, all of which we agree with. And move
onto this analysis of [off microphone] and what we
just did was turn the microphone off.

No, what we did was go through the
document and pull out places where it in fact says
very clearly the “Institute shall.” Green dots
mean we either accomplished it or we’ve done
everything and we’ll continue to do it for those that are continuous instructions. So the National Priorities for Research, establishing and updating the Research Agenda and carrying out the Research Project Agenda, I think we will all agree that that we’ve accomplished this and we continue.

But I want to draw your attention, importantly, to this next -- the next two items actually.

So at the bottom of this page it says, “The Institute shall enter into contracts for the management of funding and the conduct of research.” So, one thing to be said is that all PCORI funding is through contracts, but that’s not what this phrase is talking about. This phrase is talking about contracting for the management of funding and the conduct of research. So, it refers to the management of and oversight of research funding.

This is the adjacent language, “And the Institute in contracting shall give preference to the Agency for Healthcare Research and Quality and The National Institutes of Health, if the research
to be conducted or managed under the contract is authorized by the governing statutes of that agency of institute.”

Now, we have had, I would say a contract or a MOU with NIH to do the reviews of the Pilot Projects and we have one now with AHRQ to work with us on topic briefs for our research prioritization process. But it’s pretty clear to me that the framers of legislation envisioned a very different, had a different meaning here. They anticipated that PCORI would not duplicate AHRQ for instance or an institute at NIH and become a full service research institute. They anticipated that we would convene stakeholders, we would identify and prioritize research topics, and we would commission research. And that notion leads to a smaller organization and that notion leads to the utilization of infrastructure that has already been created. It points particularly to the infrastructure at AHRQ and NIH, but it also raises the possibility that there’s infrastructure elsewhere.
So, we are very actively looking into the possibilities of working both NIH and a AHRQ on a substantial portion of portfolio as we move from an organization that funded $71 million of research in 2012 to one that aims to commit $355 million in 2013 and $500 million or more in 2014.

The rational for thinking about this, the reason it becomes something that you can recognize as important to consider is obvious. So you will hear this afternoon about work that is underway to partner both NIH and AHRQ on two of our targeted funding announcements. And I hasten to add that the last 18 months has seem PCORI, its Board, the Methodology Committee and staff elaborate a unique way of doing research and we have a different way of soliciting research. We have a different way of reviewing research and we have a different way that we expect people to conduct research.

And those principles, those principles that make PCORI research different; we all completely understand have to be preserved as if we enter into contracts or understandings with any
agency that would then manage the research.

So, that’s our aim. I just wanted to alert you to the fact that we will be talking about this more this afternoon, but --

DR. WEISMAN: [Off microphone.]

CHAIRMAN WASHINGTON: Again, there Harlan we’ll do clarification but any discussion this, Joe’s asking us to hold until this afternoon.

Okay.

DR. WEISMAN: On the legislation, when you said the intent was that we don’t -- you know, we contract research we don’t do research. NIH clearly does intramural research and extramural research. Were you referring to or do you believe the legislation referring to only referring to intramural research or where they also referring to extramural?

DR. SELBY: No, I think almost exclusively extramural research.

DR. WEISMAN: [Off microphone.]

DR. SELBY: That, no we wouldn’t -- yes, we would fund extramural research through the NIH
or through AHRQ or through -- yeah.

CHAIRMAN WASHINGTON: Okay. Thanks Harlan.

DR. SELBY: So I will move on now, and like I said we will come back to this this afternoon or later this morning as we talk about the targeted PFAs.

There are a number of conditions for contracts; transparency, addressing conflict of interests, methodology standards, expert advisory panels, allowing publication, and issues related to data privacy and ethics. And I think it’s green because we’ve got everything covered except one bullet there and I’ll address that in the next slide. But that is the creation of certain specified expert advisory panels and we’ll get back to that in just a minute.

The next requirements, I think we’re doing very well on it. And that is requiring that research be designed to take into account the potential for differences among population subgroups and the effectiveness of healthcare
treatments. So all of our funding announcements require applicants to address this issue. We call it inclusiveness. But it really is the about the possibility that treatments differ across patient subgroups.

The Methodology Report and Standards go into assessing treatment heterogeneity in depth and the Methodology Committee recognizes it as a central theme. So I think we’ve done very well and have that one covered.

There’s another one that is a bit vague and the meaning is not entirely clear and we are going to have to get some consultation on this, I think. Review and update evidence on a periodic basis as appropriate. And since we have not generated evidence, we don’t really expect the first research to be done until the end of 2014 or 2015, we have a bit of time, but that’s one that hasn’t been started yet.

Then, the Institute shall advise expert advisory panels in carrying out randomized clinical trials. So we recognize that we are beginning to
plan this, we’ll collaborate with the Methodology Committee and the PDC in preparing a charter, which we’ll present at the September Board meeting. But it is the case that out of the first round -- out of the first two rounds of responses to the broad funding announcements, about 45 percent of the funded research is randomized clinical trials. So, we have a body of randomized clinical trials just getting off the ground and as we read the legislation we need to have this clinical trials advisory panel up and advising on these projects.

And in the case of a research study for rare disease, appoint an expert advisory panel for rare diseases. And this can be read one of two ways. Either you appoint a separate panel for each study or that you have an advisory panel that advises on a set of studies that we fund.

This is a complex area. It’s interesting that it’s in the Affordable Care Act and crucially important that it’s in there and that we attend to it. It’s an area that I think we could all use some education on, what the issues are from the
rare diseases community, and we actually have a meeting scheduled in very early June with several organizations representing the rare disease community to begin thinking about what a charter for a rare diseases advisory panel would look like. And we’ll be in contact with you on that.

Provide support and resources to help patient and consumer representatives effectively participate on the Board and advisory panels, and I’ll add and review panels. We have a lot to point to there and I’ve already mentioned the mentor training programs to support those on the Merit Reviews, the training RFP is now out to establish a body of training activities, also, I think the engagement awards provide additional support.

And then the Methodology Standards, which are out and that’s green and the translation table which we’ll hear a little bit more about this afternoon, I think, which is well underway and in progress or our response to that mandate for a translation table.

And lastly, this an interesting one that
we are going to be working on in the next several months. The legislations says the Institute shall insure that there’s a process for peer review of primary research and provide for a public comment period of 45 to 60 days prior to the adoption. This language, it’s difficult to grasp exactly what it means, but because we will have primary research coming to the point where it needs peer review in the not-too-distant future. This is another task that we will undertake during this interval between this and the next board meeting, just to figure it out first of all and then to develop a plan.

And then the last two on here, not later than 90 days after the conduct of research make these research findings available to clinicians, patients, and the public. This requirement is incorporated into all of our contracts. We’ll do it via the website and also in collaboration with relevant organizations. We are mandated to submit an annual report to Congress. The first one, two of them have already gone in -- the one for 2010, the one for 2011 and the annual report that covers
the activities for 2012 a draft is circulating now and that will be ready for submission soon.

And then I think in the area of disclosing conflicts of interest, we have a well-developed PCORI conflict of interest policy with disclosures of our Board, Methodology Committee, staff, and our advisory panels on our website.

So, that’s the summary Gene of our read of the legislation and particularly the critical points that we need to work on. The advisory panels and looking at the possibility of contracting more of our research with NIH, AHRQ and other entities.

CHAIRMAN WASHINGTON: That’s great.

Comments?

VICE CHAIRMAN LIPSTEIN: This is Steve Lipstein. I requested this review and I wanted to put this in a larger context because from a person who does what I do for a living, you get to observe a variety of aspects of the Affordable Care Act, the law that was passed in 2010 on healthcare reform and passing the law was difficult, but...
implementing the law has a degree of difficulty that goes with it, too. And I just wanted to take a moment to reflect back, because as Leah as we’re coming up on the third anniversary of our first date --

[Laughter.]

VICE CHAIRMAN LIPSTEIN: It’s important to recognize that we have done as well or better with our 60 pages of the Affordable Care Act than most everybody else is doing with theirs and I’m not objective, that’s not empirical. That’s observational. But I think we have done a very good job with our 60 pages. We meaning the Board, the Methodology Committee, especial Dr. Selby and Dr. Beal, and especially all of the staff behind us.

If you look at our 60 pages and you go through them and you see what Joe just reported, we have done very, very well. We could do some things better, we could some things differently, but we have done very well and it’s not an easy law to implement as I think others are experiencing right
now. And Joe, it gives me an opportunity just to remind me how enormously proud I am of you, the staff, the Board and everybody who has been involved in this effort. So thank you Sir.

CHAIRMAN WASHINGTON: Okay. We have Kuntz, and then we have Weisman, and --

DR. KUNTZ: Hi, yes, Rick Kuntz, Board member.

Joe, that’s a good presentation. I just wanted to ask a specific question, maybe it’s a little bit too detailed, but in some of the mandates we have about assuring methodological rigor like the treatment heterogeneity part. Do we have a hardwired method to review the grants at some level to make sure their graded and checked off on those specific mandates?

DR. SELBY: Great question. And I would say that we are working closely with the Methodology Committee on figuring out the various ways in which we can insure the methodology standards do get incorporated into the research we fund. You will be hearing more on this.
CHAIRMAN WASHINGTON: Weisman.

DR. WEISMAN: Harlan Weisman, member of the Board.

Joe, I’ll just echo what has been said. It was a really nice presentation. I agree with Steve that a lot has been done. I have two questions.

One is, and I made this comment yesterday, but I thought I would make it in the public session as well, is that review and update evidence on a periodic basis as appropriate. It is true that we won’t begin producing the results of research until 2015 and later because of the nature of the grants we’re funding, but we’re doing a tremendous amount of work on landscape reviews and understanding the current state and I believe that would be of great value to many out there in terms of what is -- what we currently know, not just from a research perspective, which would tend to show itself in publications and you told me yesterday there was a plan to publish these.

But also, perhaps, to the greater
community of clinicians, patients, and others who might benefit from knowing about some of that landscape work and what the current state of affairs is. And it’s to me a tremendous opportunity to begin testing our abilities to disseminate and test update in a way that’s rather straightforward and easy if we went through the process at looking at those reviews, what we’ve learned and disseminating it. That was number one. That was a comment, not a question.

And number two, is more of a question. And that is on the training of consumer representatives effectively participating on the Board. I think I’ve learned more from our consumer representatives than they have learned from me. But in terms of expert panels and others, you mentioned the training programs and that we’re doing them and certainly that’s a green because we are doing them. We put a great deal of effort on it. But can you give us a comment of the effectiveness of the training and how we’ve measured that effectiveness of the training of the
various patients and consumer representatives who
are participating in our external activities.

DR. SELBY: Well, first of all I agree
with your comment about the importance about
disseminating our landscape reviews through
publications. And I think I’ll need to get back to
you on the -- I know that there are evaluation
activities going on in association with aspects of
this training, but I’m not really prepared to give
you details at this point.

CHAIRMAN WASHINGTON: Before we move to
the next section, I would like to take this
opportunity to recognize one of our colleagues who
is going to be leaving the Board. This is Dr.
Carolyn Clancy. A dear colleague that I’ve known
for many, many years and I have just been thrilled
at you’re level of engagement and participation as
you’ve done over the couple of decades or so that
I’ve known you. You brought your vision and you
were quite generous with your leadership and your
contributions have been many and significant.

So on behalf of all in the PCORI family,
all of our staff, the Methodology Committee members and the Board members I would like to present you with this token of appreciation and public acknowledgment --

[Applause.]

CHAIRMAN WASHINGTON: Wait, wait, before you say anything, we have a couple of more individuals. Our Vice Chair is going to make a comment and our Executive Director.

VICE CHAIRMAN LIPSTEIN: Carolyn, one of the true pleasures of serving on this Board is being able to serve with you and over these past three years I must say that of all the people I’ve e-mailed in the administration, you were the one that e-mailed me back the most faithfully. So we would not be where we are today without your support, your encouragement, and beyond that what the Agency for Healthcare Research and Quality is today. It is in no small part because of you. So thank you very, very much for everything you’ve done for us.

[Applause.]
DR. SELBY: Yes, Gene already said the word that really I wanted to feature and that was generosity. I think you have been and I’m speaking personally now, you have been generous with your time and sharing your wisdom and your savvy and that coupled with your humor and the incisiveness with which you make comments always keeps me on the edge of my seat when you’re card goes up.

SO I really want to say a personal thank you. I also want to echo Steve’s comment that as I’ve been here in D.C. I’ve gotten to know the Agency for Healthcare Research and Quality from a different perspective and come to admire it even more than I did as awardee, an aspiring awardee and recognize, too, how much of it is your investment. Thanks.

[Applause.]

DR. CLANCY: Well, thank you immensely. I will open these at the break. I know that they are federally approved and within limits and so-forth.

[Laughter.]

DR. CLANCY: But it really has been a
privilege. There’s a lot, a lot of moving parts and exciting opportunity and I’m certainly going to miss the frequent interactions with all of you, but I am quite confident that I will be very much working in this field, particularly for the impact on patient care. That is a huge deal. I think PCORI has elevated the conversation, building on other’s efforts to engage patients throughout the research process and I think that is going to be paid in dividends for over time.

So, thanks very much. And Joe, I’ll try not to be quite so incisive.

DR. SELBY: Being incisive is good.

Okay.

CHAIRMAN WASHINGTON: Strategic Plan.

DR. SELBY: Okay, staying on -- actually, we have just a bit more before we jump into Strategic Plan. Some extraordinarily good news, especially from the perspective of Dr. Anne Beal and Dr. Joe Selby and that is the arrival of two key players in PCORI’s plans and PCORI’s future.

And I want to start by introducing Dr.
Bryan Luce. Bryan -- just arrived. Bryan is our new Chief Science Officer and he actually joins us on May 15th. He comes from most immediately from United BioSource where he’s been since 2004. United BioSource, he’s been Senior Vice President for Science and Policy. And over this time he’s really followed and contributed to the development of the thinking behind comparative effectiveness research, the methods related to comparative effectiveness research, patient-centered outcomes research. He’s a real thought leader and has been -- I knew that even when I was in California, that Bryan was really right in the thick of things thinking -- doing the early thinking on this.

Before, Bryan also brings experience from MEDTAP International, a research firm that he founded. Prior to that he was Director of Battelle’s Centers for Public Health Research and Evaluation. He spent some time as Director of the Office of Research and Demonstrations at CMS. Perhaps when it was called HCFA, I’m not sure which -- it was HCFA at that time.
And as a Senior Analyst at the Office of Technology Assessment and before that Bryan was a Special Forces officers and Lieutenant Colonel, now retired from the Army.

He has a PhD in Health Services Research from UCLA and we are all very excited to welcome Bryan, in what’s now well under two weeks.

And sitting right beside Bryan and no less exciting an addition to the PCORI family is Regina Yan. So Regina has been leading organizations for more than 20 years, specializing in financial management, grants and contracts management, program implementation, fund development with a number of leading -- particularly international organizations.

First she spent time with the National Academies of Science at the Institute of Medicine, but then she was with the International Research and Exchanges Board, IREX. Then she spent about seven years with the EURASIA Foundation, which is an organization a good deal like PCORI, in fact, federally funded to give out grants. Except that
she gives them out or EURASIA gave them out in
Eastern Europe and Central Asia. That meant that
she oversaw many millions of dollars’ worth of
research across something like 22 countries. 
Countries that many of us are not all that
familiar with. She was Executive Vice President at
EURASIA Foundation, before that she was Vice
President and COO, and before that Vice President
for Finance Administration.

So, Regina has actually been on the job
for a week. So I think when you take a former
Special Ops officer and a woman who spent the last
20 years traveling around Eastern Europe and
Central Asia, and you throw them in with two
country docs, Anne Beal and Joe, you’ve got a
pretty interesting mix and we can’t wait.

I want to take a photo the first day all
four of us are on the job together. But I want to
say now, just a heartfelt welcome to you both and I
look forward to you getting to know the Board and
Methodology Committee.

And one might ask why we’re hiring a Chief
Operating Officer since we have such an excellent Chief Operating Officer, so this has been known for some time, but now Dr. Anne Beal, who was the organization’s first COO and did an extraordinary job in that role, is able to really move to the position of Chief Officer for Engagement along with being Deputy Executive Director, and Anne does an extraordinary job at whatever she puts her mind to, but I think we all feel, and I think Anne feels that this is a particularly good fit for her skill set, background, interests, so we will continue to be the most engaged research institute around under Anne’s leadership.

So, that’s the executive team and their roles. Bryan will have full responsibility for overseeing PCORI’s five scientific research programs as well as our engagement research team, and Anne will oversee all of our engagement activities and our substantial PCORI engagement team, and Regina will oversee contracts, human resources, IT, finance, as well as our meetings and special events teams. So, that’s the line up on
the executive team.

And then I also want to acknowledge that we continue growing, and these are six folks who’ve joined us since our last Board meeting and I know that at least two are in the audience, so I’ll ask Adaeze Akamigbo to just stand so people can get to know you. Adaeze is a scientist, a program officer, Senior Program Officer, in our Addressing Disparities program.

And Suzanne Schrandt, Suzanne? So, Suzanne comes to us from Kansas. Now, we didn’t find her when we were in Wichita, she might have helped steer us to Wichita, in fact, but Suzanne is the Deputy Director for Patient Engagement working under Sue Sheridan.

And I don’t think that Kelly, Victoria, Rochelle, or Kisha are here, but they certainly have joined us, as have Sandi Myers and Katrina Wilkins.

Just want to show you our current staff, and it puts a little bit of a tint or cast on my previous comments about growth. We are heading
toward 90 staff, that was what we had budgeted for this year. We have the feeling there that 90 is -- if we continue to take on this full portfolio of $350 million worth of research and growing, that this may not be enough, but we are at 73 staff. The bulk of them are in science, that’s the 24, but you see substantial numbers in engagement, communications, contracts, finance, and then smaller in the executive, HR, and IT, and meetings.

So, that’s it for the update, Gene. Do you want to take any more questions before we go on -- see if there are any questions before we go onto Strategic Planning?

CHAIRMAN WASHINGTON: No, I think we’re ready to go on.

DR. SELBY: Okay, so, we spoke at length in our February Board meeting about the Strategic Plan, which we’ve -- with your input we’ve continued to develop, talked about it a couple times with you in between. Under Michele Orza’s leadership, we have engaged the entire PCORI staff. We’ve talked with the MC as well, and what we’re
presenting today represents pretty much the next plateau, if you will, in the strategic plan. We feel that this gives us everything we need to move forward, and I want to walk through it with you and see if there are questions, comments, suggestions, and then talk about next steps.

So, I wanted to recap it. I’m going to focus particularly on what the Strategic Plan tells us about -- what it points to in terms of critical activities for 2013, what we call the Priority Activities. Sometimes we call these the big rocks.

I want to also review plans for monitoring our progress, so this is crucial both -- particularly because it in fact is the quintessential Board activity, to monitor according to an agreed upon set of metrics and milestones, to monitor how the staff and the Institute is measuring up to what we planned and promised. And then I want to have some closing comments related to a particularly important strategy, which is our research portfolio.

So, this is just a picture of what’s going
to be expected of us and how we will do it over the next seven years. So, on top, we have our sights set on how we will be evaluated. It’s a very wise idea to set your Strategic Plan to how you’ll be evaluated, so we get annual financial audits that are submitted to the GAO. We will have a full audit of our processes, procedures, and activities by the GAO beginning at some point in 2014 and delivered in, likely, 2015.

Then an eight-year review in 2017 and then the second every five-year review about 2020.

We’re talking, and you’ve seen this slide before, we’re talking now about the period, we’re in 2013, where we are building and implementing, but that will progress over time to where we begin seeing results, and those results ultimately will start manifesting as impact, and these words will become clear to you as I proceed through the next slides.

So, again, this is our Strategic Plan, and our Strategic Plan is supported by five pillars or imperatives -- engagement, methods, funding
research, dissemination, and infrastructure.

So, this is the latest iteration of a picture that pretty much shows the full Strategic Plan. We begin with a set of values that we’ve agreed upon: patient-centeredness, the usability or usefulness of the research, transparency in everything we do, inclusiveness, which we mentioned a little while ago but which means that we consider the entire community of patients, the entire population of patients, in all of our research and look for differences within that community, and the central importance of rigorous evidence.

The strategic imperatives, we’ve already mentioned and I’m not going to go into them anymore, but those are engagement and methods and research.

In the middle column are the activities which we have deemed from the Strategic Plan to be critical in 2013, and a subsequent slide will blow those up so that you can see them. But these are -- by and large, these are -- many of these are foundational activities, activities that have got
to be put into place for the Strategic Plan to have a chance of leading to our goals. So, as I said, I’ll show you these in moment.

We’ve previously presented our goals and agreed upon them, and those are to increase the availability of usable information, to speed the implementation of that information into patient and clinician practice, and to influence the way that others do research to make it more patient-centered. And those are in support of our mission and vision, which we’ve gone over with you numerous times.

CHAIRMAN WASHINGTON: Joe, could you pause there for just a minute? Give those who are seeing it for the first time and the public just a chance to absorb it. And I would emphasize for the Board, beyond looking at the entire framework of this and making the connections, the central column is going to be key because that’s eventually what we’re going to be looking at in terms of red dots, green dots, yellow dots, to see whether or not we are, in fact, making progress. But we’re only making
progress to the degree, even if they’re all green lights, that we think that they are aligned with what we really want to do in terms of our goal longer-term, but the focus for the next year is going to be in these boxes that you see right in the center. And so I think it’s a very important presentation, but also a very important point that’s being made here.

DR. KUNTZ: Sorry to interrupt, just a quick clarification. This isn’t in the slide deck and the slide, unfortunately, is over-scanned.

DR. SELBY: Oh, okay, so the titles of the columns, Rick, are from left to right, “Our Values”, PCORI’s values, “Our Strategic Imperatives”, “2013 Priority Activities”, “Our Goals”, our overarching strategic goals, and “Our Mission”.

CHAIRMAN WASHINGTON: It’s not showing up on yours?

DR. KUNTZ: It’s over-scanned
DR. SELBY: It’s funny because it looks great on the other --

[Off microphone discussion.]

DR. SELBY: If somebody from AV, perhaps, could give us a hand at fixing these two screens.

DR. WEISMAN: I really like it, but one suggestion, which I think was done in developing this, that since, to reach our vision and our mission to get to our vision, all these things step in place, we must have a further out roadmap, like these are the things that have to occur to get there, and that might be, I’m not sure if that is in the presentation.

For our -- not for our consumption, but maybe since we’re showing this to the public, it would help them to see how everything we’re doing, beginning with 2013, which is the gray column now, will eventually lead to the green boxes on the right.

DR. SELBY: Right. The whole message of this presentation is that there are activities we’ve got to do in 2013 and then there are
activities that we continue to do, and the measures of the success of what we’re doing tend to grow and mature over time. And I hope I can convince you that I’ve covered that by the end of this presentation.

So, as Gene said so well, the first thing we have to focus on are what are our priorities for this year. So, to identify that, we kept a focus on our three goals, we applied what we call a logic model, which I’ll show you in a minute, we gave the highest priority to, first of all, the mandated activities in the statute, the foundational activities, without which we can’t really move forward, like infrastructure and plans, and then certain rate-limiting activities.

We considered in concert with the staff we considered the resources that are available to us. No resource is more precious than time these days at PCORI, so time really had to be factored in.

We moved some activities from 2013 to 2014, ‘15, or beyond, or maybe even out of consideration, and I think in the appendix of your
materials you have a list of things we decided not
to do.

So, here are the ten building blocks for
2013. These are things that we absolutely must do
in 2013. The first two at the top are obviously
ongoing activities, funding research through broad
solicitations, which you are well familiar with,
and funding research on targeted topics. So,
that’s, obviously, our bread and butter, that’s our
long-term responsibility as well as in 2013.

But developing a framework for evaluating
our work and establishing the baselines is a
critical activity. That’s actually, I’m happy to
say, well underway on a couple fronts. We have a
program evaluation group that is in formation that
will include, as well as along with staff members,
Board and MC members, and several external members
as well, and this work is underway. We’re really
focusing on supporting the Strategic Plan by
building an evaluation that allows us to measure
progress in the Strategic Plan and building
evaluation that allows us to demonstrate that
engaging patients and stakeholders makes research more effective, more disseminateable, more relevant.

We are well underway, and I’m moving sort of down the left hand column here, toward establishing programs to build the capacity of patient groups to match patients with researchers, and I point to the engagement awards that I mentioned earlier that will be available beginning in -- the announcement will be out in July of this year, that will bring patients and researchers together and provide funding to get started.

We have a match program, which will -- it’s a challenge grant that is now being reviewed. We’ll announce the awardees really shortly and that attempts to build an app or an application or a process to actually match patients with researchers.

Some of our training programs will build the capacity of patients and patient organizations and certainly our infrastructure awards, the Patient Powered Research Networks, all play into
The next one, in fact, is to launch the Patient Powered Research Networks and the Clinical Data Research Networks along with a coordinating center, and that’s on target to be completed right at the end of 2013.

And the last one in the first column, to launch dissemination and implantation plan to promote our methodology standards, that’s underway. We continue to develop it, but a number of activities are underway, one of which will be a workshop associated with Academy Health this year, which will focus specifically on PCORI’s methodology standards.

Developing a skilled community of patients and stakeholders to participate in our research processes, we have a large body of activities already underway in that area, continue to refine those. I mentioned the dissemination blueprint, and that, it’s important to say, is done in collaboration with AHRQ, which also has responsibilities in the area of dissemination under
the PCORI trust fund, so that activity is well underway and will come in in 2013.

Establishing multi-stakeholder advisory panels and workgroups, we’ve done a lot of that already. We have these two that really stand out as needing to be addressed this year and, as I’ve said, we’re on our way to doing that -- the Clinical Trials Advisory Panel and a Rare Diseases Advisory Panel.

And lastly, and you’re going to hear about this later today, implement an active portfolio management process, which enables us to be supportive to our researchers and their stakeholder partners and to actually stay on top of the research we’re funding to get the most out of the research we’re funding, to recognize opportunities that need -- and findings that need dissemination.

So, you’ll hear more about that.

So, those are our ten building block activities for 2013 and I think it’s very fair to say that activities are vigorously underway in each of these.
CHAIRMAN WASHINGTON: Joe, could we pause for a minute?

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: One question I have is, what will be our reporting timetable for monitoring progress? In other words, when will we, as a Board, hear about these -- the progress we’ve made in these areas toward the goal for the year, in the form, I assume, of red light, green light, yellow light?

DR. SELBY: Right. So, I failed to mention this title. It fooled me because it’s at the side of the slide, but this, in fact, is -- you could say, this is our dashboard for 2013.

CHAIRMAN WASHINGTON: That’s how I’m looking at it.

DR. SELBY: Yeah, it’s our dashboard and you’ll see some pictures, cartoons, if you will, of what that dashboard’s going to look like, but the metrics, developing the metrics, we’ll talk about that some today, but the development of metrics for each of these and for our subsequent measures out
through time is actually well underway as well.

So, we are working on exactly what metrics we’ll use to show you our progress in each of these areas.

CHAIRMAN WASHINGTON: Right, but I was asking a slightly different question. So, we’ve got, let’s say, we’ve got four meetings in a year, which means we’ve got, you know, four quarters, and in some Boards, you take two or three of these at one meeting, you take two or three at another meeting, you take two or three at another meeting. So, you expect, on a quarterly basis, that you’re going to hear from key programmatic areas and certain -- so, give some thought to whether it’s ten, you know, each quarter or whether you want to spread them out and lump them in a way that makes sense in terms of evaluation.

DR. SELBY: Good. Very good. So, I mentioned our logic model and this is it. It looks something like what you saw in the prior slide that people said they liked, but it introduces a new notion, and that is this notion that we are not
going to get to this area. This is where we want to get. We want to increase information, speed implementation, influence the way others do research, toward a vision of better healthcare decisions, improved outcomes, better healthcare, health decisions, and improved outcomes.

That is not going to be demonstrable for a while, but in the meantime there are a series of metrics that we can look at and monitor, and those are called outputs and they are the product of our strategic activities and they predict, via a logic model, that we will move toward these three critical goals.

So, long term, you can imagine a dashboard that will focus on our goals, and even on their impact. So, in the area of increasing information, we can talk really not only about the proportion of study results, but the number of studies and the proportion of all studies with results that are usable.

And usable is a word you’re going to be hearing a lot from us in the near future. We’re
working with folks from other organizations on, in fact, developing a notion of usability of research from the patient’s perspective and I think that’s a word that means that, in fact, these results do support decision-making, by patients, by their clinicians, so, that’s goal number one, in terms of speeding implementation, the number of studies, and the proportion of study results that actually do show signs of implementation within five years. And the third, influence how others are doing research, the proportion of patient-centered outcomes research funding that comes not from PCORI but from other funders.

So, those, obviously, are long-term goals. We don’t have much to report on them in 2013, but that’s -- you can imagine that that’s a dashboard that we will eventually look to.

We’ve added a fourth, which we call “Operational Excellence”, and that is, we think that in many ways it’s critical to measure the performance of the organization itself and I expect that we’ll be doing a lot of this in concert with
the FAAC.

So, that’s a fourth goal and a set of metrics that we’ll keep our eye on.

And then, overall, there is a -- the importance of being able to look qualitatively at activities that we’re doing, and so our report will tend to feature activities that we’re particularly proud of that look, on their face, even though it’s qualitative and not quantitative, like they really are bound to move us toward these goals. So, we see our dashboard as always including this qualitative component of stories and examples as well.

CHAIRMAN WASHINGTON: Okay.

DR. LEVINE: Sharon Levine, Board member.

Before you move on from that slide.

DR. SELBY: Yes.

DR. LEVINE: The speed implementation, I’m assuming that we’ve agreed that implementation means incorporated into practice?

DR. SELBY: Yes.

DR. LEVINE: And it would be helpful, I
think, to make that clear because implementation means different things in different venues, and we’re measuring impact. We’re looking for --

DR. SELBY: Right. And sometimes it’s patient practice and sometimes it’s clinical practice.

DR. LEVINE: Exactly. Exactly. Yes. Or

public health practice.

DR. SELBY: Or public health, yes.

CHAIRMAN WASHINGTON: Good point. Gail?

MS. HUNT: Gail Hunt, Board member. On that same little box there, on speed implementation, I think we should be sure to recognize that there are perhaps results of studies that are done that we have not done that actually have good results that maybe, for whatever reason, haven’t been implemented and that we could be helpful in trying to implement them within the five-year period, so we don’t just have to wait for our five-year results to come up.

DR. SELBY: Allen?

DR. DOUMA: Allen Douma, Board. You were
talking a little bit earlier about developing the metrics and we’re working on that, and looking at the outputs, just the list that’s here, I think you’ve got a really big challenge because at least the words that are in the outputs are not very quantifiable, and so I presume a first step is to convert those words into quantifiable statements, and then actually develop the metrics for them once you’ve done that.

Could we get a sense on the timeline on that, particularly from the Board’s point of view? Our next meeting is in September and then there’s only three months left until the end of the dashboard year, and we might run out of time before we get any metrics that we can actually evaluate.

DR. SELBY: So, I just participated in a meeting on Friday where I was updated on some work that’s going on on developing both the evaluation framework and the metrics, so I think -- and I’m looking over at Michele, but I think that we will basically have that wrapped up by the next Board meeting. So, I think we’ll have a lot to say about
the specific metrics at the next --

DR. DOUMA: At the face-to-face Board meeting?

DR. SELBY: At the face-to-face Board meeting.

DR. DOUMA: Okay, great. And it might be of value to get some input from us as well with regard do we agree with your -- what you’re measuring?

DR. SELBY: Absolutely. Yes. I think you’ve got to -- ultimately you’ve got to agree that the metrics are the right metrics.

DR. DOUMA: So, we’ll talk about these along the way?

CHAIRMAN WASHINGTON: Clancy and then Becker.

DR. CLANCY: Carolyn Clancy, Board member. I had a comment, but also wanted to respond to Gail, so I think I’m going to go there first.

The legislation says that for AHRQ’s allocation from the PCOR trust fund, we actually do have a mandate to disseminate other research. I
think that just reinforces the value of collaboration between AHRQ and PCORI here. And it also, frankly, gets PCORI a little bit out of a box of we have to only count what we’ve specifically funded because all science builds on what has been done previously.

My question, Joe, was about whether you and discussed in this increase information, whether you need a modifier there. I mean, after all, in theory, a big part of where the healthcare system is going is making a shift from volume to value.

Frankly, if you gave out the money randomly, we will increase information, so it just feels to me like there’s a word missing there. I don’t know if it’s relevant, if it’s valuable, or something along those lines, but my guess is that this has already been debated some internally?

DR. SELBY: Yep. That’s why I said keep your eye on the word usable, I think, or your ear. Usable is yet to be fully defined, but I think it embodies everything that you would hold dear, in other words, it has to be valuable, and not
necessarily because it changes practice. I think we hold out the idea that some research builds toward changing practice, and that’s the tricky part, really, is how do you identify research that’s genuinely useful but doesn’t, by itself, change practice?

MR. BECKER: Larry Becker, Board. So, back to speed of implementation, and maybe some people have said this in different ways, but, I mean, five years is a long time from now, so understanding up front what the key levers are that need to be hit in order to actually speed implementation so we can course correct before we get out there and say, gee, that didn’t quite work, so that we know that we’re doing the right kinds of things up front and trying to figure that out is not a simple task. But getting some understanding of those levers would be critically important.

DR. SELBY: Yeah, and that underscores the importance of the dissemination and implementation blueprint, the work we will do with AHRQ. We really do need to have a plan, and I think we see
the outlines of it and I think we believe that you can engage with the disseminators at the very beginnings of projects rather than waiting until the end, and I think that’s -- you know, we’re actually banking on that as being a key strategy for enhancing the chances that our research, when appropriate, will disseminate and get implemented.

CHAIRMAN WASHINGTON: Joe, can I emphasize the point that Larry is making in a slightly different way, it’s a recurrent theme, that if we take each one of these and we take speed implementation, we’ve got a statement now that clearly defines what we mean by implementation. What I thought I heard Larry saying, and it’s embedded in here though, is that we stripped away everything else out at the end, five years, we have speed implementation, and that’s in 2018, and we’re here in 2013, so what is the causal chain that results in the speed of implementation? And it doesn’t have to be detailed, but here are the big five or six things that need to happen over the next five years, and here’s the big one that we’re
going to take in 2013 or 2014, and here’s the big one that we’re going to take in -- so that for each one of these, rather than the whole framework, we see what -- at least the key steps or big rocks that need to be, you know, in place in order to feel that we’ve sped implementation.

DR. SELBY: And we actually discussed with the COEC yesterday the dissemination and implementation blueprint. And I think, you know, Anne Beal is leading that effort, I’m confident that it will have those big rocks identified and they will turn up as the outputs that we look at in 2014 and ’15 to give us some confidence that we’re following our plan and we have an indication that we’re moving in the right direction and can expect to speed implementation.

CHAIRMAN WASHINGTON: Great. Thank you. Harlan?

DR. WEISMAN: I wanted to supplement on those two comments that -- and I was thinking about this when you were talking about the scorecard and I don’t remember which, or dashboard, and I don’t
remember which one you were on at the time, that we really are talking about a fundamental change in the way research is done and perhaps even bigger in influence and change in healthcare.

And whenever there’s change, whether it’s small or large, there’s natural resistance, and it isn’t because of bad intent, it’s just human nature, we’re talking about changing behaviors, and behaviors can be changed, but they’re awfully hard to change, whether it’s the way research is conducted, the way we think about research, it’s the way medicine or clinical care is practiced, change is involved.

And I think we’ve done a really good job of getting ourselves on board with this, I’d give us probably an A on that, although it took us a while to get there, and I’d probably give us a very low grade on how well we’ve managed the change that we’re trying to have happen in terms of communicating it.

And I think one of the things that both Larry and Gene are talking about plays to that idea
of really thinking out, not just a communication plan, because communication plan implies telling people what we’re doing, and change -- communicating change and bringing people on board is far more than telling or even selling, which, and I think we’re trying to sell to people who don’t necessarily think they need to be sold anything because they’re happy or they have another idea of what it ought to look like. We’re talking about how do we get people to understand what we understand and embrace what we have embraced. That’s a much tougher task, and I don’t know how much time we’ve spent in really thinking about that.

You know, what we tend to do is just tell people the same thing over and over again and say, why don’t you get it? You know, listen to us, and clearly, that isn’t as effective as spending more time on thinking about where they are and how do we bring them to where we are while we’re listening to them.

DR. SELBY: That’s an excellent point. I
just wrote down communicate change, and I think that’s a good point. I will say that I think we have thought about this a fair amount in the plan and we place a lot of emphasis on demonstrating that change makes a difference through evaluation, so demonstrating that the ways -- demonstrating to researchers, demonstrating to stakeholders that having them involved has made the research different.

DR. WEISMAN: The only thing I would tell you is that change and resistance to change has a very emotional aspect, and fighting change or arguing for change along only intellectual, rational, logical grounds, entrenches the other side to fight you back with their facts, and what happened and what transformed, I think, the Board, and members of the Institute, was not just the factual reasons to be doing this, but it captured our hearts as well as our minds. And I think maybe we haven’t done a good job in capturing the imagination and the hearts of people, the emotional buy-in that’s really important if you’re going to
get change, because it’s a tough thing to do, it’s really tough, and you run into resistance, and I think that’s what’s happened, and I’m worried that we’re not taking it -- so, it’s not just communication, I said not communicating change, but communication as an aspect of change management. We haven’t really thought out all the steps that are necessary to occur, I think, you know, along the lines maybe that Gene was talking about.

CHAIRMAN WASHINGTON: Okay. Good point.

Douma?

DR. DOUMA: Allen Douma, Board.

Just to build a little bit on what Harlan’s talking about with regard to communication plan. Communication is not just telling and developing a communication plan is the core of what we need to be focusing in on now. And the core of that is to decide what change in people’s thoughts and behaviors do we want to occur as a result of our communication plan.

And then, it’s not until you make those decisions of what the end result is you’re trying
to achieve before you can actually define a really
good communication plan and we talk about it, but I
think we need to be more prescriptive and more
focused on that aspect of it.

CHAIRMAN WASHINGTON: Okay. Please
continue Joe.

DR. SELBY: Okay. So, I think this is
where we were. Just pointing out these six outputs
and at our last meeting we discussed outputs and
Steve Lipstein suggested that nine was just about
too many for anybody to keep an eye on. And we got
it down to five at one time, Steve and we had to
give in and go back up to six. But it’s down at
the request of some Board members, actually.

So, dissemination and implementation
activities is an output and there you have our six
and we’re going to move onto dashboard that shows
them.

CHAIRMAN WASHINGTON: Joe, just so you
know, there is some literature on the cognitive
burden of whether it’s five or six or seven or
three. Most of the literature show that when you
go beyond five you lose doctors, so, keep that in mind.

DR. SELBY: How about hospital administrators?

[Off microphone discussion.]

DR. SELBY: But how hospital administrators?

CHAIRMAN WASHINGTON: They’re much smarter, so they can handle the six.

[Laughter.]

DR. SELBY: Again, a very crude rendering here of a dashboard that would draw your attention to the six outputs that we featured on the previous page and we will develop metrics for those, which we’ll get into a bit in the slides to come. We preserve this qualitative featured studies portion of the scorecard, the dashboard, and keep operational excellence at least for those of us who want to keep an eye on that.

So this is too much to look at, but its intention is down the left hand column are the six outputs and the intention in this slide is to show
over time the metrics, and you can begin to see
some metrics here, begin to mature for any
particular output so that we start with just a
number of people trained, but then a number of
people involved in PCOR by 2015, we’re looking at
the number of people involved in PCOR -- not just
PCORI work, but PCOR more broadly who receives some
PCORI support. And survey result, like the level
of interest in PCOR. And I will actually move onto
the next slide.

The idea here is that as we begin to
develop our metrics, we see an evolution of the
metrics to capture the point in time that we’re in
and how we’re moving toward our goals.

So, here’s an example from building a
portfolio of patient-centered outcomes research
studies. In the early implementation phase, early
in 2014, we can look at the number and types of
topics that we’ve targeted. The number of types of
studies that we’ve funded. And also importantly,
the bottom one in this column, stakeholder views of
the appropriateness. So we do believe that surveys
of appropriate stakeholder populations;
researchers, patients, patient leaders, clinicians
and others, will be a critical part of evaluation.
And we aim to get baseline results on that,
hopefully in 2013.

But as we go on in 2014, for the studies
that are funded we begin to look at the usability
of those studies. So we established criteria for
is this the kind of study that we want to fund.
Usability is something in our view you can assess
as soon as you’ve funded a study, you go back and
assess it more carefully when the study is done and
you’ve got results. And then overtime we can begin
to look at studies that for which results have been
implemented.

And the same on the bottom, again, this
notion we’re going to be assessing through surveys,
assessing stakeholders views of the quality and
utility of the studies that we’ve completed. And
then later on in time, in the lower right hand
corner, the proportion of study results that have
in fact had an impact on health outcomes.
VICE CHAIRMAN LIPSTEIN: Joe, I think this is brilliant. And it’s brilliant for a couple of reasons. One is as Board members, I think it’s important, you know, there’s a lot of detail here, but as Board members I think we want to know that you’ve thought about how the metrics will mature over time. That’s very creative and it gives us a sense of direction. That’s number one.

Number two is, it also helps us dispel the notion that research is an instantaneous kind of a thing. So we can’t fix problems through research in immediate time. Because this lays out how it really works, so I think this is a great tool to show how the metrics and the deliverables will mature over time and is very reassuring.

DR. SELBY: Okay. So, again, here’s --

CHAIRMAN WASHINGTON: Harlan has a comment.

DR. WEISMAN: I like it, too. But to me, I know we’re calling it portfolio management and I don’t want to get, you know, slice on words too much.
This is more to me like program management or project management of our portfolio. But portfolio management, to me, is the strategic aspect of what you’re doing based on what your strategic goals are. So, for example the number of studies that will have results or things that we will have results in the next two years versus five years, you know, short-term versus long-term, new topics versus old topics, or this field versus that field.

That to me is a portfolio question in which the Board plays a role with the Institute’s staff, whereas project management, program management is something that allows the Institute to manage itself once those strategic choices of a portfolio are made.

So I don’t want to diminish this, because I think it is extraordinarily important and I’m really glad to see it. It’s a very useful way of tracking and measuring what we’re doing and reporting what we’re doing. But it’s not quite the same thing as I think of when I think of a
portfolio process, which is a section of choices.

DR. SELBY: That’s a very useful comment and I think it’s one we’ll take to heart. I would say that if we do the kind of management that you’re speaking of, we have a better chance of getting to that third column. We’ll have more useable results, they will be more often implemented, and they’ll have more impact if we’ve done the Portfolio management selectively and thoughtfully, right, we’ll have more in a higher proportion, but to articulate that and it isn’t easy. Is very helpful.

At the end of my presentation you are going to see a couple slides that begin to get at that.

CHAIRMAN WASHINGTON: Okay. Douma.

DR. DOUMA: Allen Douma, board. Just quick. Just to reinforce what Harlan was saying, there is that difference and I think it’s an important difference. It would be interesting, although it’s a thought process obviously. It would be interesting for all of us to weigh in at
some point on what proportion of studies being on track do we think would be successful. And first of all we need to figure out what usability means, and once we’ve done that is our assessment of what percentage of studies end up with usability or useful information.

Just to get what our expectations are for ourselves, so that when we get out two or three years then we hit or we don’t hit whatever we decided, at least we’ll be forewarned.

A little minor thing. On this slide and the next slide, 2016 is missing. I’m not sure why, but it may show to people on the outside world that we’ve got something planned in 201y6 and we’re not telling.

[Laughter.]

DR. SELBY: I’ll take full responsibility for that. It used to say 2013, 2015, and 2017, which wouldn’t have bothered anybody then they would have seen we’re just trying to spread things out. And I said no, this is really -- we’re talking 2014 here for this and I messed it up. So,
we’ll think of a way to fix it so we don’t raise that question whether we’re taking 2016 off.

Okay, so a little closer look now. This is our early implementation dashboard, a preview of it. And you’ll appreciate that in 2014 we’re going to be focused mostly on outputs and here are some beginnings of some proposed metrics, or at least the sources of metrics in 2014. So again, don’t let the arrows at the top, the dates distract you. This entire dashboard is the 2014 dashboard, so you’ll see it’s mostly numbers and types of topics and numbers of standards developed, numbers of PPRNs and CDRNs funded. Still pretty numerical early counts. But I don’t want to suggest that we’ve done all of our thinking about the metrics for even this early implementation dashboard.

Harlan?

DR. KRUMHOLZ: [Off microphone.]

MS. GOERTZ: Harlan, can you turn your mic on?

DR. KRUMHOLZ: Oh, sorry. Harlan Krumholz, from the Board. I was just saying John
Eisenberg liked to do this, where he sort of almost simulated, say okay today the results came in. What’s going to happen? How are things going to be different? How will it be received? What are we doing about it?

And I always remember at least in a session I was with John that he did that, that was so powerful. And these kinds of simulations I think you’re able to do with the funding. Say okay -- just with the team. Because you’ve laid this out now, you’re basically saying okay, look at the best case scenario. It’s the strongest possible result that you would have expected given the design in the study, now what’s going to happen? And it just would -- I think would be helpful as an exercise, both for us and for your team.

DR. CLANCY: So just to a word to the wise. Harlan was the only person who aced this particular exercise.

[Laughter.]

DR. CLANCY: Other people were very, very
uncomfortable as I recall. But, I do remember --

CHAIRMAN WASHINGTON: Zwolak, please. And
would you each use your microphone? This is being
recorded in addition to people wanting to hear it
more clearly.

DR. ZWOLAK: Bob Zwolak, Board member.

Using my mic.

This is spectacular. I think it’s just

wonderful. And I’m wondering as we go along,
necessarily have these in boxes, but for instance
as PCOR methods involved, are we going to determine
how our research portfolio incorporates the PCOR
methods and likewise as we develop the data
networks, how are they doing to crosslink with the
research portfolio? Is the research portfolio
going to take advantage of the data networks and
the PCOR methods and the skilled PCOR community?

DR. SELBY: Good thought.

CHAIRMAN WASHINGTON: And Joe, when I’m
sitting here thinking, at the level of the Board
and I go back to quarterly reports to whenever
you’re going to report on progress. We’re not
going to want this kind of detail at every Board meeting. You and Michele, and the group, you need to step back and think, okay. What will the dashboard really look like when we’re reporting to the Board? Behind which we will know there’s more detail and if we want more detail, then we can drill down to it, but it’s a higher level reporting that we’re going to want at the level of each one of these goals as well as with each one of our imperatives and as it relates to our working activities.

DR. SELBY: Yeah, that notion of being able to drill down is, I hear that word a lot these days in our discussions. They show me a picture and they say, and yes, you can drill down.

CHAIRMAN WASHINGTON: Okay.

DR. SELBY: And so, the big question is what’s on the front? What’s at the top?

CHAIRMAN WASHINGTON: Right. That’s exactly right.

DR. SELBY: What do you look at and then, those of you who like to drill down will most
certainly be able to.

And, again, I’m just going to move quickly through this. This is the next year when we’re toward full implementation and these are beginning to mature now. You’ve seen some of the, for example, in the research portfolio the proportion of studies that are on track, the proportion of studies that by our measure look like they will be usable to decision-makers, and for completed studies, the quality and degree of uptake. And that’s really is measured through surveys, again.

And in each one of these, the metrics are changing as we go through time.

So here’s 2017 and so here, for example, is a metric. The proportion of PCOR studies that adhere to our methodology standards, the usability of results from those studies, that adhere to the standards. Again, we have metrics in each one of the output areas, but they are now much further along and they are actually moving towards our goals.

CHAIRMAN WASHINGTON: Hunt.
MS. HUNT: Gail Hunt, Board.

Joe, when you talk about surveys, I think of surveys of being very broad, like we’re going to survey physicians to see if they understand PCORI or they know more about PCORI or whatever. Are we also planning on more intense surveying of people, patients and caregivers a primary care docs, who are the focus of implementation? So actually finding out whether there’s been implementation of a specific project that has great results and going and looking and seeing how that’s worked in whatever the area is?

DR. SELBY: Well, I think we have to choose our survey respondent populations very thoughtfully. We’re going to want some that we think are worth measuring over time. You know, just broadly, so get a baseline and see if we’re moving it. But then as we begin to have specific results, I agree with you there that it may well be that if we’ve made a big investment and have some results that we think impactful in a particular community, then we would, you know, add in a later
year a targeted evaluation of that or we could.

CHAIRMAN WASHINGTON: Okay, Clancy.

DR. CLANCY: So, just a quickie, because you know, the fact that you don’t have the Paperwork Reduction Act to deal with is just so spectacular. You can also build on other people’s surveys. So Gallup and you name the pollster, will let you buy space to put in one or two questions, which is another way to go about it.

For us, whether it’s a 100 questions or one single item, there’s a whole process. But you don’t actually have to deal with that.

CHAIRMAN WASHINGTON: Okay.

DR. SELBY: Good. So here’s a picture. Those who are really working on the metrics and the dashboards have no bounds on their imagination. So this is a proposed, Gene, perhaps a top level -- perhaps, this would be the set of metrics that the Board said, you know, we want to keep our eye on most closely. Perhaps not, but it’s just for example under Skilled PCOR Community. The number of stakeholders that were trained.
This is an early, this is a very early implementation phase. So we’re looking at counts, so the numbers of stakeholders that we’ve trained and the methods in the Methods category. It’s the number of number of PCOR methods projects we’ve funded and what they’re focused on.

These actually look like the methods for all of our research, not just the Methodology awards.

MR. BECKER: Just as long as we’re imagining and dreaming, Larry Becker, Board.

And I can’t read it exactly, so I’m going to turn around here. So in the upper right hand corner, you talk about funded, total funded, number of projects, employees and staff. As long as we’re imagining, I wonder if we could imagine a fifth line that said customer satisfaction? In other words, what do our customers say about our outputs and where do we stand?

DR. SELBY: That’s very good. I think we really do see that, you know, what the research community is saying about, what the patient and
clinician communities is saying about is very important, but when you say customers you may mean our awardees in particular?

MR. BECKER: I think it could be a whole series of people and I think we need to define who our customer is and once we do that, keeping track of them, because at the end of the day in 2017, '18, '19, someone’s going to make a decision about whether it ends. So the customers will decide out fate.

DR. SELBY: Very good.

MR. BECKER: Thanks.

DR. SELBY: So this slide just makes the point that our dashboard will evolve over time. That in 2013 you’ll see a dashboard that really looks like those really big rocks that I showed you a while back. 2014, we’ll begin having a dashboard that is really focused on outputs and operational excellence. And as we move through time, the dashboard begins to focus a little bit less on the outputs and more on our goals and ultimately on the impact it will have.
So, as I said the development process for these metrics is well underway and I can say with confidence that we will have sets of metrics to show to you and to discuss with you and get your input on as we go through the next several months and I think a mock dashboard with the detail of the actual metrics we’re proposing is not at all out of the question for the September Board meeting.

So, this is just a closing word on the Strategic Plan, per se, and how it might be used. So, this proposes a quarterly dashboard. Gene, I think your thought that the quarterly dashboard might -- we really might accompany that with a discussion of one or two items per quarter is a good idea. But we start with the review of the previous year. That will be the fourth quarter’s dashboard and an annual report. We go through the mid-year and then around the time the third quarter’s dashboard is available to look -- we begin proposing the budget for 2014, or for the following year. So this applies to any particular year and with the dashboard in mind, the budget is
arranged according to the imperatives and the activities, and we also have a time when we set the specific milestones that we think we should hit for the coming year even as we approve the budget for that year.

So that’s our vision of how the dashboard would be integrated into Board activities and used to guide, particularly, the budget development process and the annual reporting at the end of the year.

CHAIRMAN WASHINGTON: That’s great Joe. We have a couple of comments or questions. So I’ll start with Hole-Curry and the Gabriel, and then Norquist.

MS. HOLE-CURRY: Leah Hole-Curry, Board member. Just a quick clarification around the potential for highlighting a few. We would still get the dashboard report on all -- each quarter, correct? On all measures? And then you would -- the reporting would be to highlight a few each quarter?

DR. SELBY: Yeah.
MS. HOLE-CURRY:  But we wouldn’t see it for a whole year?

DR. SELBY:  Absolutely.

MS. HOLE-CURRY:  Okay, that makes sense to me.  Thanks.

CHAIRMAN WASHINGTON:  Gabriel.

DR. GABRIEL:  Sherine Gabriel, Methodology Committee.  So the dashboard’s really helpful but when I look at the dashboard I still see boxes that say Methodology Committee, boxes that say other stuff, other activities of the PCORI.  And one of the challenges we’ve had is how best to integrate our work.  So how can the work of the Methodology Committee really be integrated and advance some of the key strategies of PCORI, rather than simply, you know, counting new standard or counting how the standards have been adopted?

So, I’m just wondering how those more integrative goals are going to be advanced, since you know, it’s something that we’ve struggled with, I think since day one.

DR. SELBY:  We have a just a little bit of
a structural issue here that we’ve named as one of the outputs, PCOR Methods. That is clearly not in our minds meant to suggest that’s where Methodology Committee activities go. In other words, if we don’t have Methodology Committee contributions to building our research portfolio, we’re making sure it follows methodology standards, then it’s much less likely that it’s going to be impactful. And so, the methodology is there. The CDRNs and the PPRNs, the Methodology Committee, I think, has a lot to contribute to thinking about the infrastructure that we’re building. The evaluations we certainly hope there’s substantial Methodology Committee representation in our evaluation group. And similarly, and we already know there’s substantial Methodology Committee involvement, so I see Methodology Committee integrated with us in every one of these outputs.

And, in fact, methods there is really focused on kind of what we funded rather than what the Methodology Committee did. So I think, that just says the Methodology Committee is just hand-
in-hand with the Board and the staff in all of these activities.

CHAIRMAN WASHINGTON: Norquist and the Douma.

DR. NORQUIST: Gray Norquist, member of the Board. I have two issues. One, it’s fine. I think one of the things that worries me this allusion earlier about our cognitive abilities, that you get so many boxes -- so much stuff here that, you know, we have some beautiful trees, we miss the fact that the forest doesn’t look very good or something. So, somehow we’ve got to be able to scale back up because we can get so focused on the details, we miss the big picture and then we have nothing.

The other thing I would say, in looking at all of this. I always thing, because I’ve shown some of our stuff to a people in my office and they look at it and they go: “What? I don’t understand it.” And part of the criticism we had about our communication and what we’ll talk about tomorrow is some of what we do makes perfect sense to us, we’ve
been at it but if you’re the average person on the outside trying to understand this, I don’t even know where the fuel gauge is. You know, what I mean? It’s like are we running on empty? The car is going to run off the road because I don’t -- I think people will get this on some level, but it’s too much. So I think another aspect here is to think about how communicate this to our consumers, if you will, so they really understand it quickly. They’re not going to go through all of these things.

So that’s a task for our Communications group to really think about how to present this kind of information outside of, excuse me, a wonky group, so to speak. Okay?

DR. SELBY: Yeah, I think we can clearly work out with the Board what level of information, what quantity of information, the number of different metrics they want to see. But I do think that as soon as they see a metric that is not exactly where they wanted it to be. They’re going to want much more detail. You’re going to want
much more detail to begin to understand it, so,
what’s on the top, what we look at as an initial
screen is absolutely crucial and we’ll have to work
that out.

DR. NORQUIST: Yeah, I think that’s an
issue of thinking who your audience is. You
carried all of this stuff -- let’s just say some on
the Hill or something, they would be like, “Oh no,
give me what the one or two things are and let’s
make it very quick and easy.” You know what I
mean?

It’s just tailor this to the audience
you’re going to have -- we may want all of the
detail.

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: Douma.

DR. DOUMA: Hi, Allen Douma, Board. Would
you go to the last slide?

Yeah, that slide. Maybe purely semantics,
but maybe not. You’re talking about the dashboard
all the way through and you get to the end and then
you talk about milestones. Is milestones a synonym
for dashboard?

DR. SELBY: Actually the dashboards had the milestones on them, I think.

DR. DOUMA: Milestones are typically part of a dashboard, but not all of the dashboard.

DR. SELBY: Yes. And you see in the upper right hand==upper left hand corner, we actually have a placeholder for milestones. So, out of the metrics that are shown here, they’re -- you know, some you may not set milestones, but some of them you will and those will be featured there.

DR. DOUMA: Well, if you go back to that slide, I would just suggest that it would be better in the last slide, if milestones there -- in this slide, was replaced by dashboard since that’s what we’re doing. If that’s what we mean?

Also, question. Could you talk about the decision to review the dashboard all the way through on a Board call versus a face-to-face meeting?

DR. SELBY: That’s a good question. I have to say, I didn’t quite notice that until now
and I think probably whether we talk about it on a Board call or not, I think the critical thing would be that we do in fact talk about it in public meetings.

DR. DOUMA: Yeah. Okay, thanks.

CHAIRMAN WASHINGTON: Okay, Zwolak, sorry.

DR. ZWOLAK: Bob Zwolak, Board member.

I just wanted to react briefly to Gray’s comment. I’m starting to feel good about this basket of measures as a Board member, and so, I want to speak up in appreciation of what you’ve done.

I think that Gray’s comment is very important because we have a whole number of different audiences who are not going to want to have the level of detail that we necessarily want to have. So, I think it’s a translational issue. Personally, I think this basket of measures is starting to feel pretty good to me.

DR. SELBY: I think we have a big basket of measures and we create dashboards that are tailored to the audiences. Exactly, yes. I mean,
Regina as the COO is going to want gory details on a very large number of metrics and Bryan is going to want and Anne is going to want and I’m going to want to see a lot of detail and the Board is going to have a certain level that it wants to start with.

CHAIRMAN WASHINGTON: Norquist.

DR. NORQUIST: And I’ll make sure -- you misunderstood, I’m not saying this wasn’t a good -- I said that at the beginning. I’m just saying you have to make sure you tailor it to the different audiences. I don’t want us to get stuck in this particular --

DR. SELBY: Right. Okay. So, in closing, I want to just say a word and this gets back to Harlan Weisman’s comment about being strategic about the research, your funding. We really do need to maximize our -- I mean, we have a limited amount of funding, maximizing, and a little bit of time -- our research portfolio’s efficiency and ultimately its impact. So, that involves planning beforehand on how do we attract and select the best
proposals and a matter of fact what kind of proposals do we solicit? During the funding period, how do we manage and facilitate and support the completion and dissemination of the studies that we fund, and after funding, how do we disseminate and how do we measure and learn from that dissemination and update?

So, critically important to manage that portfolio and Harlan really put his finger on several issues that we talked about a lot, but I don't think we’ve put them into the -- I honestly don’t think we’ve gotten down to quite this level of strategy at which is short term versus longer term. It’s complex, there’s a lot of tradeoffs, large number of studies in different topics versus smaller number of focus topics. That actually is a topic that we have discussed. So, this final here just shows you our view from the staff level of what’s likely to happen over time as we get more and more strategic about managing our portfolio.

In 2013, if you add up the funding that we anticipate to getting to the broad announcements,
in response to the broad announcements, and the funding we anticipate committing in response to Targeted Funding Announcements plus the infrastructure which I include as a Targeted Funding Announcement, about one-third of our funding is you’d call targeted and two-thirds is broad. But as the number of Targeted Funding Announcements increases in collaboration with our advisory panels, we anticipate that as early as 2014, we’ll have a portfolio that’s about half targeted and half broad and we anticipate that over time, just because of the continued flow of critical ideas, the conviction on the part of the staff and then the Board that these represent crucial areas for PCORI to make investments. I think it’s predictable that more than half of our funding will be directed funding and that’s certainly the way that we are thinking and it’s open for discussion.

That’s open for discussion and just to say in closing that we’re hoping that we will finalize the draft plan, including if you can believe it a
written version, so, something beyond the PowerPoint of the strategic plan and we will seek your approval.

And Gene raised the point last time of getting public input. This is not something that the statute says we need to get public comment on, but getting public input and I think this speaks to Gray’s and earlier comments about making sure that people begin to understand what it is we’re trying to do here. Mechanisms for getting public input would be an interesting question to put to the Board. We continue working on our evaluation framework, developing those metrics and creating tailored dashboards for the Board, for the staff, and for others. And then, of course, over time, we will keep revisiting the strategic plan.

I think it’s fair to say that it’s seeped into the way that we think and talk already at the staff level and it’s been an extraordinarily useful exercise and will continue to be so for us in conversations with each other and increasingly I think board activities will be around looking at
the dashboards, looking at our performance, looking at the milestones, if you will, that is the targets on those metrics and figuring out what we’re doing well and what we need to perhaps change or improve.

So, with that Gene, yes --

CHAIRMAN WASHINGTON: Okay.

DR. SELBY: We have a few more minutes for questions and particularly that question about when we get the strategic plan that we’re comfortable with and it’s a form that can be disseminated or shared, what’s the Board’s thoughts and advice on getting public input?

CHAIRMAN WASHINGTON: Okay, and before I open it up, I would also like to invite all those in attendance as well as those that are listening to us on the telephone there, video, that please send us your thoughts about the best way for us to share this with you and solicit your feedback.

I see a few cards up. I’m going to start with Weisman, then Douma, and just work our way around and Hunt.

DR. WEISMAN: Joe, I really do like what
you all put together. The amount of work and particularly the progress between beginning and end is really remarkable.

I want to go back to the earlier comment and you acknowledged it. Our vision when it was stated was really putting 2019 out there because it’s a question of whether PCORI continues or not at that point. Obviously, that question could come up any time, but at least that’s the end as it’s defined in the legislation and I’m wondering in order to achieve that vision, what our expectations are on what our work product will be at that point. So, I think we’ve defined nicely 2013, 2014, and 2015, but it’s just getting things underway.

So, I really would encourage us to be able to articulate what our work product will be at the end, not in exquisite detail because, of course, we don't know, a lot of things are from solicitations of grants and from advisory groups and so forth, but there must be -- I think the public and the stakeholders in general would very much like to know what they could expect that we could set
expectations for where we’re taking things and what it will look like. Like if the only thing we’re saying is oh, there will be a bunch of studies and we won't start getting results until 2015 and we think a lot of them will be useful, that isn't enough for me and I think if we really put that stake in the ground of 2019 and really flesh out what that’s going to look like, what is that information that patients, consumers, caregivers, clinicians will have and payers and other parts of the health care system will have at their disposal as a result of our work, the more we can paint that out for people of what that looks like.

Take the current vision which is sort of an impressionist painting and turn it into a realistic painting of that world and how we’re going to get there, including our infrastructure build, our change in the way of helping contribute to health care becoming more patient-centered and then the means by which we’re going to do that. I think that direction will be extraordinarily important for us, but will also help get people
onboard with what we’re trying to do.

CHAIRMAN WASHINGTON: Thank you, Harlan.

Allen.

DR. DOUMA: Allen Douma, Board.

One of your last slides, the pie chart showing movement from more broad funding to targeted funding, my interest in this is because I’m so profoundly ignorant about why we would make those choices. It would be really helpfully and particularly since there's so many smart researchers on the Board itself to have a little more conversation about the why behind the what because I couldn’t explain it to somebody at this point why we would make that decision and I’m not questioning the decision at all, just understanding what's behind it.

DR. SELBY: Well, I think I can give you a very brief answer. If you solicit the issue broad funding announcements, you get a real bouquet of individual projects, but you don’t have a focused body of work on a particular area, you haven't thought about putting several projects together
into a portfolio that really aims where you’ve had stakeholder input, researcher input beforehand saying this is a high-priority topic, these are the studies that need to be done, and if you do these studies, you have a good chance of moving the needle.

So, those are the kinds of studies we mean when we say “targeted funding,” and we think that, on average, you have a better chance of moving the needle than you do with the broad solicitations which tend to attract high-quality studies, very interesting studies, studies we are extremely proud of, but they are across every condition known to man and prevention, diagnosis, treatment, and it’s a little bit more difficult to see your way through to impacting population health with just one study.

CHAIRMAN WASHINGTON: Could I say, Allen, that I think most of us consider this to be an open question, so, there will be debate along the way. Joe is laying out a target, so to speak, of what it might look like based on this supposition about potential impact of one approach versus the other.
DR. EPSTEIN: [Off microphone.]

CHAIRMAN WASHINGTON: Okay, Hunt. Okay, please since we’re going this way.

That’s all right, you keep mike off, Dr. Epstein. Keep your mic off, okay. Go ahead.

MS. HOLE-CURRY: Leah Hole-Curry, Board member.

I also had a question on this one. I think what would be helpful is to tie this approach back to some of our strategic initiatives and as we evaluate the research to see whether the supposition that the targeted produces better outcomes that we have identified is true before we move to the 2015 target.

CHAIRMAN WASHINGTON: Yes.

MS. HOLE-CURRY: So, I would support more information before we decide that this is the strategy to get us to the initiatives that are laid out.

DR. SELBY: Good point.

CHAIRMAN WASHINGTON: Okay.

MS. HUNT: Gail Hunt, not a lady on the
Laughter.

CHAIRMAN WASHINGTON: Whoa.

MS. HUNT: I agree with Leah, and that was going to be my point that I think for example in the disparities which is a broad area, some of those grants or contracts we’re funding are going to be sort of moving into the targeted area. There are not just totally dealing with disparities in general but about specific disease issues around disparities, and so, I think we should have a discussion at 2014 before we move into the let’s make a more targeted and less broad.

CHAIRMAN WASHINGTON: Okay. Why don’t we stay this way and we’ll go around it? Levine.

DR. LEVINE: Just a tactical question.

CHAIRMAN WASHINGTON: Name please.

DR. LEVINE: Sorry, Sharon Levine, Board member.

A tactical question around the funding we get to award research grants continues through 2019?
DR. SELBY: Yes.
DR. LEVINE: Is that correct?
DR. SELBY: Yes.
DR. LEVINE: Money is awarded in 2018 for more than a one-year grant. How does that mesh with the date for reauthorization and the fact that, I mean, are we thinking through --
DR. SELBY: It’s a fabulous question. It’s one that’s on all of our minds, particularly the folks in finance and the folks on the FAAC. We’re actually going to be talking about it tomorrow morning a bit in a committee meeting at seven o’clock. You’re invited and my sense is that we’re going to come of that meeting with some questions that we need to put to the GAO about that because you can imagine that it’s possible that we will get a big influx in mid-2019 and then not be able to spend any after --
DR. LEVINE: Because we’re building momentum.
DR. SELBY: -- the end of September. If that should be the case, we hope it’s not for
several reasons, but if it should be than that
would say fund some long studies early and have
their tails go into 2019 so that you actually pay
the money out almost as soon as it arrives.

DR. LEVINE: Okay, and then just a related
question. In terms of both the networks that we’re
investing in, is there a plan for them to be self-
sustaining long-term, a business plan that says --

DR. SELBY: Right. I think at this point
what the funding announcement says is that there
will be a Phase 2, but they are very definitely
designed and intended to drive toward
sustainability. Sustainability doesn't mean
necessarily that you don’t need any infrastructure
support, but that basically you grow and survive in
part by doing the work.

And basically I just want to add one
thing. That notion of getting all the money in
July or August and having to shut down the end of
September would be a horrible way to run a business
and we trust that it doesn't turn out that way, but
it’s unclear; your question is right on target.
DR. LEVINE: Thanks.

CHAIRMAN WASHINGTON: Krumholz.

DR. KRAMHOLZ: Thanks, I just wanted since --

CHAIRMAN WASHINGTON: Harlan.

DR. KRAMHOLZ: Harlan Krumholz, Board member.

Since we’re in the strategic planning mode, I was hoping to see the Board get animated not just about process, which is so important, but about what are some of the big ideas that we’re lifting and some of it is around the general ideas we’ve been talking about for a long time and that are integrated into this plan, but I hope also we’re able to bring the energy around some different ideas and I at least wanted to throw out two that are some of my favorites, if you don’t mind.

One quickly is I’ve been thinking a lot about sustainability and we talk a lot about dissemination, but what truly anchors this kind of work in the marketplace, what kind of research
truly reshapes the way the patients receive care and promotes better outcomes. If you're in the basic sciences and you're trying to find a cure to cancer, I mean, it’s pretty clear what you're trying to do.

We’re much more distal than that, we’re proximal to the patient and proximal to the care delivery system, but we’re in a very different position. So, if we’re going to come up with insights, we’re going to generate knowledge.

If we wanted to get anchored, the question is: Given the current environment, and that’s changing, but given where we’re seeing things, and the dynamic changes, what truly anchors this kind of change? What was it if we’re going to fund a program would get Steve Lipstein, who might have jurisdiction over some of those kind of care facilities, to say that's exactly the information I’ve been waiting for and I’m going to pull the trigger on this because I just learned something from PCORI versus Steve saying that’s just another article passing over my desk and I’ve got bigger
fish to fry than to worry about whether I can implement that?

To what degree are we exciting entrepreneurs around the country? When I look at Datapalooza and I see the number of entrepreneurs that are coming to the government and trying to help leverage the efforts that they’re making in order to extend the reach of the data and to try to make sure that it’s having impact on people and to be able to demonstrate that impact because there are people willing to pay for those services because their reshaping of the data is adding such value to data that’s otherwise sitting fallow in the databases of the government that they’ve got business models and they’ve got people willing to invest and they’re trying to make that go and to me that’s the ultimate test of sustainability, someone’s willing to pay for it.

So, what are we doing to think about this because how much research is being done in our fields that no one would be willing to pay for it after it’s done, I couldn’t go up to auction and
sell it really. It’d be very penny auction even though millions might have been spent on it that isn't really reshaping the way in which patients are cared for and isn't that really fundamentally elevating the outcomes of patients that are achieving?

Arnie and I have gone back and forth on a number of descriptive studies on disparities, but we can talk even about what works to fix disparities, but if it’s not going to anchor, be embedded, if people aren't going to be eager for it, if we can't sell it, then it doesn't make much difference how insightful and clear it is. So, that’s one point I want to make, which is where are we thinking differently about having our Datapalooza where it’s actually not only -- and I was saying, and I Tweeted this, why can't we do Hackathon equivalents where we’re pulling people together?

I saw a Hackathon where it started off where people said what do you hate about buying a car and that led the entire group of a very diverse
group of individuals to say you know what I hate, I hate X, Y, Z. And people saying what if we weren't constrained to do it the way we're currently doing it? And then it starts getting into well, what kind of business would you do?

And I'm not just saying business, but what is it that would drive value in a new way of doing this that would lead Steve to say wow, this not only is good for patients, but it helps me stay open because I've got a mission to serve a wide, broad community and we're having trouble making our budget each year and we've got to figure out how to stay open.

So, you can show me the best thing in the world, but if it's going to break my budget, I would love to do it, but I'm not going to be able to do it. And so, we have to find ways that are attentive to the various forces within the health care system to be able to drive this kind of peace.

The second one I want to just raise quickly is this notion about the cycle time with which we need to generate new knowledge and my
continued commitment to the idea that what we can do differently is to focus very specifically on the patient-reported outcomes because I still see this as a large missing piece that I think patients would have a demand to know if I undergo chemotherapy, how will I feel? How does it really feel? What do different people feel like in experiencing this course? And once I’m given this diagnosis, what are the various trajectories? Now personalize it to me. Best that you know about my characteristics.

Going back to the four questions, what's going to happen to me if I undergo an ablation for atrial fibrillation; lay it out for me. I mean, what are the possible courses? But more than that, tell me how people feel. Tell me six months later after people have hip replacement who are the people who say I’m really glad I did this versus the people who say I regret having that surgery.

And, of course, you're going to say well, the people with complications, but it’s not always that way. Take the people without complications,
go six months out, say how many people are glad
that they made that choice under best case
circumstances? We lack this information now. This
is the vital information that I believe need to
inform choice about what does it feel like and what
do people like me say after they’ve been through
it? Are they saying it was tough, I sort of needed
to have strength and courage to go through it, but
six months later, I am so grateful because of the
way I feel.

And if we can start figuring out how to
communicate that because I feel in medicine we are
handicapped in our ability to convey percentages,
likelihoods, and so, we need to figure out, not
just to say well, gosh, patients can't understand
that. We need to pioneer novel ways of helping
people understand and make those choices that with
the understanding what's likely to happen to them,
not just death or not, but how they feel. So,
those two leverage points to me are areas that we
can truly distinguish ourselves, and we talk about
this plan.
I’m so grateful that Joe’s putting this process in place and the processes are so important to the success of the organization, but I’m not hearing at the Board meetings the energy of the fostering ideas, the excitement that I did when we first got together about some of the ideas and I worry that we’ve just become a group that is marching forward but that we’re not like walking out saying like I’m on that PCORI Board and I can’t wait to get to the Board meeting because it’s like the kind of ways that the ideas that are being fostered and listening to the new approaches that are being made are fundamentally shaping our view. That’s all.

CHAIRMAN WASHINGTON: That’s great.

Steve, I had a comment, and --

VICE CHAIRMAN LIPSTEIN: Harlan’s a brilliant diagnostician because he knows where all my buttons are. And this one, the one he brought up earlier about fall prevention in the elderly I think is a good case on this because as some as you know, I’m interested in fall prevention in the non-
elderly because I know people who have disabilities that cause balance challenges, and if I ever worked with the elderly, I’d get hit.

CHAIRMAN WASHINGTON: You would.

VICE CHAIRMAN LIPSTEIN: So, a part of it is when I think about this as a hospital administrator person, we always talk about fall prevention in the hospital, but there’s a lot of fall prevention that needs to occur outside the hospital, and one of the fascinating things about this is if you ever spend a Saturday -- you probably don’t do this because you have more exciting lives than I do, but spend a Saturday in a medical equipment store where they have lots of equipment for fall prevention and watch how people go through and make decisions about what they think will help them maintain balance, they really don’t have a lot of information that helps guide their decision-making, and so, this is a big rock, fall prevention, and we have the wherewithal to take this evaluation outside the hospital environment, where I’m worried that when we put out our PFA,
we’ll get a lot of grant applications from people who have been studying falls in hospitals for a long time, but we don’t want to do that. He’s shaking his head no, and so, that’s really a great opportunity. But I do think Harlan makes a good point. Now that we have this framework in place and now that we as a board have been a governing board for a while, and so, we’ve got all of our governance processes, the structures, and framework in place, we do have an opportunity now to step back and devote more of our time and energy to the kinds of -- I guess topic generation might be a way to think of it that Dr. Krumholz is asking for. But fall prevention really is a great one.

CHAIRMAN WASHINGTON: Okay.

DR. KRUMHOLZ: Just a follow-up point, I was thinking more, Steve, is you’re a decision maker with regard to whether you would implement such programs. So, we need your perspective about what is it about these that would make you say yes, we’re doing this at BJC and because of X? It’s a
consequence. I wasn’t commenting on importance of topic.

VICE CHAIRMAN LIPSTEIN: Right.
CHAIRMAN WASHINGTON: Right.
Okay, Jesse.

DR. JESSE: This is Bob Jesse, Board.
So, I was going to pull on a couple of threads that Harlan started to lay out, but that conversation leads to one of them, and that is the first is value. We accrue a lot of information, but how do we take all that information and bring value to the health care system for it? Knowledge is information put to productive use and I think we’re spending a lot more time talking about generating more information and less time really understanding how to implement that in ways that improve outcomes for patients in ways that they understand and some of that is, again, a language issue. We need to spend a lot more time listening to the conversation among patients, between patients because they in a construct of health literacy, we may be the illiterate ones, not the
patients. They very specifically know what they want.

And I think we as a board spent much of our time in the early days really trying to burrow into that, really trying to get into the notion of how do we begin to speak in the language of patients to try and drive our agendas about meeting some of those needs?

For the record, I actually am excited to come to board meetings.

CHAIRMAN WASHINGTON: Thank you, Jesse.

DR. JESSE: And one thing that Harlan who has taught us a lot about in the past but didn’t really get into, and that is the whole notion of open science and how do we set up the principles for discovery that say if we indeed are going to really change how medical research is done, do we begin to enact these principles at the front end? If you get a PCORI grant, these are the principles around how the dataset you generate gets handled in the immediate, near, and then long term, and I think that’s one of the discussions and whether
that’s in the purview of the Methodologies Committee or a broader Board decision, I think at some point we need to begin to discuss that.

CHAIRMAN WASHINGTON: Yes, Harlan, just for the record, Leah Hole-Curry is on her honeymoon at the Board meeting, so --

[Laughter.]

DR. KRUMHOLZ: That’s why I came this time.

CHAIRMAN WASHINGTON: So, she’s excited.

[Laughter.]

CHAIRMAN WASHINGTON: Goertz, please.

MS. GOERTZ: Christine Goertz, Board member.

I just want to emphasize the point that’s been made about having an opportunity to really brainstorm and set aside the time. So, for the last three or four months, it has been my intent and almost every time the PDC has met both during our two-hour calls and in-person to set aside some time to talk about what Harlan had called the big rocks that Arnie now says we’re dropping, but and
each time, that has been pushed off the agenda just
because we have so many other things that we’re
trying to do and I would love to find a way either
through the committee structure or even more fun I
think for the whole board to have some protected
time where we really are able to have the type of
conversations that Harlan and Steve are both
talking about.

CHAIRMAN WASHINGTON: Okay, Joe.

DR. SELBY: I just want to say that I
appreciate those comments and Harlan’s, as well.
And it is true; it feels that we’re always doing
all the things that we have to do so we don’t get
time to do this.

But a word of comfort, if you take a look
at the research we’ve funded, you will be delighted
by the extent to which we’ve incorporated the
thinking of the Board and staff and Methodology
Committee into what we request and into the ways
that it’s reviewed so that there are many projects
that we’re funding that incorporate these ideas of
what is important to patients. The projects that
get funded, and admittedly, the pay line is not high, but they are very distinctive, I think, and so, I say this to myself as much as anybody, really getting familiar with the portfolio of funded work is crucial and it’s also exciting.

CHAIRMAN WASHINGTON: Okay.

DR. KRUMHOLZ: And I just feel the need to say the comments are said with admiration for the accomplishments --

DR. SELBY: Right.

DR. KRUMHOLZ: -- that have been made and with an eagerness to come to each of the Board meetings. But it’s with a challenge for us for the future more than that, but I totally agree with you, Joe.

CHAIRMAN WASHINGTON: Okay, that’s what we took.

We’re already 15 minutes over, so, I have Douma and then Becker and Gabriel and Epstein, and then we’re going to wrap it up.

Please.

DR. DOUMA: Allen Douma, Board.
I just want to really reinforce what Harlan is saying and what we’ve heard after his comment. I think it’s critically important. I think it’s particularly important that we have a process, whether it’s through the committee level or through the Board level, that’s recognized, agreed to where we gather input, creative ideas from everybody, the Board and other people who perhaps are listening to us now on the Internet so we have this defined process and there’s somebody on staff who’s responsible for collecting the ideas and vetting the ideas and bringing them back to the Board to talk about them. Yes, I think it’s well worth out of 70-some that we have to add another staff person just to do that. I think that’ll keep us in the forefront and we won't have to refer back to what we have been doing, but what we will be doing.

MR. BECKER: Larry Becker, Board.

I just wanted to comment on the confluence of what Harlan and Steve just said and falls and Steve’s example of going to the medical device
store, oftentimes, it’s the simple stuff and it’s stuff that other people have lived, but as we get to a place as a patient and you’ve said health care’s everyone’s destiny that being able to disseminate and share those learnings so that when you go to the store and you go and you look for the right kind of equipment for your home, you get the right kind of stuff. I mean, we’ve spent all this money; we have this knowledge, finding a way to share that knowledge so that each one of us isn’t learning because we’re going through it the first time.

DR. GABRIEL: Sherine Gabriel, Methodology Committee.

I’m actually back to the slide, but first of all, just to say this is an incredible advance, an incredible piece of work, the strategic planning and the sort of strategic path that you and the staff have helped craft here.

I completely take your point with respect to targeting, that once you identify a few targets, you will certainly make more progress on those
targets than if you had a broad announcement. My question has to do with how those targets are chosen. If that’s the case, then we must be very strategic and thoughtful about how those targets are chosen. What is our process with respect to choosing those targets at present?

DR. SELBY: Well, subsequent presentations, particularly the presentation on the advisory panels will detail that. So, I think it’s the advisory panel process with topic generation, input from board, staff, advisory panel members that will get us to a set of topics that the Board will then prioritize, that the Board will then make decisions about, but I think we talk a lot too about -- again, I just want to say that the advisory panels, we’re all delighted to have them onboard as our thought partners, in particular in the specific priority areas, but we also talk a lot about well, if we set up this process, then does that sort of foreclose the possibility that somebody may have a brilliant idea in the middle of a board meeting, and the answer is very clearly
not, that we together with the advisory panels and
the Board want to build a process that keeps PCORI
open to these obviously great ideas when they
arise, however they arise.

So, I think that’s our aim and I think
we’re succeeding in building a stakeholder-driven
process and the Boards mostly certainly are among
the stakeholders as is the staff and as are the
advisory panel members and the Methodology
Committee. So, but we do want a process that we
can point to, to say why did we choose that?

CHAIRMAN WASHINGTON: Okay. Dr. Epstein.

DR. EPSTEIN: Do I have the last word?

CHAIRMAN WASHINGTON: I have the last
word. Here it’s a penultimate last word, okay?

[Laughter.]

DR. EPSTEIN: What will it take for me to
trade up in the draft? I’ll leave that.

So, I’m going to mostly follow-up on
Sherine and Harlan. I’m in a business where you
usually try and be first to say something, but in
this case, I think what Harlan said was so incisive
and thoughtful that I want to just underscore what I think the implications are.

    For us, I think that arguably the most valuable part of our portfolio is the comparative effectiveness portfolio. Done a different way, but nonetheless, comparative effectiveness and that’s going to draw us into two lines of questions when we’re done. Has the information told doctors, patients, and the stakeholders more about what works and what doesn’t? Do we now know when this is done in a definitive way, but why millions of people who are getting this before and now we don’t give it to them or vice versa.

    And then second, and I think Harlan pointed to this in a way that really got my attention, which is decisions like Steve, decision makers are really important. He’s not the only one running a large org. Docs are important, patients are critical, other stakeholders are important. But we need to ask the question: Is this work going to produce information that will change what they do? And I’d urge us to use that metric as we
think about the program, the targeted programs
we’re going to hear about this afternoon.

Yesterday, I sat on the PDC and I think
there was enough of a case for one or two of them,
we thought. The answer to that was a qualified
probable yes and for others, we were less sure, and
I think that should guide us.

The second point is really just a
corollary to what Sherine was on. We’re going in
the same direction, which is if you’re talking
about moving targeted programs from roughly one-
third of the portfolio to two-thirds, as you’ve
heard, we don’t really know the exact number, but
that’s a really good place and pencil to be pushing
us. Some of what we can do as a board is
independently bring ideas here, and we have to some
extent, but I think this is also a really
structured way that we can build into every meeting
some period of time in which we’re focusing on the
next generation of targeted PFAs and asking the
questions that Harlan just asked about those
targeted PFAs to remind us.
CHAIRMAN WASHINGTON: First, and I have a couple of comments to make, but first I want to really applaud all the work that Joe and Michelle and others at staff have done in bringing before the Board this just impressive body of work that represents, I believe, a significant step forward for the whole organization. So, thank you, everyone.

[Applause.]

CHAIRMAN WASHINGTON: And what I’ve learned from riding bicycles, as some call the false peak, which means you go up a hill and you’re pumping as hard as you can because you think that you’re going to get to the top, and when you get to that peak, you realize it’s a false peak, you just can’t see the other one that’s over there and you gear up. And it’s testimony that we’ve been successful with the strategic planning effort and I can tell you how many conversations I’ve had with Board members over the last couple of years and months about we’ve got to have a strategic plan and I know the group world. The fact that we’re now
having a conversation about sort of what's next to me is testimony that you’ve hit this out of the park, the Board is completely satisfied with it, at least where it is at this point, and so, these comments are in light of a transition to what we now need to do and where we need to focus our energies.

And I would throw out to the Board that as we think about whatever our individual big rock or big rocks are, that one way to test this framework, and that’s what it is, is to see where your big rock or your big idea fits within this framework. You should be able to pinpoint, and if it doesn't, then it means that we need to modify it in some kind of way, but I’m going to argue, would be willing to lay some odds that the overwhelming majority are going to fit somewhere within this framework, and so, I take the comments really to mean we now had a framework, we now have a process, we want to go back to thinking more about how we move the organization along within this framework and get back to ideas and questions which will help
us maintain the focus as we move forward. But I would say to the Board that at this
point I’m going to challenge you either in writing or in some form to think about Harlan has
articulated a couple of what he considers to be big ideas for himself that he’d like to have on the
table, Steve has articulated one very specific idea. I would think that we all do that, and like Joe, I think we’re going to discover when we step back and look at it, that we’re actually in our research portfolio been listening and have been incorporating many of those suggestions. And, yes, there will be some new ideas that we can use to further reshape our portfolio as we move forward. But I want to close this session by saying, I mean, I think this has been a marvelous discussion, very stimulating, and represents to me how far the Board and with the help of Joe and all the staff, the institute has come. So, thanks to everyone for your continued engagement and contributions.

And so, with that, it is now 10:35. We’re
20 minutes over, so, we’re going to take a 15-minute break. And so, we will be back at 10:50.

Thanks.

[Recess.]

CHAIRMAN WASHINGTON: We’re going to continue in this next session with a discussion about targeted PCORI funding announcement. So, Dr. Selby.

DR. SELBY: You all know that we launched this initiative to create an initial set of targeted funding announcements in September and we have come a long ways. We had identified five topics. In the last three months we held all-day, multi stakeholder advisory panels on each of the five topics, stimulating meetings, and our program directors, Chad Boult, Romana Hasnain-Wynia, and David Hickam, are here to report to you on the recommendations from those work groups.

You’ll see that the recommendations varied, just as we expected they would, and I’ll say, and Christine can add to this, that we have presented these on several occasions to the PDC and
in addition to describing the results of the workgroups and the directions we’re thinking of going, two of these targeted PFA ideas have been endorsed by the PDC and we’re here to seek Board approval for moving right along quickly with developing the funding announcements that go with them.

So, I think, the agenda says we’ll start with Dr. Chad Boult.

DR. BOULT: Thank you all. I will briefly review PCORI’s progress toward launching, really, I guess, it’s first targeted PCORI funding announcement called “Preventing Injuries from Falls in the Elderly.”

We have some slides.

DR. SELBY: Do you have the advancer?

DR. BOULT: So, as Joe mentioned, we convened a multi-perspective workgroup on March 12th and it was a very productive day. We had national experts in the topic of preventing falls, as well as patients, caregivers, and people with other perspectives in the room.
And the workgroup identified four broad research questions related to preventing injuries from falls in the elderly, and they are briefly summarized here.

What is the comparative effectiveness of different models of, first, medication management, in other words, evaluating and modifying an older person’s medication regimen so as to reduce the risk of falling that might be attributed to the medications?

Second, what would be the comparative effectiveness of different models of tailored treatments for specific balance deficits? In other words, all balance deficits are not the same. Some are caused by strokes, some are caused by diseases, like Parkinson’s disease, others are caused by medications, and so on.

And so, we need to advance the science in this area of figuring out exactly what treatments are appropriate for what deficits.

The third question about the comparative effectiveness of models of IT, a lot of interesting
new IT for, for instance, measuring people’s balance, day to day, moment to moment, what’s causing them to be off balance, for monitoring them, people can wear monitors that detect and record their falls, their near falls, their activity levels, and so on, and also the use of IT for messaging, in other words, if the person has a treatment plan to prevent falls, a way to send them messages and receive messages back from them about their adherence to their treatment and the results of their treatment on a minute to minute or hour to hour basis.

And the fourth realm of comparative effectiveness has to do with different models of multi-factorial, personally tailored, fall prevention programs, either in institutional, or possibly both, in community settings as well.

These were the broad questions that the working group came up with and we then went about trying to determine which of these the staff would recommend to go forward for possible PCORI funding announcement, and we considered these factors in
making our decisions: the need for the research, in other words, what’s the variability in practice out there? Does everyone agree on the same approach and they’re doing it? And the answer was a resounding no. There’s virtually no agreement and very little consistency in practice in terms of preventing falls.

So, there’s a great need for comparative effectiveness research so that patients, doctors, other health professionals, and even system leaders can make good decisions based on credible evidence.

The second criterion was the likelihood that the new evidence that would come from the study would lead to widespread improvement in practice and then fewer injurious falls, in other words, what would the uptake be? Would this be something that patients would adopt, doctors would adopt, other professionals, systems? And so, we considered that likelihood.

The third factor was the time needed to produce results. So, we have to consider, some questions can be answered relatively quickly in the
space of maybe two or three years, others may take a decade, and most are going to be somewhere in between.

And the fourth factor that we considered was the opportunities that we had before us to leverage the PCORI support in collaboration with other organizations, such as NIH.

So, we went through a process considering those factors for those questions that I mentioned, and we now present to you this proposal for going forward: that we collaborate with NIA or another trial center, two, first solicit and review applications from research collaborations in the field, and then after selecting a winner, to co-manage a cooperative agreement with an awardee. And then, as a result of that cooperative agreement, to collaborate in implementing and evaluating the effectiveness of a preventive program that includes screening of older people to identify those at high risk of falling, assessing them to determine each individual’s set of risk factors for falling -- why are they at risk -- and
then third, designing a tailored, multi-factorial treatment for each person. So, depending on their profile of risk factors, design a treatment protocol that aligns to address each of their risk factors.

That’s the protocol that has been developed by a joint panel of the American Geriatrics Society and the British Geriatrics Society. So, this would be a test of the implementation of that protocol in real life settings.

So, the contractor that would win this agreement would comprise several types of experts, people who are experts in falls prevention, health services researchers, provider organizations, and a patient advocacy organization.

The design would be a randomized trial where the people in the experimental arm would receive this intervention that I’ve described, and the people in the control arm would receive usual care. This would be focused on people age 65 or over, and the outcomes -- primary outcome would be
the rates of fall related injuries. We’d also
measure as secondary outcomes total falls, fear of
falling, functional independence, and other
outcomes that are important to patients, care
givers, and providers.

So, we ask for any questions and also,
ultimately, for a Board decision on moving forward with this.

CHAIRMAN WASHINGTON: I’ll start with Barnett.

MR. BARNETT: Just go back one slide, if you would? Kerry Barnett, on the Board. I guess I’m just not clear who the contractor is here. It appears -- we’re going to solicit a number of applications, we’re going to choose a contractor, but the first bullet, halfway down there, seems to suggest that the contractor is actually kind of a committee, a multi-headed committee, if you could explain that.

DR. BOULT: Yeah. We see it as a consortium. It would have a leader and the leader might be a falls expert, might be a health services
researcher, could conceivably be someone representing a provider organization, but we imagine that the consortium that would win the contract would have to have at least the representatives shown in the first bullet as a part of their consortium.

MR. BARNETT: And we expect them to put this consortium together as part of the application process or we’re going to choose somebody to head it up and go out and create a consortium?

DR. BOULT: I think an application that already had the consortium would be much stronger than one that said they were going to create the consortium.

CHAIRMAN WASHINGTON: I’m sorry, Christine, please. Put this all in context.

MS. GOERTZ: Yeah, Christine Goertz, Board member and chair of the PDC. I just wanted to let the Board know that this is -- this is a process that the PDC has been very involved in throughout its inception and development and we had a very detailed discussion about the proposal yesterday,
and while we still have questions, primarily because there are a lot of details that had not yet been worked out, and are planning to continue to be involved as a committee in the further refinement and development of this proposal that the PDC did, in fact, vote to recommend that the Board consider approval of this particular proposal.

CHAIRMAN WASHINGTON: That’s a very important statement that you just made. Thank you. Okay. So, why don’t we just work our way around, simplify my day? Douma, and then Clancy, Becker, and Newhouse.

DR. DOUMA: Allen Douma, Board, and Arnie, thank you for making me feel really good about being first, but I’m probably the most ignorant, and out of that ignorance, I want to bring up something that I think would be helpful generically, and in particular, using this as an example, perhaps, to be illustrative.

What you talk about in one of your bullets in making a selection is likelihood that new information would lead to widespread improvement in
practice and outcomes. It would be really helpful for someone like me to have like a description of what actually was done and what kind of quantitative analysis, perhaps, if any, was done, to understand that process as it applies to this particular targeted funding, but to all of the other funding in the future as well.

DR. BOULT: This is a really essential point that you raise, and I think it’s one of the main guides for us, at least in my program, for selecting these targeted PFAs. And within this likelihood that it would lead to change are the concepts of sustainability, for instance. In other words, an intervention that can only operate with contract funding does not have inherent sustainability. So, we look at that strongly.

But we don’t have a quantitative method for doing this, as yet. We look at this and use our best judgment about the possibility of the intervention if it were successful in the research for it to be widely disseminated and adopted by organizations because it would be attractive to
them, and then it would be sustainable because there’s a business case for it.

DR. DOUMA: I have a sense of what the generic things are that would go into the thinking process, but again, it would be helpful and this is not for today, but in the future, to actually have a case study of how did it work in this particular instance that led you to make the decision you did.

DR. BOULT: Right.

CHAIRMAN WASHINGTON: We have a clarifying, complementary comment here.

MS. HOLE-CURRY: This is Leah Hole-Curry on the Board. So, Allen, I think to your question, what you’re asking for, is how, if these are the criteria by which the topic was selected, how did this topic rate and how did it rate versus other topics. So, I think that’s something that we’ve talked about internally as well and whether or not they were ranked and the input of the expert panels was considered as well as the background research that was done on the topic.

So, providing a little bit more of that
detail was, as even a background document, I think is a good point and something that we’ve talked about on the PDC is trying to mature that piece of it.

CHAIRMAN WASHINGTON: Clancy, then Becker, and Newhouse.

DR. CLANCY: So, I have a bias here, which is on behalf of some relatives for whom falls were a critical inflection point, and not in a great direction. I’m thrilled about this.

I would have to guess that the biggest risk factor for falling is that you’ve fallen before? It seems to hold up in every other area of medicine. Is that correct?

DR. BOULT: Especially if you have fallen more than once.

DR. CLANCY: Got it. The other question I had is, you’re comparing the intervention to usual care. Why is that? And what is usual care in this construct? I mean, it strikes me it will be pretty tricky. And I’m sorry I couldn’t get to hear this at the PDC or RDC, I’m not sure which we are just
yet, yesterday.

DR. BOULT: Well, usual care is a very
heterogeneous situation and we’re not going to
define that up front, but the applicants will,
depending on the setting they choose. So, an
applicant might say they’re going to test the
protocol, the AGS-BGS protocol in assisted living
facility or they might say they want to test it in
the community or in a nursing home environment, and
then the usual care would be different in each of
those settings, but they’ll have to describe to us
what that would be.

And we -- the only other choice is to come
up with a different falls prevention program and
compare it to that, but we don’t think we’re at
that point. The best that there was available
right now is this protocol, it’s an evidence-based
protocol developed by the world’s -- or at least
the English speaking world’s leading experts in
these two societies for what is recommended as a
falls prevention protocol, and so compared to -- we
don’t have anything really, other than usual care,
that would be a valid comparator.

DR. CLANCY: Among a number of issues, it just strikes me that you’d -- the applicants or the people in the study would need to figure out or assess whether folks had inadvertently, not as part of the treatment protocol, but been part of other well intentioned efforts to help them avoid falling.

DR. BOULT: Yeah.

DR. CLANCY: The last comment I’ll just make very -- fear of falling, I think, is big, but I also think it’s got more generalized impacts and I’m hopeful and optimistic that as the actual details get unraveled, you could get to that. I mean, there’s something about overall confidence that has been heartbreaking, at least for folks I know.

DR. BOULT: Yeah. And it has implications for people’s ability to carry on their life roles, because if they lose that confidence and have that fear every day, they tend to constrict their world, do less, get de-conditioned, and accelerate the
downhill spiral.

MR. BECKER: Larry Becker, Board. So, the phrase “likelihood that new evidence” piqued my curiosity and I wondered if you would comment on what process might be followed by these folks who get selected in terms of looking at the old evidence, and whether that’s been useful, where the holes are, and whether, in fact, that’s been implemented or not leading to clues about, so what might we avoid in the gathering and implementation of the new evidence, if there is some?

DR. BOULT: Let me make sure I understand your question. You’re talking about why would the new evidence be more likely to create universal change, whereas the old evidence hasn’t?

MR. BECKER: Why, in a sense, did the old evidence fail to make the changes -- what was deficient about it, and what are we doing to understand that, and then, ultimately, built on that so that whatever we spend our resources on, makes it even better rather than it maybe not getting implemented either.
DR. BOULT: So, what we have in the literature review that we did leading up to this is literally hundreds of randomized trials of either a single intervention, like what is the effect of reviewing this person’s medicines or what is the effect of looking at their feet and their footwear, lots of studies like that, and dozens and dozens of other randomized trials looking at various combinations of interventions, these multi-factorial approaches.

But they’re all small, they’re all underpowered in terms of detecting injuries, difference in injuries, most of them -- almost all have been powered to detect a reduced number of falls, but without any ability to say with any statistical confidence that it changed the amount of injuries that occurred.

So, by two main factors that distinguish this kind of a study from the previous studies that have produced evidence are: Number one, that this is an evidence-based protocol that incorporates the best evidence from all the hundreds of studies that
have been done, so it’s got that weight behind it. And then, second, it would be large enough so that it could actually determine whether injuries were reduced.

And, of course, we’re all aware that although we can’t measure cost effectiveness, that we certainly care a lot about older people getting injured from their falls, and those injuries have consequences, they require medical care, which incurs cost, and so an intervention like this, if it were successful in reducing injuries, and we could show that pretty conclusively, then there would be a case for others, perhaps, to look into the costs of doing the intervention compared with the cost saved because people didn’t get injured and have to be hospitalized and put in nursing homes.

CHAIRMAN WASHINGTON: Newhouse and then Sigal.

MS. NEWHOUSE: Robin Newhouse, Methodology Committee. So, just have a question and a comment. First of all, I’m so thankful for this focus. I’m
a daughter of an 81-year-old father who I promised he’d be safe until his death, and he has fallen six or seven times, and I have been to the medical supply store because I bought a bed alarm about a month ago.

Which gets me to the science question.

The falls in people over 65, in my observations -- my father’s in an assisted living -- is not just a matter of the intervention, it’s a matter of the context. So, these studies have to consider the type of staffing that’s available, for example, in these assisted living it’s all unlicensed, assistant personnel. They have a great will and a great heart, but in terms of the science and developing a protocol, it’s not something that’s really in their portfolio.

So, I think the attention to understanding why it works is more than just the intervention. So, I’m hoping that there’s more staffing variables, there’s more observational kinds of data being collected so that we understand why it works and under what conditions, because a randomized
control trial itself really won’t give us the answers we need.

But incredibly important area, those of us that are caregivers would be incredibly thankful if PCORI could answer this question, and help us and these medical supply stores, understand what bed alarm, you know, to buy, and what are the best strategies. And, you know, of course, the last thing they offer are things like sitters, and it’s not about an intervention like that, really, so, thank you and please consider those health service contextual variables as well.

DR. BOULT: Yeah, thank you very much. In the presentation that we did yesterday, we presented considerably more detail, including the requirement that this be a mixed method study where we looked at barriers and facilitators to implementation in the various settings where this protocol could be used.

MS. SIGAL: Ellen Sigal, Board. So, the PDC had substantial conversation on this, so I don’t want to repeat what was said. I think that
we unanimously think this is very important.
However, I do want to repeat that it is really
important to get to some level of specificity
because of the heterogeneity of the population, and
we’re asking a huge amount of questions and, you
know, 65 to 75, huge variables in age and
conditions, so if we’re going to have an outcome, I
would just stress that we really try to be tangible
and maybe not ask so many questions, but a few that
would be meaningful.

So, I think that we’ll get there, and I
assume -- I know we discussed yesterday, this will
go back to PDC for refinement, but I do want to say
publically that I think this is a very important
subject.

CHAIRMAN WASHINGTON: Okay. Zwolak,
Levine, and then Weisman.

DR. ZWOLAK: Bob Zwolak, Board. I also,
in my day job, live in this space and applaud the
concept that we’ve chosen to attack falls because
it’s enormously important for senior citizens.

If I understand this correctly listening
yesterday, what you’re testing is a combination of nine different evaluations and interventions, all of which have been assessed and recommended by the two geriatric societies. So, my question is one from the perspective of an IRB, for instance, considering this. What will be your control groups, considering that what you’re recommending as the test are treatments recommended already in practice guidelines? The IRBs sit and wonder about controls. Will the controls be historical? Do you have historical data? Or if they’re better, if they’re contemporaneous, will an IRB be thinking that you’re withholding currently recommended therapy from the control group? And that troubles me a tiny bit.

The other question is, how will this eventually -- the results of your study eventually make it down to the seemingly very granular level of Steve and the medical device store?

DR. BOULT: Certainly the control groups will have some degree of assessment and treatment of people at risk for falls, and there will be no
attempt whatsoever to blunt that. So, in other words, people would get whatever falls intervention program their providers would provide, even in the control group. So, that’s okay. And that’s the standard against which this comprehensive approach would be compared. So, I don’t think there’s any issue about ethically withholding treatment that’s been recommended. It’s out there, it’s available, it is used, but very inconsistently, and that’s the comparison group.

Because this is what we would call a pragmatic controlled trial, it will be trying to get -- gather information to answer a variety of stakeholders’ questions. So, we will want to know, not only did the number of injuries from falls go down as a result of this, but we’ll want to know, what did the providers think of it? How satisfied were they with implementing this? What did the patients, what did their family caregivers think of it?

And so, we’ll try to answer those questions so that at the end of the day, if, in
fact, it reduces injuries from falls, then we can turn to providers who would be charged with using it and answer their questions about what providers who’ve already done it, what did they think of it? Did it fit into the way they did business? And was it satisfying? And would they want to continue doing it? And same kind of questions for patients and their families.

CHAIRMAN WASHINGTON: Levine.

DR. LEVINE: Sharon Levine, Board member.

I’m having -- maybe because I’m a pediatrician, but I’m having a little trouble wrapping my head around whether this is a study, a randomized control trial, or a portfolio of randomized control trials. If you -- could you go back to the prior slide?

So -- well, it’s the one that had contractor and awardee on it. Yeah, so is the awardee the contractor? Is that the same person?

DR. BOULT: Yes. One.

DR. LEVINE: A, an awardee. And that individual will either come with or constitute a consortium of interests. And the selection of
people -- 100 percent of those enrolled in this randomized control trial, and I assume you’re going to need a very large number because it’s a pragmatic trial.

DR. BOULT: About 5,000.

DR. LEVINE: Five thousand -- would be anyone 65 years or older who would be screened?

DR. BOULT: Correct.

DR. LEVINE: And either assigned to a -- will they all have the risk assessment? Is 100 percent of the 5,000 --

DR. BOULT: They would all be screened, initially there’s a brief screen to determine who’s at risk, and then everyone who, in the experimental group, the intervention group, everyone who screened positive, in other words, they are at risk -- high risk for falling, they would all receive the comprehensive assessment of their individual risk factors.

DR. LEVINE: So the 5,000 are all people who, through some screening process, are determined to be at risk?
DR. BOULT: No, I’m sorry, let me run it through again. So, there would be 5,000 total, 2,500 in the experimental group, 2,500 in the control group. Of the 2,500 in the experimental group, they would all be screened. We might find, perhaps, 40 percent of them were at high risk. Those 40 percent would get a comprehensive risk assessment and then would get a tailored program to address those risks.

DR. LEVINE: Okay. And with that number and that design, you can answer multiple questions?

DR. BOULT: Yeah, it’s preliminary because we don’t know the setting exactly, so we can’t specify the exact design. That will depend on the applications that we get. But we’ve made some assumptions in coming up with these numbers, and our goal, though, was to create a sample that would be large enough to be powered to detect significant reduction, not just in falls, but in injuries from falls.

DR. LEVINE: And will it be a setting or multiple settings? So, will it be --
DR. BOULT: That’s up to the applicants. An applicant might say they wanted to address people in assisted living and nursing homes or people in the community who show up in emergency rooms. There’s a variety of approaches that could be suggested to us.

DR. LEVINE: But one will be selected? I mean, it will be a single trial?

DR. BOULT: Yeah. Logistically it would be very difficult to split this and then try to pool the data in order to come up with sufficient power. It could be done, but it would be much more attractive to have it all in one system.

DR. LEVINE: Thank you.

CHAIRMAN WASHINGTON: Okay, Weisman, Douma, Kuntz.

DR. WEISMAN: Harlan Weisman, Board member. I’m going to reinforce, I think, some of the things that you’ve already heard, but I’ll put out the caveat. I totally support this, but I’m very biased and I probably wouldn’t vote on it. I think I’d probably have to recuse myself, but one,
I’m a former NIA intramural investigator, so -- and two, my father died of a subdural hematoma. My father was 93 years old, very healthy, exercised every day, was an active playwright with his plays being performed in multiple theaters across the East Coast and had just gotten a play accepted for off Broadway, ironically, I live on the street where the theater was now or have an apartment on the street where the theater was in New York.

And I experienced what this is -- what it’s like to deal with falls.

So, there’s prevention so that he wouldn’t have fallen in the first place, because he was a very active guy. In fact, I diagnosed his subdural over the phone when I recognized he was having memory problems acutely and some confusion and we got him to a hospital, but from the very beginning I had a very -- numerous and poor interactions with the healthcare system.

In fact, it probably colored me a little bit -- this was in 2010, I was already on the Board, I was already meeting a lot of people and
patients, families, and others, who were interacting with their healthcare system, and it was really very healthy for me to experience first-hand.

But this issue of settings is incredibly important. It is very different to do fall prevention at home to prevent the first fall, my father’s first subdural, and then as he made his way through the healthcare system at extremely good places in the Washington, DC area, I learned that, for example, once you make it out of the acute care hospital, anything that happens, whether it’s in a rehab hospital, assisted living, a nursing home, whatever it is, is almost entirely dictated by reimbursement and Medicare guidelines.

And to a T, every place you look at has exactly the same approach because it is everything that will be reimbursed. You’re basically handed that the moment you enter and are made to read it before you even get a tour because they want you to make sure that, and a lot of it, a lot of the disclaimers and everything, is against holding
anybody liable for fall prevention.

And, you know, you’ll see lots of --
you’ll learn a lot about nurse to staff ratios,
other staff ratios, and then find out it’s a
fiction anyway because whatever they say, there’s
usually at most one RN, if any, at night, and the
best way of dealing with this is that people ignore
alarms, I know that, even if you have them there,
and the best way of handling old people who are in
danger of falling is to tie them down in the bed,
and that happens more than you’d want to think.

And I had a good experience because I make
a lot of money, more than most people, and I was
able to have somebody, a nurse, if it wasn’t me or
my sister, sitting by my father’s bedside
protecting him from what was being done to him or
not done for him, and those are all setting issues
and confounders in all of this that really bother
me, because I’m concerned that we can show
something very beautiful in a randomized trial in
which we’re measuring things, and it will, perhaps,
not have real world validity or applicability
unless we can find a way of real world testing some of this, because I suspect that a lot of it has to do -- particularly in facilities -- has to do with things that are not related to specific intervention, but related to something that’s missing from healthcare, and that’s care.

And if there is true care in delivery of these, I think you can go a long way, and ironically, you know, you said, Sharon, you’re a pediatrician, and there are a lot of good geriatricians, most of whom have nothing to do with these facilities nor are there, they’re understaffed, under -- and these are expensive, really good ones.

So, I think this is extremely important. I was biased toward it. But, you know, things like length of stay in these facilities and specific interventions, if they’re being driven in the real world by reimbursement considerations, it almost doesn’t matter how it works, and also it’s not clear to me that this -- the confounding of setting and the specific healthcare system in which it’s
being conducted, may be the most important
determinants of the outcome of fall prevention than
any specific thing that you’re doing in it.

And I also worry that the people who are
going to apply for these grants are the very people
who are probably already doing extraordinary
efforts and will get a good result, but it won’t be
-- as I said, it won’t be applicable, you know,
things like training and the number of staff
available, the socioeconomic status of the
individual, all those things -- and where they’re
located -- matter so much that -- I don’t want to
be overly nihilistic because I love it, I just
don’t know what the solutions are.

It’s really important to do though.

DR. BOULT: Harlan, I’d just comment that
I think all of us feel your anguish and your
family’s anguish and it’s the reason why many of us
left our previous occupations and came to work at
PCORI to try to deal with these issues.

DR. WEISMAN: By the way, my father had a
complete recovery and died of a second subdural
hematoma from the second fall. That’s the end of the story. Sorry.

CHAIRMAN WASHINGTON: Douma.

DR. DOUMA: I almost want to apologize for bringing something up that is so superficial compared to what I just heard. I have experience with my father, which is equally profound, to me, anyway, but I feel for what you were talking about a lot. And it is superficial, but I think it’s important at least to say what we’re not going to fund.

The description of the targeted funding is preventing injuries from falls. Are we going to be looking at falls that occur but were preventing injury with things like changing the environment with sharp objects, with helmets, et cetera? Is that part of the equation? Or really looking at preventing falls and we’re interested in whether they cause injuries?

Can somebody -- let me just be specific. Could I come in and say, I’m going to make everything in my apartment round and soft and
spongy and I won’t get hurt if I fall. Is that on our table?

DR. BOULT: Yes, I think so. We’re aiming at reducing injuries, and obviously you have to reduce falls in order to reduce falls injuries, and so they’re inextricably linked, but --

DR. DOUMA: Well, and my example is, I would submit, I think it’s being nitpicky, but you could have just as many falls, but you’re decreasing the injuries because of what you’re falling on?

DR. BOULT: Yeah. That’s our focus, is the injuries.

CHAIRMAN WASHINGTON: Kuntz.

DR. KUNTZ: Rick Kuntz, part of the Board -- member of the Board of Governors. I just want to make a general statement. I think it’s important to identify these devastating conditions, the human conditions we have, such as falls, as being a really critical, important thing to try to solve, but also I think that part of our job here is to determine whether or not they can be solved.
One could make a case that this might be a chaotic situation, the ubiquitous, you know, presence of gravity, you know, makes this a very difficult thing to classify. And while I would hope that we’d find solutions for this, I think we also have to determine, we have, you know, critical resources and we have to make -- we have to balance the critical needs in our society with things we can actually solve.

And so, listening to this discussion, I think it’s important to kind of sort that out and understand whether or not we’re trying to stop tornados and fix the weather, which is a chaotic situation, or we’re going to put a school guard at the crossing zone, which actually is a very discreet thing that can be solved.

DR. BOULT: Maybe just to give a little encouragement. The Cochran Collaboration has done a couple of recent surveys of all the literature on this, as recently as six months ago, and concluded that there’s a -- on average, there’s about a 23 percent reduction in falls that are possible
through these combined, multi-factorial approaches, though we’re not going to eliminate them all together, but we certainly -- there’s the potential, even with previous sort of incomplete approaches to reduce falls by around a quarter.

DR. KUNTZ: If that’s solved already, then why don’t we implement those programs? Or are we testing -- are we just confirming that?

DR. BOULT: Yeah, that evidence is out there and it’s not being implemented, so what we’re trying to do here is show that a systematic form of implementation in one or more settings can actually lead to widespread adoption.


MR. BECKER: Just a quick question. Does anybody want to have a discussion about the strategic use of NIA in this process?

CHAIRMAN WASHINGTON: It looks like Ellen Sigal has a comment related to that.

MS. SIGAL: We spoke about that extensively because they’re efficient, they have the mechanism, they certainly have the knowledge.
What’s very, very important is that the PCORI branding and input and evaluation be part of it, and Francis and Kathy have assured us that that will happen, because we don’t want to just have them do it, we want to really be able to shape it and to do it in a way that’s very substantial that really answers the questions that are most important for PCORI and have the Board and our experts involved, and our patient-centered value is a part of it, but what we’re told, and I and others asked the question, is that this is now going through legal counsel and they believe they have the mechanisms for doing it, and the legislation does call for NIH. You know, so as long as we can shape it, there’s no reason not to do it that way, I think.

CHAIRMAN WASHINGTON: Norquist.

DR. NORQUIST: I may be the only geriatrician here, I’m a geriatric psychiatrist, so I deal with these kind of issues all the time. So, I won’t give you stories and all that kind of stuff. What this is reminding me of is when I was
at NIH and we had to do all this comparative effectiveness research and we started on looking at depression, and you cannot imagine the numbers of comments, the design issues, all this stuff, and at the end of the day we had to say, you know what, let’s pick one question here, let’s be very specific what the question is that we’re going to do, because the contractors will be all over the place confused, we cannot solve all of the issues about falls, but we can start somewhere, at one point.

And so, without second guessing, the only thing I would say to you is that when you go out to bid the contract, that when you get together with folks, that you’re very specific, what is the question that you want to ask in all the ones about falls, and maybe you’re going to have to narrow your population, and then I would strongly urge you, because I’m sitting right next to the Methodology people, to get them engaged very early on, because we had to do that, because in our depression study, we went to primary care clinics,
which everybody thought was going to be a disaster because we different -- and then people wouldn’t select what the thing was, and we came up with this idea, which I love to keep repeating, because it makes me sound very intelligent, equipoise stratified randomization, which actually allows you to let people make choices and then you can sort for that later and fix it.

So, their --

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. NORQUIST: Equipoise stratified randomization. Isn’t it wonderful? And I actually know what it is.

Anyway, so what I would say at this point is, it’s an incredibly important topic. I would go back to what Harlan K. said earlier, which is that we need to pick the big topics and then focus, but it’s a complicated topic, because I see it all the time, but there are answers and we need to test what we think is the best possible solution and put that out for bid.
DR. BOULT: Thanks. And I don’t know if I mentioned it earlier, but we’re envisioning this to be a cooperative agreement, which allows PCORI and NIH to have involvement in the steering committee as the whole process unfolds over five years.

CHAIRMAN WASHINGTON: Hunt.

MS. HUNT: Is it -- some reason that we haven’t used the number for how much money in the budget this is going to represent? It’s a contract or cooperative agreement of $30 million?

DR. BOULT: That’s right. That was the NIA’s estimate of the budget for doing a properly powered study to show a decrease in injuries from falls.

MS. HUNT: Can I just follow up then? We need to -- one of the many things we need to clarify, and this is following up on Larry’s comment too, is what their “in kind” -- what -- we’re coming up with the $30 million. What are they -- what’s the “in kind” that they’re coming up with?

DR. BOULT: These are ongoing negotiations
right now. They’ve expressed an interest and an acknowledgment of the need to make some in kind contributions, but I think because they’re in process, I probably shouldn’t speculate much more about the details, but they’re in agreement with that concept.

CHAIRMAN WASHINGTON: Christine, any concluding remarks before I provide some summary.

MS. GOERTZ: Just -- I just want to reiterate what’s been said about the agreement with NIH. I mean, they really -- we had both Francis and Dr. Richard Hodes, the director of NIA, on the phone with us yesterday and both of them reiterated the fact that they would -- they were very committed to working with PCORI to make sure that this was, in every way, a PCORI-driven effort and also that their intent was that all of the management would, in fact, be an in kind contribution from NIH, which obviously is a great cost savings to PCORI as we’re moving forward.

Now, they did reserve the right, if it became horrifically expensive for some sort of
unforeseen reason, that they might come back to us on that, but that their intent, at this point, is that it would be an in kind contribution.

CHAIRMAN WASHINGTON: Okay, so, before we -- because -- Dr. Levine, you have a frown, which is unusual for you.

DR. LEVINE: I think I’ll pass on explaining the frown for now.

CHAIRMAN WASHINGTON: Okay, but before we vote, because we do in this case, about whether or not we want to move forward today, I want to remind everyone that the point that we’re at now represents, again, multiple steps. We decided some time ago that we wanted to develop some more focused PCORI funding announcements.

We then had an exercise that involved quite a bit of work on behalf of staff and in consultation with others, to identify what those areas would be. Originally, I think we identified four, and then we added a fifth one.

And then, on top of that, we took that to our newly established workgroups. So, we’ve got
workgroups now with experts who have now taken the
topics. So, we’ve gone from the big area of just
targeted, down to identifying five topics, which
one of them happens to have been or is fall
prevention in the elderly, then we brought together
outside experts, in terms of a working group, to
sort of say, this is a general area where we
believe, given what we know, you should be focusing
your attention.

And based on that, under Chad’s direction
and others with Joe, we’ve now come up with sort of
a set of questions, which he laid out. And now we
have comments that will get incorporated into that.
But at the end of the day, what’s on the table is,
do we move forward with developing a PFA related to
fall prevention in the elderly in this general
area?

Okay, and so, this is an question of all
those who --

DR. SELBY: Francis is on the phone.
CHAIRMAN WASHINGTON: It looks like
Francis is crying to speak. I think he’s saying
“trying,” but it looks like “crying” to speak.

Francis, we don’t want you crying.

DR. COLLINS: Can you hear me now?

CHAIRMAN WASHINGTON: Yes.

DR. COLLINS: Oh, because I’ve been speaking quite a lot, but I don’t think you’ve heard a word. I think we had some technical issue.

So, I just wanted to reiterate that NIH is very enthusiastic about the partnership proposed here on this project and I think it’s already been well stated by Chris and Ellen and others, that we had a very good conversation about this yesterday.

Richard Hodes is listening to the conversation right now but is not in a position to be able to be heard and as the director of NIA, I think he also wants to provide strong assurances that we would do this in a partnership that reflects PCORI’s very strong interest in patient-centeredness and to make sure that we do this in a fashion that meets those goals, and that NIA is prepared to be a donator of the in kind staff time, which is pretty significant in a project of this
magnitude, and so just again to reiterate, that we think this could be a great opportunity to work together.

CHAIRMAN WASHINGTON: I’m going to call the question, having explained what’s on the table. All who support moving forward to develop the PFA related to falls prevention in the elderly and this general area, raise your hands.

[Show of hands.]

CHAIRMAN WASHINGTON: Okay, we have 17 -- Francis, I take it you’re a yay?

DR. COLLINS: I am a yay.

CHAIRMAN WASHINGTON: So, we have 18 out of 21. We have two Board members missing. And all Opposed?

[No response.]

CHAIRMAN WASHINGTON: Any abstentions?

[One.]

CHAIRMAN WASHINGTON: Okay, so we have 18 in favor, we have one abstention, and two people absent.

DR. DOUMA: Just a clarification on your
wording. It says, we just approved moving forward in this area and let me give a hypothetical. What if we find we get more confirmation from Cochran and from the guidelines that have been created that a major issue, if not the major issue, is that it’s the -- actually the implementation of what is already known is more of a barrier to decreasing injury than knowing more? Do we still have the opportunity to branch down later on or even focus on that more later on?

CHAIRMAN WASHINGTON: I would think so and I would trust that Joe and staff and PDC and others involved would take advantage of just that kind of discovery.

So, Joe, we have support and we’re going to move forward. And thank you very much, Chad.

DR. SELBY: Thank you very much.

DR. BOULT: Thank you all.

CHAIRMAN WASHINGTON: And I want -- thanks to everyone involved including all the staff and in particular also those involved in the work groups, the experts who came forward to assist us.
DR. SELBY: So, I'm not quite sure how we're doing on time here, but —

CHAIRMAN WASHINGTON: Well, we're behind, I can tell you that.

DR. SELBY: It's crucial to hear from Dr. Hasnain-Wynia. I think, David, we're going to have to defer those which don't have an endorsement from PDC for moving forward, but we feel a real urgency at PCORI to get these targeted funding announcements developed, posted, and we sincerely hope, funded by, at, or near the end of the year. So, I recommend we turn this over to Romana.

DR. HASNIAN-WYNIA: Hello everyone. My name is Romana Hasnain-Wynia and I am the director of the Addressing Disparities Program at PCORI, and my goal is to really talk to you today about the proposed targeted funding announcement for asthma.

We also had a workgroup for treatment of obesity, and there are slides, I think, in your Board Book related to that, but because of time issues, I won't go through the obesity discussion of the workgroup and focus on asthma.
So, just briefly here, we identified the goals of the program in Addressing Disparities. I think many of you have already seen this, so I’m not going to read this slide, and again, it’s referenced in your Board Book.

Again, we have had two ad hoc workgroups, one on treatment options for severe asthma in African-Americans and Hispanics/Latinos, which was held on March 1st, and then the second workgroup that also fell under the disparities program was obesity treatment options in diverse populations. That workgroup was held on April 16th, and we continued to receive questions through April 30th, so we’re still synthesizing the information, but the information that we have synthesized to date, is available in the Board Book.

So, the goal of the targeted workgroup, I think it’s important to reemphasize why we pulled this workgroup together, and you can see it was to obtain input from experts, including patient stakeholders and others.

We wanted to work with this group to
identify the high impact research questions that will result in findings that are likely to endure and that are not currently studied, and to understand the potential for the research to lead to improvements in practice, and again, to confirm the importance and timeliness of particular research questions within the area, in this case, of addressing asthma disparities.

And then, finally, I think it’s also very important to recognize that the goal of the ad hoc workgroups was to reach consensus, and as all of you know, when we strive for consensus, everybody gives up a little and everybody gets a little, so it wasn’t really a prioritization process, per se, it was really a consensus-driven process.

And we took all of this information and synthesized it, and this is what I’m going to present to you.

So, our chair and moderator for our workgroup was James Kiley from NHLBI, and we continue to work with NHILBI in terms of identification of the gaps that the workgroup
addressed.

We put forward to the workgroup the criteria for the research gaps that we wanted to have highlighted, so, again, to be patient-centered, to assess current options, the potential to improve care, particularly patient-centered outcomes, to provide knowledge that is durable, and to be comparative, to compare options.

So, what we ended up with at the end of the day was six overarching themes, and these themes were distilled from about 60 topics or questions that were submitted vis-à-vis the workgroup members and also vis-à-vis others who submitted information through our website, through Twitter, et cetera.

So, what I’m going to do here is go through each of these key themes, because these are the areas where the workgroup identified key gaps in addressing asthma disparities, and what we did after the workgroup meeting is that we went back and we looked through the literature, we looked at the Cochran review, to confirm that these gaps
were, in fact, real and to really validate that we were -- if we were to move forward with a targeted funding announcement, that we were addressing gaps that needed to be addressed based on the criteria that I’ve already identified.

So, the first gap, focusing on communication, what we found was that there were very few studies that examined whether or how different provider and patient communication or engagement strategies might affect outcomes in asthma. There were a few studies, for example, that looked at mobile phone messaging to facilitate self-management and provider interventions to promote patient-centered care in clinical settings, but those studies were not necessarily focused on asthma care. So, I think that’s just important to recognize.

And then in terms of what you see on the slide here, are examples of potential desirable studies that might be considered.

Moving on, we also identified the integration of care for asthma, for severe asthma,
and in particular, for reducing disparities as one of the gaps, and again, when we went back to look at the literature and we looked at the Cochran review, in particular, we found that there were several studies comparing newer models to usual care, but there were no studies that actually compared innovative models to one another.

So, it’s just important to recognize that what we found was, again, comparisons of one model, for example, using some kind of high tech intervention, using smart phones, et cetera, but using that -- comparing that to usual care versus comparing two different, innovative models.

We could not find any studies that examined integration of pharmacists into the care team. This was particularly important because it was something that was raised by multiple workgroup members as a really important area, so we think that there are opportunities here.

And then finally, there were no studies that examined models to examine transitions in care. And, again, you can see examples of
potentially desirable studies that could be considered within this particular domain.

Moving on to systems, we found very little in the area of systems. Basically, in the Cochran review, we only found one study on asthma that basically assessed a web-based, comprehensive, health enhancement support system. There were no studies that addressed data integration to identify or target high-risk communities or comprehensive interventions that linked multiple systems, in particular, healthcare systems with home or work-based or school-based, for example.

I’m not going to go over behavior, because we actually kind of melded it -- it trended very, very closely with the communication domain, so I’ve, in a sense, addressed it.

There was a lot of focus here in the response to therapy, in terms of the workgroup, really emphasizing this as one of the key gaps. What we found were three studies, which addressed modifiable factors such as baseline vitamin D levels. There was one study that addressed genetic
factors. And then we found 19 reviews, but of those 19 reviews, only five were moderately relevant to disparities.

So, what I mean by that is that there wasn’t information on racial or ethnic or language groups, so even though they were relevant to the topic, they did not target disparities specifically.

There is also quite a bit of current work taking place, for example, the BELT Trial, which is being led by Elliot Israel in Boston, which is looking at the effect of LABAs versus other treatment in African-Americans in particular. We’re very interested in the potential gap here in response to therapy because we do think that there is an opportunity here to do a real comparative effectiveness study to engage patients and also to potentially work off of current work that is in the field.

So, we’re very mindful of the timeliness issue in terms of proposing a funding announcement that calls for projects that can be completed
within a three-year timeframe. So, given that, we would like to be able to encourage potential applicants to really build off of current work, so long as that work is making a unique contribution or extending work that is currently underway.

And then, finally, a gap that was identified again by the workgroup relates to the environment, and you can see some of the sample desirable studies in the bulleted points here. I will say that this is a really important area, however, I think that this is an area that others are addressing quite effectively. There’s the Coordinated Federal Action Plan to reduce racial and ethnic disparities in asthma. There’s a lot of good work taking place at the CDC. So, I don’t believe that this is a space that PCORI, per se, needs to place a lot of focus because there’s other areas where I think PCORI’s investment would see a stronger return on investment.

So, at this point, what we are proposing is a portfolio of projects, about eight to ten, within the area of addressing asthma for African-
American and Hispanic/Latino populations. If, in fact, we move forward with this and we do end up supporting a number of studies in this area, I think that there is a real opportunity here to develop a learning network and to also potentially work off of other work that is currently underway at PCORI, particularly around the patient powered research networks that you heard about earlier from Joe.

So, at this point, I’m happy to take questions. Thank you.

CHAIRMAN WASHINGTON: Christine, please.

MS. GOERTZ: Christine Goertz, Board member and chair of the PDC. Just, again, we had a very detailed -- well, a somewhat detailed discussion about this yesterday at the PDC and we were presented with four concepts for targeted PFAs for our consideration and of those two, we felt that two of them were ready to move forward and two were not, and this was the other one that we felt was ready to move forward.

CHAIRMAN WASHINGTON: Douma.
DR. DOUMA: Allen Douma, Board. This comes out of my experience and shows somewhat how old I am. Back in the early 80s I worked for the AMA and one of my areas of responsibility was doctor/patient communications, and we looked at asthma, and there were studies going on in the early 80s. My question is, when we do a review, how far back do we go before we think something’s invalid?

DR. HASNIAN-WYNIA: In this case, we kept it within about ten years.

DR. DOUMA: Okay, because there was a lot of stuff going on before that.

DR. HASNIAN-WYNIA: Yeah.

CHAIRMAN WASHINGTON: Norquist?

DR. NORQUIST: Yeah, and maybe this is to Christine and Romana, what I’m unclear about, you said -- I mean, the first one we talked about, the targeted, it was a little more -- we were coming down to one specific. You’re talking about eight to ten questions, and so, you know, that implies a smaller, I mean, the studies themselves may be
smaller. I mean, what specific topics out of all of these did you guys narrow down? It might be helpful because when I think about voting to move forward, it would help me to know exactly what -- I mean, instead of a broad concept, it sounds like you narrowed this more, and I didn’t hear that actually when you said --

DR. HASNIAN-WYNIA: Yeah, so, what I highlighted here were the five main gaps that were identified by the workgroup. I mean, one pathway for us would be to issue a funding announcement that motivates all five gaps and request proposals that addressed any one of them, and we can provide sample questions. The other pathway, which I think for a targeted funding announcement is more appropriate, is to target maybe one to three gaps.

One of the things that I think is really important to recognize is that the gaps that were identified are interrelated, so communication barriers and integration of care and systems are highly interconnected.

One of the topics that did rise to the top
much more specifically was within the area of response to therapy, so one of the questions that many on the workgroup, and then we went back and verified, that’s much more specific is the question of both modification and adapting the current guidelines for asthma, which have been in place -- the NHLBI guidelines have been in place for 20 years.

There is still quite a bit of question about the most effective ways for, particularly clinicians, to enhance clinician implementation of the guidelines. The question within the disparities domain is not just the implementation of the guidelines, but also the modification of the current guidelines, which again may connect to some of the other gaps that we’ve identified because some of the barriers that we know are very, very closely related to issues that were addressed in the other gap around communication and integration.

Dr. Norquist: Let me just push you a bit on that. So, the issue is, is that the gaps are broad concepts, and so if you go out and say, we
want funding announcements in the broad, you can get a lot of very specific questions. If we’re going to really be targeted, as we say, we may want to a priori say these are the very specific questions that we want answered within integration of care. I mean, this one first bullet here has got tons of different research projects that could be there. So, if you really want to be targeted, you may say, these are the ones we’re prioritizing first, this is just advice, otherwise it sounds like just a general funding announcement to me.

DR. HASNIAN-WYNIA: Right.

CHAIRMAN WASHINGTON: Add something?

DR. SELBY: Yeah, just to point out, because this is the first time we’ve all been through this, that we predicted and it came to pass that out of the workgroups would come different approaches to targeted funding announcements and you heard a very specific study from Chad and you did hear this idea of a portfolio study from Romana.

I think we have had conversations,
including yesterday, that -- and I think your point is a very good one, and I expect that we will clarify a set of questions and say, we’re interested in proposals that address one or more of these questions, because Romana says they’re related, but we will also craft language that says -- and I’m not sure, Romana, if you’ve mentioned the dollar amount yet. I don’t believe I heard -- did you say that?

DR. HASNIAN-WYNIA: I did not. So, we have $17 million for this particular targeted funding announcement.

DR. SELBY: So that’s the proposal on the table, and the language will say that we have $17 million and it will not say that the upper limit is $2 million.

So, we will be open to a smaller or larger set of larger or smaller projects depending on how the special emphasis panel that’s convened with patient stakeholders and asthma experts to review these helps us prioritize them.

DR. NORQUIST: About that, say an issue
about that that worries me a little bit is if you have a pot of money, and I can imagine several studies that come in at $17 million, and then you’ve got 10 that are at $2 million or something, and then you better be sure how you’re going to make that selection because somebody come in with a blockbuster study of $17 million on asthma treatment and very specific, so I would just warn you in advance, that could be a problem. I mean, we ran into this all the time -- and I’m sure Carolyn has run into this sometimes too with these announcements, but I mean, just be aware, that could be a big issue.

DR. SELBY: And we will have the usual, you know, if your proposal is more than X amount, I don’t think we’ve actually settled on the amount yet, but if it’s bigger than a certain amount, you’ve got to talk us in advance.

So, anybody that was permitted to submit a $17 million application would have talked to us in advance.

CHAIRMAN WASHINGTON: Joe, this point is
important because when we do vote, we’re voting on a portfolio of studies, and even though we don’t know the exact number, you’re giving us a range of, you know, six to eight or whatever the number is going to be, I think it would be a different conversation, although the outcome might be the same, if we were talking about one study.

And so, let’s acknowledge that we’re talking about here guidance that says you’re going to fund a portfolio of studies, and so we’re not voting on one for $17, just to clarify that particular point. Good point, Norquist.

Yeah, Leah, please.

MS. HOLE-CURRY: Leah Hole-Curry, Board member. I think this is along the same lines. The gaps are significant and I think the group did a great job of getting it to the five, but I think for the purposes of what we had originally anticipated for targeted funding announcements, we should prioritize within those and select a few of those gaps, and I don’t know that we necessarily have the knowledge to decide which ones, but using
the criteria that brought us here to begin with might be the proper approach.

So, I don’t know if that’s necessarily an actual amendment to the motion, but I think moving forward on all five is counterproductive to the targeted, even though we may eventually do that for this round, I suggest a smaller group, and you all could decide how to get to that group.

CHAIRMAN WASHINGTON: Good point. Epstein.

DR. EPSTEIN: Arnie Epstein, Board member. I was on the PDC that discussed this yesterday. I supported it then, I support it now. Truth and consequences, I do want to say a word of what I think we’re getting and what we’re not getting. Having said I support this, which I do, this goes against some of the criteria that I set up myself personally for what I would support things for.

Number one, I wanted an important issue. Number two is I wanted information to be lacking that I thought would tell us what works better and what doesn’t. And number three was I wanted to find some external shock to the system that
increased the probability in my mind that we could
discover something which had heretofore not been
discovered. And I’m not convinced that number
three holds here and I’ve watched this literature
closely for many years, and this is a very tough
nut to crack.

I can think of almost no articles that
have done this or studies that have done this, so
it’s formidable. I support it, having said that,
because I’ve chatted with Romana and seen her
present, and it’s clear to me that she understands
the issues really well and has -- is headed for the
right direction, and I can’t think of anything
that’s particularly more important or more in line
with what PCORI’s objectives ought to be, so I’m
personally persuaded to move there.

I do take as friendly amendments the
cautions that Gray and Leah have put up about maybe
we’ll do better to concentrate further. I find
myself nodding when I hear them about that.

CHAIRMAN WASHINGTON: Thank you, Arnie. I
would expect that that particular criterion, his
last one, would weigh in your thinking as you’re deciding how you focus and prioritize among the five areas.

DR. HASNIAN-WYNIA: Absolutely.

CHAIRMAN WASHINGTON: Levine, please.

DR. LEVINE: Sharon Levine, Board member.

Just a quick -- in the category of systems, there’s an awful lot of innovative thinking -- I’m not sure how much work, but thinking, around the use of mobile health technologies, particularly in hard to reach populations, and I’m hoping that when you describe systems you’re including mobile health technologies explicitly.

DR. HASNIAN-WYNIA: Yes and it came up quite a bit during the discussion as well.

CHAIRMAN WASHINGTON: Okay, are we clear? I know we are, but I was going to ask, are we clear about what we’re voting on? Okay.

Similar to our last discussion, you know how we’ve arrived at this point now. We’re really looking at a proposal that’s been endorsed by our Program Development Committee, being brought forth
by staff to spend $17 million focused on this
particular targeted PFA in the area of asthma,
particularly as it relates to health disparities,
and in this case, the motion is calling for a PFA
focused on treatment options for severe asthma in
African-Americans and Latinos.

And you’ve seen the questions, you’ve seen
the background, you’ve heard the discussion. We’re
going to, if we approve this, rely on the judgment
and expertise of not only our staff and PDC, but
others who have been engaged with us through our
workshops and our other expert groups to more
clearly define and prioritize how this would appear
in the public.

With that description as to what we’re
voting on, all in favor moving forward?

DR. SELBY: Ask for a motion first.

Actually, formally call a motion.

CHAIRMAN WASHINGTON: Okay, somebody’s
saying they want us to have an actual motion.

Okay, so --

UNIDENTIFIED BOARD MEMBER: So moved.
CHAIRMAN WASHINGTON: I have a motion.

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: Second. All in favor?

[Show of hands.]

CHAIRMAN WASHINGTON: Okay. So, we have 17.

Francis, are you still on?

[No response.]

CHAIRMAN WASHINGTON: Francis has moved on. That crying was just breaking him up. Okay, all opposed? Any abstentions? Okay, motion carries. Thank you.

Joe, we’re at a point where it’s after noon, and I think we need to take a break or we’re going to take a break. Do you want to tell the Board and the staff sort of how we might cover these other topics that you wanted to cover today? Or do you want to think about that over lunch and we’ll update people when we return?

DR. SELBY: Well, my motion would be to try as best we can to make up time this afternoon,
but anticipating that we probably won’t be able to, I expect that we’re going to go to 5:30 instead of 5:00.

CHAIRMAN WASHINGTON: Let’s look at the agenda.

DR. SELBY: But starting what -- when do you want to return? An hour from now?

CHAIRMAN WASHINGTON: It’s an hour from now, which would give us 50 minutes about, that’s about right.

DR. SELBY: It’s 12:15.

CHAIRMAN WASHINGTON: It’s actually only giving you 45 minutes, but we’re behind, so we’re going to reconvene, but before we go, I really do want to thank Romana for superb work and leadership in bringing this forward, and likewise again to Chad. Thank you. This is important stuff.

DR. SELBY: And thanks to David for intending to present.

CHAIRMAN WASHINGTON: And for your patience. So, we’ll see everyone at 1 --

DR. SELBY: Gene, can I -- I have one very
brief correction to a slide I posted and something I said earlier. There was a modest discrepancy in the dates presented on the slide, and we will correct the slides before they go up on our website, but I want anybody who was listening to be aware that -- and this is good news -- the letter of intent deadline for the National Patient-Centered Clinical Research Network is not June 14th, it’s June 19th, so you have five more days to deliberate on your letter of intent.

And the applications are due September 27th instead of September 23rd. This is all over our website already, but just so we didn’t create a disparity, you have four more days to work on those applications.

CHAIRMAN WASHINGTON: Okay. See you at one o’clock.

[Whereupon, at 12:17 p.m., a luncheon recess was taken.]
AFTERNOON SESSION

[1:12 p.m.]

CHAIRMAN WASHINGTON: We’re live. Good afternoon everyone. Welcome back to this afternoon session of the Board of Governors meeting for the Patient-Centered Outcomes Research Institute.

We’re now going to move into our next topic, which is a discussion on the advisory panels and we have Dr. Rachael Fleurence to introduce this topic for discussion. Thank you.

DR. FLEURENCE: Thank you, Gene. So, I’m going to be talking about the advisory panels that took place April 19th and 20th in Alexandria, Virginia.

We have some questions that we’d like you to consider as I present, so asking you to think about feedback on both the run of the advisory panels and on the outcomes that we obtain from the advisory panels, and then if you have any recommendations for future advisory panel activities.

So, just as a quick recap about the
advisory panels, they’re authorized in PCORI’s authorizing legislation. The expert panels are here to help us assist PCORI in achieving its goals. Their purpose is to work with both PCORI staff and the Board to identify research priorities and topics, but also to provide input in other activities such as patient engagement.

The framework and composition, they’re composed of 21 members and they each have a charter, a term duration, and a clearly-defined scope of work. The members were selected based on their expertise and ability to contribute to the work of the specific panels.

Just a quick reminder of where the advisory panels fit into PCORI’s overall structure, so the advisory panels are set up to give advice and to provide input. PCORI staff manage the day-to-day activities of the panel and they also carry out PCORI operations.

The Board of Governors provides overall governance and insight and oversight and they approve PCORI strategy and direction.
So, I’m going to provide you with a recap of what happened on April 19th and 20th in Virginia. We had three scientific advisory panels meet, one was for assessment of options, one was for improving health systems, and one was for addressing disparities. We also had a patient engagement panel as well.

The Scientific Advisory Panel has a number of tasks. They are tasked with identifying and prioritizing research topics within their area. They’re tasked with providing us with feedback on specific research questions and possibly on study designs, and then further down the road, they’re going to help us look at our research portfolio and identify potential gaps, as well as consider study findings and give us information on how to better disseminate and implement research results.

The Patient Engagement Advisory Panel has -- their role is to assure the highest patient engagement standards and to help PCORI establish a culture of patient-centeredness in all aspects of its work.
The specific tasks of the Patient Engagement Advisory Panel is to give us advice on how to identify research topics that are important to patients, but also to advise us generally on the conduct and review of research, to advise us on how to evaluate the impact of patient engagement in research, and then generally to advise us on communications, outreach, and dissemination with that particular perspective of patient engagement.

So, the panelists were selected and came to meet in person on April 19th and 20th. Prior to the meeting itself, we did send them out some materials and some orientation to PCORI. My colleagues developed PCORI one-on-one training that they took online prior to coming.

We had developed some research prioritization training materials that they were sent and they were able to read prior to coming to the meeting, and then for the scientific panels, they were all given between 10 and 20 topics to review, and these topics were sent to them with associated topic briefs using our five criteria for
research prioritization.

On the day itself, they were provided with additional training in the morning on how to conduct research prioritization, and then they broke out into their specific groups for the next day and a half in order to fulfill the tasks that we’d asked them to do.

So, the patient engagement panel, which was led by my colleague Sue Sheridan had a number of outcomes on April 20th and they’re listed on this slide. Her panel started working on the framework of their work plan for their patient engagement panel. They also made suggestions to improving the PCORI ambassador program and they’re in the engagement awards, and then they made recommendations on how to enhance best practices and meaningful patient engagement in research.

For the scientific panels, I’m going to list for you the topics that came out as priorities, so I’m starting with David Hickam’s panel, assessment of options. They were provided with 20 topics to conduct prioritization on and
these are the four topics that came out ahead of the pack.

The first one is research in ductal carcinoma in situ, the second one is comparing strategies for managing symptoms in osteoarthritis, the next one is comparing treatments for migraine headache in adults with episodic and chronic migraine headaches, and then the last one was comparing effectiveness of medication regimens in adolescents and young adults with bipolar disorder.

So, this was the first scientific panel assessment of options.

Moving on to the addressing disparities panel, which was led by my colleagues Romana Hasnian-Wynia and Adaeze Akamigbo. They had five topics come out as high priority topics. The first one is health communication associated with competing treatments, so how to -- what are the better communication models for patients and clinicians to communicate risk to minority populations.

The second one was heart attacks among
racial and ethnic minorities, so looking at the intervention -- looking at different health interventions to enhance the Million Hearts Program and reduce major vascular events among racial and ethnic minorities.

CHAIRMAN WASHINGTON: [Off microphone.]

DR. HASNIAN-WYNIA: Because it’s about communicating risk so that’s how the link is --

VICE CHAIRMAN LIPSTEIN: [Off microphone] -- come up from this panel at all?

DR. HASNIAN-WYNIA: Yes, it did.

VICE CHAIRMAN LIPSTEIN: Are we allowed to ask questions? I don’t know what, Gene, the protocol here is.

CHAIRMAN WASHINGTON: Well, if you have a question, a clarifying question about the slide, yes.

VICE CHAIRMAN LIPSTEIN: So, people, when you’re addressing disparities, I just didn’t see it in the slide and maybe it came up in the conversation, but people with resources have to
solve -- are able to solve problems differently than people without resources. It’s not here.

MS. FLEURENCE: It’s not there, but it did come up in the discussions. Yes.

VICE CHAIRMAN LIPSTEIN: Great. Thank you.

MS. FLEURENCE: Yes, and we have longer feedback on them, this is just a summary.

So, the next three topics that were prioritized by the addressing disparities panel were different delivery models for addressing hypertension in minorities, interventions for improving perinatal outcomes, and then interventions to reduce lower extremity amputations in minorities.

And then moving onto the last panel, improving health systems that was led by my colleague Chad Boult, so they came up with five topics -- they prioritized five topics. So, models of patient empowering care management, so looking at the effects of care management on patients with chronic or progressive conditions.
The second one was models of transitional care, so looking at different models of transitional care on patient safety and patient outcomes. The third one was models of integration of mental health care and primary care, so looking at the effect of collocation of mental health services and primary care.

The next were models of perinatal care, so looking at the effects of care management on pregnant and postpartum women. And then the final one was looking at different features of health insurance coverage, so the relative effects of different insurance features, such as benefit designs on chronically ill patients. I am finished with the priority topics, and I just want to make the point that this is informational to the Board, so I will talk about what we’re going to do with these topics, but for now it’s just letting you know what the outcomes were of the panels.

VICE CHAIRMAN LIPSTEIN: So, I just want to add to the information, because this one on improving health systems was the one, in reviewing
the advanced materials, that I wanted to speak to
because this last one, for example, is one where
recently an article got written about BJC
Healthcare about changes to our insurance design
that we made to encourage wellness and prevention
and early detection screening, and we made those
changes in 2004 and the article was written based
on data from 2005. And we just hadn’t changed much
in one year, and the article got published in 2013.

And so, part of the issue on this
particular one is that timing becomes a critical
issue in that it will take us a long time before we
realize the impact that changes in health insurance
design coverage, and I know that PCORI has an idea
that by 2017, we will show results. This is one
that’s really hard to do.

There are immediate impacts on cost if
you’re going to look at cost, but the immediate
impacts on health improvement, whether the patients
are chronically ill or whether the patients are
healthy, is really going to be -- there’s a time
dimension here that we need to add to that
information.

So, that was one. And the second one is, in order to get the attention of people who are involved in improving healthcare delivery systems right now, it’s hard to get their attention around things that don’t have substantial cost attached to them. I know we’re not allowed to do that by virtue of our statute on the one hand, on the other hand, given the time that we are in that it’s very different from when the law was passed, which is, we are looking at really substantial changes in the financing as well as the delivery of healthcare systems.

When we look at high priority topics, if it’s possible to look at one that has substantial cost implications, either for the patient, which, you know, we’ve talked about before, which is out-of-pocket, cost sharing, or financial responsibility after insurance, and the impact that that has on outcomes, or to look at how we actually can maintain outcomes in a more efficient way.

And it’s just going to be very hard to get
the attention of the things that people out in the
delivery care sector really care about right now
and at the same time ignore dimensions of cost.

So, I just wanted to throw that out there.
I’m not trying to break the law and I’m hoping
nobody’s going to come and put me -- are you going
to put me in jail? Oh, okay.

CHAIRMAN WASHINGTON: Okay. We appreciate
those comments. Why don’t we, Rachael, if you
don’t mind, field a few questions?

MS. FLEURENCE: Sure.

CHAIRMAN WASHINGTON: Starting with Douma
and work your way around, Kuntz and Sigal?

DR. DOUMA: Yeah, thank you very much,
Rachael. Allen Douma, Board. You, in one of your
earlier slides, indicated there was research
prioritization material that was sort of used as
training.

I know we’ve talked about that in the
historic past of this ancient organization. It
would be nice for me, at least, to be able to take
a look at that material.
MS. FLEURENCE: Absolutely, and it is actually available on the website as well.

DR. DOUMA: Okay, if you could just point me to where to find it.

MS. FLEURENCE: I will, yes.

DR. DOUMA: That would be great. I appreciate that. You also talked about you gave the group 20 topics to review?

MS. FLEURENCE: We gave the assessment of options panel 20 topics.

DR. DOUMA: Right. Twenty topics.

MS. FLEURENCE: The others did --

DR. DOUMA: How did you select those 20 topics?

MS. FLEURENCE: So, these are the topics that came through a number of sources, including our webpage, including all the questions that were prioritized for the targeted funding announcements, so the questions from the IOM, from the AHRQ future research needs reports --

DR. DOUMA: So there are a thousand of them maybe.
MS. FLEURENCE: There were close to 1,600.

DR. DOUMA: You winnowed those down to 20?

MS. FLEURENCE: We winnowed these down to 20 using modified versions of our PCORI prioritization criteria.

DR. DOUMA: Okay. Yeoman’s effort. Then you’re going to talk about later about kind of what’s next after --

MS. FLEURENCE: The next slide is the timeline. Yes.

CHAIRMAN WASHINGTON: Rick.

DR. KUNTZ: Rick Kuntz, Board member.

These are great topics. I kind of wanted to know where in the sequence you are. These are really complicated things to study. They’re highly confounded. Whereas picking dimensions like the healthcare system or something and trying to isolate that as a factor when there are a lot of clear confounders associated with the outcomes of patients who are actually in those systems. Are you going to -- if we agree that this is where to go, are you going to drill down to a more
methodological question to guide researchers? Because I think this is too broad to ask researchers to answer personally.

MS. FLEURENCE: So, the next steps are for our program leads are going to look more in detail at these questions and commission landscape reviews, so do some real homework over the summer on exactly what you’re speaking about, and I’ll show in the next slide the timeline. Then they’ll come back to the Board with the topics that they think are ready for targeted funding announcements.

DR. KUNTZ: Well, I was specifically thinking about the fact that this is the most complicated research -- observational research on complicated systems, and there’s been a lot of research on this that doesn’t get answers. So, are we going to really heavily engage the Methodology Committee to help really direct questions about this? Because I think that’s the best way to leverage the Methodology Committee because I just think that the analysis of systems themselves through an observational process, 90 percent of the
challenge is the methods.

MS. FLEURENCE: Thank you.

CHAIRMAN WASHINGTON: Norquist and then Sigal.

DR. NORQUIST: [Off microphone.]

MS. SIGAL: That’s okay. Ellen Sigal, Board. So, Rachael, nice work. So, a question, I think all of these topics are important, a little bit about the process and the -- okay, usually I can be heard.

Okay, so a question about the topics and the prioritization. So, a while ago, through the IOM and after the cancer community worked on priority topics, and maybe even Ethan Basch can help me, but the -- and it’s not that this topic isn’t important, it is important, but it seemed to -- in our ranking it was in the last quartile of feasible projects, and I can’t remember exactly why. It could have been because there was a lot going on, on the subject.

So, I guess the issue that I’m trying to raise is, it is important, but if we were to get
experts in this area or oncologists or people that are really in the field, you perhaps would come up with a different ranking. So, how do we adjust for that, because the legislation calls for advisory panels but it also calls for expert panels and I would bet, if you had given five or ten other priorities in cancer you probably, at this point, may not have come up with this? So, how do we adjust for that?

MS. FLEURENCE: This was our first sort of round of working with the questions that we had. I think we’re certainly planning on doing more rounds and I think that as we get feedback we will, I think, we’ll make changes to the process in order to accommodate comments that you’ve just made.

MS. SIGAL: Well, I just think it’s very important, as we get into a specific disease setting, that we start to then go to the people that are really expert in that setting to see what’s going on and what the opportunities are.

MS. FLEURENCE: So, one thing that we will be doing is commissioning these landscape reviews,
but on the topics that have already been chosen, and I think we’ll have to have further discussions on how to expand to the expert communities where we feel maybe that we haven’t captured exactly all the right questions.

MS. SIGAL: So, just one other point and I’ll let others speak. The problem with that is we may consume a huge amount of time and then go to the experts and they say there’s 25 or 50 studies on this, and there are other opportunities. So, how do we adjust for that, you know, earlier?

DR. NORQUIST: Gray Norquist, Board. I’ll just follow up on that because this is exactly the thing -- I mean, I looked at the two mental health topics, one of which we supported a research trial when I was at the NIMH on bipolar, I just did -- I can save you the trouble of a landscape review. I just wrote a chapter that reviewed all the research on integration and mental health in primary care, including a recent Cochran review. So, there are topics -- and I agree with Ellen, I think -- I just worry about the process is
that if you ask a bunch of people what are the big
topics, they’ll give you a list, and then you’re
going to have to -- and I wonder if we go back to
kind of what Harlan is thinking is if we have this
idea about what do we think are the big ones who
are really going to make a change and it’s really
going to make a difference and then start from that
perspective and start to narrow down, then we’ll
save a lot of work, because I’m afraid you’re going
to get into a bunch of -- you’re going to do a lot
of landscape reviews, come back -- I mean, I don’t
know. Maybe I’m wrong about that, but just another
way to kind of look at how to pick the topics here.

MS. FLEURENCE: So, as part of the
background work that we did do for the panels, we
prepared topic briefs using our criteria and one of
the criteria is feasibility of implementation,
feasibility about what’s already known on the
topic, so we did do some of the work that you’re
describing just to sort of make sure, but in the
time that we had, we weren’t able to do sort of a
full systematic review on any of these topics.
But I think we’re learning as we’re going and both your points are well taken that we need to sort of make sure that the process can answer these concerns.

CHAIRMAN WASHINGTON: Joe, you want to comment on that question please?

DR. SELBY: Yeah, this goes back actually to a bit of a discussion we were having earlier today too, but I think it is really the -- it’s an essential question for PCORI and for its identity how we blend this -- these expert advisory groups, and so these are people, researchers, systems leaders, clinicians, patients with special interests in these areas, so it’s a remarkable resource, how we blend the questions that come into us through all the channels that we’ve described with the sudden great idea that may come up in a meeting here or it may come up through an e-mail between Board members or it may come up from one of the advisory panel members, and so that’s, I think, what we are working on now.

I really like Gray’s idea of over time
putting more of the landscaping work up before the prioritization process rather than, as we did it this time, a portion of the work up front, but leaving broad questions that we then now go out and do another landscape review on. So, I think that prioritization work actually goes better when the questions are more specific.

So, I agree with Gray that doing more of the really -- you know, the honing in on the right question and questions that we feel strongly about, before we get to the prioritization process, and really just picking from refined questions, will be an advance over what we’ve done the first time even though I think these are compelling topics and the discussions that led to them were quite amazing.

CHAIRMAN WASHINGTON: Joe, I think it’s a question of sensitivity versus specificity and how much we’re willing to pay for that extra sensitivity because there is an argument to be said that, you know, this broader group of experts actually might have, you know, a deeper reservoir of knowledge and more breadth of experience than
this small group of us trying to hone it down. So,
I understand the question of efficiency, but I
would also urge us to weight, you know, what we’re
giving up when we define what the focus areas are
through our landscapes up front before we go out to
a broader group, and so I don’t think it’s as
straightforward as jumping from one to the other.

DR. SELBY: No, it’s a blend, it’s
blending the strengths of each and recognizing that
a great question can, in fact, come from anywhere.

CHAIRMAN WASHINGTON: Right. Okay. I’ll
work around, we have Levine and then we have
Weisman and then we have Gabriel.

DR. LEVINE: Rachael, yesterday in our
joint COC-PDC meeting, we had a fair amount of
conversation about what was categorized on that
slide as incentives in the system, and one of the
things that we’ve said from the beginning is we’re
not going to fund research that others are likely
to do or are doing, and I think on this issue of
health insurance coverage, benefit design, and
incentives, there’s a tremendous amount of work
going on by people who’ve been doing this work for a long time.

So, before we commit to something like this, I think we need to be really careful that it’s something unique that we can do that would not come up or come out of research that’s already being done given that we’re in a period of rapid transition around payment designs, incentives, and benefit design.

CHAIRMAN WASHINGTON: Okay. And before I go to Weisman, just a question. When I go back to your -- about PCORI roles and you have advisory panels, the staff, Board of Governors, I mean, it’s very clearly laid out, what’s the role of the committee structure in this process? I know the committees are committees of PCORI, but in contrast it sounds like you’ve had experts with the staff and now you’re coming to the Board. Understand this is really information and it’s much earlier on than where we just were a few minutes ago in terms of recommendation.

But in that case, it had benefitted from
an in depth discussion, you know, at another level of the Board before it came to this Board, and so, something to think about in terms of us benefitting from that expertise, including Methodology, by the time it comes to the Board.

I appreciate that you’re coming very early on, but much of this may have sort of -- at least you’d have more to say, well, this is what the PDC or the Methodology thought about these two different approaches.

DR. SELBY: And the only -- just as Sharon just offered some cogent comments on that fourth one, I think that kind of input at this stage is useful to us in deciding whether there’s a reason maybe not to move forward with the landscape review. And I think actually we do -- I completely agree with you, Gene, we need to work out how we pull the committees in, including the Methodology Committee, and at what point we do what we did this morning, which was approve a topic.

MR. BARNETT: So, just clarification, so, to be clear, these aren’t recommendations being
made to the Board.

CHAIRMAN WASHINGTON: No.

MR. BARNETT: This is just sort of a report on what we heard from the advisory committees, so there’s still a lot of subsequent steps before these turn into any sort of a recommendation.

DR. SELBY: Right. Likely some -- most, if not all of these, that we’ve shown, will get some sort of a landscape assessment, and then the decision would be whether to bring them here.

MR. BECKER: So, can I comment on Sharon’s -- just build on it for a second?

CHAIRMAN WASHINGTON: Okay.

MR. BECKER: So, before we did anything, the one other thing I would do if you’re going to go after health insurance coverage and benefit design, is I’d link in with somebody by the name of Suzanne Delbanco, who’s running the Catalyst for Payment Reform, and I think she’s done a whole lot of this landscape reviewing of what’s out there and she has lots of people inputting to her.
CHAIRMAN WASHINGTON: Okay, thanks.

[Off microphone.]

DR. WEISMAN: So, you know, I’ve been reflecting a lot on the day and this specific topic. Gail asked me how I was feeling and I said me, or about the meeting, and she meant about the meeting. But I said, look, I’m unsettled about something and I think what it is, is that some of these issues, to me, don’t seem to be issues of facts. I mean, it does seem that -- so, integrated care, in which there’s continuity of management, aligned incentives that are in the patient’s interest, you know, transitional -- better transitional communication between teams, that’s sort of mom and apple pie, and we can do the studies and maybe we discover what people already know about these topics, and somehow we feel that by us doing it, and by us disseminating it, it’s going to make it stick.

And I just wonder whether we’re not going after the underlying causal factors. What I’m saying is true with almost all chronic conditions.
Now, seems to me the factual questions are easiest around acute care, you know, whether in somebody who has brain trauma, you know, what type of decompression actually is more effective than another one. That’s sort of a factual thing that maybe people don’t know, or treatment of a patient with acute myocardial infarction, is it this type of cure versus that type of cure, or is it hypothermia during some types of surgery -- those are factual things that could be determined acutely and fairly short time span.

I mean, basically, we have a sort of messed up health system that’s fragmented, that doesn’t have continuity, that doesn’t have a lot of things, and I think people know that -- I mean, some of this is common sense, maybe some of it needs to be tested. I would imagine, just based on what I know about healthcare systems and seeing ones that work very effectively and those that improve their outcomes, they’ve done their own tests, they’ve looked at before and after and shown they’ve had marked improvements of, say, outcomes
on delivery and so forth when there’s good prenatal care, they’ve had great improvements in diabetes management when they spend more time engaging the patients using health workers besides endocrinologists involved in some kind of integrated -- we know that, but it’s not being done.

A lot of the problems, whether it’s on the patient’s side, the doctor’s side, the hospital side, the coverage side, is there are -- it goes back to what I said earlier, there are changes that need to occur that are so deeply engrained that piling more facts and throwing more facts and findings, p-values, I don’t think is going to have any more impact than it already has in some of these situations, and I wonder whether it’s worth us really seeing what are the true barriers to improvements and is it lack of data about that, about the specific intervention, or is it behavioral impediments, disincentives for doing the right thing? I don’t know what it is. I don’t know what that problem is. I just worry we’re
going to have a pile of new data and we’re not
going to make that much difference unless we pick
things where there really is, in a landscape
review, no information available and we’re really
going to add something, and I suspect -- you don’t
usually ask a patient who’s comatose what their --
to give their buy in and their opinions about the
kind of care and what options they want to choose,
because it’s acute and you’ve got to do something.
And, you know, sometimes we’ve got to know more
facts there.

It’s really chronic disease, and I just
wonder whether -- how much of it is lack of
information versus lack of putting it into effect?
And why isn’t it? Why are guidelines not followed?
We don’t need to issue more guidelines. Why isn’t
it that people aren’t doing what we already know
they ought to be doing?

I love the topics though, but I’m not -- I
don’t think our approach of getting more -- doing
more randomized studies is actually going to answer
this -- is going to have the impact we want it to.
CHAIRMAN WASHINGTON: Okay, thanks, Harlan. Gabriel and then Norquist. No, he came up later. So, he’s on the next round going around.

DR. GABRIEL: So, okay. So, you’ll be both first and last, Allen, right? Sherine Gabriel, Methodology Committee. This discussion reminds me a little bit of the discussion we had earlier about targeting and really underscores the importance of being both strategic and transparent in those topics that we target for our targeted PFAs because, you know, at the end of the day we’re putting all of our eggs in fewer baskets, I guess.

So, what I’m going to suggest is that we bring back to the Board, and really to the public, a discussion of the process, because I agree, these are terrific topics, but I’m not sure there aren’t six or eight other equally terrific topics out there, and I don’t know enough about the process to say, oh yeah, I believe in the process so that I believe in the outcome.

So, maybe a full discussion -- full and open discussion of the process of how you get from
here to there, generic discussion, might be useful.

CHAIRMAN WASHINGTON: And could I suggest that the Methodology Committee, particularly in response to our current deliberations about what new roles and/or activity the committee is going to take on, weigh in on this? Because this is about a method, you know. We use the word process, but it’s about method about prioritizing or selecting where we’re going to focus going forward.

So, Joe and I were agreeing with your comment that we need to find a way to bring it forward.

DR. GABRIEL: Yeah, no, I think that’s right. And we’re going to be working, yay, more closely with Rachael, so that will be a nice tie-in.

MS. FLEURENCE: I mean, I do want to say that we do have a description on the website, so it’s publically available how we got down to what we did. And so there is some information available, but I’d be happy to report back on it.

DR. NORQUIST: Real quick. I mean, I would second that because there are ways of getting to a number from different ways, and do you narrow down in appropriate ways, because the Methodology, which is very good -- I just want to raise one thing as we think about priorities. One category -- I mean, one criteria we haven’t thought about is, given a timeline, how quickly -- because having launched a lot of CER studies myself and seeing them take eight years and whatever, it sure would be nice to think, also, if we’ve got a high priority topic, something is already -- an infrastructure is in place, if we could add onto that. So, I think at some point we really seriously need to know from a landscape review what exists in a topic area that we might quickly, with some infusions of funds, put into and move something very quickly, and that might put something up a little higher on the priority list than -- it might be the big question, do you know what I mean?

MS. FLEURENCE: I do and one of our criteria is duration of information where we take
into account sort of how quickly we might be able
to produce results, so that would fit into that
nicely.

DR. NORQUIST: But I’m thinking it’s like,
go out there to the foundations, NIH, others, and
say, what’s already in existence? What are you
going ready to shut down but that we might be
able to add on to or run on very quickly and get
[turned off his microphone mid-sentence].

CHAIRMAN WASHINGTON: Hole-Curry and then
Zwolak and Douma.

MS. HOLE-CURRY: Leah Hole-Curry, Board
member. I think Gray’s point was the one that I
was going to raise, just related to this, and as
you move forward with the landscape reviews in
really not only identifying the current state of
the evidence, but what’s in process, and maybe the
reach out would be new to certain funders that
maybe are getting underway with studies, so CMMI
around this last one about health insurance
coverage. While there might be a lot of studies,
maybe they’re mostly focused on what the cost
outcomes are versus the outcomes on a patient that
we would want to add and fund that component of it,
just as an example.

So, when you’re thinking about the
landscape reviews, some additional questions about
how we might strategically partner around some of
these priority topics.

DR. KRUMHOLZ: Can I -- just on top of
this?

CHAIRMAN WASHINGTON: Please.

DR. KRUMHOLZ: Just to say that a lot of
people who’ve received CMMI money, including $10,
20, 30 million to do these demonstrations, told me
that they’ve pulled all the evaluation out of the
money so that many of them, and I know Joe’s aware
of this, are desperate for this kind of leverage,
and so I think it’s a good point that you’re
making.

DR. SELBY: And especially for any look at
what we would call patient-centered outcomes,
right, I mean, there’s a certain amount to look at
cost savings and changes in utilization, but
nothing about how it affected the patients. And that’s from CMMI, they say that.

CHAIRMAN WASHINGTON: Zwolak and Douma.

DR. ZWOLAK: Bob Zwolak, Board member. My comments build on what just had been said. I think it’s treacherous to dive into healthcare system improvement because it’s a pretty busy space, but from my perspective, what PCORI could offer is, I think, what a lot of these other evaluations are missing is the patient, what happens to the patient in all of these things, and I think it’s a fabulous opportunity, if we really work at it, to apply not just the PCORI sauce, but maybe double sauce or triple sauce, because I think many of these evaluations, the ACO projects and the high value projects, are really potentially overlooking what happens to the person and the patient.

CHAIRMAN WASHINGTON: Is that ultra PCORI sauce, the super PCORI sauce?

DR. ZWOLAK: [Off microphone.]

DR. DOUMA: Thank you. This is really a process question, but I put a little context, and follows on a couple of other folks looking at the topics that were selected, and I’ll just pick the one which is models of patient empowering care management.

Out there in the world, a lot of study going on in that -- ACOs, medical homes, in Oregon CCOs, we call them, so there’s a lot of activity. My question is, was that presented to the Advisory Board, say there’s a whole lot of activity going on out here, do you still want to choose it?

MS. FLEURENCE: So, we did do some brief homework on each of these topics and able to present ongoing -- and part of the task was to present ongoing research. So, the panels would have received a certain amount of information on ongoing research in each of these topics.

DR. DOUMA: But they then had to make a decision to still choose that topic?

MS. FLEURENCE: Then they had to decide whether, according to all our criteria, this --
they still thought that for PCORI to put money into that topic was still valuable, and in this case they came out saying that they did.

DR. DOUMA: Okay. That dynamic is intriguing.

CHAIRMAN WASHINGTON: Okay. Thanks, everyone, for your informative comments and suggestions.

Rachael, I notice we have the table, but I’d ask you not to spend much time on this. I mean, we pretty much covered it. I do have a question. Landscape reviews in general, what’s the cost range, so we have some sense, of what kind of expenditure we’re talking about here?

MS. FLEURENCE: I’m not sure I know the answer to that.

DR. SELBY: Let me just ask if any of the program directors want to weigh in on this from any experience you’ve had up to this point. Romana?

DR. HASNIAN-WYNIA: [Off microphone.]

CHAIRMAN WASHINGTON: Okay.

DR. HASNIAN-WYNIA: [Off microphone.]
So, the cost would go up for additional data [inaudible].

CHAIRMAN WASHINGTON: Right, but that gives us -- we’re not talking about hundreds of thousands of dollars and we’re not talking about a million dollars for a landscape review. Okay, Harlan.

DR. WEISMAN: Really, it’s just a sense, it’s not -- I’m coming out of my funk. To me the question is, if not for us, this difference that needs to occur would not have occurred. And that’s what’s really not clear to me on any of these. It may be that just because a lot of other organizations are studying something doesn’t mean it’s going to drive what we believe is needed to get to our vision.

So, I would love to know the answer to that. What is it that we’re going to do, because we’ve used the triple sauce or whatever it is, that others aren’t doing that will make a big difference that otherwise would not have occurred had it not been for PCORI?
CHAIRMAN WASHINGTON: Okay, that’s yet another criterion that you will incorporate into your thinking and decision making. Okay, Rachael?

MS. FLEURENCE: Okay.

CHAIRMAN WASHINGTON: Mr. Vice Chair.

VICE CHAIRMAN LIPSTEIN: Gene, one of the things that this brings up when you think about picking one to five topics per program area that come out from the advisory panels is, does the Board -- the Board’s never done this, the Board’s never, at least to my knowledge, we’ve never sat there and said, what are the one to five areas that we would like landscape reviews performed on, you know, almost as if we were an advisory panel? Because these advisory panels are advisory to staff, but they’re also advisory to us.

But it might be useful at a next meeting if we could carve out a couple hours and say, okay, if we were an advisory panel, the Board, what would we want staff to do five landscape reviews -- what topic areas would we want landscape reviews conducted on?
And maybe those five areas turn out to be what Dr. Krumholz refers to as a -- as the big rocks, but he’s thinking of a different kind of a -- you know, other topics we’ve yet to get to.

I’d kind of think it would be fun for us to be an advisory panel to ourselves for a couple hours.

CHAIRMAN WASHINGTON: Okay, I’d have to speak with Larry Becker about the potential conflict of interest there, but we have it on the table now. Kerry?

MR. BARNETT: Well, I like that idea, in part, because what it would do is it would help refine the advisory committee process by forcing us to sort of go through it, and so the question that I was actually going to ask Rachael is, now having been through this, not for a complete cycle, but for a significant portion of it, are there things that you would change about the process? Do we have the right people on the advisory panels? You know, when you empanel a body like that, one of the most critical pieces is to make sure that we’re...
getting the assignment right to them, that they’re not kind of all approaching it from a different angle.

  So, as you kind of think about it now having been through this once, are there any adjustments that are worth making?

  MS. FLEURENCE: Well, I actually think that bringing the different stakeholders together is enriching the process because they do share all the different perspectives and they have a really rich discussion, and the discussion is structured according to our criteria.

  So, I didn’t go over our criteria again, but they are patient-centeredness, they’re about what we currently know is -- is it going to be implementable in practice, what’s the duration of the study?

  So, we had them talk about really important criteria to PCORI’s mission in a structured way, and that’s new about how we do research prioritization.

  I think part of the improvement to the
process is making sure we start off with a good set of questions. So, we don’t have the universe of good questions out there yet and I think that’s going to be part of the improvement is making sure that we start with a good bucket of questions.

I think the process with the panels was a really rich and good process.

MR. BARNETT: The only final comment that I’d like to make on this is just a reminder to all of us that what comes out of this process is sort of, I think, a very useful set of new data points for staff and for us to consider, and we have to be careful about treating them as if it’s a kind of a set of recommendations that we then jump in and critique. I think we have to think about it as sort of useful input, as all of us figure out the right direction.

The fact that the advisory panels told us A, B, and C, isn’t something that we want to push back on, it’s something that we want to help shape and mold as we move forward.

CHAIRMAN WASHINGTON: Okay, this -- again,
these have been great comments, and so it underscores the interest that the Board has in this, but I also want to emphasize for the Board that this is not a fixed process, and so Joe and Rachael and the staff will be incorporating this and Steve, we will plan to have some time for the Board to serve in that kind of capacity, really, at the next meeting if not before. I think that’s an excellent suggestion.

And I would just underscore the last point that was made regarding at the end of the day, one of the screens being, what is PCORI going to add that no one else would have contributed? What really distinguishes what we’re doing here from what’s being done anywhere else? And what, ultimately, is the impact, in terms of two of the criteria that the other Harlan mentioned earlier regarding how is it going to reshape practice and/or improve outcomes? So, just weigh those as considerations from the Board.

And I know -- yeah, there’s a question here that we need to vote on.
MS. FLEURENCE: That’s correct. So, we’re requesting a minor modification to the charters of the four advisory panels, and this is simply to include the possibility of having a co-chair on the panels. So, currently the charter only allows for the selection of one chair, and so, if we were to — if you were to vote to allow for the selection of a co-chair, we’d have to amend the four advisory panel charters, and this is what it would look like in terms of changing the language.

So, the changes are in red. There would be two changes. So, one would be saying “a chairperson and a co-chairperson if desired”, and then the second amendment would be modifying the — for modifying the stipend, the compensation, where we would add the co-chairperson in there as well.

CHAIRMAN WASHINGTON: So I see -- I have one question. Why wouldn’t we -- if we vote for a co-chair, why wouldn’t we have a co-chair? So, the question is, why would we add the language “if desired”?

DR. SELBY: I think we just wanted to
leave for future panels the choice.

CHAIRMAN WASHINGTON: It’s optional.

DR. SELBY: Yeah, that’s all we meant.

The previous charter just called for a chairperson.

We didn’t feel that we needed to go all the way to
requiring a co-chairperson in every case, but we
wanted to make it clear that such a person could be
appointed.

If the Board feels strongly that we should
insist on a co-chairperson in every case, I don’t
think we’re opposed to that either, but we thought
we’d leave it up to the individual panels.

CHAIRMAN WASHINGTON: I’m asking in terms
of symmetry across these, and importance, are we,
in fact, somehow signifying that when you’re on a
panel and it’s just a chair, that he or she has
more authority than a panel that’s got a chair and
a co-chair?

DR. SELBY: No, I think we’re only saying
that, to some extent, we respect the autonomy of
the panel to make that decision. That’s all -- it
doesn’t reflect a value or preference from our
point of view.

CHAIRMAN WASHINGTON: Okay. Who appoints the chair?

DR. SELBY: The Board.

CHAIRMAN WASHINGTON: If the Board appoints the chair, then we’re not leaving it up to the panel to decide whether or not there’s a co-chair. That’s all I’m getting at. And so, I’m just trying to understand the circumstances under which we would have a chair versus a co-chair, and if we don’t have those kind of circumstance -- I’m just raising, why do we set up the latitude? We’re appointing the chair and we’re appointing the leadership.

DR. SELBY: I think the Board can vote to go that direction. In point of fact, all four committees concluded that they wanted a co-chair as well, so there could never --

MS. FLEURENCE: There will be more panels, though, set up.

DR. SELBY: There will be future advisory panels. So, I don’t see a big -- any constraint.
MR. BARNETT: I think the only reason why we’re discussing this is because the charters themselves used the word “chair” instead of “co-chair.”

DR. SELBY: No, there was a chair, now we’re saying there will be a chair and a co-chair.

MR. BARNETT: Not two co-chairs.

DR. SELBY: There may be a co-chair along with the chair. It’s not two co-chairs, it’s a chairperson and, if desired, a co-chairperson. But one person is the chair.

MR. BARNETT: And the co-chair is somehow less than the chair?

DR. SELBY: It’s quite a bit like the Board of Governors of the Patient-Centered Outcomes Research Institute or the Methodology Committee.

MR. BARNETT: We don’t have co-chairs.

DR. SELBY: We have chair --

MR. BARNETT: We have a chair and a vice chair.

DR. SELBY: Okay, well, I think we’re using the word --
MR. BARNETT: Is that what we’re talking about?

DR. SELBY: We’re using the word co-chair like vice chair, but we’re saying chair and co-chair.

CHAIRMAN WASHINGTON: No, no, no. If you look in the Institute of Medicine reports and our many, many governing bodies, there’s a chair and a co-chair and it’s clear what that means, that’s right, it’s a PI and a co-PI, and what it says -- really, what you’re doing is giving the second person a little higher order title and it really promotes more engagement than being just a vice.

But it’s a big difference between the chair and the co-chair, and so --

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. SELBY: No, but I can imagine that there could be a panel who just, considering the people who were on the panel, they felt that there was an obvious chair and there was not an obvious co-chair, so they didn’t vote to appoint one.
Imagine a five- or six-person panel. I think it’s unlikely. I think most, when faced with the choice, would probably say yes to the type of co-chair.

CHAIRMAN WASHINGTON: Except for the only part I’m not understanding, Joe, is we’re appointing the chair.

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: So, the co-chair would be appointed at the same time?

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: But the panel wouldn’t be weighing in on it.

DR. SELBY: Well, the panel is sending us suggestions. You’ll see in closed session tomorrow, because this is a personnel issue, you will see that the panel is forwarding to us nominations that actually come from, among other things, polling panel members or soliciting nominations from panel members.

And from those panels came nominations for chair and a request for co-chairs as well.
CHAIRMAN WASHINGTON: Okay. By the way, I’m okay with the language. I was just -- no, I wanted to understand why.

So, is there a motion?

MS. SIGAL: A quick question please. So, I really would like to have a vote and I’m okay with it, but I don’t understand the 1,500 to 2,000. How many -- that’s -- if they’re meeting a lot and putting a lot of time and energy in it, it seems that that may not be enough. I don’t know. I mean, I don’t know how we decided on that, but if they’re meeting multiple times a year and spending a huge amount of time on it, I don’t know how -- I can’t remember how we came up with that number.

CHAIRMAN WASHINGTON: It’s a stipend.

MS. SIGAL: It’s a stipend, but it’s a stipend for, what, five days? Eight days? Ten days?

DR. SELBY: The exact number of days hasn’t been nailed down yet, but it looks like they’ll meet three, conceivably four, but probably more like three times a year, like every four
months, and I think most of the meetings will be a day now. The first one was basically two days.

MS. SIGAL: I mean, I know people are not doing this for money, but there may, if there’s a lot of work between meetings and a lot of stuff they have to do, it may not be sufficient. So, I don’t know.

I think, for me, if there’s a lot of work for people --

DR. EPSTEIN: [Off microphone.]

CHAIRMAN WASHINGTON: That’s a good point. Is there a suggestion?

DR. CLANCY: Arnie, could you repeat that comment. I’m sorry. Too many concerts over here.

DR. EPSTEIN: I don’t know we would not want to pay on the high side of reasonable.

DR. SELBY: So, I’d ask -- I’d ask the Board maybe to go with this at the moment and let us judge over time whether the number of days or comments or complaints from -- or suggestions from advisory panel members call for a higher fee. We talked about a daily rate and decided that we
rather wanted an annual rate, and this seemed very
fair at the moment, but we’re not wed to this
number long-term, we just think it’s the best
number to start with.

CHAIRMAN WASHINGTON: Is there a motion?
UNIDENTIFIED BOARD MEMBER: So moved.
CHAIRMAN WASHINGTON: Second?
UNIDENTIFIED BOARD MEMBER: Second.
CHAIRMAN WASHINGTON: Okay, language is
there if you go back to the other slide, but all in
favor?

[Chorus of Ayes.]
CHAIRMAN WASHINGTON: All opposed?
[No response.]
CHAIRMAN WASHINGTON: Any abstentions?
[No response.]
CHAIRMAN WASHINGTON: The motion carries.
Thank you, Rachael. A very efficient
group, tough group, but very efficient.
Okay. We’re ready. I think 2:30 --
DR. GABRIEL: [Off microphone.]
CHAIRMAN WASHINGTON: Okay, Joe. It’s up
to you then.

DR. SELBY: I guess it really doesn’t matter, so why don’t we stay in order?

CHAIRMANN WASHINGTON: Okay.

DR. SELBY: Which would be --

CHAIRMANN WASHINGTON: Active portfolio management.

DR. SELBY: Yes.

CHAIRMANN WASHINGTON: Joe and David.

DR. SELBY: Yes.

CHAIRMANN WASHINGTON: [Off microphone.]

DR. SELBY: We really think they will be onsite for three days a year. Yes, three times a year. It generally is not entirely worked out. It could differ by panel. It could be more work on one panel than another and there will be some work at home. There will be.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. SELBY: Okay, I think this is probably not the forum -- this is not the forum to debate this.
UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. SELBY: Right. And you could even ask me to survey the panelists for their level of satisfaction with the compensation.

[Off microphone discussion.]

VICE CHAIRMAN LIPSTEIN: Joe let’s push on.

DR. SELBY: Okay, so I want to welcome Dr. Lori Frank and Dr. David Hickam. At the last meeting we had some beginnings of a conversation, some questions about how PCORI manages its research portfolio now that we’ve got one and the notion of active portfolio management took off and has actually worked its way into our strategic plan and certainly into our daily dialog at PCORI.

And so, we have two presenters that are going to talk about active portfolio management on two different sets of projects, but we really, you know, intend this almost in a sense as a manifesto that in fact PCORI does intend to be very actively engaged with those we fund and we really look
forward to your suggestions about how we might refine that and make it as effective as possible. So, thanks. You guys know who is going first, I’m sure.

MS. FRANK: Thanks Joe. David’s going first.

DR. HICKAM: Thanks very much. It’s a pleasure to be here and to interact with you for a few minutes about how we’re thinking as a staff about managing the portfolio of projects at PCORI.

So, our goals today is to review with you the status of the PCORI portfolio management plan, to review insights gained from work with the PCORI Pilot Project Program. As you all know, that was the first batch of projects funded by PCORI. Those projects are now underway, so there’s an opportunity to gaining experience that we can apply to our more programmatic groups of projects that are sort of coming along about six months behind the Pilot Projects.

And then, to seek input from you on the key priorities of these management efforts. So, we
just might stop for a minute and consider why do this. Why should be actively manage a funding portfolio? I mean, we could take a very conventional sort of grant-based model and just make decision and turn money over to projects. So, what might you gain by this?

And the first point we wanted to make was this is an opportunity to optimize the knowledge that we gain from the projects that are funded and especially to start thinking at an early stage about where there is important knowledge that’s provided by the projects and how a dissemination strategy might build out of the information from the projects.

Secondly, to realize that all research projects have barriers and some are more successful than others, and so, to basically have an active process by which we can identify problems with funded projects and make any kind of corrections or modifications that might optimize the probability that the project will deliver useful results. And so, we kind of think of this as a risk management
strategy.

Third, to really try to get insights from our experience with our early projects, about how we can design our future funding initiatives and so to really use the lessons learned as projects are underway to make plans for future.

Fourth=, to facilitate the ability of individual investigators and groups of investigators to learn from others that are also part of the PCORI program and possibly to facilitate collaboration among those groups.

And finally, to sort of build up the infrastructure, to build up the base of investigators who can perform patient-centered outcomes research.

VICE CHAIRMAN LIPSTEIN: Can we hold off on the questions for the Board until you go through the whole presentation, because you have the same questions coming at the end and nobody --

MS. FRANK: Right.

DR. HICKAM: Yeah.

MS. FRANK: So --
VICE CHAIRMAN LIPSTEIN: -- more efficient.

MS. FRANK: I agree. We wanted to orient you to the questions we have for you, so you can be thinking about them over the next few minutes as we --

VICE CHAIRMAN LIPSTEIN: These guys are always thinking. I promise you. Go ahead.

MS. FRANK: Okay, so the questions that we do have for the Board are these and you will see them again at the end. So we do ask that we not discuss this until David and I are through presenting the vision for active portfolio management at PCORI.

[Off microphone discussion.]

MS. FRANK: First, we’re asking if the goals that we’re presenting are the right goals and should any be added. Second, we ask whether the Board has specific examples for us from other funding agencies. For example, that could be incorporated into PCORI’s practices. Third, we want to ask for suggestions for ways in which we...
can be nimble and flexible with our portfolio. We want to steer the portfolio, so we’re interested in a discussion about how we can take promising areas based on our own surveillance of our portfolio and invest in them in different ways. And the finally, we welcome your input on how PCORI can best measure success. That last one is a big area.

So, I wanted to just share with you that this is connected to the strategic plan that Joe presented this morning. So by all means active portfolio management is intended to increase the quantity, quality and timeliness of relevant research and it’s most definitely intended to accelerate dissemination and implementation of findings. By actively driving our results into implementation, we should influence the field.

A priority activity for this year is to implement portfolio planning, management, and evaluation, so that’s right out of those priority activities that Joe shared with you as part of the strategic plan.

DR. HICKAM: So I’m trying to sort of
think through to what the kind of -- the blueprint for portfolio management looks like. We found it useful to divide it into three categories. Really only two of which we’re going to talk about today.

No surprises here, it’s the pre-award phase in which we essentially design our funding programs. We identify key gaps within each of our priority programmatic areas, as has been shared with you already to identify the potential for collaborative opportunities. We heard an example of that with the work between PCORI and NIA this morning. To identify co-funding opportunities where there might actually be sharing of resources or contributions of research funding for more than one organization. And then, to sort of flow all of this through to Program Funding Announcements to build upon the plans for designing the portfolio.

And I think as I had mentioned before, there’s a certain amount of feedback into this process where as we gain more and more experience with the projects that are funded by PCORI that’s in the future going to affect the planning for, you
know, building our portfolio plans.

Then there’s the next step in which people actually submit applications and a peer-review is performed and projects are selected. We’re really not going to talk about that today, but we do acknowledge that that’s a really important part of the overall portfolio planning activity. And then, once decisions are made for which projects are likely to be funded then there’s a series of steps that we can use to ensure that the research is as successful as possible.

First of all, is to do an evaluation of each project and then do follow up of the issues that are identified through a monitoring plan. And I’ll speak a little bit more to that issue in the slide after this one. But the other sort of post-award activities include identifying and being aware of early findings from projects that would guide portfolio planning, but it also would guide possible avenues of dissemination so that the dissemination strategies that don’t apply necessarily just to single projects but to apply
across the portfolio, sometimes to multiple projects, can start to be kind of thought about and sort of put on the plans for future work.

Third, we can also identify opportunities for collaboration among the funded investigators and Lori is going to speak more to than in a few minutes. And then also, to look for situations where some very targeted supplemental funding might really increase the output of particular studies, and so, to be adaptable as we develop the work -- as we monitor the work on the individual projects.

So just to speak more to this kind of risk management aspect of managing individual projects, the various things we want to look at. First of all we want to look at the team of investigators, identify any areas where -- not that they’re incompetent, but where they make lack in experience and that we just need to sort of keep in touch with them and, you know, see if there are situations where some very, very targeted consultation might be useful.

Second, might be to understand the setting
in which the study is being conducted and the requirements for developing the datasets that will be used in the study and so, this I think all of you would be very familiar with a clinical trial scenario where you need to be concerned about recruitment rates into the trial. But this can also apply to observational studies in which there may be barriers to access to data that are being used to develop registries and this sort of thing. So, we just need to try to identify those kinds of barriers and monitor the projects.

To look at any sort of institutional barriers, procedural barriers, IRB issues that might be applicable to an individual project, to look at the limitations of the methodologies and the methods that they plan to use. And there was a really nice discussion at your meeting last night involving both the Board of Governors and the Methodology Committee about one way that we might be able to augment the work, to really identify important improvements and consultations that can be applied to projects at the front end. To make
sure they’re using the best methodologies for achieving the aims and objectives of each study.

Also, a few other things we can identify barriers to disseminations so we can at least start developing strategies for dissemination, realizing that we really can’t make decisions about dissemination until projects are all through. And then, since all PCORI projects involve patient and stakeholder engagement to try to help individual groups of investigators the may not have very much experience with engagement to use the rich expertise of PCORI to help them with those activities.

And I think we went backwards.

MS. FRANK: You did. Okay, so what David was just alluding to was managing the risk, the potential risk within the portfolio but our internal discussions are about balancing risk and reward. And so, we obviously see a lot of opportunities to optimize the portfolio by considering risk, but also considering the reward side of the equation. So how is this PCORI unique
and what’s the potential impact?

So, for us we’re taking an active portfolio management approach with our Pilot Projects as David mentioned and from that we’re finding ways to bring together information across different projects and communicate that information to the intended end-users.

We considered this a pilot for active portfolio management for PCORI going forward then. We’re using different forms of dissemination to communicate with our awardees, including professional presentations and having meetings among the awardees, which I’ll talk about more in just a moment.

We’ve particularly pleased with what we have learned about the cross-cutting themes, including how to identify the relevant themes. And while each individual research team has thoughts about how to disseminate and implement their own findings, by working across projects we can identify enhanced opportunities for dissemination and implementation, so we’re taking advantage of...
the bird’s eye view we have of the portfolio as a funder.

Academy Health is assisting PCORI with actively managing the Pilot Projects and establishing an active learning network. It’s actually quite vibrant and we’re very excited about this. We have a lot of people involved in this work, so Alison Rhyne, Laura Esmail, Raj Sabharwal, and Emily Moore and Veronica Thomas from Academy Health. And from PCORI, Kara Walker, Natalie Wegener, Rochelle Bent, and Laura Forsythe have all been involved in this.

Academy Health completed a qualitative content analysis and form that content analysis we created thematic groupings as one way to identify potential cross-collaborative opportunities. Four different groups formed based on these thematic groupings and most communications now between the research teams is happening within these smaller groups.

We’ve established different channels for the awardees to communicate with one another,
including teleconferences, webinars, and an online collaborative tool. And each group determines their own desired outputs for collaboration. So PCORI is facilitating the communication and collaboration, along with Academy Health. We see that the Pilot Projects are gaining experience with active portfolio management themselves, and PCORI’s gaining that experience, too so we can apply it as I said, moving forward.

With Academy Health’s assistance, the Pilot Project awardees have initiated some cross-collaboration already. As Joe mentioned this morning, several awardees have already joined together to submit abstracts to professional meetings. Right now, we’re in the midst of share and tell webinars, where a couple of awardees from each of the thematic groupings presents a brief overview of their work and the group discusses it and identifies crosscutting issues, including those that can be work shopped in follow up. Common challenges are being identified and then we get the benefit of suggestions from across multiple
research teams.

So, this is really an example of the whole being greater than the sum of the parts. And it’s a very exciting aspect for us, the portfolio management.

So, with that here we are at the end with the questions.

VICE CHAIRMAN LIPSTEIN: Gene, what we agreed to do was hold the questions for the end and I guess before we open it up for questions, is there anybody on the Board that doesn’t feeling like active portfolio management is a good idea?

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. WEISMAN: I raised this, I think in an earlier conversation. I think personally, I think this is a good idea, but there’s another -- this is what portfolio management of what operationally managing the projects that we’ve agreed to fund. The other aspect of portfolio management, the way it’s used, is to decide on the distribution of the types of projects you want and what their returns
are going to be. Similar to the way you do investment portfolio management and decide on your risk tolerance and decide on your timeframe, you decide on the kind of returns you want.

And so, we have a portfolio -- as we’re currently doing, which may or may not be a great fit for eventually what we want to achieve and we need to -- it’s about grouping and sequencing the types of things we’re doing and making sure that it’s maintaining the balance that PCORI wants. That isn’t what I heard here. This sounded like once you have a portfolio, how do we manage it?

It’s a type of project management of projects. So you have project management of individual projects and you have project management of the family of projects. That’s a very good thing to do from a management standpoint. From a strategic standpoint it gets not close to what Harlan K. was talking about earlier, what should be in your portfolio and what’s the right balance of the types of -- maybe it’s the size of the rocks, I don’t know.

VICE CHAIRMAN LIPSTEIN: Lori, were you
going to say something?

MS. FRANK: Yeah I am. The reason why the emphasis was on the post-award with this was because we were using some examples out of the Pilot Projects and all of you are deeply familiar with --

UNIDENTIFIED OVER PHONE: Talk into the phone, please.

MS. FRANK: All of you are familiar with what went on with the pre-award phase.

[Discussion over microphone.]

MS. FRANK: Okay, this one’s on. We can all tell.

So I was saying, everyone here is aware of all of the pre-award active portfolio management that you all engaged in. And so, we were given examples then from the post-award side. but I went back to the slide, because David did talk through some of the pre-award activities and absolutely, perhaps it’s not broken out in sub-bullets there, but it’s part of our ongoing discussion. The gaps within each priority area and how best to emphasize
different areas within each of the five priority areas, in each of the programs also.

So, we very much have incorporated that aspect into our discussions about portfolio management. We just aren’t giving examples of that quite yet, because it’s in an early stage for the actual PFA program.

DR. WEISMAN: What I heard today though was some -- not using this terminology, but some challenges to our portfolio from a strategic aspect. One of them came from Gail earlier, which was about we don’t have enough short-term stuff or low hanging fruit stuff, like work that’s already going on that we could bring about, disseminate and implement, help implement it very quickly. So, that’s a time-kind of portfolio decision.

What I heard Harlan talking about, there are some strategic opportunities that would, you know, leverage our efforts in a much greater way than perhaps we’re thinking. We’re not having that discussion. So even your pre- is more about given about what we already decided and how are we doing
against it?

I heard some sort of more fundamental questions about does our portfolio today match our aspirations of what we want to achieve and what do we need to do about it? That’s more of a strategic question. It’s like what your investment profile.

MS. FRANK: Yeah, so that definitely has been part of the discussion.

VICE CHAIRMAN LIPSTEIN: Christine.

MS. GOERTZ: Yeah, Christine Goertz, Board member. Thank you.

I’m a huge advocate of active portfolio management. I think that’s really critical, especially pre-award. I mean, I really want to get to the point where somebody can==who has a question is able to call up a real person and have a discussion with them while they’re putting their grant application together about whether what they want to do fits within our priorities. You know, how will we advise them on being patient-centered and all of that. I think that that’s really critical.
I think what we’ve done with the Pilot Projects is, you know, that level of monitoring and involvement is what we plan to do because we consider the Pilot projects to be a learning laboratory and we wanted to make sure that we learned as much as we could from that experience. But I feel a little bit this is pounding in a tack with a sledgehammer with some of this. It’s just too much. And I think some of these things, perhaps, you know, like qualifications of the team of investigators and the steady settings and data requirements, I hope we’re handling all of that in peer review and that applications that we actually fund are, you know, that we already know the qualifications of the investigators.

I mean, on average I’m not saying that might not be true of some projects that for whatever reason we accept out of order, but I think most projects that we would fund I would hope the qualifications of the investigator and their construction of data files would be something that we would just be able to assume. Now, I do -- you
know, we have had some talk about having a methodological review of some or all our applications, I think that could be very important and very helpful. And I’ve been on both sides of this, as a program officer who was managing cooperative agreements, sometimes multi-million dollar cooperative agreements as well as smaller projects, and also as an investigator who is being managed by another program officer. And I can tell you that there is a line at which it’s helpful and then there is a line beyond which it’s not particularly helpful. And, in fact, it can be really difficult especially if the program director-manager is not a content expert in what you’re trying to do.

So, I just think we have to be really careful about what it is that we’re trying to do here and make sure that -- first of all, we have the staff to do this. Because Lori, you mentioned all of the people involved with managing the 50, you know, Pilot Projects. I mean, as we’re scaling up, I don’t know what the costs, you know, would be
to manage at that level. Though, I think some of the stuff you’re talking about with going across portfolios and providing opportunities for people to get together and share ideas and such could be extremely helpful. It’s really whether we can balance it or not.

So I just think -- I think this is a really good concept, I think we’re definitely moving in the right direction but I think we need to think a little bit more about where to draw that line.

VICE CHAIRMAN LIPSTEIN: Carol.

DR. CLANCY: So the answer to the question we offer active portfolio management is of course. I mean, we owe that to the taxpayers. Period.

Now, what I think I’m finding confusing about this conversation is where you’re new to an area, starting up a research entity, trying to put processes in place, what I’m seeing is a mix of stuff that I think of as SOP. And stuff where PCORI could actually make a unique contribution, okay?
The follow on study area for selected areas and disparities immediately comes to mind because studies haven’t been powered enough in some areas. But that I think is what I would be focusing on. I can’t believe that anyone funds research without some hope and aspiration and lots of cheerleading, that the grantees will want to play together nicely. And you know what? Some do, some don’t. That’s all I’m going to say.

And I think some of this will also will ultimately need to be linked back to what is in a PFA or the front materials, you know, how do I apply for my grant? So, this all feels a little bit confused to me. You know, some of this is just standard stuff. The other thing I would be a little bit leery of, and I have to think about how to say this diplomatically, so I’ll use a little parable.

We had an evaluator once. in fact, we still have this evaluation team under contract and one would think by the way they wrote the evaluation that they got paid by the word. So, I’m
not sure I would be looking to the entity who is
managing grants for us necessarily as the only
source of input in terms of what might be done. Am
I being clear enough? Okay. Thanks.

VICE CHAIRMAN LIPSTEIN: Ellen and then
we’re going to pause for a minute, because we have
another segment on our agenda coming up that can’t
be delayed.

MS. SIGAL: I didn’t have a question.

VICE CHAIRMAN LIPSTEIN: Your thing is up.

CHAIMAN WASHINGTON: Your card is up.

VICE CHAIRMAN LIPSTEIN: Okay, that’s
good. Now we have accelerated.

I think as I summarize some of the
comments and the thought is that there is
bureaucracy that you could put on this process pre-
award and there is bureaucracy post-award and it
can involve methodological review, it could involve
active portfolio management. I think the challenge
for staff to think about is how much bureaucracy
both pre- and post- added value and when do you get
to diminishing returns. And so, I think you’ve got
some good insight, some good input from the Board and I think it would be good if you take that input back and then figure out how best to act on it.

Gene, we have a little bit of time before the Public Comment session. I don’t know exactly what you want to do with it, so I’m glad you’re back.

CHAIRMAN WASHINGTON: Okay. Joe any additional comments at this point before we thank Lori?

DR. SELBY: No, let me ask David a Lori if you have any closing comments. I think this is an ongoing process, the notion of risk management was something we got as we sort of did a survey of other funding organizations to see how they approach a portfolio. I think Christine’s and Carolyn’s point about not getting overly bureaucratic. I’m not too worried about that at this point, but it’s just because of the time we really don’t have time to be too bureaucratic yet.

Certainly, it is an important point to keep in mind.
Lori.

MS. FRANK: yeah, I just wanted to add that the Pilot Projects having a methods focus for us is part of the impetus behind how far we’ve gone with this. But we’re mindful of not being intrusive, so it really now is up to each of those teams if they want to pursue things we’ll support it, but if not, of course that’s fine.

DR. SELBY: David? Good. Thank you both.

CHAIRMAN WASHINGTON: Thank you Lori, thank you David.

Okay, we have a couple of minutes before the Public Comment period and to ensure that we’re on time for the Public Comment period you will not be recessed from this room. There is a guard at the door. However, I want to in my role as Chair take a moment to recognize an individual in the public health world who is going to be recognized tomorrow at three o’clock. Someone named Toni Yancey. Some of you may know the name.

She popularized the notion of instant exercise, where it was sort of the idea if you sat
60 minutes, you should get up and stretch at least three. Regrettably, Toni died last week at the age of 55 after a battle with cancer and nationally tomorrow at three o’clock when we will be gone, around the country organizations have banded together. We were going to do it, but we’re not going to be together. To just at 3:00 p.m., is it East Coast?

DR. SELBY: It’s 1:00 Pacific, so it’s 3:00 here.

CHAIRMAN WASHINGTON: Three here but we’re going to do it today. And so, just instant exercise means you just stand up in place and often, what Toni used to do it there was somebody leading you in it and she could have you doing some really goofy things. But you’re just going to do whatever exercise you want to do, stretch --

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

CHAIRMAN WASHINGTON: This is good, this is still live.

[Laughter.]
UNIDENTIFIED BOARD MEMBER: It will
CHAIRMAN WASHINGTON: It will be a hit on
YouTube, that’s for sure.
UNIDENTIFIED BOARD MEMBER: How long are
we supposed to do this?
CHAIRMAN WASHINGTON: Three minutes.
[Off record discussion.]
CHAIRMAN WASHINGTON: Can we cut the
cameras for seven minutes? We’re okay, and then
we’re going to reconvene in seven minutes for the
public comment period.
[Recess.]
CHAIRMAN WASHINGTON: Welcome back to this
meeting of the Board of Governors of the Patient-
Centered Outcomes Research Institute. And this
next session we’re going to hear from members of
our public who are going to provide us with some
comments. And so, I turn it over to Sue Sheridan.

MS. SHERIDAN: Great, thank you, Dr. Washington.

First, we’re going to take comments from
those commenters in the audience who have
registered. We have two right now, and then after everyone has spoken, we’ll see if there’s any comments by phone, and from what I understand from our operator, Nikki [phonetic] we have three people on the line. And then individuals offering public comment must limit their remarks to no more than 3 minutes and I apologize for that but we want to make sure we get through everybody’s comments and I’ll give you a 10-second warning when you’re getting close to your 3 minutes.

Your written testimony should be submitted to PCORI via e-mail to info@pcori.org. And all testimony and additional materials submitted to PCORI will be provided to appropriate Board members, Methodology Committee members, and staff for review and consideration in our work that we do at PCORI.

So, I’d like to first welcome Mary Alice Lawless from the Foundation for HealthSMART Consumers. You can just come join me up here next to me and provide your statement.

MS. LAWLESS: Thank you, Sue. Thank you,
everybody. I wanted to just take a few moments just to come up and say hello and also to thank you. Hello. Thank you for the really great work you're doing.

I am with an organization called the Foundation for HealthSMART Consumers, and we were actually founded in 2009 to just take a little tiny step toward this. We've done much more modest work, but we have done a lot of really interesting work in terms of I would say our work is not on the research side per se, but much more on the communications and dissemination aspect of this. So, we've taken a lot of what you've discussed here, which is fantastic research that does exist. A lot of good clinical best practices, a lot of evidence-based medicine, and we've tried to reorient it in some cases for clinicians based upon the types of care they provide and where they work and also to reorient it in ways that real people can just sort of understand, even some of the most basic elements because medicine is so very mysterious and how it works is so very mysterious.
So, I’ll just tell you a little bit about one project that we’re working on right now which is really neat and it happens to be in conjunction with the University of California San Francisco and the Smoking Cessation Leadership Center and the Convenient Care Association, which is the association that organizes all of the retail clinics like MinuteClinic and Walgreen’s Take Care, organizations like that.

What we’ve done is we’ve taken -- you can imagine the body of work that’s been done on smoking intervention, but we’ve reorganized it and reoriented it for that particular point of care, which is a very quick visit, people that are sort of shopping in Wal-Mart and stop in for health care. So, it’s gone very, very well. It’s actually launching at the Retail Clinic Education Congress. We’ve had a number of clinical practice leadership in that domain working with us on this just to make sure that this becomes really usable material for that patient provider interaction and
we’ll hopefully have outcomes data coming forth shortly, as these things are disseminated out through the networks of retail clinics. These are run, as I mentioned, some are run by those larger organizers like a CVS or Walgreen’s. Others are run by hospital systems where they sort of have their nurse practitioners coming and working there. So, we hope to see a little bit of reverse migration of some of this practice even maybe back into other points of care where those NPs are cycling.

In terms of what you're doing, obviously, we’d really love an opportunity to explore a whole bunch of different ideas that perhaps some of which we may have had as we’ve done our work, but perhaps haven't gotten off the ground just due to our own size. We also get a lot of feedback in the work we have done with public entities and patient groups in terms of any information is good information.

So, I do ask that you not think in terms of only being able to put forth the best packaged final product, but maybe to let people in on even
just the good work that’s going on here right now. This feels a little bit -- my first time, I’m a brand-new first-timer. I met one of your colleagues at the World Health Care Congress and heard about the work you're doing and decided to participate in today’s session as a result.

This almost has the makings of a reality TV kind of approach where whatever steps are being taken, the conversations you're having here, we used to say this after the World Health Care Congress, if only people out on the street could hear what's being discussed in here. It’s actually not really above their heads. So, whatever we can do to help you with that, we certainly will look at communications and disseminations. That’s probably our domain opportunities, but look to other exploratory collaboration opportunities with you, as well.

CHAIRMAN WASHINGTON: Thank you very much for your comments and for that invitation.

MS. LAWLESS: Okay, thank you so much.

CHAIRMAN WASHINGTON: Okay.
MS. SHERIDAN: I’d like to welcome Regina Greer-Smith to share her comments.

MS. GREER-SMITH: Thank you, Sue, and I want to welcome everyone to the Board and Dr. Selby to Chicago, home of the Chicago Bulls. We are happy that you decided to have your Board of Governors’ meeting here. I think it’s energizing not only the city, but all of us patient advocates who have been really dreaming of an opportunity like PCORI to finally appear.

First, I’d like to congratulate you and encourage you on the PPRN, the Patient-Powered Research Networks. I find this very encouraging because it’ll ensure patient-centeredness of research by empowering and providing opportunities for networks and collaborations of patients to be involved with research. This is the actual patient-centeredness that we’ve been dreaming of for decades. The PSA also encourages and addresses the requirements of targeting underserved and hard-to-reach and high-risk communities. Very important for us.
I’m also extremely encouraged by the use of technology and the recognition of mobile applications to reach underserved and minority communities. We know research shows us that minorities, especially African-American women and Hispanic women are higher users of mobile technology. You have that in the PFA and that’s just perfect. So, we’re very happy of that.

Finally, and my comments are short, I do have an ask. We’re looking for opportunities from PCORI that will enable patient-initiated research where patients and stakeholders can identify and orientate researchers to the topics and questions that impact the health outcomes and quality of our life. So, we want to have the opportunity of identifying researchers who can work with us, as well. We want to initiate research. We do have topics that we are sending to PCORI and we want to develop questions from those topics, but we want to grow our own researchers or identify those researchers who can work with our uniqueness and our health incomes and disparities.
So, with that, I want to thank you for the opportunity and thank you Sue.

CHAIRMAN WASHINGTON: Thank you very much, Ms. Smith. Although we’re in Chicago, we do have some New York City-based Board members, so be careful about the Bulls.

[Laughter.]

CHAIRMAN WASHINGTON: Thank you for that suggestion and, Sue, we will follow-up to make sure we have that request in writing.

MS. SHERIDAN: Absolutely.

CHAIRMAN WASHINGTON: So it can be passed up.

MS. SHERIDAN: I do want to acknowledge that Regina is on our Inaugural Patient Engagement Advisory Panel.

CHAIRMAN WASHINGTON: Oh, great.

MS. SHERIDAN: So, she brings a wealth of information and passion to PCORI.

Now I’d like to ask Nikki, I think we have our operator online, and, Nikki, if you could introduce our next commenter and could you please
introduce their names, as well?

OPERATOR: If you’d like to make a comment, you may press star one to be placed into queue. Again, we ask that you press star one to be placed into queue.

Please give me one moment while they queue up.

We do have Andrew Auerbach. Your line is live.

MR. AUERBACH: Thank you. My name is Andrew Auerbach. I know a few of you on the panel, but I want to introduce myself to you all. I’m a professor of medicine at University of California, San Francisco, and a hospitalist here. For those of you who don’t know what a hospitalist is, we are a specialty of general internal medicine that is now caring for more than 65 percent of hospitalized patients in the U.S.

One of my other jobs here at UCSF is general hospital medicine, which gives me a good overview of the field of hospital medicine and what’s going on in the hospital medicine world.
And relevant to this phone call in my time here with you today, the cofounder along with my friend Peter Lindenauer at Baystate Medical Center in Springfield, Massachusetts, of a research network called HOMERUN, the Hospital Medicine Reengineering Network.

So, let me take a minute to introduce HOMERUN to you. We are a 13-hospital network of nontraditional academic medical centers, two safety net hospitals and two community-based teaching centers that are taking advantage of the role of hospitalists in their hospitals to understand the opportunities for improvement, affect meaningful change, and create generalizable evidence in that process.

In contrast to some research networks though, the central tenant for how we operate, we seek engagement from all of our stakeholders, patients, frontline caregivers, and our health systems in a variant of community-based participatory research we call hospital-based participatory research.
The reason I’m talking to you today is we represent one of many different research networks that we think are [inaudible]-ready research networks that can link research discoveries to implementation, shorten the time from discovery to widespread health impact.

So, as an example of our project, with support from the AAMC, the Association of American Medical Colleges and our hospitals, we’ve just undertaken the first U.S.-based study of why patients are readmitted from the hospital, but using the patients’ viewpoint as the central source of information.

We’re now finishing our first resource phase which will result in the largest study of its type and we’re prototyping interventions which I think will make really fundamental changes in the way, at least our hospitals kind of work with discharging patients and educating their patients and families in how to take care of themselves when they go home.

Let me stop here for a second and be very
clear. HOMERUN is not necessarily unique. We’re aware of several other research networks that have similar features. There’s one that’s focused on pediatric acute care, emergency medical care, critical care, pneumonia, COPD, those are the ones that just I’m aware of and Peter is aware of. There are probably dozens of other ones. Each have patient outcomes as the central focus, they engage patients directly. They have outstanding frontline engagement with their health systems and their providers. These clinical data and research observations then turn those into interventions to improve care.

The reason I asked to be allowed to comment to you today is I think networks like HOMERUN provide at least two major opportunities for PCORI to extend its impact. The first is we view PCORI as a natural partner, but we have had some challenges in identifying ways other than this phone call where we might become more engaged in your work. As PCORI continues to grow, I encourage you to consider a systematic and broad engagement
of clinicians and researchers whose interest in infrastructure while at the same time it works to understand the goals of patients. I think you just heard this from the previous speaker.

I really believe this will shorten the time it takes to develop knowledge and forward to all stakeholders. For example, our network, we could provide a ready group of providers, researchers, and patients focused on our case, acute care and general medicine. Groups such as ours would be well-suited to co-develop programs that meet high priorities in these areas.

Second, available RFAs have been a necessary [inaudible] but may have been missing an opportunity to take advantage of existing networks of patients, health systems, and researchers poised to make the widespread change I think you want.

As you develop your portfolio RFAs, we encourage you to consider mechanisms that support the development of networks that can answer multiple questions simultaneously and which produce evidence that can be translated to practice.
Quickly, these networks that you’re envisioning and ones that I’m mentioning here are somewhat different than the networks that you’re developing currently and that they would collect data specifically tailored to patients involved in the study. It’s been our experience, certainly with the work we’ve been doing at this point that even the best administrative databases lack the best patient-centered outcomes making us have to spend lots of money to develop infrastructure to collect data from patient surveys, cellphones, and the like.

Networks like HOMERUN and our brethren can simultaneously support studies that focus on risk readmissions, methods for preventing hospital [inaudible] methods for improving functional status, but what we need is the support for the data systems as well as the people who are needed to carry out the studies in a model that in some ways is akin to what we would we call the [inaudible] Program Project, but there are lots of other ways to achieve that same operational goal.
It’s possible and even likely you’ve thought about these issues, so, I hope my comments encourage you to consider ways to excel your efforts and certainly to engage clinical-proven networks and my colleagues who are doing research in conjunction with their patients more directly.

So, I’ll end by thanking you for your time and I’ll speak for my colleagues in HOMERUN when I say we welcome the opportunity to raise these issues and to contributing to the conversation in the future.

CHAIRMAN WASHINGTON: Thank you, Andrew, and good to hear your voice. We appreciate your comments and they certainly will be incorporated into our thinking and deliberations.

MS. SHERIDAN: Thank you.

Nikki, could you invite the next person in queue to provide their comments?

OPERATOR: We have no one at this time, but as a reminder, you may press star one to make your comment. Once again, star one.

[Pause.]
CHAIRMAN WASHINGTON: Okay.

OPERATOR: I have no one in queue at this time.

CHAIRMAN WASHINGTON: Well, Sue, as we have done in the past, if there's someone in the audience who has not signed up but would like an opportunity to speak, we invite you to come forth. And if not, we will ensure that the time is available if someone shows up in the next 15 minutes, but we'd like to proceed with agenda for this afternoon.

And, Dr. Gabriel, we have Methodology Committee up next, correct, Joe?

DR. SELBY: That's right.

DR. GABRIEL: So, thank you very much.

CHAIRMAN WASHINGTON: And before you -- again, I want to emphasize to all of our presenters, commentators that we greatly appreciate and highly value your input. So, please continue to share with us your thoughts and suggestions for how we might improve and then ultimately be more effective in achieving our mission.
DR. GABRIEL: Okay. Thank you very much.
If I could have my slides up, please. It was
scheduled to be just prior to the public comment
period. Thank you.
Okay, so, it’s late in the afternoon and
the good news is I’m not asking the Board for
anything today. So, this is really just an update
for your information to give you a sense of what
we’ve been up to. And we’ll be presenting and I
think both David and Robin will be commenting and a
number of our Methodology Committee members.
Actually the plan to stay until the first part of
the afternoon, but I see that a number of them had
to catch flights. So, we don’t have too many of
our members here yet. So, we’ll try and muddle
through without them.
What I’d like to do is give you a bit of
an update in four areas. One, the methodology
standards, the recommended actions, what we’re
doing to finalize the actual report, which sort of
is the wrapper around both of those and some other
things and then just some additional initiatives
that we’re working on.

First with respect to the standards, as you know and as you heard from us previously, the goal here is not to provide methodological standards to cover the entire waterfront of clinical research, but really just to focus on standards, creating standards where standards do not currently exist, and where a revised or improved standard would really advance patient-centered outcomes research. So, we’re trying to be fairly specific there.

Of course, in December of 2010, this Board approved our first set of methodological standards and they’ve been on the Web since then and we’re working to ensure that our reviewers are familiar with them and our folks submitting grants are ensuring that their grants align with those standards, but we’re also looking to develop new standards and perhaps even improve on the current ones. And to do that, the Methodology Committee reviewed again the work that we did for the draft reports that you saw back in December, went back
and reviewed in detail the public comments, looked at all kinds of other sources of input that we’ve received over the years and began to have a discussion about new standards development. We haven’t completed that.

As you’ll see I think on an upcoming slide, we expect to bring that to you in September, but just to give you a sense of the areas we’re talking about and it’s probably not completely by luck, but some of the areas we are talking about creating new methodologic standards for align very nicely with this morning’s discussion on falls and some of the other priorities that Rachael discussed because we’re looking, for example, to develop methodologic standards to evaluate system interventions, to develop methodologic standards to evaluate those contextual factors that impact outcome in addition to things like cluster randomized trials and research prioritization and others.

So, we’ll put all of that information together. We hope to share that with the
PDC for their input and then we’ll propose at the next board meeting the next set of standards we will work on from the Methodology Committee.

Concurrently with that, however, because that process is a little less ad hoc than the first one, but still too ad hoc for the Methodology Committee, we’re going to develop a more systematic process for synthetizing and soliciting very broad stakeholder input for the subsequent set of standards we’ll work on and we’re going to be relying a little bit on Gene and others to look at what other organizations have done. So, put out RFIs and really cast a pretty wide net in terms of what else should we be looking at, what other kinds of methodological standards are needed in this domain? So, that’s what we’re doing with respect to standards and Robin will stop me if I miss anything here important.

With respect to recommended actions, you remember that back in December, we brought forward the set of methodologic standards as we are required to do by the statute and the other
requirement of the statute was for the Methodology Committee to draft what they call recommended actions, I’m not going to remember the language exactly, that facilitate adoption of the standards or something like that.

So, other things we should be working on. They're not methodologic standards, but other activities we should be working on that would facilitate the adoption and implementation of the standards. And we had a long list of those. And we were asked by the Board -- these were not things that needed to be voted on. That was made clear. That’s what the legislation says. But we were asked by the Board to sort of prioritize them, put them in categories because it was a really long laundry list that we presented at the time. So, we did that.

We categorized those activities into four topic areas and they kind of fit nicely into four topic areas and assign four workgroups to look at those areas, look at the recommended actions within each, and if not exactly prioritize, at least stage
them. In other words, what things need to be done sooner, what things can wait a year or later. So, to try and stage the activity and these were the four areas that they fell into and this is a bit dangerous, but I did hand out -- it’s a bit dangerous because it’s got a lot of information on it and we can talk about it for a long, long time, but I did hand out because we weren’t quite sure how to summarize it in a reasonable way in a slide a handout that really talks through what each of those categories contain, what kind of recommended actions are contained in each category.

So, you can see on the first page is our first category, which is methodological research gaps and evaluation and then if you go on, I think the second page is a category of training. The third page is category of infrastructure, support for applicants, and then on the very last page policies and procedures. So, all of the recommended actions fit into those topics and they’re summarized there and we summarized them this way. So, you’ve got the action. In some
cases, we did a little tweaking of the language to clarify things and then we identified the timeline associated with that particular activity. And then we also have a category, a column here for responsibility.

So, you can see that in some cases, these are things that we need the Board’s help with. In some cases, it’s Methodology Committee, in some cases, it’s staff or a combination thereof, and in some cases we thought we could contract or outsource to accomplish the activity.

The other good piece of news that as we looked at these recommended actions, we determined that about one-third of these, a couple of dozen things we’re already moving forward on. And so, the bottom of each one of these pages are those efforts, those recommended actions where there’s already progress. So, we determined we’re already working on those areas and not a lot more needs to be done except to complete that work.

So, this is sort of my brief summary of the recommended actions, responding to what the
Board asked us to do, which is to categorize them, figure out what we’re doing and what needs to be done by whom and when.

The third category just to provide an update is the Methodology Report, the actual report. So, this board has approved the methodological standards, which is really kind of the core content of the report, and the actions, the recommended actions that you can see here, but really what we thought was important to do and we started to do in the draft report that I realized it wasn’t complete or probably adequate back in December was that there needed to be what we call a demystification or just more explanation to make the standards more accessible. And I’m just reflecting last night on a couple of comments I think Leah and Ellen both made comments about having not taking as full advantage of standards as perhaps we could.

And so, this is the goal of the report which at least in paper copy will be completed by the end of May to demystify the standards using
explanatory stories. And, again, if you remember
back in December, we tried to do that kind of on
our own within the Methodology Committee, but what
we’ve done since then is pull in real experts, so,
people with medical journalism backgrounds and so
on to help us and relying on stories that are
already in the public domain, but and pulled
patient stories, so, it’s kind of not standard by
standard, but category by category, used patient
stories to really illustrate the centrality of the
patients’ voice in PCOR methods and for each group
of standards. We also had some research stories or
what we called research and practice stories which
are real-world examples of research that’s ongoing,
demonstrating how these methodological principles
can be applied and have been applied successfully.

So, again, the hope through these stories
is to demystify the standards, make them more
accessible to a broader community of investigators
and other stakeholders and really get more from our
report than we currently have.

So, that’s the content and the content
piece I think is essentially completed. We’ve been working on that since December. In terms of the delivery piece, we will have, as I said, the actual report and it’s very pretty, there are lots of pictures and things. We’ll have the paper report completed by the end of this month. But we’re also working with other groups to help us make sure that the information is available in a number of other ways.

So, we’re going to create an eBook with some interactivity where we have a patient story written in words, and then in an eBook, you might be able to click and the patient could actually tell you her story, Web versions and so on. So, we’re going to be looking at that probably shortly after May and then a number of derivative projects. So, PowerPoints.

So, for example, there are lots of groups around the country that want to talk about PCORI or the PCORI Methodology Standards. We do as much as we can, but if we put a PowerPoint out there, we can have many more ambassadors talking about the
standards, again, to help explicate the standards, continuing education modules, and other kinds of training vehicles. So, that’s basically the work that is ongoing around the report and, again, the actual content and the paper version will be completed by the end of this month and hopefully the team that we have on our staff plus some outsourcing, we’ll be able to move forward with the other activities, the online activities also.

So, my last topic, other initiatives. The Methodology Guidance Panel, we had a discussion about that last night and I won’t go into that, but that’s kind of a new idea that we’re launching and we’re very happy that we were able to share that to Steve Goodman and this really comes from Steve Goodman and Clyde Yancy and it was an idea that really germinated just a month or so ago from the Methodology Committee how we can work more closely in partnership with investigators to help improve the methods of their studies with funded investigators. And we’ll be working more on that with members of the Board and the PDC.
We’ve also been active in a number of workshops, methodological workshops, the IOM workshop, and observational studies. Not only had a number of Methodology Committee members actively involved, but Larry Becker was there the whole time.

MR. BECKER: Yes.

DR. GABRIEL: We’re recruiting him to the Methodology Committee soon.

MR. BECKER: Thank you.

DR. GABRIEL: The Academy Health Workshop on Implementation of Methodology Standards, that’s coming up in June and a PCORI workshop on PROs coming up in 2013 and we’re considering some others that you'll hear about.

Also, dissemination implementation of methodology standards, again, that's something that we really need to work harder on. It’s not just a matter of creating the standards, but making sure they're out there and accessible and usable and it’s really unfortunate that Brian had to leave because this is really his effort and he has a
proposal with a number of tools for more easily assessing and applying the standards and he expects that by the end of 2013 we’ll have some of those tools actually developed, David, and as I said, a comprehensive implementation dissemination plan of course working. He works very closely with the COEC and some targeted conferences. So, dissemination implementation is really sort of in full swing at this point now that the standards have been completed or at least the first set.

And then we’re working with Rachel and others on the staff to figure out how the Methodology Committee can participate in the review of the research projects consistent with our COI guidelines, the Methodology Research Projects just to ensure that the projects that we consider for funding are in alignment with what we initially anticipated as the goals. And, again, we’re very much aware of the COI guidelines and they’re working with in those.

So, that’s a very quick overview and I’m happy to, maybe I’ll ask Robin or David if I may if
they had other comments --

CHAIRMAN WASHINGTON: Please.

DR. GABRIEL: And then we’re happy to take questions.

MS. NEWHOUSE: No, the other only comment I have is it was --

CHAIRMAN WASHINGTON: Robin, would you state your name, for the record.

MS. NEWHOUSE: Oh, excuse me, Robin Newhouse, Methodology Committee.

In reviewing the recommended actions, it was amazing to think this was a year ago that the report was recommended and the 28 recommendations, how much forward progress we’ve made without even thinking. I mean, we just have kept on moving in a direction that’s so strategic and thoughtful.

The other thing, I just wanted to reinforce this whole discussion about methods and complex interventions and system complexities and systematic reviews of system interventions. Were certainly topics that we talked about in terms of needed standards. Those of us that work in systems
really struggle with what evidence one can adopt.
So, this whole discussion, it just added to what we
had discussed yesterday about the need for this
kind of standard to help clarify standards for
implementation, standards for context, standards
for systematic review of complex intervention. So,
this was a wonderful discussion, much appreciated.

CHAIRMAN WASHINGTON: David, anything to
add?

Thank you, Robin.

DR. HICKAM: No, no, nothing to add.

CHAIRMAN WASHINGTON: Okay. Well, I see a
few cards. I’d like to first express my
appreciation and our appreciation to Sherine and
Robin for their leadership and to all the
Methodology Committee members along with all of our
PCORI staff members who work in this area. We
continue to see your group as making a significant
contribution to our overall efforts and
specifically to improve in all the research that’s
conducted not just at PCORI, but across the nation.

One question I have, when I look at the
list of recommendations here, and this came up when it was first presented is which of these have we sort of adopted as priorities and you don’t need to answer this today. I think we need a metric system to measure progress in the same way that we have for other areas and particularly something very similar to what Joe presented this morning. Remember when he put up the legislative mandates where they have the statute, the institute shell, then he had the status red light, yellow light, green light, and then a progress report. So, something as simple as that as it relates to these recommendations would be very helpful.

DR. GABRIEL: Yes, and we would love to sort of hook into the staff to help us do that --

CHAIRMAN WASHINGTON: Oh, absolutely. I would expect that.

DR. GABRIEL: -- in the same way that they’ve done it for the Strategic Plan. That would be great.

CHAIRMAN WASHINGTON: Okay.

DR. HICKAM: Could I comment on that for a
CHAIRMAN WASHINGTON: Please, David.

DR. HICKAM: So, some of these recommended actions do have resource implications. So, we thought it was a good idea for the Board to sort of re-familiarize themselves with those and we’ve tried to make some estimates both about timetable and resource needs.

CHAIRMAN WASHINGTON: Okay, go on.

UNIDENTIFIED BOARD MEMBER: Resource implications over what timeframe? Are you talking about next year, next cycle, or now?

DR. HICKAM: Well, whenever you want to start carrying through with the recommendations.

CHAIRMAN WASHINGTON: But, I mean, that’s actually my question here is to the group. So, the long list, which ones are we already sort of quasi, unofficially or officially adopting and we’re moving forward?

DR. GABRIEL: Right.

CHAIRMAN WASHINGTON: And which ones or --

DR. GABRIEL: So, on the bottom of each of
these sections, it says “efforts already underway,” and you can see that they’re underway -- some of the things that are already in place and for each of these, as I said, we have a timeline and a responsibility. Now, of course there are resources associated with everything. We have a budget and much of this I think can move forward if we had the support within our current budget, but I think you make a very good point. This needs to be part of the strategy of the institute and needs to be woven right into that and we’d be happy to do that.

CHAIRMAN WASHINGTON: Okay, sounds good. Okay, I’m going to start here with Zwolak and make our way around. Hunt, Levine, and Krumholz.

DR. ZWOLAK: Bob Zwolak, Board member.

I’d like to acknowledge your great progress and efforts and my brief comment here is simply that on the PCORI Web site under “Research Plan,” our directions still say “Applicants are encouraged to refer to the contents of the PCORI Draft Methodology Report in developing their research plan.” It seems like we should be fed up
in terms of "refer to." It seems to me it needs stronger wording. I think we should be following -

DR. GABRIEL: So, yes, if I could just comment. Yes, we’d be delighted to see that and we talked even yesterday about creating a checklist or whatever makes it easier for reviewers to ensure that the work that we’re funding is aligned, but I think that would have to come from the Board rather than the Methodology Committee.

DR. SELBY: So, if I may, Bob. There’s a reason why the instructions haven’t said that yet and it’s because as we implemented the Methodology Committee standards for purposes of eliminating any advanced knowledge advantage, we put in a six-month lag between the actual publication of the standards in November, in late November after our Boston meeting and their actual applicability. So, when the applications guidelines go up, next week, Martin, on the 15th, there will be that change. You will now see that applicants are in fact expected to adhere to the methodology standards and
absolutely, Sherine, Robin, and David, we need to work on aids for our peer reviewers to know how to apply them best.

David, you may have something to add to that.

DR. HICKAM: So, the initiative that Sherine described in her presentation was to develop those tools specifically for reviewers, and so, that’s on the launching pad to get done in 2013. To get completed.

UNIDENTIFIED BOARD MEMBER: Sooner.

DR. HICKAM: Well, again, so, the viewpoint here is that these are tools to help reviewers apply the standards to the evaluation of individual research applications. Now, again, we’ll have to see how well the reviewers sort of take that to heart.

CHAIRMAN WASHINGTON: Hunt.

MS. HUNT: Gail Hunt, Board.

I was just asking what happened to the translational table that we talked about a whole bunch, but maybe I haven't seen it.
DR. GABRIEL: Well, the reason we haven't presented it is frankly because Sebastian was away yesterday. So, the plan now is to -- and I think we talked about this the last time we were here -- is to put forth an RFA to develop the translation table according to the specifications that we've discussed and we don't have those specs, I think, completed to share with the Board yet.

DR. HICKAM: I'd be happy to speak to that. As you probably remember, there was a description of the concept for the translation table in the Draft Methodology Report that was posted last summer. In the revised Methodology support that. That has been changed. And so, there's sort of a new description of or an updated description of the concepts for the translation table. And so, that's going to be coming out with our final report, which is going to be coming out within the next month or so.

And so, our thinking was to sort of use that then as kind of the launch to move forward with further activities associated with the
translation table. And I think that one of the things maybe just for consideration is that it might not be the case that it’s really a cable or an algorithm, that it’s a more comprehensive approach to applying the standards. We do feel that there's a close link between the standards themselves and a translation table activity.

CHAIRMAN WASHINGTON: Okay, Levine and Krumholz --

DR. HICKAM: And you're looking very puzzled there.

DR. WASHINGTON: -- and I’ll work my way back down.

MS. HUNT: [Off microphone.] I just thought we actually were going to get that a while back. That’s the only reason I was asking.

DR. LEVINE: Sherine, you may have already have this in the works or thinking about it, but from a consumer perspective, we’re in the biggest areas of the confusion and frustration around research is the very real ongoing cycle of
findings, refuted findings, new findings, changing findings, and one of the areas, the why methods matter piece could actually I think in lay terms bring a lot of clarity to the issue of why different studies delivered different results and why translating the work of the Methodology Standards into a vehicle to enable consumers to understand that all research isn't the same, that methods do matter, and linking it to what is massive ongoing investment now in electronic health records that many people believe will deliver us into a world where you push a button and answers come out. And I think there are lots of areas of hope and expectation that the consumer version of this work could really help to bring some understanding and some clarity about how to fit research findings into the universe of information about health.

DR. GABRIEL: Yes, and so, thank you for that. I mean, I couldn’t agree with you more. That’s why I’m excited about the patient stories that are now going to be part of the report and I
think that will be the start, perhaps, of a communication that would be more broadly acceptable to the public and I really hope it is just the beginning of that kind of communication. I mean, is that what you were talking about? I think those patient stories are meant to illustrate why the methods are important and in a way that might be more meaningful to patients.

DR. LEVINE: I know one of the things that many people have struggled with is this issue of communicating risk and probability to a lay audience and I include physicians --

DR. GABRIEL: Yes.

DR. LEVINE: -- in terms of the lay audience. At least many physicians. And there is a group at Stony Brook University in Long Island. It’s the center for communicating science to the public that has been working in this area for a number of years and there may be some learnings there about translating complex ideas into simple or accessible information for consumers and I think this is a ripe area for that.
CHAIRMAN WASHINGTON: Okay, thank you, Levine.

DR. KRUMHOLZ: Hi, Harlan Krumholz.

Four quick things. One, on last night, I just wanted to at least follow-up. There was a suggestion that this be layered on top of the peer review. What I asked Steve to do yesterday was to see if they could go through a sample of grants that we have funded and see what percentage of them have major methodologic flaws that he thinks would undermine their competitiveness for journal-like annals because I think it would give us a good indication of the potential value of this extra review plus it would also be able to feedback into our current review process in order to strengthen it and I felt getting some data on that might be a very useful thing to do and would demonstrate -- I told him I thought if he had opened his presentation with that saying 20 percent of what we funded have methodologic issues that would have precluded publication in a high-tier journal, that
would be very useful for us in terms of if -- or if they weren't remedial, then it's a different remedy for the future, yes. So, you either fix those or they never should have gotten through if they weren't remedial. Remedial, so.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. KRUMHOLZ: But, anyway, just one thing is to try to get some data on that.

The second thing is as I've been reflecting on the Methodology Committee's great work and thinking, Michelle, about the logic model and trying to figure out where does it fit in that model because what we're talking about there, we don't actually have in the model as far as I can see better research and we want to increase information, speed implementation influence research, we want better informed decisions to improve health incomes, better health care, the better research somehow all fills into that, but we just need to be clear, I think, where this fits in that model and how that's feeding in.
Because when I first started listening to you, I started thinking gosh, we need a logic model for the methodology group because what are their outputs? And then I thought well, we don’t actually want to create a parallel logic model, it needs to be in our organizational logic model, and I’m sure you already have this in your thoughts, and I’m probably looking in the wrong place when I’m thinking about what we create, but, anyway, I think it just needs to be firmly integrated so that our success is dependent on funneling in the products of the work that the Methodology Committee -- because it fits so well with what we’re trying to do on the ultimate outputs that we do.

Two other things. One is as I think about this, the major problem that I would want to solve is the poor quality of much of the methodology that’s embedded in studies people want to do or the lack of access that so many people have to high-quality methodologic consultation. And I think if we said those of us who are fortunate enough to be surrounded by exquisitely talented methodologist
are spoiled, we can go back and forth so much with people who are so talented so that by the time we submit something, we have the benefit of being told why we were wrong about 100 times before we finally get it right.

There are precious few of those places that have such easy access plus if we’re trying to reach out to atypical investigators, investigators who aren't necessarily in the usual places but have good ideas, then we need to find ways to assist them and I just wonder why PCORI wouldn’t want to say well, we’re going to allocate $20 million a year to creating a national resource, a clearinghouse where people can get consultation and somehow we need to figure out what is it that gets people in, but that people could have an hour where they sit down with people who know what they're doing and can give them feedback.

Now, some of that feedback may be you do not have the -- where you are, you're not going to be able to get to where you need to be because we can't serve the role of being your methodologist,
but we can tell you you’re too far away, you need to find a partner who can provide this for you. In other cases, they may at the margin be able to point them to places in the Methodology Report and give that kind of consultation.

But to create a clearinghouse, there is no place that most -- if a non-profit says we want to do a project and we’re doing this in New Haven because our scholars program is working with non-profits, they can't write grants without help on the methodology section. And we’re helping them now, but before that, that part was just a deal-breaker for any application because they didn't have the background in order to do it even though they had great ideas.

So, I just wanted to at least put this on the table because I know we’re thinking about how we can improve the grants that are submitted, but I’m more concerned with trying to get out into the environment and provide the kind of support that people need in order to know what can I do, how do I use the Methodology Report and in many cases the
urge to find a partner, go to your universities or find somebody who can help you do this, you got a great idea, but this is just not going to work unless you get that done.

The final piece is we’ve talked about this, and I bring it up at about every other meeting, is our own capacity building and the degree to which we’re going to provide funds to expand the group of people who are qualified to engage in this kind of research and I don’t just mean physicians, although physicians are part of that. I don’t just mean nurses; I know the nurses are a part of that. I mean a whole wide range of people who are committed to putting careers in PCOR and I still think we should have PCORI scholars who are being trained around the country who then will eventually expand our capacity.

So, anyway, those are the four points I wanted to make.

CHAIRMAN WASHINGTON: Okay, thank you --

DR. GABRIEL: Oh, pardon me, a very quick comment on two of them. This is Sherine Gabriel
again.

With the motivation that you described regarding pulling in nontraditional investigators with great ideas who need methods support is exactly what led us to the discussion last night and I guess our hope is that if we can develop a pathway working with the peer review process where the PCORI peer review process helps identify great ideas with what they perceive as solvable, fixable methodologic gaps and we can move that forward, that can be a first step in doing exactly what you say, but it’s challenging and we have to do it in a way that’s integrated with the current peer review process.

And then training, I just wanted to underscore that. If there's something we can do, and training was one of the categories of recommended actions, if there's something we can do to move that forward, the idea of PCORI scholars I think is important. It’s a big piece of sustainability.

CHAIRMAN WASHINGTON: Joe, did you want to
comment --

DR. SELBY: Yes.

DR. WASHINGTON: -- because Douma is next.

Well, go on, please.

DR. SELBY: I just wanted to say that I think from the staff’s point of view, we’re open to discussing the issues of training again. We have a number of plans underway, including the engagement awards, which provides certain kinds of opportunities to train. We have a training RFP. We have stayed away from formal fellowships, for example, K-like awards and because AHRQ funds those -- they have one out right now, as a matter of fact.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. SELBY: So, Gene is here, and I don't want that we need to discuss this right now, but I think, for example, the PDC would be a great forum and maybe the PDC in concert with the Methodology Committee would be a great forum to continue discussing this.
And I just wanted to say also just this notion of the awards that we give in attention to or our desire to optimize them methodologically, I think it’s very safe to say that the awards that we funded have met a high standard of methodologic rigor already, but that is never to say with any funding agency that the opportunity to collaborate with, as you say, Tom, not just methodologists, couldn’t make it a bit better in some cases. So, that’s I think what we’re looking for there.

And this notion about identifying nontraditional researchers and bringing them to the level of competiveness for funding is yet a third idea and I think that’s one that I’d have to understand more how this fits in with the Methodology Committee’s proposal, but it’s certainly something that we’d love to see, in other words the ability to extend PCORI primary research funding to nontraditional research teams.

CHAIRMAN WASHINGTON: Okay. Becker and Norquist and Hole-Curry.

DR. DOUMA: Allen Douma, Board.
Let me start off by saying, Sharon, I don't think you can say that loudly enough the need for us to be able to communicate to consumers and particularly to be able to communicate research, what is research? I think that should be a core goal of PCORI and, in fact, it will sustain us or make us sustainable if you want to pull up the perspective 2019. And so, we ought to focus on that and the methodology folks a great resource to do that or at least being engaged in that.

Gene, I also want to reference back. I think it is critical for us given all of the great stuff, and I had no idea how much you’ve been doing, Sherine, and balancing all those balls and if you look at the stuff that’s being recommended to do, put that on the same plate. It’s huge to be able to track it and monitor it and measure it and to show it off is going to require some kind of strategic planning and operational plan that we can all watch and look at.

And apropos to that, I know, Sherine, you reflected back saying if you want us to do that, we
need help. We need help. My question is: Because of the importance of what you do, what the Methodology Committee does, and I think we need to make sure you have enough help and that this board needs to be supportive above and beyond just the routine reflex to make sure that you have staffing that’s dedicated and focused on providing what you’re doing to leverage because so many of the programs you’re working on are leverageable as compare that to spending a few million dollars on a single study as compared to some of your stuff, which will reflect in every study. So, I think we need to make sure that staff understands that the Board is very supportive and if you have any issues with that or with them, just remind them.

CHAIRMAN WASHINGTON: Well, just to pick up on Allen’s point that it’s really a very good point that you also made, Sherine, and that is, going forward, we really expect that everything that you just presented would be incorporated into the PCORI Strategic Plan. And so, Joe, the idea here is that when you get to -- I was looking for
the diagram, but the section that talks about advancing research methods, essentially at the high level, there’s a dashboard and then as you push the button and go deeper and deeper, you get down into the very recommendations that Sherine has laid. So, it’s not something separate, and so, in the future, we’d expect that we would see this as part of the PCORI Strategic Plan and I suspect you’re already seeing it that way, but it’s coming through very clearly that it’s that’s what it is.

DR. SELBY: Yes, I couldn’t agree more. I think that starting with the pillar of rigorous research methods --

CHAIRMAN WASHINGTON: Right.

DR. SELBY: It leads to just about every output and all three goals.

CHAIRMAN WASHINGTON: Okay. And Norquist.

MR. BECKER: So, I’d like to hear from somebody who’s smarter than I on this topic, but I thought in response to Arnie’s question about the use of methods adopted by the Methodology Committee the response was we’ll see whether the reviewers
take it to heart. I think that’s what I heard.

So, that’s one.

And then the second question is: What are we doing to leverage the inflow and so, the use of the methods for research not PCORI-funded? Because I thought the whole point of this was this was a national effort, PCORI, we set up this Methodology Committee and we’re going to disseminate these methods so that we change practices so patients can rely on the information that comes from research?

DR. GABRIEL: Everyone’s afraid to talk because there’s nobody smarter than Larry.

[Laughter.]

CHAIRMAN WASHINGTON: Well, Larry’s put a question on the table and Joe reflect on it and respond at some point in the near future.

DR. HICKAM: So, I think I was the one who made that comment, so, maybe I should reply. So, you remember that PCORI recruits reviewers from a wide range of disciplines. We have a large group of reviewers that sit on the individual merit review committees. Of course, we want them to be
aware of and adhere to the methodology standards in conducting their reviews. We want to give them tools that will make it as easy as possible and as successful as possible and those applying them. I just meant to acknowledge that this a diverse group of reviewers and that we’re going to see some variability in the way they interpret and apply the methodology standards to individual projects.

CHAIRMAN WASHINGTON: Okay, Norquist.

DR. NORQUIST: Yes. I’ll just add, that wasn’t what I was going to say, but it’s very easy how -- what, you want to say something?

DR. GABRIEL: Oh, I just wanted to respond to your second question --

DR. NORQUIST: Okay.

DR. GABRIEL: -- which had to do with I think it was how did the Methodology Standards help people who aren't submitting grants or who are unsuccessful, and in our recommended actions, there are under the training section we hope to create some training modules that would be widely available so that anybody can learn about what the
PCORI Methodology Standards are all about, whether they want to apply or not. So, hopefully, that can be built into some of the educational modules that we build in as part of the report and even beyond that.

CHAIRMAN WASHINGTON: But, Sherine, I thought I heard Larry asking, which I think is an excellent question, us as an board, an organization, what are we going to do to proactively promote these? And, I mean, that’s a step in the right direction, but that’s a rather passive way of advancing the methods, and so, it’s a question, Larry, that’s on the table. Joe’s going to get back --

MS. NEWHOUSE: No, I just want to mention that we have an active implementation plan. So, this is a piece of our work. Beyond these recommended actions, there’s a whole group of work that’s also occurring that we’re moving forward with, and one of which is the implementation plan that Sherine mentioned. Part of that implementation plan is active strategies. So,
training is part of it.

The Institute of Medicine project that we just completed is part of training that had a diverse group of stakeholders. The Academy of Health is a diverse group of stakeholders. That’s on strategy. But in addition to training, there are other kinds of communications that will need to occur, the tools are a piece of that, but it’s part of the bigger implementation plan.

CHAIRMAN WASHINGTON: Okay, Norquist, Sigal, Hole-Curry, and Epstein.

DR. NORQUIST: So, I would just add that you can tell people all day long to do something and they won’t do it, and I deal in this every day.

[Laughter.]

DR. NORQUIST: And there are strategies like don’t fund them and they will learn very quickly that they have to come back. So, we have some leverage in that way in our active portfolio management and do that. Influencing other funders is a whole different issue that will take some time and some strategy to get them, but once that
message gets out, you can change behavior pretty quickly.

That wasn’t what I want -- but first, I want to thank you. I mean, I just can't imagine what this is like to do this all day long and have another 150 percent job. So, I really appreciate all the work that you're doing and all of your group is doing.

Just a couple of concrete things. One is you, Sherine, and myself and Christine talked about at one point picking topics. So, one of the topics might be like exactly what Sharon is talking about is how do you really take these methods and educate and even what Harlan is saying, what I worry about are the people who don’t have these high resources, living in an area where you don’t have is and how do you really help bring these people up to speed? So, it’s one of those things that as a group, we talked about COEC, PDC, and the Methodology Committee working on a specific issue with kind of a timeline on some kind of thought about how you might move forward in that. So, I would suggest
that might be one area and one kind of concrete
thing we could do as a board and with staff also to
take on.

The other thing that I haven't seen and
just want you to think about at some point is as we
move to larger CER-type trials and stuff, we got to
think about some other big-time methodology issues
and like DSMVs, are we going to have that in house,
are we going to contract these out? Some of these
big issues that I haven't heard. We've been
focusing on methodology for smaller, but when we
think about big-time trials, those are big issues
and we better start thinking about however we're
going to handle that or when we run into stopping a
study or somebody looks at something, what are we
going to do, like early looking at data. I mean,
what are going to be our methods issues on that?
So, at some point, that would be important, too.

MS. NEWHOUSE: No, I just wanted to --

CHAIRMAN WASHINGTON: Robin.

MS. NEWHOUSE: -- respond by saying we had
a discussion just yesterday about the same topic,
about the additional kinds of oversight and input
that we might need to prepare ourselves for.

CHAIRMAN WASHINGTON: Okay. Sigal, then
Hole-Curry and Epstein.

MS. SIGAL: Ellen Sigal.

CHAIRMAN WASHINGTON: Krumholz.

MS. SIGAL: So, Sherine, again, I want to
thank you for all your amazing work on this.

I do think that there are certain core
values that PCORI has, patient-centeredness, and
this Methodology Report. The Methodology Report is
a core value, as I see it, and we have an
obligation to integrate this now that it’s final
into all of the research and we’re just going to
have to figure out how to do it and I agree with
what Gray said earlier. If it’s not, we don’t
fund. I mean, there can be some teeth. We can't
make others and other professional societies or NIH
adopt it, but we certainly can for our own research
and I think we have to be really rigorous about it.
If we believe in it, it has to be a core value and
it has to be part of everything we do and you're
right, there are different people that may interpret it. I deal with statisticians all the time. They drive me crazy, but the truth of the matter is --

UNIDENTIFIED BOARD MEMBER: I can help you with that.

MS. SIGAL: Well, I think there are other things on the list that I’m crazy about, too, but if you can help, it would be great, but it is really as the Board I think and I see it or all of us see it is a core value for PCORI and there should be no excuse for why it’s not adopted in our research that we fund.

CHAIRMAN WASHINGTON: Okay, thank you, Ellen.

Hole-Curry.

MS. HOLE-CURRY: Leah Hole-Curry, Board member.

I think that I’m just going to add because I really care deeply about this issue. I think the tradeoff of conflict of interest even for methodology members versus enforcing this right off
the bat was a compromise that we should have voted on here. But --

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

MS. HOLE-CURRY: Well, basically, the reason that we haven't enforced these standards to date is due to our conflict of interest policies that we wanted to make sure that no methodology member would be prohibited from bidding on the first couple of rounds. And I just think that's a compromise of our core values and I think we should have voted on it here, but we didn’t.

But what I’d point out is that we had a briefing that says we’re in the green for the conditions of our contract for the statute and it’s required that we comply with the Methodology Report as a condition of the contract for funding. So, I don't believe we can be in the green right now based on my personal feeling about this issue, but also it’s a core requirement. So, I think that status needs to change and it really should be in front of the Board if we have a review process.
that's I hear what you're saying, I know that the standards are not necessarily only black and white, so, there will be debate about it, but those are things that we have to address if we care about it deeply. They're not barriers to saying we can comply with is in my view.

So, add another layer for the methodology compliance if we need to. The discussion that we had yesterday might help. There's a lot of ways to get at it. I just think it's just we're a research institute and if we can't even follow our own standards, I think that's a core failing. So, I really feel like this needs to be front and center.

DR. GABRIEL: So, I think we agree with that, but maybe a minor correction. I think one of the reasons that it's written a little fuzzy right now was more of a timing issue I think than a COI issue. The standards weren't completely ready to give investigators really enough time to write their proposals to be fully compliant, but now we don’t have that excuse and I completely agree with you. If we believe in the standards, we need to
require them. There's certainly no hope of other
organizations adopting our standards if we don't --
or fix them if there's an issue with them.

MS. HOLE-CURRY: So, that was mostly an
ask of the Board, not of you. My ask of the
Methodology Committee would be to consider whether
the actions that are identified here help us with
that piece or if there's some additional ones that
you all could help us with to consider.

And then the other thing was just specific
to the standards. There's a new set of standards
you're working on because the first Methodology
Report did not address all areas. There was also
controversy around some of the standards that were
adopted and some folks felt like they were more
minimum standards and we could move to aspirational
areas.

Is there work on the core set? Let me put
it that way, the currently adopted set of -- there
was consensus that these are core. Are we leaving
those in place or is there also work on those
related to moving to an aspirational level or
adjusting?

DR. GABRIEL: Yes, I think our feeling is, and I’ll have my colleagues chime in, is that the standards need to remain as minimal standards because we’re going to require them of everybody.

Okay, aspirational piece is really what we tried to speak to last night because that almost needs to be individualized to a study or to an investigator group, and so, that was the piece that we talked about last night, yes.

MS. HOLE-CURRY: Okay.

DR. GABRIEL: The standards are minimal, everybody, it’s sort of a must do, but beyond that, how do we help investigators and teams ensure that they have the best methodological approach that could be imagined? Well, that almost requires mentoring and interaction with the right kind of methodologists and that’s the kind of thing that we were describing last night.

MS. NEWHOUSE: The only thing I would add would be -- Robin Newhouse -- is that these aren't static standards and we know that they outdate and
we don’t know the time that it outdates, but like
systematic reviews every three years. So, there
has to be some kind of plan that they’re regularly
reviewed and regularly updated and we absolutely
have to do that.

CHAIRMAN WASHINGTON: We have two more
comments and/or questions and suggestions and then
we’re going to take a 10-minute break. It’s 3:56;
I expect we’re going to break by 4:00.

So, Dr. Epstein and then Dr. Krumholz,
you’ve got the last word.

DR. EPSTEIN: Arnie Epstein, Board.

I thought I’d take just a couple minutes
to establish myself as a softie. Yes, after years
of that tough veneer.

So, I think of the job of a reviewer as
analogist closely to a job of an editor. And the
editor gets in a paper and he gets a bunch of
reviews or she gets a bunch of reviews and the
reviews talk about the merits of the paper usually
and the ways that the paper is not working very
well and often in reviews, the way they could even
make it better. And the editor’s job is not to make a decision on the basis of what’s come in the door; the editor’s job is really to make a decision on the basis of what could come in the door if the people on the other end of the telephone heard what the editor had to say and the reviewers had to say and made a good-faith effort to get it back the right way. So, the editor is always thinking ahead and what makes a good editor often is enough experience to know what a good paper writer can do or not and make the decision on that basis.

And we’re doing the same thing with grants. I think the standards that are in the report, and I’ve spent a lot of time reading it come a year ago, were reasonable and good common denominators and pretty basic and I think in the kinds of people that Harlan was talking about before who’ve spent a lot of time at this, they’re going to get this except in a rare case and they’ll be others who won’t and I think our posture shouldn’t be you did, you son of a gun, here’s the formed rejection and get to our Web site. I think
it can be something much gentler than that like you
didn’t do a power analysis. In fact, we had our
fancy statistician do one for you and it looks like
your numbers are good, so, you got it right even
though you didn’t tell us. Please though do the
formal work putting in the power analysis or some
variant on that for a different standard.

So, it’s a little bit softer than why
aren’t you listening, go to our Web site, because
people frankly, they’re not going to go to the Web
site and read that that way. Most of them think
they’re pretty good, some of those who think
they’re pretty good could be dead wrong, and we’ll
educate them, but I think we can do it in a way
that moves the field over time. That’s my bias.

I get the alternative to that, which is
let’s get the word out that we’re tough and mean
and be out at Dodge without their weapons, but I
don’t think so.

CHAIRMAN WASHINGTON: Okay.

DR. EPSTEIN: I’m a softie.

UNIDENTIFIED BOARD MEMBER: [Off
Dr. Gabriel: So, I think --

Dr. Epstein: I'll be quiet now.

Dr. Gabriel: No.

Chairman Washington: Dr. Gabriel and then --

Dr. Gabriel: In the spirit of being a softie, I think the message isn't you didn't do it, you're out, it is providing every opportunity for that group to improve and then if they don't step up and take those opportunities, then we do have to say that's --

Dr. Epstein: I took an example where they committed the grievous law, they didn't put in a power analysis, that's one of your standards, but they had plenty of power. So, just dot the damn I, would you, please?

Chairman Washington: Thank you, Arnie. Last word, Dr. Krumholz.

Dr. Krumholz: In making four points, I think I maybe I obscured one suggestion that may be
better made with clarity. If an applicant gets through the Letter of Intent process, we approve it, I would like to be able to give them two hours of methodologic consulting time in the period where they're preparing their application. I would even like to consider giving one hour of patient engagement consulting time and then that's just going to be up to us to create the army of people who can provide that kind of information back to them.

As it stands now, investigators have trouble talking to someone at PCORI. A person from my institution could not get anyone on the phone at PCORI and I think that if we want to get these people out before, then we find -- I don't care if we have to outsource it, I don't care where these people come from, we go around the globe and we pay for it, by the way. And not everyone will want it, but some people who want it, you've gotten through the Letter of Intent process. Then you say we're going to give you two hours of consulting, here are the people, we'll help you schedule it, and you get
two hours on the phone. And some of that might be
you need to find some people locally, that this
thing is such a mess that you need help. It’s not
to fix it; it’s not to write it for them, it’s to
give them consultation on it. And the two hours
might be one hour of preparation for the call, one
hour of talking on the call, and that I think would
be of enormous help to people who are applying. I
know it’s going to be logistically challenging, but
I think it would send in a very important message
and then it would also mean people could send in
Letter of Intents without having any frigging idea
exactly how they’re going to do it, but they want
to get in the door in order to be able to start
engaging. Just a suggestion.

DR. EPSTEIN: [Off microphone.]

DR. KRUMHOLZ: We would have to train a
cadre of people who could give the advice on the
phone about what we mean when we say “patient
engagement,” what represents best practice. That’s
why I added both. But I think this would be very
helpful to people who were applying.
CHAIRMAN WASHINGTON: Okay, thank you, Dr. Krumholz and everyone for that robust discussion and I think we’ve heard, Joe, some valuable ideas and suggestions that we’ll take back to consider. And, again, Dr. Gabriel, would you convey our gratitude to all members of the Methodology Committee and likewise, David, to all of our colleagues on the staff for the great work that you continue to do? And the message is clearly, at least for me, is that we’ve got to incorporate this and integrate it as though it’s just a part of the everyday activities and one way we may do that is to rethink about the presentation here actually. You’re the only committee chair that literally does most of the presentation and it’s maybe a reflection of what Allen was getting to. We have to make sure you have the right staff in terms of level, and this is no slam on David in any kind of way, but he may also be overwhelmed, but we want to ensure that the activities are no different from the activities related to patient engagement or related to dissemination or research as it relates
to methodology. So, thank you again.

DR. GABRIEL: Thank you for the input.

Thank you for the support.

CHAIRMAN WASHINGTON: Okay, we’re going to reconvene [off microphone].

[Pause.]

CHAIRMAN WASHINGTON: We’re live. Welcome back to this last session of the afternoon for the Board of Governors’ meeting for the Patient-Centered Outcomes Research Institute.

And now we’re going to have a couple of announcements from Executive Director Dr. Selby before we move to the next item on the agenda.

DR. SELBY: So, this is about dinner tonight. We do have guests from the community tonight for dinner. We have representatives from Access Community Health Network, which is Chicago’s largest private provider of primary health care. It’s a network of more than 40 community health centers in the greater Chicago area and surrounding suburbs. So, they’ll be here. We have a reception at 6:00, dinner at 7:00.
CHAIRMAN WASHINGTON: Okay. We look to see all Board members at the reception and dinner this evening. Thank you.

Dr. Norquist.

DR. NORQUIST: Thank you. So, for this, I got a bottle of wine, but anyway. That’s an inside thing.

So, what we’re going to do, and I think this is our little plan of keeping the audience with us for the day because I’m sure there are a lot of people who want to hear whether or not they’ve been funded at this point. So, what we’re talking about here is Cycle II Applications.

Now, I chair the Selection Committee, and let me say who else was on this. You see here myself, Arnie Epstein, Kerry Barnett, and Gail Hunt from the Board. From the Methodology Committee Robin and Michael were on there and very helpful, and then the staff is you see Joe, Romana, David, and Chad. These are their programs that they see. Stanley and Martin have also been incredibly helpful, and I would say particularly
because we really had to work hard at trying to get people together, and so, I want to apologize. I hope all the Board members who are on this have seen the final slides. I just saw them last night and we sent them around because we had to hurriedly go through this.

So, what we started with, and this is the overall issue is that the PCORI staff, you’ll see there are four different funding announcements, remember, and that the PCORI staff is recommending a funding line of responsive applications. What we mean are those who made it to the review and came out with a score which ranged between -- so, it depends on the funding announcement; we’ll get to that in just a minute, hang on -- 9.8 to the 14.7 percentile.

All right, so, of each of these, and we’ll detail those in just a second and maybe I should just go on with that because that’s what the last thing says. So, here they are quickly. So, we have four programs are, right? Assessing options, that’s David’s program.
Now, we didn’t ask them all to come up here because that would take more time, but if there are specific questions, you can ask him.

So, in the assessing options, the program is proposing, which we went over with them, 20 of these successfully-scored applications which represents 11.5 percent of the total. Now, what do we mean by the “total?” You can see down there in the small print that the percent of total is of those who were successfully scored. Not all applications that came in, okay, the ones that came in. All right, that totals an average budget -- well, the average budget for those 20 is around $1.6 million with a total budget for all 20 applications over the 3 years of $33,648,774, depending on how they contract with them.

All right, for the Improving Health Care System, 13 successful applications. We’re going to say a little bit more about this; I want to say something about the numbers here in just a second, but let me get through each. You can read the average budget for those for a total of
$24,000,500, and then there were 8 of the applications in the Communication Dissemination Research Program, which actually I forgot to say that Chad runs the Improving Health Care Systems. Joe was actually I guess in charge of the Communication Dissemination Research. He presented those for us, which he selected 8 for 9.8 percentile. And then Romana’s program in addressing disparities, she went with 10 of the successful applications and that’s a 14.7 percent success rate there. And so, the total average success rate is about 12.3 percent. It varies, obviously, so, I wouldn’t pay much attention to the average. It gives us a total of 51 total grants for a total of $88,600,000 over 3 years. That’s close to what we had allocated about what was it $6 million, yes. Okay.

So, let me just say also that what we did in our Selection Committee, and I’ll get to this in the next slide. Well, actually, let me go to the next slide and we can come back if people have a question about the numbers.
Here are the steps because everybody wants to know the process, how did we get to this? We didn’t just randomly pick these and stuff. So, what happened is the PCORI program directors and the senior staff reviewed the applications after the review panels. So, they went through peer review. Then they established an initial pay line. So, they said let’s draw it at the 10 percentile and let’s look and we asked to look above that pay line, meaning a worse score and below the pay line to say if you look at the group of grants that you’re proposing within that 10 percentile, how do you feel about them? Do they really add value to your portfolio? Do they address high priority areas and these kinds of things and they felt pretty comfortable to a program.

I mean, I think we went over this with them again and again and we said now, look above that line and just in a kind of active portfolio way look at some grants above that and tell us do you see any in your judgment that you feel meet a high priority topic, it’s an innovative thing that
might be successful, adds value to your portfolio. So, they did that and you can see and they had these a priori criteria they use, high priority topics, studies of priority population and fits within the vision of the program, meaning adds value to the program.

So, let me go back and point out that in the assessing options, David actually picked up -- and, David, you’ll have to correct me -- if was either another two or three grants that he pulled right above the -- David’s not there. Martine, was it three? Yes, so, originally.

So, he actually went back with a little bit of active portfolio management picked up some right above the pay line because he felt they met these criteria. I think Romana picked up an extra one in the addressing disparities one and Joe didn’t see that there were any above that that he felt comfortable with an I don't think in improving health care, unless I’m wrong, that we picked up any others in that one. Is that right? So, in essence, we added another about four above what the
initial pay line was as a kind of active portfolio management.

Did you want to say something, Joe?

DR. SELBY: Well, just looking at the percent of Chad’s, it suggests that they did. He picked up five.

DR. NORQUIST: He picked up five.

DR. SELBY: Five.

DR. NORQUIST: Okay, so, I was wrong about that.

DR. SELBY: Yes.

DR. NORQUIST: So, he started out with eight and he went forward, picked up five that were right above that pay line. So, thank you. I had forgotten that one. Okay.

So, then that was discussed and I would say it wasn’t just Chad sat down and picked, we wanted to be clear that they vetted this with other program staff, went over them, felt comfortable with the fact that these did meet some kind of -- so, it was kind of a group process and then the Board Selection Committee and the methodology group.
that was on that with us went over that to some
degree, but we then blessed basically in going with
the recommendations that they're making without
going into too much detail on the grants
themselves.

So, here it is. The next four slides are
the grants with their titles that are being funded,
and so, we -- oh, I'm sorry, I got to say this,
this just gives you an outline of the priority
population. So, you'll get a sense about the range
of, for example, rural children, elderly, racial
and ethnic disparities and a variety of other
points here by each one. So, you can see there's a
pretty good range across that.

Distribution, again, we're distributed.
We missed Texas and my state and some others here.
So, you can see we -- we hope to do more outreach
in some of these to get some of the states that
don't have green in them.

Now, this is for this round. If we put
this right, Joe, if we match it with our other one,
we might fill in some of these, right? Because
this is just this round. Okay.

DR. SELBY: It’s done particularly east of the Mississippi.

DR. NORQUIST: East of the Mississippi.

Yes, we might fill in more there, okay.

All right, here we go. So, this is the lead into the project titles, which I’m sure the people on the phone and otherwise want to know whether they’ve been funded, and so, the first one is the assessing options and I’m not going to sit here and read every one of them. You guys can read, but this gives you an idea of the topical areas of the grants. So, these are the actual literal titles of the grants. I’ll give you a minute to look at that. So, everything from the first one there and these are not in any particular order, generating critical patient-centered information for decision-making in localized prostate cancer. There are actually, Ellen, you’ll see there are a couple or two or three there on prostate cancer.

MS. SIGAL: [Off microphone.]
DR. NORQUIST: Sitting next to --

MS. SIGAL: [Off microphone.]

DR. NORQUIST: Yes, and you can see a
number of others there, which we will post
immediately I think on our Web site.

DR. KRUMHOLZ: Do we fund grants that have
surrogate outcomes as their outcomes or do we
require that they have patient outcomes?

DR. NORQUIST: Good question. I think,
Joe, you want to answer?

DR. SELBY: I mean, I can't honestly say
that I know this for everyone, but I think just
based on the review criteria, it'll be unlikely to
have a study that had surrogate outcomes and no --

DR. KRUMHOLZ: Like glucose control or
something.

DR. SELBY: Yes, we always beat up on
glucose control.

DR. KRUMHOLZ: We would avoid that, right?

DR. SELBY: But yes.

DR. NORQUIST: Yes, be careful about
reading titles and we don't know the whole grant
here. So, that’s the thing that I --

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. NORQUIST: Yes, you'll see one at the end that I’ll show you the title and I was like this doesn't give me any information. So, you'll see in a minute. These are the grants that are recommended still in assessing options. Remember, there were 20. So, there are two pages here, so, there are 10 on each page. So, this continues on the same program.

You will see one at the end here, “Comparing Patient-Centered Outcomes after Treatment for Uterine Fibroids.” And so, the question came up points of adding that to the portfolio, in fact, that we might be doing a targeted announcement, but the feeling by the program staff was that this would give us a head start and would be an important addition to their portfolio.

Improving health care systems, I hope 13 grants if that’s the number, correct? You will see
there a range of different things, including, Ellen, evaluating cancer survivorship care models.

So, there are a range of different --

MS. SIGAL: Is there a printout of this anyplace?

DR. NORQUIST: I'm sorry, what?

MS. SIGAL: [Off microphone] -- a printout.

DR. NORQUIST: We'll have a printout as quickly as we get this up. The point was to share this with everyone at exactly the same time.

And then under the communication dissemination, there are only eight awards. So, these are the awards out of -- Joe, that's your program. So, if you want to comment on anything about that program.

DR. SELBY: No.

DR. NORQUIST: Okay.

DR. SELBY: As you said, we followed the scores.

DR. NORQUIST: He followed the scores directly up to the line.
And then the last but not least is the Addressing Disparities Program. So, these in Romana’s program were the grants. You can see the first title was originally “Ms. A and Mr. B,” and that didn’t tell you much information about what -- the actual literal title, I was like this is very interesting and then Romana filled in some other things about what the grant is actually about. So, that’s not the real title of the grant.

UNIDENTIFIED BOARD MEMBER: [Off microphone.]

DR. NORQUIST: Back to the previous slide, yes.

Oh, okay, I'm sorry, Communication Dissemination we’re back to.

DR. DOUMA: Gray.

DR. NORQUIST: Yes.

DR. DOUMA: [Off microphone] summary of it.

DR. NORQUIST: Yes, as we’re looking at these, let me just tell you a couple other things that came up in our discussion with the Selection
Committee. So, we had advised that at least the abstracts certainly be quickly put up and then I guess the issue about the rest of the grant at some point. Then remember they have to do some discussions with the applicant and things like that, but we felt it was important to at least get the abstracts up also so we at least know. Now, sometimes abstracts don’t tell you everything, and so, it would nice to know the whole grant.

And let me just say the other thing that we had a discussion about is this idea of kind of active portfolio management when we’re doing the selection and what’s the role of the Board in that or some sub segment of the Board as we help the program staff make these decisions about going above a certain line, coming below, whatever, and we didn’t -- Arnie actually chimed in on this one in a big way, too, and we never came to any complete conclusion, but something we may want to have more discussion about as we talk in general about active portfolio management is what is the Board’s role when we do the selection? We did
better this time instead of before, we were completely masked. We didn't know the names of anybody, anything else.

This time, at least we knew a little bit more about what the topical areas were and stuff. We felt more comfortable about actually serving a role than just drawing a line and I think we would like to see that we have that kind of role and I think as I pointed out to Joe and them that when I was at the institute, we had these advisory councils and advisory councils serves that purpose kind of like the Board when the staff want to pick something, it’s above a line or really pick something innovative, it’s a good role for the Board to have to be able to step in and say yes, this adds value, whatever, and we agree with you or something. But we don’t want to get to micromanagement into the program staff as they build a portfolio.

All right, we’ll go on to the final one here.

DR. WEISMAN: Well, like with the duration
UNIDENTIFIED BOARD MEMBER: Turn your mic on.

DR. NORQUIST: Turn your microphone --

DR. WEISMAN: It is. It’s Harlan Weisman.

What the median or average or range of durations of these trials are and including the fact that there's going to be a startup period, there's going to be notification, contracts, all the stuff. So, it takes a while to get any study up and running and then there's the initial inertia of any study before it actually starts enrolling and there's a time course for which the enrollment has to occur and then there's the analysis and interpretation phases.

So, I guess what I’m asking is when would any of them produce results? When would we expect to start seeing the results of these? And then on top of that, I’d like to --

DR. NORQUIST: Yes, so, let me -- let’s address the first issue. So, first, you're right. They’ve got to negotiate with the potential
grantees, get them started. So, let’s say the earliest start date might be the fall or something and then you’re looking at I think almost all of them were three-year grants, maybe one or two were one-year grants. So, you’re looking three years, you’re looking at 2016, the end of 2016 or maybe a little before, depending on how soon they can get it. I think on average is your average question.

DR. WEISMAN: Now I understand what’s been bothering me all day, it’s that clock ticking that I’ve been hearing and we’re basically at Joe’s 2017 right now and I think not now, because I love the grants, love the titles, I think it’s a real issue for this board, not for the institute, for the institute, too, to take ownership of the fact that this is basically a work product as far as our plan horizon of when we’re going to start doing things to have impact.

Now, I may be exaggerating, but I think it’s a big issue and I think that we’ve got to do some things with a sense of urgency beyond this because I’m not sure we’re going to have a lot to
show for what we’ve been doing. I'm sorry. I mean, we’ve got to think about it.

The next round is going to be going into 2017 and then the next round after is that is really outside of our funding horizon. That’s a big deal and I’m not sure we’ve really been facing it from a portfolio standpoint. Our portfolio isn’t producing something that’s going to deliver what we’ve committed to ourselves to deliver what we’ve committed to the public to deliver. I’m not blaming anybody; I just think it’s a reality that we’ve got to face.

DR. NORQUIST: So, yes, I mean, it’s a reality of where we are that makes the targeted announcements even more critical to get them out very quickly if you want to get some other results out because the next round, I don't know when those will be reviewed, but then you're looking at not getting --

DR. WEISMAN: We’re doing something else.

DR. NORQUIST: Yes or doing something else, you're right. I mean, but that brings up the
bigger question, not the question about the
specific issue.

DR. WEISMAN: Right.

DR. NORQUIST: So, before we get into some
of those bigger questions, can we take specific
questions about this funding, about these grants,
because what we’re going to ask is that the Board
approve what has been recommended for funding.
Yes.

DR. WEISMAN: Okay.

DR. NORQUIST: I'm sorry, Sharon.

DR. LEVINE: Sharon Levine. If you could
go back to the prior slide, so, I thought, and
maybe it’s my error, the communication and
dissemination research was going to be researched
into the communication and dissemination of
research results. So, and maybe the problem is all
I can see is the titles, but I’m not sure how some
of these fit into that mindset.

DR. SELBY: So, the Communication and
Dissemination Funding Announcement calls for
research, as you say, on among other things
patient-clinician communication, shared decision-making, tools for decision support, those kind of activities are called for in that, as well as work-related to dissemination. So, a lot of what comes out is decision support in patient and clinician interaction and tools to support that. And always comparative studies with patient-centered outcomes.

So, not just the development. It’s not methodologic in the sense that it’s the development of a new decision aid or shared decision tool.

It’s a trial or observational comparison of two approaches.

DR. NORQUIST: Kerry.

MR. BARNETT: Just remind me, the total amount of all these grants combined is $88.6 million and that’s against an original budget of what when the PFAs were first released?

DR. NORQUIST: This particular round, 96 I think they planned on.

UNIDENTIFIED BOARD MEMBER: Up to 96.

MR. BARNETT: Up to 96.

DR. NORQUIST: So, we’re off by $8 million
here.

MR. BARNETT: But we were reasonably close. So, what do we draw down from that? Why are at $88 million instead of closer to the $96 million? Is there something process-wise that we would want to tweak or something about the way we handled the announcements that would have gotten us to the full amount? I mean, we’re prepared to give away 96 --

DR. SELBY: Yes.

MR. BARNETT: And we wind up giving away 88.

DR. SELBY: This is a little --

MR. BARNETT: I’m just trying to understand the dynamic there.

DR. SELBY: I have to get a little bit technical here, but we’re used to the scores that come in from -- many of us, we’ve seen scores from study sections at NIH and AHRQ and we’re used to scores actually carrying names like exceptional and outstanding and when we see the distribution of scores that come from these reviews, they are
1 higher. They're substantially higher, I think,
2 than the distribution of scores from the typical
3 NIH or AHRQ study section and given that this is a
4 brand-new process, new review panels, we have
5 several options for why that is.
6
7 One option is hey, these are just not as
8 good as the average application coming in to NIH
9 and AHRQ. The second is that the review criteria
10 are somewhat different here and we’re incorporating
11 the criteria of patient-centeredness and patient
12 engagement and that’s what’s bringing these scores
13 down. And the third I think is a variant of that,
14 which is that people are just learning to do
15 patient engagement and patient-centeredness and
16 it’s tough to distinguish, it’s impossible I think
17 really to distinguish between them.
18
19 So, we’re faced with actually funding
20 applications that score pretty high when you just
21 look at the absolute scores versus NIH, but on the
22 other hand, percentile-wise, it’s not very
23 different in what NIH is funding. So, then we take
24 a look at the applications that are above the pay
line and we think that the peer reviewers pretty much got it right, that it looks like the pay line is about where it ought to be.

DR. NORQUIST: So, and let me just say, Kerry, I think one thing you need to address here is the 96 was a guess. We had no idea. I mean, that was just a guesstimate amount that we thought we should spend after we looked at how much money we had.

What we ended up with after we did peer review and then a certain line that we ended up with applications and I wouldn’t say these are bad applications, they are actually high-quality applications and we cut our line at a point that we didn’t feel comfortable going up another $8 million just to solve for X because we got into some other issues, methodological problems, some others, but we did ask. I mean, if we had not asked the staff to go back and so some as we would say a little bit more active portfolio management, the number would actually have been lower.

MR. BARNETT: Right, and that’s really my
point.

DR. NORQUIST: Yes.

MR. BARNETT: I’m certainly not suggesting lowering the bar in order to spend more money. It’s more a question of is there something we can and should be doing that will increase the quality, the relative quality of the grants such that we’re going to want to come back next time and not spend $96 million, but really want to spend $106 million.

DR. NORQUIST: Right, so, that’s part of what we’ve been talking about today, the training of folks to have them understand what it is we want to do and then I think -- remember, these people can come back. I mean, it would be very unusual for NIH, I mean, in many times to pay first-time grants without them expecting them to come back revised and that’s what we need to do a good job of, right?

All right, let me --

CHAIRMAN WASHINGTON: Okay, we have a few.

DR. NORQUIST: -- go on this side because you guys were already up first. Christine, we’ll
just come down this way.

MS. GOERTZ: Yes, thank you. Christine Goertz.

Can you tell us what was approximately the cutoff for scores?

DR. NORQUIST: Yes, the actual priority score.

MS. GOERTZ: The actual priority score.

What range were the priority scores --

DR. NORQUIST: Yes, so, we’re up around the 3.5 here, but I don’t remember. So --

DR. SELBY: Three point --

DR. NORQUIST: David, do you remember? Is David in here?

UNIDENTIFIED BOARD MEMBER: No.

MS. GOERTZ: Thirty-five.

DR. NORQUIST: Three point five. All right, 35. That was in assessing options in the Improving Health Care System.

DR. SELBY: It’s all pretty because the --

DR. NORQUIST: I think it was pretty close to 3.5. It just happened the percentile was --
DR. SELBY: Yes, it was close to 3.5.

MS. GOERTZ: It’s not bad.

DR. NORQUIST: Yes, no, it’s not bad.

DR. SELBY: Another point Martin just points out that if you compare from Cycle I to Cycle II, things got better. It looks like things did get better, and so, we’re hopeful that with a bit more time, scores will come down some and we’ll find it easier to fund everything --

DR. NORQUIST: Yes, we’re paying a little bit higher priority score this time. We were paying close --

MS. GOERTZ: Round 1 was closer to three, right?

DR. NORQUIST: -- to three, now we’re at 3.5. Yes, yes, that’s right, exactly.

MS. GOERTZ: Yes.

DR. NORQUIST: Exactly.

UNIDENTIFIED BOARD MEMBER: Gray, on a scale of what?

DR. NORQUIST: On a scale from one to nine.
UNIDENTIFIED BOARD MEMBER: One to nine.

DR. NORQUIST: So, you get a one to nine, and so --

DR. SELBY: It was good.

DR. NORQUIST: Once you get above a three, the review group is judging it. There are one or two kind of moderate problems and that starts to get into an issue. So, but a 3.5, I mean, NIH and them are paying at the two or 2.5. You’re lucky if you get there. So, three and 3.5, those are still solid, very good applications.

CHAIRMAN WASHINGTON: We’re going to move around.

DR. NORQUIST: Yes, moving.

CHAIRMAN WASHINGTON: So, Douma, Allen, then Gabriel, Hole-Curry. So, we’ll just go this way.

DR. DOUMA: Allen Douma, Board.

I just want to follow-up on Harlan Weisman’s question, concern. Can you just talk about what would happen if we decided if a certain number, significant number of our next grants had
to be two years or less?

DR. NORQUIST: Well, I don't know until I saw those grants what they would be. I mean, I think that's a bigger issue. But to me, let me just --

DR. DOUMA: But if we put it out there and we acquired, what if we’re only granting it two years?

DR. NORQUIST: Let me say my own perspective on that, and everybody can else can be -- I don't want to just have a bunch of two-year grants just so we meet some deadline or something. What we want is quality research that is going to answer the questions and do the kind of things that we want to do as opposed to moving sure we've got 5,000 reports to issue in 2017. I mean, that’s a bigger, to me, an issue about what are we really trying to do?

DR. DOUMA: Yes, I was just adding to the discussion because four-year grants are going to be better than three, also, but we choose three. So -
DR. NORQUIST: It depends on what the question is. I mean, if you're really trying, I mean, this is where the methodology -- I mean, if you really want to answer a hard CER-type question and for what you're comparing and over a period of time, it may take you three or four years to answer that question. You can't do it in two years, you know what I mean, if that's the thing --

DR. DOUMA: I understand, but there are some things you can't, right?

DR. NORQUIST: No, that's true.

CHAIRMAN WASHINGTON: Gabriel.

MS. GOERTZ: So, just to Kerry's question of we had budgeted more funds and we couldn't fund as many grants as we had budget for, presumably because the quality just didn't meet the bar, do you have a sense of what it was, what the big issues were? I mean, were they grants, and I'm thinking again of the Methodology Guidance Panels and the discussion from the last section. Were they projects or research questions that were really on the mark and they were the kinds of
things that we want answered, but the group just
didn’t have the wherewithal to answer it properly,
they didn’t have the methods, or were they just
totally off the market?

DR. NORQUIST: So, in most things, it’s
all of the above. So, there were some that were
like that, but a lot of them just didn’t add
something else, we would say a value to the
portfolio in PCORI kind of terms, if you will. We
ask this to them, we ask their program staff about
that very question and we asked them to look at it
hard and to make a decision about that and they
just felt it didn’t add something more, there were
some methodological problems in some of them that
they felt they could work with them and address and
have them come back. So, it would depend on the
grant, I think, in general.

Joe, did you have --

MS. GOERTZ: So, some of these were
salvageable --

DR. NORQUIST: Absolutely.

DR. GOERTZ: -- if we had the right
mechanism?

DR. NORQUIST: Oh, no, I think there's some of them that we were led to believe by the staff were quite salvageable, yes.

CHAIRMAN WASHINGTON: Okay, Hole-Curry and the Zwolak.

MS. HOLE-CURRY: Leah Hole-Curry, Board. And I think with our earlier round and it may just be you haven't had time to do this yet, but we did a little bit of analytics around geographic distribution and distribution by major conditions and distribution by populations. So, I guess the biggest one I was looking at was by condition, which we did before.

DR. NORQUIST: No, we had that slide, and if you saw it, you would be so -- I mean, it has like so many bars in how you write those.

MS. HOLE-CURRY: Okay.

DR. NORQUIST: So, we have it. We actually have it, but if you see it, it doesn't give you much information to be honest. It’s all over the place.
MS. HOLE-CURRY: Okay, so, maybe for this type for the Board by individual slate isn't as important as overall portfolio?

DR. NORQUIST: So, you do have on the right --

MS. HOLE-CURRY: It would be less busy?

DR. NORQUIST: -- there on the population.

MS. HOLE-CURRY: Right.

DR. NORQUIST: You see by the individual slate. We didn't here because of the numbers just to show you this on geographic, but you --

MS. HOLE-CURRY: Right, no, that's great.

DR. NORQUIST: I'm sure they could pull that.

MS. HOLE-CURRY: No, no, I think if it was too busy to represent the other way --

DR. NORQUIST: Right.

MS. HOLE-CURRY: It may be just at a high level for us to get some mental images of the slate. As I think somebody else mentioned as we went through it, the first one had three on prostate cancer. So, just going back to Harlan's
comments about active management, I think that’s something for us to try to figure out as we move forward how we address something like that. It may be these are all studies that are important and there are lots of unanswered patient-centered questions or it may be some other clustering and we want to make sure that that’s not clustering specific to PCORI. So, I’m not sure how you do that going forward, I just think it needs some discussion.

DR. NORQUIST: Well, no, let me just say that gets back to what is the role of the Board --

MS. HOLE-CURRY: Right.

DR. NORQUIST: -- and the active portfolio management. We relied on the staff to make that decision as they do let’s say at NIH. I mean, when I was there, that’s what we did. But what is the role of the Board at some point and how much of a micromanagement we want to get into, that gets difficult at some point when we start second-guessing. So, but it is a discussion we should have at some point.
MS. HOLE-CURRY: Right, and it may not be that the Board looks at those individual ones, but now that we have some history and we can combine those with our other 60 or so and start to look across it, maybe we say we have a slate for this specific condition or this specific population and encourage staff to take that into consideration as they make the recommendations. I’m not saying that we have to pick, I’m just saying that triggers a discussion point.

DR. NORQUIST: Right. And I think one of the things we could do is like we did yesterday, where we had the staff present their portfolio to the joint session of the PDC and the COEC, and that’s another option where we could have that kind of a discussion with them as what’s in their portfolio because it helps to do it a priori. You don’t want to tell a grantee afterwards oh, we don’t like your area.

MS. HOLE-CURRY: Correct.

MR. NORQUIST: Yes.

CHAIRMAN WASHINGTON: Okay, Zwolak and
then Epstein and then Weisman, and we’ll move around.

DR. ZWOLAK: Bob Zwolak, Board.

Congratulations for getting these done.

That’s great news.

This is Cycle II, and as the way I try to look at the calendar, we still are on target, I guess, to get Cycles III and IV announced, recruited and announced during calendar 2013, with the last one being in November.

DR. SELBY: Cycle III is already in.

DR. ZWOLAK: Right.

DR. SELBY: The deadline is closed and Cycle IV opens. August 15th we’re going from the year forward which reflects the due date. It opens May 15th. So, that’s the one that will be announced in December.

DR. ZWOLAK: In December. So, if --

DR. SELBY: Just like last year.

DR. ZWOLAK: If the scores were hurt a little bit by the patient involvement, which is what people are having trouble with, is the staff
looking at those grants that may have been really good otherwise say for the patient involvement piece and not just assuming that people may dive back into the pool, but potentially encouraging people to look at and maybe help them a little bit with the patient involvement piece and to dive back in the pool so we can make sure we get high-quality spend for as much as we hope to in these last two cycles.

DR. SELBY: One thing we know is that a number of applications are being resubmitted to cycle for really the first time, and so, we’re excited by that. I think we actually do have the capacity at this point to analyze the data to some extent in terms of what scores may have influenced the overall score. We only get those scores before the discussion, so, it’s again technical, but there may be some work that we can do in that area, as well.

DR. EPSTEIN: Three quick things. First, the Selection Committee met by teleconference three times in the last two weeks. I found it arduous
myself, but I do want to congratulate the staff for putting together a lot of information, for responding coherently, and Gray did a terrific job of sharing the meeting in what was pretty directive. So, I really want to put that forth.

Second, I think we may have some advantages and a challenge here with what's happening with resubmitting grants. The good news here is I think we’ll see the scores go up, God willing, and they separate higher and that’ll maybe address some of the concerns that Kerry raised.

Joe, what are you planning to do about giving reviewers copies of past reviews and especially holding people blameless? And the issue that comes up here all the time is someone gets advice, they listen to the advice, and a new reviewer comes out of left field and says I don't really like those [inaudible]. So, and I think we have to make a decision about that and you could tell where I fall out on that, but --

DR. SELBY: I will make a comment and I’ll also add Martin to add comments if there's
something else, and the comment I’ll make is I know because I just asked Martin the other day about this. We are working hard to get reviewers back if reviewers reviewed the application the first time. We’re working hard to get at least some of those back this time on the basis of what we know about who has resubmitted.

DR. EPSTEIN: I guess the question is:
Can we enforce essentially a contract and the contract is if they make a change in their proposal to address what we told them to do, we’re not going to criticize them again for it.

DR. SELBY: That sounds good. I think we actually do have some work to do in prepping the SROs and the reviewers for these resubmissions.

DR. EPSTEIN: Yes. And the third issue I want to raise, this is going to be -- Gray made a faint at this -- I want to underscore it because I think it’s important and put it out for a little bit of discussion, which is how does the Board want to relate to actual applications? I’ll give you how I was feeling, but that’s not meant to say that
we all want to do this.

I was feeling that I did not want to second-guess staff. They made some judgments. We gave them pretty clear direction and license to go back, actively manage at both ends of the spectrum, ones that were scored highly to say I don't think so and ones that were on the opposite direction. They say again and again that their own views correlated very highly with the viewer views.

I should say that’s not my own personal experience in life, but they did it. And then for myself, I found myself wanting to get not to double-guess the staff, but to understand better what I was dealing with. And I talked and Gray will remember this and I think he had some interest, as well, at least for us, but maybe for everybody spending some period of time from each of the major sections, let me blow an hour, let me blow an hour-and-a-half, tell me a five minute’s piece about two of the grants that you really liked, describe it, why you liked it, what’s the information that you hoped to get from this and how
it will change what patients and doctors are doing or not and then go above the cut line, just above it, where you said no and tell me what was driving you. Not with the sense that I was going to say how could you do that, but for that. But the bigger issue is also how much the Board wants on that, and so, it’s really with that spirit that I bring this forth here.

DR. NORQUIST: Yes, and I just want to second that Arnie and I felt very strongly about this and that it also means that we need some consistency across time and who’s doing the selection and stuff if we’re going to have the Board involved in that, which requires some work, but I know that Arnie and I, I don’t know how the others felt, but we felt fairly strongly that that is an option.

DR. SELBY: Well, first of all, I want to say from the staff’s point of view that the Selection Committee and the Board and the Methodology Committee’s participation in it was extremely constructive. I think we learned a lot.
This was the first time that we really did any of what we might call “active portfolio management” to speak of and my hunch is that we’re going to get more active with your encouragement over time. So, we’ll just get more facile at it.

I think there are advantages to the Board not actually digging into individual applications. One of the immediate advantages I can think of is that we don’t have to worry about recusals and conflicts of interest and you can review this one, but you can’t review that one because it’s from your institution. And so, that’s huge.

And, Gray, your comment about consistency, did you mean consistency from the staff or did you specifically mean consistency on the Selection Committee?

DR. NORQUIST: I’m talking about both. I assume the staff would be consistent.

DR. SELBY: Yes, I assume, too.

DR. NORQUIST: It’s the same program. I’m not sure it’s planning on --

DR. SELBY: Yes.
DR. NORQUIST: -- getting rid of someone, but --

DR. EPSTEIN: And you get rid of the recusal issue by showing this last year’s applications. In other words, the issue here for me is to get a little bit more familiar about what’s under the hood, what are we really funding, what goes into people’s thinking when they think it’s really good? How do they relate to the fact that this will really yes or no change what a patient gets in this world, because that’s what we care about and one way to have done it would be the applications that just came in now, but if you want to do it in three months or two months from now with the applications that came in and are already funded --

DR. SELBY: Right.

DR. EPSTEIN: -- it’d be just as useful to me.

DR. SELBY: Yes, that makes sense.

DR. EPSTEIN: I just want to learn a little.
DR. SELBY: Some on either side.

DR. EPSTEIN: It will make me wiser in how

I relate to --

DR. SELBY: Yes.

DR. NORQUIST: And let me just say it’s
not a problem with recusal. I mean, NIH does this
all the time in the advisory group. People walk
out when they have an actual grant or something.
So, it’s possible to address that.

CHAIRMAN WASHINGTON: Okay, Wiseman and
then Goertz and Douma and Kuntz.

DR. WEISMAN: Harlan Weisman, Board
member.

Again, I’ll just reiterate what I said
earlier. I think these all seem like very good
projects and I would not second-guess. I mean, I
think as far as I can tell, you followed everything
we said we were going to do and we have some
research projects that are exciting and worthy of
funding.

However, I do feel that we’re in a bit of
a crisis in terms of what we want to accomplish and
what we can accomplish in a finite period of time, which is dictated by legislation and also the patients of the multiple stakeholders that we have in terms of what will be done. How many of these studies, although they're really worthy, will move the need the way we want to move the needle? And certainly in isolation, it’s unlikely that that many of them really will do that because that’s just the nature of things. And we don’t have the luxury of time to really expand on these.

The nature of any startup organization like we were and I guess still are, we’re transitioning out of it, that moves quickly, that’s innovative is that you try things and not everything works the way you expect it. I mean, we went out and we set about setting up a structure that was going to accomplish things that we wanted it to accomplish. I think what we’re learning is that things that we didn’t know about are conspiring against us a little bit in terms of estimating how difficult it is to get patients truly involved in meaningful ways or not the
typical set of researchers able to complete our applications and do high-quality grants and the ability of very experienced researchers to be able to reach out to the community and engage patients and clinicians who are outside of the academic realm.

And that’s led to things that we’re learning, but I think we got to just really take a good look at what we’re doing now. I don’t think it’s accomplishing what we wanted to accomplish. It doesn’t mean we’re not doing things well. Please understand that. To me, it’s a question of understanding the difference between precision and accuracy. We have good precision here, we’re doing things very well, but accuracy means just because you can hit a target over and over again very close to what it is, it may not be the target you want to hit.

The target we want to hit may be somewhere else and I suspect that if we look at our vision and our mission that we are unlikely to hit the target we’ve said is ours if we keep going about it
and I hope that we reflect in an honest way, say
what's working really well for us and what things
aren't working the way we wanted them to or things
aren't rolling out the way we expected and it may
mean after reflection that we have to make an
adjustment of not our goals, but the way we’re
going about trying to achieve our goals.

And Harlan Krumholz has come up with some
ideas; I think a lot of people have ideas. Gail
suggested the ability to take what's known because
on top of all this, we’ve got to figure out not
only what the research results are, but somehow we
have the idea that unlike others who have done all
this stuff before and, Gray, you’ve mentioned a few
times you were doing CER a few years ago and
everyone has been on it.

Nobody has really gotten the stuff to
stick and I think without really understanding how,
one, the research we’re funding isn't ahead of
things when we want it to. And two, that we really
have the knowledge once it starts coming at us in
2015 through 2017, well, once we’ll have the time
and two, we’ll have the ability to really not only disseminate it, just throw it out there, but really get it to stick.

And that’s why I say I think this is a crisis, there’s a sense of urgency. I don’t blame anyone. I think the institute’s staff is doing exactly what we asked them to do and they’re doing it very well. And I think the Board had good intentions, but I don’t think we’re doing what we need to do in terms of making the adjustments if we’re serious in delivering on the promise of Patient-Centered Outcomes Research in the timeframe we’re given.

CHAIRMAN WASHINGTON: Okay. Thanks, Harlan. Goertz.

MS. GOERTZ: Thank you, Christine Goertz, Board member.

Two things. First of all, I want to pick up on the comment that Leah had made about noticing that there were several applications in particular topic areas and leading back to the discussion that we had earlier today about to what extent our
portfolio made the switching from more broad funding announcements to more target. I think part of becoming more targeted is not only have targeted PFAs, but also being able to assess our portfolios and to say we have at least for right now enough applications in this particular area, so, you would need to really talk to us first or before you would be advised to submit an application in this particular area because we more or less have that covered. So, I hope that that’s something we’re considering as we’re also looking at more aggressive portfolio management.

And second of all, I would just like to thank all of that applicants who have put in the huge time and effort to submit these applications to us and to congratulate all of the investigative teams that are represented in these applications that are being proposed to the Board for approval today.

CHAIRMAN WASHINGTON: Okay. Thank you, Dr. Goertz.

Dr. Kuntz.
DR. KUNTZ: Yes, just a real quick comment. First of all, I think this is great. I’m looking at the very small sample distribution in the states, and we mentioned this earlier, and the grants fall where they can, but are you planning on looking back at the geography again because I remember that a lot of the motivations that we had about PCORI early on was about the nurse in Mississippi who had the idea that nobody would else would think about, and when I look here, there’s a big missing part in the South and I’m especially surprised by Texas, which is like number four in the NIH and number two in the CDC. So, they clearly have world-class, outstanding researchers all through that state and got zero. And I don’t know if it was just a sample issue or not, but it’d be kind of fun to look back to see can we do some maybe more projected analysis of why that happened.

DR. NORQUIST: Yes, I think one thing, thanks to my own state, where I know there were applications, I think one thing to do is look back and look at the applications that were from these
states and see if there were particular issues
around that. I mean, I think that may be some of
the issue which would be interesting to see, also.

CHAIRMAN WASHINGTON: Okay, Mr. Becker.
Larry.

MR. BECKER: Larry Becker, Board.

So, we've spend a lot of time getting
input from patients, clinicians, and researchers
about the questions and if others agree, it would
seem to me that in simple math, we've had two
cycles and we had the Pilots Projects and we
probably had 1,100 not successful grants,
applications, and it might be interesting to look
back at those 1,100 and see if there are questions
that our clinicians, the researchers, the patients
really wanted answered. They may not have met
muster, right, they may not have hit the line, but
there may be some themes in there that would say
but the customer really wants the answers to these
questions. So, we might learn something from the
other 1,100.

CHAIRMAN WASHINGTON: Okay. Gray.
DR. NORQUIST: I want to say one final thing. Thanks to the group who really put in a lot of time and the staff and I just want to say I agree with Christine about making clear that there's certain areas we no longer may want, but please do it quickly because one of the biggest nightmares I ever had when I was at NIMH was where we did this where we cut off one area and somebody had a grant coming in for the next review and we ended up with a congressional inquiry about why we didn’t fund that one grant. So, I think it’s not fair to the field if you decide to cut off some area, cut it off, be very clear about it right now so that people who are out there thinking about submitting to us will stop and go down some other path, okay?

CHAIRMAN WASHINGTON: Okay, well, I also want to -- Hunt.

MS. HUNT: Yes, real quick.

CHAIRMAN WASHINGTON: Ms. Hunt.

MS. HUNT: Gail Hunt, Board.

I just want to reiterate the fact that if
there's any way we could figure out how to foster innovation more in these proposals, that's something that we really need to do and I know it's hard, but when you talked about the nurse in Mississippi that has the great idea, that's exactly -- I'm not sure we're getting to that, so, it would be great. Thanks.

CHAIRMAN WASHINGTON: Okay. Sharon.

DR. LEVINE: And this is just a question for Christine and Gray in light of the comments that were just made, I mean, would you really want to cut out something that had prostate cancer in the title before you even looked at it? I mean, perhaps it's looking at or answering a question that is applicable across conditions and I'm wondering how you make the judgment that sorry, we're full up on prostate cancer research or hypertension research without looking at the question --

DR. NORQUIST: I agree with you. I mean, I think you have to be very careful about what you're saying, but if it were the same test of some
very specific intervention --

DR. LEVINE: Okay.

DR. NORQUIST: -- in prostate cancer,

that's what I was talking about. That's where we got in trouble. It was about chronic depression and somebody had a similar kind of intervention.

DR. LEVINE: Okay.

DR. NORQUIST: And we cut that off.

DR. LEVINE: Yes.

DR. NORQUIST: But I think yes, you're right. And we didn't look at this and I think in fairness to the grantees, those particular grants may have relevance across a number of cancer conditions, for example.

MS. GOERTZ: Right, and again, what I had said was that they would talk to us before they would submit just to make sure that there wasn't any overlap. So, I don't think we would ever say absolutely no, but with some, we might come to the point where we would say talk to us first.

CHAIRMAN WASHINGTON: I have Sigal and Hole-Curry.
MS. SIGAL: Ellen Sigal. So, I agree. I think it’s very hard for us to cut off conditions to say no more on prostate, because there’s a compelling need and we don’t absolutely have a clue on how to treat it is an example, I looked at these.

The proposals, and I’m sure they’re all good, they’re not going to give us the answers. On the other hand, we do have to do some management and do priority-setting and I must say that I agree with Harlan Weisman. And it may be Harlan Krumholz, too. The big rocks, the big things that are really going to be transformative for PCORI are not in this group. There may be some really nice, important things we do and we have to think about what we want to do about those big things because money and resources and time are starting to run out.

CHAIRMAN WASHINGTON: Okay. Hole-Curry. This is the last comment.

MS. HOLE-CURRY: Thanks. So, just to respond, I mean, you could weight it and not
everybody has access to the grants that we've already funded and I don't know the exact solution, but you could say for every novel condition we haven't yet funded, if you wanted to encourage that, you get some percent additional point for every -- I mean, there's a lot of ways to do it without saying no, never and given current information, just like there's a lot of ways to say what we really want right now is good applications that can be completed in a year. You could bump those scores up if people actually met other methodological standards because when we say the basics is $2 million in three years, that's what we get.

So, that's a reality. That doesn't necessarily mean we couldn't encourage something else, even within the structure we already have here. And I hear a lot of resistance to active management, which is all of these ideas. It doesn't mean a specific one is right, but we have to start talking about it and I don't know how else to get out that --
CHAIRMAN WASHINGTON: Right.

MS. HOLE-CURRY: -- in our meetings.

CHAIRMAN WASHINGTON: Okay, I want to -- Harlan, if it’s something new.

DR. WEISMAN: [Off microphone.]

CHAIRMAN WASHINGTON: Okay, because I am really hearing the same things over and over again now, so --

DR. WEISMAN: Well, I agree with what Leah just said and what we choose to fund should have less to do with what the topic is specifically or how many we funded before and more to do with what we want to accomplish. The research in many ways is a means to an end, and so, if the means, meaning a specific research topic, advances us toward the end we want to achieve, then we should do it, and if it doesn’t, I would say no matter what the quality, we may not want to fund it because it doesn’t advance us toward what we’re trying to achieve. Thank you.

CHAIRMAN WASHINGTON: Okay, thank you.

Well, Gray and Christine and all the Board
members involved, along with Martin and other staff
and this selection process, thank you. We are
going to ask for a vote in a minute, but there are
two themes that I heard I just want to underscore
and let everyone know we heard you very clearly.

One is, Larry, I took what you said and
some degree what Harlan W. said is in my mind it’s
equivalent of an impact analysis, only you have us
a very specific way to go about it. Take the last
set of grants, take this set of grants, and we’re
here to define what we mean by impact and that
impact, the process indicators, but there’s also
the indicators of some expectation that it’s going
to reach a care, so to speak, or it’s going to
improve outcome, and we may have to get outside
help to help us define that. But we need that kind
of framework going forward because I think that
also helps us to understand a little bit more
clearly whether or not we are moving closer to the
goal, even though I like what we’ve laid out in
terms of the metrics, but those are different
pieces. We’ve got to have measure of impact.
That’s one thing.

Two, the other is I’ve heard three
different definitions of “active portfolio
management,” and that’s good, that’s good. Okay,
at one level, what I’ve heard is we want to
actively manage a process of soliciting grants.
And that means we want to be proactive, it means we
want to have training in place, want to have
certain criteria to drive us toward our goals. We
may want to look at a timeframe, whether it’s one-
year, two-year, but active management in that case
is more akin to what I think the two Harlans were
referring to earlier in stepping back and thinking
about exactly where we want to be and proactively
generating those kinds of proposals and/or grants.
So, that is sort of active management in terms of
soliciting proposal.

The second one would be what I just also
heard is active management and selecting actual
projects because we just did that. That’s what you
did. We got a set of projects in, you had a cut
line, but you actively looked above and you looked
below. And that was active management and we want to continue to do that. We want to make sure that its objective in how we approach it, but that’s another component.

And then the third one, which is where we actually started and where I was when I was hearing active management is essentially management of projects. We funded projects, now we’re managing them to make connections and ensure that we’re optimizing the return on the investment in those projects.

I would suggest, Joe, that we develop -- it should be a one-pager that sort of lays out what we mean by “active portfolio management,” and if we are serious about this as sort of a core activity, then we ought to also have a metric around active management, which says there are a set of activities related to it and instead of outcomes in some kind of way where we also have a dashboard related to -- I know we have you on dashboards today. But I like what I’m hearing about active management and we should be a little bit more
explicit on a sheet of paper and use it as a guide in all of these areas of our activities.

Okay.

DR. SELBY: I think we agree and we’re actually quite close to having that and we think of it just that same way in the three compartments that you mentioned.

CHAIRMAN WASHINGTON: Great, thank you. Kerry.

MR. BARNETT: [Off microphone.]

CHAIRMAN WASHINGTON: Oh, we need to vote. Vote, it’s been a long day. Okay, would you put a motion on the table?

DR. NORQUIST: Yes.

CHAIRMAN WASHINGTON: Can you, Kerry?

MR. BARNETT: I move that we approve the slate of applications that were listed here today for funding.

CHAIRMAN WASHINGTON: It’s been moved and seconded. All in favor?

[Chorus of Ayes.]

CHAIRMAN WASHINGTON: Okay, all opposed?
[No response.]

CHAIRMAN WASHINGTON: Okay, it was everyone in terms of the record, actually.
Any abstentions?
[No response.]

CHAIRMAN WASHINGTON: The motion carries and the slate is approved, and, again, thanks to everyone involved.

Now, on to institute policies.

MR. BARNETT: I know it’s very late and I think we can move through this really very, very quickly. It frankly does not have the sort of substantive or rather strategic girth of what we’ve been talking about for these many hours.

DR. KRUMHOLZ: I just want to go on record with that. The strategic girth --

MR. BARNETT: Strategic girth is a good thing. You want to have lots of it.

And I want to start by welcome Regina, who is trying to find the clicker here, for her willingness to really jump right in. We’re really delighted to have her onboard and thanks for being
here and then being willing to carry this agenda item, albeit very, very quickly.

I just want to provide about a minute, two minutes of context here in starting with the notion that Anne and her team over the past several months has really been working hard to sort of take the organization to the next level.

If you remember, we sort of began by creating the basic structures and controls to get the organization up and running and then we’ve been going through this process of sort of going back and perfecting and refining and expanding those processes as needed in order to move towards a more sophisticated, more disciplined organizational alignment.

So, what we have here is the culmination of an effort to formalize some of our procedures and I guess I want to stress that we don’t want to become too bureaucratic. That’s certainly not the intent here. We do want to maintain certain elements of flexibility along the way, but it’s clear that having clear, written policies in place
is important from an organizational discipline standpoint, but also frankly from an audit standpoint because the nature of the audits that we go through, the auditors come in and they want to know specifically what our board-approved policies and procedures are and then they want to see if we’re following them. So, it is important to note the phrase “Board-approved policies and procedures,” which frankly is why we’re here asking for board action.

I do want to stress on last thing, and that’s that if you’ve gone through these policies and procedures, you’re going to scratch your head a little bit and say it just doesn’t seem like it’s all that new and different and the answer is that it’s not. This is really a codification of what we’ve been doing and what we have in place today, but it’s important to put it in that kind of more formal, written format so that we can satisfy auditors and whomever.

So, that’s my context. I’m going to turn it over to Regina, who’s going to walk us through
this very quickly.

    MS. YAN: Okay, thank you. Okay, Kerry
just gave you a quick overview of what we are
trying to do and we have several things that we
have updated that we need your approval and before
we go to the policies, we have updated our
decision-making matrix. What we have done is that
previously Anne held the title of both the deputy
executive director and also COO. So, right now,
with the decision matrix, we need to update it to
separate out the two. So, this is what we have
done, and since you have approved this decision
matrix before and as we have updated it, we also
want to seek your approval for this one. So, I'd
like to take care of this one first.

    UNIDENTIFIED BOARD MEMBER: So moved.

    CHAIRMAN WASHINGTON: Okay. There's a
motion, it’s been moved.

    UNIDENTIFIED BOARD MEMBER: Second.

    CHAIRMAN WASHINGTON: And second. All in
favor?

    [Chorus of Ayes.]
CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Any abstentions?

[No response.]

CHAIRMAN WASHINGTON: Okay, the motion carries.

MS. YAN: Thank you. Going back, we have right now to put out policies into two buckets. One would be the bucket that would require the Board’s approval. These we consider it as into two policies. They include policies regarding governance, risk management, and finance and control. And finance and contracts and the other we consider as administrative and operational policies that will be taken care of by management, so, we won't bother you with those.

The policies have been developed and the FAAC, they have reviewed them and we have legal counsel also reviewed them. That review was done last week and we have sent the draft policies to all of you and I thank you for taking the time to review them carefully and I also thank many of you
who have sent me responses. And based on your comments, we have made several updates. At least the comments I have received so far have not been significant, but we have incorporated those comments anyway.

So, these set of materials were sent to you electronically and these are the draft policies that you have given me comments on. And this morning, we have given you a set, the only 3 policies among the batch of 12 that we sent you that we have gotten comments on and I want to very quickly let you know what modifications we have made. One slight modification we made was on the employee acceptance of gifts and payments. In the definition of what is a widely-attended event, we had both the number, 25 people, and also the nature of events, and the comment was the number may not be most helpful, is probably more important to really look at the nature of event. So, we have removed the number of 25.

Secondly is about board meetings and hearings. In the executive session of board
meeting, there was only slight clarifications. We said that the Board can call a closed meeting for matters concerning personnel and also privileged or confidential advice of counsel. And with that, we have simply added one word there, “that means concerning matters requiring privileged communication or confidential advice of counsel.” It’s a very slight change, but I think that it is much clearer and much easier for us to carry out.

And the very last one is in the pre-award policy, that is under the approval of funding slate. The current practice is that we have one sentence there that says “the Board of Governors’ approval of the funding slate. In doing so, the panel will reveal only general information and will not be aware of the names of PIs or institutes being considered.” That is our current practice. We can choose to continue that. That is fine, but the comment is that we don’t really need to have that in there and we can decide whether to continue the current practice or change. So, we have just removed that one sentence.
And, of course, the Board approval will continue to be made in the public setting. So, those are the several minor modifications made to the policies.

CHAIRMAN WASHINGTON: Okay. We all received --

MS. YAN: I just want to add one thing. That is that all our policies will be reviewed periodically and will be updated and revised as necessary. And we’ll be presenting them to you as a batch. So, we have another about 16 policies to be developed and present to you in the future meetings.

CHAIRMAN WASHINGTON: Okay, I see Zwolak and I have a clarifying question and then Zwolak and we’ll go this way. Okay.

DR. EPSTEIN: Arnie Epstein. I’m not sure I understood. Right now, we’re reviewing the policies, blind institution investigator, and are you proposing to strike that?

MS. YAN: There was a comment that coming in saying that that is our current practice and
that practice can continue as we choose, but that
may not need to be in the policy as --

   DR. EPSTEIN: So, you're proposing to
strike it?

   MS. YAN: Strike just that one sentence
from the current policy.

   CHAIRMAN WASHINGTON: Okay, Zwolak.

   DR. ZWOLAK: Bob Zwolak, Board.

   In reviewing these one last time and in
consideration of the discussion about the
importance of the Methodology Committee and the
Methodology Report, there is in the post-approval
section a comment that says "An investigator may
unilaterally deviate from the adopted PCORI
methodologic standards by only informing the
staff," and I think given the importance we lay on
the methodologic standards that we should strike
that clause where an investigator can deviate from
our standards just by telling us that he or she is
doing so.

   CHAIRMAN WASHINGTON: Okay.

   MS. YAN: The Board can approve with that
amendment if that’s what the Board wants.

CHAIRMAN WASHINGTON: Okay, I know it’s late in the day. We received this ahead of time. So, I’m assuming we’ve read them and are comfortable because we don’t have to, as Kerry is reminding me, approve these today, but most of it, 99 percent of it is the way we’ve been operating since we developed policies.

So, other than that amendment, is there another amendment?

[No response.]

CHAIRMAN WASHINGTON: Okay, Harlan and then Allen, and Rick, is your card up?

DR. WEISMAN: So, when I look at the slides originally, the ones that were sent to us in advance, and it was actually on your slide that introduced getting to this point, which is -- I’m not sure where it is. But, anyway, you relegated the Board and through the FAAC, recalling institute policies and then to the executive director policies related to human resources and --

MS. YAN: Administration and operation.
DR. WEISMAN: Administration, and I was worried about that delegation until I went through the appendix, and in the appendix it’s clarified that in terms of human resource policies, if you put compensation into that, that executive and director compensation should be taken out of the institute, which it is. I think there’s a creation of what’s called an Executive Compensation Committee. I wasn’t really clear on its structure, but that would be very typical that a committee of the Board asks on matters of executive and director comp, but it isn’t clear in the presentation.

MR. BARNETT: Yes, you’re right. It’s not clear from that one slide, but, in fact, if you look at the --

DR. WEISMAN: It’s in the appendix.

MR. BARNETT: If you look at the authority, the full authority matrix, the authority for executive compensation is delegated to the Executive Compensation Committee, which is -- who is it again, Steve? It’s --

VICE CHAIRMAN LIPSTEIN: [Off microphone.]
DR. SELBY: Yes, NFAC.

MR. BARNETT: So, your point is very well taken, and, in fact --

DR. WEISMAN: I just want to make sure we weren't abrogating --

MR. BARNETT: -- that that is not fully in the hands of staff.

DR. WEISMAN: Right, right.

CHAIRMAN WASHINGTON: Any other amendments or any other comment?

DR. DOUMA: A comment.

CHAIRMAN WASHINGTON: Please go.

DR. DOUMA: Yes, that's right.

Unfortunately, I didn’t get this until I was basically getting on a plane to come here.

CHAIRMAN WASHINGTON: That means you had about five hours on the plane, Allen.

[Laughter.]  

DR. DOUMA: And I had three other books to read.

CHAIRMAN WASHINGTON: Oh, okay.

DR. DOUMA: Plus, actually, I didn’t even
have a martini. It’s also I assume we have some
change for a discussion, which it sounds like we’re
not going to, plus we got stuff handed out this
morning, which I haven't looked at. Didn’t know we
were going to be voting on those. But and I do
have some items that I would like to talk about,
but given the sense of the committee and where we
are and when we are, I don't want to be persona non
grada for bringing up issues.

MR. BARNETT: Well, let me make a
suggestion, if I could, and Allen, I want to make
sure you're comfortable with this. What I’m going
to suggest, and maybe this is self-serving, is that
we go ahead and have the vote, approve it.
Remember that these are our policies and which
means that we shape them, we change them when we
decide to change them, and maybe this can be done
right away, but certainly between now and the next
board meeting, we’ll have a detailed conversation
between Regina and you and I’m happy to participate
and make that any questions that you have are
answered and if there are some proposed amendments
that come out of that, then we can consider those at the next board meeting. But that’s the request that I would make. If you’re comfortable with it.

DR. DOUMA: I am, but let me have one minute just to sort of skip around and say why I’m concerned.

One is it talks about the duty of obedience for a Board member and it talks about the duty and obedience to the organization’s values. And we’re supposed to be faithful to the organization’s values. I don’t even know how to be faithful to the values.

[Laughter.]

DR. DOUMA: So, it also talks, and this one is more significant in a way, under committees, it says “Unless otherwise provided in a resolution of the Board designating any committee, a majority of the whole committee shall constitute a quorum and the act of a majority of the members presents at a meeting in which a quorum is present shall be an act of the committee.”

That sounds to me a lot like deliberation
and voting. Okay, which makes it a meeting. And so, just for me, there’s a conflict between this language and the language that came before with regard to how we define a meeting. And I’m okay to let that ride, but that’s the level of discussion I’d like to have some time.

MR. BARNETT: And Allen, I appreciate the questions. I think we’ve got really direct, straightforward responses to both of those questions, which is why I think that offline conversation would be useful.

DR. DOUMA: And that would be good. Last one.

MR. BARNETT: Okay.

DR. DOUMA: Because this might come up sooner rather than later. It says in here “The Board must not commit acts that are outside the scope of the institute’s powers and must abide by federal and state laws.”

Two questions. If I get a speeding ticket, what’s going to happen to me because I broke a state law? What is the remedy for this
recreant Allen Douma for having gotten a speeding ticket?

CHAIRMAN WASHINGTON: You’re going to get voted off the island, Allen.

DR. DOUMA: All right.

[Laughter.]

DR. DOUMA: I just want to know how I can get off gracefully.

UNIDENTIFIED BOARD MEMBER: You have to go back to the FAAC for a year.

DR. DOUMA: No, no, that’s cruel and unusual punishment.

VICE CHAIRMAN LIPSTEIN: So, Gene, I kind of shared Allen -- I had some ideas, too. But I think what we should do is I’d like to make --

DR. DOUMA: Well, it --

MR. LIPSTEIN: -- a motion to approve these policies, that we approve these policies and that --

CHAIRMAN WASHINGTON: With the amendment?

VICE CHAIRMAN LIPSTEIN: With the amendment, and at some point in the future, we will
revisit with the FAAC updates to these policies that would reflect Allen’s input and some of the ideas that I have, as well. But I would make a motion --

DR. DOUMA: I second that motion.

MR. LIPSTEIN: -- that we go forward.

CHAIRMAN WASHINGTON: Okay, so moved and second. The motion actually included the amendment, so --

UNIDENTIFIED BOARD MEMBER: [Off microphone] that document.

CHAIRMAN WASHINGTON: Bob’s amendment. All in favor?

[Chorus of Ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Any abstentions?

[No response.]

CHAIRMAN WASHINGTON: Okay, the motion carries. Thank you.

MS. YAN: Thank you very much, and this is not the last batch. There will be more to come.
If there are further comments, send them to me.

Thank you.

CHAIRMAN WASHINGTON: Yes, thank you.

Joe, a couple of comments before I wrap up. It’s been a long, productive day.

DR. SELBY: We always say this was an action-packed day more than maybe any in memory. I have a set of four or five slides of next steps, but I really feel like I should spare you at this point and if we get a moment, present them tomorrow in closed session just so that you can see where we’re going, but a lot of --

CHAIRMAN WASHINGTON: I think for the public, if you have them, you just --

DR. SELBY: Post them?

CHAIRMAN WASHINGTON: [Off microphone.]

Okay.

DR. SELBY: Okay, all right.

CHAIRMAN WASHINGTON: Because it’ll take less than five minutes. I know [off microphone]. We have to remember that there are others that are participating.
DR. SELBY: So, in the area of the Strategic Plan, it was very clear that our work includes developing the metrics for our Strategic Plan, continuing to develop them at the level of both the outputs and the goals in close consultation with --

MS. HOLE-CURRY: Sorry, Joe, can you use the other mic, please? It’s not clear that that one’s carrying. I just want to make sure our public can hear it.


But now what did I do? Good.

So, in close consultation with the Board of Governors, we’ll develop those metrics. And dashboards need to be developed, tailored to individual audiences. For example, the Board, other stakeholder groups, staff. We need to develop charters for the clinical trials and advisory panel and the Rare Diseases Advisory Panel to have for the September meeting. Part of the Strategic Plan also includes continuing work and completing PCORI’s evaluation plan, which is linked
to the Strategic Plan and builds actually on the
metrics that we’re talking about. And to continue
developing PCORI’s dissemination and implementation
blueprint.

We want to, this is Harlan Weisman’s and
others’ points, build into our Strategic Plan a
more refined, and I would say now we’ve categorized
it a more refined pre-award portfolio management
strategy. The numbers, sizes, length of award and
types of awards. And in developing the metrics for
outputs, we need to consider the interaction and
crossover between outputs. So, this really is a
call for more complex metrics which are actually
sometimes to put the influence of two or three
outputs together and to look for patterns among
those outputs as we build our metrics.

Okay, in the area of dissemination and
communication, and this actually came from
discussions. Part of it came from the discussions
yesterday, the Scientific Publications Committee,
develop a strategic publications plan, and so, that
means what audiences, what messages, what papers
Today, we heard be certain that as we commission these landscape reviews, we push for publication of them and to think of communication as a change management tool. So, think about communicating change.

In the area of research prioritization, the suggestion that as one way of generating research topics, particularly big rock type of research topics, consider carving out a piece of future board meetings simply for brainstorming good research ideas. These could be linked to a consideration of proposed targeted PFAs, they could be linked to review of what we’ve already funded. But we need time for those good ideas to surface and I saw a suggestion came up offline during the meeting today that maybe even an offline process among Board members might be a good way to get that rolling.

Regarding the targeted PFAs and prioritization of those, one approach that was
suggested was to enhance the landscape data
collection before the prioritization process so
that we’ve done more of the data collection and
maybe gotten to a smaller number of more specific
topics which get prioritized, although it was
recognized that you have to balance that against
respecting the basic process, and it looks like I
got cut off in midsentence, but not undercutting
the other parts of the process that we’ve set up.
So, both approaches. The broader solicitation and
prioritization and more topics and the more
detailed landscaping before we prioritize both have
attraction. And I think really the trick for us is
working with the advisory panels and the Board to
create a balanced mutually agreed upon approach
that allows for good topics to rise to the top
quickly, but also to have a systematic approach.

In launching the landscape reviews, we
really need to be sure to standardize the request
when we send out review for landscapes, make sure
that we ask the same questions in the various
landscapes so that we get findings that can be
compared and weighted against each other.

And in terms of active portfolio management, the point was made that we need to, and it’s not easy, identify the boundary between useful involvement of staff and being overbearing or bureaucratic. So, that was a point well taken.

And from the methods discussion, we need to develop metrics for monitoring the implementation of the recommended actions. This is at a national level. And this is critically important and actually there are -- let’s see, work with the Methodology Committee to develop tools for training and supporting the Merit Review Panelists for this exercise.

So, this was a point that was made well. We heard it and we will get on with one way or another finding the staff support, working with the Methodology Committee to develop these tools for training and then supporting reviewers as they determine with each application whether it adheres to the appropriate methodologies standards.

Let’s see. Oh, so, that’s very
interesting. Somehow, these made it on and I
didn’t know I got these on.

So, this is the same topic again, this
first one. I’ve just already said that.

The second one is consider strategies, and
this was Harlan Krumholz’s point and others’,
considering strategies for increasing pre-award
support, and perhaps especially for nontraditional
researchers, the idea of an hour or two of
consultation on methods, possibly some time on
patient engagement, we really hear the message that
we need to get the examples out, we need to get
more information out to the entire research
community on what we think we mean by good patient
engagement.

We also need to analyze those applications
that don’t quite get funded, looking at the scores
and what drove the scores down. Were there some
that could be brought up maybe with enhanced
engagement? And then the last consideration,
and I apologize for the rapid and faulty note
taking here, consider setting aside a certain
amount of dollars or in some ways influencing the way we score applications to give particular note to applications that might be completed in less than three years.

So, that was what I got and I’m sure I missed some stuff. So --

CHAIRMAN WASHINGTON: No, we’re not going to open it for a discussion right now, Joe.

DR. SELBY: Oh, come on.

CHAIRMAN WASHINGTON: Okay, discussion is closed. This was for the public and we will be following up.

So, I want to conclude today by thanking all of those who joined us in-person as well as via Webcast or via the teleconference and to remind everyone that all the materials presented today are available at our Web site at www.pcori.org and also the Webcast from today will be archived and available later this week. And, finally, you’re always encouraged to provide us with feedback at info@pcori.org or through our main Web site pcori.org. And thanks again to the staff and to
the Board for your tremendous work on behalf of the institute and I will see all the Board members tonight at the reception and the dinner. We’ve had a very productive, I believe invigorating day and thanks, everyone.

[Whereupon, at 5:46 p.m., the PCORI Board of Governors meeting was concluded.]