PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

WHAT SHOULD PCORI STUDY? A CALL FOR TOPICS FROM PATIENTS AND STAKEHOLDERS

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DR. SELBY: Good morning, everyone. How are you this morning? You look fantastic. You look marvelous. Welcome to PCORI’s Patient and Stakeholder Workshop that’s entitled “What Should PCORI Study? Call for Topics from Patients and Stakeholders.”

So, imagine that two years ago this month, two years ago last month, you were called by the GAO and asked to serve on the board of a new research institute created by the Affordable Care Act and charged with conducting research that answered questions that patients, their caregivers, and their clinicians needed answered. That was about it. And, by the way, your institute was called the Patient-Centered Outcomes Research Institute.

That’s what our 21-person Board of Governors ran into in November of 2010, when they convened for the first time. And today is really in many ways the culmination of an amazing amount
of thinking and amazing amount of work that has
gone on since that time. Much of it done already
in coloration with people in this room and other
stakeholders representing patients, people who care
for patients, their caregivers, clinicians, health
care delivery systems, payers; that is insurers,
employers, the research community, and
policymakers. All of those folks have met with
PCORI’s board, with PCORI’s staff, with PCORI’s
Methodology Committee over the last two years
beginning to wrestle with this notion of how do we
identify the questions most critical to patients as
they make decisions, most critical to their
caregivers as they assist in making those
decisions, most critical to clinicians as they face
the fact that oftentimes today, we practice
medicine with an amazing, shocking degree of
uncertainty as to what works best. And if we know
what works best, we’re at still at a bit of a
disadvantage because we don’t necessarily know what
works best for whom.

That’s our mandate. What we need to now
is decide exactly what research PCORI will fund. PCORI has a substantial amount of money after you take out the portion that goes to HHS and AHRQ, we’ll likely have by 2014 approximately $400 million to spend on research. It sounds like a lot, it is a lot. There are an awful lot of questions out there and the legislation really gave us amazingly little guidance on what in fact would be most important to research.

So, I’m going to show you kind of what our board did in the intervening time that brings us to this date and that addresses that very question. So, this is a picture of the Board. It’s a very handsome group of people, very prestigious group of people. I say that because five of them are in the room and I talk like that. And you're going to hear from the vice chair of the Board in just a minute.

But these folks have done a remarkable amount of thinking and a remarkable amount of work and one of the first things they did and they did it just about the time that I arrived in July of
2011, they crafted this mission statement and the mission statement says “PCORI helps people make informed health care decisions and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information,” and this is the key part here “that comes from research guided by patients, caregivers, and the broader health care community.” So, that’s driving us.

It’s an inspired statement and you ask what's in a name? The Patient-Centered Outcomes Research Institute is the name we got and I think that has an amazing amount to do with how the mission came to be worded the way it is and how our activities and our strategic plan come to look the way that they do.

And it all comes down to stakeholders. The research that we conduct is not aimed at explaining some hidden mechanism of what causes disease. It is not aimed at pursuing the personal interests of a researcher or a research group. It’s not based on the last piece of research
someone did which makes the next piece of research more fundable. It has only one aim and that aim is to ask questions like what do patients need to know? What's most important for this condition? What's most important for these patients? What research is most likely to change practice, change behaviors, and improve outcomes? That’s a tough question. These are stakeholders. You're in there, whether you are a patient or a caregiver, clinician, delivery system, payer, employer, policymaker, or researcher. You're in this picture and you're in our hearts and minds.

This is what we’ve come up with and I hope that shows up. We have two different ways of getting to this research and I’ll explain both ways.

This first way is in many ways more traditional. Some people would call it the investigator-initiated track for research. We’re not interested in investigator-initiated, we’re interested in research that’s initiated by investigators partnered with patients and other
stakeholders. But here, the idea is that PCORI issues broad funding announcements and we’ve done that. We did that last May. We’re actually deep into our second cycle of these announcements so we issue broad solicitation. Send us your best ideas, they must be patient-centered, they must be likely to change practice, you must be partnered with patients and other stakeholders.

So, we issue the broad announcements. Researchers partner with stakeholders and generate the research questions. They pay attention to our review criteria and they tell us why this research question is critical to patients and why it’s likely to change practice. It comes to our study sections, our review panels. On those review panels, 30 percent of the members are either patients or other non-technical stakeholders. So, unlike a review section at NIH or AHRQ, where either 95 or 100 percent of the reviewers are scientists, in PCORI’s study sections, 30 percent of the reviewers are either patients or stakeholders.
The study sections, the review sections pay attention to our criteria, they pay attention to the applications, and they select those applications they believe are most patient-centered and most likely to change practice. We wind up with a diverse portfolio of highly specific, high priority research. That’s method number one. That’s going on and we’re not really here to talk about that much today. We’re here to talk about method number two.

In method number two, and we’re here to talk about this in part because when we launched method number one, people said this is the same old same old. This is the way that research has been done for many years and it’s not likely to change things. We do feel, as I said, that we made a number of changes in that process to make it more patient-centered and to make sure that we’ll get to high priority research.

But in process number two, we start by simply sitting down and talking to patients and other stakeholders and that’s what today is all
about, sitting down and talking about what are the questions that are most important to you, whether you represent patients or another one of our stakeholder groups. This is not the only way we intend to get this information, but it’s certainly probably one of the richest and most human ways and one of the most compelling ways to really sit together and talk about what questions are most critical. We don’t intend to sit and talk to patients one day, clinicians the next day. We think it’s much richer to bring all the stakeholders together as we’re doing today and in the name of patients and in decision-making by patients, we find the questions that are most critical and the questions that are most answerable.

So, we start by identifying questions. That’s today, generating topics. We then move onto prioritizing those topics. So, together with patients, together with other stakeholders, we decide, given that we’ve got limited funds which are the topics that are most compelling, most
likely to change practice, most important to patients? You're going to hear about that prioritization process today at noon from Dr. Rachael Fleurence.

Once we determine what are the most important questions, PCORI staff put together funding announcements, very targeted funding announcements, and they go out rather than those broad announcements, we have a set of targeted funding announcements. They go out, researchers get together with patients again and other stakeholders, create their proposals, and send them in, and, again, the review process is the same and in this case, we also get very high priority research this time targeted to the questions that patients and stakeholders have told us are the most important. That's what we're going to do today, start that process.

We're interested not only in your questions today, but we're also interested in talking about how we maintain communications with all of you. What works best for you?
One way that we’ve already put into place and gotten about 500 questions. Imagine that we have 500 questions on day 1, is one the PCORI Web site, we have a place where you can go and simply state your question. It’s quite straightforward, it’s not real structured, it’s inviting of everyone including patients to put their questions in. Those questions will be among the questions that we will ultimately prioritize and some of them will wind up turning into funding announcements. But, as I said, there are other ways and today is one of those other ways.

I want to just mention briefly that we are anxious to move toward having some of our research be targeted research. The Board recognized that even before PCORI existed, a number of stakeholder groups had come together, one of them being the OIM and fielded questions from across the country and prioritized them.

So, we went through a process, the Board instructed us to go through a process and we went through a process to look for research that was
patient-centered, research that had been recommended by other stakeholder groups, research that wasn’t already funded, that the answers hadn't become apparent in the time since the OIM report. We looked at agendas of NIH and AHRQ and other non-governmental patient organizations and funding organizations, and we ultimately came up with three topics and these are the first three topics. We have not issued these funding announcements yet, but we will after we convene an expert stakeholder advisory group to talk about each one, we will release our first targeted funding announcements and they will be in these three areas.

Options women face when they are suffering from symptomatic uterine fibroid, so, a very common condition in women as they approach menopausal years, causes a lot of pain, causes a lot of missed time from work, interferes with family life and social functioning, and there are a number of treatment options, including some new high-tech treatment options and the answers are not yet in on what works best given a particular woman’s personal
situation. So, that’s topic number one.

Number two, the safety and benefits of the treatment options for African-American and minority patients with severe chronic asthma. So, again, asthma is a very prevalent disease. It leads to a lot of morbidity, it leads to mortality. It particularly leads to mortality in African-American and other minority populations and there are some treatments that look like they may, in fact, although they work in majority populations, may have some particular adverse consequences. So, the safety and benefits of various approaches to treating severe asthma is topic number two.

And falls prevention in the elderly, a very common event, often the event that signals the end of an independent and productive life. Much work to be done in figuring out what can a health care system do to prevent falls in the elderly and who is the target population among people 65 and above? Who’s the target population?

So, there I have given you the first three targeted topics that PCORI is going to release
funding announcements on, but your job, our job
today is to come up with the next 10 or 15 of
those.

So, I’m going to stop and before I
introduce Susan Hildebrandt, our director of
Stakeholder Engagement and the mastermind behind
today, I have the pleasure of introducing the vice
chair of the PCORI Board of Governors, Mr. Steve
Lipstein. Steve is from St. Louis, and he is the
CEO of BJC Hospitals. That includes the Washington
University Hospital complex and hospitals scattered
throughout the Midwest and south and Steve is a
real force on the Board and a good friend and he’s
come from St. Louis to add the welcome of the Board
this morning.

[Applause.]

MR. LIPSTEIN: Good morning. Just
curious, how many others of you have come from west
of the Mississippi River? You're all on that side
of the room, okay.

[Laughter.]

MR. LIPSTEIN: Good, welcome. Well, I’m
glad you're here this morning and on behalf of our Board of Governors, I wanted to just say a few words and welcome you. I also would like to share with you that, as Joe pointed out, we are in the second year of our journey with PCORI and this is a very exciting time for us and this is a very important meeting that we're having today. And so, what we're asking you to do in participating with us to identify some of these key areas of investigation and research is really important and I’ll talk a little bit more about that in a minute.

But, first, let me introduce -- as you know, we are a stakeholder board and we came together. Many of us hadn't met each other for the first when we got together two years ago, and so, if I can, just because we are representatives, where is Larry Becker? Larry. Larry is an executive with Xerox Corporation, and so, Larry is representing many of the employer stakeholders who are interested in patient-centered outcomes research.

Debra Barksdale is right in front of me.
Debra is a professor of nursing. I always have to point this out -- at the University of North Carolina at Chapel Hill. I went to Duke, so, this is a challenge.

[Laughter.]

MR. LIPSTEIN: But Debra’s a professor of nursing. I saw Harlan Weisman. Harlan is a physician, cardiologist. He and I actually started out in our youth together at Johns Hopkins Hospital many years ago, but Harlan was formerly of Johnson & Johnson and brings both a scientific and a pharmaceutical perspective to our work.

Gail Hunt. Is Gail here yet? Gail in the back is the CEO of the National Alliance for Caregiving and represents caregivers as a stakeholder group within our board as well as one of what the statute refers to as our consumer representative.

And then Ellen Sigal will be here later this morning. She’s not here right now, but Ellen is the founder and CEO of Friends of Cancer Research. And so, we have some other perspectives
on the Board that are more disease-focused.

So, we are a stakeholder board. As Joe mentioned, I come from BJC Health Care in St. Louis, which many of you may recognize names like Barnes-Jewish Hospital or St. Louis Children’s Hospital and at the place where I work, in our organization, we admit about 3,000 patients a week to our hospitals and we see about 20,000 patients in our outpatient environments. And so, when we talk about getting specific with the research agenda for PCORI, I always think about the who, not just the what, were the topics. So, who are the people that are going to benefit from our research agenda? Who are the people that are going to be included as we get more specific and we identify key areas of investigation?

So, as Joe mentioned a minute ago, many women patients who suffer from uterine fibroids will be among the first beneficiaries of our work. Many of our more vulnerable patient populations and our minority populations who suffer from asthma may be the first beneficiaries of our work, but one of
the things we’re asking you to help us with today is to really focus in on our research agenda and our priorities as we get more and more specific in the coming timeframe.

So, I welcome you, I can't overemphasize enough the important role that you play today. We are going to work you hard. We have had workshops like this before and I can tell you it’s a long and exhausting day, but I hope at the end of it, you will find it as meaningful as we do in securing important stakeholder input into the work of PCORI. So, again, thank you, all, for being here today. We look forward to working with you.

[Applause.]

DR. SELBY: Thanks, Steve, and I’ll just say in closing that whenever we have one of these events, it always turns out that at least five board members show up. They drop what they're doing in their jobs. I guess, Steve, you don’t have a boss, really, so, I don't know what their bosses say back home, but they're here and we’re most appreciative. It makes the board meetings
that much more interesting because they've actually been here and seen this happening.

Okay, I’m going to now turn it over to Susan Hildebrandt, who, as I said, is our director of Stakeholder Engagement. She came to PCORI from the American Academy of Family Physicians and she has the very interesting job of developing and growing and maintaining relationships with every group of stakeholders except patients and caregivers and that’s Sue Sheridan’s job.

Where’s Sue Sheridan? So, many of you have met Sue Sheridan. Sue sort of manages our connections to patients and patient advocacy organizations, caregiver organizations, and Susan gets all the rest of you.

So, without further ado, here is Susan Hildebrandt and thank you, Susan.

[Applause.]

MS. HILDEBRANDT: Welcome and good morning. I’m absolutely delighted to see all of you here today for this workshop and also enjoy meeting and speaking to a number of you last night,
hearing your stories, what brought you here, that sort of thing. We really appreciate it.

I just wanted to quickly mention three things, tell you how else you can get involved in PCORI outside of this workshop. We are really seeking to build a PCORI community, and so, I’ll talk to you in a bit about that.

Second, let me just kind of reemphasize the purpose of today’s workshop for you and then, third, also want to thank the Planning Committee members who really also were the other masterminds behind this workshop.

So, PCORI really has been involving stakeholders in four key ways. As Joe indicated as well as Steve, we think of stakeholders as really anybody who is interested in PCORI or could potentially be affected by our results and that's all of you in this room. So, we’re delighted to have you.

So, we’ve been getting stakeholders involved in topic generation, what should we study? Of course, that’s why you’re here today. Secondly,
actually reviewing our funding proposals, helping us share our findings and, again, always telling us what we’re doing.

Let me just talk a bit about those in a little more detail. So, you are here and the first way that we involve stakeholders is, again, getting your research topics, and, of course, that is really the purpose of the workshop today. And so, your involvement is absolutely key. We hope that with your topics, we can put them into our prioritization process and then ultimately make them into some sort of PCORI-targeted funding announcements.

Second way you all can get involved is review our funding proposals. That means sitting around a table with other scientists, stakeholders, patients, and others and looking at the impact and what I mean by that really is does this research proposal make sense? Would it make a difference to me as a patient? Would it make a difference to me as a clinician? And that’s what we are trying to do which is different about PCORI.
I actually attended the stakeholder review of the proposals a few weeks ago and was really struck by the fact that the scientists, the patients, caregivers, and others really sat around the table and discussed the proposals on equal footing. There was a real sense of community and a real shared vision. And it was a tremendously exciting experience. So, I thank those of you who have already signed up to be reviewers and I urge the rest of you in the room to do so, as well.

Similarly, you all can get involved in forming research partnerships and we really want to answer your questions, your research questions. We want to answer questions that are relevant to patients, clinicians, and others, and the way we’d like to do this is involve you at all steps of the process. So, that means things like determining the research questions, as we have indicated today, but also really helping us define the key characteristics of the individuals that should actually participate in the study.

A third way to get involved is helping us
get the word out, dissemination, and I think everyone in this room would agree that we want to shrink the gap, shrink the 17-year bench to practice gap. And we are deeply interested in this issue. How do you communicate? How do you disseminate? How do you get uptake of your results? And, as you know, one of our funding announcements is actually on that very subject. And we think that stakeholders like you would actually be very interested and excited about doing that if we can produce information that is relevant to patients.

So, really, the fourth way to get involved is to give us feedback. We are continually seeking information and input. We really pride ourselves on being a learning organization, and so, we are always evaluating our activities. So, after this workshop, probably the moment you are walking out the door and breathing a sigh of relief, you’ll get an e-mail from us asking you to tell us what you thought. Did you learn something? What did you like, what didn’t you like? What can we change?
And we really urge you to take this very, very seriously because we will. We will take your information and input and that will help us improve or change future events at PCORI.

So, as both Joe and Steve have said, you're here today to give us research topics. We would also like to get your thoughts on engagement with PCORI and then we’re going to give you kind of a sneak peek about our draft prioritization process and that really answers the question of what are we going to do with all these topics that you give us with all this information that you generate? Well, we’re going to put them into our prioritization process, so, we’ll explain what that is, actually do kind of a mock walkthrough in terms of how that works, and then, of course, invite your feedback.

So, I need to conclude by thanking all of the other masterminds on the Planning Committee. I’m going to embarrass all of you and ask you to stand when I read your name.

So, I’m going to start with Andrew Baskin, Ann Caldwell, Lynne Cuppernull, Maureen Dailey,
Nancy Foster, Andrea Garcia, Jennifer Graff, Helen Haskell, Dan Leonard, Jennifer Meeks, Jennifer Phillips, and Sylvia Trujillo. Thanks to all of you and I really deeply appreciate all of your assistance.

[Applause.]

MS. HILDEBRANDT: I am now going to turn the meeting over to Jonathan Peck and Marty Hatlie, who will give you more details about how we will be handling the rest of the day. Thanks.

MR. PECK: Thank you, Susan.

So, Marty and I are going to be playing a role of co-facilitators throughout this session and first, I want to get you oriented to what we’re going to be doing. We’ll be in the plenary session until 10:30. We’ve got to break then and then we’re going to go into the small group sessions.

So, each of you have signed up for two small group sessions, and they’re going to be facilitated by PCORI teams and we’ll have those go through noon and we’ll have lunch with a talk from Dr. Fleurence. And then we’ll go back into the
second small group session after the break. And we’ll have another break along the way. Then we’ll go and we’re going to hear feedback at 3:00 from the small group sessions.

So, the session leaders will present kind of an overview of what we’ve learned from you through the day and that’s when we’ll move towards a final how do you prioritize? So, Dr. Kara Odom Walker will go through the PCORI priority process and then Dr. Anne Beal will give our closing remarks. So, that’s the overview of the day.

This morning, after you’re sort of oriented to how we’re going to work together, we’ll have a panel come up of different stakeholders and Sue Sheridan and Marty and I will be co-moderating. You’re going to hear what does success look like? If you go to the seven years that PCORI’s been funded for, at the end of those seven years, what does success look like from the perspective of the different stakeholders? So, we’re going to have about a 45-minute panel centered on that and then a 45-minute discussion with you so we can get your
views of what does success look like for PCORI?
And then from there, we’ll move into the small
group sessions.

MR. HATLIE: And, Jonathan, we noticed
last night that there are a handful of people here
from our first workshop, too. So, they’ll be kind
of a bridge in that panel between that workshop
which was about a month ago and this workshop. So,
it’ll be great.

My job now is to cover the roles, which
are pretty basic and we do want to hear from as
many people in this room today as we can hear from.
So, please don't kill the messengers if we are not
picking the person whose hand is always up first.
We really want to hear from you, but we also want
to hear from the people who are a little less
likely to jump in first. And don’t worry about
that, that will be our job to kind of keep the
carosonversation flowing. But all of your input is
important.

We do have to stay on time. I mean,
that’s our main job. So, we’re going to ask for
your help in helping everyone stay on time and
then, of course, if you could turn off anything
that makes noise. So, all electronic
communications, all of those things that keep us in
touch with the real world, if you can kind of
distance yourself from that a little bit today and
just kind of turn that off during our session so we
don't distract others. And those are the basic
rules, Jonathan.

MR. PECK: Great. Thank you, Marty. And
so, we're going to have lots of breaks where you
can turn those little devices back on.

Just so you're prepared for the small
groups sessions, which is where each of you really
get the most airtime, if you will, that there,
you're going to get quickly oriented, teams of
facilitators. You've got assigned rooms. The key
here is your recommendations for research topics
and that's the key to success for today's meeting,
that we get to hear your thoughts about what PCORI
should be looking at for research topics. Then we
also want to find out from you how you see your
organizations using comparative effectiveness research. And then we also want to learn from you what are the best practices, what’s worked best. So, this is our opportunity for PCORI to learn from you and that’s the key through those.

So, without further ado, let’s bring Sue Sheridan up and we’ll bring our panel up. Helen Haskell, if you would come join us. Thank you. Greg Biggers and Pat Quigley. Dan Leonard. Ardis Hoven and Rebecca Culyba.

[Pause.]

MS. SHERIDAN: Like Jonathan mentioned, I am Sue Sheridan. I am the director of Patient Engagement at PCORI.

I’d like to welcome the panel to the stage. I have, like Joe Selby said, the pleasure of working with patients and patient organizations, caregiver, caregiver organizations to bring their voice, their collective wisdom into the research enterprise and it’s actually a really exciting opportunity. I’ve had the privilege of witnessing the power of partnership between patients and
researchers and the nursing organizations and
physicians and industry to really drive change.
And so, I can say I have seen it work.

So, as we welcome this panel, actually, if
you look in your bio books and realize where they
are all coming from, this is really a dream team.
I mean, just imagine what we can do as a research
organization and as a group of stakeholders,
imagine what we can do in the research enterprise.
I think it’s very powerful.

So, I’m thrilled to be here and I’m eager
to hear about the vision that this panel has on
what is success in Patient-Centered Research and
Patient-Centered Outcomes Research and comparative
effectiveness working as partners.

So, I’m going to start with I believe
Helen Haskell, is our first to share her vision.
Helen is a mom and she is a nationally renowned
patient advocate. She and I have grown up together
in the patient safety world. So, I welcome Helen.

MS. HASKELL: Thank you, Sue. Well, as
Sue said, I am here as a mom. I have an
organization called Mothers Against Medical Error and I am also here as a representative of CUE, which is the consumer arm of the Cochrane Collaboration which has training for patients, education, and learning to interpret scientific studies which is an indispensable part of this that we should not forget about.

So, I want to start with thinking about the PCORI mission statement because I think that’s actually one of the best mission statements I’ve ever seen. Helping people make informed decisions and improve their outcome delivery and outcomes to evidence-based information derived from research guided by patients, caregivers, and the health care community. This is the foundation of good health care. And I think what we’re trying to do here is to transform health care from the inside out by going right to the most fundamental aspect of health care, which is what we do and why we do it.

I’ve been in patient safety and quality for about 12 years now. I’ve worked with a lot of medical error victims and with providers and what I
have concluded over all those years is that it really all comes down to the research.

    My son died from complications to the procedure that he should not have had. And in many areas, including that procedure, research doesn't address the important issues. It doesn't ask the right questions. It is not correctly interpreted and it's not properly disseminated. And the result all too often is expensive, fragmented, ineffective care that's serving the aims of someone other than the patient and patients are often left bewildered as to what is best and safest for them to do. So, that's what PCORI is all about, asking the right questions for the right reasons, and only patients can make that happen because patients are the reason for research.

    So, what will PCORI do if it works as it's supposed to? The first thing is it will change the power gradient. Paternalism, which is the dangerous idea that patients don't know enough about their own health to really say what they think or what they think should be done will be
affected, hopefully will be turned on its head.

Overtreatment, overuse, overpayment, if we focus on outcomes that patients want, we can take on the big challenges that are facing health care today. We can only have good health care if we have solid Patient-Centered Research. And once we’ve mastered the patient-centered aspects of research, Patient-Centered Outcomes Research has the power to change the way that health care is delivered. We should not take our eyes off that goal. Research must have a point. It shouldn’t just be knowledge for its own sake. It is not enough to find the truth; it needs to be a real truth. It needs to have real benefits that get to real people who need them and that’s where PCORI can take us. Thank you.

[Applause.]

MS. SHERIDAN: Thank you, Helen.

I’d like to invite Greg Biggers to the podium. I met Greg at the Patient Engagement Workshop a month ago and his spirit, his energy, and his vision of partnership was compelling, so,
we wanted to bring him here to share his message with you.

MR. BIGGERS: Thank you, Sue. So, in addition to the three organizations named in the biography, which you can just peruse it at your own leisure, in addition to representing these organizations, I’m also a patient with vitiligo, thyroid disease, back pain, and possibly some other kind of autoimmune mysteries that we’re still investigating. I’m a caregiver in areas including stroke, spinocerebellar ataxia, mental illness, and child development. I’m a parent. I’m also an advocate. I love helping others be heard and I often try to represent many others, but I think today at a time when many of us are trying to represent larger groups, it’s helpful for us to remember that none of us can ever do that truly and completely, that even when we are our best advocating selves, there will always be voices that are not being heard. And I think that should give us pause and that should be a context for everything that we do today.
So, what does it look like when PCORI is successful? What does it look like when we get Patient-Centered Research right? We think of four things.

The first one is all involved parties self-identify as we. We think that we are doing it, not you are doing it, not me doing it, not them doing it, but it is we. When I stand at the sidelines as a patient and refer to some of you as you, when we other one another, that undermines sustainability of what we’re doing.

So, language and roles really matter and we’re seeing a continuum of enlarging roles of the patient in research. We’re seeing a continuum that stretches from unwitting subject to willing subject to participant to collaborator to shareholder in the research endeavor. So, language and roles matter and when you think about how we’re going to refer to one another as patients, well, you refer to as subjects, patients, participants, or how about partners, collaborators, shareholders, maybe even investigators. That’s how we express it is we
doing this research. So, that’s number one.

    Two, patients are and feel like collaborators at every step in the research project, so, not just occasional advisors, not just boxes to check, but actually involved. So, we want to see less of we have designed a study for question X and now we’re looking for some patients who sign off on it and much more we have a group of people including patients who are designing a study about question X and let’s go do this. That’s number two, collaborators.

    Three, patients are spreading the word. Because we had ownership at every step along the way, patients are spreading the word about the results of studies with vigor and sometimes maybe even often, patients are authors or even investigators in published studies. That’s three, patients are spreading the word.

    And then four, we have a sustainable culture of deep collaboration in this culture is spreading, replicating, affecting all of health research, even outside of PCORI and PCORI-funded
projects because we believe we’re at an inflection point in the history of human health research. And if the PCORI community, if we seize this moment of opportunity, we will have dramatic effect on the future of research for years and years to come.

So, those four things: the involved parties self-identify as we, patients are and feel like collaborators at every step, patients are spreading the word, and, four, we have a sustainable culture of deep collaboration. So, we think that those four things can be, we hope they will be PCORI’s gift to the world not just getting great research done, but also a sustainable way to do research because patients are at the center. A few things to think about.

[Applause.]

MS. SHERIDAN: Thank you, Greg. I’d like to invite Pat Quigley who is representing the American Nurses’ Association. I’d like to let you know that in your bio book, there was an incorrect reference to the organization that she’s with and I just want to say, Pat, thank you and I’ve also had
the opportunity and privilege of witnessing the
power of nursing in research and you're a bold and
energetic profession that we need more of.

MS. QUIGLEY: Thank you. Thank you so
much. Thank you. And thank you for having us be
part of this dream team. Really, this dream team.
What a great day to be in this nation’s capital to
really address patient outcomes. And thank you for
correcting in the program that I am not with the
Mothers Against Medical Errors, but certainly
patient safety is indeed our world.

So, on behalf of that to bring you
greetings on behalf of the American Nurses’
Association and Dr. President Karen Daley, Dr.
Maureen Daley, as well, who’s here, a senior policy
fellow on ANA. We thank you so much for this
opportunity to be able to participate in this
dialogue. Rich in our ability to be able to really
inform the research that is being directed to help
with patient and caregiver, patient-centered
outcomes.

The American Nurses’ Association is the
only full service professional organization representing the interests of the nation’s nurses, the single largest group of health care professionals in the United States. Our membership includes direct care nurses, advanced practice registered nurses, nurse educators, nurse administrators, nurses across all settings, military, civilian.

In a patient-centered system, it is essential that the information and communication techniques are leveraged to engage the patient’s ability to make thoughtful, informed decisions about approaches to diagnosis, to treatment, to stay well, to manage chronic illnesses, and to experience optimal end-of-life care. The ANA’s vision for patient-centered care is a health care system in which teams embrace empowered patients who identify the care goals to own and manage their own care. Patient-Centered Research is needed in interrelated areas of care coordination, patient engagement, and safety to identify the team’s best practices in a learning health care system.
First, care coordination. A priority area of research to inform pathways to Patient-Centered Outcomes to improve care coordination is essential. The ANA has identified key care coordination competencies as well as gaps in research and effective quality measures such as in primary care and preventive care and the care of those with multiple chronic conditions as well as functional changes that occur with aging. Nurses view there are patients as deep and full partners in only their own care.

An example is daily care planning that is being done in the Department of Veterans’ Affairs, where patients and caregivers come together to talk about what are our goals, what’s our plan today, how can we achieve these goals together? And, beyond that, we need to ensure that there are processes to support critical paths that are really guided towards effective and Patient-Centered Care using Electronic Medical Records. How can we best utilize Electronic Medical Records to really fully engage patients as owners in their care? And this
needs to be an interactive engagement of patients throughout all of their care settings and the continuum of care.

So, the ANA’s vision for the design implementation, evaluation, and dissemination of Patient-Centered Outcomes Research really needs to address a reducing of disparities, improving care and access across all settings, self-care management, and patient safety. Patients and caregivers can inform and be needed and really drive the research that’s needed to help us best team communication practices so that we can empower our patients to truly own their care. And this will require that we address fully health care literacy. In addition, how to be able to address socio and economic and cultural barriers, as well as removal of the power gradient that exists between patients and caregivers and health care team members. So, the American Nurses’ Association believes that this research must address really prioritized areas throughout the entire episode of care.
In addition, our secondary that we’d like to help really draw this patient engagement. Nurses are uniquely positioned as proximal caregivers at the point of care in all settings of care to engage patients and Patient-Centered Outcomes, another key area, patient engagement. Nurses as interdisciplinary team members can engage patients to accurately access their own symptoms. Patients can be involved in reporting their own outcomes, their own symptoms related to pain, fatigue, maybe conditions, functional status, aging, urinary incontinence, and patients conduce kind of reporting with reliable and valid tools to be able to really be engaged as a full partner in their fall prevention program.

And then as well as safety, to really help patients be able to be totally engaged in their patient care environment, advocating for our health care providers to wash their hands, safely dispense medications, and to learn how to be able to prevent falls not only in hospitals, but after discharge. What are the best practices to be able to help
this?

So, the American Nurses' Association is so honored to be part of this and our vision is, indeed, Patient-Centered Health Care System where patients are full partners in their care, that patients own their care, patients value health, not just the health of today, but to have a healthier tomorrow, and that we all understand our roles in being able to help this be achieved for all those that we serve. So, thank you on behalf of the American Nurses' Association.

[Applause.]

MS. SHERIDAN: Thank you, Pat.

I’d like to welcome Dan Leonard, the president of the National Pharmaceutical Council. A part of our health care system that helps people in chronic pain, with disease management, we welcome you. You are an important stakeholder here to share your vision in Patient-Centered Outcomes Research.

MR. LEONARD: Thank you, Sue. And, yes, indeed, it is nice to be here. Thanks, everyone,
for coming and Sue mentioned just a couple of areas in which our member companies are the primary pharmaceutical companies in the world, they're involved in every disease state that's represented here in the room and beyond, and so, we're going to be relatively agnostic as to what PCORI should study, but we'll be exuberant cheerleaders when it comes to saying yes, get out there and study these questions and we’ll be very involved in talking about how the research is done.

So, my organization represents, yes, the pharmaceutical industry, but more specifically, the scientific side of the industry and the health outcomes research organizations and our companies play a big role. So, how the research is done and conducted is very important to us.

And in any setting like this, there are challenges and opportunities that are in front of us and you can say that really about anything in our society, but if you think about an aging population, that’s a great thing to have, the fact that people are living longer. This is a victory,
but it creates challenges and it generates challenges in caring for those older Americans.

And we have this great technological boom. We’ve talked already about Electronic Medical Records and the importance that they will play, the human genome being understood more robustly. All of these technological breakthroughs are great and will create much more information. But more information isn't always better information. So, a key will be harnessing that information and understanding and using it for good.

PCORI specifically can have an important role and will play an important part in ensuring that we are equipped for this environment of tomorrow and that we can improve the quality of health and health care that’s delivered and probably most importantly, improving the health care decision-making that takes place between the physician and the patient because that’s really at the end of the day what this is all about.

As I mentioned, my organization is very involved in the health outcomes side of the
pharmaceutical business and we are ready and willing, there are folks in our companies that do outcomes research and study the promising medicines of tomorrow every day. So, we want to be a willing partner with PCORI going forward, and so far, the relationship has been just terrific.

So, three things that I really want to stress, and in a previous call with Jonathan, he said paint a picture of the land flowing with milk and honey, right? So, in the 7 to 10 years out, what is the ideal situation that PCORI could find itself in and what positive developments will we see? So, I took him up on that.

So, in the land of milk and honey from where we stand, first, health care decisions are more about the individual than about the masses. It’s more individually focused. It’s very easy for research to devolve to answering questions about large populations or about averages and none of us in the room are average, we’re all above average, of course, right?

This is Lake Wobegon, of course. But
getting beyond averages and finding out what really
works to the individual patient.

Now, we had a meeting just a couple of
days ago and one of the things I learned at that
meeting because it was on this topic of “The Myth
of Average” and Joe Selby was there and he made a
very good point, which is that to get to the
individual, sometimes you have to find out what
works for the population first. So, it’s not a bad
thing to be asking questions that work for the
larger hole or the average, but it’s going to take
that and then drilling deeper and drilling deeper
until you find answers for the specific individual,
what works for that individual. And that's what
patient-centeredness is all about. So, I applaud
PCORI for putting patients in the process at the
beginning and the middle and the end during this
whole exercise. Because what works best for the
average will not always be what works best for the
individual.

I think the key, and what I’ve referenced
it up top, is where we are now with technology, and
to get to treatments for the individual, it’s going
to take an understanding of the whole. So, big
data, the larger that we can utilize in the
research, the Electronic Medical Records, records
from CMS and from large databases. It’s going to
take big data to answer small questions, to be able
to get down into those individual questions and
what works best for whom. Its’ going to take the
robust technology that’s becoming available to us.
So, that’s point one on treatment for the
individual.

Point two would be related to that, but
it’s real-world evidence in how different types of
research can be used to answer these questions.
And the pharmaceutical industry for many, many
years, it’s been all about randomized controlled
trials; you take one population and pit it against
another to find out what works. That is not going
to be a practical solution for much of PCORI’s
work. It may be for some, that’s yet to be
answered, I think, but for much of the work that
PCORI will be doing, it’ll be in different types of
research, observational research, registries, database studies.

So, understanding, having a clear set of standards as to what is good when it comes to that type of research will be important. Particularly when it comes to observational studies, there are many out there. Many are good, many are not so good. So, getting a clear set of standards or rules of the road when it comes to this type of research will be important to making sure that when that research is done that is recognized and accepted by the research community as solid research and it’ll get the buy-in from the physician community going forward. So, that’s point number two.

Point number three is on the communication and the dissemination aspect of things. At the end of the day, it could be the best research on the planet, but if it’s not getting into the hands of the clinician who needs it at that moment when he or she is talking to their patient, then it’s of no use. So, how can PCORI take this robust
information and get it to the right place at the right time and making sure it’s easily accessible, breaking down that 17-year gap that Susan referenced between bench to bedside, shrinking that, but also shrinking the chasm in the language? So, if the research is written for an academic audience, a clinical audience, it may not make any sense to the patient who really needs it. So, there’s also a chasm in the language that needs to be used when you’re disseminating this information.

So, and the third part with regard to communication is the sort of the who, what, when, and where. Who can speak about this research and when is it appropriate? With all of this new technology and information and the Internet, anything you can search is up there, but how will PCORI’s work stand out from the din on the Internet? And, also, will PCORI’s research stand on top of the shoulders of research that has come before it so that it’s building on the already existing evidence base. That’s an important part.

So, those are really the three points that
I wanted to make and as we look forward to the land of milk and honey is that the research that’s relevant to the individual, that new types of research, real-world evidence as we call it, is utilized in an appropriate fashion and standards are set so we can all salute it when it comes out, and, three, that the communication that takes place is appropriate and gets to the physician and the patient in a timely and efficient way.

So, thank you very much for having me.

[Applause.]

MS. SHERIDAN: Thank you, Dan. The land of milk and honey, wow.

I would like to welcome Ardis Hoven up from the American Medical Association who represents the clinicians who are those making important, sometimes difficult decisions with their patients. This is a really important partnership that PCORI recognizes. This is why we’re doing research to provide this critical information to the clinicians and the patients and caregivers and other stakeholders to make these tough decisions.
I recall Ardis at our very first stakeholder engagement event. She talked about the importance of partnership in the dissemination to make sure that we disseminate our findings from the clinician throughout the whole system, including the patient. So, I welcome Ardis to share your vision on the future.

DR. HOVEN: Thank you and good morning. I’m delighted to be here and participate in this very good activity.

The AMA has been a consistent and vocal advocate and supporter of comparative effectiveness research. Our support has been rooted in the belief that comparative effectiveness research should build the clinical evidence base of medicine and inform clinical decision-making so that physicians are better equipped to provide patients with recommendations on the best diagnostic and treatment options and by extension, support patient-informed decision-making. I, we, all the members of the health care team need reliable evidence-based clinical information that is readily
available at the point of care and relevant to the specific needs, preferences, and insurance coverage options of our patients.

In this setting, one size does not fit all and it is something we must consider. In our view, a surprising success of PCORI would not be simply the identification, but rather the widespread adoption of the best in class infrastructure that facilitates the uptake of the highest quality and up-to-date clinical information to inform and support physician decision-making at the point of care during a physician-patient interaction.

Physicians need information that is intelligently and intuitively organized that is part of their regular workflow, and most obviously relevant to the specific health needs of the patients that they are seeing.

The most pressing challenge for PCORI is not identifying the relevant and important research priorities and conducting such research, this is being done in lots of areas, which was mentioned earlier. But their work needs to continue and we
do support PCORI’s work in areas where there is significant health burdens such as chronic conditions. We’ve already seen the first level that is going to be discussed. This is very important. But the greatest achievement of PCORI would be providing research findings rapidly and I’m talking about diagnostics, therapeutics, prevention strategies, and even health care delivery methods to physicians and others in ways that are relevant at the point of care, in my office with a patient, real time, intuitive, and part of my workflow.

We strongly support the use of clinical registries, which not only provide information in a rapid cycle to practicing and treating physicians, but enable rapid feedback on pressing research needs relevant to practicing physicians. We support efforts by PCORI to develop a viable and ambitious strategy to scale up infrastructure, to support uptake and application of comparative clinical evidence. These efforts should be integrated into infrastructure that would
facilitate access to information that promotes a learning health care environment at the point of care across a broad spectrum of areas, including genomics, quality measurement, combatting prescription drug abuse, prevention screening, for example, and many, many others.

PCORI needs a thorough and creative view of the role of new technologies, which has been mentioned, that could simplify and enrich the quality of information at the point of care in addition to building on the evidence generation that can be used to inform clinical decision-making. Physicians want to support their patients and their decision-making and to promote the best outcomes. We believe that equipping physicians with the tools to serve as navigators and learned intermediaries would be a surprising and much allotted success for PCORI. The questions are: How do we do this and what are the tools that we are going to need? Thank you very much.

[Applause.]

MS. SHERIDAN: Thank you, Ardis.
I’d like to now welcome Rebecca Culyba to the stage and I want to point out that you received a new bio that’s on your tables. We referenced her being with a different organization. So, Rebecca, please join us.

MS. CULYBA: Thank you. My name is Rebecca Culyba and thank you to PCORI and to the Alliance of Community Health Plans for inviting us to be here from the UPMC Center for High Value Health Care.

Our center was established in 2011 as a non-profit within the UPMC Insurance Services Division. We’re just a subsidiary of UPMC located in Pittsburgh, Pennsylvania. It’s one of the nation’s largest integrated health care delivery and financing systems. The Insurance Services Division has a range of products: Medicaid, Medicare, commercial, children’s health, behavioral health, employee assistance. Their products and services reach nearly 1.4 million members and as such, as a regional, integrated service delivery financing system, have had a long relationship with
ACHP and really have strived to be a role model to other regional and community health plans and being on the cutting edge of innovation to transforming health care and addressing the triple aim.

So, our center, founded very recently, really aligns ourselves with that mission, to be on the leading edge, and we really believe actually that engaging patients and other stakeholders in our community is a requirement of that, and so, we appreciate PCORI because it supports our work and it supports our work currently because it’s not always -- well, our mission is to integrate research practice and policy and we collaborate with the university, with our provider network with the hospitals, and so, Jonathan asked us to look ahead for 5 to 10 years and what would success look like? And, to us, we think that it will be successful because we aspire that to reach high-value health care that’s not defined just by economics, but is also through the engagement of patients, local and state governments, community-based service providers, and clinical practices so
we can focus on technology, therapeutic approaches, and system level change. And as we do this and as our analytics and program evaluation that’s coming from a payer becomes more sophisticated, disparities rise to the surface, it shines the light on addressing disparities. And so, we believe that in 5 to 10 years, that will also be something that we’re successful on.

And we know that PCORI is not mandated to address cost-effectiveness, but as we partner with payers, we know that the results of comparative effectiveness research can be integrated into the marketplace which can increase the pace of translation. So, I just want to thank you for having us here today and look forward to the discussion.

[Applause.]

MS. SHERIDAN: Thank you, Rebecca, and when I introduced you, I failed to give you your correct institution of the University of Pittsburgh Medical Center. So, thank you, and I just wanted to make that reference.
So, we are now done with the dream team vision and we're going to move into just some dialogue to look at where maybe there are some overlap and some topics that we might want to highlight. And something that really stuck out to me was when Greg introduced the new we and PCORI is now trying to develop this new we, and so, I would like to ask the panel if you could address how does PCORI develop the infrastructure and support to create this new we in Patient-Centered Outcomes Research? Any volunteers?

DR. HOVEN: Do you want me to turn my --
MS. SHERIDAN: Yes, do we have --
DR. HOVEN: Am I on?
PARTICIPANT: You're on.
DR. HOVEN: I've been called wired before, but this is the actual literal translation.
I think the whole -- and I sort of touched on it a little bit as I started talking about I, we, and all the members of the health care team is a first bridge, if you will, to beginning to have this conversation. And from the provider side, the
clinician side, this is a big shift, I think, to the first step in the “we.” The next step in the “we,” obviously, is the bridge to the patients, their families, their supporters, and care, and I think we have to be very careful as we talk about patients, we can currently address the issue of the family member, the health care surrogate, the whomever is involved in the decision-making for that particular patient so that it’s not just a patient, it is that team care. So, I think that’s a logical first step as we begin to talk about it and that we include this in our dialogue in every venue we’re in.

MS. SHERIDAN: And can the panel address maybe how PCORI can help facilitate some of this? How can we help create this new “we” as a research organization?

MS. QUIGLEY: May I?

MS. SHERIDAN: You may.

MS. QUIGLEY: I think one other suggestion is to really, really examine how to engage --

MS. SHERIDAN: Do you want to come up to
MR. PECK: I think the rest of us need to turn our mikes on. There's a little switch on the console here.

MS. QUIGLEY: Thank you so very much for that help.

[Laughter.]

MS. QUIGLEY: I’d like to suggest that I think one of the strategies is to really look at what is interactive patient engagement? I hope everyone can hear me now.

PARTICIPANTS: Yes.

MS. QUIGLEY: Traditionally, care planning processes really have been owned by a team. For example, in nurses, we have nurses’ process, nurses’ care planning, but how do we really, really transform that into patients’ goal-setting and we look at how do we really merge and make sure that the patients’ goals are really considered what's important to them based on their preferences and how to really have that be a driver and then how to help them integrate.
So, I think really getting into based on socioeconomic status, cultural preferences, the whole spectrum that you have addressed is how do you really transform the interactive engagement of patients that it is that we do ask what's important to them? What are their goals? What do they want to accomplish while they're here? And then we can always talk about the disease issues, the health care management issues, the functional status issues to improve their safety, but what's really important to people? How can that be the first question that we ask patients when they come into our care? What is it that you want to be able to achieve to be as independent as you can be and as self-sufficient and as productive within your family and your society as you can be?

And I think that that would be really transforming is to put that question first before we do other kinds of initiatives. So, I think if you could help as PCORI to really help patient-centered and patient preferences become one of the top priorities, certainly beyond someone who’s
really acutely ill, but really when we’re dealing with preventive health primary care, how can we help that be one of the top priorities? What's important to you?

I know in the world of rehabilitation, fall prevention, and even in health literacy, patients prefer to be involved, patients prefer to have a team sit down with them and talk with them, to spend time with them, and to really engage them. So, I would like to suggest that that really emerged to a top priority is how to really make them full partners and ask them what's important to them.

MS. SHERIDAN: Thank you, Pat.

Greg, did you have anything to add?

MR. BIGGERS: As you know from my brief opening remarks, we think that part of the PCORI opportunity is about the culture of research. And so, we think there's a concrete opportunity in PCORI facilitating this new kind of “we” about investing in some cultural context setting and even focused training. And this is true we think for
the whole ecosystem.

So, researchers probably could use some actual cultural training about what is it like to partner with somebody that you used to call a subject? A likewise on the patient side, many of us need some help, need some guidelines about how do we get in the trenches in something from which we felt outsider for so long?

MS. SHERIDAN: That’s a great point, and PCORI is looking at opportunities to do training in the future, to look at the cultural environment.

MR. BIGGERS: Yes, right.

MS. SHERIDAN: I know there are researchers out in the audience who have partnered with patients and I think if we reach out to that population, we could learn a lot and bring that wisdom and knowledge into PCORI.

Any other comments on the --

MR. LEONARD: Well, quickly, if I could, because you asked Sue what PCORI could be doing in space. I think we are already at one level and Joe outlined a little bit this morning.
So, traditionally, research has often been top-down, it’s been investigator-initiated. So, an academic is sitting in their institution and they think up what they think is a cool question and then they go find money to fund it. Well, that works to an extent, but I know PCORI really wants to hear from the grassroots up, from the patient up, which is the purpose of today. So, you don’t really get to “we” until those two triangles come together in the middle where you have investigator-initiated questions that are important, they are coming down toward the patient, and the patient ideas that are coming up. You get to the we when those are both kind of synced up and moving forward together.

MS. SHERIDAN: And PCORI hopes to create that space.

MR. LEONARD: Right.

MS. SHERIDAN: That space to create that dialogue and bring these voices together and in the Patient Engagement Workshop, it was actually brought up by patient groups to consider flipping
the funding and making funding available to patient organizations through micro contracts, small seed money to start creating this dialogue in partnership and also looking at really facilitating this culture change that would be so very beneficial.

I’m going to move onto another question that as you all talked, you talked a lot about the electronic health care record, and, of course, PCORI’s very interested in data and data networks and the future of the electronic health care record. I think Pat and Dan, you both brought that up, and if anybody has any comment. I think you all probably have thoughts about this. How can we as a collective we address this issue?

DR. HOVEN: Okay, here I go again.

[Laughter.]

DR. HOVEN: I'll take a first crack at it because I think this is one of the biggest challenges we’ve got in many arenas right now with Electronic Medical Records and various platforms for information sharing that are not really out
there and I think maybe one of the parallel works that PCORI needs to be thinking about is how, in fact, an ideal platform would look for us, in fact, to share and have this information.

And when I talk about this platform, I’m talking about the science piece coming in, coming in on the clinician side of it so we can see the data and the science that’s out there. The platform then being able to allow me as a physician to share relevant and important information with my patient in a way that’s translatable to what they need and understand and concurrently, that information is then send out other members of the team because at the end of the day, it’s not going to be just me, it’s going to be the nurse, the secretary, the administrator, a lot of other folks engaged in the process. So, we’re talking about a platform that looks and smells differently from what we’re used to doing in the traditional Electronic Medical Record. It’s an expanded type of a thing and it’s not just purely documenting what’s interesting the medical record.
MS. QUIGLEY: And I’d like to add, too, that I think that there's still so much more work to get Electronic Medical Records operational. In 2012, moving into 2013, we still have hospitals that are using paper records. We have to move that forward. But, nonetheless, with Electronic Medical Records, I think that the patient perception is changing.

There were a lot of concerns at first that clinicians, providers were spending more time looking at the computer than they were really engaged with the patients, and I think some of that is shifting again as we really help patients to see how -- to be able to follow their own lab values, to be able to see the improvement in their health care, to be able to follow their functional status, to be able to report on their measurement of fatigue and pain. I think that there are ways to be able to really engage patients with that not only when they're in our care, but when they go home. I mean, it’s a transition of care.

As a rehab nurse and all the nurses at
American Nurses, it’s how we work with patients throughout their entire continuum of care in their lifetime, so, how do we move this beyond just the episode of care and into their own real health care management and really own their own care planning. So, I think that there are ways to even be able to do that, to know their plan of care after discharge and be able to communicate back to us how they’re doing and the progress that they’re making.

So, I think that that are some really great opportunities. It’s not just managing the acute disease episode, but really their whole health care and be able to move Electronic Medical Records in a different way and electronic communication.

MS. SHERIDAN: And you kind of are leaping to another question that I had about the Patient-Reported Outcomes, the PROs.

MS. QUIGLEY: Yes.

MS. SHERIDAN: And this is a new area even for the patient community to recognize the power of Patient-Reported Outcomes. Several of you brought
that up.

Would some of you like to comment on the future of Patient-Reported Outcomes and how that can help drive improvements and outcomes and how we use that data?

MR. BIGGERS: Can I throw in one more short comment about the EMR?

MS. SHERIDAN: Absolutely.

MR. BIGGERS: So, I think everyone realizes that researchers would love to have all of that data that are going into Electronic Medical Records and it seems to me there are two approaches that we can use in research to harness that data and one of them is already beginning to happen where people are consenting patients at the point they enter a system so that that data in an identified way can be used in the VA and the U.S. has done a lot of work in this.

But I think specific to PCORI’s context, we have an opportunity to help patients actualize their own locus of control regarding that data and take potentially a different or additional approach...
by enabling patients to become the control point
for contributing their data to research and that
carries with it a few other benefits around the
consenting process and crossing the HIPAA and
HITECH Act firewall and all that kind of stuff.

MS. SHERIDAN: Yes, very good points, and
there are many patient organizations that are also
very supportive of this concept.

Helen?

MS. HASKELL: In terms of Patient-Reported
Outcomes, I think, first of all, we need to start
at the individual level, interactive medical
records so that patients can input their symptoms
and concerns, make corrections in the record. I
think this is really essential for safety in
addition to just sort of moving things forward, and
I think one of the things that we found which is
something that patients have known for a long time
is that there are a lot of complications, symptoms,
outcomes, sequels that patients are well aware of
that are somehow not in the medical literature and
you can capture that in the medical record if the
medical record is interactive and you can use it to do further research, to refine treatments. And so, I think this is a big area for research and for [inaudible].

MS. SHERIDAN: Thanks, Helen, and that supports what many organizations have been talking about recently about interactive health care records as well as open notes, and it looks like the future is going to be this sharing and giving and taking of information and packaging the data for research.

Thank you, all -- oh.

MR. PECK: I can say [off microphone] --

MS. SHERIDAN: Yes.

MR. PECK: In a good way.

MS. SHERIDAN: Yes.

MR. PECK: And I think we can bring people into the dialogue with the panel.

So, Marty’s got a microphone there and if you would like to speak and ask a question or make a point to the panel, a brief point, please raise your hand and Marty and I will -- he’s got that
half, I’ve got this half.

MS. QUIGLEY: And I think while they're travelling, I’d just like to add that in relationship to Patient-Reported Outcomes, that there are valid and reliable instruments out there. For some of them, outcomes to measure, but they still need to look at cultural preferences, gender preference, and gender considerations. I think that there's still more opportunity for enhancing those measures and those tools that are out there.

MS. SHERIDAN: Great. Thank you.

MS. QUIGLEY: Thank you.

MS. FRIEDMAN: Good morning. I’m Susan Friedman with the American Osteopathic Association and I have a question for Dr. Hoven.

As you talk about the team-based care approach, can you address how this is going down to the medical school level to sort of change the culture to enhance that?

DR. HOVEN: Great question. I didn’t pay her to ask this question.

[Laughter.]
DR. HOVEN: As we’re moving forward at the American Medical Association, one of the first important legs of our new strategic plan is actually changing medical education. It has been what it’s been for 100 years; it hasn’t really evolved to meet the demands of the 21st Century.

So, in fact, our medical students will now be taught team care, how to work with others, how to play in the sandbox appropriately, how to get the work done by a team and involving team members to their highest level of function so that they can get the work done. So, I think you’re touching on something which is very important and what I kind of alluded to earlier because I think to do what we’re talking about, it’s more than just the doctor and the patient because there are many other moving parts to the system of care and they’ve all got to be on the same pathway. But thank you for the question.

MS. WISE: Hi, I’m Leslie Wise and I’m from Biomet Orthopedics. And, actually, my question had to do with the Patient-Reported
Outcomes.

Last week, I was in Boston at an industry meeting on real-world data and how we’re going to be able to make it actionable and impactful and take clinical research from random control trials, which is the very homogenous population to population health, which is what real-world data should help us with. But one of the things that have been identified is that the traditional tools that we used for PROs have maybe 100 measures on them, right? So much information that it doesn’t become enough to really be impactful.

How do we begin, and you kind of spoke to that, to develop tools in this area for Patient-Reported Outcomes that really matter to patients? Because it may not be 100 things and that’s a lot of things in 1 area. How do we hone it down to those four or five things per disease state, per research area that can really impact their lives rather than sort of collecting a lot of things that researchers maybe want to know that patients don’t necessarily find important?
MR. LEONARD: I’ll take a cut at that. I think, again, that bringing the patient in earlier in the process is an important step in that direction. I think PCORI certainly gets that and is taking those steps, but asking patients or a patient what are their preferences before you go into a study? So, it may not be what the academic or what the researcher is looking for or traditionally put in a questionnaire, but it’s questions around side effects, it’s questions around does this therapy make me drowsy or inhibit me when I’m at work, whatever those questions that really are germane to the individual patient. So, getting the patient involved in designing the research or designing the questions that'll go into the study on the frontend clearly is the first step.

MS. CULYBA: I would echo that and also just from a real-world data perspective, we’re challenged by this in our work by partnering with a health plan or a hospital system with existing data.
MR. HATLIE: Rebecca, we can't hear you well. Can you -- there you go.

MS. CULYBA: Can you hear me now?

MR. HATLIE: It’s on your battery pack.

MS. CULYBA: Can you hear me better now?

MS. SHERIDAN: Use your big voice.

MS. CULYBA: So, we’re challenged by this in our work because we do partner with health plan analytics and hospital system analytics and I think just coming together of multiple systems can be a challenge, but to have those folks at the table, too, from the beginning alongside patients so that there's this reconfiguration of the “we” and to also have our scientific partners who can speak to the best statistical methods is important, too. So, that’s part of what we’ve been trying to do in Pittsburgh at our center.

MS. QUIGLEY: And maybe one of the strategies with PCORI is to really narrow down and specific any of the reported outcomes related to your three top priorities now and to really look at what can we address and what is really of value and
a priority to patients and caregivers related to
those three top priorities that are going to be
your funding priorities in 2014. That might be a
strategy to help narrow and focus.

MR. BIGGERS: I thought that was a really
insightful question because it highlights the
complexity of the problem that we’re trying to
solve, and so, I just had it back to culture again,
that we have the opportunity finally to let
patients be the experts in some of these things.
And I think that has great power, but we have to
become comfortable with the emergent nature of
letting things like that bubble up from the bottom
versus a top-down ontology and I think that’s a
major culture shift.

MS. SHERIDAN: Good point, Greg.

MR. HATLIE: [Off microphone.]

DR. WILLIAMS: Good morning. I’m Dr.
Pamela Williams. I’m a nurse scientist from the
Medical University of South Carolina, and I wanted
to respond to the representative from big pharm and
you’re saying that you come here “agnostic” and
trying to understand what you mean by that.

And in addition, thinking about that agnosticism that may be out there beyond just your identifying yourself as that, here we are and we’re talking about culture change and culture change takes time. We’re trying to develop a space and it’s a very fine space that we’re talking about developing, but those cultural changes will take time.

So, what can we do now to start instigating the culture change? And I believe that as a scientist, we can even in these traditional top-down type of formats like clinical trials, pharmaceutical clinical trials, we can start collecting patient perceptions, Patient-Reported Outcomes should be included in clinical trials, not just Physician-Reported Outcomes.

So, I’m trying to say a couple of things mixed together in that those scientists that are married to and grew up in the historical culture of a top-down research design, if we can start stimulating change by even provoking Patient-
Centered Outcomes collected even in the most traditional study design.

MR. LEONARD: Well, what I meant by agnostic was with regard to what should we study in the disease states specific. So, should PCORI spend its money in cancer or diabetes or heart disease? That’s where we’re agnostic. We’re very engaged when it comes to how it should be studied and the types of research and the models of the research and the standards around observational studies or whatever you’re going to do, but when it comes to what should be studied, what specific disease states, I think PCORI’s onto that and they’ve got a process in place, but that’s not where we’re going to have an opinion specifically.

MS. TRAN: Yes, my name is Ho Tran and I’m with the National Council of Asian Pacific Islander Physicians and I just want to go back into the issue of the we, very innovative, and also a comment because for our organization, we also look at the concept perspective of changing the health care system, especially for the workforce. So, we
call it the 21st Century Medicine.

So, going back to Dr. Hoven, it is kind of a paradigm shift. So, what I would like to ask, especially for PCORI, it is that when we talk about the we, we talk about the public education, about involving the residents, the people. So, for us, we look at it should be a shared responsibility and that someone is missing in the panel. It is the legislature, the one who makes the law. Because when we talk about that, physicians say that we would like to be a partner with patients, but we also are very much liable. So, how can we have that discussion, education that the patients are also responsible for their behavior?

MS. QUIGLEY: I would like to comment on that, as well, because I think wouldn’t it be wonderful if we knew what is the best practice model of the family that values and owns their health today for tomorrow and how can all of health care industry be able to help them be able to achieve that? I mean, do any of us know what that best practice model is where family members really
and all of us are really taking responsibility? If PCORI could be able to help create, pull families and caregivers together to find the best practice model where people really do value and their own their health and, again, not just for today, but for tomorrow and how can we as a health care industry and all the analytics and all the support system really be able to help people achieve that? Wouldn’t that be wonderful?

MS. SHERIDAN: The land of milk and honey.

[Laughter.]

PARTICIPANT: Yes.

MR. MAILMAN: Good morning. I’m John Mailman. I’m a patient advocate. I represent a rare disease, neuroendocrine tumors. I’m also an executive board member of the Society of Integrative Oncology. I’m also a patient stakeholder at BraveNET.

And I wanted to come back a little bit to a conversation about Patient-Reported Outcomes and do we need to develop new tools? And I also happen to sit on the NCI Taskforce for Neuroendocrine
Carcinoma, so, I see a lot of questions on quality of life and Patient-Reported Outcomes and what I see across a bunch of studies is different methodologies for reporting patient outcomes and when clinicians are looking across different methodologies, they can't compare these apples-to-apples. And so, what I've seen recently and certainly I've had some training on and I think building the bridge, using the same methodology across multiple studies, there is, of course, the PROMIS, the studies that the NIH is doing to help promote Patient-Reported Outcomes so there's a consistent tool, but the same types of questions can be asked across all sorts of studies with certain disease-specific questions that can get at, but so there's consistency so that when we see Patient-Reported Outcomes, they're consistent across studies. So, they're not treated differently so commissions can actually have some idea that they have the same relevance and using the same measurement.

So, I heard kind of an idea we need to
create new things and one of the challenges, we need to use things that consistently across a broad spectrum of research, creating new things will only add some more confusion to that. I just wanted to add that as a point.

DR. HOVEN: Can I jump in here?

MS. SHERIDAN: Yes, absolutely.

DR. HOVEN: Because I want to make a comment and because I think what he’s saying is very important, number one. Number two, I also think that we have to look at the balance, the appropriate balance between the scientific outcomes in terms of disease management and at the same time the issue of the Patient-Reported Outcomes, which I think it’s easy to talk about, but it’s really going to be hard to try to narrow some of that down specifically when you get into certain illness types or you get into cultural issues. You’ve got to be able to address that across a spectrum of entities and I think we’ve got to do a better job of doing that, but I caution here that we have to concurrently not only talk about Patient-Reported
Outcomes, but we at the same time as givers of care have to talk about what the outcomes are in terms of the science and it’s a very, very difficult balance sometimes to get us to the right place and I think that also goes to the question over here about the liability pieces of this, that these are significant. And so, therein comes the balance between the science and the patient needs and reported outcomes. So, there's a lot of work that I think PCORI may need to do in this particular area, as well.

MS. SHERIDAN: Thank you, Ardis.

MS. LINKOV: Hi, can you hear me well? So, I’m Faina Linkov from the University of Pittsburgh and I’m a cancer epidemiologist and a researcher so I represent sort of the rare breed in this room.

My question is about the culture that most of you mentioned, the changing culture of research involving patients and development of research. I have to admit that as researchers, we are very much puzzled as to how exactly to do it. Like, for
example, if in my research I need to involve diabetes person or like breast cancer person, I know that they can go for the leader in the field and have like this one person and that would be enough for my grant to represent expertise in this area.

When it comes to patients, one patient would not necessarily represent all the issues involved in designing a study or basically giving us a better idea as to what a patient would be looking for. So, when we develop our teams, how many patients do you think should be involved? How many patients is enough? Especially those of you who are involved like as patient advocates. So, like basically with research, we know what the sample sizes are, like we have the methodologies. For something like this, I feel like methodology is not there. So, my question is to the entire panel: Do you envision some kind of methodologies for identifying the magic number of patients?

MR. BIGGERS: And when you say “the magic number of patients,” you mean in helping design
this study, right? You don’t mean the “n” that is actually being studied?

MS. LINKOV: No.

MR. BIGGERS: Okay.

MS. QUIGLEY: Well, I know in PCORI, one of your entities within PCORI is to address that very issue about research methodologies and what are the best research methodologies to really move forward to be able to help answer the questions that are coming forward and how to be able to engage patients and families. So, I don't know if we have the actual answer for you, but I know that you have one of the organizational infrastructures that you have is to really, really help guide research methodologies surrounding this area.

Go ahead.

MS. CULYBA: I would just say as well that I think that the opportunity that PCORI provides us is to start to just experiment with this, with this whole notion of the “we” and how patients can be involved from being participants in a study all the way to being full collaborators, and we’ve really
tried to do that. We’ve tried to really just throw ourselves in there by applying for PCORI’s and we’ve gone all the way to identifying collaborators, so, which I have up here patient investigator on the team, which is a really new thing and we don’t really know the best way to do it, I would say.

So, we also try to get input like I think a lot of people who are writing grants may do, focus groups and things like that. So, we’ve tried to kind of get a broad range from fully collaborative to just informing the questions and vetting our questions and then the challenge that I think PCORI gives us is how do you demonstrate in your proposal that you’ve done that? And they ask you to do that. And so, it forces us, I think, eventually to have best practices for that.

MS. SHERIDAN: And just to add to what you said, PCORI does in our funding announcements require that there are patient collaborators or stakeholder collaborators to partner with the research design team and we are pioneering new
territory. Now, there are some examples of
patient-stakeholder partnerships out there with
researchers and they have been more on an ad hoc
basis if PCORI wants to create this by design. And
so, we through our 50 pilot projects and current
announcements we’re going to make about some
awardees, we hope to provide to the community
eexamples of what we find is the best kind of
partnership. I don't think it will necessarily
fall on a specific number, but what's the richest
kind of contribution that the patient stakeholder
partners can make to the outcomes of the research?
So, we call ourselves a learning organization. We
are learning and we are sharing, and as we learn
and grow, we encourage your input to help us
identify what are the best practices.

MR. BIGGERS: So, I have to weigh in on
this one, but it’ll be brief. So, I agree with Sue
that this is an absolute frontier and I’ll skip out
on a small limb of presumption to say I’m one of
the people in the world who has a lot of experience
in this area, but that’s only because there aren’t
very many of us with any experience. And so, this
is the first time I’ve even heard that question
asked, like what is the right number? So, I think
the answer today is more.

[Laughter.]

MR. BIGGERS: And we’re going to find out
what the parameters as we go.

MR. HATLIE: We also just got a lot of
offers at the last workshop from patient advocates
about ways in which they’d be willing to help us
count the numbers or figure out the right numbers.
So, just rich feedback there.

MR. LEONARD: A thought on that maybe is
for PCORI to set up some network or to connect the
patients with the research community so you have a
question, but where are these patients that I
should bring in, and PCORI can play that role.

MS. SHERIDAN: And, actually, we announced
at our last workshop kind of a soft launch of a
challenge that we will be announcing shortly on
we’re calling it finally the Match-Making concept,
and this came up, this was a very robust discussion
at the Patient Engagement Workshop because the message was we patients are eager, we’re here, we’re ready to partner. How do we find our researchers? And on the flipside, the researchers understand the value of incorporating the patient stakeholder wisdom in the research, but the researchers also say to us how do we find the patients? So, through a challenge that we’ll be announcing, we hope to create some creative thinking and possibly applications or systems that will actually help facilitate researchers finding patients and vice versa.

MS. QUIGLEY: And if I just may add, I know that there are people waiting, but always to be conducting mixed method research where you are doing the qualitative part where you have focus groups and you get patient preferences. And then there are organizations that are research in the effectiveness of patient advisory councils, too, and health care systems. So, I know that there's movement in that area.

MR. BIGGERS: So, you can teach us what
the right number is.

MS. QUIGLEY: Yes.

[Laughter.]

MS. SHERIDAN: Thank you.

MS. SALY: Hi, my name is Martha Saly. I’m the executive director of the National Viral Hepatitis Roundtable.

I am hearing a lot about the new we and I appreciate the comments, some really great ideas coming from this stage. I’d like to ask the panelists if you could talk about additionally besides engaging the patients, how in your programs and in your work are you engaging both the caregivers and the family and wider support network of patients, especially among very vulnerable populations of patients? Sometimes, it’s difficult for the patient themselves to engage and also if you would talk about how or if you are engaging your wider community, meaning the community-based organizations addressing the issues that are important to you in your practice, the policymakers, and other areas within your
communities.

DR. HOVEN: Well, I’ll jump in on this one. I’m an infectious disease specialist. So, I hear what you’re saying. I think it is very clear in various populations, particularly vulnerable populations, and I alluded to this earlier, is that it’s not just the patient sitting in there, it is the health care surrogate, it’s the family member, it’s the life partner, it’s whomever it is helping that individual navigate through all the pieces that have to be dealt with. Built on top of that is part of the health care team, which is the care coordinator, the case manager, whomever it is that’s necessary to help us, again, navigate the various challenges and portals that have to be met.

I think that’s an inherent issue in this whole discussion and it cannot be left out in any way, shape, or form. It also goes to the issue of the community-based entities because I firmly believe that much of this health care, all of this health care is local and our engagement with community groups, be they the health department,
whatever it is in our community’s hospital-based systems, teaching institutions, integrated practices, church groups, whatever it is, we have not done the best job necessarily at linking all of these together.

So, I think part of what we’re going to have to do, and, again, it’s another thing on the to-do list for PCORI, but for all of us who are engaged in this is that we’re responsible for providing the leadership in our grassroots level that gets that accomplished, but I think this is a huge issue and it’s going to bear watching and deliberation as we go forward. Thank you.

MS. SHERIDAN: And let me just add that when PCORI, and I’m just speaking on behalf of PCORI, but when we talk about the “new we,” I mean, we’re seeing a global “we” when we might speak of patient engagement and we mean patient community caregiver and the broader health care community. We don’t see us moving forward individually in silos, but, collectively, we believe that. So, we’re going to find the power.
MR. HATLIE: Sue, Jonathan, we have a number of comments, people that have asked to get in line. So, we’re about 20 minutes away. We’ll try to get to as many comments as we can. But thanks.

Jonathan, you’ve got something teed up?

DR. ANDREAE: My name is Michael Andreae, Albert Einstein College of Medicine, New York.

As a critical care physician, I’ve seen a lot of patients pass away in the ICU. That’s where a lot of health care dollars are spent in the last weeks and days of our lives. And let’s face it, everybody of us eventually will have to pass and we would all like to do that at home in our gardens, surrounded by a lot of family and friends, but that’s not what’s happening at the moment.

And so, my question is: How can we get the most bang out of the buck in the later years of life? How can we add life to years instead of years to life and how can we -- yes, that’s my question for you.

DR. HOVEN: I'm sorry to be talking so
much --

MS. SHERIDAN: No, go for it.

DR. HOVEN: But these people are hitting all of my --

MR. SHERIDAN: Your buttons.

DR. HOVEN: My flags and I'm excited about it.

The whole issue about elder care, end-of-life care, end-of-life decision-making, again, I think is another thing that PCORI needs to be talking about. I had a conversation at dinner last night with some of my new friends about this whole issue of self-determination, value recognition, what's important to that patient, what's important to that patient's family, and getting that laid out there, and I think to your point, many, many seniors don’t want to die in the ICU, which is exactly where they're dying. We’ve got to do a better job in this country of allowing them to tell us and we are responsible for initiating conversation and we are responsible, all of us in the health care team, for making sure we value what
that patient and their family needs and wants so
that transition and the ultimate death can be
made at the right place, at the right time, and the
right way in a care model that isn't an
institution-based model; it is, in fact, a home
model or some other model that allows these folks
to get what they need and deserve as Americans.
So, thank you for that question.

MR. PECK: Sue, we have questions not only
in the room, but a Twitter question. One for the
panel is: How can PCORI best support translational
research?

MR. BIGGERS: So, maybe we have to ask the
statute to that question.

MS. SHERIDAN: What's that?

MR. BIGGERS: Maybe we have to ask the
statute that created PCORI.

PARTICIPANT: Ask the statute.

MR. BIGGERS: There are some boundaries
there, I think.

MS. SHERIDAN: Are there any comments on
that from the panel?
DR. HOVEN: I don't have an answer to it —

MS. SHERIDAN: Yes.

DR. HOVEN: But we’ve got to answer it.

MS. SHERIDAN: Right, I don’t have --

DR. HOVEN: Because it goes to the very issue we’ve been talking about that transparent platform of doing translation and passing information on includes that translational research, as well.

MR. BIGGERS: And one of the frontiers is the boundary between translational and clinical seems to be blurring. It’s so much more of what happens in the clinical setting is actually a little bit experimental and we don’t have the rules for doing that.

MR. LEONARD: PCORI does have the translation table exercise underway, as well.

MS. SHERIDAN: Right.

MR. HATLIE: Okay, we’ve got another comment here.

MR. SPERLING: I'm Andrew Sperling with
the National Alliance on Mental Illness.

Another layer of complication on this, and not only a public health burden, but also scientific opportunity and tie it to where I think the health care system needs this work the most and that is with the cost of the highest and that’s with chronic disease management.

Particularly for individuals with multiple chronic conditions and it’s certainly an issue with the population I represent of individuals that have disorders such as bipolar disorder, schizophrenia, major depression, but the real high cost associated with the care is not their psychiatric disorder but the fact that they have two, three, and sometimes four multiple chronic conditions: diabetes, heart disease, COPD, and how we deal with these complex situations in real-world treatment settings where largely they’re excluded from other types of industry and other types of government-funded research because they have all these multiple chronic conditions. It makes it difficult to isolate the particular condition that a particular
institute at NIH or a particular target that a private sector drug company is looking at. I think there's an enormous opportunity for PCORI to move the health care system forward to deal with what -- we're a part of a group called the Partnership to Fight Chronic Disease. I think their estimate is 75 percent of the health care cost in this country, dealing with chronic disease management and I think this is an enormous opportunity for PCORI to look at populations in real-world treatment settings where physicians are interacting and dealing with not just one condition, but three or four conditions at the same time.

MR. BIGGERS: Yes, ironically, comorbidity is kind of a novelty in research. I mean, isn't that strange because that's real life?

So, perhaps, there's an opportunity as PCORI starts to develop some priorities to earmark within topic areas that PCORI would like to see some number of studies explicitly include comorbidities even though that might not always be
true.

MS. HASKELL: I’d like to add to that. I think that PCORI needs to be sure that it is addressing the big questions, and I don't think there's one bigger than mental health. The really big issues, how effective are these treatments? What can we do this fragmented, dysfunctional system that deals with mental patients? How many of these comorbidities are caused by the treatments and is there anything we can do to prevent that, to change the treatments to help people? So, a big comparison is mental health. Other big issues like infection, chronic disease, all of those things I think we need to not be afraid to tackle.

MS. SHERIDAN: And some -- okay.

MR. LEONARD: I alluded to it in my opening remarks. Andrew mentioned “real-world evidence,” and isn't that what this is all about, is finding out what happens in the real world and not the clinical world? And the irony is that research done on a traditional clinical randomized trial would disqualify the people that Andrew is
talking about right now because they have a
condition outside of what investigators are looking
at. So, expanding the scope of real-world
evidence, but then making sure that there are
standards that are set. So that when the research
is complete, it’s appreciated, understood, and
recognized as high-quality.

MS. SHERIDAN: And part of PCORI’s mandate
is to address multiple chronic conditions, and so,
that is definitely on our radar and it’s something
that we appreciate very much and address in our
funding announcements.

MS. QUIGLEY: And I’d just like to add, too, I know there are so many in line, but
certainly underfunded is what are the best
effective patient and family education strategies
so that people really do learn to the point that
they're able to take what they learn and change
their practices, to change their behavior? What
does it take to change behavior? So, I think that
really getting into the best effective patient and
family education strategies is such an important
priority.

MS. SHERIDAN: Very much, and some of our Pilot Projects address kind of the doctor-patient communication and the best, most effective methods and way to communicate and educate patients.

DR. UNDERWOOD: Hello. I’m Willie Underwood. I’m a surgeon, neurologist. I do health services research, I do health policy, I do disparities research, and I’m also African-American.

Now, I’m going to tell a story and I’m going to talk about this in a way that I hope we get to the point. So, when I was young, I remembered learning to make phone calls. I would take a pencil, you had that big circle to dial, right, and if you started at zero, sometimes you never made it all the way around. Today, look at us today. We have telephones that are computers. We call long distance for free. We interact with each other in ways that we never have before. However, the phone company didn’t do that. So, at the time when I was a child, if I talked about,
hey, one day, we’re going to be able to look at each other on the telephone and talk to each other, my grandmother would have said yes, maybe, highly unlikely.

Okay, now, PCORI has the opportunity to do the same thing for the health and health care in this country. How do we focus on improving the health of America? How do we step out of we are as researchers, as scientists, as nurses and doctors and say yes, I understand this little piece right here, but how do we come together and say listen, if we put our intellectual and experiences and things together as individuals into the “we” as we call it and create something that we can even imagine today existing because that’s our goal, is to do something that we cannot imagine and that is truly making America and the world a healthier place. How do we do that? And that’s the question I have for PCORI and that’s what I thought we were going to do when I came here because I believe we can do it.

MS. SHERIDAN: Thank you.
[Applause.]

MR. WHITE: Hi, I'm John White. I'm a rehabilitation researcher in Philadelphia.

My question has to do with the "we" of the many stakeholders and the fact that, right now, we're all together because there's no actual evidence being weighed, but, historically, when evidence gets weighed, not everyone sees eye to eye and it's not cut and dry and we still have large portions of our health care industry that are in corporate culture whose primary mission is not the patient-centered outcome.

So, I guess what I'm interested in how PCORI imagines navigating the political landscape given that we will likely face situations where by some people's eyes, the evidence is in favor of something that is very much not in the financial interests of another stakeholder. Thanks.

MS. SHERIDAN: Any thoughts? I thought maybe you'd respond to that.

DR. HOVEN: Well, let me jump in --

MS. SHERIDAN: Yes.
DR. HOVEN: If I may.

MS. SHERIDAN: Go ahead.

DR. HOVEN: Because I think we are going to have to develop very tightly-knit collaborative work and relationships with all of the moving parts that deliver health care and that interact with patients in any venue. Now, what I’m getting at is, for example, speaking as a physician and the American Medical Association, utilizing our relationships with specialty societies, with state medical associations, leveraging that information, getting it out there down to a grassroots level and getting the buy in from my physician colleagues so that they can begin to work on the ground with this information. I think the ANA doing the same kind of thing. I think physical therapists, everybody engaged in this dissemination of information. This isn’t going to be something PCORI is going to be able to flip a switch on at the top. I think this is going to have to be driven really down deep and it’s going to take some collaborative effort. But we, back to Willie’s comments, have to do this
because we’re capable of doing this.

MR. BIGGERS: Well, it’s unfruitful to have a conversation about costs if we don’t any evidence. So, let’s generate a lot of evidence and let somebody else figure out what that means about cost.

MS. CULYBA: Well, and I would just say from our perspective, I mean, this is a real challenge in the work that we do working with hospitals and providers and we really try to have the goal of collaborating knowing that we’re not really going to come to consensus all of the time.

So, if we’re leveraging, for instance, a quality initiative that’s a payer provider initiative and then we bring patients and other community stakeholders to the table, it kind of changes the landscape of what we’re trying to do. So, when we were putting proposals together and asking questions, I think sort of the smaller scale of these PCORI announcements, it suits us because it doesn’t ask for huge, huge change which is ultimately, I think, what everybody wants, but
maybe to start on smaller scales and really try to get everybody at the table at the beginning, but it’s a real challenge.

MR. LEONARD: So, the question is around what happens at the end when research comes out? There may be dissent in the community or political dissent. I think the answer is actually at the beginning and a lot of the work that PCORI is doing with the methods upfront and making sure that the methods of the research going in are pure and are accepted so that when the research comes out, it’s more bulletproof to the politics of the day.

MS. SHERIDAN: Yes?

MR. LIPSTEIN: [Off microphone.]

This is really an important point and I’ll speak loudly about it. It’s important for everybody to know that PCORI is not [off microphone] except by statute independent of government. And so, really, there really aren’t political considerations in our board room at all. And so, the research that we’re doing is really being guided by what we believe is in the best
interest of patients and their caregivers and their clinicians.

And so, I just wanted to reemphasize that point really because the founding fathers and mothers of PCORI went to great lengths to ensure this was set out outside of the political infrastructure. And so, just keep that in mind because that also prevents us from a very great, unique opportunity to do research and produce information that is completely unbiased and then we think will help inform federal decision-making without [off microphone] somebody referred to as corporate or financial interests.

DR. WEISMAN: [Off microphone.]

MS. SHERIDAN: Here, come on up.

DR. WEISMAN: When the Board started, we came from all different places and different backgrounds, different jobs, different representation of stakeholders, and what you find is what we found is that all stakeholders, whether it's from medical product industry, insurance industry, hospital industry, whether they're
physicians or nurses, chiropractors or patients, we all want the same thing, it’s just that we don’t trust anybody else and their intent. And so, one of the things, one of the rules is you’ve got to assume good intent when you start and you can’t start with the assumption that my intent is good, but I don’t trust the other person. And that allows you to move forward.

Everyone has conflicts of interest in this, everyone does. If you’re a doctor and specialist, you believe your specialty ought to be performing a procedure rather than the other guy’s procedure. You don’t trust the hospital; you don’t trust the insurance companies. Everyone’s making your life miserable. Nobody takes the patient at the center and the patients are totally lost in all this.

If we all come to the table at the beginning and agree on a fair way of going forward by methods and other things, I think the most important thing is transparency and openness in the process. That cures everything. And if everybody
agrees at the beginning what we want is as close to truth and relevance that informs decisions, the best will come out. From an industry perspective, they’ll be winners and they’ll be losers. But that’s the nature of capitalism, right?

All we’re saying is the information flow will be more open and that’s to the betterment of everyone. Overuses of technology is a big problem, but so is underuse. There are a lot of patients who don’t get treatments that they ought to be getting. So, hopefully, it’ll be a flat -- everyone holding hands. That’s what the Board has done. Everyone holds hands and we’re in it together, it’s for the good of all of us to get this right.

MR. HATLIE: Jonathan, Joe wants to jump in here and then Carol and Venus.

DR. SELBY: I really apologize for hijacking the sequence of questions, but Jon did ask kind of perhaps the elephant in the room question, and since we have all stakeholders here, it’s a good time to say two things.
Number one, the genius of the name, the Patient-Centered Outcomes Research Institute, it is an amazing field leveler, if you will, to say that as we convene from our various perspectives, we all are here to ask and answer questions in the interest of patients. We’ve seen that happen and we saw that happen at our stakeholder forum in February of this year, about 900 people convened and it was striking to hear everyone subscribe to the notion that this research is done in the name of patients. So, that really levels the table.

The second thing is, as Steve said, this is not a federal entity. We are not told what to do from somewhere inside government. It means we are much more of a democracy. Democracies, as you know, can get hijacked. So, it really speaks to the essential requirement that all stakeholders embrace the opportunity that we have as a country.

I mean, this is an experiment at the national level. Embrace the opportunity to do research differently, stay at the table. We, as PCORI, are passionate about keeping everyone at the
We think that’s the way to get the best research done. We couldn’t do it without researchers, we couldn’t do it without industry, couldn’t do it without payers, clinicians, or patients.

MS. PRICE: I'm Carol Price from Ohio, and I have to say that I was a nurse for 40 years and I retired from nursing because of the state of health care and have focused on advocacy work to try and improve health care.

I’ve heard a lot of discussion about how do you get the patient, the caregivers involved in their health care to want to improve their health. Ms. Quigley bought up the patient care plans and patient conferences. I feel that health care workers have been the cause of a lot of the problems within the health care system because they run the show and a lot of the patients will back down, figure the doctor knows best, the nurse knows best, they're afraid to speak up. It’s very evident a lot of times in those care plans and care conferences.
I want to put a challenge forth to the ANA and the AMA to follow PCORI’s mission and flip the paradigm and have the patients run those care conferences.

MS. QUIGLEY: Thank you so much for sharing. Your passion, your drive, and for all of your service as a professional nurse in this great country. And I would like to say that that is, indeed, the heartbeat of our entire code of ethics and our standards of care is that everything is patient-centered and everything is patient and family-centered.

So, thank you so much for your remarks and, indeed, it is a journey to engage people and I think even when you think about PCORI, I think that there's real opportunity to look at how do we help patients really to become their own advocates? How do we really help patients and families exercise autonomy? And what does autonomy mean? I think that there is some opportunity to really be able to help bring that to a higher level of importance in all of this effort that we’re doing for patient-
centered care. But thank you so much for your comments.

MS. GINES: Okay. My name is Venus Gines. I am a 20-year breast cancer survivor and a Latina applicant, and I don't know how many Latinas are in this room, but one of the things I want to talk about is I heard a lot of the “we” and I heard about culture. One of the biggest cultural barriers within our Latinos and African-Americans and Asian Americans is mistrust and unless we see us reflected in panels such as this or on the boards or on major committees and planning committees that are putting together the protocols, we will not trust the research.

[Applause.]

MS. GINES: And I am frustrated because I was here for the October -- I was one of the reviewers and I looked around the room and in my hand I can count the five Latinas in the whole review process and even worse with the African-Americans. And that’s unacceptable. So, I think PCORI really has to make a commitment to diversity
from top down and then that’s where we really are
 going to get the patients, those of us who are the
 vulnerable patients.

    African-Americans are dying in bigger
 numbers of breast cancer. Latinas and Asian
 American women are dying in big numbers of cervical
 cancer and we can go on and on, but all the
 research is always top, and then they invite us.
 After they get their money, they invite us and they
 give us gift cards for us to do 200 surveys to get
 data. You got to understand that that’s not going
 to work anymore. Latinos and African-American
 community folks are tired of being used for
 research when all of the research dollars goes to
 the major institutions and nothing comes back to
 the community.

    So, thank you, and I’m celebrating my 20-
 year breast cancer survivor last week, so, I had to
 say this.

    [Applause.]

    MS. SHERIDAN: I’d like just to respond to
 that. Thank you very much for that comment, and
something that PCORI is going to be focusing on next year is going to where the patients are and we celebrate and we invite you to help us develop strategies to partner with communities that are well-represented within us. So, I will reach out to you and that is definitely something that is a priority of ours, to address health care disparities, hard-to-reach populations, the vulnerable populations. So, with that, I thank you.

I think we’re headed to a break. So, I just want to wrap this up and just reflect on what we have discussed today. I mean, we’ve discussed on our panel the “new we,” we’ve discussed culture change, we’ve discussed Patient-Reported Outcomes, new data structures. We’ve been challenged to address cultures that are under-represented. And we were challenged about the political environment. And so, this is not going to be easy, but PCORI has made a commitment and I think that people on this stage have shared their commitment in what this will take going forward. And change requires
passion. As Joe mentioned, passion, and it also takes courage. So, I encourage us to go forward this afternoon with passion and courage trying to develop the collective “we,” and let’s ask ourselves dare we embrace this opportunity to go forward in partnership and help create PCORI in a successful way that will improve outcomes for all of us, our family members, and our communities?

So, with that, I close this session and I invite you to, I think, refreshments and then we will continue in our breakouts on developing this new vision. Thank you very much and thank you to the panel.

[Applause.]

[Recess.]

[Whereupon, at 10:22 A.M., the workshop went into Facilitated Small Group Sessions.]
MR. MARTIN: I’m Greg Martin. I’m the deputy director of Stakeholder Engagement here at PCORI.

A few of you were fortunate enough to be in sessions with myself and Carol Walker, who was my wonderful co-facilitator. But here now, we’re going to hear from some of PCORI leads who led some of the other sessions that we had today on what topics PCORI should study. So, they’re going to summarize just in broad strokes the discussions that we held today and then we’re going to turn it back over to you, the audience, to help bring it all back home to us and help us go a bit deeper into the content.

So, with that, I’m just going to keep it brief and turn it over to David Hickam to talk about the Assessment Program.

DR. HICKAM: Thank you. Can everybody here me okay?

So, I had the pleasure of facilitating the
sessions both this morning and this afternoon that
examined research topics for the program area of
the assessment of options for prevention diagnosis
and treatment and I was very impressed with the
amount of energy and enthusiasm that the people who
came to the sessions brought to the discussion.

    In terms of thinking about the really
broad sort of overarching themes, I think the major
theme that I heard was stressing the importance of
understanding the way that research results can be
applied to decision-making by patients particularly
and patient provider dyad.

    And one of the individuals in our
afternoon session had a great comment in which she
said that she likes to think of outcomes based upon
whether they are relevant to and resonant with the
interests of individual patients. And so, I think
that sort of captures the idea that we’ve got to
think hard about outcomes. There’s the
understanding that the important outcomes vary
across patients and that we need to understand risk
groups and how comparative interventions may differ
across those different groups.

There was really quite a range of clinical areas that were identified in the discussions. There was a lot of interest in chronic diseases affecting adults. Issues such as chronic obstructive lung disease, depression, arthritis, diabetes, kind of generic chronic pain, and the multiple possible interventions that are available for those diseases, try to understand how comparative information results from comparative studies can be brought to bear to the decisions of those individuals make and in the realm of ongoing chronic care.

There also though were many pediatric topics that were brought up. There were a lot of interests in disabilities and rehab-oriented interventions. There was interest in lifestyle, obesity, substance abuse, the kinds of clinical problems in which behavioral interventions may be quite important. There was interest in some acute decision-making that runs the range from postoperative pain, chemotherapy for cancer, end-
of-life decision-making in settings in which patients may be hospitalized close to the end of life.

So, there was, I think, quite a range of topics that resonate with people, but I think it all comes back to really trying to understand how the results from comparative studies can really help people participate more effectively in the decisions that are important to them. Thanks very much.

MR. MARTIN: And thank you to Dr. David Hickam. And next up is Dr. Chad Boult, the director of Our Improving Health Systems Program.

DR. BOULT: Good afternoon. I came to PCORI about a month ago, then kind of getting acquainted with people and procedures and computer systems and so on. This is my first foray into interacting with stakeholders since I’ve arrived and if I had any doubts about the value and the commitment to our incorporating stakeholders into the PCORI, they rapidly dissipated as I had a chance to co-lead with Sue Sheridan our two groups.
today. This was truly fantastic. I think honestly we can say we had two dream teams, meaning the members in the room. They were very different from each other. We had every conceivable perspective represented and our discussions were very rich.

I want to just very briefly summarize some of the main points that came out of this. This was the sessions on how PCORI can help discover new information that will lead to improved performance by health care systems leading to improved outcomes for patients.

Before we could even get into defining questions, however, we had to deal with some infrastructure issues like what is a system? It isn't just the usual payers and providers and so on, but it was clear that it's also family caregivers, it's also community agencies, and we have to expand our thinking to incorporate these essential elements of care, especially for people with chronic illnesses.

It was also brought up that we need to think about our lexicon, the words we use. No
one’s ever aware of it, but we tend to use jargon and we fall into jargon and we use words that don’t mean the same things and we have to be very careful about that.

Some more infrastructures, tools. In order to do the kind of research that we’re talking about doing, we need tools that measure certain things like Patient-Centered Outcomes, particularly that are non-disease-specific, but they’re just common across all patients. What do they need, what do they want, and how well are our systems meeting those needs?

And a third infrastructural element has to do with design. In other words, we have to make sure that our designs for studies of systems incorporate a variety of populations, including underserved ethnic and racial minorities and rural areas as well as urban cities.

So, that’s all just to get started, and then here, I’m just going to give you a quick list of some of the specific issues that came up and if I didn’t incorporate your suggestion, throw
something, but it’s not intentional. We only had a
minute to put this together.

So, a lot of questions about what is the
effect of information technology on a variety of
things like patients’ decision-making, clinicians’
decision-making, monitoring, and sharing of data?

Next, how should we best deploy our
professional personnel so that everyone is working
at the tops of their licenses and we’re maximizing
efficiency and minimizing waste? What kind of
coordination programs can we create within systems
coordinating across hospitals, across specialist
and primary care and weaving it all together,
especially important for people with multiple
chronic conditions.

How can we enhance patient self-management
or engagement in one’s own health through behaviors
like taking medicines and eating and exercising and
variety of other things? How can we enhance
support for family caregivers, the unsung heroes of
the health care delivery system?

How about using databases that are already
out there? Some have yet to be linked; others are already linked, but we’re not using them yet.

How about systems for improving quality? There are a variety of different types of creating learning communities where different systems share learning with each other and share best practices? For instance, do advisory councils involving patients and caregivers and so on really make a difference in system performance?

Incorporating patients’ values and preferences, the core of patient-centeredness. We don’t really know how to do it. We need to fund research that shows us.

Providing access to the right care at the right time and the right place for patients in all different phases of their illness. And, finally, and not least is collaboration. We need to find ways to collaborate effectively with other funding agencies so that we’re filling each other’s gaps and ultimately creating a continuum of research that ranges on the NIH end from the discovery of basic biologic processes to the PCORI and which
focuses on application of new knowledge to producing actual better outcomes for patients.

Thanks.

MR. MARTIN: And thank you to Dr. Chad Boult.

Next up is Dr. Anne Beal, our chief operating officer to discuss the addressing disparities sessions.

DR. BEAL: Great. Okay, so, as you heard from Greg, my task was to synthesize the work that we were focused on in disparities and it was actually a very interesting and energized group of people who we had to try to corral.

One of things that’s very nice in terms of how PCORI’s thinking about disparities is that we’re definitely clear that we want to move beyond simply describing disparities and really understand what are the interventions that are available to address disparities. And so, this was a group that was really quickly able to move in that direction. I think, historically, there’s been a lot of work which has really gone onto really study and
research whether or not disparities exist, but I’m a believer in the fact that they do exist and I think the people who were in the room also believed that they do exist and we were able to just jump forward and start to have a discussion around what are potential topics that we can study?

So, one of the first things that struck me was actually because I was tasked with trying to identify some of the themes that came about from this discussion was the absolute lack of themes, particularly in the first group that we had. That there were 21 people in the room, then we had 21 different and distinct ideas that I thought all had merit in and of themselves. But, actually, over then the course of two sessions, there were then some themes that we started to hear that were able to start to emerge.

So, one, and many of them actually are somewhat similar to what we heard in the health systems group, was thinking about opportunities to leverage technology and think about the role of technology to reach different populations, but also
to think about delivering care in new and different ways in order to address the issues around health disparities.

There was also a very robust conversation around the role of policy and particularly payment policies and payment policies within the safety net and what role does that play in terms of access to care, in terms of providing high-quality care, and also thinking about the current opportunities that exist as a result of the Affordable Care Act related to both payment policies particularly in Medicaid as well as policies related to collecting race and ethnicity data to looking at clinical performance measures and to providers to have to hold themselves accountable for specific outcomes.

And so, one of the things that emerged was that we talked about the fact that policy matters in terms of really affecting the population health and I will say the research question that then emerges is so then how do we look at the impact of these policies on populations that experience disparities in care?
There was a lot of discussion around disabilities and the disabilities community, but also not only looking at disparities within disabilities, but then disparities as a result of having a disability. And so, looking at how people with disabilities are sometimes treated differently within the health care system.

There was also a lot of discussion around geographic disparities and the fact that particularly as we have primary care providers and safety net providers closing down across the country, what does this mean then in terms of geographic availability of different providers to different populations and then what is the subsequent impact of that on different populations?

A lot of discussions around the need for integrated care, and this actually came up in both sessions where people were talking about the fact that we need to think about bringing together different types of providers. So, whether it’s school-based, clinically-based, or whether it’s the Department of Health based, community health
workers, we’re really thinking much more holistically about bringing together the different types of providers that can touch on different populations. And in both sessions, we had this discussion around hard-to-reach populations and had this discussion about we really need to understand exactly what does that mean? Is this a term that we want to use? And do we challenge ourselves to not necessarily say that they are hard to reach, but we are not reaching out appropriately to different populations that are thought of as hard to reach.

In addition, we had a lot of discussions around mental health and behavioral health, and, again, thinking about it both in terms of disparities and accessing care for people who have those conditions, but then also disparities as a result of having particularly serious mental health conditions.

And so, overall, I would say that there was a lot of energy and enthusiasm, a lot of interest. And then also one of our sessions was
quite interesting because then we were able to
devolve into a conversation as to what is the role
of CER in terms of your own work and how would you
use the kind of work that PCORI is trying to
develop? So, there were a lot of interests in
terms of training as well as a lot of discussion
around the fact that people are already observing
changes in terms of -- researchers in particular in
trying to engage patients in the work that they're
doing because of the requirements that we have for
PCORI to engage patients and other stakeholders in
a substantive way. So, I’m glad to hear already
that we’re starting to see some preliminary impacts
as a result.

    Okay, thank you.

    MR. MARTIN: All right. Thank you, Dr. Beal.

    And next up is PCORI’s Director of
Communications, Bill Silberg, to talk about the
communications and dissemination research sessions.

    MR. SILBERG: Welcome to the non-clinician
portion of your program. I had the great privilege
of co-facilitating two sessions today and I think as you’ve heard from my colleagues here, the level of engagement, and not to make a pun, but the level of engagement and enthusiasm that I experienced that the rest of them experienced really was quite special and quite important.

The two sessions had somewhat different personalities, if you will, but I think we got at a lot of the same issues and very effectively. Two very robust discussions, and what I found most interesting about both of them is we spend a lot of time talking through the recognized importance value and criticality, if you will, of communication and dissemination as a core component of what it is we were all trying to do, understanding that the dissemination and communication and implementation use of actionable evidence is really what we were all about with an end goal of affecting outcomes. So, we spent a fair amount of time talking about some of the critical core questions related to that, acknowledging that there's been a lot of work in
this area that has recognized and elucidated the barriers, if you will, the challenges, the bars to the effective communication dissemination uptake of actionable evidence, but that didn’t stop us from trying to figure out how we might in this context with PCORI as an engine and a catalyst building on the work of others, try to do a better job.

So, we talked about such things as the important nature of message development, issues of trust, who does one trust in delivering and receiving the message? How do various parties in the communication process which by definition we thought was a two-way process. How do folks on the receiving end wish to receive that information? That varies depending on who that person or that group is. We talked about the importance of customization of messaging and information, that the value of the information, the likelihood that it will be heard, listened to, utilized, followed, and applied broadly really depends on the meaning, the context within which it is delivered and the meaning that it has for the person receiving the
We talked about, as I think you’ve heard a little bit, issues of tools, channels, technology, what role do new communications technologies play in giving us new opportunities to perhaps get around or get over some of the barriers that we know traditionally face us in the communication and dissemination process.

We spent a fair amount of time talking about the different kinds of evidence and how different audiences weigh different kinds of evidence differently, and this was not a detailed discussion about classes or categories of evidence, it was really much more a matter of how meaningful and real-world the evidence that was being presented was to the person hearing about it and how it was presented to them. So, we really touched on some very basic areas of communication practice and implementation science, if you will.

I don’t think we came to any conclusions on what is perhaps most important, but there was a great deal of discussion of how we might generate
research questions based on some of those key points, and these tended to focus, in my view, in three broad areas. There was the notion of intra and inter-professional communication dissemination and implementation. How do professionals talk to and work with each other within and across groups? What might we learn from both the research and the clinical world in terms of how best practices are shared and new evidence is promulgated within and across groups? That was a very interesting discussion.

We also talked about the interaction in a similar context between professionals and consumers, patients, caregivers, advocates. How do those processes work? What can we learn from best practices and what appears to be some successful models? How might we apply them broadly? Much of this occurs in sort of a vertical context. One if talking about a particular problem or a particular condition. Might we learn from effective communication in a particular context and apply that more broadly?
And then the final grouping was patient-patient, patient-consumer, consumer-caregiver. I won't call it the nonprofessional side; it’s an expert side. But the question of how consumers and patients and advocates and other stakeholders talk to and amongst each other. And, again, much of this, as we took from the discussion, occurs in a vertical sense by condition, by disease, but, surely, there are ways that we can learn from what seems to be working in these vertical slices and perhaps applying through PCORI’s special sauce, try to help folks talk to each other and amongst each other and perhaps push best practices out more broadly.

So, I want to thank the folks who participated in my two groups. I learned much more from you than you learned from me, I assure you, and we have quite a bit of follow-up information to take back to the office and start working on.

MR. MARTIN: Okay, thank you, Bill, and thank you to the panel and please remember, folks, the six o’clock show is entirely different from the
three o’clock show. So, we encourage you to come back from the buffet. Right now, it’s looking like the midafternoon Diet Cokes are probably wearing off a little bit. I’m seeing some faces kind of sag a little bit and maybe you’re dragging just a little bit.

So, let’s do one of my favorite things, which is really these sessions overall because I like to hear what folks have learned because I’ve learned a lot today. Oprah has her favorite things, and, unfortunately, we couldn’t find 76 Rancheros to put keys for new cars under your seats. So, instead, we’re just going to have to make do with each other’s company.

So, let’s do a quick show of hands. Have you learned something today?

[Hands raised.]

MR. MARTIN: That’s incredible. That’s what we were really hoping for out of this was that folks would learn and that we would learn something, too.

So, now is the time when I would actually
love to turn this back over you, the folks, the
stakeholders, the patients, the caregivers who have
taken time out of your busy schedules to come to
Alexandria, Virginia, on a Tuesday to help us
understand how we can achieve our mission.

So, Jonathan and Marty are out in the
audience with microphones, so, we’d like to hear
from you. What have you learned? What are the
topics that we should be studying? What have we
not covered up here and the summation of the day’s
discussions? What are extra things that might have
occurred to you since then? So, we’re ready and we
want to hear from you.

PARTICIPANT: One of the first things that
I thought of [off microphone] you mentioned
depression and diabetes [off microphone.]

MR. MARTIN: Thank you. And if anybody on
the panel has thoughts that they’d like to add to
any of the responses from the audience, feel free
to jump in.

DR. BEAL: I’m a pediatrician, and I
agree.
DR. BOULT: I’m a geriatrician, and I agree.

[Laughter.]

DR. HICKAM: I have one thought about that. I think it’s a really important point that you made, and, again, we’re always sort of getting back to Patient-Centered Outcomes and part of your thought there to think about outcomes in kind of a long-term sense, yes, I think that’s a really good point.

PARTICIPANT: Hi, thank you. Actually, I have a question. Originally, options to choose from included rare diseases and I see that we didn’t have that today. I’m just wondering if you could speak to the reason that had been eliminated.

MR. MARTIN: Well, actually, we were really disappointed that we removed those breakouts. We were really hoping that we could use those as an opportunity to learn more about rare diseases as an institute.

Unfortunately, we did not have a large enough response and we asked folks to indicate
their primary and secondary areas of interest in discussing today. And so, we are examining different ways that we can do some outreach and engagement on rare diseases and it’s something that we’re really looking forward to and I would encourage you to keep an eye out for early next year and we’ll have some more activities based around rare disease.

DR. BEAL: The only thing I would add to that is that there were a couple of comments that did emerge in the disparities session related to rare diseases, particularly about uncertainty around time of diagnosis and making sure that people had information.

MR. HATLIE: Anne, you’re hard to hear.

DR. BEAL: So, there were a couple of things that did emerge in the disparities session related to rare diseases and specifically there were three themes that I heard related to the rare diseases.

So, one was issues around diagnosis and uncertainty around the time of diagnosis and people
describing that there were often challenges in terms of getting an appropriate and timely diagnosis. Secondly was around creating measures so that as we think about outcomes and Patient-Centered Outcomes Research that we have the appropriate outcomes. And then the third was actually then having the appropriate data associated with really looking at some of the rare conditions so that we can study them over time.

So, we did get some of that information, although, as Greg said, we weren't able to have a session devoted just to that.

MR. SILBERG: And I would just add in the communications sessions, there was actually a fair amount of discussion of rare diseases from two or three points of view. One, we were privileged to have one of our Pilot Project awardees who is a rare disease investigator.

So, we talked a little bit about communications issues related to professional patient communication about a rare disease. From the patient point of view, it was this issue of
uncertainty about what the problem is and how they could be better served by having professionals more readily armed and equipped to deal with their questions in a way that wouldn’t send them to other physicians before they finally get a diagnosis that can give their lives some certainty. That was one.

A second one was the whole notion of how professionals across different rare diseases, because there are something like 6,000, I guess, how professionals across those different rare disease states might be able to share best practices more effectively because even though the diseases are quite different, this notion of how one communicates evidence within one’s field about a rare disease professionally as well as with patients seem to be quite an important point.

And the third was there was some discussion of -- and you get into this a little bit -- how we might leverage data networks and registries as repositories of information that could allow both on the input side and the output...
side some new types of communication dissemination research.

So, we actually had a fairly robust and rich discussion with several folks from the rare disease community. It was quite helpful.

MR. WHITE: Hi, John White from Philadelphia.

I wanted to ask about -- well, I applaud PCORI’s focus on Patient-Centered Research and research that will make a practical difference, but I’m quite interested in the developmental process of clinical research and the fact that it typically involves stages of development and I guess what I’m wondering about is that in some agencies that have been pressed to fund the practical, it’s my observation that sometimes they prematurely fund studies that are intended to answer a practical question, but where the tools have not been adequately developed or the background research has not been done.

So, in the prioritization that we heard about earlier, I don't think there was any filter
that asked sort of what's the scientific readiness
to be answering this question and I’m just
wondering sort of how PCORI will facilitate in
making sure that these practical questions are
asked at a point where we have the tools and the
preliminary work to make the money go well?
Thanks.

PARTICIPANT: Yes, I could answer if I had
a mike.

DR. BOULT: So, I’ll try to answer.

PARTICIPANT: Okay, go ahead.

DR. BOULT: So, to get back to this issue
of trying to really think about how the results of
the research project may be useful to decision
makers, do you think that that may be a strategy
for trying to get at the issue about the readiness
that you're mentioning?

MR. WHITE: Well, I mean, I guess the
concern I would have is supposed the answer is this
study as it could be proposed today won't answer
that question. Is there a step back that gets
supported to get us to the point or if it turns out
that the tools aren't there today, oops, drop that from the priority list and let’s move on.

DR. BEAL: So, what I would add is that if you look many of the Pilot Projects that we’ve funded, many of them are designed to answer just those questions. So, what are some of the best tools that we have to capture some of this information?

So, the first answer is that we’ve already done some work, but then the follow-on answer is, clearly, there will be more work that needs to be done and it’s certainly one of the things that we are considering as we’re looking at potential questions that are out there, if there's really just not this fundamental baseline work that has been done that allows us then to answer these questions. It’s certainly something that would be considered.

PARTICIPANT: I know you’ve put it onto us, but I would put it back to you just for a second just to thank you for the opportunity to be here and be part of this. I’m pretty overwhelmed
by the kind of openness to different perspectives and the emphasis on the patients’ voice and the caregivers’ voice, things that I don’t hear or see that often, unfortunately, outside of this arena. So, we used the word “we” this morning. I would reiterate I wish we have great luck in the future. I do have a more practical question, too. Working in academic medicine, I’m curious where does medical education fall within your research priorities and so on? Because I’ve heard it’s easier to teach new dogs old tricks, something like that. I don’t want to be ageist. I work in geriatrics, but if you get trainees at a younger point in their career, you might reap better benefits.

DR. BOULT: I’m not really knowledgeable enough to fully answer that question, but I certainly resonate with the theme of it. In other words, to be training the next generation of people who are going to be doing research, they have to be viewed with these kinds of principles that otherwise we’re just going to keep on doing the
same old same old. So, I’m just not sure what
PCORI has done so far or plans to do with regard to
training the next generation.

DR. HICKAM: Well, I think that’s a couple
though of kind of natural applications of your
question and one is the communication and
dissemination work. I think there is opportunity
there for projects that are applicable to trainees.
The other thing is PCORI just recently came out
with a broad announcement about infrastructure and
it’s worth examining that because it’s got some
workforce components in there.

MR. SILBERG: Yes, following-up on the
communication dissemination piece, we talked about
that in our group a little bit in two specific
contexts. One was research projects that would
look at how communication dissemination can be
better incorporated into training. So, what might
best practices be that docs on and other clinicians
on their way up through training might be taught
that might be more effective than whatever training
and communication is there now, which depending on
where you come from, may or may not be adequate.

There was also quite a bit of discussion in that context, but even more broadly about this whole notion of the new communications landscape with regard to tools. So, you were in the session, so, I know you will recall some of this. This gets to not just clinical and scientific training, whether you’re a physician in training or a nurse or some other clinician, but this whole notion of the technical environment in which all of this is happening and because the tools are changing so dramatically and many of those tools either were designed for or have very specific communications functions of the way scientific information is assessed, the way that information is provided, the way research is happening, much of this technology could potentially be an evening out, a leveler of the playing field in a way, if you will.

So, there may be some opportunities there that even as we look at how these tools might apply in general communications in dissemination research, the training aspect might work naturally.
DR. BEAL: Right, and then the only other thing I would add is, so, Steve earlier today mentioned that we are not a federal agency, but that doesn't mean we don’t pay attention to what other federal agencies do and our board is a very active and engaged board and we’re actually very fortunate to have Carolyn Clancy from AHRQ as well as Francis Collins from the NIH on our board. And so, one of the things that we pay attention to is to not do efforts that would replicate the work of others. So, in fact, AHRQ is actually doing a lot of work in this space to support training and development for the conduct of people or Patient-Centered Outcomes Research. So, we pay attention to that to make sure that although as an independent entity, we are not lapping and duplicating the work of others.

PARTICIPANT: To follow-up briefly on John’s question on the tools and also as someone who’s only a quasi-researcher and half the time is more an advocate trying to clear up some things in my mind about PCORI maybe you could help me with.

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So, one of the tools that we would want is we would want patient health status measures, right? So, we’ve known for a while we have things like the SF-36 and how is my hip implant doing and all the rest, but some of these have been in not a very well-developed state because, frankly, there hasn’t a demand for them. The demand the payment system rewards, new tools for orthopedic surgeons, not new tools for orthopedic surgeons to know how their patients are doing. Just to pick one aspect of medicine.

Now, if you all were something like DARPA, the defense research people who are probably on this side of the river, you would have a goal that says we want to advance America’s defense capabilities, so, we will reach out and fund certain kinds of things so that they can be implemented to help us. Will you all reach out and say you know what, if we want to transform the health care system, we need to go and, in fact, proactively fund better measurements of patient health status. We need to proactively make sure
that some of the technology that Bill’s talking about is able to be integrated from off the grid into the grid. I mean, that kind of sort of with purposeful kinds of transformational research that you will actively seek or you're more well, we want to go disease by disease and things like that. That’s kind of swirling around in my head.

DR. HICKAM: So, I would direct you, again, to the recently-released announcement, the broad funding announcement for methodology and infrastructure because I think it does give some room for development of better measurement methods, which is what I think I heard you say was a goal, that it would be important.

PARTICIPANT: There’s a larger question there [off microphone]. That’s a terrific health services research answer. I’m trying to get beyond that to see whether you guys are trying to transform the health care system and, therefore, the strategic way will fund certain kinds of research or are an enormous academic funding mechanism.
DR. BEAL: Right. So, our first stab at this has been actually very explicit language in all of our funding announcements that the kind of outcomes that we’re interested are the sorts of outcomes that matter to patients.

So, if I’m a working mother with condition X, I’m interested in can I take care of my children? I’m interested in can I go back to work to maintain my health insurance. I’m interested in my level of fatigue. And so, one of the things that we’ve demanded in all of our funding announcements are that the outcomes that we ask and that the investigators ask are the kinds of outcomes that matter to patients. So, it’s not just about morbidity and mortality, it’s about what matters most.

And is that ideal? No. And is it the total comprehensive way of looking at it? No. But it is a very first important step and one of the things particularly in some of our areas related to communications and health systems were people who have asked us well, really what is a PCORI-like
project? The PCORI-like project is the one where
the outcomes are the ones that my aunt, my mother,
my father would recognize as being important
because they matter to patients, not just to me as
a clinician.

DR. ANDREAE: Traditionally, researchers
in the United States have been trained with
mentored research training grounds and there's a
whole generation of researchers like me who would
like to learn how to research patient-centered and
I wondered will you put out some K08 awards,
mentored research training grounds, or do I need to
turn back to the old-fashioned kind of NIH
institutes?

DR. BEAL: So, we're currently not
planning, which is not to say that we never would,
but we are exploring different ways to think about
this. If you've ever done training programs and
training grants, they actually take years to
develop and then maintained in order to do them
well. So, it gets back to the question that was
asked earlier about training around this area.
And so, one of the strategies that we’re taking is thinking about outreach particularly to different types of medical centers to think about how do you do this research and what are some of the different types of training opportunities that we can make available to different types of medical schools or to make people aware of the sort of training that we do for our reviewers with immediate training that we can do for researchers.

And so, we are thinking about training and helping to develop and refine the field, although not right now within the context of a classic K award.

PARTICIPANT: I’d like to build on some of the workforce comments that I’ve heard throughout the day and Dr. Quigley brought up in health systems improvement, that we really need the teams in order to engage patients, we really need the teams to function to the top of the scope of their practices and license in line with the OIM Future of Nursing Report.

So, we could certainly involve patients
and caregivers and research, how can we get that to happen? The drivers in the Readmission Action Team convened by the National Quality Forums National Priorities Partnership, the Readmission Action Team for the Partnership for Patients was patient engagement and the real crux of the way to get that to happen is to get the team functioning as a team with the right mix, with the right staffing, with the right certification, knowledge, and skills all practicing at a high level to the scope of their practice and their license.

MR. PECK: I couldn’t agree more.

[Laughter.]

MR. MARTIN: Any final questions or comments? One more.

PARTICIPANT: Sorry, I just can't help myself. I need to follow-up on that and just suggest that we need all of that, but we also need a mechanism for patients and families to learn how to be a team member, to accept the roles and responsibilities, or for us to understand if they have limitations that they can't accept those rules
and responsibilities that we understand how we manage that. So, team-based care has to, as we know, include the patient and family, but it has to do it differently than we’ve done it in the past. We have to start giving them some better understanding. It’s almost like illnesses doesn’t come with an owner’s manual, as I said recently, so, I think we need to figure out a way of being able to help them understand what their roles and responsibilities will be so that we actually do have a full participatory team.

MS. WILLIAMS: Okay, so, I’m Pam Williams and I’m one of the Pilot awardees and I have now heard the last two comments, the physician up at the front as well as the lady that just spoke asking about training to do community-engaged research and to have community partnerships. Getting the partners trained as well as getting the academic scientists trained. And I’ll just share what my success story was, was going to my CTSA, their community engagement core. And CTSA’s are parked all around
the country. Most of them should have a community engagement core, a community member should be able to go to that CTSA office and say I want to be trained. That’s what happened at my academic institution, that’s how I got my matchmaker. PCORI wants to have a matchmaker initiative. Sometimes they're already out there, these models are already out there and I just want to urge people to look to their local CTSAs.

Oh, okay, CTSAs are funded, I believe, through NIH and they are Clinical Translational Science Awards and they are at local -- across the country -- academic institutions. Duke had one. UNC Chapel Hill has one. They're all over the country and they call themselves by different names. So, afterwards, anybody that’s interested, I’ll be here for the rest of the day and I’ll try to get you hooked up with that.

But there are so many different research institutes out there on the horizon for community members to try to interface with and it is alphabet soup. So, but just remember not one institute’s
going to meet all your needs. Sometimes, you have to think about diversifying the different institutes to get all your needs met.

MR. PECK: So, we have a question that’s come from Twitter. How can imaging be used as part of Patient-Centered Research to maximize efficiencies around diagnostics?

MR. MARTIN: A question from the Twitter-verse.

DR. HICKAM: Well, that’s a comparative diagnosis question, I think. So, I think that is open to creative research ideas.

MR. MARTIN: Okay.

MR. BIGGERS: I just wanted to add, going off of the comment over here, as well as the earlier comments about the rare disease communities, I think connecting with the rare disease communities will be helpful to the PCORI effort to the “new we” both because PCORI has been mandated to help serve that community, but also because in our view, that’s the best place where we find the highest concentration of success stories.
and case studies about how to do patient-
collaborated health research. And, in fact, when
we set out to build this online platform for doing
participant-driven health research, we went and
studied a bunch of the rare disease communities
because that’s where it’s happening now.

So, I’ve already offered to Sue and Susan
to help convene more of the rare disease community.
I think there are other people here, too. But if
you have an urgent need in addition to the CTSAs,
which it sounds like she’s connected to a better-
than-average CTSA. That’s another place to go to
find some lessons.

MR. HATLIE: Did we get an answer to the
Twitter question? I’m not sure. I guess we did.

One more hand over here. Greg, do we
still have time for questions?

MR. MARTIN: We can take one more. This
will be the last train to Clarksville.

MR. HATLIE: Okay.

PARTICIPANT: So, you said the rare
disease communities, and I wanted to actually
second that, but not just the rare disease communities; also very common disease communities. So, the Michael J. Fox Foundation Parkinson’s Disease Research, Parkinson’s Disease Foundation, a number of epilepsy disease communities, CURE, et cetera. So, that was my comment about that.

But the one question that I wanted to ask that I didn’t get a chance to ask earlier today is: Where is this research going to be done? Academicians, in my experience, haven’t been really good at this Patient-Centered Outcomes Research, although, we’re trying to foster an environment where they can do more of this, but it’s an uphill battle and sometimes I feel like Sisyphus at the bottom of the hill every Monday morning, but where is this research going to be done if community providers don’t have the infrastructure to do research? Does PCORI plan on providing enough funding to provide that infrastructure for those community providers to do some of that research?

MR. HATLIE: Dr. Beal? Chad?

DR. BEAL: So, one of the things that was
very exciting when I came onboard was to actually read the legislation and the legislation was clear that they wanted the research to be done in places that do research, not necessarily in places that are academic medical centers or schools or public health or schools of business or whatever, but in places that do research. Combine that with the essentially directive that we’re received from our board to think differently and think out of the box, I think actually that there’s a lot of opportunity for us to not do it among the usual suspects, and, in fact, I will say with a lot of certainty that our board is really pushing us to think very creatively and not necessarily have all of our grants go to the usual suspects.

We have to make sure that that is balanced with making sure that the research is rigorous and extremely well done because patients are going to be making decisions based upon the results of what we’re going to be sending out. But it is actually very exciting to not only see it written into the legislation, but then hear the directives from our
board to say do this differently and think about research differently, which means, obviously, doing it in places that are not where we usually do research.

MR. MARTIN: Okay. Thank you. And thank you to everyone on the panel and now actually, because everyone was so wonderful, we have a great treat for you now. We’re going to turn it over to our resident rocker, Dr. Kara Walker.

I’ve spent the last five minutes trying to think of a clever way to introduce her. She’s going to give you a real-world example of how to prioritize. So, basically, this is going to help bring it back from the framework that Rachael Fleurence discussed earlier and how we can take these wonderful topics that you’ve been giving us today and prioritize them.

So, with that, I will get off the stage and hand it over to Kara.

DR. WALKER: So, I have a set of slides that should pop up. So, good afternoon, everyone. This is almost the last session of the day and it’s
really meant to wrap up everything that we’ve done
from the breakout sessions to hearing about
research prioritization.

I want to walk you through a real-world
element of what may happen to one of your questions
that you came up with today and use that as an
element of a way to walk you through the process.
So, I might call on you, and so, if you don’t want
to get called on, you should volunteer.

So, this is the example question. So, I’m
a family physician and I’m a researcher, but one of
the things I know is that patients come to you with
questions and they come to you with questions when
they're really making decisions. So, this is an
example. Mr. Jones is a 77-year-old man who has
several medical conditions. He has diabetes,
congestive heart failure. His doctors say we need
to keep an eye on your kidneys and make sure
everything’s okay with your blood pressure. But
over the Thanksgiving holiday, he had a great time
with his family, probably had a little too much
salt in his diet from that great gravy and had some
chest pain and his family was very worried. They’ve rushed to the hospital and the doctor said well, we think you’re having a heart attack and we need to figure out what’s going on. So, his wife was there with them and they were trying to think through along with the doctors what they should do in this case. It was pretty severe and we definitely needed to think about it. So he’s listening to the doctors, he’s really stressed about making the right health decision, and his wife is trying to help him along, but he doesn’t necessarily have the information at the tip of his fingers.

So, this is an example of a research question that could come into PCORI. They go home, they’ve decided what may happen, but we’re going to sort of go through this process. So, Ms. Jones goes home and says I’m going to send in this question to PCORI’s Web site because I think I need better information at the point of care when I’m making these decisions along with my doctor about what to do for my husband given all these medical
conditions, his age, his other comorbidities. And so, this is an example of what could come into PCORI.

So, now I’m going to put some of you on the spot. How many nurses are in the room? Great, I’m so excited that you’re in the room. How many cardiologists? Do we have any? I know there’s one. How many internal medicine docs? Great. Wonderful. How many payers? Employers count. Absolutely, wonderful. I can’t wait to engage you in this next step.

So, as you heard from Rachael, we’re planning to generate a series of questions from our topic generation process. The question about what to do in the treatment of coronary artery disease is one of those questions. But just as you heard, we’re planning to have a wide range of questions that come in in a variety of clinical areas. And some of them will be about health systems questions, some of them will be about comparative treatment options. And so, this will just be one of those topics that come in through this process.
So, the next step that we’ll have to go through for this question that Ms. Jones presented us is figuring out what evidence exists. What evidence exists for the treatment of coronary artery disease for this particular situation? So, PCORI will think about it and we’ll think about it for a range of topics, including what systematic reviews are out there and exists? What systematic evidence has been compiled to date to answer these specific questions given Mr. Jones’ specific heart condition and his specific medical decision-making that he’s going through right now?

So, as a high level, some of the cardiologists in the room and internists may know the evidence at a much more detailed level, but right now, what we do know is that there’s a lot of information about whether it’s better to have open heart surgery, so, CABG, Coronary Artery Bypass Surgery, or percutaneous angioplasty, where they use a balloon to go in and open up a vessel, depending on how many arteries are blocked. That could involve stents, but for some people who are
really sick and can't necessarily go through a surgical option, it might be that medical management is the best option for them given their risks and benefits and all of those type of questions that are out there. So, for this particular question, there's more research that's needed and PCORI says this is something that should go into our research prioritization process.

So, as you can see, we this list of questions that’s coming in. We’ve eliminated a few that maybe, as Rachael Fleurence said, already has evidence and what we need to do is a better job of disseminating the information at the point of care so that people can implement existing evidence. But this is one of those questions where we actually may need to gather more evidence and research.

So, we’re thinking about all these different factors about which topic should be highly prioritized and funded in a targeted way and these are some of the criteria that we’re trying to think through. So, what we’re going to do is this
group today is going to be a virtual advisory panel where we’re going to talk through how we evaluate one topic. It could be a topic one of you submitted, but we’re going to talk through this coronary artery disease example and think about all the different tradeoffs as we go along.

So, okay, I’m going to take a poll. So, in terms of patient-centeredness, is this question that Mr. and Mrs. Jones have patient-centered in your mind? Is it something that patients and clinicians are asking for? Is it something that may make a difference in Mr. Jones’ life as he makes this decision? I’ll just take a show of hands for this one.

[Hands raised.]

DR. WALKER: Oh, wonderful. So, we all agree that it’s patient-centered.

Would anyone like to volunteer an argument to say why it’s so patient-centered? I know someone out there is dying to tell us. Anyone, anyone?

[No response.]
DR. WALKER: There are lots of volunteers. You need more caffeine. It’s the end of the day. Well, I’ll say while you think about your argument that this is obviously a question that many people face and that has to do with specific decision-making and it’s something that’s not that uncommon and we’ll get to that, as well. But there are probably other issues that we could talk about in terms of this specific question. It’s not yet a research question. So, maybe some of you in the audience might say well, to make it even more patient-centered, we need to think about how we incorporate Mr. Jones’ preferences to make this a really patient-centered research question. Maybe there are other questions about quality of life and how he can interact with his grandchildren that we need to account for when he’s making decisions about whether to have a risky surgical option or go with some other lower-risk option for his condition.

So, I’m going to ask one more time: Any other arguments about why this is patient-centered
or not? Maybe somebody says this isn't so important. Great.

PARTICIPANT: There is a flaw in your story and that is that the patient you presented to us is in an acute care situation. We don't know whether they've had a heart attack, and so, we do know what to do in that situation. So, I think it's premature to say that we would go to all those other options.

DR. WALKER: Great, thank you. Thank you. You're right; we don't have enough clinical information to say what the true decision factors are.

Please.

DR. WEISMAN: There are a couple things besides -- let's say he had a heart attack and we do know what best practice might be in an academic medical center or a tertiary care center with those options available, but if Mr. Jones lives in a rural setting where some of these are not immediately available, but could be available by some type of transportation, that also is going to
go into personal preferences and what’s practical.

It may be that being very close to his family and having them around him are far more important than being at a hospital three hours away where people can't be around.

So, there are a number of factors that will go into both his immediate care and his ultimate outcomes that matter to him that must be individualized.

Another one that I think is really important is that it sounds like he’s retired by his age, but driving may be something that’s very vital for some reason in his life. You can't drive for two to three months or longer after coronary artery bypass surgery. So, there are lots of things that go into choices that go beyond what we know from randomized clinical trials that have given us very clear algorithms on what to do.

DR. WALKER: Great, thank you.

PARTICIPANT: Okay, yes, I guess I do want to comment also now because as you're right, it’s a very complicated situation and even if we know that
he has acute coronary syndrome or he’s just had an MI, we don't know if he’s already been on Plavix, has he been taking warfarin? You can't go right to CABG if the person has already had too much of a blood-thinner. So, there are definitely decisions that will have to be encountered and is he a candidate for stenting? Everybody is not a candidate for stenting. Stents close on people. I mean, there are definite real questions that need to be -- did he end up a center where they have standards in place when the patient comes into the emergency room? Because I used to work for Bristol-Myers Squibb and was part of the team that helped get a lot of those admission orders in place, but there are still lots of hospitals around that don’t have standard operating procedures when somebody comes in with an MI.

So, it’s a lot of pieces that are floating around and it’s not just that clear just because you know that he’s had an MI. So, you're right, there are a lot of things that have to be considered.
DR. WALKER: Absolutely. So, we'll go to the next slide and -- oh, please, one more comment.

MR. WHITE: Yes, well, I'm not sure exactly how this maps onto patient-centeredness, but this is one of many examples where the different interventions are offered by different specialties which I think makes it harder for patients to weight and pros and cons because they're not getting the information from a particular professional who weighs them, but potentially from people who have vested interests.

DR. WALKER: Yes.

PARTICIPANT: And just one more comment before you go to your next slide.

DR. WALKER: Okay.

PARTICIPANT: Your example should have been a woman and it should have been stable angina, and the reason I say that is that I was on the evidence review that just published this summer on the treatment options for women with heart disease and the evidence gap is truly in women and the evidence gap for whether you should get bypass
surgery, PCI medical therapy is probably the largest gap for gender-based outcomes. So, next time when you do the example, she’s a woman.

DR. WALKER: Thanks.

[Laughter.]

[Applause.]

DR. WALKER: I like that suggestion.

So, we’ve already kind of touched on this next factor that should be considered by all of our panels, although we are interested in highly prevalent diseases, we also are interested in rare disease or understudied populations, as you just mentioned. And so, as we think about this question, I think the questions that come up around are we studying a common disease, I think most people in the room would say yes. We know 1 in 6 have the chance of having coronary heart disease in their lifetime, but we also know that there are subsets of the population that are understudied and those that are older, over 75, are not often included in randomized controlled trials, those who are women and those who have multiple chronic
conditions because they're high risk, and so, sometimes they get weeded out of these kinds of studies.

So, would anyone else like to make the case for why this disease topic area should be studied from the perspective of thinking about individual suffering and loss of productivity?

[No response.]

DR. WALKER: Go heart disease. Everyone thinks it’s a great topic, sounds like. Great. We’ll go to the next slide.

So, this gets to this question of where is the evidence? So, the difference in benefits and harms and reduction and uncertainty is something that PCORI wants to make sure we’re addressing. We want to find those research and evidence gaps that we can fill and do that through comparative work. So, how do we look at this question that Mr. Jones and his wife have brought to PCORI? How do we think about what are the needs in terms of new research? And I think we just heard that we need more research in cardiovascular disease in women
and particularly for unstable angina.

Are there other issues that we should bring up? And maybe that makes us change the research question slightly, depending on where those gaps in evidence are. Anyone else want to add to that, build on the last thought?

[No response.]

DR. WALKER: Do you think there's sufficient uncertainty for those of you may have heard about these kind of decision-makings? Sufficient uncertainty, raise your hands. Hands, hands. Maybe. There's a couple of maybes.

[Hands raised.]

DR. WALKER: There is a lot of research that’s out there right now about whether you choose open heart surgery, CABG, or stents or others and who has been adequately studied?

So, okay, well, how many people think we know the evidence, we don’t need to pursue this as a topic? It’s been over studied. Anyone want to make that case?

PARTICIPANT: [Off microphone] case for
that --

DR. WALKER: But you think it’s over-studied. Great. There are other topics that should be placed at higher priority potentially?

PARTICIPANT: Yes, I think it would be difficult for PCORI now to say well, we had some input from the patients and the stakeholders, so, we are shifting gears and Mr. Jones has now become Ms. Jones and we also are interested in incorporating more stakeholder comments like, for example, location costs and you mentioned conflict of interest and how they can impact that. So, I would say we should change the research question in that direction and then yes, indeed, there is enough uncertainty.

DR. WALKER: Great. Excellent. And what you don’t have in front of you is the range of other topics and other research gaps that we’re considering across. So, right now, our agenda item is to talk about this particular question, and so, I think that’s great input. Wonderful.

MR. HATLIE: We have a comment over here.
DR. WALKER: Oh, we have one more. Gail, please.

MS. HUNT: Yes, this is kind of small, but my understanding of open heart surgery is that one of the harms that’s not often discussed is the possibility of having stroke subsequent to it. And I think I saw a paper on that once and I know that there are people who’ve gone and had open heart surgery and no one ever said there are a such and such percentage of people who have stroke post-surgery.

DR. WALKER: Thank you. Thank you. And those are personal choices that need to be made and weighed when you're thinking about how you make these treatment options and treatment decisions.

So, this next one is really a question about how do we choose research topics that are likely to be implemented and practiced in a relatively short timeframe? How do you find those research questions that if we knew what to do in women, with Ms. Jones in particular, how likely would that change practice? And if we had that
answer, would we know what to do next? So, I wonder if anyone would like to make the case that this is really important now that we’re studying Ms. Jones and it’s something that will be used and picked up by clinicians and something that will add to improving the health care for this population. Anyone? Please. Microphone is coming.

MS. LINKOV: I have a comment and a question. So, the answer to your question is I think that if this, whatever it is that’s being developed, if it helps with patients like this couple, it will get picked up. But, unfortunately, doctors tend to be busy. So, depending on what’s involved, there are many decision supports out there that doctors are not willing to use.

So, when we, the researchers, developed our grants, how do we know what PCORI or reviewers will view as something that might or might not be implemented? Because, to me, it seems like depending on how long of a physician time this intervention or whatever it is will take place, it will determine whether or not it will be uptaken or
I don't know what reviewers or whoever will be using. So, I would appreciate your response to that.

DR. WALKER: That's exactly right. And so, as we develop the information that will guide these advisory panels and the research prioritization process, part of it is asking for the views of those who are at the table to decide whether this is something that’s implementable without having a study in front of them, without having necessarily the research protocol in front of them. It’s really looking at a topic and a research question.

So, I think that’s challenging. It’s challenging to figure out which things will be easily implementable and I saw some other hands up about this particular factor and criterion as we evaluate research topics. I’d love to hear some other thoughts about this one.

PARTICIPANT: One of the things that we know in industry is that if whatever doctors train on -- now I’m giving away the Dark Empire secrets,
but we know that whatever physicians train on, that
is generally what they will do when carry on
through their lives. It’s what you learn early.

The VA system is a big place that they do
the majority of training of residents. And so, if
you have your intervention, the VA system
physicians will train on it, but that’s one reason
why with respect to women. Now, that’s changing in
the VA system, but for many years, there were very
few women in that system and most clinicians train
in that system. And so, they learn their practice
habits there. So, I think that as we have more and
more women in the VA system, you’ll start to see a
lot of the practice patterns become broader.

But speaking to cardiovascular disease,
like for instance we know today that it’s not the
site -- for instance, we’ll tell people oh, you
have a 70 percent blockage, you have an 80 percent
blockage, and it’s like oh my God because that
makes sense to the common mind, right? But it’s
really the less than 50 percent on stable Plex that
are more dangerous than the 80 percent stable Plex.
They don’t understand that variance. Nobody takes the time and sometimes people get surgery or interventions that they don’t need and it’s that kind of detail that I think she’s speaking to where we sit down and explain those differences. I think it’s easier, as he said; it depends on the specialty talking to them.

So, if it’s interventional radiologist, he’s like yes, we can take you to the cath lab right now and stent you and you can go home tomorrow. We have to begin to communicate the level of information down to the patient so they can understand when and when they should not, but you’re right, they don’t have that today.

PARTICIPANT: And I think my comment kind of jobs tops onto that in terms of sorry to be a little bit cynical, but at least there are some people who would say that depending upon which center you go to and what specialty is strong at that center, they will find that the best therapy is whatever is their strength. And so, I think what’s relevant here is that a study which brings
all of those stakeholders to the table and involves surgeons and involves cardiologists and involves minimally interventional vascular folks is probably stronger than one that is only representing one point of view.

MR. LIPSTEIN: Kara, one of the things, you haven't read our Methodology Report. It’s a real page-turner.

[Laughter.]

MR. LIPSTEIN: But there's a section on there on what they call value of information research which I didn’t really know what that was until I became a member of the PCORI Board, and it turns out that there’s this whole area of investigation where you actually say if I had this information, would it have changed what I did anyway?

And so, in Mr. Jones’ situation, I’m thinking okay, here’s a man, he’s in the emergency room, he’s got bad chest pain. He and his wife and probably at heightened levels of stress, anxiety, fear, and they may have actually looked into this
ahead of time, but if they didn’t, is there any information that would be available that would actually change the decision-making at the point of care? And if it wouldn’t change the decision, then according to this methodology logic, it has a low value of information even if it would be good to know.

And so, part of what I would encourage as we think about this is where are those circumstances in a land where we have 800,000 physicians, many times more nurses than other health care professionals at 320 million people, where is the real value going to take place when we add in information into the mix?

PARTICIPANT: And I’ll bring up one more point around this evidence stuff. So, at the American Heart Association meeting, they brought up the fact that diabetics do better with bypass and so does your patient diabetes. So, as we talk about patient-centeredness and making decisions around individuals, already in the cardiovascular society, and I’m a general internist, but I follow
the heart.org. They did say that diabetics have an advantage with bypass surgery. So, if you told me this patient’s a diabetic, I might have a more serious conversation around the surgery than if knew that they didn’t have that risk factor and I might think about stenting that person or medical therapy. So, just something to bring it up that there is some uncertainty in this topic of treatment options.

DR. WALKER: Absolutely. Particularly because some of those studies weren't conducted in those who are older than 75 and have other comorbidities. And so, it is challenging, but it is also a question about how do we find things that will be implemented because, as you said, if guidelines are already out saying diabetics do better with open heart surgery, then maybe physicians won't be likely to listen to a new study that’s much smaller in size. So, it’s an ongoing discussion and question.

Are there any other hands that I missed?

[No response.]
DR. WALKER: That’s a great discussion.

So the next criterion that we are going to talk about is if we conduct this study to answer some of these research gaps, how long will evidence exist? Are there going to be new technologies that emerge that will cause us to have to revisits the research gaps all over again? Are there going to be new types of drug-eluting stents that need to be now evaluated against CABG?

And so, I wonder if anyone in the room would be willing to chat about whether these research findings will be still valid or whether there’s going to be some new technology, some new intervention, some new procedure that will take the place of these other strategies that have been tested and would be tested through this existing study. Anyone? And I guess part of it is it’s a little unknown. We’re not sure what may emerge. Maybe someone in the pharmaceutical industry or the device industry knows some advanced knowledge, but as part of the advisory panel process, we’re going to be asking these types of questions. Some of
it’s a little bit of fortunetelling to see what the case is and using your own judgment and experience to make those assessments.

Please.

PARTICIPANT: I think one of the research that PCORI could fund that would have longest impact would be methodological research. So, in fact, we’re trying to do off-pump CABGs and we’re going to have many more blood-thinners in the next couple of years and those will be strongly impacting the results of the comparison study, particularly with Patient-Centered Outcomes like stroke incident or patient is different afterwards and not quite as sharp anymore as before, which will be important for me personally, for example, when I make that choice.

So, with that regard, we are concerned about the lack of validity after a short period of time and having to repeat the study, but if we develop a new way of doing a study, a new way of taking the patient’s outcome interest into account, then future studies could be modeled on that study.
So, I think mythological improvements and a sense of patient-centeredness will be where this study would gain its validity beyond the short time period it’s followed.

DR. WALKER: Great, thank you. Wonderful. We’ll go to the next slide. So, what we’ve just done is talk through all the criterion for one particular question. You can imagine that the advisory panels in reality will actually go through multiple questions in this way. The evidence may be different, the level of the questions and research gaps may vary across these topic areas, but we’re going to ask a wide range of people and views just as you did today.

And as you could see from our draft process, there are a range of people who are going to be involved in this process, as we talked about in our pilot process, which Rachael led. We had patients, but we also had caregivers and family members and clinicians and patient advocacy organizations represented and that’s what we envision happening with these advisory panels, that
people will get some background knowledge about the evidence and the gaps that we know. But we also expect the variety of opinions and experiences will add contextual information to these kinds of prioritization processes as we go forward moving forward with the value of information analyses, you do have the ability to characterize and numerically assess between topics. But some of it still is about how do people come to the table and bring their input and views into finding the right research questions that will have high impact?

So, now everyone is in the process of voting. So, everyone has decided which topic should be highly-ranked on certain criterion, as we just walked through. You're going through this process and you're thinking about it with the information in front of you. And so, the next step will actually be to vote using a software tool. So, we right now have used some decision analysis software to walk through how we'll characterize and rank all of these topics. What we've found is that using different types of software does generate
some variance in the answers.

So, interestingly, for one of the groups that we went through in our pilot process, this very question about how do you treat coronary artery disease ranked very highly. And as Rachael emphasized earlier, some of the other topics were sorted differently, but what we found is that there were a few voices that said this issue was very important and they brought in their own experience to say why we should think about this duration of information and the implementation likelihood more highly for certain topics over others.

And then in another group, there were other questions that came up and the treatment of coronary artery disease was the second-ranked topic. And it was still highly-ranked and thought of as something that needed additional research dollars and investment, but we also saw other topics sort differently. And so, we’re learning from this process and we’re learning from even these conversations we’re having today about what topics to study and how we consider and evaluate
each of these topics, one against another.

And so, what you’ll imagine is that as we take this question and we’ve gone through this ranking process which you have seen our draft process to date, we do plan to have this fully-ranked list that will then go to our board. Our Board of Governors will go through and see this ranked list and then they will finally approve the topics and the research questions that’ll move forward for targeted funding opportunities for the research community, stakeholders, patients to apply for.

So, we’re still learning. I would like to emphasize that all of these conversations and your thoughts about this are truly being taken into account as we move forward with the process. We’re really interested in figuring out how we capture this patient-centeredness through research topics and research prioritization, how do we emphasize the patient’s voice? How do we clarify the criterion, how we describe them, whether it’s talking about the duration of technology, the
ability to implement the research, or how do we think about finding the right level of supporting information? People have a variety of inputs. Some people have clinical stories that can add to the systematic evidence that is out there and that we present to our advisory panels, but some of it is about having the right tools to facilitate a conversation and to collect consensus around all of these different topics.

So, we’re looking forward to moving forward with this process. As we talked about today in our small groups, we’re looking forward to getting a long list of questions and I’m sure Rachael, you and I will have a long list of questions to think about as we leave today’s meeting. We’re really looking forward to figuring out where they fall and some may overlap with our different priority areas, but we’re looking forward to moving forward with this research prioritization process in this coming year and welcome any of your feedback, welcome your questions, and welcome the opportunity to think about how we create high
impact research moving forward.

So, back to Mr. Jones, which we are now replacing with Ms. Jones. So, as we talked about, he had a huge team of physicians and interventionists come to him and talk to him about options and he really thought about what he should do given his issues. And we’re not really sure, but in the future, he’ll have information available to him that’s in a lay summary that he can understand and apply, he can talk to his wife about it, and he can talk through the decision-making with his physician and care team in a way that allows him to make these tradeoffs between having the fewest risks and the greatest long-term benefits for his health, taking into account his own preferences and his own expectations for his health.

So, we’re looking forward to being able to guide patients in this decision-making process, whatever the clinical situation, and making sure that we are able to make a difference in moving forward with generating evidence that makes a
difference.

We have to say thank you again to all the people who have helped us think through how you do research prioritization, how we collect the questions that you’ve generated today, how we’re going to move forward with putting those questions in the public domain so that others can learn from the questions and then move forward with generating new evidence together. So, thank you so much for this opportunity. I’m open to taking questions. I’m sure the other members of the PCORI staff would also be very interested in your thoughts and comments on this process. Thank you.

MR. HATLIE: Okay, thank you.

[Applause.]

DR. WALKER: Are there any comments, questions?

MR. HATLIE: Are there any comments or questions for Kara before she steps down?

MS. HUNT: Yes, yes, me. I’m interested in and maybe you could clarify what do you envision as the level of detail that the research questions
that are coming out might be? Because it makes a big difference. I mean, people could have lots of different ways that they would bid on this, which I think is great. So, could you just talk about it?

Is it going to be kind of like Mr. Smith or whatever his name was and then --

DR. WALKER: From the questions that have come in through the Web site, we’ve seen a wide range. I mean, there are questions that are about how did I get this condition? What is the etiology? And we’re really looking forward to those comparative questions that address Patient-Centered Outcomes Research. And so, how do we collect those questions in the right way? As many of you heard during the small group sessions, sometimes those questions come into us like stories.

People talk about a scenario such as Mr. Jones’ scenario and we can think about how to partner them with a researcher who can create that specific research question that we need answers to.

But we could also imagine that some of the

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questions may come in and not have a specific design in mind or specific outcomes in mind and then we might present that as a portfolio of topics.

Many people in one of my breakouts today talked about the importance of care coordination and you can imagine that that as a thematic area could involve studies of a wide range of conditions and scenarios. And so, it may be that we need to think about how we’re going to prioritize within that thematic area and not necessarily on specific questions.

Does that -- yes, we’re definitely working hard on thinking about how to do that thoughtfully. So, wonderful. Wonderful. So, this was wonderful, thank you.

MR. HATLIE: No, I was just going to say if there are any more questions for you, Kara.

DR. WALKER: Yes, any more questions.

Great. It looks like there's maybe a question here.

MR. HATLIE: There's a comment here.
DR. WALKER: Or comments.

PARTICIPANT: Yes, not really a question, a comment. Thank you very much for having me. I thought this was one of the most interesting conferences I’ve been to in a long, long time, and it was amazing to see the diversity of stakeholders and that every single one had something for me meaningful to say and it certainly changed my perspective and it was exciting to be part of the future because this clearly is the future.

DR. WALKER: Thank you.

MR. HATLIE: Great. Thank you very much.

DR. WALKER: Thank you.

MR. HATLIE: Okay, Kara, I think --

DR. WALKER: Great, thank you, everyone.

And I think we’re inviting --

MR. HATLIE: I think we’re inviting Anne to close, yes.

DR. WALKER: Yes, come up.

MR. HATLIE: Thanks very much. Kara, thank you.

[Applause.]
DR. BEAL: Great, so, it has been quite a
day and actually I was just thinking nice closing
comments, Michael. Maybe next time I’ll have you
come up and say them. But really first of all,
it’s just thank you because I know that we actually
ask a lot from all of the participants who came
today and we’re really asking for a lot of input
from the field.

And so, first of all, we want to thank you
all for the time, the energy, the enthusiasm that
you brought to today’s meeting. I also want to
thank the PCORI staff who spends a lot of time
pulling this together and it was really great to
see us just all work together to be able to have a
vision and really execute it.

One of the things that I wanted to make
clear though is how does this fit? Today’s
session, how does it fit? Because one of the
questions that we often get is: All right, we’ve
all come together, but then what’s next? So, many
of you who are here, particularly those who come
from patient advocacy or patient backgrounds
actually know that we also had about six weeks ago a Patient Engagement Workshop where we wanted to hear from patients around best practices for engagement. We also have plans to engage in these types of activities to hear from the field around the country to hear from different interest groups, to hear from different perspectives. I actually received a lot of comments in terms of making sure that we really engage in making sure that we have inclusive elements to really bring the voice of diverse patient populations into this discourse. And so, we’re definitely working on those activities, so, look for more in terms of 2013.

So, today, I heard a lot of great ideas and everything that you all shared with us today is going into the process that Rachael described earlier today, but I heard actually a lot of comments around training. And so, I think that we need to think a bit more in terms of what are our plans around training. I don't think that we’re going to do the classic type of K awards, but that doesn't preclude us from thinking about other
opportunities for training and I hear that there's a lot of hunger for that kind of work.

I also heard a lot around mental health and mental health issues and integrating mental health into physical health. And so, what does that mean in terms of some of the future research questions that we had? And heard a lot around disabilities and the disabilities community. And so, I know that this is an area that we've been doing a lot of thinking around and actually we've had roundtables specifically seeking input from the disabilities community on our work. And definitely heard loud and clear on the need for us to really think about rare diseases. We’re not only hearing about it from the rare disease community, but, frankly, it included in our legislation. So, we’re definitely going to be doing a lot of thinking to provide specificity for that.

So, what I would say as a follow-up, stay tuned. There's going to be a lot of work that you're going to hear about coming from PCORI. You heard Joe mention this morning that we’re going to
be releasing targeted funding announcements early in 2013, and those are going to relate to uterine fibroids, treatment of asthma, and prevention of falls in the elderly. And so, when you think about the process that Kara just described and think about so, what are some of the criteria that we would apply, in many ways it becomes, I think, increasingly evident why we would pick these kinds of topics where there is not a lot of certainty, where there is a real impact on patients, where the outcomes are really Patient-Centered Outcomes. And so, look more for those types of announcements.

In addition, and you’ve heard a couple of people talk about advisory panels, and so, we are actually going to be forming advisory panels that will be created to help advise us in terms of our research programs, as well as some advisory groups that are going to help us with some of the development and refinement of these funding announcements. So, there's going to be a lot of opportunity for engagement in those.

What I would say is for those of you who
are not already signed up to receive announcements from PCORI on our Web page, please go to PCORI.org and subscribe in order to sign up to receive announcements because whenever we do have a call for advisory panel members or a call for a meeting, we use that list in order to send out announcements. So, definitely sign up as well as encourage the people from the organizations that you represent to sign up, as well.

And then one of the things that I’m very excited about is in the new few weeks, our board is going to be voting on the first round of projects that are coming out of the broad funding announcements that we released in May. And so, some of you actually participated as reviewers in that process and we thank you for your time and attention to that activity, as well. And so, we now have the final high-scoring proposals and will be developing in the final slate, which is going to go to our board in the next few weeks. So, look for announcements on those to be coming out shortly.
So, lastly, I want to thank you for your time and thank you for your interest in PCORI, but really recognize that when we talk about we are trying to do research differently, we want you to own PCORI. One of the things that came out of the Patient Engagement Workshop was that people raised their hands and said we want to be PCORI ambassadors.

We also are starting to talk about welcome to the PCORI family when people come to our events or when they become award recipients from PCORI. And so, as part of owning this, we want you to challenge us and to help us make this better because part of what we’re doing and you’re hearing this a lot is that this is a new paradigm, a new way of thinking about research, a new way of evaluating the value of information that is coming out of the research. And so, as we’re trying to create this, we’re really eager to hear from the field to make sure that we’re doing the right thing and that the work is truly relevant to yourselves and to the nation, honestly.
So, thank you again and have a good trip home. Bye.

[Applause.]

[Whereupon, at 4:47 PM, the workshop was adjourned.]