



THURSDAY AFTERNOON PLENARY SESSION

How Engagement Is Making Research More Useful

Moderator:

Tanisha Carino, PhD

Speakers:

Bridget Hickson

Elliot Israel, MD

Maureen Mauer, MPH

Dolly Stokes

Tracy Tracy, OT, MSCS

Discussants:

Janice Bowie, PhD, MPH

Judy Zerzan, MD, MPH

SESSION TRANSCRIPT

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Future View Productions
PCORI 2019 Annual Conference
How Engagement is Making Research More Useful
Thursday, September 19, 2019
1:00 – 2:35 p.m. ET
Remote CART Captioning

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>> Announcer: Ladies and gentlemen, please take your seats at this time. Our program begins in five minutes.

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>> Announcer: Ladies and gentlemen, welcome back to the 2019 PCORI annual meeting and our Thursday lunch plenary. Please welcome PCORI board of governors member Dr. Kara Ayers.

[Applause]

>> KAREN SYRJALA: Good afternoon. I'm Kara Ayers, a member of PCORI's board of governors. It's my pleasure to welcome you to today's lunch plenary. How engagement is making research more useful. I hope you enjoyed this morning's breakouts. My apologies if it was difficult to choose to attend given the richness of this year's programs. There are more difficult programs to have, however. This plenary expands on the themes of one of this morning's breakouts on the values of partnerships and research. I have to say, that was a fantastic presentation. So thank you to those presenters and all of the breakout presenters this morning.

As you might guess, this topic is particularly meaningful to me. I am someone who lives with a disability and heads up research initiatives designed to improve the lives of people with disabilities. It's from a deeply held professional and personal perspective that I say that patient centeredness is the true north of PCORI. When congress named us, our board paid attention. We decided that a crucial way to embody this vision was to ensure that the outcomes of our research focused on what was important to the patients and those who cared for them.

PCORI also realized that the best way to do that was to involve or engage patients and other stakeholders in the entire life cycle of our work, from how we generate and prioritize topics to study, to how we support the research and results in practice. We do this based on our conviction that if patients and other stakeholders are involved in everything that we do, the research we fund will be more relevant, useful, and trusted by the patients and clinicians in making health care decisions. It will also be more likely to be widely used.

To make this idea a reality, one thing we have done is to require our awardees to engage patients and stakeholders throughout the planning and results of the funded studies. PCORI has become a catalyst for engaged research, not only just among our awardees, but the entire health care community. Engagement can take

many forms. The guidance that we've offered on this topic has not dictated what should be done at different stages of a research project. This was a conscious decision given the newness of this approach and the lack of explicit evidence about what engagement should look like and how it should happen exactly.

Along the way, we've shared lessons about engagement from the experiences of our awardees and partners as they reported to us. This has been very helpful in finding insights on how partnerships are initiated and fostered and the benefits and challenges that individuals and communities face and experience along the way. Now we are at a crucial juncture. Our approach and engagement has become a realtime experiment. It's a laboratory, if you will, for an innovation that offers a rich set of experiences and data to generate real world evidence about what exactly is changing thanks to engaging patients and other stakeholders and exactly how that change is occurring.

That brings us to today's plenary. Talking about our effort to study what we've learned and how we can apply those lessons in the future. This initiative involves rigorous qualitative analysis of an incredibly rich array of engagement activities across our research portfolio. Our goal is to understand how people are making engagement happen and how that engagement is influencing the studies we fund and their outcomes and impact in the real world. It's part of a series of activities we're undertaking to understand engagement at PCORI so we can generate new knowledge, enhance our approach, develop paths to improving practice and advance the field overall.

So let's get to it. Welcome the moderator for our lunch plenary, Tanisha Carino, executive director for FasterCures.

[Applause]

>> TANISHA CARINO: Thank you, Kara, for that kind introduction. Thank you, PCORI team for the invitation to be with you today. My name is Tanisha Carino. We're a center of the Milken institute. Over the past 15 years, our mission has been to identify and disrupt the bottle necks that slow the progress of treatments patients need. Key to this mission has been in supporting the role that patients and patient organizations play as a catalyst across the entirety of the biomedical ecosystem and health care at large. It's been our point of view that I'm sure all of you in this room share that patients are critical to fixing a system that is too often too slow, too siloed and too bureaucratic. For them, time does equal lives and for us lucky enough to work in this field, it's this urgency and the focus that drives us to do more and do it better.

Our board member David Feinberg at Google health was quoted as saying health care is broken because we designed it around the wrong people. So congress, with the support of many of you, sought to right this wrong as it relates to the research on what we need to know works and doesn't work for us. And PCORI has been transformational in changing the mindset of researchers and others for the importance that patient-centered research has had in blazing trails to finding collaboration, methodology and investing in compassion building that we all need. I hope to provide you with a range of perspectives for what we've learned to date and also engage all of you in what the future holds for all of us. The discussion include what does it mean to engage research. For the research and the patient community, where are there critical incidents and pain points. How do we know that the approaches that we use are taking a representative view of the full patient perspective. What has been the impacts of engaged research and what can you learn from the cases we'll discuss today. And finally, where is the science of patient engagement going and what can be the role of PCORI.

I want to begin by giving you context for how we're going to structure the

panel. It's not going to be one big discussion. Maureen Maurer at the American institutes of research will share with us the results of a study on how engagement has influenced the planning and conduct of PCORI-funded studies and what changes to studies have resulted in that influence and how it occurred. Next, we're going to be featuring the experiences of researchers and patient collaborators for two PCORI-funded studies. First we'll have the principal investigator Elliott Israel who is the director of clinical research in the pulmonary division of Brigham and women's hospital and professor at Harvard university and patient caregiver collaborator Bridget Hickson from the PREPARE study. Then Tracey who is a clinical research coordinator and her collaborator dolly Stokes from the team study. We're going to have a ten-minute discussion with these two project teams, Maureen about the experience in these two studies and how it can be generalized. Next, I'm going to be inviting Janice Bowie, the associate professor at Johns Hopkins school of public health and Judy Zerzan, chief medical officer for the Washington state health care authority to join us in a discussion of how this type of research is influential and impacts communities and policymakers. Finally, Kristin carmen will join for a discussion of where is the future going and how do we see the role of PCORI evolving. As many of you know, Kristin is -- let me make sure I get the exact title. Kristin is the director of public and patient engagement at PCORI.

We're going to have 20 minutes at the end for questions. I invite you to write your questions down discussion the discussion and then you'll see mics available to you. Let me invite Maureen to come to the podium and start our discussion.

[Applause]

>> MAUREEN MAURER: Hello! Thank you for having me. Show of hands. I actually can see people. How many people in this room are researchers who engage a partner on a research study? Woo! How many people are a patient, caregivers or other stakeholders that partner or lead research studies? Yay! I think we can see from this fifth annual conference and this room that PCORI has demonstrated the feasibility of engaging patients and other stakeholders in comparative effectiveness research. Yet, people still have questions about how engagement influences and effects those studies.

So today, I'm going to share with you some findings from interviews we did with the researchers and their stakeholder partners that sought to answer these questions. I have nothing to disclose. So our research questions were: How does engagement influence the planning and conduct of PCORI-funded studied and what impacts to the study result from that influence? So who did we talk to? To answer our questions, we wanted to speak with reliable witnesses, people who were -- had experience and knew what they were doing and could really talk to what they were doing. So we talked to researchers who reported that engagement had influenced their study and their stakeholder partners.

We selected 58 projects. For the researchers in the room we had a stratified purposeful sample. We conducted hour-long interviews in English with 58 principal investigators and/or another member of their research team. And then we encouraged those researchers to share a list of partners -- of their partners for us to contact to interview. And we were able to interview 51 stakeholder partners. 19 of them primarily identified as patients or caregivers. And the rest as clinicians, subject matter experts or representatives from patients or consumer advocacy organization and some had multiple roles. You can see that today. So we achieved diversity in study completion status. So all projects were one year in, and 19 had been completed and there was diversity in PCORI funding announcement type and priority areas. And people were

candid about their experiences with engagement. So people told us both about their positive experiences and their more stressful experiences.

And just as a note, PCORI doesn't know which individuals we talked to. So some of you may be in this room. If so, I just want to thank you for taking your time to speak with us. We learned so much from the interviews. And today I'm going to share with you findings from looking at a catalog of examples that we captured from the interviews that identified both types of influence or how partners contributed to this study and types of impact or the results of those contributions.

So I'm going to start with two examples. From a partner, from the very first glimmer I was involved, we sketched out what a trial would look like together and wrote the grant together. From a researcher, "the providers were really critical in helping us make decisions around how the intervention was going to be integrated into the clinic workflow."

So those were two brief examples. And in fact, researchers and partners shared nearly 400 examples from the 58 projects. So each dot up here represents an example. It's a lot of dots. It's a lot of data. So it's a little overwhelming actually to see it up on the screen like that, but we were able to summarize in some key ways. So what did partners influence? Partners influenced study plans and conceptualization. So things like selecting the overall study design. They also chose outcomes or measures for the study. The partners influenced the content and format of study materials and dissemination products. So things like recruitment materials or contributing to a manuscript. Partners led or carried out study tasks like rolling study participants or collecting data. Partners designed or carried out engagement. And then finally, partners taught researchers about the lives and circumstances of patients, clinicians, organizations, and others involved in and affected by the research. And I think we can see -- at least I've observed at this conference how partners and other stakeholders are doing that throughout the plenary sessions, the sessions this morning. It's just been amazing.

So we also looked at how partners exerted influence. So working from the examples, we identified types of influence and then classified each example to that type. First up was co-producing influence. And in this type, partners and researchers worked together or collaborated. So, for example, they co-conceptualized a research question together. And this block here gives you a relative sense at how often this type showed up in our data. Next up is redirecting influence. And in this type, partners shifted the direction to create a new approach. So, for example, researchers might say, you know what, no one is going to take that drug in that third study arm, maybe you should think about dropping it or thinking of something else. So it kind of created a new approach. There was also a finding influence where partners edited or modified existing plans or materials, so suggesting tweaks to recruitment materials. Confirming influence where partners reviewed and validated existing approaches and moved things on their way. And last up, there was limited or no influence. And in these cases, influence didn't occur for a variety of reasons. For example, maybe an institutional review board regulation prevented a partner's suggestion from occurring. And when we looked at how these different types of influence showed up in individual studies, we were surprised. So instead of a study having mostly one type of influence, most studies reported two or more types of influence within a study.

Okay. So who's ready now to learn more about impact? Which I think is something that a lot of people are interested in. So I'm going to go back to the data and the quotes. From a partner, the survey questions were coming in at a slower pace than what the researchers wanted. So after we gave our suggestions, they realized a huge

difference. They mentioned 80, 90% up from 50% last year. From a researcher, they gave us -- oops, sorry. Insights and suggestions that we probably wouldn't have come up with on our own that in the end improved the trial design, trial implementation and hopefully will give us the most meaningful results. So we went back to each example to understand what researchers and partners reported as the impacts. And we found that for about 20% of the examples there was no reported impact. So people either -- the interview participant didn't know or they couldn't remember and in some cases it was just too early to tell what the impact was. And then we classified each example to a type of impact including impacts on how well the study reflected the needs and preferences of patients, caregivers, clinicians, and others involved in the study. So, for example, making a questionnaire more user friendly or reordering how data collection was going to occur to reduce burden on site staff. There were also impacts on study feasibility. So, for example, meeting or exceeding enrollment goals. In some cases, partners actually came up with the idea for the study. And so the study wouldn't exist without their contributions.

There were also impacts on study quality. So, for example, a studies comprehensiveness by adding data collection time points or by increasing or decreasing the rigor of study design. There were impacts on the scope or quality of engagement. So an example here would be setting aside time at a large multi-stakeholder group meeting for the patients to get together and meet and feel comfortable with each other so they can contribute effectively.

And then there were also reported impacts on acceptability. So, for example, adjusting the study aims to make the study more interesting -- of interest to patients or impacts on relevance. So, for example, selecting outcomes that would be -- matter most to patients and clinicians. And just like with the types of influence, most people reported two or more types of impact within a study. This is a question that we get often, is, you know, was it positive, was it negative. I would say overall, people shared positive impacts, but there were also some reported impacts that were neutral or maybe slightly negative. So, for example, engagement might be creating delays in the project. Researchers also mentioned tensions, challenges, negotiating kind of tensions from engagement input and science best practices. So having difficult conversations. I think this quote summarizes that thought nicely. It's challenging to put varied opinions together and come up with something that is scientifically sound that addresses what the project is actually designed to do. Takeaways, engagement is changing how studies are done. We are starting to understand the extent and range of examples of how engagements influence and affect those studies. And researchers and partners on the whole found value in engagement. We can also use these results when planning engagement on the study. So for -- you know, I think it might be helpful to come to agreement on the expected types of influence and impact. Sorry. Just, you know, at the beginning of the study. And then also having more support for conversations that may be difficult. And negotiating those tensions and possibly unsurfacing different values that each party is bringing to the table to the study.

We also need to think about measuring engagement differently to look at how the different types of influence and different types of impact are working together on individual studies. And there's more to share from our interviews and so much more to learn. We're just scratching the surface. To leave you with some final quotes. At first we viewed it as burden some. Over time, we started to see the value in the way it was impacting the decisions we were making and how we were carrying out the study so it would be more relevant to patients and providers on the front lines. And from a partner. PCORI and this study has opened my eyes personally to how important my

input is. I did not know that until I got involved with this study how important my voice, how important a patient's voice is in studies.

So thank you for your attention. I also want to thank the team. I think they're sitting way in the back there from the American Institutes for Research and the PCORI team and to PCORI's patient and -- their advisory panel on patient engagement. So thank you, thank you, thank you so much for your input.

[Applause]

>> KAREN SYRJALA: Thank you, Maureen. That was an excellent overview. Sets us up nicely to hear from the project teams. Elliott and Bridget, if you don't mind going up and presenting about the PREPARE study.

>> ELLIOT ISRAEL: It's really a pleasure to be here to be able to give you an example and a real on the ground implementation and things that Maureen found in her discussions. I'm the principal investigator for the PREPARE study that we're going to talk about. I'm going to let Bridget Hickson introduce herself. She's substituting for another patient partner, Mary white. She didn't know until Friday she was coming. We're appreciative. Bridget?

>> First of all, this is a beautiful audience and thank you for having me. My name is Bridget Hickson, I'm a patient, a caregiver, amongst other things a parent.

>> ELLIOT ISRAEL: I'm going to have the privilege of going through some of the findings and describing to you what we found was really unbelievable impact of having our partners. These are my disclosures. Bridget doesn't have anything disclosures. So the PREPARE study which is the Person Empowered Asthma Relief study is based on the fact that African-American and Hispanic Latino patients really suffer a greater mortality, hospitalizations and morbidity from asthma and it's much greater than it is in Caucasians. There's greater rates of hospitalizations, there's greater rates of death. This disproportionate impact has really been very hard to improve. It's been a very tough nut to crack. The interventions that have been shown to work are usually very expensive and very personal and are very hard to implement on a broad scale.

The treatments for asthma are varied. One of the treatments that are effective are inhaled corticosteroids. Patients are reluctant to use them regularly. Patients like to use reliever medications. They're the medications that give them immediate response. You're feeling a little tight, short of breath, you're starting to wheeze, you take a reliever medication and within five minutes you're feeling better. The inhaled corticosteroid is prescribed in most cases twice a day and you're told that you're supposed to use them even when you're feeling well. Only 25% of patients renew prescriptions for inhaled corticosteroids. This is a diagram of what happened to us in terms of our study and how we actually implemented. We had multiple stakeholder groups. We had patients, as you can see on the top lines. We involved providers. We involved insurers, we involved pharmacists because they're on the frontline and they're the ones giving patients advice. We involved advocacy groups and we involved professional societies and we involved content experts. And I don't think you can see it that way, at least you can't see it that well on mine, but we asked them to help us initially with two domains. We asked them to evaluate a different strategy for inhaled corticosteroid use. Our patients told us it was a barrier for them. They don't like to do it and they vote with their feet.

We also asked them to identify outcomes that would be important to them. We didn't want to do a patient-centered study with outcomes we thought were important. We wanted to do a patient-centered study with outcomes they told us were important and the people at the frontlines told us were important. We came up with the following research question based on data before in terms of possible models for

reducing inhaled corticosteroid. Can we reduce exacerbations, emergency room visits and hospitalizations. These are the things that patients told us were most important. Not a quality of life questionnaire. They said the real things on the ground to us are exacerbations, end up not being able to go to school, go to sleep, our kids come home and we can't go to work because they're having an exacerbations. We put exacerbations front and center as the outcome for our study and asked whether we can reduce those exacerbations in African-Americans and Hispanic Latinos, the patient populations that were really most affected.

The partners have been involved in every aspect of our work and really enriched our work. They've been involved in the intervention, talking about how to make it more patient friendly. They have been involved in the outcomes, talking to us about primary outcomes, what other questions we should be asking about other effects this intervention might do, talking with us how to engage with patients, develop videos. The partners reviewed all our videos, changed our videos, changed them again, changed them again until they were happy with them. They helped us with our surveys. Keep it short. Keep it short. As a researcher, that's painful for me. I like to keep it long and long.

[Laughter]

But keeping it short was really important. They advised us for a reasonable compensation for patients doing these things. That resulted in an unbelievable outcome. And they've been talking to us about the analytic strategy. We have retreats and started to talk about how to prioritize the different parts of what will go into the analysis. The study is still ongoing. We've completed enrolling our African-American patients and we're 90% -- 85 to 90% complete in terms of enrolling Hispanic Latino statements. I can tell you about some of the results which is astonishing in terms of the participation. We've had a consistent 93% return rate after 15 months.

If you participate in other studies where you have a monthly survey, you know those results are astounding. I asked them to review the numbers and said this really can't be. We've had a consistent 93% response rate. Our dropout rate, we've had 15 patients drop out and stop completing surveys. All 1,026 are still completing their surveys. 87% are reporting using the inhaled corticosteroid over the time 15 months. 94% report using it exactly as we asked them to document there was only one visit at the beginning of this study. Patients watched the video, got the instructions and that was it. They were off. This is really quite amazing. The success of this is really based on the fact that we got so much feedback on how to make videos instructional, how to make them friendly and how to make patients feel like they wanted to do it.

What we've learned. We learned you have to involve multiple partners. It wasn't only the patients. It was the providers as well telling us this is what we can do in the office, this is what is practical, this is what will work for us. The early involvement of partners was a key contributor to their satisfaction. Partners felt like we weren't bringing them on late, okay, here it is, here's the whole dinner and you can choose the dessert. We had them involved in actually baking the cake. We found face-to-face interactions with the partners were critical. When we had the first session, we had breakout sections with a mix of all the partners in each breakout group. It meant that partners got involved and felt they were personally involved. It was also an opportunity to understand the valuable lessons we teach each other.

One of the other things we were surprised by was how much cross-talk when you got partners together, different types of partners how much cross-talk there could be between the partners and how insurers that hadn't really talked to patients were talking to patients and hearing about the patients and hearing from providers at the

frontlines and how that helped in terms of strengthening it and having people understand each other's perspective. The other thing we learned is that patient partners need to be enabled. It's not good enough to say we'd like you to participate, here's what we're thinking about, we want your feedback, it really takes more than that. We needed to provide tools and education. We needed to provide facilitation. We also needed constant contact. We're in touch with our patient partners on at least a monthly basis. We heard feedback from the patient partners that evidence that their feedback was being incorporated and its effect was really very empowering to them. It wasn't only kind of, I gave you the feedback and it went into a black hole. It was constant reinforcement, this is the feedback, this is the things we could do, these are the things we couldn't do and this is why we couldn't do them and let's have a little dialogue about why we couldn't do them.

In terms of facilitation, just throwing the partners in with the entire group wasn't effective. It was important for the patient partners to get and have a separate meetings as well as incorporating with the entire group. I'll leave it there. We'll answer questions later. I want to thank you and thank PCORI who I never would have imagined doing any of this. It's been an enriching experience for me and the research team and good for the partners as well.

[Applause]

>> KAREN SYRJALA: I'd like to invite Tracy and dolly up next to talk about the team study.

[Applause]

>> TRACY TRACY: Hi, my name is Tracy. I'm here on behalf of the TEAMS study. We're going to give you an overview of our study today. I have nothing to disclose. So a little bit about our study, we're looking at the effects of delivering an exercise-based rehabilitation program to people who have multiple sclerosis at home through a tele-cam program in which we give the participant a tablet versus coming into the clinic either an occupational or physical therapy outpatient clinic to do the exercises onsite in more of a standard approach of care.

Our outcomes were established early on by our stakeholder panel and the areas that we're hoping to show improvement is an increase in physical activity, a decrease in pain and fatigue, and an improvement in quality of life. We are using the intervention is actually a yoga and Pilates based program with dual tasking which is composed of balancing on something while doing a vision or a cognitive or a coordination task. We're looking to seek or actually reduce the barriers to receiving physical and occupational therapy for people who have multiple sclerosis in areas across the deep south. In addition to our tablet program, the tele-cam program is also able to participate in what's called an interactive voice response system which is an extra component that actually checks in with the participants on a weekly basis. So what makes our study different? We started early actually before we were even -- even funded on recruitment and we currently have around 1,500 potential participants that have completed our pre-screening form.

We have baseline tested as of the state over 600 people and we also have now currently over 150 people who have completed the study. We like to think of our engagement approach as kind of like an onion. It has many layers. One of our outside layers would contain our nonprofit partners and organizations that we have contacted early on in our proposal process and that we continue to work with, MS coalition as you see listed here and other hospital and university systems that have helped us in this process. The second layer would consist of our clinicians and our clinic partners which we have 43 clinics currently participating in the study across three states. We service

Alabama, Mississippi and Tennessee which we like to term as the deep south as you probably can tell from my accent.

We also -- we've trained over 80 therapists at these clinic sites to deliver our program. We also train them specific on how to actually treat and some of the nuances with multiple sclerosis. So that's been very rewarding to me because my background is in therapy. And then our middle layer would be our stakeholder panel and that's kind of the core of our onion. I'm going to let Dolly tell you a little about that.

>> DOLLY STOKES: Hi, I'm Dolly stokes and I am an MS patient. I would like to first thank PCORI for awarding me the patient scholarship so that I could attend.

[Applause]

And PCORI really is patient centered because when I was awarded the scholarship, I was so excited to be able to come. However, because of MS, I can't -- I cannot travel by myself. And so I reached out and ask if perhaps my husband would be able to attend with me. And PCORI immediately responded and said of course, we're interested in patients and caregivers, not just patients. And so my husband, Jeff, my caregiver, is here with me.

[Applause]

So the TEAMS study, the panel -- the care -- the stakeholder panel, I am part of the stakeholder panel as a fitness professional. That doesn't really encompass everything I do. I write education -- continuing education programs and certification programs for fitness trainers ranging from general fitness to aqua fitness to Pilates to yoga. My neurologist knew that I had that background. So she invited me to be part of the panel.

And our panel consists not only of me as someone with MS, but we have a patient who is very well versed in challenges of people who are wheelchair -- in wheelchairs as far as navigating, traveling. And so he has really played an integral role in that. And another stakeholder has a strong background in research. One of our other stakeholders is an MS specialist nurse. We all just work together to help the research team and the clinicians understand how to put together a exercise program for people with MS on various levels.

So it's been a big journey and lots of fun and Tracy has been wonderful to work with. Our center of our onion is really the integral part and has really made a huge impact on the study and the way the study has been conducted.

>> TRACY TRACY: So the way we have set up our stakeholder panel meetings is that we're able to meet virtually two times a year and then we meet in person two times a year. I reach out individually, for example, whenever I'm lucky enough to be in Fair Hope, Alabama, then I'm able to go to Dolly's studio and see her there as well. I try to meet in person if they're in their areas because they are spread across three states or I reach out via e-mail or we use other virtual platforms to reach out.

Ways in which I'm in contact with the clinicians, our other layer to our onion, is on probably a weekly basis I'm in touch with them however they best communicate be that text or e-mail. I also go to the clinics. I help set up their baseline testing, make them feel comfortable in what they're doing. We also offer continuing education for them to participate in our study during the training process, kind of an extra benefit for them as well. And our nonprofit organizations have really helped us. They let us know about events in their area that it might be helpful for us to be at, be that talking or just able to present on recruitment ideas, things like that. They help us by advertising the study on their website and give us feedback in terms of dissemination and things that we'll be able to do going forward. So just some specifics. I could have listed a ton of stuff under this. I think I did and they definitely condensed it. So one example of the way our

stakeholder panel was very helpful for us is in video production. Like we heard before, they reviewed videos. And one of the things they identified is that the actor in the video, it would be better if they were at the same ability level as a person doing the exercise. So instead of having someone like Dolly who can perform all the exercises perfectly, have someone that might have some nuances.

So just one little funny story. We had a participant that was in our clinic for a follow-up visit and we had an actor that was in his videos there doing physical therapy. And the participant acted like he had just met a movie star and was asking for selfies with him, wanted his wife to come in and meet him. And our actor was like, okay, I've written books and I have been -- I've been given advertising awards and I'm getting recognized for these exercise videos.

[Laughter]

So that was a really important component we would not have thought of that had it not been for our stakeholder panel. Also transportation, Dolly mentioned we have someone who is a full-time wheelchair user. When I tell you he goes above and beyond waiting at bus stops sometimes all night to determine whether things are accessible in Mississippi. He added that transportation, if we wanted people in wheelchairs to participate, was going to be a huge something to add to this study, and he was correct. Other ways that people within our stakeholder group have added to this study, our clinicians have helped us determine the flow of our outcome measures, what makes sense for their work flow, but also what I know creases patient burden. And then some of our nonprofit organizations help early on identifying things that they had already research such as specific yoga poses that might be most beneficial for the people within our study to perform them as well as they suggested some outcome measures which actually led to a sub-study within our study about different balance measures that are used within a PT and OT clinic.

Okay. Dolly, tell us what works.

>> DOLLY STOKES: Okay. So for me as a patient, what really worked with this group was that the patients were given the opportunity to voice our opinions. We were not told, well, no, we can't do it that way. If -- if our ideas were not possible, we were given valid reasons of why that wasn't possible or perhaps it might be something that we would study in a later study or that we would address in a later study. And we were -- really, in our meetings, we were always first and foremost and the researchers kind of sit back and let us talk. They just tell us what has been done so far and what needs to be done and then what are our ideas about how to do that and how to coordinate it with the patient.

So it really gives us a sense of being heard which gives us a sense of ownership of the study. And so I think that's one of the biggest things is that your patients and caregivers in your studies feel as if they actually really are engaged and their voices actually being heard and listened to.

>> TRACY TRACY: So what didn't work? I think we all have shared this technology can be a burden. The it can be your friend, it can also be a burden. We sometimes experienced difficulty in our virtual meetings in terms of being heard and everything working, also our app working and our interactive voice response system has not been perfect. We've had to re-record it based on our stakeholder feedback. There have been definitely some challenges with working together, working across three states. We have people who have very -- very different backgrounds, very different knowledge levels. So just learning how we all communicate best and most effectively and making sure everyone feels like they're incorporated somehow into the research. And that's it. Thank you so much.

[Applause]

>> Great. Thank you Tracy and Dolly. You might hear my Alabama accent start to creep into the discussion. These are great examples of what's happening in the field. Maureen, thank you again. This is the first time where we've actually been able to synthesize what's happening in the area of patient engagement and start to look at the impacts.

I wanted to spend a few minutes on digging a little bit deeper. I think most people would have understood that patient engagement would benefit areas like recruitment and retention. You know, Elliott, I think we all knew this in principle, but were you shocked at the degree of improvement and benefit that engagement seems to have in your study?

>> ELLIOT ISRAEL: Yes, totally shocked. I think we thought that we kind of -- you spoke to experts, you talked about how to improve retention and how to improve responses. And still, even when you do that, you're lucky if you get 75% response rates. And here we were based on the feedback that Bridget and Mary and her groups -- their groups gave us. As I said, we were pinching ourselves and weren't believing the numbers when they came in and when they continued to come in as high as they were. It's truly astonishing. I think it has to do with the fact that you have another perspective that says, okay, I'm the consumer of this, how does this interfere with my life, how do I make it interfere less and how do I want to participate. I think a lot of that had to do not only with the questionnaires but also with the feedback in terms of the videos that we showed people that helped them understand that the patient partners really worked on -- on our -- the clarity of what we were saying and why patients should think that this is important and how this study was going to make a difference by patients participating in it. I think that's an additional motivation that has really helped as well.

>> TANISHA CARINO: And Tracy, I love your perspective. It sounds like even engaging with Dolly and others created a sense of authenticity for the content you were trying to provide to your target population. What were some areas you were really surprised by in terms of the patient benefit had on your research?

>> TRACY TRACY: I think that just the fact that they developed even our logo. I was amazed at how much we were actually asking them to do. There were times that I felt kind of bad asking them, you know, to review an idea or a call or to test with me to see about the workflow, things like that. But when I saw how excited they became to actually be able to use their specific expertise in that area, then it all just kind of came together very nicely. I think it was surprising to all of us and continues to be very rewarding for sure.

>> TANISHA CARINO: One of the themes between these two studies and in Maureen's work is the idea of being heard, how do you feel engaged as the patient collaborators or the caregiver community. And I've noticed that, you know, there's a lot of in-person, high touch that might be needed as it relates to the type of culture you create in the community. When you-all were putting your study plans together and your budgets, did you expect that level of high touch was going to be as important as it ultimately has been?

>> TRACY TRACY: I can speak to that because I travel now to the 43 clinics across the three states. I had no idea how much I was going to want to engage my clinicians in this study, really have their buy-in, and make them feel like they were really impacting their community. It is important to be there and to see it working in place and to learn how maybe one community, maybe lots of their self-help groups or within churches, other communities might be more medical centers and learning specifically

about how to best deliver this kind of study in their community so that it impacts them in the best way.

>> TANISHA CARINO: Dolly and Bridget, I know probably when you were asked to participate, it was like sure, what am I getting myself into. Did you find yourself more engaged than you had expected and how did that change over time when you started working with the teams?

>> DOLLY STOKES: Initially I was very -- well, I was very excited to be asked to be part of the stakeholder panel. However, I really didn't know what it meant. So I've served on many panels in my capacity as an expert on fitness and fitness education. And so I was -- I've always used to being on the panel that gives the answers. And I wasn't used to sitting back and listening. And so this -- I learned how to listen and -- and just only give my advice when it needed to be given.

I think one of the biggest things for me just when I was first asked, the first thing I ask, because I am a businesswoman, was am I volunteering for this or am I going to be compensated.

>> TANISHA CARINO: Good question.

>> DOLLY STOKES: As you can imagine, as a fitness expert in south Alabama I'm called on a lot to do a lot of volunteer work. And I love to volunteer, but I used to do a lot more than I do, with the diagnosis of MS, you have to sit back and you have to prioritize and, you know, work when -- work when you can and also work on what really drives you and what really is your passion. And this -- I don't know, I might have -- close your ears. I might have participated even though I wasn't being compensated.

[Laughter]

>> TANISHA CARINO: Edit.

[Laughter]

>> DOLLY STOKES: Because I'm just so passionate about -- I know what exercise and a healthy lifestyle, how much it impacts my quality of life and I want to share that with other people that have MS. And not only people with MS, but also people that have other neurological diseases, autoimmune diseases, how diet and exercise can actually create a positive impact. So there was not really -- I wasn't ever really not going to participate in the panel.

>> TANISHA CARINO: And Bridget, how about yourself? Did your perspective change?

>> My father had MS, he passed away. Also, I have a younger sister that has MS, so thank you. Me, I was really, really honored and I had envisioned that I would be on this stage looking at this wonderful audience.

[Laughter]

So I am ecstatic.

>> TANISHA CARINO: Great. Maureen, one of the things I noted in your report -- and I'm glad that you-all touched on pain points. It's not all roses. Every one of the project teams probably has their own set of pain points. The one for me that keeps coming up is this notion of what happens if the feedback being given which is reflective of a real experience for a patient is in contrast to what is considered to be current scientific best practice? Maureen had this quote in her report that I loved. The quote was from a patient collaborator. The quote that we were involved with the measures but it was uncomfortable around the measures because the researchers were using these measures for years. For us to come and say I wouldn't ask anybody that question, it's offensive, it's not going to work, we were embattled with the regular researchers and us as people with the condition. So I'm sure these types of interactions happen all the time and it is intentional that you've got conventional research paradigms now clashing with

what we think of as patient engagement, how do bring these things together.

How did you work through this? Sounds like you had to have a pretty strong relationship to get through these types of pain points?

>> ELLIOT ISRAEL: I was going to refer to Bridget and ask her how you felt when we told you some of the things weren't things we could do and what you felt we were doing in terms of things like that.

>> I think we come from different demographics and have a different way of living. African-Americans sometimes don't view things the same way as the doctors or physicians. And some of the things they would ask, I know I've been in a lot of studies and I know, no way, I'm not doing that. So I'd be like don't ask certain questions because sometimes you're thinking it's -- your thinking is not the same. And a lot of African-American or Latinos that are in lower income areas, they're distrustful. So they're like, you know what, we're not doing that. Then this study has been really, really great because they involved everybody on all aspects. So I am very happy to be a part of this.

>> ELLIOT ISRAEL: And we -- and when we got that type of feedback, there, as I think I mentioned, what we would do is then come back and say, you know, these are all the things you talked about. These are the things we can do. These are the things we don't think we can do. And here's the explanation of why we can't do it. And this was a part of education talking about validated instruments. How you can't just pluck a question out of a validated instrument when the whole instrument has been validated as the instrument. So this was an education piece in terms of helping people understand there's a limit to what we can do even if we wanted to or we understand and we hear you, but we can't do this because then it really upsets the whole apple cart. What we would do then is though try to work to prioritize interrupts where there was a lot of concern.

>> TANISHA CARINO: Maybe invent new instruments and get them validated.

[Laughter]

>> Some of the project teams reported doing that. If patient partners or patient stakeholders said this really isn't going to work, it would mean going back and maybe creating an instrument from scratch.

>> TANISHA CARINO: Tracy and Dolly, anything you'd like to share on this pain point?

>> TRACY TRACY: I would watch the researchers or our investigators take just a deep breath when the stakeholders would ask questions. One question that came up is can people just choose they want the tablet or they want to come into the clinic. We know that would definitely not help with the rigor of our study. We have a great biostatistician on our team that took time to explain rationale and why that couldn't be that way and why we had to randomize the sites for contamination purposes. As we spoke as a group, I saw other stakeholders come up afterwards to get maybe a better understanding. He spoke to them each individually. So just making sure everyone was comfortable with the decisions we had to make to maintain the rigor of the study.

>> ELLIOT ISRAEL: I think it's important to understand that it's not only the researchers learning from the patients. I think there was a really good opportunity for the patients to learn from the researchers as well.

[Applause]

So I think it really was a two-way street. You know, helping to bring those worlds together as opposed to saying bring that world over here. It really was bringing them together.

>> TANISHA CARINO: Maureen, now you've heard two case studies come to

life. How representative is the examples of what we heard today of what you saw in your studies?

>> MAUREEN MAURER: So I think these are really great examples. The thing is that we heard so many examples. So I'm not sure that recruitment has gone as well on every study as it has on Dr. Israel's, Bridget's. But I think what has happened with engagement is when problems arise on a study and problems can arise any time, any point on any study, that you have a group of people to go to and help problem solve and figure out what can we do differently.

So even cases where patients and other stakeholders worked with researchers to develop a recruitment approach and all of a sudden that's not working, well, let's go back to the drawing board and see, okay, what can we do differently to make it work.

>> TANISHA CARINO: Not like a perfect sequential project plan.

>> MAUREEN MAURER: Not always.

>> TANISHA CARINO: I'd like to ask -- I'm going to ask the discussants to be brought into the discussion. Janice, you're in community-based organizations and faith settings. You've conducted research in this area, trained and built capacity. These examples that were given today, a lot of what you ultimately hear is the creation or the cultivation of the community. How should we think about not just the individuals that are engaged in the study, but the broader community of people that are impacted by research such as this?

>> JANICE BOWIE: Thank you so much for inviting me to be a part of the panel and to be one of the two discussants. Unfortunately, because we're down this end, we absolutely can't hear anything from that end. It's very muffled. So I don't even know if I'm going to be responding to your question.

[Laughter]

>> TANISHA CARINO: You can say whatever you want to say, Janice.

>> JANICE BOWIE: I just wanted you to be aware that if I repeat anything that's already been said, just consider it as reinforcement.

[Laughter]

I want to thank all of the co-panelists that you -- that you've heard from because I think that the work that they've done really demonstrate their commitment to engagement. And for me, that's really where the rubber meets the road, that you have to ask yourself as a researcher, as a clinician, a clinician researcher, as a patient, as a consumer, as a caregiver what is it that you value. And -- and the extent to which either you do or you don't will dictate your level of involvement. And if your answer is I don't value this so much because it takes time, it takes resources, it means I've got to train, I've got to build capacity, I've got -- I have to share, I have to quote, unquote engage, then you probably shouldn't be doing it.

And you might not expect that as an answer, but I shouldn't be doing auto mechanics because it's not my skillset. It's not that I don't value my car being able to get me from point A to point B. But the point that I'm making is, is that it isn't for everyone. And even though many of our grant opportunities and study opportunities now may even be requiring it as one of the specifications, I think you have to ethically think about whether it's right for you and that there is a benefit that you expect to see not only for yourself as a researcher to check off your metrics for promotion and tenure or whatever that happens to be, but for really wanting to -- to bring about change and improvement in quality of life for patients and families.

So for me, that level of commitment and value is really the first part of -- of this work. The other thing I think that we have to think about as well is the selection of

the right outcomes. So we've heard from a variety of different -- different outcomes and impacts. And I always try to think what are the -- what are the questions that we want to answer. What is it that we, the collective we, want to achieve. And how do the study design or the project map onto that. Because sometimes we end up saying, well, nobody came. That wasn't the case in any of your work because you had lots of people wanting to participate, committed clinicians and others involved, but that isn't always the case. And we come away saying, oh, wow, these are some hard to reach populations, you know.

[Laughter]

We used the wrong language. You know, we -- we are some of the worst when it comes to language. You know, we have our own lexicons, morbidity, mortality, all these sorts of things. But all of those things in some ways distance ourselves from the very people that we want to engage with us.

So I say, you know, there are lots of things that -- that I can respond to. I just want to just point out just two more. One is, is that capacity has to always be a part of that process. That, you know, don't just use the language of we're looking for educated patients and consumers. You're looking for people who are interested, who are informed. Education is very relative. There's a lot of smart people in the world who didn't have to have formal education. If I had thought I was smart, I would not have gone after a Ph.D. it's time-consuming.

[Laughter]

Thank you, ladies and gentlemen, for that. My point is, is that people are educated in very different ways. And we are -- not to dismiss that or ignore that, but if -- but the capacity that we are providing where we are training each other, we all bring unique contributions to -- to this -- to the work, to the -- whether it's research, whether it's trying to get a clinical trial, whatever it happens to be.

And then finally, don't assume anything.

>> Exactly.

>> JANICE BOWIE: Don't assume that all African-American people are the same. Don't assume that any race or ethnicity of people are all the same, but to look for their unique contributions.

[Applause]

So I'm going to stop. Again just say how much I appreciate the effort. There are always going to be challenges, but I really also just was really moved by the attempts that you made to, one, anticipate those challenges and, two, to try to reduce them. So I'm going to turn this over to my wonderful colleague from the Pacific northwest.

[Laughter]

>> TANISHA CARINO: Great job for all the muffling that you can hear.

>> JANICE BOWIE: Whatever I said is from the heart.

>> TANISHA CARINO: Judy, the Washington state health care authority administers the state's Medicaid program as well as its employee and retiree benefits. So you have a very big job as the chief medical officer. Part of the intention of PCORI was to inform policymakers in the decisions that you have to take every day. How do you see this kind of research being helpful to you and what would you say in terms of how we should continue to evolve and mature this area?

>> JANICE BOWIE: You want me to interpret?

>> TANISHA CARINO: It's a whispering campaign.

>> JANICE BOWIE: She talked about your very important job.

[Laughter]

>> JUDY ZERZAN: Yes. So engagement is super important. We've had a couple

of really nice examples of how that works out. And I think engaging all sorts of different stakeholders is important. Today, I'm here, I'm a physician, I'm a mom, I'm a wife, I'm a patient, I am more actively a patient than I wish I was, but I'm a patient. I used to be an academic researcher and I've been a chief medical officer for Medicaid for 11 years in two states. And PCORI has really been a game-changer in the conduct of research in the last decade. By engaging stakeholders, patients, families, communities, policymakers, you get to ask better questions. The conduct of the study becomes -- I think we've had good examples a little more relevant. The research products are better, all of which makes the results much more usable and makes them able to be used by people like me to change policy, to change benefits in health care.

We are all smart and thoughtful people. And we didn't plan that. But we are all smart and thoughtful people. And I think only by engaging in dialogue with each other about what are the right questions, what are the important outcomes for us and getting out of our own little bubble of our own world view do we get to some of the -- the really meaty questions that help us. We are all doing this. All of you, all of us because we want to make the world a better place. We want to make a difference in people's lives and we can only get there by talking to each other and by listening.

So as CMO, I have a lot of questions. A lot of questions. I wish I had data, I wish I had evidence for. And health care is very complex these days and very expensive. So there's an urgency to get the right question answered, to get the right results faster, with good methodology, but faster, and then how to figure out how to pay for all of this stuff. And I've certainly been on the side of conversations with researchers that don't work out so well. As an example, I talked to a researcher once that wanted some Medicaid data. They were very interesting in something right here -- oh, thank you -- I was interested in something over here. I wasn't so interested in this question. And said, you know, can we get to maybe a middle part that answers some of your question, some of my question. The researcher's response was no, this is the kind of researcher I am, this is the question I'm asking. So that doesn't help me, and it probably didn't help the researcher either.

Another example. I once used the results of a study to help inform a benefit question we'd been struggling with for a while. And the researcher got a little bit anxious. Didn't you read the limitations, we're not quite ready, why are you using this now. And it's super important. We need information like this that we can use to help guide, to help make people better. It's very clear talking with PCORI researchers, reviewing PCORI grants, engagement makes the research different, and I think it makes it much more applicable and much more usable. So thank you.

>> TANISHA CARINO: Great. Thank you. Good job for all the muffling.

[Applause]

Now it's time, we are probably not going to have as much time in this section before we go to the Q&A, but I'm hoping that you-all ask this panel the same questions I'm going to ask the panel. Before we do, Kristin, you know, as somebody who leads and thinks about this area, you've been a scholar in this area longer than I think anybody has. We were just remarking that almost two decades ago in this word patient engagement first came up here in Washington, Kristin was already working on it as one of the researchers.

Why don't we start this Q&A part with just a quick reflection of how far have we come and what questions you have.

>> I think that's actually -- it's a great question. I really always take the long view of this. I think we're having a conversation that we probably wouldn't have even had 20 years ago. I think what's really neat and interesting and for me it's part of the passion

place and really is the extraordinary part of being able to work for PCORI is at every stage, there are certainly challenges to the doing of this, right? What Maureen's study has shown and these conversations here is the ways in which these -- having people involved can make a difference in studies. We're having conversations with data and information. We're not just positing in the future. We also have data and information. We also understand we have challenges to doing this. It's complex. It can be hard, it can be time-consuming. Those are opportunities for us to think about how do we make this more efficient, how do we make this more effective, how do we provide resources for individuals to be able to do this in a way where both parties are prepared for it and both parties have the research they need.

A critical place for PCORI right now is really thinking about enhancing our approach to development of new tools and approaches, developing products to improve practice. I think the big picture is we also are generating new knowledge all the time about, okay, so we're at the point now where we figured out the influence on projects and we figured out some of the impacts. We have to look at now on the ultimate impact of the projects and we're also going to have to help people in critical places. We're developing tools to support teams working together. In fact, we've been reporting on some of them today where you can have tools on the website from your peers. We have difficult conversations sometimes. We need to support them in the research. At every stage, what I'd leave you with, when we work collaboratively, when we work together as teams, we actually figure out how to solve these problems and move to the next step.

So my reflection is, we have come from an astonishing place where people didn't even believe we should be measuring patient experience in care. We are today talking about partnership and research and care in ways that has been about all the people in this room and everybody involved being willing to take those steps together, making those changes, solve those problems and get to the next level. For me, that's where the future is.

>> Great --

[Applause]

Good job. I'm going to invite you to come to the mic. I think there are mics that are floating and standing mics back there. I see a question right over here. My one request is I know we have a lot to say. If we can say less and frame questions more, that would be great.

>> Hi, how are you doing? My name is Juanita and I'm an education doc. But I am community faculty at Charles Drew University where we represent the patients in the community and a lot of the research in health care. My question is did any of the patients -- because I know in the community, I know from the patients that many times we are service providers and we don't really -- we want change and policies to happen, but we don't really understand the process of research and policy, how that really works.

So did the patients -- and this is a question for all of you guys. Did the patients have a hand, a real hand in the analysis and have you moved to the manuscript part of it, did they have a part in the manuscripts?

>> TANISHA CARINO: In the interest of time, I'm going to have one person respond to each question. Who would like to respond? Elliott?

>> ELLIOT ISRAEL: We haven't gotten to the manuscript, but we actually thought very hard about how to involve our different stakeholders in analysis. I eluded to this a little bit. And we -- we actually pressure tested and experimented this a little bit in our last retreat where we had our patient partners, we actually put up what they had chosen as the outcomes and then talked about how do you do protocol analyses and

talked about these are ten possible things we could put into per protocol, what do you think are the most important pieces. So we started that conversation. We're not going to be doing analysis for another two years, but we thought it was important getting everybody on the same page about what the analysis means, what choices have to be made, how they would weight those choices. We started surveying patient partners about what they thought were the important pieces in this. We're not finished yet, but we're still thinking about other ways to engage.

>> TANISHA CARINO: We have --

>> Oh, I'm sorry.

>> TANISHA CARINO: We need to move onto the next question if that's okay.

>> Regina, I'm a PCORI ambassador. Thank you for the session. It was very insightful. I have one question or just asking your observation and thoughts on your engagement rigor as far as the time from beginning your project to selection and bonding with your partners and also for your partners. Any time, emotional intelligence or thoughts and observations you've had as far as engagement is confirmed.

>> TANISHA CARINO: Tracy and Janice, do you want to chime in as well? Tracy, why don't you start?

>> TRACY TRACY: Like dolly has mentioned before, in the beginning when we first met, before we got funding, when we were working through the proposal, perhaps we were all a little uncertain of our role or a place and getting to know each other, but I definitely see a big difference. It kind of started happening, I would say, after our first year in terms of everyone understanding their different backgrounds and the best ways that we communicate together. It truly does feel like a family now when we are together and we do celebrate our successes together kind of like you would when you come together again as a family. We actually had --

>> TANISHA CARINO: Go ahead. So there was -- there was some bonding that had to happen, too, it sounds like.

>> TRACY TRACY: Yes.

>> TANISHA CARINO: Great. We have a question in the middle.

>> Hi. My name's Arty Merit. I've been living with a chronic condition for over 20 years. I thank the panelists. At one time you said to make sure there was patient engagement in finding patients. For myself, and I tell the health care providers if you can show the patient and build the self-worth of the patient, then they will participate. So when you look for stakeholders, patients in the categories, just showing them that -- you know, maybe a little slide of what you've already done for the patient involvements. So it's really not a question. It's just thanking you.

>> TANISHA CARINO: Okay. Thank you. And then over here?

>> Hello. Thank you for everything you've put in. My name is Travis. I'm a clinician researcher. Just two simple questions. What do you do to help onboard consumers from the community, patient stakeholders that are coming into research so they understand? And vice versa, what do you do to help researchers better understand how to engage maximally with your stakeholders?

>> TANISHA CARINO: Janice and -- great.

>> JANICE BOWIE: Two things. One is -- and this is just a follow-onto the gentleman that just spoke. I think it's very important to be transparent from the very beginning. However you're setting up that stakeholder engagement structure, whether it's going to be advisory, steering, full-on, just so that -- that people make an informed decision to be involved. The second thing is to not have just one person. And if you're going to just have one person as your token representative, you need to let that person know that that's the role that they're going to fulfill.

[Laughter]

[Applause]

With respect to training, so part of my work also is with consumers united for evidence-based health care. And what we do -- and it's free to you, we have a website that provides materials on -- for patient, consumers who want to serve on panels or, you know, other kinds of studies, provides them with training of how to do that so that they don't feel intimidated in those settings. And then second -- secondly, we also have that same kind of information for clinicians.

Because we make the assumption that we only need to train the patients and consumers and caregivers. For them to learn how to work with us. It's just as important that we understand how to work with them. So that bidirectional learning has to take place.

[Applause]

So we can make that resource available to you.

>> TANISHA CARINO: Great. We have a question here.

>> Hello. My name is Teal, and I'm from Augusta University in Georgia. I think we all agree that engagement is something that is important and necessary for best practices and research. I was really interested in PCORI's research on the engagement processes. One thing that I haven't heard about at this conference is engaging stakeholders from regulatory groups such as institutional review boards and other people who are involved in the research process. And as a previous engagement awardee, we have experienced some challenges in terms of communicating the importance of patient stakeholder engagement in the research process to some of these regulatory groups. I was wondering if any of the panelists wanted to think about that or findings that PCORI has found related to engaging IRB institutional officials and others in this process?

>> TANISHA CARINO: Maureen, do you want to weigh in on that or do you have a point of view?

>> MAUREEN MAURER: I know early on -- you're not alone with the IRB issues in terms of challenges and that projects have been working one-offs with their institutional IRB to make things better. I'm not sure, Kristin, if there are PCORI-wide resources around working with IRBs.

>> So I would note that a lot of what we've been focusing on today at PCORI and this meeting is focusing on the research projects and engagement in the projects. But PCORI as an institution, and I work in a broader division in engagement and dissemination. We have a broader unit that does a great deal in stakeholder engagement. We have a policy group engaging with regulators, various entities, specific to the IRBs, this has been a real passion point for Joe. We are finding it's getting better as we are distinguishing. I just had a lengthy conversation the other day. What we're finding is, even as simple as clarifying roles and responsibilities, what often gets people stuck with IRBs is clarifying with them these are not subjects of research or objects of research, they're participating on the team and their compensation is for that. Some of the things we're looking at is providing that supportive language. I think this is area where there has been improvement. I could point you to resources if you would like to.

>> TANISHA CARINO: We probably only have time for two more questions.

>> Hi. I wanted to say I was really interested in what Bridget raised earlier about the difference in perspective, African-Americans or other diverse communities may have about research and the importance of centering the leadership of people most experiencing inequities. Bridget, I wondered if you could respond about what type of strategies worked best in engaging diverse voices in the project you were in.

>> BRIDGET: I think mostly it was the language barrier. Sometimes they explain things in a academic way and lower communities or different communities sometimes doesn't understand that. Sometimes you have to make the language parent friendly where it's understood and then I think they're more on board.

>> ELLIOT ISRAEL: If I could comment, we actually based on advice, our studies Hispanic Latino and African-American, we actually had those groups meet separately.

And we found that the needs were different, the views were different. We also had them come together, but we needed to give each group a voice and make sure that they were really understood and heard for their background and what they brought to the table. And that was one of the -- in response to the question, it's getting experts like Janice on board who explain to us about these things that we thought we had an approach, patient engagement, I'm going to go meet with the patients. And the person said no, you won't, they won't talk if you come.

[Laughter]

So you need to not be there. Things like that that really helped us eventually really get through.

>> TANISHA CARINO: Great. And our last question over here.

>> Hi, my name is Karen Joiner. I have RSD which is called reflex sympathetic dystrophy. I just closed a case for workers' comp 12 years ago. So today I can stand and ask y'all, and I need to know how to stay alive on all of these opiates that I take. Without them, I cannot function. But there have to be something for patients with RSD where there is more knowledge as a patient to be able -- to be able to help us other than with the opiates because every day I'm fighting to just stay alive on the opiates. But without the opiates, I can't function because the pain is just as severe. And I just want to know how do I learn to teach myself and other people that's going through what I'm going through to get up every morning and fight because I don't know and there's not enough research out there. And I've Googled and I've read everything, to just get up, to keep going. And I want to ask doctors around the world on get more information dealing with RSD, which is reflex sympathetic dystrophy, to teach people like me that wind up having two knee surgeries and is a very rare disease. And they got to be other things other than opiates to teach us how to get through the day. So if y'all can help me to help someone else, that's all I ask.

>> TANISHA CARINO: Thank you for having the courage to share your story with us. I know this panel may have a perspective in terms of how we would engage you and others with your condition on the research. But maybe this is a good time for me to also transition to Kristin. I know at the heart of where PCORI's mission has been is to identify research that is going to be helpful for the patients that need them. Kristin, with that, do you want to even just quickly respond to where we are in terms of opioids and come up here and close the panel for us?

>> So one is I always think this is sort of one of the remarkable moments at PCORI because we are involving patients and stakeholders, sometimes we have to contain people's pain. I just kind of want to note that and sort of acknowledge that people come to this work and the clinicians and everyone involved in this work are involved in this work because they care so deeply about patients and others.

I will simply note my science colleagues would know -- know all the specifics. We do a great deal of work on opiates right now. I'm not in a position to acknowledge whether or not any of our projects -- we actually have quite a large portfolio that's looking at critical areas both in terms of preventing abuse, helping people get off opioids and use alternative treatments, and various forms of getting treatment in communities. It is a huge priority for this organization and a lot of really fascinating and

important research is coming out from PCORI because it is a public health crisis, it's a community crisis. And we are a stakeholder-driven organization. So guess what. We are doing research that really focuses on this issue. Your specific issue I do not know, but I will put you in contact with my very good colleagues who are leading this portfolio who could answer your question.

>> TANISHA CARINO: Would you like to come up and give some closing remarks for the next transition?

>> Thank you very much. I won't say much more because I think this has been an amazing and extraordinary panel. I do want to share with you, because I think it's really important, I heard a couple of comments and desires for tools and resources, to remind you that we actually have up on the website as of today a -- basically peer-developed tools that you can find tools to support your engagement efforts. This has been a collaborative effort within PCORI. There's things right away for folks looking for those immediate tools. We are also developing a training program, learning modules to support teams working together. Very much like you, we're trying to take best in practices and relying on the Q work to develop trainings, how do we support all parties to this relationship and working together. In part to help address some of what we're hearing in this research is how do we enable and empower and make this kind of work happen. How do we help reduce the pain point for the people participating in it and -- and move it further forward.

And really ultimately PCORI's goal is through our research, our development of tools and practice is to advance the field. And I hope you heard today all the ways in which -- and ultimately we are enabling you-all. I just want you-all to kind of take a moment in this audience as you think about thanking these wonderful people up there, but as Maureen said, I want you-all to take a moment and congratulate yourselves on the extraordinary laboratory of innovation and the extraordinary things you have accomplished. Before I send you to the next thing, I just want you to give yourself a hand and give this panel a hand. I think it is a shared enterprise.

[Applause]

I apologize for my voice, I have a sinus infection. You get to go off to break now. I want to remind you that after your break, you have afternoon breakouts. Don't forget as you enjoy the rest of this afternoon, there will be a networking reception. Please go see all those amazing and wonderful posters where people are providing their experiences and the engagement awards, in the research projects, as well as engagement in the research projects. I think you'll find it fascinating. Thank you, everybody. Did wonderful. Thank you, Tanisha as well. Fabulous job.

[Session concluded at 2:35 p.m. ET]