Adrian Hernandez:

Hey, this is Adrian Hernandez and welcome to the NIH Collaboratory Grand Rounds Podcast. We're here to give you some extra time with our speaker and ask them the tough and interesting questions you want to hear most.

If you haven't already, we hope you'll watch the full Grand Rounds webinar recording to learn more. All of our Grand Rounds content can be found at rethinkingclinicaltrials.org. Thanks for joining.

Lesley Curtis:

Today we're here with Erin Holve and Russell Rothman, who will be reflecting on "From Observational Studies to Pragmatic Clinical Trials: (Almost) A Decade of Research in PCORnet". It's really a pleasure to have both of you join us today for this podcast.

Russell, I'd like to start with you. You and I have been with PCORnet since the very beginning, and I'd love to hear your reflections on some of the major accomplishments from these almost 10 years of work as a network.

Russell Rothman:

Yeah, thanks, Lesley. It's really been an amazing ride. I think we've come a really long way since we first started the network a little over nine years ago. It's amazing to think about when we first started, we came to this meeting with PCORI in Washington D.C. and we really had nothing. And from that, we've built a tremendously successful and large national network to support patient-centered research.

I would highlight a few key accomplishments. I think first of all, and most importantly, was building the network itself. We now have eight large clinical research networks that represent over 60 health systems from across the country that really come together almost every day interacting about how we can do research and how we can do impactful research that really makes a difference.

So, we've created a great sense of unity with the network really coming together and thinking about how we can do studies, small studies and large studies, and really try to do studies that can have national impact on how we learn about healthcare and how we deliver care. So, I think building the network has, in and of itself, been a huge accomplishment.

The second thing I would highlight was building the data network. We started with no agreement on how we were going to standardize or use data for research, and were able to come together around a new common data model, the PCORnet Common Data Model, and all build data marts where we house standardized data that we extract from our electronic health records, so that we can write one query at the coordinating center and send it out to all the sites and query our data and come back with results pretty rapidly.

Not just to build the Common Data Model, but to do it in a way where we do a lot of quality checks and we have a lot of deep data, and we have potentially, with appropriate regulatory approvals, identifiable data. So we can not only dig into that electronic health record data to understand more about health issues, but we can use that data to potentially identify study participants and contact them for recruitment into observational studies or into pragmatic trials.

We can also link our data to other sources, to claims data, to geocoding, to registries, to really get a deeper understanding of social and other determinants that impact upon health, and to also be able to follow patients longer when they do participate in studies.

I'd also highlight the work that we have done in doing comparative effectiveness research in pragmatic clinical trials. So, we've been able to do some pretty impactful large national trials. The ADAPTABLE study was our first large national trial. We successfully recruited 15,000 participants to try to understand the optimal dose of aspirin.

We're currently participating in a large NIH funded study called PREVENTABLE that's already recruited over 5,000 older patients, 75 and older to understand the role of statins in preventing dementia. So we're able to leverage the common data model, our network connectivity, our stakeholder engagement, and other components to really rapidly perform these large national trials that are patient-centered and focused.

Then finally and perhaps most importantly, I would highlight all of the work we've done around engagement. Really ensuring that every project that we do in the network engages patients and other stakeholders in identifying research priorities, in designing the research, in performing the research, in analyzing the research, and ultimately in disseminating the results.

Lesley Curtis:

Russell, thank you for highlighting those major accomplishments. That's a lot of work in a relatively short period of time. Let me maybe follow up and ask you to think back on what are some of the major lessons that either the PCORnet community has learned along the way or that others outside of PCORnet have been able to learn from the network as it's developed?

Russell Rothman:

There's been a lot of great lessons learned along the way. Probably one of the most important lessons learned is just the value of coming in with shared goals and then actualizing those goals. The one thing that we had going for us at the beginning of PCORnet is everybody who came together at the beginning was really passionate about this idea of how can we do research differently? How can we do research that is more patient-centered, that leverages informatics and other tools to be more efficient, and that really embraces stakeholder engagement in everything that we do? I think with everybody coming in with that goal, people were really willing to push the envelope and make sacrifices and really do what needed to be done to make the network work successfully.

I think that the other lesson learned has though been around allowing the network to operate both as a cohesive group, but also having some independence at the individual site and data mart level, so that each health system still has governance over their own data and how they access and work with patients.

So we really operate both individually and collectively at the same time, and that allows us to be very successful because we can work individually for the things that need to be done at the individual level in terms of contacting and connecting with clinicians and patients and electronic health record data, but then come together collectively for the things that require us to share things for research and other purposes.

Then finally, I would say the third lesson learned is being willing to take some leaps of faith when pushing for innovation and pushing the margins about how things should be done. So, sort of pushing people to stop doing things the usual way and start embracing how to do things differently.

Some of that required sharing new approaches to our local IRBs and saying, "Hey, these other five sites are doing this, or these other 10 sites are doing it this way. Can we do it this way too?" We're now in the 2020s, we need to embrace new technologies, new ways of contacting and following participants when we do research just as an example, and trying to help move our systems forward by really embracing innovation and working together to sort of push the envelope to do research in new ways.

Lesley Curtis:

Great, Russell. My final question for you requires that you pull out your crystal ball and give us your sense of where do you see the network going from here?

Russell Rothman:

Yeah, I think we're very excited about the future of the network. I think there are tremendous opportunities for the network to continue to grow and support patient-centered research. For one thing, we're very interested in expanding the reach of the network, adding additional sites over time that allow us to engage more diverse populations from across the country. We're very interested in expanding the depth of the data that we have right now.

We have very deep electronic health record data, we're interested in expanding our efforts to link to other data sources, but also to bringing in a lot more patient-reported measures, including patient-reported outcomes. Again, our network is very patient centered, so we really want to do what we can for every research project and within our own health systems to think about how can we better capture patient-reported data so that we're doing research that is as patient centered as possible. I think we want to continue to embrace new technologies in terms of how we leverage access and use data and collect data from patients when we do research.

Then finally, I think we want to continue to build out our infrastructure to support engagement activities, including things not just on the front-end when we engage patients and other stakeholders into projects, but how we return results to study participants and how we share those results back out to health systems, to policy makers, and to others to really have an impact on how healthcare is delivered.

Lesley Curtis:

Oh, thank you, Russell. I'd like to turn next to Erin, and first of all, invite you to add anything to Russell's perspective on where the network is and where it goes next.

Erin Holve:

Well, thanks so much, Lesley. Really appreciate the opportunity to talk with you all. Likewise, I share Russell's enthusiasm and excitement about not only what the network has accomplished, but where we have yet to go. What I really appreciate in listening to your comments, Russell, and the presentation that we had a couple weeks ago, is that the exact kinds of outcomes that, Russell, you described really were the initial intent of PCORnet.

So, PCORI obviously funds PCORnet to facilitate the development of these types of definitive studies that are really national in scope and leverage the kind of high quality data, patient partnership, and research expertise in the research community that can deliver the kind of fast trustworthy evidence that advances health outcomes and helps Americans make decisions to improve their health.

I really think, Russell, that all the examples that you provided of the work that PCORnet has done, both for PCORI-funded research, as well as partnerships with our other federal funders and research funded by NIH institutes, the Centers for Disease Control, some private groups and so forth, really demonstrates that PCORI has succeeded and seen the value of that initial investment in the infrastructure, which as a funder, from PCORI's perspective, is really fantastic to see, right? It's really demonstrated value that we're all looking for.

Likewise, I would say I was initially trained in biology and ecology, and the metaphor that I tend to come back to here is that PCORnet really is intended to be this very effective and robust commons. So, a lot of the role that we play from PCORI's standpoint in funding the infrastructure of PCORnet is to do all the things again that Russell described.

Promote and fund the development of that high quality data resource, promote and fund and build on the best information that we have from PCORI about engagement science and the opportunities to make sure that patients are partners and are at the center of this research throughout every step of the process. And then, again, facilitating that really rich, diverse community of investigators and research partners and participants, that's going to get us the information we really need to improve health and healthcare.

Lesley Curtis:

Thank you, Erin. During the Grand Rounds broadcast, you mentioned some new funding opportunities that are coming out from PCORI. Can you talk about those in the context of PCORnet?

Erin Holve:

So, we are really excited about this new direction and we see it, again, as really reflecting the strong support of PCORI's board. There were a number of activities that were undertaken over the last several years, and several public documents, by the way, that perhaps you can share as well that really illustrate the direction that the board has suggested they want to see PCORnet go.

So one of the outcomes of that effort is that starting in our cycle two, which is in early May, our cycle two of our Broad Pragmatic Studies funding announcement, there is a new Category 3 of studies that will be funded in order to support those who are using PCORnet to conduct that type of large scale definitive research. We have certainly indicated that we're excited and trying to get folks prepared and ready to respond to that opportunity.

I will note that there are a couple of considerations folks should be mindful of in terms of the requirements to be a PCORnet study, because again, we do want to achieve that type of definitive national scale effort with these types of projects.

So, the requirements are that you have to really use two or more clinical research networks or have two or more clinical research network partners, that you have to commit, as Russell nicely described, to sharing your study progress and performance metrics so that the whole of the network improves over time by sharing that information, as well as exchanging best practices to promote continuous learning and improvement.

So again, it's that culture of shared objectives and outcomes that really are sort of the core components of the requirements to be a PCORnet study, and that are likewise carried forward with this funding opportunity for the Category 3 Broad Pragmatic Studies.

Lesley Curtis:

That is so exciting, Erin, and I'm glad you walked us through that. You mentioned that PCORI is also eager to make sure that there are researchers who are ready to use the network. I think maybe on that note, maybe tell us a little bit about an upcoming workshop, I believe?

Erin Holve:

Yes, and Lesley, I think you might be implicated and involved in delivering that workshop as well. So, very excited to announce that at the AcademyHealth Annual Research Meeting this summer on June 27th, we will be holding an afternoon workshop at the conclusion of the meeting that will cover a jumpstart or a quickstart guide to getting involved in PCORnet as a researcher who would like to use the network, right?

So you do not have to be connected to, affiliated with an institution that is currently part of PCORnet network or one of the network partners, you simply need to be someone who's interested in potentially using PCORnet for your next project.

So, there's no cost to participate. My understanding is that the registration link for that session will be posted probably next week, so I'm happy to share that back with our Collaboratory colleagues and really welcome folks to sign up. I think that registration link will be posted through the PCORI website, but again, it will be affiliated at the conclusion of the AcademyHealth Annual Research Meeting at the end of June.

So, we think it's going to be a fantastic opportunity to introduce investigators to one another and really facilitate that community development and collaboration that Russell mentioned. It's also really going to be a great overview and guide to using the Common Data Model and really thinking about how PCORnet can be most effective to help you develop that next big national study of your dreams.

Lesley Curtis:

Great. Well, thank you Erin Holve and Russell Rothman for joining us today and telling us a little bit more about PCORnet.

We invite those who are listening today to join us for our next podcast as we continue to highlight fascinating and informative changes in the research world.

Adrian Hernandez:

Thanks for joining today's NIH Collaboratory Grand Rounds Podcast. Let us know what you think by rating this interview on our website, and we hope to see you again on our next Grand Rounds, Fridays at 1:00 PM Eastern Time.