Podcast August 2, 2021: Diversity Workshop Series: Increasing Diversity in Pragmatic Clinical Trials

(Robin Boineau, MD, MA; David Chambers, DPhil; Lesley Curtis, PhD; Emily O'Brien, PhD; Wendy Weber, ND, PhD, MPH; Kanecia Zimmerman, MD)

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.

Robin:

Hello, this is Robin Boineau from the National Centers of Complimentary and Integrative Health. I'm the moderator for today's podcast. Today we're here with David Chambers, Leslie Curtis, Emily O'Brien, Wendy Weber, and Kanecia Zimmerman. We'll be reflecting on the Grand Rounds Diversity Workshop Series, 'Inclusion of Diverse Participants in Pragmatic Clinical Trials.' This is the sixth in a series. Our last two years have been remote. And so we held this as a series of talks over the summer on this topic. And we're going to start today with Kanecia Zimmerman, who was the moderator for our keynote speaker Clyde Yancy, who I know well as a heart failure clinical trialist, but he's also the Vice Dean for Diversity Inclusion at Northwestern University. So Kanecia, what were the key points you've heard from his presentation to..on..at the beginning of this session in May?

Kanecia:

So, Dr. Yancy really set the stage for us. He provided the landscape of how currently..how current clinical trials are running. He reminded us that most of the clinical trials are actually taking place in the U.S., but they do not represent the population here in the United States. He reminded us that over cardiovascular diseases, oncology, psychiatry, and many others, African-Americans in particular have been disproportionately underrepresented in clinical trials. This is a problem. We've seen it in the setting of COVID-19 and the disparities that have existed there. We've seen it in outcomes related to other cardiovascular diseases as well. This is a problem because our clinical trials don't reflect the people for whom the drugs and devices are actually made and may eventually lead to poor outcomes. Dr. Yancy, however, provided a pathway forward. He talked about potential options, specific solutions, including policy changes, dedication to making sure that clinical trial teams or representatives, building the pipeline, educating the public and accountability.

Robin:

You did a very nice job Kanecia of setting up this series. Why it's important that we think about this, and particularly what we're talking about with this series is pragmatic clinical trials. So Wendy, you were the moderator for the planning for diversity stakeholder engagement and site selection to maximize diversity. And you had a number of investigators that are doing research in this area and have a lot of experience with developing relationships with healthcare systems. What were the take home messages that you heard that you'd like to share today?

Wendy Weber:

Thanks Robin. I thought it was just a really excellent session. I mean, both of our sets of speakers, we had not only the principal investigator, but also their partner on their trial, who helped them with sort of the community outreach activities that they were doing, and the partnerships that were built with the clinics that they used. Both of the groups were working with federally qualified health systems in

different regions of the country. And I think one of the things that was really interesting is they knew so much about the health care systems going into their trials because they'd have a long-term relationships already with these healthcare systems and with the clinics that they were working with. And in reality, both of the projects came out of needs from the clinics themselves. Specific areas where the clinics felt like they needed help to improve care for patients.

And then their partners were looking for researchers who could actually address those needs. So I think it was just a really wonderful sort of set of presentations to talk about how do you build those relationships? How do you stay with, and continue to work with those community clinics and really have them involved as partners truly in the research? And that long-term relationship that they built, has built trust. And as we keep hearing time and time again, is that it takes time. And so I think both of those trials are just excellent examples that the community can take a listen to.

Robin:

Thank you Wendy. I really liked that you hit on the highlight of creating these relationships leads to trust because he had made the point during this discussion that it's difficult to teach trust. But there are a number of steps you can do that can lead to trust. And if you want to hear more about what they're doing, please listen to that June 4th podcast. I want to move next to Emily O'Brien, who was the moderator for 'Meeting Participants Where They Are: Outreach, Trust, and Consent to Maximize Diversity.' So Emily, you had several speakers. One was Jonathan Jackson who talked about the need for equity, not just equality and that healthcare systems are often hopelessly segregated, as well as Stacey Sterling, who is working on bringing in a Spanish language cohort and doing it in a broader than a typical way. So Emily, what were your take home messages?

Emily O'Brien:

Yeah, I thought the session was a really nice balance between these sort of theoretical motivations that we often hear. Why we need to achieve health equity and sort of philosophically why it's so important. And then some real-world examples of how that theory is put into practice. And I thought the investigators were very candid about some of the challenges that they experienced along the way. I thought one of the points that Dr. Jackson brought up was really critical that every organization that we work with in the setting of a PCT is inherently complex. And if we're trying to understand that complexity, nothing beats being on the ground, talking to people and going through the workflow of an organization step-by-step. And that we're not alone as scientists or clinicians in doing this. That the field of implementation science is really there to help us think about these factors in ways that can inform our design and make sure that it's implemented in the most efficient and effective way.

The other piece that I thought Dr. Sterling really nicely highlighted was the importance of adaptation and flexibility. This concept that it's not just about translation, linguistic adaptation, but that going beyond that and thinking about how a study might be most effectively done within various cultural settings and making appropriate adaptations to reflect that diversity can really result in a study that is more well received and in a better position to accomplish its objectives. So it was nice to see that demonstrated through her overview, 'The guiding good choices program.' Which was also interesting because it incorporated the viewpoints of several different generations, which is, I think a nice reminder of why a singular concept of diversity can often be broadened to other facets that that can be important to consider as well.

Robin:

Thank you. And I love that you're leading us into the next topic because you talked about the importance of engagement of community, and I think that's something that we'll hear David Chambers talk about. So David led the..moderated the topic 'Maximizing Diversity in PCTs: What Can We Learn from Implementation Trials?' So David, we had two speakers, Amanda Midboe from the VA and Anne Trontell, from PCORI. What stood out about their discussions and how we can increase diversity in pragmatic clinical trials? What have we learned from implementation trials?

David Chambers:

So thanks Robin for that, there was a..the expertise was definitely both from implementation trials and broader with Anne Trontell from 'Lessons Learned in Comparative Effectiveness Research.' And the first thing was really thinking about the design of our trials to ensure that there is an active concentration on diversity. So, we discussed and we're benefited from the presentation of a number of different tools, whether it's the PRECIS-2 tool or various tools that have been amassed around helpful engagement. Engagement not just early on, but continual engagement of key stakeholders throughout the life of the project. And the true investment in those partnerships was seen as a really important factor toward trying to maximize diversity.

The speakers spoke about tailoring outreach and communication efforts to the key partners within the trial. And one other key lesson that popped out was the use of available data to try and drive the way in which the trial is conducted. So, Dr. Midboe talked a lot about the use of administrative data to identify places where we can try to improve equity. And Dr. Trontell also spoke about research on underlying social determinants of health, that would also define efforts to improve equity in health outcomes and wellbeing.

Robin:

Thank you, David. And then we'll move to the last moderator talking with us today, Leslie Curtis. She led the Diversity in the Pragmatic Clinical Trial Ecosystem. How Do We Develop a Pipeline of Diverse Investigators and Leaders in PCTs? And so Leslie, you had three speakers that came from very different perspectives. Can you pull together what they reported that is going to be valuable to these listeners we have here today?

Leslie Curtis:

Sure. Thanks. Thanks Robin. So, Dr. Bernard really set the stage by reminding us of the strong commitment that NIH has made to really eliminating those systems and processes that contribute to structural racism, right. So they're targeted on that, and that absolutely permeates through any efforts within the NIH to develop, any and all efforts, to develop a more diverse workforce. So hearing that was just a great way to start then George Mensa provided us really with that perspective from an institute or center and reminded us, much like we've heard from some of our other presenters during this workshop series that it's really important to start early. In fact, you can't start early enough and he highlighted the opportunities and funding mechanisms that exist to train even high schoolers, right. Really focusing on bringing generations along in promoting diversity in our scientific workforce.

And, related to that, although we are very much focused in the Collaboratory on growing that diverse workforce of people who do pragmatic clinical trials, really the challenge is to build the entire workforce, and in so doing, increase the number of scientists who are also doing pragmatic clinical trials. Then finally we heard from Natalia Marone who, as a collaboratory PI, has of course direct experience doing pragmatic clinical trials. And she also has led some programs specifically focused on developing a more diverse workforce. The seed program that she described, where she really highlighted kind of the on the ground learnings.

Including.. just reminding us how important representation is and creating a tailored safe space for underrepresented minority scientists to share their experiences and learn from each other. What I think impressed so many of us on that webinar was the metrics. The data that she shared about their evaluation of that program and how participants in the seed program, they were publishing more in peer reviewed journals. They had the metrics of success, and the differences between those who had participated in those who had not was real. So it was just really terrific to hear from these three perspectives at different places in the ecosystem.

Robin:

Thank you, Leslie. That's a wonderful summary from all of you about the talks we've heard this summer. I think in summarizing some of the key lessons we heard, including 'trust is important,' and we build that by talking to stakeholders, which are communities and the patients that are going to be engaged as well as people within the healthcare systems and the researchers that you're working with. It's important to grow the pie. We need to increase the people that are available to do this research. We need to start early with both training, as well as engaging with people that this is the population we're studying. And I think the other thing to keep in mind that I think a number of us have been hearing in talks with this webinar and others that we've heard is it's important that if we don't address this and make sure that we address issues of diversity, that was outlined very well, that Kanecia mentioned that we're not doing very well, that the gap that we have in healthcare that we're seeing at this time, we're going to only worsen if we don't really take this on as researchers and close the gap with our research and make sure that we're being inclusive.

The work that's been done and that we've talked about is going to be highlighted in future Grand Rounds series. There's much work to be done in this area. This is the next step. And so we hope that you will continue participating in these Grand Round series. Please join us for our next podcast as we continue to highlight the fascinating and informative changes in research.

Adrian Hernandez:

Thanks for joining today's the 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.