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Diving into Diversity: A Look at Representation in Cardiovascular Clinical Trials

Dr. Butler:
Clinical trials provide the key evidence needed to evaluate the safety and efficacy of new medications and products for our patients. But not all subgroup of patients respond in the same way, making equal representation in clinical trials essential. So, how can we ensure better patient representation to achieve the best and most inclusive results? You're listening to *Heart Matters* on ReachMD. I am Dr. Javed Butler and joining me to talk about diversity in cardiovascular clinical trials is Dr. Ileana Piña, a Heart Failure Cardiologist and Clinical Professor of Medicine at Central Michigan University. She's also a Medical Officer in the Food and Drug Administration's Center for Devices and Radiologic Health. Dr. Piña, thank you for joining me, today.

Dr. Piña:
My pleasure, Javed, thank you.

Dr. Butler:
Always great to discuss with you. So, let's get started. Dr. Piña can you give us an overview of how we are currently doing when it comes to achieving diversity in clinical trials?

Dr. Piña:
Well, Javed, you and I have had this conversation before, we're actually not doing well. And I don't think that the population that we serve is well-represented in clinical trials. We recently took a look at this in late breaker presentations both at the American Heart and the American College of Cardiology and looked at how many patients had been actually described by race and ethnicity, how many had been published with descriptors and it was really, like, 7 or 8 percent, which is so incredibly low. It's kind of heartbreaking to see that.

Dr. Butler:
So, what do you think keep us achieving this diversity and participating in clinical trials?

Dr. Piña:
Well, I think a lot of it has to do with where the trial is sitting. If it's sitting in an academic medical center, it may have a good diversity of patient population. Maybe the trial is not within the heart failure group. Because I know that I have always had a really diverse clinic and I choose my patients from my own clinic. And for example even women sometimes you have to work a little bit harder to get an older woman into a trial, talk to her family, that may take a little bit more time, than say a Caucasian male that can make a decision quickly and say yes or no. So, it may take a little bit more work but you've really got to do it and I think we owe it to the patients to have diverse clinical trials so that when we use these drugs, and devices for that matter, we can say these are equally functional or these are equally effective and they're equally safe, which is a very important part of the drug development and device development.

Dr. Butler:
So, let's unpack that a little bit more. Do you think that part of the problem is just the overall clinical cardiovascular trial operations in the U.S. that part of the reason we don't achieve diversity is that U.S. is the minor enroller in most of the trials and people come from other parts of the world?

Dr. Piña:
I think that's one very important piece of it. We know in the United States that we're having trouble enrolling in clinical trials, I mean, even the NIH, I think TOPHAT is a perfect example, had to go abroad to finish and, and recruit successfully you know and included countries like Argentina and Brazil, but also went out into Russia and the Republic of Georgia and obviously the results were concerning because those countries were different. So, I think that is part of the problem.

When you have a low number of U.S. patients, you're especially going to have a low number of African Americans. And forget Hispanics; they're not even mentioned most of the time.

Dr. Butler:
Yeah, so you mentioned about race and ethnicity but tell me a little bit about women participating in clinical trials.

Dr. Piña:
Well, you know, for many, many years I've been doing clinical trials for over probably 25 years and I personally have never had problems getting women in. However, I choose women that are my patients in the clinic, so they already have that trust relationship. And I generally never consent an older woman in particular unless there's somebody else in the room. A relative, a family member, a good friend that's coming with them, because if somebody else is hearing my informed consent process, they're more likely to share the knowledge experience with the woman. Very often these older women may in fact say to you, well, let me go check with my family and I'll come back. So the family may not understand the trial and say oh no, no, you don't want to be a guinea pig, you know, I hear that word a lot, you don't want to be a guinea pig or transportation may be difficult to bring you to the study center, they're less likely to participate. So it may take a little bit more work but I've never had that problem.

Dr. Butler:
It's interesting you mentioned transportation, so we talk about social determinants of health, do you think there are social determinants that keep people away from being able to actively participate in clinical trials and maybe that's part of the reason for race, gender, and ethnic lack of diversity in clinical trials?

Dr. Piña:
I think that's a very big part of it because where are most of these clinical trials? So, they're in the academic medical center or maybe it's not academic, maybe it's just a big center. The patients don't like driving in there and finding parking and it's usually, you know, in the middle of traffic, parking then walking to the clinical. So, what we did, for example with a GUIDED trial, which had a lot of visits for the proBNP trial, we actually did an arrangement with Über and this is in the

Bronx, New York and so we had Über pick up the patients and bring them in because I wanted to test our strategy of getting the NT-pro-BNP lower. I didn't want to test whether the patients can get to the center or not. So, I think we may be testing the wrong thing when we have patients who can't get there. And if you add a little bit more to the budget, you can actually pay for transportation. We did this with the HF ACTION trial for NIH, as well. And so, we had less lost visits. But it certainly has a lot to do with it.

Dr. Butler:
So, Ileana, let me ask you one more question. You're, sort of, laying out the lay of the land but my one question is, is that changing? Are we better than where we were 10 years ago or are these trends for less women and less racial and ethnic participation in clinical trials and diversity pretty much unchanged at this point still?

Dr. Piña:
I haven't seen many changes and I think it looks exactly the same as it did even ten years ago. For example, the women in heart failure trials I mean we wrote about this ten years ago and it was about 20 percent. Now, it's still about 20 percent. So I think, sometimes, , sponsors of trials want to get it finished. Want to get it done. And they may need to take a little bit more time in selecting sites whose population is equally diverse. If you go into a very expensive suburban cardiology practice, you may get a lot of Caucasian males. But if you really want that diverse population, you should be giving your trials to centers that have already a diverse population of whatever disease you're testing. In our case it's usually heart failure and heaven knows we have plenty of heart failure. And certainly African Americans present with heart failure at an earlier age and have more hospitalizations. So, if you go to a population that's multi-ethnic and multi-racial, you're going to get the numbers. But it does take a little bit longer time; you may have to do an extra amount of work, and the companies want to get it done. But you have to have a plan in place. When you put the trial in place, what are your actual plans to get a diverse population? And then work on it. And I think that we on the regulatory side often ask companies what are your plans to get a diverse population and I think that the medical side should do the same thing.

Dr. Butler:
For those just joining us, you're listening to *Heart Matters* on ReachMD. I am Dr. Javed Butler and I'm speaking with Dr. Ileana Piña about the importance of diversity in cardiovascular clinical trials.

So, Ileana, now that we have discussed some of the challenges that can impede diversity in clinical trial and you started talking a little bit about what can be done from the sponsor's perspective, but tell me a little bit about from an investigative perspective, what can we do?

Dr. Piña:
I think from an investigator perspective, I would look at the population that are in, for example, my clinic and take a look at the composition, the racial and the ethnic composition. Let's not forget that we've been talking about race, but ethnicity is very important. The Hispanics participating in these trials is an awful number. And maybe for Hispanics, for example, those patients may be more in their own neighborhood, and they may be in those practices. Well, aligning yourself with those practices from an academic medical center may enrich the population. So, you have to, work your plan and then when you have enough racial diversity and ethnic diversity, that would be a satisfactory end. So, just like the sponsors, I think the investigators need to plan ahead of how they're going to recruit a diverse population. I think trials need to look like the United States population.

Dr. Butler:
So, am I hearing you right that one of your suggestions is that don't wait in larger centers, but reach out into the community for enrollment?

Dr. Piña:
Absolutely. We did this in the Bronx because I knew that even though for example, I'm Hispanic, I don't have a problem communicating with Hispanics patients, but culturally, many of these patients don't want to go to the big center. They're very happy to go to their local cardiologist that's down the street from them or down in the community center from them. Well, partner with those people because they would be happy to have their patients enrolled in studies, particularly if you're going to facilitate their transportation. So, like I said, it may take a little bit more work, but you can do it.

Dr. Butler:
So, let's look at this issue from another perspective. You're talking about diversity of participants in clinical trial; minorities and women. What about the leadership of the trial? Do you think that people who are running the trial, if that was also a little bit of a diverse bunch, would that help enrollment of diverse populations in the clinical trial?

Dr. Piña:
Well, you know how I feel about this, and we now have publications showing the lack of gender diversity in clinical trial leadership and

sometimes sponsors will go to their easiest communication venue, which may not necessarily be the women who are in leadership positions. And so if we had more women leaders in trials, I think the women leaders would push to get a good sex diversity and I think they would also push for race. So, we should look in our study groups just like we look in the population.

Dr. Butler:
Now, can you give us a little bit of the patient's perspective? You have talked to a lot of patients about enrollment in clinical trial. What are some of the concerns that might be keeping them from participating in trials and how can we address those concerns?

Dr. Piña:
Well, the general public may think of studies as patients being guinea pigs. That's a very easy word to use. And so, it takes a bit more time to really explain to the patients that what you're doing is you're really answering questions and reminding them that even if they were in the placebo group or in the control group, because they could be, right, if they're being randomized, that patients who go into trials generally do better than the standard population with exactly the same disease process. So, again, it takes a little bit more time to explain to patients what clinical trials are. And I don't think that we as a community of trialists have done enough to publicize what we do. What a clinical trial is. Why patients should be involved. Why it's good for them. And there are now patient groups, I know the UK has a wonderful heart failure patient group that continues to educate the public of why they should participate. So, I think on our end, we haven't done as good a job.

Dr. Butler:
Well, I really appreciate your, your insights and your experience and this 360 look at the problem and potential solutions. But before we close, Dr. Piña, are there any final thoughts about achieving more diversity in clinical trials?

Dr. Piña:
Yes, I think that uh this is the time to do it. There is enough social concerns about diversity in so many aspects and heck, this is patients' health. Why can't we do it? We should be able to do it. And I think we need to do it.

Dr. Butler:
Well, given the importance of ensuring diversity in clinical trials, I want to thank my guest, Dr. Ileana Piña for sharing those best practices we can all apply to our own practice. Dr. Piña, it's been a pleasure speaking with you today.

Dr. Piña:
Thank you Dr. Butler for having me. I appreciate it.

Dr. Butler:
And for ReachMD, I am Dr. Javed Butler. To access this and other episodes in our series, visit ReachMD.com/HeartMatters, where you can be part of the knowledge. Thanks for listening.