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MS in Black and Hispanic Patients: Examining Prevalence and Disease Characteristics

Dr. Caudle:
Welcome to *NeuroFrontiers* on ReachMD. I'm your host, Dr. Jennifer Caudle. And joining me today to discuss the results from the CHIMES study, which focused on the demographics and disease characteristics of Black and Hispanic patients with multiple sclerosis, is Dr. Mitzi Joi Williams. Not only is Dr. Williams the lead trial investigator, but she's also a board-certified neurologist and world-renowned multiple sclerosis expert in practice at the Joi Life Wellness Group in Smyrna, Georgia.

Dr. Williams, it's great having you with us today.

Dr. Williams:
Thank you so much for having me, Dr. Caudle.

Dr. Caudle:
Well, we are so excited that you're here. So why don't we start off with some background? Can you provide an overview of what the CHIMES clinical trial is and what you sought out to do?

Dr. Williams:
Absolutely. MS has traditionally been thought of as a disease that affects mostly people of Northern European descent. However, over the past few decades, we've realized that MS occurs much more frequently in Black and Hispanic populations than we previously thought, and here in the U.S., the risk may be up to 47 percent higher in Black women. So the CHIMES trial really set out to try to understand why we see the disease more prevalent in some of these populations than we previously thought as well as why some of the characteristics of the disease could be more severe.

Dr. Caudle:
That's excellent. And that's really important information to know. As a family doctor, I think about the demographic that we were taught in med school of who is most commonly affected by multiple sclerosis, and my eyes are enlightened as I hear you speak. What methods did you use to achieve these objectives?

Dr. Williams:
So the CHIMES trial is actually the first phase IV clinical trial that focuses exclusively on Black and Hispanic Americans living with multiple sclerosis. So what we sought out was to look at a therapy that is already approved for multiple sclerosis, which is ocrelizumab, because there is some data that medicines that work by this mechanism, primarily affecting the B cells and B cell pathology, may be a little bit more involved in Black and Hispanic populations with multiple sclerosis. So essentially, we are monitoring people with this medication. We are looking at a variety of markers that we look at in our traditional trials, such as MRI measures and relapses, but it also gives us an opportunity to look at things like ancestral markers and other serum biomarkers that we don't have a lot of information on in these populations, so it's a really comprehensive study.

And I think the other thing that was very unique about this study was that we set out with the intent of making sure that the trial was accessible to the population, so we did things such as having patients involved from the inception of the trial. We also looked at things like our inclusion and exclusion criteria to make sure that it was not too narrow to exclude populations, as well as looking at measures to compensate people for their time, childcare, etc. so that they could have access to this trial.

Dr. Caudle:
So with all of that being said, can you walk us through the results of the study?

Dr. Williams:
Absolutely. So it is a one-year study, which we completed the first year of data, followed by a three-year extension phase. All patients will be on a therapy, so it's unblinded, and we're going to be monitoring MRIs as well as relapses, which is clinical activity and disease progression over this time. What we found were some interesting things. Number one, one of the reasons that we have postulated in the past that certain populations have done worse is that they may have been late to diagnosis, and what we actually found in this study is that the African American and Hispanic patients came to diagnosis fairly early. However, the African Americans did have higher burden of disease on their MRIs. So even though they were diagnosed in a timely fashion, let's say within six months of first symptom to being diagnosed, their MRIs still looked worse, which can affect their overall prognosis.

We did not find any significant differences in terms of efficacy, in terms of effect on relapses. The results were very similar when compared to some of our larger phase III clinical trials. And we also do not find any safety side effects or concerns, which was also very reassuring for a medication that's been on the market for some time: ocrelizumab. There are many other measures that we have not gone into detail about that we still have a lot of analysis to do in terms of looking at things like ancestral markers and other biomarkers about inflammation and disease activity, and those results will be forthcoming, but we're very excited about the initial results of the trial.

Dr. Caudle:
For those of you who are just tuning in, you're listening to *NeuroFrontiers* on ReachMD. I'm your host, Dr. Jennifer Caudle, and I'm speaking with Dr. Mitzi Joi Williams about the CHIMES clinical trial.

Now, Dr. Williams, if we zero in on the issue of health inequity, how can the underrepresentation of Black and Hispanic patients in clinical trials impact research efforts and the treatment of multiple sclerosis?

Dr. Williams:
Yeah, so this is an extremely important topic. When we think about our therapies and when we think about the interventions that we're doing, we want to make sure that the people in our trials reflect the people that we serve in our general population. Social determinants of health, such as access to care, play a large role in health outcomes, but there may be nuances, let's say, environment or biological genetic nuances, that we're not able to recognize because we don't have a broad enough population of people in our research studies. Ultimately, I think the goal is to have adequate enrollment in our general trial so that we don't have to go back and do a CHIMES trial. But I think this is an important first step, and I think there are some learnings from the way that we designed this trial that could help increase recruitment of underrepresented populations in future MS research.

Dr. Caudle:
Given kind of what you've just talked about, what steps can we take to ensure that patients are equally represented in clinical trials?

Dr. Williams:
So to ensure that people are equally represented in trials, it is going to be a multifactorial and multistakeholder effort. I think that one of the issues is that when we talk about enrollment in clinical trials, it often comes from a place of people don't want to participate. There often is a focus on mistrust, which is rightfully so. There have been many injustices in the healthcare system and in research in the past. However, the research more recently shows that people do want to be involved in clinical research, but often they do not know where to find out about trials or they are not asked, and so I think that it first starts with not having the assumption that people don't want to participate and actually asking.

I think empowering people as well as educating them about the research process and the importance of involvement in research is extremely important, but I think also from scientific and stakeholder perspectives, it's important for us to look at how we design trials to make them accessible so that people can participate and maybe not have to take so many days off of work or miss all of this to be involved.

And then I also think for our industry partners, looking at the sites where research is conducted. Can we conduct research where people live so that they don't have to travel four and five hours and miss precious time from their jobs or families? So I think it's going to be a multi-pronged effort, but I think that there are definitely important strides being made, and there definitely is improvement that can happen in this area.

Dr. Caudle:
Understood. And before we close, Dr. Williams, do you have any final takeaways that you'd like to leave with our audience?

Dr. Williams:
I think the takeaway for me is that we can get people involved in clinical research. I think one of the triumphs of the CHIMES trial is we were very intentional from the beginning about including patients, patient advocacy groups, and other partners to help us design a trial that people, hopefully, would participate in, and I think that it's a testament that we were able to enroll all Black and Hispanic people in

this trial during the middle of a pandemic. We started in July 2020, and we enrolled two months ahead of time and overenrolled by 25 percent. We actually had to stop enrollment because we had so many people who wanted to be involved.

So I think it's a proof of concept. Again, it is one small step, but I think that the next step is to try to expand these learnings and ultimately to try to make sure that our studies are representative from the beginning so we don't have to go back and do these on the back end.

Dr. Caudle:
This is fantastic, and it's been a great discussion on a very important topic in multiple sclerosis research. I'd like to thank you, Dr. Mitzi Joi Williams, for joining me to share your insights from the CHIMES study. Dr. Williams, thank you so much for being here.

Dr. Williams:
Thank you so much, Dr. Caudle. It is absolutely my pleasure.

Dr. Caudle:
For ReachMD, I'm your host, Dr. Jennifer Caudle. To access this and other episodes in our series, visit *NeuroFrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening.