

FEMALE SPEAKER: Welcome to Mayo Clinic COVID-19-- Expert Insights and Strategies. The following activity is supported in part by an independent medical education grant from Pfizer Inc., and is in accordance with ACCME guidelines.

NOREEN STEPHENSON: Thank you for joining us. I'm Noreen Stephenson with the Center for Health Equity and Community Engagement Research. My co-host today is Dr. Angela Donaldson, Assistant Professor of Otolaryngology in Mayo Clinic's College of Medicine, and Consultant in the ENT Department here at Mayo Clinic Florida. We're so glad you could join us for this COVID-19 discussion.

COVID-19 has brought to the forefront many inequities in our country. Health disparities are not new, but they have certainly been highlighted by the pandemic. We want to focus today on the disparity in the number of minorities in clinical trials.

Mayo Clinic and Xilinx Incorporated partnered in 2012 to talk about how critically important it is to have as wide and varied of a population represented in clinical trials as possible. Here's a testimonial from one participant.

[VIDEO PLAYBACK]

- I offered to participate in a clinical trial because I care about the rest of humanity, and I have kids, and I want them to have access to newer research, newer treatment options, better medical care as they grow up.

[END PLAYBACK]

NOREEN STEPHENSON: Now, that video was released several years ago, so let's fast forward and review some more recent data. This slide shows the percentage of minorities enrolled in overall clinical trials as reported by the National Institute of Health. When you look at this data, you'll see that there has been an increase from 27.8% in 2015 to 29.3% of minorities participating in clinical trials in 2018.

However, when we take a look at the data showing the minorities enrolled in cancer clinical trials, we see a decrease in enrollment. So non-Hispanic whites were more likely to be enrolled in clinical trials than African-American and Hispanics, and there's been a decrease-- an overall decrease-- in the recruitment of minorities over the past 14 years, as compared with historical data from 1996 to 2002. So currently, this snapshot shows that minorities in clinical trials are represented at about 15% to 20%, which is persistently lower than the minority population of the US as a whole, which is 36.3%.

If we look at the percentage of minorities participating in Mayo Clinic's COVID trials, 9% of participants reported being in a minority category. 7% of participants chose not to disclose their race, or reported that their race was unknown. Now, if we consider that the other category is often selected by individuals of mixed race, then the number of percentage of minorities participating in COVID clinical trials at Mayo Clinic is closer to 13%.

If, in the future, we can do a better job of converting those unknown and other categories into known racial and ethnic categories, we can perhaps get a better picture-- a better, more accurate picture-- of exactly how many and what percentage of minorities are participating in clinical trials.

When asked if they would be interested in being vaccinated if a vaccine for COVID-19 was found, 53% of minorities participating in a survey done at COVID testing reported that they would not be interested in being vaccinated. 46% said yes.

It's clear that there is still a persistent fear of clinical trials and new vaccines and new medications in minority communities. We have a long way to go to dispel the myths and mistrust that keep minorities from enrolling in clinical trials.

FEMALE SPEAKER 3:

Here are some things to consider when thinking about community engagement research.

FEMALE SPEAKER 4:

As you learned in the Insider and Outsider Challenges section, it is not uncommon for communities not to trust an outsider because of previous past hurt. This goes back to understanding the historical consequences of the mistreatment of many community members over time. Thus, we must find a way to connect directly and determine ways that community members and researchers could partner over every aspect of our medical research.

Communities and researchers need to determine the research question, determine a plan that fits both the needs of the community and the research team, and create a process for implementation, interpretation, and evaluation of the plan. This leads us into how we use the information collected by these groups in a way to spark change and meet unmet health care needs.

When the researcher, the community, and potential study participants do not speak or appreciate each other's cultural norms, this will impede the process. For instance, when language is a concern, strategies to manage multiple languages may include working with an organization who offers forward and backwards translation to ensure appropriate interpretation of the dialogue, creating close relationship with community insiders to promote open and honest communication, and making a concerted effort to draw out and acknowledge the voices of all participants. Also, adding a researcher from the community as a part of the team to serve as a cultural broker for both the researchers and the community members.

As a researcher, language is very important when working with the community. When researchers or community members are becoming more aware of cultural norms, we must create opportunities to gain insight on the cultural norms and expectations of the community.

This may also mean taking the time to learn some of the cultural traditions and words that convey "thanks," "hello," and appreciation. This also means watching our use of scientific jargon that may not translate to our community partners. Remember-- at all levels, it is important to always take communication seriously.

FEMALE SPEAKER 3:

As mentioned in the previous video, language can be an important part of overcoming barriers to community engagement research. Having community leaders run a town hall meeting is one way to tailor your study approach to the customs of the community. Take into account all voices, even those of the minority. Everyone's opinion counts. A dissenter might have a good objection that no one else is thought of. And working through that opens up an opportunity to work through the challenge and build trust.

Everyone's time is valuable, not just those of the physicians and scientists who were part of the study. Be respectful of timelines and set reasonable expectations for the study. Don't try to rush. Setting reasonable expectation builds trust and creates better partnerships.

Be realistic as it regards your funding. Make sure to leave room in your budget for unexpected expenses. And finally, be clear, concise, and transparent. Explain to the community participants why this study is important to you. It will make you more relatable to them. Be sure to engage community stakeholders who can help you navigate customs of the community, as well as be champion for recruitment and enrollment.

NOREEN STEPHENSON:

And now, I'll turn it over to my co-host, Dr. Angela Donaldson.

ANGELA DONALDSON:

I think it's important to kind of figure out the historical data in regards to minorities and women in clinical trials. And so I wanted to highlight one of the legislative acts that have increased or at least encouraged researchers to include minorities and women in clinical trials. The NIH in 1993 passed an act called the NIH Revitalization Act of 1993. It was signed by President Bill Clinton.

And in this act, one of the directives was to establish guidelines for the inclusion of women and minorities in clinical trials. The goal was to ensure that trials, including their design and how they were carried out, were done in a way that had valid analysis of whether that research variable being study affected women or minorities in a different way in comparison to others that might be included in the trial.

There were some considerations in this trial, including the fact that they could exclude the requirement for entering women and minorities into trials if they could confirm and demonstrate that substantial scientific data showed that there was no significant difference between others that were in the trial and women or minorities. The language was slightly controversial, as it allowed for a lot of variability in interpretation.

However, the two statutes that they stated must be shown from a scientific data standpoint or that the effects of a variable to be studied has on women and minority groups and the effect that variables on individuals who served in the trial were not required, meaning that if they looked at other preliminary studies, they showed that women or minorities were not affected significantly by that variable in comparison to others. And that overall, that variable, it didn't matter who the gender or what the gender or the ethnic group was. That variable was not important in comparison to gender or the ethnic group.

20 years later, they revisited the revitalization act, really with the emphasis on making a case for enhancing minority participation in clinical trials. So 19-- or excuse me, in 2013, they published a cumulative analysis of all the papers that had been sponsored by the NIH, and they looked at what kind of trials had an emphasis on ethnicity or race. And that was approximately 1%, meaning lots of studies looked at different things. But if you emphasize what was the impact on race or what was the impact of ethnicity, only 1% of trials actually did a study looking at this.

So one of the positives that they did find was that there is a significant trend towards an increase in the enrollment of minorities in clinical trials. From the onset of this act in 1993, it was about 1.5% minority enrollment. And by 2011, it was 57%, which is a significant increase. However, they had the increase in enrollment, but they weren't analyzing that data. So only 36% of the studies of that increased recruitment actually analyzed data specifically in regards to race or ethnicity. Before we hear from Dr. Colon, we're going to watch a video about why we should engage in community engaged research.

FEMALE SPEAKER:

I think it's important not just for me, for the community as a whole, if we're all healthier. We're all doing better. But as African-Americans, I think we don't have the benefit of knowing what diseases affect us. We just had that opportunity to participate in a study like this is good for me personally. But if more people are aware of these numbers, it alerts us all to the importance of taking better care of ourselves. And we should all take that opportunity to help each other.

ANGELA DONALDSON:

I would now like to introduce Dr. Geraldo Colon-Otero, who is a professor of medicine at the Mayo Clinic College of Medicine. He's also a consultant in hematology and oncology, and he is the site director for health care equity and community engagement research here at the Florida campus.

GERARDO COLON-OTERO:

Yes, on the issue of enrolling disparities in-- enrolling minority minorities in clinical trials is a big issue. There are significant disparities with a significant lower percentage of minorities actually entering clinical trials, which is a real problem because as a result of that, if you're testing a new drug for its effectiveness and potential side effects, if you don't have a diverse patient population, it is difficult to conclude that the observation of effectiveness and potential toxicities could be applicable to all patients that we encounter in our clinical practices.

So historically, there had been a significant under-representation of minorities in all sorts of clinical trials, including cancer clinical trials, which I am involved with as a clinical researcher in oncology. Part of the problem is that most of the clinical trials are offered at institutions where many minorities are not able to receive care as a result of insurance issues, like they may not have the right insurance to be able to receive the care at those institutions or access issues. There are also issues that relate to their willingness to participate in clinical trials because of lack of trust in research in general.

We had had experience bringing clinical research studies to minority communities by partnering with institutions that provide services to uninsured s like Volunteers in Medicine Clinic in downtown Jacksonville, which is a clinic that provides care to uninsured, low-income working patients. So we have been providing services to patients in Volunteers in Medicine Clinic for the last 13, 14 years, and been able to bring them to the Mayo Clinic for their care once breast cancer is diagnosed, for example. And as a result of that relationship, those patients are able to then participate in clinical trials and receive clinical trial treatment, and having access to newer drugs and so forth.

We also have collaborated with African-American churches in providing education programs on the importance of clinical research and cancer research. And as part of that education effort, we have actually brought clinical research studies during those clinical education efforts, and had found that providing access to the clinical research at their communities leads to a greater acceptability of tribal participation and a greater percentage of patients participating in the study. So eliminating those barriers of lack of access.

So if you provide the access and you provide the education of the importance of the research, you can eliminate a lot of the barriers that are present that are limiting minority populations from participation in clinical trials.

NOREEN STEPHENSON: Thank you so much, Dr. Colon. Now, I'd like to introduce Monica Alberti, who is an assistant professor of Healthcare Administration and the operations manager for the Center for Health Equity and Community Engagement Research. Thank you.

MONICA ALBERTI: So this afternoon, we are going to talk a bit about strategies for clinical trial recruitment and retention. So when we think about COVID-19, there are a lot of research opportunities. However, one of the things that we see is that there are some challenges with trial recruitment as it relates to COVID-19, but really overall. Clinical trial recruitment and retention are two of the main challenges for many studies, especially when we're talking about racial and ethnic minorities and those that are living in remote areas or rural areas. So we're going to talk a bit about some strategies for improving clinical trial recruitment and retention.

The first step is to think about your study design. What is the overall purpose and the goals of the study? Can it be explained in a manner that is easy to understand and relatable? So oftentimes, when community members or participants are interested in participating in a study or interested in learning more about the study, it's important to really have what I like to call that 30 second pitch. So what are the goals of the study? How is it going to benefit the person? What are going to be the risks?

And also, the most important thing is to also think about the WIIFM, or What's In It For Me. So as you're designing your trial, yes, for most clinical trials, the what's in it for me or the overall goal, the ultimate goal, is really the betterment of population overall. However, we also have to think about, well, what is going to be the benefit for that individual who's participating in the study.

Also, think about your study flow. So when you're designing your study, think about the participant in mind. So how many visits are required for the study? Will the participant have to make special arrangements to participate? Will they have to, say, drive far to participate in the study, and then maybe have to stay overnight somewhere? So really think about how can you design your study so that the participants-- so that it does not cause too much burden to the participant?

Because the less burden that we're able to cause to potential study participants, the more we see, the more willing they are to participate in the study. Also think about inclusion and exclusion criteria. Recently, in the last few years, what we found, particularly for racial and ethnic minority populations, is that the inclusion-- the exclusion criteria in many studies are greatly limiting. So they really impact the ability to really recruit from a wide population or a wide audience because the exclusion criteria really limits the number of people who can participate. So think about that exclusion criterion. Is there any way to make it a bit more broader? Is there a way to make your inclusion criteria a bit more broader?

And finally, participate remuneration. So we have to balance ensuring that remuneration is adequate for participants time but also not coercive. But it is important for us to think about that. When we are building studies and we're thinking about our study budget, are we putting in remuneration? So whether it's a nominal fee for participation. Whether it's covering their transportation or meals or anything that may make participating in the study easier, those are things that we need to think about. And those have shown to greatly improve trial recruitment and retention.

So there are some special considerations, particularly when we're thinking about racial and ethnic minority populations. For one, looking at your study team. How diverse is your study team? So the coordinators that are on your team, your folks that are going out and really informing the community or informing the population and patients about your study, is it representative of the community that you're serving? But also, is it representative of particularly the target population that you're looking for?

There's an opportunity to use patient navigators for research, and we'll get into this a little bit on the next slide. But thinking about, how can we use this idea of patient navigators? So someone who can really help navigate a study participant through the research process.

The next thing is to consider are your study materials. So are your materials developed in other languages? I think that what we find is that when we are developing our consent forms or our study instructions or surveys, oftentimes, we immediately, of course, have them developed in English. But we should really consider making sure that we develop them in particularly other languages, especially if there are numerous languages in the communities that we serve.

Are your study flyers and other recruitment materials culturally tailored? So the visuals that are on your flyers, if you have people on the flier, do they look like the communities that you're really trying to target? Have the flyers been vetted and reviewed by folks that are in the particular target population?

And the risks and benefits. Are they clearly stated? So we know that in racial, ethnic minority populations, there are some historical events that have happened that have really led to mistrust of research. And because of this, we really need to take extra precaution to make sure that we clearly state the risks and the benefits to participating in the research study.

Also, your study visibility. So who knows about your study? If your study is targeting a particular community, are you working with community leaders? Are you working with particular businesses or organizations that cater to that particular target audience? Where are your recruitment materials?

Oftentimes, when we're recruiting for research studies, we may just keep our study fires within our own institutions. And that's fine, and that's something that we should do. But if we're really wanting to make sure that we are targeting a broader audience, then we should think about where other places that we can put these recruitment materials. Are there public spaces that we can have flyers? Can we use social media to put things on Facebook, and can we use other avenues in order to increase the awareness of the trial?

And then also, how do you utilize study ambassadors as advocates for the study? So if you have a particular study that is targeting either a particular population or that is focused on a particular disease, are there patients or advocates that you are connected to as an investigator that could really serve as an ambassador for the study? They really can be your advocate. So they can talk to community members or potential patients about their experience in the research study or about why it's so important if they're not in the research study, why it's so important that this study is done. So those are some things that you could think about as you think about how to increase your study visibility.

So I mentioned a patient navigator. So we typically see patient navigators in the clinical setting. Oftentimes, these patient navigators help patients really get through kind of their medical journey. So they may help with appointments, and they may help with trying to find medication assistance, and those sorts of things.

But a patient navigator can also be used specifically in research. So really, the overall goal of the patient navigator is to focus on the participant's, the study participant's needs. And so that person could also be a research coordinator that has some added responsibilities. And really, the goal is that they guide the participant through the research process, and they work directly with the participant, the investigator, and the participant's family to overcome obstacles that may hinder study participation.

So when we think about what are some of those particular responsibilities that a patient navigator would have-- so organizing schedules. So if the participation in a study requires multiple visits or requires multiple study-related appointments, a patient navigator can really work directly with that study participant to really ensure that it is not a burden for them. They can work directly with them to ensure that the appointments are made, and to really check on them throughout the journey to ensure that the participant actually is able to make it to the appointment and can overcome any obstacles the participant may have in getting to the numerous study appointments.

They can facilitate communication. So if the study participant is having any challenges with the study or if there are some logistical issues with participating, a patient navigator that's used in research really can be that mediator, that facilitator of communication between the study team, the study participant, and the family. And this really does ensure satisfaction and quality of care.

They can, of course, manage study-related records. And then explaining the financial aspect to the study participant. So if this is a study that requires insurance is billed for participation or if this is a study that something isn't covered, a medication isn't covered, or that it's going to have some sort of financial impact to the study participant, a patient navigator can work directly with the patient, the investigator, the finance office, to really try to come up with the best scenario that can make it easier for a patient or a community member to participate in a study. And they can also connect them with financial end community resources that can also lessen the burden.

And finally, they can accommodate interpretation services. So if we have community members or study participants or potential study participants who are interested in participating but they may not speak the language, a patient navigator can ensure that there are interpreters at every appointment that when there's any kind of communication with the study participant that an interpreter is present. And that also lessens the burden for the study participants and also their family.

So in summary, when we think about the best strategies for recruiting and retaining clinical trials, there are some things to keep in mind. The study design-- keeping the participant in mind is key. So again, thinking about how many visits are required. Is this going to be a burden for a patient? Or is this going to interrupt their daily life? If you answer yes to any of those questions, then most likely, it's going to be-- it may be a challenge to really recruit a participant. And then if you are able to recruit a participant, it may be difficult to retain them and to keep them throughout the length of the study.

Ensuring that there is intentional diversity within your study team. Especially when you are particularly targeting or wanting to enroll racial or ethnic minorities, it is very important that as an investigator and as a leader of the research study that you are intentional about making sure that your study team is diverse and reflects the population, particularly the population that you're wanting to target.

Navigators, as we discussed, are great assets for recruitment and retention. Being with the patient or being with the study participant kind of at their side really does, and throughout the research journey, really can help with retention and ensuring that the patient overcomes any kind of obstacles that may be in the way of them being able to complete the trial.

Study flyers-- they are a easy and effective tool. They're very simple. Oftentimes, we don't think much about those study fliers, but study fliers really allow us to put the high points of our study, why it's important, who should participate, and it's an easy tool to use to be able to get out to communities. Participant remuneration also is a consideration. So when we're creating these study budgets, we should always think about, how can we write into the budget something that can help with the patient's participation but that isn't coercive?

And finally, study materials-- they should be easy to understand, they should be culturally tailored, and they should be available in different languages. As a research team, as an investigator, as you're developing your consent forms, really thinking through, is this simple enough for a patient to understand? Oftentimes, our consent forms are sometimes written in eighth grade language. But even still, sometimes we have acronyms and letters, long words with lots of letters.

Is there a way to really simplify that? Is it culturally tailored? If you are having-- if there are flyers, are your flyers diverse? Are they representative of the community? And then, of course, being able to accommodate community members that may speak different languages. Community members and patients that may speak different languages. So ensuring that all of our study materials are able to be translated into different languages and are available.

So with that, I thank you so much. And I hope that these strategies are helpful to you as you build your studies. And hopefully, they can lead to a higher level of recruitment and retention. Thank you.

NOREEN STEPHENSON:

Thank you, Monica, and thank you all for joining us today for our discussion on the disparity in the numbers of minorities in clinical trials.