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## SUMMARY KEYWORDS

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## SPEAKERS

Dr. Halena Gazelka, Sonya Goins, Dr. Gerado Colon-Otero

- D** Dr. Halena Gazelka 00:06  
Welcome everyone to Mayo Clinic Q&A. I'm Dr. Halena Gazelka. Like many healthcare organizations, Mayo Clinic is working to address disparities and equity and health care. This work is not only underway in the clinic where we see patients, but it also includes addressing equity issues in medical research and clinical trials. Joining us to discuss this today, is Dr. Gerardo Colon-Otero, and Sonya Goins. Dr. Colon is the medical director and site lead for the Florida campus of the Mayo Clinic Center for Health Equity and Community Engagement Research. Ms. Goins is a Mayo Clinic patient and clinical trial participant, and we are so grateful to have them both here today. Thanks for joining us on Mayo Clinic Q&A.
- S** Sonya Goins 01:20  
Thanks for having us.
- D** Dr. Gerado Colon-Otero 01:21  
Thanks for having us.
- D** Dr. Halena Gazelka 01:23  
Well, thank you for being generous with your time just as you have with being in a clinical

trial, Sonya, and we'll get to that in a little bit. Dr. Colon, could you tell us first for our listeners, what are clinical trials, and what is the role of research volunteers like Sonya in conducting clinical trials.

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Dr. Gerado Colon-Otero 01:42

So, clinical trials are treatments that are part of research, it is the way that we study new treatments that hopefully will improve the outcomes of many diseases, including cancer. I'm a medical oncologist, so I take care of cancer patients. So, the way we make progress in the management of different diseases is actually by doing clinical trials. So, whenever there's a new drug that is being developed, it is brought into what we call the clinical trials where we test this new drug in patients with a given condition in hopes that the new drug will become eventually the standard, and will improve the outcomes of those given conditions. So, for example, if it is a breast cancer, that is already metastatic and spread, we need new treatments. We need to improve the outcomes and hopefully eventually cure all the women with metastatic breast cancer, which we are not there yet. And by doing the clinical trials, we're hopefully able to get there. So, I mean, that has happened, for example, with lung cancer. So, I remember very well, when I first started at the Mayo Clinic in Florida, 35 years ago, visiting with a 34-year-old young man who had widely metastatic lung cancer. And back then 35 years ago, the standard of care was to refer them to hospice, because any of the treatments that we had available back then would not prolong their survival. But now, 35 years later, that standard of treatment, and second line on third line and fourth line treatments have been shown to improve the survival of lung cancer. So, that same young man, who I saw 35 years ago, thanks to clinical trials, now has the chance of surviving beyond five years, and having standard of treatments that prolong survival beyond first, second, third and fourth line. So, that's what that's why we're doing clinical trials. And that's the main goal of clinical trials.

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Dr. Halena Gazelka 03:54

That's amazing. Now, I can imagine that for the participants, patients, at times, it feels a little risky to do this, a little like, well, am I being a guinea pig for a new drug or a new way of doing something. What are the risks to patients in being involved and what are the potential benefits to them?

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Dr. Gerado Colon-Otero 04:12

So, any treatment with a new drug potentially has some side effects, but by the time they reach the human trial stage, they have been tested in animals, and there's enough data to suggest that they may work to warrant them being tested in humans. And usually, by the

time they reach humans, we first test any new drug that has never been tested in humans, we are very careful about how we go about that starting at a lower dose that we know is not going to cause significant side effects. And then increasing the dose gradually once we don't observe side effects to reach the dose that we think will lead to significant beneficial effect. That's what we call a Phase I clinical trial. And then once that drug has passed that trial, and we find that it's safe, and we do what we call a Phase II clinical trial, where we test that drug that is showing some potential beneficial effect in a number of patients, perhaps 20-30 patients with a given condition, and expecting to see a significant improvement in what the standard treatment offers. And hopefully, we will see that and if we see that, we frequently then do what we call a randomized Phase III clinical trial where we compare that new treatment with the standard treatment, hoping to show that the outcomes are better, response rates are better, the time before the tumors come back are longer, or that the patients will live a lot longer as a result of that new treatment. And after that, the drugs become approved then for that particular condition. And then even after that, after the drug is approved, there's ongoing testing on the drug to make sure that they don't have unexpected side-effects that will be seen in a larger number of patients that are seen after the drug has been approved. So, there's a significant concern about safety. And what is the best for the patient as we design these clinical trials.

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Dr. Halena Gazelka 06:24

That's very interesting. Sonya, I'm very interested to get to you. Because we don't often have listeners and patients on our program. We're often speaking with physicians or other providers, and so thank you for being here today. It's just lovely.

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Sonya Goins 06:38

You're welcome.

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Dr. Halena Gazelka 06:39

I am wondering if you would tell us a little bit about your journey to come to Mayo Clinic and how you decided to participate in a clinical trial, what it's been like for you.

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Sonya Goins 06:49

Yeah, so I was diagnosed with Stage II HER2-positive breast cancer last July. And so, I had five rounds of chemo at another hospital. But then I went to the Mayo for a double mastectomy, reconstruction and proton beam radiation, which I just finished on Friday, so YAY!

**D** Dr. Halena Gazelka 07:12  
Congratulations.

**S** Sonya Goins 07:14  
Thank you. Yeah, it's been a long journey. But Mayo is the best in the world. And luckily, I live like an hour and a half away from the Rochester clinic. And I was able to participate in their new vaccine study for HER2-positive. And so, this past week, I just underwent a CT scan, bloodwork, and a body scan to participate in the trial. So, in a couple of weeks I should be getting my first vaccine. You don't know if you're going to get the real thing or not, because it's 50/50. But for me, 50/50 I'm like, hey if I could participate and possibly get this vaccine, I'm going to do it. So, that's one of the reasons why I wanted to participate. Also, you know, you're helping mankind by doing this. And so, you know, it's an easy thing to do. And you also get medical procedures that you might not be able to get, like with your regular insurance. Like that body scan, I got, it was a nuclear medicine body scan. I doubt my insurance company would just say, yep, go in and do this. But with this vaccine study, it's included, you know, and they also watch you really carefully. So, I'm like, why not do this. So, that's one of the reasons why I participate in trial studies. I also have Crohn's disease, and I've participated in two drug trials, and they're on the market now. So, to be able to see these drugs on the market, and be able to have access to them before they become available to the public, is a big win. So, I always tell everybody, you should participate. I know you don't often see a lot of African Americans participating in drug trials too. And I want to make a difference. I want doctors and researchers to include African Americans in their studies. So, that's another reason why I do this.

**D** Dr. Halena Gazelka 09:19  
Well, we are delighted to have you here today, Sonya, because we want to change that too. And we are talking, doing a lot of work on diversity, equity, inclusivity here at Mayo Clinic. And we really want to expand that within our research work. Dr. Colon, why do you suppose it is that research trials haven't always been very inclusive, and what are we doing about that?

**D** Dr. Gerado Colon-Otero 09:43  
No, that's a real concern and a real issue because you want to make sure that the results of the clinical trial are applicable to the whole population and that the whole population would benefit from it and have access to these studies. So, like Ms. Goins was saying, she has HER2-positive breast cancer. That particular cancer before the discovery of the

monoclonal antibodies that attack the HER2 protein that are now commercially used, used to have the worst outcome of all breast cancers. And now, thanks to clinical research, and that medication being available, now has one of the best, if not the best, outcomes of all the breast cancer subtypes. And it's not only one drug, but we have now like five drugs. Just over the last year three new drugs for HER2 only cancer have been approved, that are actually incredibly active, and are likely going to be used. They're approved now after failure, but likely will be used upfront to even cure more women upfront. But it is critical that the representation on those studies be diverse, that includes all patients so that we can learn about this toxicity and the beneficial effects to make sure they're equal. And we're working really hard at Mayo to make sure that happens. Historically, throughout the country, African American participation and Hispanic participation has been lower, in great part due to access to the studies and to where the studies are available. And hopefully, Mayo and many academic institutions with increased awareness of these, with industry support as well, we're going to make a mark to make sure that the representation is representative of what our country is.

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Dr. Halena Gazelka 11:35

Yes, it makes sense that that will be very important. I remember in medical school, talking about certain clinical trials, and I'll just use the example of heart disease, Dr. Colon, but a lot of the trials had had been done on middle aged white males, and didn't necessarily apply even to females or to black males and females. And so, it's not just widely applicable, you need to test in in all communities where you might use that and all ethnicities, etc. which is where you might use the drug, correct?

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Dr. Gerado Colon-Otero 12:09

Correct. Yeah, no and for example, in breast cancer, there are some mutations that predispose the patients to breast cancer that are inherited. And those had been studied, initially, predominantly in Caucasian or white populations. And it was initially discovered by studying Ashkenazi Jewish population that had these mutations to BRCA 1 and 2, but most recently studying African ancestry Caribbean females, we find that they have a huge high very high incidence of these mutations as well. So if we don't study those populations, if we don't do the research, we fail to really discover the findings that are essential to lead to better treatment for those populations. So, now for the BRCA mutated breast cancer tumors, for example, we have specific medications that work in that subset of cancer. So, it is critical so that all the populations can be benefiting from this research.

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Dr. Halena Gazelka 13:13

That's interesting and a terrific example. Sonya, Dr. Colon has talked a little bit about why it's important to the medical community to be inclusive in clinical trials. Why was it important to you in particular to participate? And, why do you think inclusivity might be important?

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Sonya Goins 13:31

Well, for instance, like when you get your lab work, right, and you look at, say, your kidney function, they don't even have it for African Americans, because it was studied on white men. And I'm like, you need to have a variety of people participate in your studies, like the doctor said, because the different patients or different genes, and I know there is some, you know, stereotypes when it comes to African Americans not participating in studies. You look at the Tuskegee Airmen experiment, people are scared. And for me, my dad was a nurse. So I'm kind of, I'm not scared. But at the same time, I also want to do research, I'm a news reporter, and when I researched stories, I, you know, I'm going to research my medical history, too. When I went on the Mayo website, I did not find the study for this vaccine. I asked my oncologist and they told me about it. So, I think getting the word out is really important, especially when it comes to diverse communities, maybe advertise on radio stations, or, you know, put them in magazines or something, but people need to be aware that these studies are out there, and that they give you hope. That's, that's the reason why I do them. It's because they give me hope. When your doctor tells you, hey, you have breast cancer, and you have one of the fastest growing breast cancer, and in my case it's really aggressive. They rate you from a scale from one to three, and mine was three. And I'm like, I want to do everything I can to prevent this from, you know, recurring again. So that's the main reason why I'm doing this vaccine study. And I'm hoping and praying that I'm actually one of the participants that that doesn't get the placebo but actually gets the real thing.

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Dr. Halena Gazelka 15:19

I love what you said about hope Sonya, because we talk about that so often that that really is why we're here because we want to bring patients help where they might not have found hope before. And so that's really, that was wonderful. Thank you for sharing that. I just wanted to bring up a comment about what you said about that you may get the vaccine or you may not. And maybe Dr. Colon can just briefly explain this. But I think that Sonya is discussing randomization and you had said earlier that often the study drug is compared to what would be, quote, the standard of care or the typical way to treat someone. Can you explain just briefly why that would be?



Dr. Gerado Colon-Otero 15:57

Yes, because the reason you have to compare with the standard of care is because sometimes the new treatment ends up being not any better than the standard of care, or maybe more side-effects. So, it's critical before you bring some something to the general population to use, that you know for sure that it is better than the standard of care. In the case of Mrs. Goins study, she had the standard treatment that hopefully leads to cure the majority of the patients. And the vaccine is a new treatment that has hopefully minimal or no side effects, but hopefully will stimulate her immune system to kill any microscopic cells that may have escaped the chemotherapy and improve the outcome in her case. So, the reason why it is compared to a no vaccine treatment, it's just a placebo that has no side effect is because the outcome of that particular study is looking at recurrences down the road, and the standard of care is very good. So, I'm hoping that the vaccine will improve on that further. And the vaccine is approved for this particular trial, because the side-effect profile is quite good. It's very low profile, low toxicity. So hopefully, we'll be associated with the improvement or what we're doing nothing aside from the chemotherapy and the radiation that she just completed.



Dr. Halena Gazelka 17:24

And Sonya, I have to say that that truly shows it's an incredible example of the generosity that comes with participating in a clinical trial, because you don't really know that you're getting the study drug or not, but you're still willing to participate. So, that even if this trial doesn't help you, it may help someone else.



Sonya Goins 17:46

Exactly, it's a 50/50 chance, but if I have that 50% chance of getting this vaccine, you know, yay for me. But also, I want to give researchers tools that they could use to you know, prevent this from reoccurring in somebody else, if not myself. I'm going to be on T-DM1, which is a chemo and targeted therapy drug for about a year and that'll be used with a vaccine. So, I'll be at Mayo every three weeks to get this.



Dr. Halena Gazelka 18:18

Wonderful, we'll wave at you when we see you.



Sonya Goins 18:21

Right, but I'm really blessed to be able to participate. That's how I feel about doing drug

studies. And I mean, this is a gift, you know, to be able to participate in a drug before it comes to market, so.

**D** Dr. Halena Gazelka 18:34  
We are blessed to have patients like you who are willing to further research like this.

**S** Sonya Goins 18:39  
Thank you.

**D** Dr. Gerado Colon-Otero 18:39  
And it's absolutely fantastic that you're doing that. And actually, the T-DM1 being used in your case is a result of a clinical trial that was just completed and presented just a year ago that showed that doing T-DM1 instead of Herceptin or trastuzumab is better, improves outcome, patients live longer. So, as a result of that other study, which was also a randomized study that compared patients like you who had trastuzumab versus T-DM1, the group that had the T-DM1, compared to the standard of care did much better. So, that's why you're benefiting now, from that other clinical trial that was completed recently.

**D** Dr. Halena Gazelka 19:23  
Like a domino effect.

**D** Dr. Gerado Colon-Otero 19:24  
Yeah, so your participation in this study will show that the vaccine improves over what T-DM1 does, and it will become part of the standard of care. So, this vaccine trial is really exciting to me because it was actually developed at the Florida campus of Mayo. So, this shows the collaboration of all the three campuses, by Dr. Keith Knutson, and his team and Dr. Saranya Chumsri, M.D. here is the PI of that study.

**S** Sonya Goins 19:52  
Well, I'm very grateful that you guys are doing this study and hopefully in a year it'll be you know, standard treatment and everybody can benefit from this.





Dr. Halena Gazelka 20:02

That's wonderful. Dr. Colon, what can researchers do to be certain that they are increasing inclusivity in clinical trials as we go forward?



Dr. Gerado Colon-Otero 20:12

Yeah, there's increased awareness of the need for that, at all levels, at the federal levels, the government level, at the academic medical center. So, there's increased initiatives to make sure that the representation in our clinical trials represents our country, racial and ethnic composition. So, there are a lot of reasons why that hasn't been the case. And addressing those issues, is critical. And it's not going to be only Mayo who is going to make it happen. It has to be a collaborative effort among all academic centers among the government, on the patients among the population. Because there are many, many factors that contribute to that, for example, African Americans, and Hispanics have worse outcomes from different diseases and less participation in clinical trial for many reasons, including less access to health insurance, higher prevalence of poverty, and other factors that contribute to them having less access to care. So, it's going to take a huge effort by everybody to make things that all those barriers are eliminated. But as Ms. Goins was saying, there's less awareness to have clinical trials, and it's less easy to access them among the minority population. We have done studies in Florida, where we went to African American churches to tell the African American population in Jacksonville about the availability of clinical research, the importance of clinical research on participation, and making a clinical study available at the churches, which we were very successful in accruing to it. So, when you make the studies that answer the questions and the needs of the community, make them available, the participation is not an issue. The issue is the access and availability of access to those studies.



Dr. Halena Gazelka 22:15

That's wonderful. And we've certainly started doing more virtual medicine during the COVID pandemic. And I would hope and imagine that the ability to use some virtual visits with patients, etc., might improve some of those access issues as we move forward.



Sonya Goins 22:32

You're probably right, Dr. Gazelka. Because now with the COVID pandemic, we had to do a lot of virtual things in terms of maintaining the accrual for our clinical trial participation, we had to convert some of the consenting for example to virtual, but some of that may persist beyond the pandemic, as a way to facilitate the availability of trials to different communities and different populations. We have to deal with the issue of whether the

population have really equal access to the internet and all those things, which are other issues, but those hopefully will lead to greater participation in trials.

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Dr. Halena Gazelka 23:15

Sonya, what would you tell family and friends who are thinking about participating in a clinical trial?

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Sonya Goins 23:22

Well, it's funny, you should ask that. I belong to a couple of breast cancer support groups on Facebook. And I've already told them, hey, there's a vaccine study going on. And you should, you know, contact Mayo. So, hopefully, they'll do that. But I would tell them not to be afraid. And then for the fact that you get access to, you know, top grade medical procedures, they watch you carefully, like, while I'm participating in the study, they're gonna watch me for like five years. So, it's a big commitment. But I think it's worth it in the end, if there's a product that's available to everybody and, you know, can help everyone. I mean, if you could avoid breast cancer, why would you not do this vaccine? So, I tell people, don't be afraid. You know, it's gone through, you know, the FDA and all that other good stuff. But, you know, there's hope, so participate is my answer to people.

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Dr. Halena Gazelka 24:19

And I think the other thing that I think about Sonya, having worked on sort of the side of the of the desk, is that people aren't allowed to participate in clinical trials if they aren't the right participant for it. So, the goal is always to keep the patient safe, to keep the individual safe at the same time that they're participating.

S

Sonya Goins 24:40

Exactly, because I have Crohn's disease, they were hesitant to let me participate in this study. So, I had to have, you know, GI had to be on board. They watched me for two or three months to make sure that I was okay on the T-DM1. There were no issues. I have an ostomy so they're worried about that. And so far, so good. There hasn't been any issues. So, going forward, I'm looking forward to participating in this study.

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Dr. Halena Gazelka 25:09

Wonderful. Dr. Colon, what would you tell patients, friends, family who are thinking about participating in a clinical trial?



Sonya Goins 25:17

We always encourage that, because we don't want to be doing the same thing we're doing now within my area of medical oncology. Unfortunately, once the tumors are metastatic, or have spread, frequently leads to the patient dying. So, there's a lot of progress that needs to be done. And we don't want to see our next generation who is caring for those patients having the same outcome. Just like I mentioned about the young patient I saw 35 years ago, who I didn't have anything to offer. And now here we are, with five or six different drugs that prolong survival. So, we want to be 35 years from now curing all metastatic cancer patients. And the only way we're going to get there is with the clinical trials, doing the standard of treatment for them is not going to get us to where we need to be. So, that's how I encourage them. There's a lot of safety as part of the trial so that patients are safe. These decisions about which drugs to try and not and what are the toxicity and there's a lot of safeguards, if we see toxicity, to stop the trial and analyze it. So, we're all working together for the patient's benefit. So, there is definitely the preferred treatment whenever we have an option. But obviously, we take into consideration the individual patient's needs to decide what is the best treatment for the patient, and most of the time clinical trial may be the best option. And so, we in general, try to encourage patients.



Dr. Halena Gazelka 26:46

That's Wonderful. Thank you, Sonya, for being here today.



Sonya Goins 26:49

Thank you for having me.



Dr. Halena Gazelka 26:51

Thank you, Dr. Colon, for being here today.



Dr. Gerado Colon-Otero 26:53

My pleasure. Nice, to meet you Ms. Goins, and thank you so much for participating. You're gonna do well, you're gonna see.



Sonya Goins 27:03

Thank you, thank you and I'm like, it's all about options and the fact that this is another

tool in the tool bag for the doctors to help me is wonderful.



Dr. Halena Gazelka 27:13

I love that tools in the tool bag. I use that all the time with patients. That's right. Our thanks to Dr. Gerardo Colon-Otero and Ms. Sonya Goins for being here today to talk to us about inclusivity and clinical trials. I hope that you learned something today. I know that I did. We wish each of you a wonderful day.