Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/ash-action-center/a-look-at-representation-in-hematologic-clinical-trials/14198/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

A Look at Representation in Hematologic Clinical Trials

Dr. Turck:
Representation in clinical trials continues to be a challenge, and specifically for leukemia and multiple myeloma therapeutics, clinical trials have often underrepresented racial and ethnic minorities. So, to what extent does this lack of representation impact our ability to extrapolate study findings to cancer patients in general?

Welcome to *ASH Action Center* on ReachMD. I'm Dr. Charles Turk. And joining me today to share insights from the ASH Annual Meeting is Dr. Namrata Chandhok, an Assistant Professor of Medicine in the Division of Hematology at the Sylvester Comprehensive Cancer Center at the University of Miami.

Dr. Chandhok, thanks for speaking with me today.

Dr. Chandhok:
Thank you for having me. It's a pleasure.

Dr. Turck:
Dr. Chandhok, to give our audience some background, can you tell us what led you to research underrepresentation in clinical trials?

Dr. Chandhok:
Yeah, for sure. So I will say as a trainee, I did not have the background or the understanding of how important this was, but I really came to appreciate this as a really important topic of research as I became a clinical investigator. And equity in clinical trials was always important to me, but I didn't appreciate the degree of disparity until I started working on clinical trials. Now, when I talk about disparity, it actually includes race and ethnicity and all of the things that we consider diversity, but also, things like sex and age play a huge part. So, while we may not think of those as, you know, your classic underrepresented populations, women tend to be less represented in older patients, which make a huge chunk of the population that we treat.

Within the racial and ethnic populations, what's very interesting and, you know, has come to my mind now that I'm participating in a lot of trials is that, you know, the demographic of the U.S. is changing. So at this point, what used to be a pyramid with, you know, older people being a minority of the population back in the 1960s based on the census data, in 2016, we look more like a box where the number of patients who are elderly are considered, you know, over the age of 60, 70, 80, is almost the same as the younger population. And so we really need to start addressing, you know, age-related disparity. When it comes to ethnic disparities, you know, we have to start thinking about our general census now and what it's going to look like, you know, in 10, 20, 30 years. So, for example, I live in South Florida, and we have a huge Hispanic population here, but are we truly seeing and representing those patients in trials? And at this point, unfortunately, the answer is no. So, you know, just being able to actually treat the community I live in is a really important part and what brought me to clinical research or, you know, looking at underrepresentation in clinical trials in the first place.

Dr. Turck:
And if we zero in on clinical trials for hematologic malignancies, why are we seeing less representation here?

Dr. Chandhok:
So there's a host of reasons that clinical trials don't represent our population and this basically has to do with a lot of the key factors that we'll get into in more detail, but within the hematologic malignancies in particular, it's important to realize that heme- malignancies are more aggressive in certain subpopulations. So, for example, multiple myeloma tends to be more aggressive in Black patients, or the incidence of acute lymphoblastic leukemia tends to be higher in Hispanic patients, so it becomes really important to study those particular subpopulations. Now the reason that this happens is really multifactorial, so it's a whole host of factors that comes with not

© 2023 ReachMD

only geographic but also economic and other risk factors that go along with this, but we need to start focusing on how do we eliminate the barriers that keep these patients from trials.

Dr. Turck:
Now you started touching on this a little bit before, but according to your research, what are the key factors contributing to underrepresentation in these clinical trials?

Dr. Chandhok:
Yeah, and this is actually the key to everything, right? Like how do we fix the problem is we have to understand the problem. So the easier-to-think-about factors are, you know, where do these patients live? What is their socioeconomic background? What is their medical literacy? And how do we adjust for this, essentially, or make it more easy for them to relate? Then it's also about communicating effectively with these patients. So, just to give an example, a large population will not speak English, so do we have the right paperwork to make sure we are explaining data to them and information to them in a language that's accessible? So accessibility is another factor. Then also, what are we doing to engage the needs of these underrepresented patients? One of these needs might be travel, so if we're thinking about patients who live far away from a place that has trials available, how are we expecting them to get there? How do we deal with that in the first place? And then a factor that really comes down to us as providers as opposed to looking at the population is checking our own bias. So a lot of times the provider will say, 'Well, this patient lives too far away,' or 'They don't seem like they'll be able to do this,' you know, making sure we are not using our preconceived notions on the patient and also trying to eliminate any preconceived notions they may have because there is a historical bias, you know, against medicine in certain subpopulations because of prior abuses.

Dr. Turck:
For those just tuning in, you're listening to *ASH Action Center* on ReachMD. I'm Dr. Charles Turck, and today I'm speaking with Dr. Namrata Chandhok about underrepresentation in clinical trials.

Now that we've explored some of the primary challenges to representation, let's dive into solutions. Dr. Chandhok, what are some strategies we can use to overcome these obstacles and improve representation in clinical trials for hematologic malignancies?

Dr. Chandhok:
Yeah, so I think the easiest things to tackle are what can we do just from a trial design perspective and how can we simplify trials that they are available and accessible widely. So one of the big problems that we have now is that trials are primarily available at large academic centers with, you know, a subspecialist that is not really accessible or available to the larger population.

Now, how do we make this easier? Well, one strategy would be to move beyond just the flagship cancer site into the community, and make sure that, you know, there's some guidance for either community providers or for satellites to cancer centers where trials can be performed safely.

The other factor would be community engagement, so better education in a wide net of providers to make sure that they are aware of trials even before they can be moved into this smaller community practice setting. So, one, they can encourage their patients, and two, they also understand all the resources that may be available to their patients.

And then finally, you know, trying to remove barriers when it comes to other health problems. So trials tend to be cumbersome just because of all of the inclusion and exclusion criteria, and while some criteria are essential, some can be slightly excessive, so certain subpopulations might get eliminated all together because of comorbidity status. And we need to try and eliminate that, make sure trials are truly representing the patients we're seeing at large as opposed to the fittest, youngest, richest, healthiest patients.

Dr. Turck:
And how are organizations such as the American Society of Clinical Oncology and the Food and Drug Administration working to improve representation in these trials?

Dr. Chandhok:
So there has actually been huge movement in the past, you know, I would say five years in trying to eliminate some of these inequities, or at least work towards a more equitable health system. And to this end, you know, guidelines have been created for clinical trials both for folks who are writing clinical trials, and those who are participating in clinical trials. And the FDA has put out the FDA race and ethnicity guidance, and there's an international conference on harmonization guidance as well. And ASCO released a new diversity, equity, and inclusion plan in 2021 for better representation in research, and some of the factors that they address in this is that, you know, every patient should have the opportunity to participate in clinical trials. So instead of just collecting data on the patients that we see, every patient should get screened, and we should have particular, you know, information of why this patient was not eligible for a trial. And that will help us, actually, moving forward, identify what factors were creating barriers to providing the best care.

© 2023 ReachMD

Other things is also just, you know, making sure the trial design works to ensure that participants represent the racial and ethnic makeup. And, you know, if we're pushing to this, a lot of the other factors, like we were talking about getting to a site where the preferred trial is available, will be ironed out because we will see these discrepancies and we will be forced to act on them.

A third thing that, you know, has become a key thing key factor is that trial sponsors or researchers and sites have longstanding partnerships with their patients and patient advocacy groups so that you can put the information out there and help recruit patients from different racial and ethnic minority populations. And then in addition to that is to make sure that every person who is participating in a clinical trial has the appropriate information and education on diversity and inclusion and making sure that they are able to assess their effectiveness in recruiting patients on a cyclical basis.

Another factor is that, you know, every program has policies and programs in place to try and foster an environment where we are actually promoting the needs of these underrepresented patients and then collecting, you know, comprehensive data on racial and ethnic diversity of participants, which, you know, is shocking, but until very recently, was not being done on a regular basis and is still not being done in about half of the trials available. So having these guidelines helps us move in a direction where we understand which population is this trial the most represented of and often where do we expect to see the benefits.

Dr. Turck:
So, looking to the future, how do you think increasing the representation of racial and ethnic minorities in hematologic malignancy clinical trials will impact therapeutics being developed?

Dr. Chandhok:
I think we'll end up developing more effective clinical trials that are truly representative of patients and making sure that these drugs are safe and effective when we have better representation of all the patients who are using these agents because clinical trials are the platform that create the, you know, critical base of evidence for whether a drug is safe and effective, and we already know that certain populations drugs can be more or less toxic to based on their genetics. How effective a drug is different in different racial and ethnic groups. We've seen this in a variety of diseases. So, if we make sure that we test drugs in a variety of populations and ensure efficacy and safety in these populations, it is much more likely that we will have better responses to therapy across the board.

Dr. Turck:
Well, with those final thoughts in mind, I'd like to thank my guest, Dr. Namrata Chandhok, for joining me to share her insights on underrepresentation in hematologic malignancy clinical trials. Dr. Chandhok, it was great speaking with you today.

Dr. Chandhok:
Thank you so much.

Dr. Turck:
For ReachMD, I'm Dr. Charles Turck. To access this episode and others from our series, visit ReachMD.com/ASHActionCenter where you can be Part of the Knowledge. Thanks for listening.

© 2023 ReachMD