How Can Experts Overcome Language and Cultural Barriers to Increase Clinical Trial Participation?

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Andrew Schorr:
Dr. Schilsky, so we have more than 50 million people with a Hispanic background in the United States, and even if many people are speaking English they may speak Spanish at home. And then when you are diagnosed with a cancer there's a whole new language of stuff that comes into play that even if you're fluent in English it may not be either what you easily understand or even aligns—what's being asked of you aligns with your cultural background, okay? So how, beyond, let's say, the African-American community, when you look at the Hispanic community, how do we encourage participation there and get over some of these cultural or language nuances, if you will?

Dr. Schilsky:
Yeah. So it's much the same thing in the sense that the same information has to be conveyed but it may have different meaning and different interpretations in different ethnic and cultural groups. Most clinical trials now will have a consent form that is fully translated into Spanish. But, of course, there are many different languages on the globe. When I was practicing at the University of Chicago for many years on the south side of Chicago, we had Polish-speaking people, we had Russian-speaking people, we had people—Chinese-speaking people.

So the requirements actually are that there must be a consent form, at least some reversion of which is translated into the first language of the patient. So if you're a native Spanish speaker, a native Chinese speaker, you have to have, be able to see a consent form written in that language, and generally speaking you have to have your native language interpreter present in the room to help you go through the consent form and respond to your questions. And that person has to be someone who is independent from the research team so they can give you the straight answer and not be influenced by any member of the research team. So I think all of that certainly helps.

But, again, what helps a lot more is to have members of the care team who look like the patient. So we have problems with diversity in our profession as well. We have very few African-American oncologists. We have more Spanish-

speaking oncologists, but again we have few Asian oncologists. So we need to do a better job of improving the diversity of our profession, improving the diversity of the care teams. We need nursing staff and research staff and other people who work with our patients who represent them and gain their trust, who look like them, who talk their language. And I think that will go a long way toward making people feel more comfortable about participating in clinical trials.

Andrew Schorr:
I was at a conference last week and I heard some of the patient experience, people from different drug companies talking about how they were trying to simplify their forms, because I know in 2000 when I entered a Phase II trial there were all kinds of black boxes, you could die, you could this, everything in the kitchen sink was in it. I'm still here, and I think because of the trial, and most of the side effects I didn't have or they were definitely handled extremely well.

So right now, where are we, Dr. Schilsky, with participation? And why is it important? In other words, in this age of personalized medicine why do we need more black people in certain trials? Like, I know in multiple myeloma, one of the areas we cover, there's a higher incidence in the black population, right, but yet few black people are in the trials for myeloma drugs. Or maybe there are differences with Asian populations or other populations. So is it that you can't really get a clear scientific answer on the differences? Is that it?

Dr. Schilsky:
That's part of it. First of all, we want anybody who could potentially benefit from being in a trial to be able to be in the trial for their own personal benefit. Secondly, we need to learn about the performance of the drug or the intervention in all the diverse populations in which it might be used. And one of the things we have learned is that not all populations respond the same way. Some treatments are more toxic in certain racial or ethnic groups. Some are more effective in some racial or ethnic groups.

And, you know, since you brought up this whole new world of precision medicine, I'll give you the example of the lung cancer drugs that are used to treat the specific mutations in a gene called EGFR. So that's a gene which has mutated in about 15 percent of Caucasian patients with lung cancer, but it's mutated much more commonly in Asian patients. And in fact one of the clues that there was even a gene mutation that was important in determining whether these drugs worked or not was because it was observed that the drugs worked better in the Asian patients in the clinical trials even before the genetic abnormality had been discovered. And the clue was what's different about the Asian patients than the other patients in the trial.

So the diversity is critical to our learning and critical to our application of the therapy in all the diverse populations that we serve.

Andrew Schorr:
So, Mel, when you get to talk to people, what do you say? Somebody is sick, diagnosed with a cancer, what do you say? Dr. Schilsky was talking about not seeing clinical trials as a last resort, and you weren't seeing it that way, but today what would you say to people when you talk to them about it?

Mel Mann:
Well, I will say explore your possibilities because there are all different opportunities at each phase. You may not go into Phase I but you could do a Phase II, III, IV—or Phase III, and you don't know what's going to happen in each of those phases. So you just have to see what's out there. And I'm exhibit A, so they look at me and they say, well, I can work, and then not as suspicious, you know. We have Tuskegee, and that was 1972, and it was that dark period of cancer history so that kind of rolls around in their mind, but you can't let that jeopardize the opportunity such as

imatinib mesylate (Gleevec) that I took advantage of. So we know that Gleevec worked, and there are other drugs that have improved the quality of life and the life span of cancer patients. So definitely research those drugs.

Andrew Schorr:
Did you lose heart when you were first in one trial and the medicine wasn't working for very long? Some would say, well, all right, I tried a trial, forget about it, you know. But you then pursued other trials. What propelled you to do that?

Mel Mann:
Well, I was still in the game, so I saw that these trials took—well, first of all, I could not find a bone marrow donor, but a bone marrow transplant was pretty drastic in itself so I was looking at these other opportunities as maybe not even having to take part in—have a bone marrow transplant. So that was another incentive. So—and I knew that if I didn't find one—there was a very small chance, there was only about 5 percent of Americas who are on the marrow registry, so basically I was helping to build a list, maybe not for myself but for people in the future who needed a transplant.