

Moderator: Hello and welcome to Public Health Live, Thursday, Breakfast Broadcast, I'm Joelle and I'll be your moderator today. Before we get started, I would like to ask you to fill out your online evaluation at the end of the webcast. Continuing education credits are available after you take our short posttest and your feedback is helpful in planning future programs. We encourage you to let us know what topics are of interest to you and how we can best fit your needs. As for today's program, we will be taking your questions throughout the hour. The phone number is 1-800-452-0662 or you may send your written questions by fax to 518-426-0696, we will also be taking questions by e-mail. Please e-mail us at any time throughout the hour at [phlive.newyork@gmail.com](mailto:phlive.newyork@gmail.com). Today's program is *Cancer Clinical Trials, What the Primary Care and Public Health Provider Need to Know*. Our guest, Dr. Yolana Novak, the Director at the Clinical Trials at the NYU Cancer Institute Clinical Cancer Centre, and Dr. Michael Pearl, the Director and Professor of Gynecologic at Stony Brook University. Thank you both for being with us today. It's a pleasure being here. Yes. Thank you for being here, cancer and clinical trials is a very important topic and an interesting topic.

Moderator: Dr. Novak, can you explain to us what clinical trials are and what purpose they serve?

Dr. Novak: Clinical trials are research trials involving patients with cancer, so they're directly related with the patients that are suffering from cancer. The aim to lead to discovery of different novel treatments and medical intervention and the cancer clinical trials discover cancer treatment as well as cancer diagnosis prevention and screening. We have been researching cancer for years and why is it important to continue this type of research through trials? President Nixon signed the Cancer Act into existence almost 40 years exactly, December 23, 1971 and despite that, the war on cancer has not yet been won. It's the second leading cause of death in the United States, only after heart disease. There are about a million people every year that have been diagnosed with cancer and half of them die from cancer, in New York, there's 35 thousand a year that end up dying from cancer so we have long ways to go.

Moderator: Certainly, I would agree with you, Dr. Novak., why is it important to have patients participate in the clinical trials? All the advances that we made related to cancer are results of clinical trials and discovery of new treatments, and to improve the outcome, as we thought, though we still have a way to go, there are definitely improved results of clinical trials and early diagnosis and screening so it's important to encourage a broad participation in clinical trials so the patients in clinical trials, their population as we see, and the more patients that enroll in clinical trials, the faster we get new results, new drugs and better results for this treatment. I understand participation rates in cancer clinical rates look different between children and adults, can you talk about that a little bit and talk further about that if you would.

Dr. Pearl: Indeed, adults participate in clinical trials less than 5% of the time. In contrast, up to 90% of children will participate in the clinical trial. Over the last 50 to 60 years, the survival rate of children's cancer has declined from 70 to 60 percent. We have not seen the same improvement in adults. Whether the two are connected, it's impossible to tell. But you have to think that the less participation of adults has a less impact on their trials. The rates for children are much higher than adults.

Moderator: Dr. Novak, can you talk about some of the reasons why that is because Dr. Pearl has indicated, we're seeing differences.

Dr. Novak: Yes, he's right. The cancer of clinical trials on pediatric oncology became a care in many tertiary care hospitals where oncologist would develop protocols that would treat all the kids with

cancer together. There's also kids who are likely to be in better health than some adults, especially older adults, so it makes participation in clinical trials easier and there's tremendous gain, if children survive with cancer, they can have many, many years of life ahead of them. I think it's a great stimulus for both patients, their parents and physicians.

Moderator: So, Dr. Pearl, now that we have that background information provided by Dr. Novak. Let's look at more specifics regarding clinical trials. Are there different types of clinical trials?

Dr. Pearl: Yes, there are a variety of different trials. There are treatment trials that are designed to look for either new treatments or ways to use old treatments in new ways. There are prevention trials, the old saying "an ounce of prevention is worth a pound of cure" applies to cancer as well as other disorders. There are early detection studies where the goal is to pick up cancer at an earlier stage where it potentially can be treated either more easily or more effectively, there are screening studies in precursors of cancer that are otherwise healthy and have no potential of cancer developing. There are predictive studies in looking at outcomes, how do you do if you have a particular type of cancer treated in a particular kind of way, and with modern technology, there's an ever growing awareness of the impact of our genetics. We can't out run our genes and in modern era, it's become clear that our treatments effect somebody's quality of life, we may make them live a little bit longer or a lot longer but if we make them suffer along the way, we haven't done them very good, so their quality of life and support of trials.

Moderator: Now, Dr. Novak, would you take us through, if you would, of the different phases of the clinical trials.

Dr. Novak: I think it's important to understand, the development of any new treatment for cancer and new screening for cancer does take some time, and the first part of this strategy is the so-called phase 1 trial. You really explore how toxic a drug can be or how difficult it is maybe to be given whether it's given by a pill or given through the veins and how it works, the other part is if it's good enough or be tolerated well by the patient, does it work in a particular cancer and it's a trying time to establish what is a new candidate for the new kid on the block for this particular cancer. Once this is established, there's phase 3 trials which really try to establish, does this drug work and does it work for a long time, does it make our patients live longer and make their quality of life good, and then once the drug is established and compared to what used to be standard of care which is established by previous clinical trials, series and expansion, does the drugs that work in one type of cancer, can it work in another type of cancer, is there something we didn't understand before that we still need to explore. So there are multiple steps that lead to development of new interventions and treatment for cancer.

Moderator: Okay, quite complex but critical every step of the way. Dr. Pearl, can you give us examples of phase 1, phase 2 and phase 3 of the clinical trials?

Dr. Pearl: Sure, let me walk you through three studies. one of each phase 1 through 3 using a common drug in each one of those studies. The drug is bevacizumab; it's been in the news recently because of the information about breast cancer. The gynecologic oncology group ran a series of phase 1 studies, the goal was to look for toxicity, and it was to look to see what dose of an individual drug in this case bevacizumab could be used safely in a given population. Those studies are not designed to look for efficacy, it's less important although it's certainly measured. It's to see how much drug you can give to somebody safely. Once the studies have been through, once the drug has been through a phase 1 study where the dose has been determined, it is then taken into a phase 2 study where the population that

has a particular disease, in this case, cancer of the ovary, the population is as uniform as possible, it's a small group of patients and the drug is used at the dose it was determined in the phase 1 study, that study is designed as an efficacy study, does it work, is there activity, enough that it can justify going into a phase 3 study. The phase 3 studies are the big studies, these are the studies that are designed to determine whether the treatment is better, worse, the same than the existing standard treatment, so it takes the information from the phase 2 study, goes into a very large randomized generally controlled trial where it's compared directly against a standard treatment. The randomization is really critical because it tries to reduce bias to the greatest degree possible and makes the population as uniform as possible. It takes away some of the variables, so that the results can then be brought out into the population and say, yes, this new combination in this case, bevacizumab is beneficial, effective, safe and appropriate to use in this population. Just a very quick follow-up, if the efficacy brew or in terms of the outcomes of the clinical phase 2 are not impact if you will, is the clinical trial boarded at that time? Generally, there are statistical criteria to determine whether a drug is effective in a phase 2 study. In those phase 2 studies, they're done in two phases, so if it doesn't -- if there's not enough activity of the first component of a phase 2 study, it's usually aborted at that point because you don't want to give people ineffective drugs.

Moderator: Dr. Novak, can you tell us about the components of clinical trials, what it takes to design and get it up and running so to speak?

Dr. Novak: Again, to develop a clinical trial, it takes a lot of time and effort, it takes investigative who are physicians who are PhD's in the protocol which is really a book, a bible of the investigation, which includes many parts including which patients can be treated under trial, as Dr. Pearl mentioned, they can be very uniformed population for a phase 2 trial or it can be a variety of cancers. For early phase 1 trial, you need to establish what you are looking for, are you trying to prove that the cancer drug works, is there too much shrinking and how much, so it all needs to be prepared and there are steps to provide what they call regulatory approval which is assuring that we safeguard our patients in the clinical trial.

Moderator: Okay, so it's clearly a team approach consisting of investigators who are typically of PhD and medical physicians, medical doctors, correct? I also understand there are a number of different ways in which the patient is safeguarded or protected, which is very, very important. Tell us a bit about that if you would.

Dr. Novak: There is the corner stone of protection, so-called informed consent, we all take it very seriously, we don't call it an informed consent paper, it's an informed consent process, there's communication between physicians and research staff patients and it's all reviewed by institutional review boards that very clearly describes to the patients what the risks and benefits are, what the procedures of the clinical trials are, do they need to do an additional CAT Scan or not, how many ounces are being drawn for participation, so it's a detailed document and the process takes some time. There's research protection in a series of both government major organizations that oversees the human subject, and we take it very seriously because our first goal is to provide the right clinical trial for the right patient who safeguards their autonomy and their benefit. The report is their declaration which is all the documents which regulates research which we know happen because of some abuse that happened in the past during World War II and often in the 50's that we'll talk about a little later. Each industry, each organization has its own Davis-safety monitoring board, so it's not only regulatory, it's statisticians and physicians look at how many side effects occur, did some patients suffer some toxicities to make sure we protect our patients during clinical trials.

Moderator: Very good! Dr. Pearl, can you talk to us about some of the benefits of participating in the trial because I think that's very important for us to -- we're hearing the background, we're hearing about the basic protocol, if you will, and the safeguards, but what are the benefits, why would someone want to participate and should participate in a clinical trial?

Dr. Pearl: That's an important question. There are a number of reasons why somebody would voluntarily agree to participate in a trial. First is that it potentially gives access to cutting-edge treatment. There are oftentimes treatments that are unavailable in any other arena except under the hospices of a clinical trial so it can give somebody access to a treatment that is either unavailable in any other fashion or may not be available to that person down the road if they've already been treated in different ways. There are some data that suggest that patients who are treated within the confines of a clinical trial have better outcomes than people who are treated exactly the same way outside of a clinical trial, that the clinical trial in and of itself produces a benefit and probably because it's very well controlled and very regulated. Everything is done according to the book, so to speak, and then the one - personally in my book that's very important it's altruistic, as we sit here today, as my patients sit opposite me in my office, they're sitting in chairs that were occupied by somebody who in the past had listened to me or somebody like me discuss a clinical trial and had voluntarily agreed to participate in that trial, so all the knowledge that we have today came from somebody who was willing bravely to volunteer for a clinical trial 10, 20, 40 years ago so it's paying it forward, it's looking to the future.

Moderator: Looking to the future and paying it forward. Dr. Novak, Dr. Pearl clearly outlined the benefits which are undeniable, but I'm sure there are risks as well.

Dr. Novak: Absolutely, there are risks to clinical trials and participation in clinical trials, and I think we always make sure that during this informed consent process that we talked about, we describe it very clearly, first of all, when we develop a new drug, procedure or new device, there may be side effects that we don't know about, so somebody can suffer from the side effect and I think we need to be very clear is that, yes, participation in a clinical trial is altruistic because there are certain things we cannot predict. It may not be as good as we anticipated and we need to be clear when we talk to our patients and tell them we want to participate in a clinical trial and that it can happen. There may be financial hardships because there are issues about insurance coverage in clinical trials, and some patients are very concerned since they learn this autonomy of making their decisions and just sitting one on one with their physician and deciding what treatment to go for.

Moderator: Thank you very much for that information, Dr. Novak. Let's turn now and look at a video of some staff that is responsible for coordinating many of the clinical trials at NYU and Bellevue and hear what they have to say.

Video: Motivation is different for everyone for a cancer clinical trial. If you're stage 4, you don't have long to live and there's no other treatment out there for you, sometimes my patients will say, why not, I can maybe get some benefit or the opposite is to get none, some patients are really about doing it for the greater good, they really, you know, maybe this won't benefit me but the knowledge that came from this will be beneficial to the next generation. It's about paying back a little or paying forward I should say a little in that respect. Cancer clinical trials are really important because we all know that the war on cancer is not over, there are advances to be made, they're also important because they're beneficial. They're beneficial to the patients that participate on these trials and they're beneficial to the population as a whole.

The results from these clinical trials are going to be the results that we use to advance science and they're going to be the basis of future health policies and future ways that we manage all different types of cancer so they're very important. There are lots of barriers to enrolling in clinical trials, minorities especially. There are patient level barriers which include kind of misconceptions about what a clinical trial is. A lot of patients seem to think they're going to be used as a guinea pig and that guinea pig mentality is barrier to recruitment. Trust is an important issue in out care in general, we have a very bad rap, we've had a long nasty history with studies, during World War II, things were not done ethically or morally and especially in the African American community. You've got to be able to bridge that gap and get them past the idea that they are just a test subject and that we care about them as much as we care about the study itself. I'm not going to encourage someone to go on to a clinical trial if I don't think it's right for them. There are also barriers to clinical trials on the physician level. A lot of the time, the person sees the patient first which would be the primary care physician or the surgeon, they don't know about these clinical trials, getting the word out to them is important because if they know about it, they can tell the patient and the patient becomes aware and the more likely to seek out that type of treatment. For patients and for practices that are in a rural area it can be difficult to participate in a clinical trial.

One of the things that the NCI did when they formed a lot of their cooperative groups, they formed a group of community physicians and I think it's called the community oncology group, one of the best things about New York State specifically is a lot of the insurance companies don't cover cost related to clinical trials, certain states and the NCIS has a great map about this, certain states will force insurance companies through law to cover participation in a clinical trial, at least the standard of care. In terms of increasing this, I think it's still a very low amount of people in general that go on general trials and an even lower amount of minorities that are involved in clinical trials so it's important to increase, to reach out to minority communities, to get them to enroll in these clinical trials because therapies work differently on different groups of people and that's the only way we can really work towards equal health care for minorities. You want to be able to say, this study -- this medication just didn't work on Caucasians. We tested with a large Asian population, or African American population because everybody's DNA is just a little bit different and the more people you have that are more representational of the entire society, the more generalize the findings are, the more access it provides to more individuals. If I were ever in a situation where I was diagnosed with cancer and was given the opportunity to participate in a cancer-clinical trial, I would absolutely take that opportunity because I know that it could be very beneficial to me. I know that it will benefit future cancer populations and I think the people research teams from what I've seen, the oncologist, the coordinators, they're great people to work with and I know that they would take very good care of me. It's a larger grander level, what we learn today and what we learn from all these trials to do benefit us down the road. You analyze the data, you figure out what works and doesn't work, and it's building the health care of tomorrow, you know, everything that we have currently in the system that we're treating as standard of care was somewhat in the pipeline of the clinical trial and how we've come this far in treating cancer in general, but the war's not over yet.

Moderator: Well, they certainly had some great information to provide us, and very interesting to hear all of the different components. Wouldn't you agree, of what kind of work is being done? Just tremendous work. Now, Dr. Pearl, moving forward, still talking about the logistics of the trial, what can you tell us about the IRB process?

Dr. Pearl: Quite a bit actually! Anyway, the IRB is the Institutional Research Board and has been mandated for a number of decades now. Their goal is to ensure that there is -- that the research is safe and ethical, it's to make sure that the rights and the welfare of those people who voluntarily agree to participate in a research study, that their rights are protected as they go through, it's to make sure that everything is in compliance with federal state and local regulations that govern the protection of human subjects. The IRB'S are multidisciplinary committees, they're made of MD'S, PhD's, and a variety of people with different interests and there has to be a community member for example that has no relationship with the institution, no relationship with the program at all. As Dr. Novak mentioned earlier, it's an ongoing process, it's not a one step, one stop event. The IRB review starts at the beginning and it goes all the way through the research study performance and then continues for some period of time after that. So, it's not just handing -- it's not reviewing a packet of material saying, okay, signing off on a consent form, handing it off to the researcher and says go for it and do your research. There's an ongoing process that continues as long as the study is up and running.

Moderator: Okay!

Dr. Pearl: An institution may have multiple clinical trials going on concurrently or back to back, so there could in fact be several IRB'S going on at the same process. In my institution, for example, there are four IRB'S, there are two IRB'S called institutional review board that look at human subjects research, there's one that looks at genetic research so it's a specific IRB that looks at that and there's another one that looks at animal research, so every institution that participates in research typically has multiple IRB'S looking at every facets at what they do.

Moderator: Thank you. You talked about how important the research is and how it benefits future research. Can you talk about some of the barriers that prevent patients from participating in trials?

Dr. Pearl: Adults with cancer have not been that successful. I think one is that is an important point is lack of awareness. I don't think we've done a good job about availability of clinical trials, how they can reach out and get to clinical trials. I think there are a lot of misconceptions about research, about being guinea pigs and medical experimentation and I think we need to show and dissuade patients from this misconception. I think there's mistrust in terms of being randomized or lack of treatment. Sometimes that makes patients nervous. Clinical trials are also quite complex. We have different genetics. We have a predictive model, a prognosis model. The complexity sometimes can be intimidating for the patients and again, it's our job to explain the complexities of this trial as well. Sometimes it's difficult for logistical reasons, how to get transportation to get to a hospital or a tertiary hospital where clinical trials are available and solving all of this can help.

Moderator: What about physician-level barriers?

Dr. Pearl: In many ways, it mirrors the barriers that the patients suffer from. Many physicians are unaware that there is a clinical trial that may be beneficial or may be beneficial for their patient. There are language barriers dealing with patients who don't speak English as their primary language. Again, as with the patients on the opposite side, there are cultural assumptions and cultural barriers that can be difficult to overcome. Clinical trials are very complex and very demanding in time and effort and these days, many physicians just don't have the time or the financial resources to be able to spend that time with a patient to discuss a clinical trial, and then on top of it, there can be difficulties with regional access, if a physician is seeing a patient in upstate New York and a clinical trial is available in Manhattan. Getting the patient involved can be difficult.

Moderator: What about at the institutional level?

Dr. Pearl: The institutions suffer from the same problems. We have to admit, clinical research is expensive so it requires resources, staff report, patient support who undergo clinical trials and yes, can suffer from some unexpected side effects and may require some additional help with transportation and the logistics, now we need to support the primary clinical needs to make sure we provide the patients with their needs, and patients, sometimes clinical research is in the back of their minds on the institutional administrators and there is not enough staff. We also need to understand especially early phase trials do demand a lot of resources and a lot of times and physicians, nurses, nurse practitioners all deploy to provide our health care primarily, and so again, the early phase drug development sometimes steps back in this research.

Moderator: So, Dr. Pearl, when you consider all of those barriers, that can really have an adverse impact on the numbers who are participating, couldn't it?

Dr. Pearl: Absolutely! Let me walk you through some of those numbers if you don't mind. Let's take a hypothetical clinical trial, a physician decided they were going to enroll patients so they have 276 patients seen by that physician and they're going to say, okay, we'll send you off to the trial. Okay, 38% of those patients, the physician decides not to refer to the trial for whatever reason. That leaves 171 out of the 276, of those, 56 are not eligible for the clinical trial. They failed to meet the eligibility criteria or they meet some of the eligibility criteria. Forty-nine percent of those individuals decide, after listening to the discussion about the trial, not to participate. So, now there are 29 of the 276 that we started with that are eligible and agree to participate. So that's 14% accrual rate if all 29 enroll. While that number may not seem very encouraging, given the federal, the national numbers of less than 5% to be honest with you as a researcher, I'll take a 14% accrual rate any day of the week.

Moderator: Fair enough, and Dr. Novak, are there certain groups that are likely to be under-represented in certain groups?

Dr. Novak: We are trying to include all types of groups in clinical trials. Some patients with represent to racial and ethnic minorities sometimes have less than desired participation in clinical trials. The elderly, for a variety of reasons, do not have access to clinical trials. In the past, women were not offered clinical trials and children, adolescents and young adults are still groups we do not see a lot of participation from. Patients with low income or no insurance may not have access to clinical trials for all the reasons that we explained. We talked about the logistics and transportation. Patients who live far away in rural communities may have a lot of difficulties coming to a larger institution. People who have other multiple medical problems, hypertension, diabetes may limit their eligibility to be part of clinical trials, and patients who fare poorly, who didn't do well with their initial treatment of cancer would not be eligible and we would be able to offer their participation as well.

Moderator: Well, certainly, Dr. Pearl, and you, Dr. Novak, highlighted the number of reasons why participation from certain groups, is lower in the trials. Dr. Pearl, can you talk about the experiment and the impact of research like this on today's potential participants.

Dr. Pearl: The Tuskegee experiment is the one that that was run in the United States. It started in 1932 and ran until 1972 when the whistle blower called public attention to it. It was the national history of untreated syphilis and they enrolled. It followed almost 400 very poor black sharecroppers from

Alabama. They were not told they had syphilis nor were they treated by syphilis. By the early 1940's, penicillin was available. Besides that, the people in the study were not treated, they were followed along the way, they were given free meals, medical examinations and when they ultimately died, they were buried at federal cost. I don't think that sitting here today if we can imagine what that must have been like. It clearly has had a substantial impact on people's willingness to participate in studies. That is a very high burden that we have to overcome. Having said that, there are some benefits that came out of that study. First there is an awareness of doing ethics in studies on humans. The Belmont report that was mentioned by Dr. Novak was produced right after that and the Office of Human Research Protection under the Department of Human Health Services at the Federal Government level was created as a consequence of that study. Those that report, the information contained in that report and the subsequent development of OHRP and the other governmental agencies that are responsible for looking at research have significantly improved the performance of research in the United States. So although that experiment was a very bad thing, even out of very bad thing, sometimes very good things happen.

Moderator: Well said, and I think, you know, based upon that, we can all appreciate how that would certainly cause some to have mistrust and fear quite frankly in terms of participating. Dr. Novak, knowing the safeguards, and you highlighted some of the safeguards that are in place to protect participants; can you take us through and tell us why it's important to increase minority participation in the clinical trials?

Dr. Novak: We believe in fairness and equity to medical care and part of medical care and clinical trials and cancer, so we want to increase all the populations coming to our doors, coming to our offices to participate. We notice some minority groups may have a higher rate of cancer burdened to a variety of phases; some of them are more exposed to certain infections and its lack of insurance and lack of access to screening or early diagnosis that brings patients with higher stages of cancer to us. When we do our clinical trials and we enroll a population of different groups, it allows us to give your commendation to the general population when we recommend this drug to be used for cancer. There are also differences in different groups, sometimes some drugs can be broken up in a patient's body differently. In patients from different racial backgrounds and I think it's critical for us to understand it to be able to offer good treatments to patients of all ethnic and racial backgrounds.

Moderator: Dr. Pearl, can you address the barriers to enrollment?

Dr. Pearl: I think the easiest way to address this question is to say education, education, education. It is to educate the patients, meaning going out and speaking to them in ways that they can understand, cut down on the medical ease, for example, going into the various communities. I know many institutions have outreach programs that are specifically designed to go into a specific community. Those outreach programs are oftentimes run by a minority member for example, you know, so that's beneficial. It's educating the physicians, so reaching out to physicians and other health care providers, letting them know about the research opportunities that are available for their patients, and then addressing at the institutional level honestly in addressing costs. Research is very expensive and it's becoming ever more difficult to fund research. It's the institutions and above levels that have a big influence on whether research protocols are made available. So trying to convince the state and federal governments and the industry to help fund research on a global level as well as on a very specific level and reaching out to specific members of the community and Dr. Novak's comments, having minorities participate in clinical trials can be beneficial. We won't be able to make those significant inroads that are necessary.



Moderator: I understand there are certain actions that have been taken at the federal record. Dr. Pearl talked about above the institutional level to try to increase minority participation, what can you tell us about those?

Dr. Novak: Correct! The federal government and the National Cancer Institute is a big instrument of the federal government which regulates cancer clinical trials. They help multiple institutions throughout the country really perform research well. Since 1990's, there was an established grand Americanism which is the minority-based clinical trial, which was allowed to form clinical research hubs at a level of the community, of smaller communities; cancer centers and not just large tertiary care institutions. It encourages patients of different racial and ethnic groups to be part of those centers. The other act which was passed by NIH is the National Institute of Health which is the Revitalization Act of '93 which again the desperate need for them to participate in clinical trials. When they do the drug approval for participants and clinical trials they should include all minority, all racial and ethnic groups. Their conclusions of the studies are generalized. We can apply to our population, not just a very small group, and this effort continues, again at federal level as well as at state level.

Moderator: Dr. Pearl, when we look at enrollment by race and ethnicity, we can see communities of color are still underrepresented. We can see that there are certain unrepresented groups that are really not present in these studies, and among these are racial and ethnic groups that we've looked at. Let's take a look now at some footage and the patient at Bellevue Hospital to hear some of the ways they are all working to increase enrollments in trials. Let's take a look.

Dr. Pearl: Yes, so I'm involved in a few clinical trials here at Bellevue Hospital. One is a novel compound for multiple tumor types. This is a phase 1 study for several tumor types such as patients with liver cancer, lung cancer, patient with brain cancer, multiple myeloma and huge B-cell lymphoma, so this is a trial that's just opened last week, so we are screening our first subject, hopefully next week, and we hope to enroll about 15 patients here. I think the motivation really comes from twofold. One is that if the patient believes that a clinical trial actually is there to help them get better, they will participate, and also if they felt that participating in clinical trials would be able to offer additional help for patients in the community where they are part of, they will be willing to participate as well. I was giving a talk to a group of patients once who are pretty much healthy. I talked about clinical trials, and most patients in that community center are of Chinese origin.

Moderator: So they're Chinese, who are in clinical trial who are just experimenting for no reason?

Dr. Pearl: It's experimenting, so I said, "our clinical trials actually have very, very sophisticated scientific rationale to design the study, and before we do a clinical trial, there are many studies done in the laboratory, so it's not something just experimenting, it's a clinical trial where there's very good rationale." They also asked me, well, if I go on clinical trials, does it mean I'm not going to have therapy, am I getting suboptimal or worse treatment because it's not standard, so what I said was, well, remember, all the drugs that's approved in oncology come from the result of clinical trials, that participating in clinical trials gives you an opportunity to get benefit from the drugs which may not be approved now but may be later on but you are the first one to get benefit from it and as a minority, it's important to participate in clinical trials because the efficacy results of the drug. Therapy really depends on the people who participate in clinical trials, the more minority patients that participate, the more information we'll have with a particular drug that will work on a particular population. It will help us understand how they're going to respond to the drug, how they're going to handle these side effects of the medication. I found out I had cancer July 23rd, and I've been participating in this trial for three

months. I feel that by participating in this trial, I'm not only doing something for me, I'm doing something for the other patients that might have cancer. They could, you know, look into it and participate also. When Miguel came to me, he was not a great candidate for surgery because of the way his tumor was, but he was a candidate for this procedure, so we felt this was a great opportunity for him to participate in the clinical trial. It was an Eco study that's done in all the eastern oncology, a participant in that (speaking a different language). Even though he was a perfect candidate for the trial, I was worried about the compliance issue, so I saw him once and then I ordered a CAT scan for him and that was the day Hurricane Irene was heading to New York City. I was walking down the hallway and I saw him walking out from Bellevue, meaning he came, he finished the cat scan on time, so he didn't know about that but I saw him. I said, if this patient can come in on a day where the clinic was about to shut down and get a CAT Scan, I want to give him that chance, so I'm very happy because he's never made any appointments, I was glad he was able to participate. I'm grateful! Well, you know, that's certainly the pre-February blend of an outstanding physician and clinician and patient, and that was some very interesting footage.

Moderator: It seems that Bellevue is doing quite a bit to encourage participation in these trials and allowing participants like Miguel to receive treatment. Dr. Novak, what else can you tell us about Bellevue's efforts to increase minority enrollment?

Dr. Novak: I'm proud to be part of it and it oversees the clinical trial in both NYU and Bellevue Cancer Center. Unfortunately, the participation in minorities in clinical trials still lacks behind and only a small portion of Black or Hispanic or other minorities are part of clinical trials and it's a wonderful team that you would work with and you were able to witness them in the videos that we try to improve participation of minority groups in clinical trials in NYU and in Bellevue and on the small graphs. You can see that populations that comes to Bellevue, our patient population are very rich in different groups, there are a large proportion of African descent, Hispanic and when you look at the graph that looks at participation in clinical trials, they're not well distributed, we see all kinds of people that come, one of the success obviously due to our wonderful team that you've seen that does stand the ground and talks about the clinical trials availability, and what the clinical trials can bring to the patient and you've witnessed this. We can show that over the last few years, we increased almost double, the participation of patients in clinical trials in Bellevue and kudos to our patients first and to our research staff. I think one of the things that are very important is availability of translation, especially in the New York City, urban environment. It's a really multicultural, multi-language environment, and we have the majority of patients who do speak English. But, we have a large portion of people who speak Spanish, Cantonese, Mandarin, and if we go down the line, we have almost every language represented in that group and finding ways and resources and finding patients for the staff to translate the information about clinical trials is really -- is a big part of our success.

Moderator: Certainly, there are lots of projects and work going on around the state here in New York State to try to increase minority participation. We know you're both during an extraordinary amount of work and we focused quite a bit on Bellevue. But, Dr. Pearl, it's important to recognize, this is being done all around the state, isn't it?

Dr. Pearl: It is. At many levels, the National Cancer Institute has stepped up to the plate, they've offered grants to various programs around the state, not just New York State but other states to try to improve minority recruitment into clinical trials. Cancer and otherwise, institutional clinics have developed programs. NYU has developed programs to try to improve recruitment and unrepresentative members of the community into research trials and then foundations and industry have also stepped up

to the plate and participated by offering grants to institutions to try to develop ways to draw minority members into research.

Moderator: Sounds like all hands are on deck, and Dr. Pearl, is there a plan for what we would like to see regarding cancer trials moving forward?

Dr. Pearl: It's the New York State Comprehensive Control Plan, and it's going ahead to 2017. Some of their goals are to increase enrollment of all ethnic groups into research studies by outreach programs, and education. Education is crucial; it will serve as an advocate for changing insurance coverage so the insurance companies will, including the federal government, will provide coverage for non-experimental treatment programs.

Moderator: We talked about insurance earlier as being a potential barrier, Dr. Pearl, are there some states that require this?

Dr. Pearl: There's a red blue boundary in politics, there's a similar boundary in health care coverage as well. Not every state, unfortunately, many states do not require insurance coverage for those patients or those people in their states if they have opted to agree and agree to participate in a research study. So here, for example, I've had patients who have come and after we go through the whole process and they agree this is what they want to do, they say, well, is it covered, and if I can't tell them yes, it's covered, they're done, and they walk away. So in order for us to be ethical, in order for us to provide the care for everybody that anybody can get, we should have coverage for research trials across the United States.

Moderator: Dr. Pearl, I also understand that drug shortages impact participation in clinical trials. Can you tell us something about chemotherapy drug shortages that we're reading about in newspapers recently and the impact on clinical trials?

Dr. Pearl: Absolutely! I'm stunned that this hasn't become a greater issue in the public's awareness and in the media because this is having a very, very substantial effect on health care in the United States. There are drug shortages of a variety of different types but chemotherapy has been hit the hardest, it not only covers the clinical trial participants but the standard treatment within the clinical trial treatment, if the drug is not available. Even if there is an alternative potentially, the trial can't run, so for many patients with cancer, there are alternative drugs but you can't run the trial. If you cannot get the drug, you can't run the trial, we can't move forward

Now, on the screen, we will display a list of resources for referring to clinical trials. Dr. Novak, can you talk about the resources we're going to take a look at?

Dr. Novak: I think Dr. Pearl said education, education. I think we should say outreach and access and access. I think there's a variety of clinical trials run in multiple institutions, even in smaller community cooperative groups and in larger hospitals. I think many of us may try to make different initiatives to encourage patients to inform them about availability in clinical trials. There is a variety of enriched online resources. There is some grand mechanism that comes from the federal government and from the state government as we talked about to support community who are really contributing to clinical research participation and cancer, and large support and large advocacy groups. We talked about breast cancer and ovarian share a common group, pancreatic cancer, they all support a website, clinical trials

available in the area by zip code or state, so we encourage patients to become educated consumers and look for clinical trials available, and first ask to see a doctor.

Moderator: Thank you both very much, and I want to inform you that if you have questions that you need to have addressed by these two wonderful physicians that we have with us today, please make certain to send your e-mail with your contact information to [phlive.newyork@gmail.com](mailto:phlive.newyork@gmail.com). Include your contact information and we'll make certain to get a response to you.

Moderator: I want to take this opportunity to thank you, Dr. Pearl, and to thank you, Dr. Novak in a world that is very ordinary, you two are extraordinary people and physicians and you're doing fantastic work. Keep up the good work. Thank you so much for being here with us today, and thank you very much for joining us today. Please remember to fill out your evaluations online, to obtain nursing contact lines, CHE and EAE credits for learners are available. [www.phlive.org](http://www.phlive.org) Learners must complete an evaluation.

Moderator: Your feedback is always helpful to the development of our programs and continuing education credits are available. An archive of this webcast will be on our website within two weeks.

Moderator: Please join us on February 16 for the next live broadcast on Health Live on *Chronic Disease and Self-Management*. Thanks for joining us on Public Health Live. Thank you, Dr. Pearl, thank you, Dr. Novak. Thank you.

Dr. Novak: Thank you.

Dr. Pearl: Thank you.