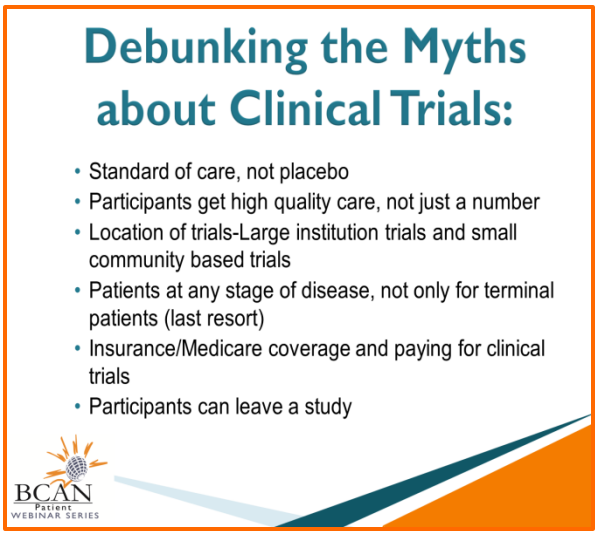
BCAN Patient WEBINAR SERIES

Bladder Cancer Clinical Trials 101

Tuesday May 3rd, 2016

Part II: Debunking Myths about Clinical Trials

Moderator: One of the things we thought would be very beneficial would be to debunk some of the myths that are out there, because some patients choose not to be part of a clinical trial because they heard something, or they weren't quite sure if maybe they would get a pink sugar pill or the actual treatment. There are some somewhat common myths that are out there, and we want to talk today about the Standard of Care that people get with cancer when they're in a clinical trial, and they don't get a placebo, they don't get the sugar pill. We'll talk about the quality care that you get as part of a clinical trial, and a lot of patients know that clinical trials are being conducted at some larger, academic centers, but perhaps they are not always in those centers, and how could you find out more about that.



We'll talk about trials for patients at any stage of the disease, and how trials are paid for, and whether or not you can just choose not to be part of a study, even though you signed the informed consent. Let's start talking about some of those specifics, ladies?

Marisa Lozano is currently a research nurse-manager at MD Anderson Cancer Center's Department of Urology. She has extensive experience in the care and management of patients on clinical trials, particularly in urologic-oncology. Marisa holds a nursing degree from the University of Barcelona, and is officially certified as an OCN and CCRP.

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Yes, just to touch a little bit on the placebo concern, I have to emphasize that most cancer clinical trials do not use placebos unless they are given along with an active drug. It is unethical to give someone a placebo if it would deny the person a chance to get a drug that's known to work. Unfortunately, there are some types of cancers for which there are no proven effective treatments, and in these rare cases, testing a new treatment against a placebo might be needed to prove that the treatment is better than nothing at all. At the very least, you should expect, from any clinical trial, to get offered the Standard of Care already being used.

About the high-quality care, this is something that I always discuss with my patients. I always tell them that they have an extra pair of eyes looking at their scans, at their labs, at their old records, at their health. They have another telephone number to contact, if they have questions and concerns. When we say that participants in clinical trials get higher quality care, we really mean it; it's because your care means the world to us. We have to be very compliant with institutional guidelines, and laws, and the protocol itself, and we want to make sure that we dot all our "I's" and cross all our "T's" and that everything is put in place to look after you, and to take care of you.

That is something that I always like to discuss with them. I also like to discuss that they are not just a number; yes, they might become a number on paper, because their personal information cannot be shared with anybody else, and we do care about that, too. It's just the person, just the individual, that we deeply care about, and we want to do the best for them.

Alice Abraham serves as a supervisor for research nurses in the Urology Department at MD Anderson Cancer Center. She has hands-on experience with the management of patients on various clinical trials pertaining to urologic malignancies. She is a nursing graduate of the University of Texas, and holds a CCRP certification.

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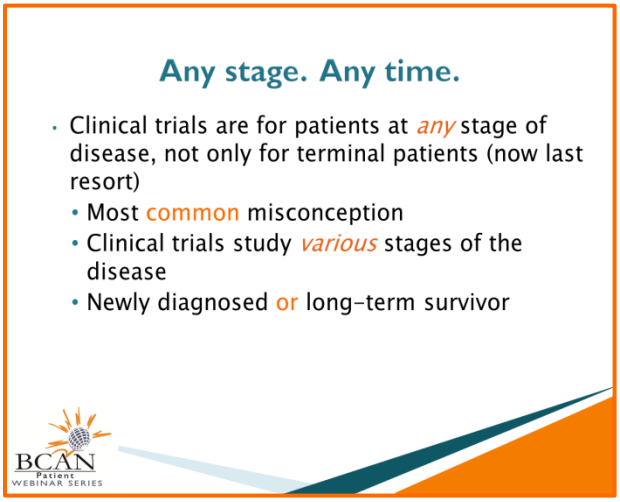
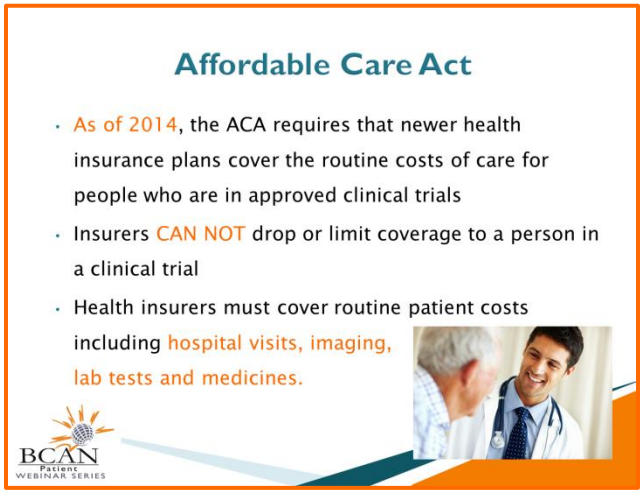
Another most common misconception is that clinical trials are for terminal patients as a last-ditch resort, and that is very, very far from the truth. Clinical trials are for patients at any stage of disease, because there are various stages being studied. Trials are designed for newly-diagnosed patients, or can be for long-term survivors, and it is not a last-ditch resort.



Another myth surrounding clinical research participation is that they offered generally at large, academic medical centers, and that is not true; the location of trials can vary. Large institutions, and small, community-based centers, offer various trials.

It is important to find out what will be paid for before you enter the study, and this is a discussion you have to have with your doctor, your researchers, and your research team, before you decide to participate in the study. You have to feel free to ask questions, if these issues were never brought up in the discussion; don't be shy, try to ask as many questions as possible regarding this, because this is very important.

In essence, we have what we call “research costs” and “Standard of Care costs,” associated with clinical study participation. Research costs are usually paid for by the sponsor of the study, which could be a pharmaceutical company, a biotechnology company, or a government agency, such as the National Cancer Institute. Sometimes, research is paid for by physicians, and/or institutions themselves. They cover the costs associated with this research, sometimes in a collaborative effort with a drug company. Research costs include the new treatment, any new drugs that might be studied, any special tests, procedures, or extra visits, and depending on the sponsor, they may also pay for travel time and mileage.



Also something important to know is that, as of 2014, the Affordable Care Act requires that newer health insurance plans cover the routine costs of care for people who are in approved clinical trials. Insurers are not allowed to drop or limit coverage because a person chooses to take part in a clinical trial. The new health law describes the clinical trial-related routine patient costs that health insurers must cover, as all items and services consistent with the coverage provided in the plan, that are typically covered for a qualified individual who is not enrolled in a clinical trial. This may include things like hospital visits, imaging, or laboratory tests and medicines.

Any patient could withdraw from a clinical trial for any reason, actually. It could be person, family, health, because they don’t want to commute any longer because of financial issues. **At the same time, you have to know that you could also be withdrawn from the study by your doctor your research team if you do not comply with protocol guidelines**. With protocol visits, with the specific tests that need to be done, or most importantly, you can also be withdrawn from the clinical trial if the physician that is taking care of you thinks it is in your best interest to stop your participation in the study.