

Clinical Trials: Progress in the Fight against Cancer

Amy: Anne, thank you for joining us today to speak about the importance of research in the fight against lung cancer.

Amy: First off, could you talk a little bit about what you mean with the term research or clinical trials?

Oh yes, I would be glad to and thank you Amy for inviting me to speak on this important topic for us.

It's important to know how we diagnose and treat cancer today is based on past research studies. Most think research is a clinical trial for new treatment but this isn't always the case. Healthy people may volunteer in research to prevent cancer; researchers are also looking to try to improve ways to diagnose cancer; as well as improving quality of life throughout treatment with supportive care options.

It is true most research will be treatment-based research, which is commonly called a clinical trial. They try to answer specific questions about the effectiveness of a new treatment, or a new way of using an existing treatment such as new approaches to radiation therapy or combination of a new drug with a standard treatment.

Amy: What do you mean volunteering as a healthy person...what can they do?

There are many ways to volunteer to help fight cancer without being diagnosed with it.

Healthy people at risk of developing cancer OR for those individuals who have been cured, perhaps from surgery or early treatment, to prevent their cancer from recurring can take part in research as well. The research may be action-oriented where they you quit smoking or exercise more, or agent-focused, such as taking a vitamin, mineral or a certain medication.

We also have screening trials to find cancer early before it causes any symptoms. Researchers may ask for saliva or blood samples from healthy volunteers to see if we can discover genetic links to developing cancer.

One great example of a screening trial is actually in lung cancer - the National Lung Screening Trial - which recruited 50,000 current or former smokers to compare low-dose spiral CT scans to chest x-rays to determine if either test is better at reducing deaths from lung cancer. The results of this trial have led to these CT scans now being an approved method for lung cancer screening.

Amy: So, outside of a clinical trial, what other types of research can a patient be a part of?

Well, patients may not always be able to be on a treatment trial due to other health conditions or criteria but they may be able to take part in research such as quality of life or supportive care trials. These trials aim to improve the quality of life for people with cancer and their families such as a new method to better control nausea and vomiting while on chemotherapy.

Also, with the fast pace of approving new drugs many patients are on research projects to collect long term data on how the drug works and any additional side effects they may have years after their treatment began.

However you volunteer to participate in research, just know you add to our knowledge and help improve care and survival for future patients. Because of this progress, many people are now living longer with cancer.

Amy: How do clinical trials lead to new treatments?

New drug trials are completed in many Phases starting in a lab creating the new medicine to animal testing and then finally many phases of human volunteer studies. Human studies first look to find the right and safe dose, identify any side effects and then look to see if it works better than what we already have as “standard of care” treatment. Generally, the whole process can take up to 15 years from lab discovery to the new treatment being approved by the FDA.

Amy: We hear that clinical trials are only offered when there is no other hope but you seem to suggest that we should look at research and trial options throughout a patient’s care?

Yes, some clinical trials are reserved for patients for which there are no other treatment options for their disease. But many types of research are open to patients at all stages.

Amy: With all of these research options, some people may fear being treated like what’s called a human guinea pig. Can you talk a little about that?

Sure. We have strict guidelines in place for your protection.

Each clinical trial is reviewed by a committee of experts to make sure it is going to be conducted in a safe and ethical way. If a new treatment is found to work, then those patients who volunteered are among the first to benefit. In addition, patients will receive high quality medical care to ensure we always identify any side effects and damage to their heart, liver and other organs.

Most volunteers say the experience was positive. They were treated with respect and felt they were more actively involved in their care with increased attention from their doctors and research staff. In addition, volunteers feel they were able to contribute to moving science forward.

Amy: What about the idea of a Placebo or “sugar pill”?

Placebos are rarely used in clinical trials designed to treat cancer.

No one is ever given a placebo when an effective treatment is available and you will be informed when this may be a possibility. Generally, a placebo may be used in combination with an approved treatment such as traditional chemotherapy paired with a new immunotherapy drug. So you will definitely receive the standard of care treatment for your disease but you may also receive a new medication.

Amy: With the increased cost in health care many are worried about whether or not their insurance will pay for a clinical trial?

Yes, we’ve had patients say they weren’t even considering a clinical trial just because they were afraid that their health insurance company would not cover the treatment. In fact, most modern health insurance plans are now required by the Affordable Care Act, to pay for treatment costs of clinical trials.

If you are considering a clinical trial, please talk with your care team about what the trial may cover such as additional testing, travel for visits to the clinics, and time away from work and home.

Amy: So what else should we consider when thinking about taking part in research – or potentially a clinical trial?

Well, making a decision about taking part in research – and more so in a treatment related clinical trial - is a very personal one. This is a question one can only answer for themselves. While a trial is a good choice for some people, everyone needs to weigh the risks and benefits.

Some of the possible benefits of participating in a clinical trial can be:

- Access to new anticancer approaches before they are widely available.
- Increased monitoring of side effects by a dedicated research team.
- Patients feel they are active participants in their care with patient reported outcomes and being able to make the decision to continue on with the treatment by themselves.
- An opportunity to make a valuable contribution to the future of cancer care.

In addition it's imperative to also look at the possible risks such as:

- New approaches may have side effects or risks that are unknown.
- Even if a new treatment has benefits, it may not work for every participant just as not every standard treatment works for every patient.
- You may have to deal with some additional costs in procedures, travel, childcare, or lost work hours as a visit may take longer because of safety monitoring.

These are all important points to discuss with your doctor and care team before beginning.

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Amy: Thank you for this valuable information Anne, as we close can you give us some key points to consider?

Most importantly, without volunteers for clinical trials many of the treatments we see today would not be available. I started in lung cancer research 18 years ago and thanks to those volunteers the drugs we were researching then I see as the standard of care treatments for patients today.

You can participate in the fight against lung cancer in different types of research; which may be as simple as a survey about your care or an extra tube of blood, or possibly as involved as a new drug trial.

Your care team is there to provide you with information about your options so don't be afraid to ask or search online and bring back for their opinion.

If you have additional questions you can always find out more detailed information on clinical trial participation on the National Cancer Institute website, cancer.gov.

Or if you are in West Virginia and would like more information on clinical trials at any WVU Cancer Institute location, visit wvucancer.org.