

CLINICAL TRIALS FROM THE PATIENT'S PERSPECTIVE

By Malinda Teel

I sometimes hear people speak of those of us who participate in clinical trials as if we are angels, sacrificing ourselves for the benefit of women who will come after us. Let me be perfectly clear: I am not an angel. My motives for participating in trials are selfish. I do so in the hope that *I* will benefit. Knowing that I may help others is gratifying, but it is the icing on the cake.

To date, I have participated in two trials. Both trials were conducted at the University of Pennsylvania. The first was a vaccine trial conducted by Dr. Coukos, the speaker preceding me. The second trial, which I just completed, combined infusions of Doxil and Interleukin-18, an immune stimulant. Both trials were Phase I trials. In both trials, I experienced minimal side effects. The worst part, for me, was periodic severe constipation and being stuck repeatedly when the nurses had difficulty accessing my veins.

You're probably wondering whether I benefited from these trials. The vaccine, unfortunately, was not my magic bullet. My cancer continued to grow. As for the Doxil and Interleukin trial, I am waiting for the results of the end-of-trial CT scan that was done earlier this week. (I should mention that the CA-125 is not a marker for me.)

Regardless of what my scan reveals, I will continue to be a cheerleader for clinical trials. And this is why: With many trials, you can receive a treatment that is already FDA-approved and a reasonable choice given your circumstances PLUS an experimental agent that may give you some extra bang for your buck. Something you probably couldn't get outside a trial. This was my reason for choosing the Doxil/Interleukin trial. Doxil was the chemo of choice for me, since I had become platinum resistant, and my hope was the immune stimulant would give the Doxil some extra oomph.

In addition, if you are interested in trying something that is not a chemo—for instance, a vaccine or a targeted treatment—pretty much the only way you'll have access to those at this point is through a trial. You might be able to get Avastin, if you have great insurance, but that's the only thing I'm aware of. I know a woman who is very savvy about clinical trials. She has participated in nine trials and has received benefit from three of them. She has known for some time that her cancer is incurable, and that her only hope of survival is to keep beating the cancer back. Her strategy involves minimizing the poison she takes into her body and maximizing her options. Thus she is doing trials as long as she is able, knowing that the FDA-approved drugs will be there when she runs out of other options. And she looks for experimental treatments with minimal side effects, such as many of the targeted treatments.

To me, participating in trials is a no-brainer, especially given the fact that you can pull out of a trial at any time—for any reason at all.

Choosing a trial is often a do-it-yourself project. When I first started educating myself about trials, I naively believed that my oncologist would be familiar with all the ovarian cancer trials in the country, and that he would tell me about any that were appropriate for me. This was a totally unrealistic expectation. No doctor has time to stay abreast of more than a fraction of the trials being conducted—ones his/her practice or institution is involved in and perhaps a few others. I quickly learned that if I wanted to find a clinical trial, I would, like the Little Red Hen, have to do it myself.

If you are interested in being in a clinical trial but don't know how to go about researching trials—and it can be pretty overwhelming at first—I'd suggest you join an online support group for ovarian cancer survivors and pick the brains of other women. Two such online resources are available through the Association of Online Resources (www.acor.org) and the Ovarian Cancer National Alliance's online support group (www.ovariancancer.inspire.com). Women in these groups can clue you in about searching for trials on the web sites of the National Institutes of Health and the National Cancer Institute, as well as the web sites of individual institutions and drug companies; they can tell you about free clinical trials matching services, such as the one offered by OCNA; and they can share information about trials they're participating in or have heard about.

There are several factors I take into account in choosing trials, including the actual treatment involved, what is known about side effects, location, and the reputation of the lead investigator. For instance, one of the reasons I entered the vaccine trial at UPenn was that I'd heard a lot of good buzz about Dr. Coukos.

One factor in particular I want to address today, and that is cost: medical costs, cost of travel, cost of lodging and meals.

I live in Atlanta. My primary expense in participating in trials has been air travel back and forth between Philadelphia and Atlanta. I received no travel reimbursement for the first trial; the second trial reimbursed me for travel in Philadelphia—e.g., taxis, trolley fare—but not for my plane tickets. Participation in my trials required periodic stays for one or two nights or more. I had no friends or family I could stay with in Philadelphia, but I discovered an organization in Philly called Hosts for Hospitals, which finds volunteer families for out-of-town patients to stay with. Now every time I go to Philadelphia, I stay with the same delightful family—the head of the Classics Dept. at UPenn, his wife, who is a freelance writer, and their teenaged son. They love to cook and feed me wonderful meals. Philadelphia has truly become a second home. It turns out that there are many resources for lodging for cancer patients and their families. To find them, start with the American Cancer Society (www.cancer.org) and the National Association of Hospitality Houses (www.nahhh.org).

Medical costs will be different for different trials and with different insurance companies, and may also be affected by your state's laws governing insurance companies. In my case, my insurance company covered items such as CT scans, which I would be receiving whether or not I was in a clinical trial. All other medical costs were covered by an entity

involved in the trial—a private lab in the case of the vaccine, and the sponsoring drug company in the case of the Doxil/Interleukin trial.

One thing I would suggest for women whose finances are limited is to concentrate on the trials in your immediate geographical region; but also check out trials at the National Institute of Health in Washington, DC. I understand that NIH may cover all medical costs, pay for and books airline flights, and provide a stipend for lodging.

Of course, one of the primary considerations in looking at a trial is: Do I qualify? At this point, I want to address a myth about clinical trials. Some people think that trials are for people who have exhausted all other treatment possibilities and are at death's door. Nothing could be farther from the truth. The fact is that the more recurrences you have and the more treatments you have, the fewer trials are open to you. Many trials require that you have had no more than one or two prior treatments. Many eliminate you if you have previously received a drug being used in the trial. For instance, I have previously been treated with Avastin. Thus I would automatically be ineligible for most trials that incorporate Avastin.

I would advise any woman open to participating in a trial to start looking as soon as possible after diagnosis. There are first-line treatment trials and an increasing number of consolidation treatment trials. I would *definitely* encourage women in remission to arm themselves with knowledge of clinical trials, in anticipation of the possibility of a recurrence. Once you discover you've recurred, treatment decisions may have to be made relatively quickly, so knowledge is power—teal power. Keep in mind that there are trials for women with ovarian cancer, but there are also many trials for “solid tumor,” for which you might qualify.

Let me mention here that most trials want women with measurable disease, so that they can do “before” and “after” comparisons to see if the trial treatment was effective. Measurable disease means lesions of a certain size that show up on a scan. Some trials will accept you on the basis of an elevated CA-125. And there are a few, including some vaccine trials, which want women with no evidence of disease. So whatever your status, you might find a trial of interest to you.

As for whether a Phase I or a Phase II or a Phase III trial is best, from a patient's perspective, I would say, “Judge each trial individually.” When I started looking into trials, I only looked at Phase II trials, because I was told that Phase III trials are randomized, and I might be in a control group that didn't receive a promising experimental treatment. I was also told that Phase I trials are too iffy, with a lot of unknowns about side effects and optimum dosage. Now that I've been doing this for a while, my advice to *you* is not to eliminate a trial from consideration based on phase alone. If a Phase III trial is being offered in your home town or area, and the control group is receiving a treatment that makes sense for you, given the history of your disease and prior treatment, you might want to participate even though you might not receive the experimental treatment. One woman shared with me that she would participate in such a trial because “you get a lot closer follow up when you're in a trial; and you have the

satisfaction of knowing that you are helping advance the treatment of this disease.” Furthermore, occasionally, Phase III trials compare two or more variations of an experimental treatment, so you will get some form of the experimental treatment regardless of which group you’re assigned to. As for Phase I trials, in many of them, the experimental treatment has been used with other types of cancer or in an ovarian cancer trial with a different design, so it’s not a totally unknown quantity.

I do want to offer this caution about Phase I trials: They are generally designed as dose-escalation studies, with the first small group of women (called a cohort) being given the mildest dose of the treatment. Then if they tolerate that dose well, the dose is increased for the next small group of women, and so on through several groups. That being the case, one woman I know was advised by a research doctor that she should avoid being in the earliest cohorts of a Phase I trial, because she may not get an effective dose of the treatment.

In closing, I’d like to leave you with this thought: The treatment of ovarian cancer is a crap shoot. But by participating in clinical trials, you increase your treatment options—and you *may*, with luck, increase your chances of staying in the game.