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**TRANSCRIPT FOR VIDEO #8: ADVOCACY FOR CLINICAL TRIALS—
WITH DR. MARCELA DEL CARMEN**
Interview, Massachusetts General Hospital
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Produced by The GCS Project

(MDC—Marcela del Carmen, MD; DR—Diane Redington, CRNP)

Slide: Patient/Advocate, Diane Redington, and Dr. Marcela del Carmen discuss the importance of clinical trials and the extreme lack of funding for gynecological cancer research

MDC: I want to be very clear in making an advocacy statement about the current state of clinical trials in gynecological cancers. We are basically under severe attack from lack of funding at a time in gynecological oncology where we are in the forefront of making some major discoveries in the way that we...how we understand the biology of these cancers, and that's going to be obviously very closely tied to interventions in immunotherapies that we can target. *This cancer's different.*

So let me start with that piece first. So what I mean is, we have a lot of data from other cancers—like melanoma, colon cancer, lung cancer—that there are mutations intrinsic to some of these tumors that will allow us to design drugs that are different from chemotherapy that will target the specific mutations. And that's the whole concept of targeted or individualized or personalized medicine. Where instead of just giving you generic chemotherapy, we will give you some treatment that is specifically designed to target the gene mutation that is individualized in your tumor. We are closer than ever to getting there in gynecological cancer at a time that there has been ***a significant detriment, a decrease in the funding for gynecological trials in the United States. In the last year we went from having 2000 patients enrolled in clinical trials to less than 200 because of lack of funding.*** And we would never allow this in the world of prostate cancer research and development—certainly, breast cancer. Right. I mean, you pick your industry, and somebody's supporting breast cancer research, and that is in some sense why we've been so successful at curing breast cancer.

But one of the biggest statements that I can make as a physician, as somebody who has dedicated a lifetime to dealing with gynecological cancers and treating patients with families and lives ahead of them, is that **we need to advocate, we need to get funding from the government, from industry, to sponsor research that will allow us to get to the next place where immunotherapy is going to be a reality.** Right now, most clinical trials that allow us to try immunotherapy in ovarian or uterine cancer are basically part of larger trials that are dealing with other cancers. And when you start looking at how that data are diluted—because you have a trial of 40 patients and 2 of them had ovarian cancer—how can you ever understand whether there is efficacy, benefit or risk? So, unless we start creating or redesigning trials that focus specifically in... People have argued, we should look at trials that only take patients with carcinosarcoma, but to do that you really need some pretty smart people designing the trials, and you're going to need funding to get them off the ground.

DR: What are the barriers to getting that funding? Is it numbers? Is it based on the smaller numbers?

MDC: It's based on numbers, right. So, it's all... it's based on numbers. It's based on politics. We have a Society of GYN Oncology try to go to the NCI [National Cancer Institute] or NIH [National Institutes of Health] to get more funding, and there's a lock. **I think that we as a society, again, if you look at somebody's budget, you look at their value portfolio.** And I don't want to get into political discussion around this, but why are we not funding research for women's cancer? With the exception of breast cancer, we are nowhere near where the folks who take care of patients with melanoma, lung cancer, colon cancer. They're further ahead than we are at a time that I think we have enough knowledge in what we understand so far about the biology of these tumors when we can actually begin to make some real difference in how we treat them.

DR: Do you think the money will have to come from the private sector versus national funding?

MDC: It may, because I think that you don't have to be a rocket scientist to understand that the health care system in the United States is completely bankrupt. Right? And so I think that you are asking, *unless we find funding from the NCI, or the NIH get a refuel of funding* that will allow some of these efforts to become a priority, **I think you will need both money and also somebody with the vision that puts gynecological cancers at the top of a priority list to get the**

funding. Otherwise, I think we're going to have to understand how to partner with industry, so that there are good research studies that are done without compromising our ethical principles as providers and making sure that there are no conflicts of interest. And then I think philanthropy and having people relying on donations from the private sector to be able to design and execute these trials.

DR: That's really sad to hear that it's so underfunded, that research for gynecological cancers

MDC: You should look—and I don't mean to be self-promoting—but I wrote a paper with Laurel Rice in the green journal, in the Journal of Obstetrics and Gynecology¹, talking about the crisis in the gynecological cancer trial community. And it's Laurel Rice and my name. If you "Google" it, you will find it. It's about a year and a half old. But we have a graph that shows the detriment over the last 10 years over accrual [placing patients] to GYN oncology trials.

DR: Did you get any response to it?

MDC: No. And it was interesting, because I can tell you that some of the medical journals that we first... we went to the New England Journal of Medicine, we went to JAMA [Journal of American Medical Association]. We wanted to publish it in a platform that would shed a lot of light on it, and no one was really interested. No one wants to read it. Right? And so finally we got it into the major journal for GYN and Obstetrics, but you're preaching to the choir, because these are all clinicians that have dedicated their lifetime to taking care of women—for whom cancer treatment and trial and research and all of this is a priority. But I can tell you that I work with Michael Birrer and the Society of GYN Oncology. We have a task force right now trying to go back to the NCI and trying to go back with patient advocates, like yourself, and it would be great if you wanted to get involved. We'd love to have you.

DR: Absolutely.

MDC: Because this is... we can no longer take this sitting and just assume that it's going to get better next year.

DR: Well, and I also think that if it were more public, women, coming from the groundswell of women who have no idea that... about the issues, then it needs to grab attention. And we can certainly do that through this project. And if there's anything else that we can do to support

that—go talk to your congressman, get women on board with—because it could affect everybody.

MDC: That’s right. And you know, every patient that I take care of has a sister, has a daughter, has a mother. I think that as I’ve gotten older, you start thinking about how you make a significant impact, not just for the patient in front of you, but also for the community at large. And I think that when you sit as an oncologist, and you watch everyone of your colleagues who does a different kind of cancer feel really good about how they have moved their field forward, and you feel like you’re still offering treatment that is 10 years old with no difference in outcome.

DR: Well, and on the other side, when you’re a patient and you’re sitting here and you’re looking at the melanomas and the lung cancers and, “Well, what about me?”

MDC: That’s right. That’s exactly right. And again, you don’t want to reduce every argument to gender or political differences. But I think that there are gender differences in medicine in the way that research is conducted and funded, and there’s always been a priority to do studies in the male population. I’m not out of context in saying that historically we look at the way that trials are funded, it’s usually looking ... in fact a lot of the metrics are metrics that only are probably relevant to a male, not to a female. And I think that a lot of women... we just don’t know that history.

DR: Right. We don’t. Well, you’re walking around here, and you’re thinking about me, and then all of a sudden you get cancer, and then you find out that the things between me and a cure is funding and money and research, and it’s there, but there’s this huge gap between being able to cross that bridge to get there.

Reference

del Carmen, Marcela G., & Rice, Laurel W. (2015). Underrepresentation of women in clinical trials: Why gynecologic oncologists are worried. *Obstetrics & Gynecology*, 125 (3), 616–619. doi: 10.1097/AOG.0000000000000695