



Bringing CLINICAL TRIALS into our **Communities**

Andrea Silber, MD, Associate Clinical Professor of Medicine, has never forgotten one of her first patients in New Haven nearly thirty years ago, a young black mother of four. She had breast cancer but had never been treated. Within a week, she was dead.

“It was incredibly sad, and it stuck with me,” said Dr. Silber, a medical oncologist who specializes in breast cancer. “I was also struck by the fact that in New Haven, whenever you see people of color with cancer, it’s worse in so many ways. They may come in later, or the onset may come at a much younger age, or they may have other chronic conditions that make it difficult to treat their cancer. I’ve had a long interest in decreasing cancer health

Andrea Silber, MD

disparities in New Haven.”

For decades these disparities didn't get much attention

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from the medical establishment. That has recently started to change, spurred partly by the Affordable Care Act. Dr. Silber is determined to add to the momentum.

One of her tools is a new program called OWN IT (Oncologists Welcome NewHaven Into Trials). OWN IT's purpose is to get more minorities from inner city New Haven into clinical trials for new cancer treatments conducted at Smilow Cancer Hospital. Minorities are under-represented in such trials nationwide. The city of New Haven, for instance, is about two-thirds black and Latino, yet those groups account for about 12 percent of the participants in Yale's cancer clinical trials. (The trials that Dr. Silber accrues to are more than 50 percent minority.)

According to Dr. Silber, these low numbers have consequences. First, minorities are missing out on the most

cutting-edge treatments for their cancers, which affects their survival rates. Second, the lack of minorities can skew trial results – Dr. Silber has noticed that new medications given to her patients often don't live up to their hype.

“So I would go back and look at the trial,” she said, “and I realized that my patient never would have been chosen for the study, because it eliminated anyone with complicating factors like diabetes or high blood pressure or obesity, which are common among my cancer patients from the inner city. If you test all your oncologic drugs only on the healthy, the wealthy, and the wise, your test doesn't equate to real life and doesn't address the problems we see in New Haven.”

One of OWN IT's tasks is to remove the barriers keeping minorities out of trials. The first barrier is mistrust. “People in town have been afraid of being someone's research project,” said Dr. Silber. “They say, ‘Why should I do this? Who is this going to help? I don't want to be experimented upon.’” To overcome these suspicions and build trust, says Dr. Silber, physicians must become more patient and communicate more clearly. “Everyone has a right to understand what's happening to their bodies, and it's my obligation to explain it in a way they understand.”

That's how Dr. Silber convinces her patients to enter clinical trials at Smilow. Maria Castellani, a mother of three, had a bout with stage 3 breast cancer in 2011 and survived, but in June 2014 the disease returned, in the aggressive triple negative form. It spread to her lungs, lymph nodes, and bones. She saw four oncologists, one of whom gave her six months to live. Three of them never mentioned clinical trials. The fourth suggested a trial, but instead of explaining it, merely handed Ms. Castellani a thick packet of baffling technical information.

Distraught and despairing, she finally connected with

Dr. Silber, who suggested a clinical trial with Orteronel. Ms. Castellani's mother, brothers, and uncles warned that she would be treated like a lab rat, but she trusted Dr. Silber and joined the trial in July 2015. By the end of the year, her lymph nodes were clear, her lungs were stable, and her bone cancer was fading.

“I'm so grateful for being in this clinical trial,” she said, crying a little. “Dr. Silber was the only doctor who didn't give up on me. She took her time and gave me this option, and she explained everything. I don't have enough to pay her for what she's done for me.”

Similarly, Marta Vega was diagnosed with stage 3 breast cancer. Her oncologist was hurried and distant. Terrified and in denial, she didn't want to consider treatment of any kind. Then she saw Dr. Silber, who carefully explained a breast cancer trial to her and said, “If you were my sister, I would recommend this.” Her warmth and patience persuaded Ms. Vega, who received experimental chemotherapy from March to August 2014. Her tumor shrank 75 percent, and surgery took care of the rest. “If it wasn't for Dr. Silber,” said Ms. Vega, “I wouldn't have survived, because I would not have done

the clinical trial.” During treatment, Dr. Silber asked her to speak to two Latina patients with breast cancer who were afraid of trials. “I was kind of an advocate,” said Ms. Vega, “and I felt good because I was helping someone else and telling them it's OK.”

After Wendy Ormond was diagnosed with breast cancer, she went into a tailspin. She began drinking and contracted pancreatitis before she could have surgery, and her blood pressure also shot up. She was referred to Dr. Silber, who sent her to a heart doctor to get her blood pressure under control. She also convinced Ms. Ormond to overcome her terror of doctors and enter a clinical trial. “I trusted her,” said Ms. Ormond simply. “I knew she wouldn't get me into something that would hurt me. I love that lady.” She began the trial in February 2015, and her blood tests continue to improve.

OWN IT will address the barriers of fear and mistrust, says Dr. Silber, by building a relationship between Yale and the people in the city surrounding it. That will take time. She has always devoted time to community outreach, but now new funding from the National Institutes of Health and other sources will allow her to hire patient

navigators and a community health educator who can hold educational sessions at community centers, schools, and churches, to explain clinical trials and their advantages.

She adds that the city's primary care physicians and Yale oncologists also need educating. Too many patients never hear about trials. Patients who don't speak English may be rejected as too time-consuming. Some trials disqualify swaths of inner city minorities because their blood pressure, cholesterol, or glucose levels tend to be higher than those of people in wealthier suburbs.

However, Dr. Silber sees signs of change. The NIH, the National Cancer Institute, and the American Society of Clinical Oncology all have started paying attention to health disparities and funding research. Things are changing at Yale as well. In May, Dr. Silber was appointed to the Cancer Center's Executive Committee as Assistant Director for Diversity and Health Equity.

“We've never been at the table before,” said Dr. Silber, “but because of the leadership at Smilow, there's a new awareness of how this needs to be part of the thinking. Everything is aligning to make OWN IT a way to really change clinical trials for inner city New Haven.”