

# Clinical trials pay dividends for patients

UB clinical trials benefit the community

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Devina Linder, a Buffalo resident and mother of four, was able to quit smoking during the first three of her four pregnancies, but there was something different the fourth time around. Four months into the pregnancy, she was still smoking 10 to 15 cigarettes a day.

“I knew the damage that it was doing, but at that time I just felt hopeless,” she says. “I didn’t feel like I would be able to change anything.”

By chance, she saw a poster in her obstetrician’s office asking for volunteers for a maternal smoking-cessation program, a clinical study under the direction of principal investigator Xiaozhong Wen, assistant professor in the Division of Behavioral Medicine in the Department of Pediatrics, Jacobs School of Medicine and Biomedical Sciences.

“I wasn’t sure what to expect,” Linder says. “I wasn’t sure being part of the study was going to help. It just brought different emotions. When you’re pregnant you have a whole bunch of different emotions.”

Linder wouldn’t have known this, but her successful participation in Wen’s maternal smoking-cessation program is just one way Western New Yorkers are benefitting from the growth of clinical research on the Buffalo Niagara Medical Campus, all led by UB’s health sciences schools.

“Similar to other researchers, we do care about data,” Wen says, “but what’s most rewarding is when you get out into the community, meet people and see firsthand how your research is actually helping them lead healthier lives.

“The big reward for me is we can make a difference in the mother’s health and also the health of the next generation.”

## Getting with the program

When people participate in clinical trials, they typically enjoy better health outcomes. This is particularly true among populations who lack access to regular health care, probably due to the extra care and attention they receive from the clinical trial staff.

Wen's research program has two aims: to test an innovative method of smoking cessation during pregnancy, and to study the correlation between maternal smoking and childhood obesity. Although children born to women who smoke during pregnancy often have low birth weight, paradoxically, maternal smoking during pregnancy is one of the best predictors of pediatric obesity later in life.

In the months following birth, babies born to mothers who smoke often undergo a period of rapid infant weight gain, surpassing their peers and setting a pattern of weight gain that may persist into childhood.

"If you look at the evidence, it's very consistent across countries, across decades," Wen says. "That's why we are trying to use smoking cessation during pregnancy to prevent childhood obesity."

In addition to education and counseling, one of the important components of Wen's treatment program is monitoring feedback. Patients are tested for two harmful chemicals during pregnancy: carbon monoxide and cotinine, a byproduct of nicotine. While checking for compliance, Wen is also able to show mothers the benefits of quitting smoking in real time as they watch levels of these two toxins in their bodies drop the longer they stay off tobacco. That means their growing children are also receiving less exposure.

"I think about that, and I think about the information that I've read, and I realize ... they are smoking a cigarette right along with me," Linder says. "Why force them to smoke a cigarette when that's something they didn't choose to do?"

Her daughter just celebrated her first birthday and, this time around, Linder has not gone back to smoking. She learned techniques to deal with cravings through Wen's program, such as finding a distraction or focusing on her breathing. These have helped her cope with the stressors that previously drove her back to the habit.

Stuck waiting for a bus on her way to a recent appointment, Linder chose one of her adaptive techniques.

"I pulled out my phone and I started playing Scrabble, with my daughter sitting in the stroller looking right up at me, laughing, and I said, 'You know what, the cigarette's not even worth it.'"

"We are so glad to see that our intervention really works," Wen said. "So far, we can get about 63 percent of mothers to quit smoking completely during pregnancy. That's not just based on self-reporting; it's based on our two biochemical tests. Our data show that those babies are born normal at birth and have normal growth."

Besides being a shining example of the impact UB's growing clinical research programs are having for patients, Wen's maternal smoking-cessation program also is a prototype for recruiting and serving Buffalo's traditionally underserved neighborhoods. Wen's study showed how UB research helps reduce health disparities in the region while enhancing the relevance of the research findings.

## Recruiting a more representative population

By far, most women who smoke while pregnant come from socioeconomically disadvantaged backgrounds. Most people who volunteer for clinical trials do not.

UB's Clinical and Translational Science Institute (CTSI) Translational Pilot Studies Program, which funded this initial phase of Wen's research program, provides seed money to advance promising new therapies. Top

priority is given to projects, such as Wen's, that address health care disparities in underserved or underrepresented populations in Western New York.

"Dr. Wen's study is exactly the kind of study on which the CTSI places a high priority," says Timothy Murphy, SUNY Distinguished Professor of Medicine and the CTSI's director. "This innovative study included members of our community who are traditionally excluded from the benefits of participating in clinical research."

Underrepresented minorities account for less than 10 percent of people enrolled in clinical trials nationally, according to Murphy, yet the population of the city of Buffalo is 50 percent minority.

Wen's study population reflects the demographics of the group most at risk for maternal smoking. Eighty-six percent of the women were recruited from two of Buffalo's chronically underserved neighborhoods: 14 percent from the West Side and 58 percent from the East Side. About 70 percent of the women in Wen's group were African-American, Hispanic or Native American. More than 60 percent were single and more than 70 percent unemployed. About 80 percent had a high school or lower level of education.

Teresa Quattrin, UB Distinguished Professor and chair of the Department of Pediatrics, heads up the CTSI's special populations core. She was instrumental in helping to enlist this diverse group of volunteers. "I am extremely proud of Dr. Wen's effort to include women with social disparities and move his research to the community," she says.

For now, Wen's team is monitoring the growth of the babies in his program up to 2 years of age. Using data gathered in this pilot study, he is now in the process of applying for federal funding to continue the program and expand it.

"Child obesity is epidemic in this country, and many other countries, and it can cause a lot of health issues," Wen says. "We know that obese kids are much more likely to be obese adults. And adult obesity is tied to a host of health problems, from diabetes to cardiovascular disease to cancer."

Recruiting volunteers in underserved and underrepresented neighborhoods continues to be a challenge for clinical researchers seeking a more representative population for their studies. Linder says she understands the reluctance some people might feel about volunteering based on a number of high-profile studies in the past — prior to strict FDA regulation — that misled or exploited subjects.

"You don't know what to expect," Linder says. "You feel that you're going to be treated different, you feel that they're going to use you ... based on what you heard from your grandmother, what you heard from her sisters, what you heard from your aunts, what you heard from your mother.

"I always say, you never know unless you actually do it. Nobody can force you to stay in any type of study. I say go for it. You may just be like me where it's almost a year-and-a-half that I haven't picked up a cigarette. I save more money and it's a better health environment for my kids."